Integrating the Healthcare Enterprise

IHE Pharmacy (PHARM)
White Paper

Supply of Products for Healthcare

Revision 1.1 – Published

Date: March 11, 2020

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Foreword

This is a white paper of the IHE Pharmacy domain.

This white paper is published on March 11, 2020. Comments are invited at any time and can be submitted at https://www.ihe.net/Pharmacy_Public_Comments.

General information about IHE can be found at www.ihe.net.

Information about the IHE Pharmacy domain can be found at https://www.ihe.net/ihe_domains/.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Pharmacy Technical Framework can be found at https://www.ihe.net/resources/technical_frameworks/.

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1 Introduction

This document, the IHE Pharmacy Supply of Healthcare Products White Paper, addresses a rising interoperability need – the interaction between the supply processes and the clinical processes, and what interoperability is possible and desired to support such processes.

This paper analyses the exchange of information around the supply and procurement of products used for healthcare purposes, for example diagnostic, therapeutic or prophylactic uses. This includes medicinal products and medical devices, as described in the use cases present in this White Paper.

1.1 Purpose of the Supply of Healthcare Products White Paper

This white paper produces the use cases and technical requirements for an interoperability framework to support the supply of healthcare products, more specifically the articulation between the logistics and clinical activities.

This white paper also describes the commonalities and differences across several domains of utilization and supply of healthcare products - from prescribed medication to consignment devices used in surgery. This helps defining a common set of mechanisms that can be used to integrate the supply and clinical processes for different products and uses. Such common set of mechanisms allows vendors and buyers of IT solutions to design or acquire compatible, interoperable solutions for small projects and large projects, as well as being ready for the future needs of traceability, privacy, etc.

1.2 Intended Audience

The intended audience of the IHE Pharmacy Supply of Healthcare Products White Paper is:

- IT departments of vendors/suppliers of healthcare products - medical devices and medication – who need to design software solutions dealing with clinical and supply flows.
- Pharmacy professionals responsible or interested in supply, purchasing and distribution of products in a hospital – who need to procure or request IT solutions and need to consult best practices.
- Manufacturers of ERP systems used at vendors or consumers of healthcare products, who want to ensure their systems are compatible with different clinical needs without extensive and resource-consuming customizations.
- IT departments of healthcare institutions who want to design their data needs and evaluate their system needs.
- Technical staff of vendors participating in the IHE initiative who need to decide which interoperability profiles to use
- Experts involved in standards development who need to articulate the current and emerging standards with interoperability on the supply chain

- Those interested in integrating healthcare information systems and workflows – for current and future purposes, ranging from Clinical Information Systems, system maintenance and design, to regulatory compliance or supply chain analysis and optimization.

1.3 Comment Process

IHE International welcomes comments on this document and the IHE initiative. Comments on the IHE initiative can be submitted by sending an email to the co-chairs and secretary of the Pharmacy domain at pharmacy@ihe.net. Comments on this document can be submitted at Comments are invited and can be submitted at https://www.ihe.net/Pharmacy_Public_Comments.

1.4 Open Issues

None

1.5 Closed Issues

None

2 Document Structure

2.1 Organization of the Document

This document starts with a description of the domain and topics, and then proceeds to the technical interoperability requirements:

Part I of this document describes the problem: What is the supply chain in healthcare, the fundamental concepts and the challenges related to interoperability.

Part II of this document analyses the problem and elicits the requirements:

Use Cases are used to show the requirements from an interoperability framework. These use cases represent a sufficient variety of needs to derive a set of requirements that should cover the simple and more complicated uses.

Most use cases introduce new interoperability mechanisms, new data, or new constraints, so at the end of each use case, there is a list of the requirements brought by that use case.

Some use cases do not introduce new functional requirements. For example, secure dispensation may not add anything to the prior use cases, but it is still mentioned, to document the coverage.

Part III introduces the requirements:

This white paper produces reconciled functional requirements, not a technical implementation – that will be described in the technical framework.

The requirements are analyzed in terms of interoperability mechanisms - what are the transactions needed to implement the use cases. After this, we analyze the data needs - what information needs to be exchanged in the transactions.

In Part IV, the existing standards are presented, to direct the development of the technical solutions.

3 Scope of this White Paper

The first IHE Pharmacy profiles were focused on the clinical processes, and for this they considered "Dispensing" as an opaque process or activity. In those profiles, "Dispense" corresponds to a chain of activities needed to ensure that a medication is made available for a patient. For example, "global dispense", "personalized dispense", "automated dispense"… are different approaches to ensure the availability of the right products to the right patient.

This document describes this delivery of healthcare products, from an external supply chain until the safe use with a patient.

Scope: Integration between logistics and clinical flows

This White Paper describes an integration of the supply flows with the clinical flows, to provide a functional overview of the needs, and to support the definition of a standard interoperability framework – the IHE Supply profiles.

Scope: Different kinds of health products

This analysis comprehends different healthcare products: implantable devices, devices used in surgery, radiological contrasts (or any medication used in a diagnostic procedure), etc., and regardless whether these products are managed by a Pharmacy, or by other departments.

Scope: Diverse processes

The processes involved in the delivery of healthcare products are diverse. For example, some products need to have a higher authorization and tracking level (e.g., chemotherapy) than others (e.g., administration of a pain killer available in the shelf). Different regions, institutions or departments may be regulating or adopting traceability at different levels. This document does not intend to constrain that diversity or choose a limited scope, but rather to support the breadth of scope by finding the differences and commonalities around several use cases.

Scope: Effectiveness and safety

The "5 rights" are a well-known guidance for medication: the right medicinal product to the right patient, in the right dose and the right route, at the right time. The same applies to all use of healthcare products: The effective distribution and use of healthcare products is essential to ensure operational efficiency and patient safety.

To support the higher goals of effectiveness and safety, this document also describes some risks that can exist in the process of distributing healthcare products. Examples are misidentification of patients and products, unintentional use of defective or expired products, etc.

Out of Scope: Authorization and payment models

The supply aspects are articulated with other aspects – for example, payment models, or authorizations like insurance coverage. These are very diverse and normally depend on legal framework and constraints. To ensure the necessary flexibility, the supply and clinical flows should be independent from other flows like insurance coverage.

Therefore this document does not rely or endorse a specific payment or insurance model, but rather allows the interoperability of supply chain to articulate with whatever model is applicable in the use cases.

4 Concepts and Definitions

4.1 Definitions

Throughout this document, the following concepts are used:

Healthcare Product: Can be a medicinal product or a medical device. The intended use for this White Paper is medicinal products and medical devices. Given the different definitions of these terms, this White Paper describes typical medicinal products (Medication) and devices, but does not exclude other items like nutrition supplies, bandages, dressings, skin ointments for cosmetic uses - These items are not the goal of this white paper, although the concepts of this White Paper may be applicable.

Medical Device[1,2]: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Medicinal Product[3]: any substance or combination of substances, which may be administered to human beings for treating or preventing disease with the view to making a medical diagnosis or to restore, correct or modify physiological functions.

Pharmaceutical Product: the qualitative and quantitative composition of a medicinal product in the dose form authorized for administration by a regulatory authority, and as represented with any corresponding regulated product information

Note 1: A medicinal product may contain one or more pharmaceutical products.

Note 2: In many cases, the pharmaceutical product corresponds to equal to the manufactured item. However, there are instances where the manufactured item undergoes a

[1] From ISO SKMT, http://skmtglossary.org

[2] The inclusion criteria for medical devices vary from country to country. It is not the scope of this document to replace such discussions, rather to provide a typical case for medical devices, and allow implementations to extend or constrain that scope according to their regulatory panorama.

[3] From ISO IDMP 11615

transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

Pharmaceutical Product Identifier (PhPID)[4]**:** the (unique) identifier of a pharmaceutical product, as defined in the ISO IDMP series of standards.

Packaged Pharmaceutical Product: qualitative and quantitative composition of the pharmaceutical product as contained in the package of the medicinal product

Note: In many instances the packaged pharmaceutical medicinal product will be equal to the medicinal product. However, there are instances where, for example, the packaged pharmaceutical product(s) must be reconstituted before it can be administered to the patient (powder and solvent for solution for injection).

EXAMPLE: Each vial of FABRAZYME contains a nominal value of 35 mg of agalsidase beta (packaged pharmaceutical product). After reconstitution with 7,2 ml of water for injections, each vial of FABRAZYME contains 5 mg/ml (35 mg/7 ml) of agalsidase beta (pharmaceutical product after reconstitution).

Generic Name: The official established non-proprietary name assigned to a medicinal product[5].

Dispense[6]**:** Dispense is the act of assigning a physical item to a patient. This is independent of all other aspects: supplying, ordering, etc. A Dispense is the unique act by which a physical item is "given" a patient's name. This can be made explicit (e.g., labeling the item container with the patient name) or implicit (e.g., simply giving an item from stock to a patient).

Dispensation Process[7]**:** The set of activities surrounding (preceding or succeeding) the dispense (the assignment of a product to a patient).

Distribution: The transport of items inside an institution (as well as outside) is not considered a dispense activity. This is called Distribution. For example, bulk delivery from a central pharmacy to a satellite pharmacy, from a central pharmacy to a clinic, surgery department, emergency department, etc. …

Medication Administration Record (MAR): The populated schedule and record of a patient's medication. For example, when a physician prescribes the use of medication 3 times per day, the patient's MAR is first populated with the planned administrations at 7:00, 15:00, 23:00, and is updated with the record of the administrations or non-administrations, as well as comments pertaining to the administration.

Radiopharmaceutical Kit: preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration to the patient (if it's going to be used in vivo, such as Technetium, Tc 99m for the thyroid imaging using γ-camera) or prior to be

[4]From ISO IDMP 11615 and 11616

[5] http://medical-dictionary.thefreedictionary.com/generic+name

[6] From IHE Pharmacy glossary and ISO 19293.

[7] Summary from ISO 19293

used for in vitro diagnostic examinations (RIA, Radio-Immuno-Assay kit for the determination, for example, of the thyroid hormones T3, T4, TSH in patient's blood, using low energy isotope Iodine, I 125). The reconstitution is an important step and its author, and especially the date and time, must be tracked, because of the half-life of these isotopes.

Note: In the context of a radiopharmaceutical kit, which is to be radio-labelled after supply by the manufacturer, the active substance/specified substance is considered to be that part of the formulation which is intended to carry or bind the radio-nuclide.

Unique Device Identifier (UDI): unique identifier assigned to a medicinal product as defined by the International Medical Device Regulators' Forum (IMDRF).

Globalized/General Distribution: A technique where the healthcare products are made available at the places of use (e.g., nursing wards) for dispensing as needed. The pharmacy handles the distribution, and the dispense is handled next to the patient.

This implies the existence of floor stock.

Personalized Distribution (synonym Nominative or Individual): A technique where the healthcare products are individually dispensed in personalized containers for each patient. The items are then distributed to the ward, already with an assigned name.

Single Dose[8]**:** the single item of medicine in an individual packaged component. This could include: a single medicine within a multi-dose blister pack, a syringe, a vial, or an ampoule. One example is a single tablet of **paracetamol 500 mg** in a blister pack. Note: it is recommended to have labeling on each single dose. See Use Case 5 Continued care institutions - preparation, dispense and pick up of patient stock (page 77) for an example, and refer to http://www.eahp.eu/sites/default/files/files/Barcode_2012%20pdf.pdf for more details.

[8] The definitions for **SINGLE DOSE, UNIT DOSE, PRIMARY PACKAGING AND SECONDARY PACKAGING** are taken from http://www.eahp.eu/sites/default/files/files/Barcode_2012%20pdf.pdf

Unit Dose: A particular dose of a medicinal product for a specific patient according to the patient-specific prescription. One example can be 2 tablets of **paracetamol 500 mg** packed together, if the prescription is for 1000 mg of paracetamol.

Note: Not to be confused with Unit Dose Distribution, or Unidose Distribution, which is a technique.

Primary Packaging: The first level of packaging that packs and protects the product. This can be the blister pack in which a medicine is contained (in contrast to the medicines packet which is secondary packaging – see below), or the physical syringe, vial or ampoule.

Secondary Packaging: the packaging outside the primary packaging, perhaps used to group primary packages together.

In the case of medicines, this could be the box packet containing a number of blister packs, and for syringes, vials and ampoules potentially an outer blister, wrap or pouch.

Unit Dose Distribution[9]**:** A distribution technique in which medication is dispensed and individually packaged for a patient. Unlike the traditional distribution, where a ward nurse picks the medication from a box or shelf and assigns it to the patient, in unit dose distribution, the medication is provided to the patient by the pharmacy, properly labeled and prepared for individual administration.

Usage Unit: The unit of using a product, i.e., the amount that represents each medication dose intended to be used by each patient personally.

For medication, it can be "tablet", "½ tablet", "capsule, "vial" or any other unit like ml or tablespoons for syrups. This is what the physician prescribes and the nurse uses.

Dispense Units: For internal distribution (i.e., for example inside a hospital), the unit of dispense can be typically a box of tablets, or a blister. This may not correspond to the unit for

[9] This practice is recommended to promote patient safety: http://www.eahp.eu/sites/default/files/files/Barcode_2012%20pdf.pdf

administration. Examples: tablets may be distributed in bottles or boxes, and syrups are distributed in bottles. These are the units of distribution.

Note: the relationship between the quantities and even the coding are partially discussed in this document and in the use cases. It is implicit that the systems ensure the consistency necessary. For example, if the barcodes available are at the box level, when the dispense unit is "box of tablets", and the administration indicated by the same code is "single tablet", then upon scanning a barcode of a box, the stocks deducted are of one tablet. This can be done by assumption, or explicit user action. It is expected that the quantities are calculated in the respective units.

Note: Besides Dispense and Usage units, other units may exist. The systems are expected to ensure a proper transition and conversion between the units as the products are distributed. See Section 5.3.2.1

Vendor (Synonym: Supplier): The entity that accepts orders and delivers healthcare products to a healthcare provider. It can be the manufacturer, an affiliate, a reseller.

Healthcare Provider: For the scope of this White Paper, Healthcare Provider is the institution that is in contact with the patient. This can be typically a hospital or clinic.

Vendor Managed Inventory (VMI): In some cases (for example for consignment items), maintaining the inventory is the responsibility of the vendor. This means that the buyer uses the products - and possibly reports on the usage of the products - while the vendor is responsible for checking and maintaining the inventory within agreed levels. See **Centrally-managed inventory** for a similar approach in internal distribution.

Buyer Managed Inventory (BMI): In many cases, the buyer defines and maintains the inventory levels - for example, when it is the hospital's responsibility to know the current stock levels of a certain item, the consumption, forecasts, etc., and based on this, to order new items. See **Locally-managed inventory** for a similar approach in internal distribution.

Note: Vendor-Managed inventory and Buyer-Managed Inventory are not mutually exclusive an implementation: at the same site, some products are managed by the buyer, while other items are placed in consignment and thus their inventory is managed by the vendor.

Centrally-Managed Inventory: For internal distribution, the same mechanisms apply: the Pharmacy can be responsible for maintaining the inventory at a specific location (for example a ward). This is a common situation.

Locally-Managed Inventory: In internal distribution (distribution inside an institution), in some cases, it is the consumer that managed the inventory. The inventory is managed locally: A system that is local to the consumer side keeps track of the inventory, and manages the stock levels, triggers reordering, etc.

Warehouse Management System (WMS): Warehouse management system (WMS) is a software application that supports the day-to-day operations in a warehouse. WMS programs enable centralized management of tasks such as tracking inventory levels and stock locations.

WMS systems may be standalone applications or part of an Enterprise Resource Planning (ERP) system[10].

Encounter (synonym: visit): contact between a patient and a provider, occurring at a given time and place, where one or more services or products are provided to maintain or restore the patient's good health.

Traceability: ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application, or location of that which is under consideration[11].

Depending on the traceability information available, the following levels of granularity of traceability can be supported:

Traceability Information Levels: traceability information can be in three levels: limited to trade item identification, or include lot/batch and/or expiry date, and/or serial number. The different levels of traceability correspond to different levels of information:

Product traceability information: When the only information available about an item is its trade item identification. This is the least granular level. It is only possible to distinguish between different types or articles (e.g., two different products from different manufacturers), not between two items of the same type. For example, is only the product code is scanned when given to a patient, it is only known which product the patient took, not the lot or expiry date.

Batch traceability information: Some healthcare products (typically medication) are produced in batches, and the batch identification allows to distinguish these batches. The information that can be captured about the product is at the level of the batch or lot number (typically accompanied by an expiry date). Items with the same article identifier and the same batch number are not discernible. But it is possible to distinguish different batches of the same article.

Unique item traceability information: For some healthcare products (typically implantable medical devices) each unique packaged item can be unequivocally identified - no two devices have the same identification, even if the devices can be identical. The identification is assured by a unique number, typically a serial number. When this information is captured, it is possible to distinguish each unique item.

Note: The availability of traceability information in a product packaging can limit, but does not necessarily ensure, the management of traceability. This depends on data capture and exchange. Examples:

- If the lot number is not available for a package, then it is not possible to provide batch traceability.

[10] SOURCE: http://searchmanufacturingerp.techtarget.com/definition/warehouse-management-system-WMS (retrieved February 2015)

[11] SOURCE: Global Traceability Standard for Healthcare, GS1, 2009

- If the lot number is available as human-readable text and not in a barcode format, and if the user does not enter it manually (for usability reasons), then the information is not captured and thus batch- traceability is broken.
- If the serial number is captured but only the lot number is transmitted between parties, the entire traceability becomes limited to lot, and no longer information.

4.2 Conventions

4.2.1 Medicinal Product and Product Names Notation

Throughout this document, the following representation is followed:[12]

Generic names are represented in **bold, lowercase**. Commercial names are represented in UPPER CASE.

Example: **diltiazem** (CALCICARD).

[12] As obtained from guidance available on http://www.mscui.net/DesignGuide/QuickGuides/MedicationLine/attributes/drugname.aspx

Part I – Problem Description

5 The Healthcare Supply Chain Processes and Concepts

Many healthcare activities include the use or consumption of certain products. The provision of these products - medication, medical devices, etc. is the result of a complex supply chain which serves the clinical goals, and must respect a series of operational rules and constraints.

The clinical flows can be in many forms - from explicit product orders like prescriptions, to ad-hoc implantation of medical devices, or emergency unplanned use of an injectable contrast.

These clinical related to the material flows. For example, in a typical "clinical order" workflow like that of a medication prescription, the flow can be represented as shown in Figure 1 – after a clinical order which gets validated, the preparation starts – which requires the material flows to have already produced a product at the preparation site (for example, the distributor to have delivered a medication at the pharmacy). Afterwards, the medication may be transported in the institution and then is administered to the patient (which are both material and clinical flows).

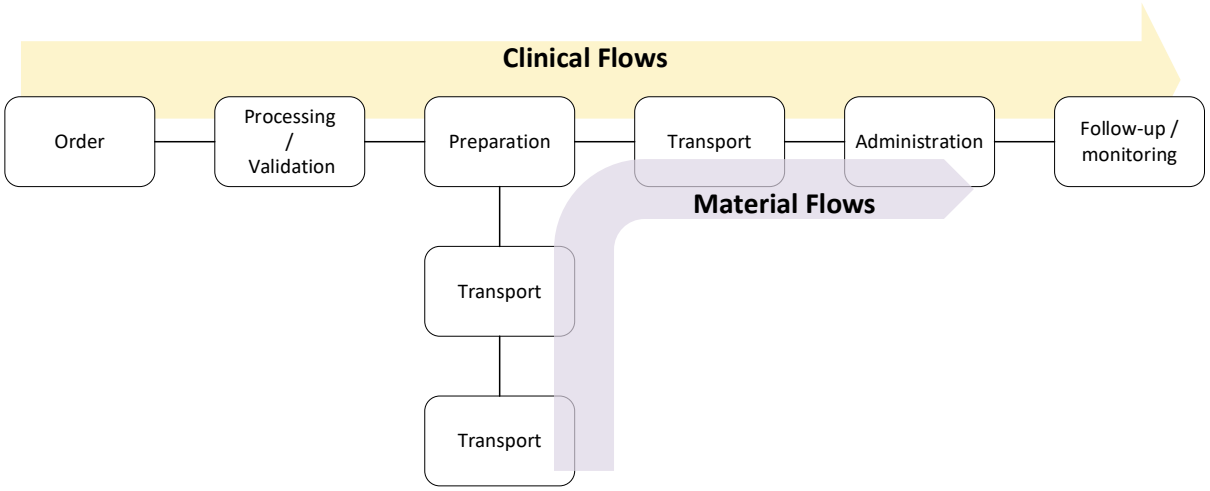

Figure 1: Clinical and Supply chains - example

The above is just one example - these flows are usually more complex e.g., by including different distribution activities, recalls and traceability, etc.

The remainder of this chapter is a summary analysis of these flows.

5.1 Clinical Flows

The clinical flows and associated information flows are broadly discussed in many materials, including IHE profiles, and are not the main object of this white paper. The key clinical aspects related to supply are documented in this document as needed.

5.2 Material Flows

The flow of information and related data must be ensured across the entirety of the supply chain. Figure 2 below illustrates a possible end-to-end overview of the healthcare supply chain actors

and major processes involved[13]: Production, Warehousing-Preparation, Ordering, Shipping, Receiving, and Healthcare delivery. Naturally, this is not representing any specific flow, rather points to some of the possible actors.

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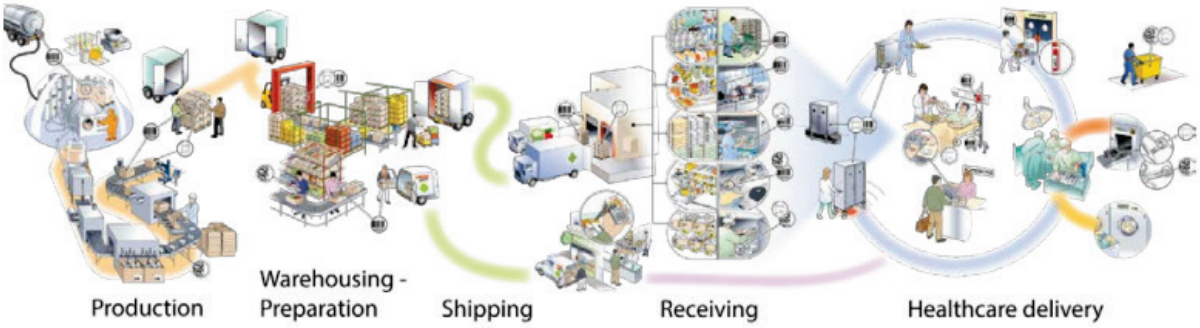
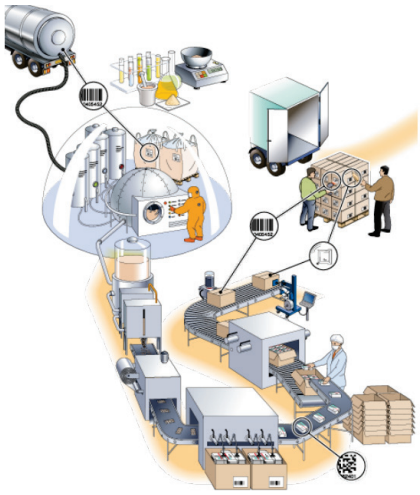


Figure 2: Healthcare product key processes

5.2.1 Production



570 The production is the activity where products are manufactured. All phases in the lifecycle of a product prior to commercialization are not in the scope of this white paper. This means that the production process on the premises of the supplier – is not in the scope of this analysis.

For the scope of this White Paper, it suffices that the result of this activity is an article that can be delivered to a healthcare institution.

[13] Source: http://www.gs1.org/ecom/standards/guidelines#s4

It is assumed that the production process fulfills regulatory requirements, according the product type, as well as the necessary traceability information regarding the process prior to distribution.

This process is illustrated here for the sake of completeness.

5.2.2 Warehousing – Preparation and Shipping

After manufacture, the supply chain between manufacturer and healthcare provider may include various steps in possibly many configurations. A more detailed analysis is not in the scope of this White Paper.

It is presumed that the supply chain provides integrity to the product (e.g., cold chain) and includes full traceability (documenting the stages of the supply chain). For the scope of this work, the last element of this chain before the healthcare provider is called the supplier. The supplier is thus the interface with the healthcare provider.

5.2.3 Ordering

Ordering is the process within a healthcare institution that triggers the request of products from a supplier. This process can have many variants – for example, items can be ordered immediately for an individual patient, or in bulk orders. The ordering can depend on many circumstances, and can interact with the clinical processes in different ways - e.g., ordering for stock, or ordering after a clinical order.

The ordering process is a diverse process, and is described in this document for the matters relevant to supply. In some cases, items are used within the context of an order, in other cases, the items may be administered before the traditional order is formalized (e.g., emergency administration before prescription); in some cases, the orders are not required at all: products like syringes may not be ordered for a patient: they are used as an implicit part of the treatment. In some cases, the ordering is only after the product has been used. Supply orders can be triggered by different events (availability, forecast). In most common cases, Supply orders are triggered by a minimum stock level.

Two major types of orders can be considered: Patient-specific orders, or supply orders. Both of these may or not exist, depending on the use. In the case of syringes and other products without an explicit order, their existence in stock is usually depending on a supply process that includes an order.

The ordering workflows can have a varying complexity, including several participants for reviewing and approving, or different intermediaries in the transaction (like distributors).

5.2.4 Delivery

The delivery of items from the supplier to the institution involves the physical transport of items. Like the ordering processes, the delivery process can have varying complexity levels: from the use of distributors to aggregating and dispatching facilities, to the simple fact that many times the entity that will receive the items (e.g., a pharmacy) is not the same entity that finally originates the order (e.g., the purchasing department).

Delivery may be associated with a previous order or not. Sometimes the order may not be explicit, or may not even be needed.

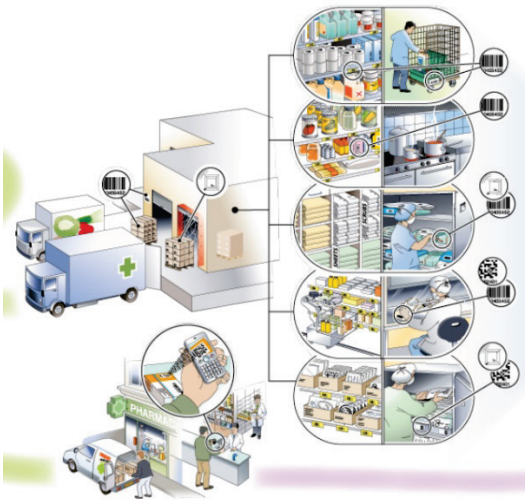
For this reason, it is possible to harmonize generic ordering and delivery mechanisms as base elements of a supply chain. It is not desired, and it is likely impossible, to define unique processes how these orders and deliveries form a supply chain.

5.2.5 Reception of Items by Healthcare Provider Organization

Reception of items is an essential step in the supply of products: When the items are received by the healthcare provider, inventory is updated and traceability data becomes available to the institution. This traceability data is important for operational, clinical and pharmacovigilance reasons.

Reception of the deliveries includes the mechanisms to secure the correct information is loaded in Healthcare provider's systems, namely the warehouse management system (WMS, which are part of - or associated with - the Clinical Information System) and downstream systems, contributing to product traceability, product availability for the provider, etc. Reception of deliveries can be accompanied and supported by a notice: when the order is dispatched by the supplier, an electronic dispatch advice is available to support the reception of the delivery.

Given its criticality, reception is increasingly assisted with automated data entry e.g., barcodes.



5.2.6 Internal Distribution

Internal distribution makes medical product available closer to the point of care. Similar to the external distribution, it can include activities of packaging/repackaging, transport, storage, tracking of products, among others. These activities may be facilitated by automated systems.

Internal distribution does not include the dispensing (see definitions) but can exist before or after the dispense act: Internal distribution may include storage in a central pharmacy, satellite pharmacies, special storage locations (e.g., controlled access locations for narcotics, cold storage, etc.), or at the ward, from which the medical products will be dispensed. After dispensing, the products may be retrieved for further distribution.

Traceability has to be ensured, as well as appropriate replenishment, so that care can be adequately to the patients.

5.2.7 Dispensing

Since the processes for ordering and delivery are diverse, there are usually different definitions of Dispensing. In this document, we aim at a consistent interoperability architecture and an analysis that supports this variety of processes. For this, we take the definition of Dispensing from ISO 19293 and consider **Dispensing as <u>the act of assigning (including or not delivery) a product to a specific patient</u>**. This is the key point where all the clinical flows and the material flows merge. A product may be prepared, manipulated and transported before or after dispensing (i.e., assigned to a patient) and a product may be explicitly dispensed or implicitly dispensed (as part of an emergency administration).

This aspect conduces to the common model that is sought in this white paper – without which each materials flow may have a slightly different interoperability approach, which is undesirable – ideally, IT solutions must be able to cope with different processes and operating models without fundamental changes.

5.3 Product Codes and Product Identifiers

The clinical processes are usually not concerned with the supply constraints. Within the clinical processes, the products are designated in a way that is not depending on supply constraints. Most products have a code, and typically for medications, product codes entail a given granularity.

For example, a product can be presented to the physician either as DIAMOX 1VIALX500MG+5ML or **acetazolamide 500 mg**, regardless of the different levels of packaging that are visible to the pharmacy system.

An articulation between product the different codes and their granularity, and product identifiers can allow clinical processes to be independent of any supply constraints – for example:

> In some cases, the physicians are only able to refer to the pharmaceutical product (e.g., **acetazolamide**) and are not entitled to see the brand names. This allows (and requires) the pharmacy to select the right medicinal product from the commercially available ones.
>
> When the product barcode is scanned, there may be a unique identifier that defines which unit of the product has been used.

It should be noted that the granularity levels do differ, so mapping to another code may alter the traceability of the ordering or supplying processes.

5.3.1 Product Types and Physical Items

Normally, the designators - codes or names - that are visible to the physicians do not represent a specific physical product. They are product codes.

For the scope of this white paper, it is important to distinguish product codes (or virtual product identifiers) from the physical product identifiers, as we distinguish the product from the physical occurrence.

An example:

> The physician prescribes **acetazolamide 500 mg.** When the software for entering prescriptions refers to **acetazolamide 500 mg**, the *code* used is XXXXXXX. This can be called a **virtual product *identifier***. The Pharmaceutical Product Identifier (PhPID) is an example of a product code or virtual product identifier.
>
> The pharmacist determines that **acetazolamide 500 mg** corresponds to DIAMOX 1VIALX500MG+5ML, from a specific manufacturer. The code for DIAMOX 1VIALX500MG+5ML is another product code.
>
> When dispensing, the pharmacist selects one box of DIAMOX 1VIALX500MG+5ML among those available in the stock. This box presents a Global Trade Item Number, a lot number and an expiry date. **This is a physical occurrence**. No two physical occurrences are the same; they may share the same attributes, but are different entities because they are two items.
>
> This distinction is essential for interoperability and for supporting the different categories of traceability.

The physical item identifiers are associated with quantities, according to their packaging, as described in Section 5.3.2.1.

In summary, product types usually have a product code, and physical instances may have an identifier. In IT systems, a code can have its unique logical identifier (like the IDMP identifiers).

Example - product types and physical items

A short example illustrates the difference between the product type and physical item identifiers:

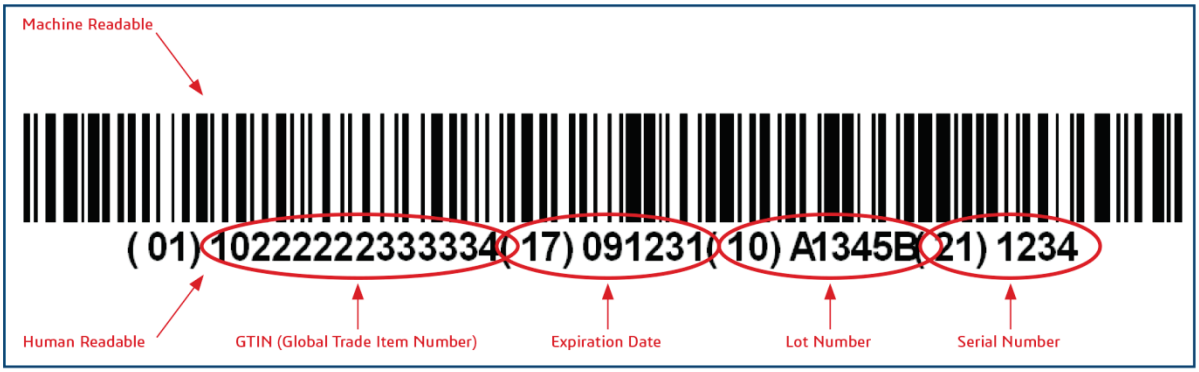
When ordering a medical device, the specialist and the procurement department both refer to the product type, for example one having an identifier (GTIN) 10222222333334. GTIN are globally unique.

Since the actual trade item is the same, all boxes from that same trade item from that manufacturer have the same actual product identifier. This allows them to be distinguished from other products.

Each physical box has a barcode label, which may identify not only the product (the same for all boxes) but also the lot number and expiry date (common to a few boxes) and the serial number (which is unique for each box).

The code 10222222333334 identifies the product.

The code 10222222333334 + lot A1345B + Expiry date 31 Dec 2009 + serial number 1234 identifies the unique physical item of that product.



When referring to inventory, the concept used is the physical item. An inventory description may enumerate the items like shown below.

Pharmacy

Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
07896112149682	DIAMOX 1VIALX500MG+5ML	LLL01	06-2016	2	2	3
		LLL55	**11-2016**	**5**		
			Total:	**7**		
	...					

For ordering purposes, it is usually not relevant what are the lots and expiry dates, so it is possible to aggregate the list of physical items by product, as is shown in the table: The inventory for that product are those 7 physical boxes (these 7 boxes exist in stock). In detail, 2 have one lot number, 5 have another.

At the administration process or at the point of care in general, acquiring traceability data will enable documentation (in the care record), traceability and other value-added processes.

Classes and instances vs. types and occurrences

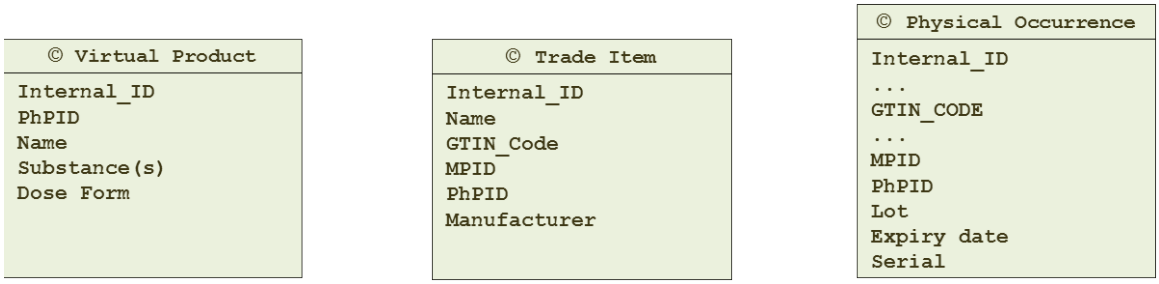
The different levels of abstraction on product types and traceability information can add complexity to the implementation. In addition, IT terminology can cause confusion between identifiers, classes, types, because these words have a slightly different meaning in the IT jargon.

This white paper uses the notions of "product types" and "physical product occurrences"; for IT implementers (for example, in Object-Oriented Programming) the notions of Classes and Instances have a specific meaning. While we do not intend to develop those definitions, it is important to mention that a data model must accommodate for all the concepts – products and occurrences - both in terms of classes and instances.

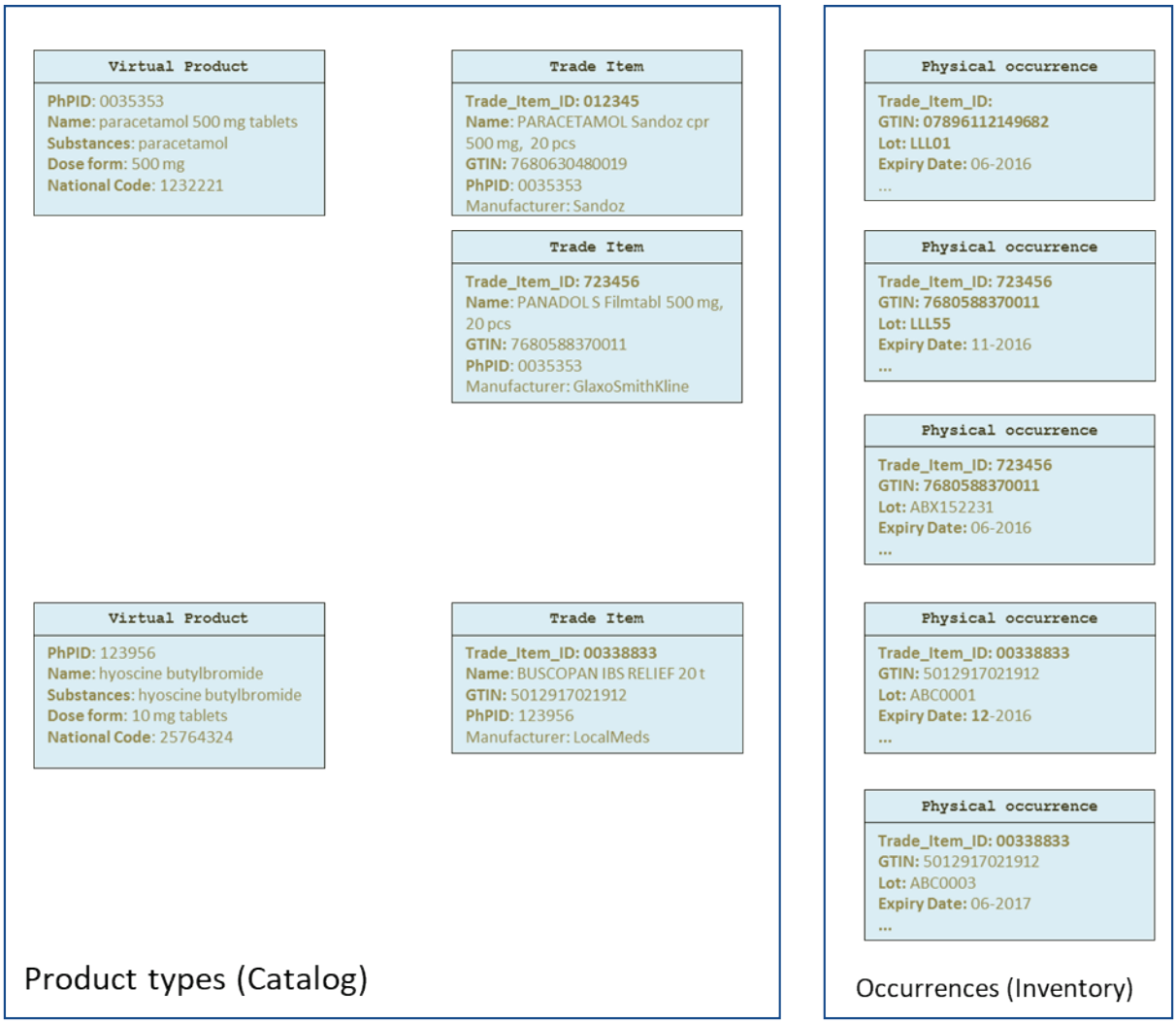
The following diagram exposes how these different classes could be present in a software model. Implementations may use the concepts in many ways, for example by using classes and sub-classes instead of defining new classes.

Let's take the example of a virtual product (e.g., a generic formulation with a code) and a physical product type or trade item, and some given physical unit of that product.

The figures below show the relationship between these Classes:



And some corresponding example Instances – Having 2 virtual products (paracetamol and
745 hyoscine butylbromide), with paracetamol presented as 2 commercial items (PARACETAMOL SANDOZ and PANADOL S) and hyoscine butylbromide as BUSCOPAN, and having some inventory (for PARACETAMOL SANDOZ, one batch in stock, and for PANADOL, 2 different batches in stock, and BUSCOPAN also has 2 different batches in stock):



Product Package Identification

In the several steps of the process above, the products will be present in different levels of packaging, appropriate for each stage of distribution or final use.

For medication, the packaging is typically

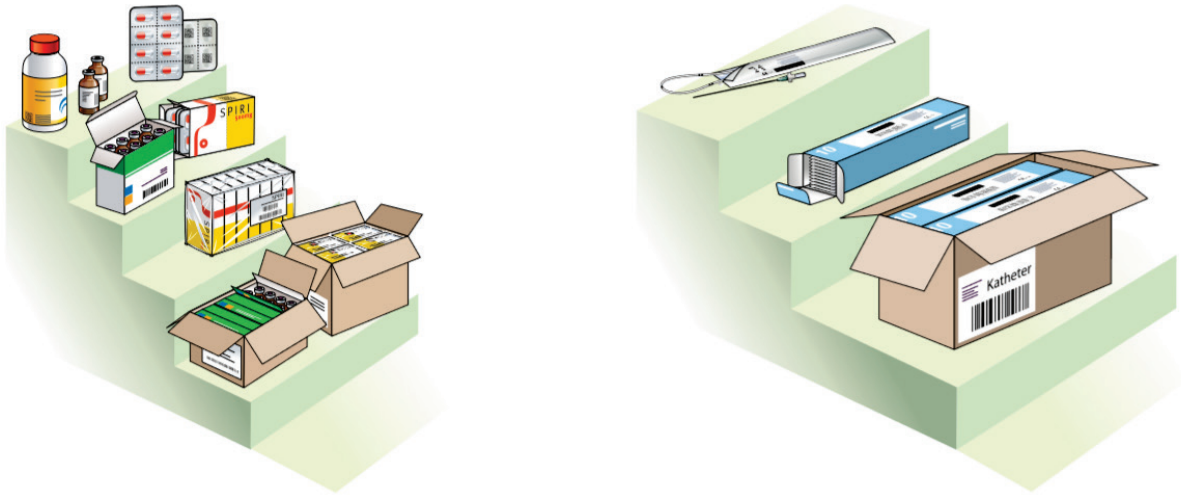
- For internal supply, primary or secondary packaging
- At administration, single unit

For medical devices, the packaging can be similar: the single unit is the one intended for use, and the primary or secondary packaging is used for storage/distribution.

Within the external supply chain, the products are typically conditioned in larger packaging.

While each of these levels of packaging contains products of the same type, the quantities are different. Besides, each unit of use must preserve its uniqueness for traceability (see traceability levels definitions) - this is obvious in serialized medical devices: even when packed in a box, each device has a unique identifier.

To aid in the inventory management, each of these packages has a unique identification: the barcode in a single unit of medication is different from the barcode in a shipping box of the same medication, even if they refer to the same product.



A structured, semantically meaningful set of identifiers allows supporting the relationship between the packaging level and the dosage form. For example, the barcode for a box of tablets corresponds to 1 secondary package, which contains 20 single units. This does not apply to products like syrups and creams, which are not available in single doses.

5.4 Product Master Data

The processes described above shall rely on consistent product data: The products must be unambiguously identified, and their characteristics known and shared along the supply chain, including within the Healthcare provider. For example, product identifiers should remain consistent between vendors and users, so that when vendors receive a request (e.g., an order), their system knows unequivocally which product is requested. The same inside the Healthcare provider: the product identification must be unambiguous from ordering to supply management to administration.

Besides the product identifiers, other attributes are required for proper operations. For a given product, some characteristics are relevant for the Ordering process (e.g., packaging hierarchy) while other characteristics are relevant for the resupply management (e.g., pack factors like "units per box"). Other specific characteristics may be important, depending on the product (for example "maximum storage temperature").

Some attributes are specific to a virtual product (e.g., the code[14] for the pharmaceutical specialty "Paracetamol 500 mg tablet" is 3030553; ATC code is N02BE01). Other attributes are specific to a trade item (e.g., the global identifier for the trade item "Paracetamol box of 200 tablets @ 500 mg" is 07896112149682). Other attributes are only relevant to a physical occurrence of a product, like the lot number, the serial number or expiry date.

Product Data Management is the area that ensures consistency of these attributes in the complete supply and clinical processes.

[14] See Definitions in this White Paper

Within **Product Data Management**, it is possible to define two main aspects: **Product Master Data** and **Inventory Data**.

- **Product Master Data** relates to the data that is available about products and is relatively invariant, like in a catalog (e.g., product name, characteristics (e.g., pack size, dimensions, manufacturer and supplier, description of packaging material);
- **Inventory Data** are evolving data and relate to the physical items, e.g., current stock levels, inventory locations, batch number on shelf, etc. and more generally traceability information.

Both Product Master Data and Inventory Data are necessary for supply, namely by enabling efficient ordering / storage / delivering processes, reduction of errors and automatic identification data capture (AIDC). These data sets are available in different types of systems and repositories: For example, there are product data repositories for manufacturers, or at a regional, national or institutional level.

Product Master Data:

In hospital systems, product master data is most of the time stored in an ERP; inventory data can be stored in a WMS. Sharing of Product Master Data is a pre-requisite for interoperability in clinical or supply flows.

Part of this information can be achieved by direct communication between vendors and users (direct exchange of product data) but for regulatory and integrity reasons, it is mostly provided by different sources, including regulatory authorities or commercial vendors 3rd party Master Data providers for Medication and/or Medical Devices.

This information is available in Medicinal Product Dictionaries.

ISO standards applicable to this area are the ISO IDMP (Identification of Medicinal Products) set of standards, and MPD (Medicinal Product Dictionaries) standard ISO 19256.

Inventory Data is described in this document as part of the supply chain mechanisms.

6 Automatic Identification

Product identification is essential for Inventory management, Order Management and other processes, as well as an intrinsic part of the product.

6.1 Types of Identification Technologies

6.1.1 Barcodes

A barcode is a machine-readable representation of data. It is important to distinguish at least two types of barcodes: one-dimensional (1D barcodes) and two-dimensional (2D) barcodes.

The data that is represented typically consists of numeric (e.g., EAN-barcode) or alphanumeric characters (e.g., 128-barcodes). The data can be optically read by a machine called barcode scanner. The barcode scanner needs to have a "line of sight" to the barcode. The amount of data to be stored determines the type and size of the barcode (representing more symbols typically requires more space). Some barcode formats are limited in the amount of characters they can represent.

Barcodes can be printed in labels that are then attached to an item, or engraved in the item itself.

One-dimensional Barcodes:

One-dimensional barcodes consist of parallel lines varying in width and spacing. The most common barcode is the ISO/IEC 15420 barcode[15]. It is also known as UPC/EAN – barcode representing a product identifier (GTIN). Each digit of the number is represented by a start sign followed by the digit coded in two lines and two gaps and finished by a stop sign. The coded number is added at the bottom of the barcode in order to support human readability.

Figure 3 shows an example of such a barcode representing numbers, which is reserved for GS1 Global Trade Item Numbers.

Figure 3: UPC/EAN- barcode

Alphanumeric data can be coded by 128-barcodes of variable length. Each character is coded by three lines and three gaps. Figure 4 and Figure 5 show the structure and an example of a 128-barcode.

[15] http://www.iso.org/iso/catalogue_detail.htm?csnumber=46143

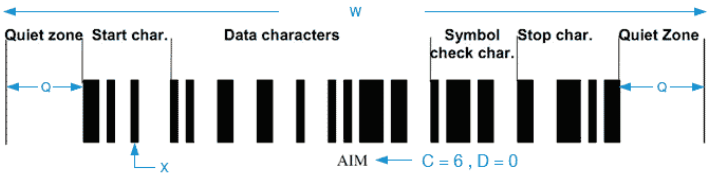


Figure 4: structure of a Code 128 barcode

Figure 5: Example of a Code 128 barcode

The barcode starts with a start sign, followed by the coded data. One check sum enables recognition of code integrity and thus error detection. The stop sign finishes the barcode. Different barcodes must be separated by quiet zones. 128-barcodes shall be produced according to ISO/IEC 15417 standard[16]. When a code 128 carries data structed according GS1 standards, it starts with a dedicated ISO 15417 character and is named “GS1-128”.

Two-dimensional Barcodes

Two-dimensional barcodes are also known as matrix barcodes. This type of codes uses a second dimension to represent more data per unit area.

ISO/IEC 24778[17] is a common 2D code, also known as aztec code. ISO/IEC 16022[18] code is increasingly used. It is known as data matrix. QR-codes are often used to scan URLs by smartphones (ISO/IEC 18004 standard[19]).

Figure 6 shows an example of an Aztec code.

[16] http://www.iso.org/iso/catalogue_detail.htm?csnumber=43896

[17] http://www.iso.org/iso/catalogue_detail.htm?csnumber=41548

[18] http://www.iso.org/iso/catalogue_detail.htm?csnumber=44230

[19] http://www.iso.org/iso/catalogue_detail.htm?csnumber=62021

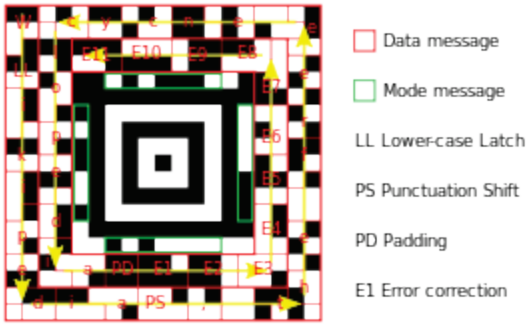


Figure 6: structure of an Aztec code

Message data is placed in square modules on a square grid in a spiral pattern around the core (square bullseye pattern).

An example of a data matrix is shown in Figure 7

Figure 7: data matrix

The data matrix code consists of black and white squares or rectangles. Text or numeric data up to 1556 bytes (2 335 characters) can be encoded. Even, if 30 percent of the code are damaged, information can be read. When such a code carries data formatted according GS1, it starts with a dedicated ISO 16022 character and is named “GS1 DataMatrix”.

6.1.2 Radio-frequency Identification (RFID)

Radio-frequency identification is used to identify or track objects automatically. This technology uses tags (electric/electronic devices) which contain information. Unlike the barcode, this information can be read without a line of sight.

In some RFID technologies, the tag has a fixed, unchangeable content, while in other technologies the data can be changed.

One makes the following distinctions regarding radio frequency tags:

An active tag has a battery and actively waiting for a scanner to start a dialogue. A passive tag is "awakened" by the wave that sends a scanner and uses that micro-energy to communicate with the scanner.

The frequency bands are either low, high or ultra-high. LF (low frequency) is used e.g., for cattle identification tags. High-frequency for a wide variety of applications such as bank or transportation cards and NFC applications. The reading distance does not exceed a few centimeters. Ultra-high frequency tags are used for some supply chain operations with a reading range of up to 3-5 meters.

Protection against reading can be done with any of these technologies:

- GS1's standard RFID / EPC (Gen2) UHF is a passive tag. It supports security mechanisms or data encryption. The implementation of these features depends on application. Its equivalent is ISO / IEC 18000-63.
- ISO standards are ISO / IEC 18000 series and more specifically:
- ISO/IEC 18000-2:2009 Information technology -- Radio frequency identification for item management -- Part 2: Parameters for air interface communications below 135 kHz
- ISO/IEC 18000-3:2010 Information technology -- Radio frequency identification for item management -- Part 3: Parameters for air interface communications at 13,56 MHz
- ISO/IEC 18000-4:2015 Information technology -- Radio frequency identification for item management -- Part 4: Parameters for air interface communications at 2,45 GHz
- ISO/IEC 18000-6:2013 Information technology -- Radio frequency identification for item management -- Part 6: Parameters for air interface communications at 860 MHz to 960 MHz General
- ISO/IEC 18000-61:2012 Information technology -- Radio frequency identification for item management -- Part 61: Parameters for air interface communications at 860 MHz to 960 MHz Type A
- ISO/IEC 18000-62:2012 Information technology -- Radio frequency identification for item management -- Part 62: Parameters for air interface communications at 860 MHz to 960 MHz Type B

Another set of RFID standards comes from JTC1 / SC 17 which is specializing in cards (banking, transportation, passports, etc.). The most common are ISO / IEC 15693 and 14443.

The advantage of RF technology is that most of the time data can be transferred wirelessly, without line of sight; depending on the RFID frequency and the context, data can be captured without stopping and/or at distance. For other applications, RFID reading (and writing) requires time and (very) short distances.

Whilst barcodes can include redundancies which enables reading even if partially damaged, RFID tags are sensible, since if the antenna is broken the tag becomes unreadable. That is the reason why RFID tags are used successfully in solid environments such as cards (credit card format) or plastic capsules for professional clothing, and less frequently on soft labels.

There are some constraints with the use of RFID (e.g., radio frequency reading is difficult in metallic of liquid environments). At the present point of time, because of its costs and limitations, RFID is not commonly used in Healthcare across the world.

6.1.3 Summary of Barcode Types

There is a wide variety of standardized barcodes, corresponding to numerous business purposes. For the open supply chain, only a limited number of symbologies are of common use:

a) Linear barcodes
   EAN/UPC
   Code 128 and GS1 128

b) 2-D barcodes
   Datamatrix and GS1 DataMatrix
   QR code

6.2 Identification of Items

The foremost use of barcodes is to identify products.

Common products are usually identified by their trade item code (GTIN, formerly EAN). This GTIN can be barcoded with an UPC/EAN-barcode as shown in Figure 3.

By identifying only the product type, that barcode provides trade item traceability information. In order to provide more detailed traceability information, more information can be added to the barcode.

GS1 128-Barcodes (Figure 8) can represent further information (e.g., lot/batch) about the product.

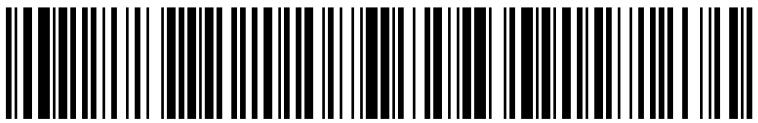


Figure 8: GS1-128 barcode representing, GTIN, batch/lot and expiry date

Adding attributes to product identification is a powerful mechanism that allows the systems to support different levels of traceability and evolution of the product identification and the supply workflows in pharmacy.

To achieve this, the GS1 standard represented above contains "Application Identifiers", i.e., prefixes that describe meaning, content and length of the following information. This makes it a semantics-enabled barcode.

In the barcode above, a few of these attributes are shown: (01) marks a GTIN, (10) a batch or lot number, (17) an expiry date.

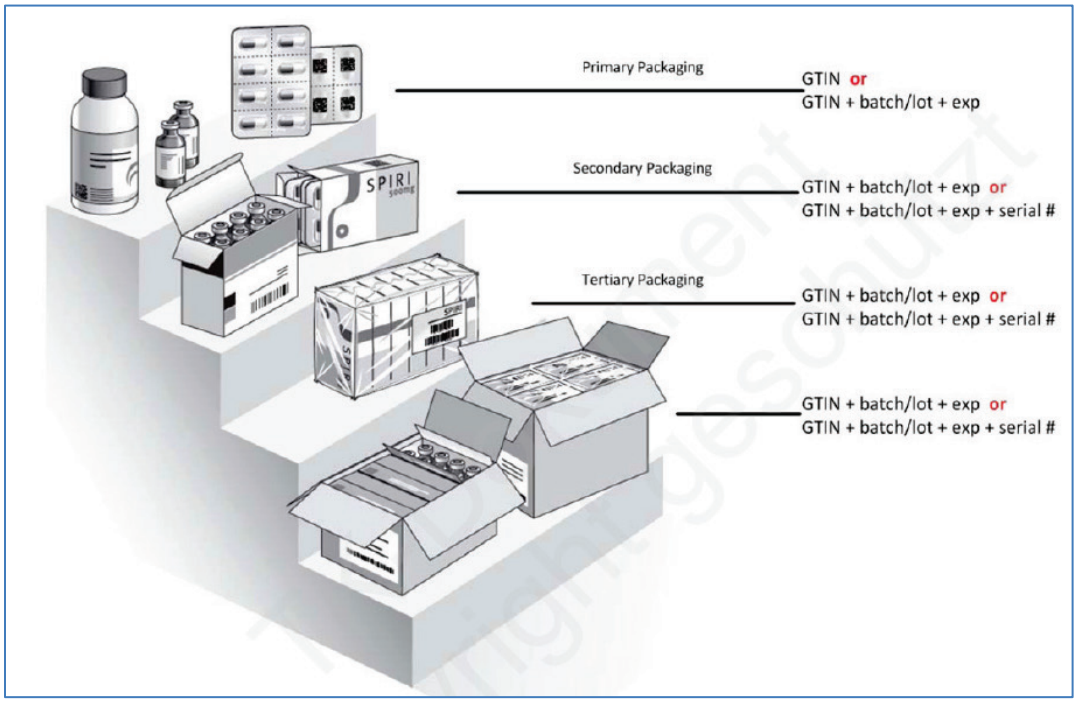
Please Refer to External document GS1 General Specification[20] for a description of barcodes and Application Identifiers.

As for medical devices, the DataMatrix barcode can be used to carry medicinal product's package GTIN[21], batch/lot, expiration date, serial number or its PPN (pharmaceutical product number). Section XXXX provides an overview of the data carrier needs - the data that can be required to be put in a barcode.

6.2.1 Identification of Package Levels

Supply chains require that different package levels of the same item are identified differently.

According EN ISO TS 16791, this can be illustrated as follows (Annex B, packaging hierarchy):



6.3 Identification of Patients

Wristbands are increasingly used to help identify the patient (subject of care, cf CEN ISO TS 18530) in the care processes. Although RFID has promising applicability, barcodes still are preferred data carriers for this process. Normally 2-D barcodes are used.

[20] See GS1 General Specification, version 2016, § 3.2
http://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf

[21] Some GS1 identifiers are named « NTIN (National Trade Item Number); they correspond to an alternative code maintenance schema, and are globally unique.

6.4 Identification of Assets (auxiliary devices, e.g., pumps)

In some cases, the devices or assets participating in the delivery of healthcare need also be identified, e.g., for automated check or traceability. Each device could be identified by a barcode or a RFID tag. For example, an infusion pump could be identified by a barcode and this would allow associating that infusion pump with the administration of the medication.

See also ISO 15459-4 (Information technology — Unique identifiers — Part 4: Unique identifiers for supply chain management).

6.5 Identification of Medical Staff

AIDC is frequently used for identifying personnel. That identification shall be distinguished from authenticating that medical staff for security / access purposes.

Medical staff is frequently identified with a card, showing barcodes and including one or more RFID tags (such as cafeteria wallet, cloths robot, access control).

6.6 Identification of Places (locations, functional entities)

GS1 has defined standards and identifiers (GLN) to identify locations and functional entities. This identification can be captured from barcodes or RFID tags (although the first is the preferred carrier in hospital settings).

An example of a barcode used to identify a location is shown in Figure 9.

Figure 9: GS1-128 carrying Ship to - Deliver to Global Location Number: AI (410) with GLN

6.7 Requirements for Identification Technologies

Identification technologies should be used to reliably identify objects. The used technology depends on the type of object and the type of process.

6.7.1 Identification of packaged medicinal product and medical devices

Packaged medicinal product are identified on retail-pack level, number of jurisdictions requiring specific means for that purpose.

A common factor between medicinal product and medical devices is that identification at a defined packaging level may include:

- Item identification (e.g., Global Trade Item Number, GTIN)
- Batch/lot number

- Expiry date
- Serial number

The use of attributes to the GTIN depends on the regulation and product characteristics (see also Section 6.2.1).

6.8 Content of the Barcodes and Regulations

For medicinal products, emerging regulation require that some medicinal products to be identified at secondary packaging level (requiring serial number as additional GTIN attribute); this is the case in the US, and will be in force by 2019 in Europe. It is already in force in several countries such as Turkey, Argentina or Korea.

Medical devices are regulated by a UDI rule adopted by the US FDA; the same type of regulation is expected to be adopted in Europe by 2020 and in many other countries. UDI rules derive from a guidance which has been published by the International Medical Device Regulatory Forum (IMDRF, www.imdrf.org). That guidance requires appropriate identification, depending on risk classes for medical devices: a pacemaker is to be identified at instance level; a bandage is to be identified at class level; a catheter is to be identified at batch/lot level (a smaller class). See Section 8- Traceability for more on traceability levels.

6.8.1 UDI

In the USA, the FDA issued legislation on the 'Unique Device Identification' (UDI) for all medical devices. The accredited organizations that are allowed to provide the UDI are GS1, HIBCC and ICCBBA. In the EU as well as other regions, adjusted to the needs and requirements of that region, similar regulations are issued progressively. In opposition to the US UDI legislation, in the EU not only suppliers need to comply, but also healthcare providers. They will be mandated to store implant's UDI information in their systems in order to fulfil traceability.

A video where the benefits of UDI are explained by staff can be seen in the following link (from Mercy Hospital and Medical Center USA): https://www.youtube.com/watch?v=A3CS8pfTmb4

6.9 Use of AIDC in Clinical and Supply Flows

AIDC - Barcodes and RFID - is intended to facilitate and reduce errors when capturing data about products, staff, locations, etc.

ICT systems at various stages of the logistical, administrative and care processes should communicate such information in a standardized manner, regardless of this coming whether from different barcodes or manual entry.

6.9.1 Different types of information capture

There are different ways to capture information:

1. Automatic data capture: e.g., scan a barcode
2. Manual entry of a label content,
3. Manual entry of the data, e.g., manually reading the product code and expiry date, and filling in that data.

These are not mutually exclusive by design: In many systems that support AIDC, there is also a way to enter data manually in the other ways. The data intended is the same, even if the format, the carrier and the structure may change.

There are several (bar)coding systems adopted by healthcare stakeholders: GS1, ICCBBA and HIBCC. Not all Hospital IT-systems can process these systems correctly on a global level. Interoperability between systems is therefore hindered which can lead to error prone work-around processes in the logistic and care processes, or simply absence of data.

It is therefore essential that product information is processed in the same manner, whether it is captured by AIDC (barcode) or entered manually from the label, or each field entered manually.

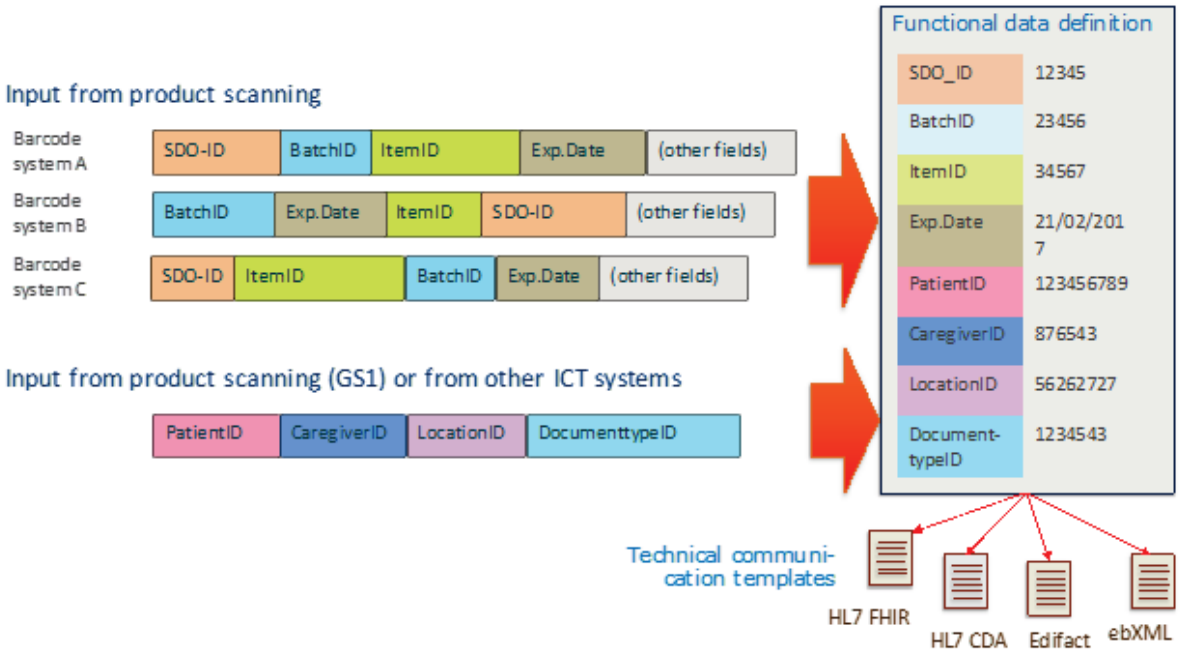
6.9.2 Using product data

To enable correct registration of used pharmaceuticals and medical devices in the hospital setting, use of standardized product information is crucial. Barcodes are used for the identification of products, locations, persons and documents. The identification can be used throughout the entire supply chain, from manufacturer up and until the patient.

When a healthcare professional scans the barcode(s) on the product that are provided by the manufacturer, following the specifications of one of the three standardization bodies: GS1, HIBCC or ICCBBA, if all of the interoperability messages use a standard model for the information, the downstream systems will recognize the type of information captured by the barcode, and are able to process this information.

Barcodes shall be read by all ICT-systems used in hospitals that support inventory management, purchase and registration of medical devices and pharmaceuticals.

By using standard information structures, even if coming from different barcode types, interoperability is supported, product data can be integrally transferred from one system to the other, securing information integrity.



For this reason, IHE profiles (Supply and others) require that barcode information is structured according to its issuing agency, captured and conveyed integrally.

In practice, this means that barcodes are expected to be parsed and their essential components structured: Product or item identifier, Batch or lot ID, Serial number, Expiry date, etc.

7 Inventory

Inventory management is the management and update of the information about the physical items available. This requires usually keeping track of the quantities of items, using several approaches as described in this document – e.g., by using the information of stock replenishment and depletions, as well as eventually checking the items in an inventory location. While inventory management is a broad area of work, the relevant aspects for this white paper are:

7.1 Inventory Location

In a more traditional inventory location, products of a specific type are placed in specific locations. For example, all boxes of ASPIRIN 500 mg boxes of 20 tablets are placed in a shelf location. In other shelf locations there are other items like ASPIRIN 500 mg bottles of 100 tablets. It is normal that items of different types share a location.

Especially with manual dispensing, care must be taken that these types are not easily confused. For example, putting the medications together in alphabetic form can lead to having AMILORIDE and AMLODIPINE in a same shelf, or acetazolamide and acetohexamide[22]. A confusion at time of dispensing can be fatal and is urged to be addressed[23]. It is outside of the scope of this document how to achieve that.

Some inventory management systems adopt different, advanced methods to determine the location of the inventory. For example, placing items that are commonly consumed together (surgical devices) in a same location to facilitate dispensing, or placing more consumed items closer to the point of consumption.

In this white paper, this is taken into consideration by assuming that a location is associated with a physical item, not with an item type. In other words, we do not assume that all items of a same type are in a location but can be in different locations.

7.2 Inventory Replenishment

As with inventory locations, there are several methods to determine stock replenishment levels, frequency, etc.

The most traditional approach would be to fix a "minimum" stock level - the reorder level, and requiring a resupply when the current inventory level reaches below that minimum. This approach may not be applicable in each case[24]. In this white paper, no assertions or dependencies are kept regarding this matter; the resupply trigger can be any adequate and appropriate mechanism to ensure product availability.

[22] https://www.ismp.org/tools/confuseddrugnames.pdf

[23] http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution1.pdf

[24] (reference needed for KPIS in healthcare supply)

7.3 Consumption and Administration of Items

Tracking consumption of items, even if not always possible, is a reliable way to track the inventory evolution.

In a common scenario, the item is consumed when it is administered or otherwise used. This action decrement the inventory for consumable items.

Several other items are consumed but in parts at a time. This is the case of creams and ointments, anesthetics, contrasts, etc., for which an administration does not correspond to a consumption of the item.

For this reason it is fundamental to assert the difference between administration and consumption.

In Section 20, Use Case 7 Falsified Medication Check, there is an example of consuming 2 items during a procedure but only administering one.

7.4 Inventory Reporting

Inventory Reporting is the exchange of information about inventory: Mostly it is about informing what items are in a certain location, and the characteristics of these items. The most evident example is reporting quantity available at hand – how many items are in a certain inventory location.

In some cases, there is a request for inventory reporting (for example when a central inventory management system requests another system for the counting of an inventory location); in other cases, this is unrequested (when a system issues this record without requesting).

The counting of inventory can be done visually or with barcodes, as demonstrated in Section 16 - Use Case 3 Inventory Count and resupply, product distribution.

7.5 Buyer Managed Inventory (BMI)

Buyer managed inventory is the traditional approach to inventory, where the buyer maintains track of the inventory, maintains the rules for inventory management, and takes responsibility for their own inventory, communicating with vendors as needed. For example, a hospital manages its stock, and orders items when considered necessary. Section 15 - Use Case 2 Ward supply Management - Pharmacy-managed inventory describes an example of Buyer managed inventory.

7.6 Vendor Managed Inventory (VMI)

Vendor Managed Inventory (VMI) is an approach to inventory management and order fulfillment where the supplier takes responsibility for maintaining an agreed inventory of the material, usually at the buyer's consumption location. A third-party logistics provider can also be involved to make sure that the buyer has the required level of inventory by adjusting the demand and supply gaps.

Section 17 - Use Case 4 Community pharmacy, stock and consignment items shows an example of buyer-managed inventor alongside vendor managed inventory.

Consignment items are placed at the point of consumption, ready for use, but have not been ordered or invoiced. They are the property of, and managed by, the vendor, and therefore this modality is called vendor-managed inventory.

This approach is typically interesting when the cost of inventory is high: for example, in medical devices and specialized products, where the variety of configurations and sizes would require having a large range of items in inventory, but the consumption of an item is not very frequent.

For these items, vendors take the cost of inventory, thus relieving institutions to incur in such costs. The products are physically placed at customer side, ready for use. Until consignment items are consumed (used or discarded) they are the property of the vendor. When used, then they can be ordered and invoiced.

Like the other products, consignment inventory management can be done by consumption reporting or by inventory snapshot. The responsibility, in this case, is from the vendor: it is in the interest of the vendor to maintain a proper status of their inventory.

For example, if an item is about to expire and is not taken, it will not be consumed by the customer, and the vendor will not only incur in the costs of maintaining that inventory, but may lose business because apparently, the customer is not interested in the item (since the item is available but never used), but in fact the customer cannot use the item.

Besides the sequence in the operations (for consignment items, ordering is after consuming) and the difference in physical location vs responsibility, the mechanisms described in this paper apply equally to vendor-managed or buyer-managed inventory.

7.7 Inventory Managed by Other Locations

Like with to vendor-managed inventory, there are other cases where the inventory is managed by the supplier entity while it is physically in a location that is managed by another entity.

Some examples:

- A central pharmacy manages the inventory that is at a satellite pharmacy
- A pharmacy manages the inventory that is at a ward (floor stock)
- A pharmacy manages the inventory that is in an automated dispenser

Similarly to the consignment items, the mechanisms are consistent with buyer-managed items - ordering, inventory checks, consumption, etc.

Some examples of this are included in this white paper.

8 Traceability

Traceability is defined as the ability to verify the history, location, or application of a physical item by means of documented identification. It applies to physical items, not to product types.

Traceability is as fine as the identification of those physical items: if a product has a serial number, then it can be uniquely traced. If the product has batch numbers, then it only possible to trace to the level of the entire batch (it is not possible to distinguish or differently trace among two products of the same batch).

8.1 Traceability - Identification Levels

In a given supply chain, the traceability depends not only on the availability of information, but also on its capture.

The availability of traceability information in different levels (trade item, batch, or unique item) enables the differentiation between different product types, different batches or between any two unique physical items, respectively.

gives an overview of the traceability levels discussed in this document.

Table 1: Traceability Levels

Traceability Level	Unambiguous identification of items	AIDC Technology used (typical)	Example
LEVEL U	Each and any single physical product can be identified.	2D barcodes (e.g. Datamatrix)	
LEVEL B	Items with different (lot) numbers can be differentiated	Linear (1D) or 2D barcodes	
LEVEL P	No, all products of the same type are identical.	Linear barcodes	

The granularity of these levels is best for level Unit, and least for level Product: this means that Traceability Level Unit is "superior" to level Prod, because it allows a finer distinction of the items.

The level of traceability information available limits but does not guarantee the traceability class: a certain level of traceability information only allows up to the corresponding level of traceability. For example,

- It is not possible to implement a Level B traceability if the item only contains a linear barcode with the product type.

- It is possible however, to implement Level P traceability with 2D barcodes containing the serial number - by simply skipping the latter information.

It is always possible to degrade (intentionally or not) traceability; once this happens, it is normally not possible to upgrade it.

Besides being available, the data must be captured throughout the entire chain, in the intended level. If, in a given point of the supply chain, the capture of traceability data is downgraded to a lesser level, the whole chain becomes limited to that lesser level.

This means that to ensure a certain traceability class in a supply chain, all of the points of that chain must ensure capture of the traceability data at least in the intended level.

8.2 Full Traceability

Full traceability can be defined as the ability to trace a product from manufacturer to patient, and, with this, to find the patients and locations where products are used or stored.

This ability requires that information is stored throughout the processes from manufacturer to patient, and also requires that this information is interoperable across the stakeholders.

Having a documented path of the products is also a condition to use such information to confer legitimacy of a specific product, as shown in Section 20 - Use Case 7 Falsified Medication Check.

9 Transport

When covering supply aspects, there matter of transportation is an important concern, as it has several implications:

- Transportation may imply a temporary transfer or responsibility to another entity.
- Transportation implies moving items from one inventory location to another, and sometimes, the transportation itself is considered as one "temporary" inventory location
- During transportation, as with any other inventory locations, the items may be misplaced, lost, damaged).
    - Some products that require specific storage conditions (e.g., low temperature) may be exposed to unintended conditions during transport.
    - Transportation may be delayed
    - Items may be lost during transport

Due to these concerns, the items that are sent for shipment may not be the same that are received. For this reason, the reception of the items is the key aspect for billing, inventory checks, etc. For example, items are not billed or assumed in the destination inventory when they are shipped, but only after a correct reception.

10 Product Recalls and Returns

Product recalls are common aspect of supply chain requirements. Typically, a product recall is triggered when some products are deemed inappropriate (or there is a suspicion of this). Product returns are the physical return of the product back in the materials flow path – for example, from a hospital back to a distributor, then back to the manufacturer).

Product returns can be triggered by the consumer (e.g., the hospital) or by the supplier (typically the case for recalls). A product return can be the result of a recall – after the manufacturer recalls the products, they are returned by the distributor to the manufacturer.

The reasons and processes for returning or recalling a product also vary. Examples:

- A medical device manufacturer may recall all products of a given model within a given batch, due to suspects of a contaminated part in a machine that may have potentially affected a complete batch of devices.
- A medicines regulator may decide to recall all items of a given brand or model
- The hospital may return products that were damaged in transport.
- The hospital may agree with the distributor to return products with a high inventory count, and that have with low rotation.

11 Medicines Shortage

The problem of medicines shortages has been reported by health care professionals, manufactures and patients over recent years and acknowledged by the World Health Organization (WHO), European Medicines Agency (EMA), European Commission (EC) and Food and Drug Administration (FDA). Shortages of medicines are a growing issue of concern globally. Several factors can give rise to the cause of medicines shortages and the causes of shortages are multifactorial. The cited causes ranging from problems in production, global consolidation of manufacturing, unintended impacts of pricing, tendering policies, natural disasters, economic issues and crises, regional national conditions, as well as problems within the supply chain.

There is no universally accepted definition of a medicine shortage. According to the Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages (AESGP, EAHP, EAEPC, EFPIA, EIPG, GIRP, Medicines for Europe, PGEU) (https://www.pgeu.eu/wp-content/uploads/2019/03/170201E-Supply-chain-Statement-on-Information-on-Med-Short.pdf),

"suspected medicines shortage is the inability for a community or hospital pharmacy, as a result of factors beyond their control, to supply a medicinal product to a patient within a defined period, for example 72 hours"

According on the meeting report of a technical consultation on preventing and managing global stock outs of medicines, convened by the WHO Department of Essential Medicines and Health Products with the financial and technical support from the International Pharmaceutical Federation (FIP), shortages of essential medicinal products are becoming increasingly frequent globally, burdening health systems with additional costs and posing risks to the health of patients who fail to receive the medicines they need. Medicines shortages of essential medicines have been reported from high-, middle- and low-income countries. They are expensive for health systems to manage, causing additional costs for replacement of medicines and absorbing significant staff time. Medicines shortages pose risks for patient health as a result of non-treatment, under-treatment and possible medication errors from attempts to substitute missing medicines. While medicines shortages are not a new phenomenon, they have been increasing in recent years, prompting international concern about long-term supply of key medicines (https://www.who.int/medicines/publications/druginformation/WHO_DI_30-2_Medicines.pdf?ua=1).

On 7 November 2018, EAHP released the results of its 2018 Medicines Shortages largest pan-Europe Survey. The results of the 2018 Medicines Shortages Survey underline that medicines shortages remain a major problem for patients in European hospitals. In a number of ways, the issues have become more troublesome since the publication of EAHP's last survey results in 2014. In particular the percentage of hospital pharmacists reporting shortages to be an issue in terms of delivering the best care to patients has seen a significant increase with 91.8% respondents compared to 86.2% in 2014, stressing that medicines shortages are a problem faced in their hospital pharmacy. Many hospital pharmacists highlighted the need for more timely and accurate information on medicines shortages. EAHP is consequently calling on all supply chain actors, the European Commission and national governments to help improve the collection of

information about medicines shortages in Europe. Only a comprehensive communication strategy on shortages targeting all European states will ensure that all supply chain actors, including hospital pharmacists, receive adequate information on the shortage of medicines in their countries (http://www.eahp.eu/practice-and-policy/medicines-shortages/2018-medicines-shortage-survey).

The International Pharmaceutical Federation (FIP) noted that there is evidence that medicines shortages are worsening with time; in some countries, medicine shortages tripled between 2005 and 2010. The causes of these shortages are multidimensional in the context of a complex global supply chain. As a result, there is a growing concern among health care professionals about the future of medicines availability worldwide. FIP has been working to address global medicines shortages since 2011, when this problem was highlighted at its 71st World Congress of Pharmacy and Pharmaceutical Sciences. In 2013, FIP organized the International Summit on Medicines Shortage in Toronto, Canada, providing a forum to discuss the causes, impact, and solutions to medicines shortages through a multi-stakeholder approach (https://www.fip.org/Medicines-shortages).

The Pharmaceutical Group of European Union (PGEU) has addressed the issue of communication in the 2017 Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages together with the European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers and hospital pharmacists (https://www.pgeu.eu/wp-content/uploads/2019/03/170201E-Supply-chain-Statement-on-Information-on-Med-Short.pdf). The recommendations call for greater transparency and availability of medicine shortage data, early detection and assessment of potential shortages, consistency of reporting, increased access to the information available across all parts of the supply chain, improved data infrastructure, and collaborative governance processes (https://www.pgeu.eu/medicine-shortages/, https://www.pgeu.eu/wp-content/uploads/2019/03/190514E-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf).

The Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) task force on the availability of medicines for human and veterinary use (https://www.hma.eu/522.html) released two guidance documents that seek to improve reporting and communication around medicines shortages. Both the ‘Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders in the Union’ (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf) and the ‘Good practice guidance for communication to the public on medicines’ availability issues’ (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guidance-communication-public-medicines-availability-issues_en.pdf) lay the foundations for an improved and harmonized EU approach in reporting of and communication on medicines’ shortages and availability issues, a key public health priority for the EU network.

The ‘Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders in the Union’ seeks to facilitate the detection and early notification of medicines shortages. The document contains a template for shortage notification which should

be used by companies when communicating to national competent authorities. Both the guidance and the template will be tested during a pilot phase starting at the end of 2019.

The 'Good practice guidance for communication to the public on medicines' availability issues' has been issued for the use by EU national competent authorities and EMA. It contains principles and examples of good practices for communication that should be adhered to when sharing information about medicines shortages with the public, patients and healthcare professionals. The guideline highlights the need for timely, accurate and up-to-date information on availability issues to ensure continuity of care.

Food and Drug Administration (FDA) receives information provided by manufacturers regarding their ability to supply the market, receives market sales data on the specific product and lists medicinal products on its website once it has confirmed that overall market demand is not being met by the manufacturers of the product. FDA does not consider a product to be in shortage if one or more manufacturers are able to fully supply market demand for the product (https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages).

American Society of Health-System Pharmacists (ASHP) Drug Shortage provides information about which manufacturers have the medicinal product available and which ones do not, since supply chain disruptions may occur when all previous manufacturers are not yet back on the market with all formulations and all dosage sizes. ASHP lists medicinal products in shortage even if the full market demand is met by the current manufacturers (https://www.springer.com/gp/book/9783030153977).

The eCOST Action 15105, Medicines Shortages in Europe, a European Medicines Shortages Research Network - addressing supply problems to patients (Medicines Shortages), is an eCOST (European Cooperation in Science and Technology) action and it was started in 2016. The Action 15105 is encouraging systematic sharing of information and research about past, ongoing and future shortages of medicines. It aims to respond to clinical, financial and quality of life interests, to achieve analytical clarity on disruption causes, to simulate decision making in medicines production and trade, to highlight restrictive legal and economic frameworks, to disclose disincentives in the supply chain such as conflicts of interest or problematic cost-benefit ratios, and to reflect on best coping practices (http://medicinesshortages.eu/https://www.cost.eu/actions/CA15105).

12 Falsified Medicines

Fake medicines that pass themselves off as real, authorized medicines (definition from European Medicines Agency) are a growing concern.

Falsified medicines may:

- contain ingredients of low quality or in the wrong doses;
- be deliberately and fraudulently mislabeled with respect to their identity or source (incl batch/lot, expiry date);
- have fake packaging, the wrong ingredients, or low levels of the active ingredients.

Falsified medicines do not pass through the usual evaluation of quality, safety and efficacy that is required for the EU authorization procedure. Because of this, they can be a health threat. The EU has issued a Falsified Medicines Directive that requires the different stakeholders to take measures against falsified products.

There are two main measures being used against falsified products:

- Anti-tampering devices that give an additional guarantee that the product is legitimate.
- Supply chain practices, including controlled, traceable supply chain. The aspects of this are covered in this document.

Refer to external document IHE FMD educational article[25] for an example how interoperability supports the safe distribution of medication, and supports this safe distribution without an excessive burden on the different systems.

[25] http://ihe.net/uploadedFiles/Documents/Pharmacy/IHE%20Pharmacy%20FMD%20Guide_Rev1.0_2017-02-08.pdf

13 Common Requirements for Supply of Healthcare Products

Besides the functional and non-functional requirements to support the use cases, there are some high-level needs (policy, strategic, legal) to consider in the scope of supply chain management.

We start our analysis with these common requirements that apply throughout the supply chain.

13.1 CR1 Privacy and Security

Supply of healthcare products may include patient identification, and other PHI (Protected Health Information). For example, a request to dispense a specific medication from a prescription includes patient name and identification; the usage of a medical device may require to be assigned to a specific patient, if there is a need for further tracking that device. In some cases, only few care professionals (e.g., clinical pharmacist) have access to PHI, but in other cases, this information must be available to several parties including the product vendor (e.g., if a customized medical device has to be manufactured).

Security and privacy must be considered throughout the complete processes, but in a flexible manner: it must be possible to have an adequate and informed balance between security, privacy, and other operational parameters such as traceability.

13.2 CR2 Independence of Workflows

Across regions, across Healthcare providers, and even inside most Healthcare providers, there is no single supply workflow, but rather different workflows for different uses (e.g., medication, surgical products, emergency items). The supply models adapt to different conditions.

In addition to this, the supply workflows are expected to be evolving: Process re-engineering is important in healthcare, especially for areas like supply where operational efficiency plays a role, and not clinical aspects.

The actors used to describe the use cases, and especially the technical mechanisms designed to address the topics in this whitepaper, should be as much as possible independent of the workflow configurations.

13.3 CR3 Support Manual and Automated Activities

There is a growing effort on automation, especially on operational activities like supply. Examples are automated dispensing cabinets, storage robots, etc. This effort is typically progressive, which means that several systems – manual and automated – are expected to coexist.

The automation effort should not require a reengineering of the pharmacy workflows. This means that the same interoperability mechanisms should apply regardless if an action (dispensing, transporting, stock count) is performed by a manual or an automated or semi-automated system.

13.4 CR4 Support Internal and External Workflows

The separation between internal and external supply chain is not always clearly defined, but it may be relevant for privacy and traceability (and other) concerns.

In some simple cases, the procurement department is the boundary – all activities beyond the procurement department are "external", the others being considered internal. But this varies – for example for consignment items or personalized medication or medical devices.

The interoperability mechanisms should support a flexible / overlapping transition between internal and external workflows.

13.5 CR5 Implementability – Harmonization of Technical Interfaces

Given the number of use cases and possibilities, and especially the expected variation found in implementations, the technical mechanisms should be designed to be reusable as much as possible. For example, a mechanism such as "resupply order" should be the same for traceable or non-traceable items, for retroactive orders, etc. This will allow that systems are evolving without the need to reconfigure the complete interoperability architecture.

13.6 CR6 Information Sharing

The current whitepaper starts by describing the traditional, point-to-point communication that is needed for fulfilling a specific, simple, flow.

However, the current needs for safety, traceability, information records etc., as well as IT best practices, recommend that the data is not discarded or contained in the simple use cases, but rather shared in a controlled (i.e., well designed) manner.

For example traceability information is essential when considering patient safety, pharmacovigilance, and even falsification of medicinal product.

Mechanisms must be considered (even if not included) for medication supply and dispense to be shared within a facility, or across facilities.

Note: Confidentiality and privacy requirements apply here, due to the sharing of information which carries protected information.

13.7 CR7 Medicinal Product Safety

The problem of falsified medicinal products is one of the concerns in the healthcare supply chain. While it is not the main goal of this document, medication safety mandates that the healthcare supply take into consideration the problems of medication falsification, e.g., by ensuring traceability and authentication of the actors and information present in the supply chain.

13.8 CR8 Efficiency and Usability

The supply management is a critical area and its best execution requires information capture and a series of guidelines to be followed. However, like all other processes, there is a need to ensure

this process is correctly used on the floor and does not introduce unresolvable practical aspects that would harm efficiency:

While the cases may require additional data capture, this is not always possible or practical - there is a need to support efficiency and usability by, for example, minimizing the manual data entry, and redundant data entry.

13.9 CR9 Automatic or Manual Data Capture

There are several ways that product information is captured – by scanning a barcode, reading a label and entering information into a system, etc. The same applies to capturing information about locations or staff.

Automatic data capture is supposed to be assisting in processes, not create separate processes, so for this document and scope, we consider that all the ways of capturing product information should be convergent, i.e., the same interoperability mechanisms and content should apply whether the information is captured from barcodes, or manually entered.

Part II – Interoperability needs - reference use cases and requirements

This section contains the reference use cases that show the interoperability needs. From these reference use cases, we derive the requirements and explain the model (actors, data exchange, etc.). More detailed use cases can be added as examples.

14 Use Case 1 – Medication order, global distribution and administration (floor stock)

This simple use case introduces the articulation between the clinical and operational aspects. It includes an order entry with mandatory validation, dispense at the ward and administration.

This use case introduces inventory management and resupply as needed for a basic scenario.

14.1 Preconditions

A patient, John Smith, is admitted to the hospital by his Physician with acute abdominal pain.

The admissions department has registered John in the hospital information system and an encounter has been created for John Smith.

This encounter specific information has been broadcast via interface to other hospital systems, including the Pharmacy Information System, Computerized Physician Order Entry System, Pharmacy Dispensing System, and Electronic Medication Administration System.

In the ward G1 (where John Smith will be admitted), there is a stock of commonly used medication. Among those is **hyoscine butylbromide 10 mg**, with trade name BUSCOPAN IBS RELIEF.

The identifier for the "virtual" pharmaceutical product **hyoscine butylbromide 10 mg** is a code: 603985.

The product is available in ward G1 and in the central pharmacy. The product is labeled as shown below:

(Each box of BUSCOPAN IBS RELIEF is marked with a vendor-issued barcode corresponding to the global trade item number: 5012917021912.)

While the product available is a commercial product, inside the hospital the users do not refer to products by their commercial names. Both the physician and the pharmacists refer to this product as "**hyoscine butylbromide 10 mg** " (pharmaceutical product).

Due to a previous bulk purchase, all of the initially available units of BUSCOPAN at the hospital have the same lot number: ABC0001. This lot has an expiry date of 12-2016.The available inventory for **hyoscine butylbromide10 mg** (BUSCOPAN IBS RELIEF) is as follows[26]:

Pharmacy						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
5012917021912	BUSCOPAN IBS RELIEF bx 20 tablets	ABC0001	12-2016	**28**		
			Total:	**28**	20	50
	...					

Ward G1						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
5012917021912	BUSCOPAN IBS RELIEF bx 20 tablets	ABC0001	12-2016	**5**		
			Total:	**5**	5	10
	...					

In this case, the Unit of Distribution is the box containing 20 tablets. The unit of use is the tablet. For purpose of reordering, this use case assumes that the pharmacy only considers full boxes.

For this use case alone when a nurse consumes one tablet, the nursing or pharmacy system can determine that there are now one box that is not full but lacking one tablet, and while the pharmacy knows the exact amount of tablets left, it considers that the open box is "in use" and no longer counts for inventory.

In some cases, the number of uses or single doses that can be obtained from each distribution unit is not known – for example when products are fractioned (injectables, or ointments). This would mean that the pharmacy may not have a clear insight into the inventory information for these products.

Due to the health system policy, in this use case, there is no need to check for eligibility – all patients are entitled to any medicinal product. Billing is calculated elsewhere and is not in scope.

[26] This table is a simplified view that shows the relevant data for this scope; it is not intended to be used as guidance.

14.2 Ordering

Upon checking on the patient, and given the diagnosis of Irritable Bowel Syndrome, and seeing no contraindications, the physician uses a Computerized Physician Order Entry system to enter an order for **hyoscine butylbromide 10 mg** with a defined dosage for patient John Smith.

This order is then presented to the Pharmacist responsible for the patient's floor. The Pharmacist reviews the orders for appropriate dosing and any contraindications or allergies. Once the review is complete, the Pharmacist approves the order.

The Medication Dispensing System and Medication Administration System are updated with the validated order, as the order is now planned for administration.

14.3 Dispensing and Administration

Because the medicinal product has already been distributed to the ward before the patient needing it, there is no need for an explicit dispense in the pharmacy. The medicinal product is to be given to the patient by the nurse, from the ward stock. This means that a specific tablet will be assigned to a patient at the ward (either at administration time, or e.g., in a preparation in the morning shift). This is the act of dispense: when a medicinal product is assigned to a patient. This notion is fundamental throughout this document. In other use cases, the dispense is an explicit action in the pharmacy, but in this case, the dispense is implicitly done by the nurse when picking the medicinal product for the patient.

The nurse consults the Medication Administration System which contains the patients' Medication Administration Records (MARs) with the planned medications. At the scheduled time, the system may notify the nurse, who then identifies the patient (by manual entry in the system, or with a barcode) (e.g., by scanning the patient's wrist barcode), and sees that the medication "**hyoscine butylbromide 10 mg** " is required. Since the ward contains some products in their commercial package, the system displays to the nurse the name that can be recognized in the package: BUSCOPAN IBS RELIEF. To administer the medicinal product to the patient, the nurse takes one pack of BUSCOPAN IBS RELIEF from the ward shelf, and scans its barcode. From the scanned barcode (5012917021912), the medicinal product administration system confirms that this is the right medicinal product for the right patient. (The barcode of the medicinal product also indicates that this is a tablet for oral administration, so the right dose and strength, as well as the right route are also verified, and the system time indicates that it is at the right time).

The nursing system informs the Pharmacy Dispensing System and the Computerized Physician Order Entry System that this medicinal product has been consumed and administered in that quantity.

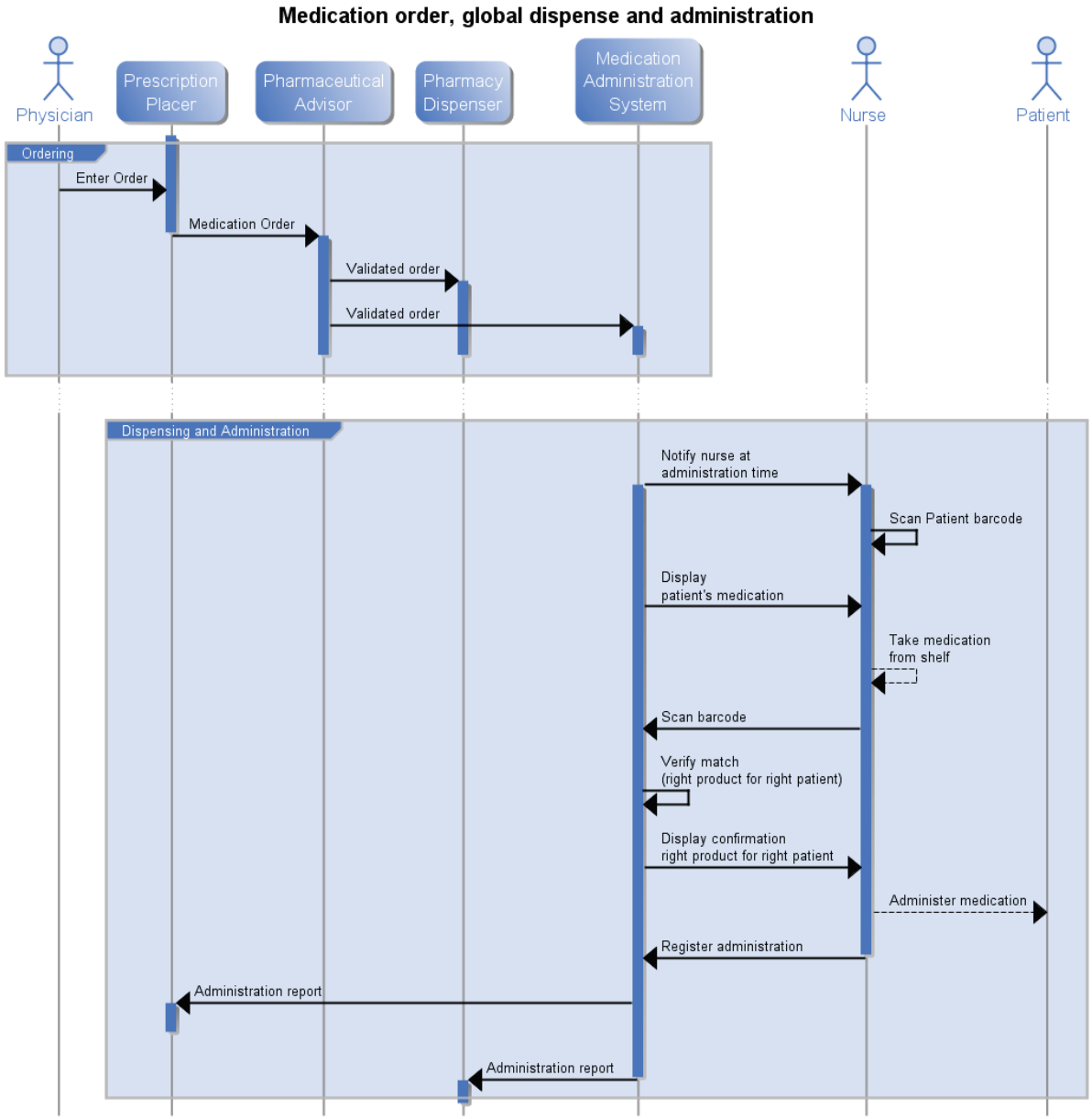
The ward stock level after picking the box is as follows:

Ward G1						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
5012917021912	BUSCOPAN IBS RELIEF bx 20 tablets	ABC0001	12-2016	**4**		
			Total:	**4**	5	10
	...					

Note: In this case, traceability is limited to the level of the medicinal product, not to its batch number and expiry date. This introduces a traceability constraint which may imply some risk.

If finer traceability is desired, the approach must include lot-traceability or unique item traceability by using AIDC technologies (e.g., barcode) at dispense.

14.4 Sequence Diagram



15 Use Case 2 – Ward Supply Management - Pharmacy-Managed Inventory

This simple use case articulates with the previous to describe the resupply of medication from the vendor to the ward.

It describes the situation of supplier-managed inventory: the consumption of items is registered in a system that is not responsible for maintaining its own stock: it reports to the supplier (Pharmacy) each consumption, and the supplier uses this information to keep track of the inventory, and decide to order any resupplies to the ward.

15.1 Preconditions

In the beginning of the year, the hospital made a contract with a supplier for BUSCOPAN IBS RELIEF, where the conditions (e.g., prices and quantities) are defined for the whole year.

As described in Section 7.1., for inventory of the ward, only the full boxes are taken into account. In this use case, a box that contains 19 tablets instead of 20 is considered "in use" and just for this use case, it is already considered "consumed" even if there are still 19 tablets. This is the case when a box of tablets is "reserved" for a patient whom this product had been prescribed.

15.2 Internal Resupply - Request and Transfer

When the nurse confirms the usage of the medication and the Nursing system issues a Dispense report, the Pharmacy becomes aware that one unit has been consumed and that the stock of BUSCOPAN IBS RELIEF at the ward is reduced: While before there were 5 full boxes, there are now 4 full boxes plus one box with 19 tablets left.

The WMS at the pharmacy detects that the stock of BUSCOPAN IBS RELIEF at the ward is now below the reorder level[27], and proposes to the responsible pharmacist to refill the ward stock from the pharmacy stock, with the default order quantity (10 boxes) (note that there are cases where the ward pharmacy disposes of a stock management system, which sends a request to the central pharmacy when stock level requires).

After approval of the pharmacist, the 10 boxes are transported to the ward.

When the items arrive at the ward, the responsible for the reception scans the barcodes of the medication boxes. By scanning the 10 barcodes, it is confirmed to the WMS that the ward stock is now accrued by 10 boxes of BUSCOPAN IBS RELIEF.

[27] The reorder level may be calculated automatically by the WMS as a function of several factors including the expected use. For example, the minimum level can be calculated as the number of tablets needed for 2 days and the maximum for 7 days of average usage in that specific ward.

The WMS system at the pharmacy considers that transfer of inventory, by reassigning those 10 units from the central pharmacy to ward G1. As a consequence, the inventory levels are as follows:

Pharmacy						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
5012917021912	BUSCOPAN IBS RELIEF bx 20 tablets	ABC0001	12-2016	**18** (was:28)		
			Total:	**18**	20	50
	...					

Ward G1						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
5012917021912	BUSCOPAN IBS RELIEF bx 20 tablets	ABC0001	12-2016	**14** (was:4)		
			Total:	**14**	5	10
	...					

15.3 Resupply Request

With this transfer, the stock at the pharmacy is now below the reorder level. Due to this, the WMS proposes to the pharmacist a reorder from the supplier, with the default order quantities (50 boxes). The pharmacist approves the order.

This resupply request is sent to the hospital's purchasing department through the ERP system. The ERP system also determines the preferred vendor (wholesaler). The ERP user issues an order for 50 boxes of item BUSCOPAN IBS RELIEF, code 5012917021912 to refill the hospital stock. This order has an internal ID MD00015 in the ERP. Given the existence of a contract, the resupply order does not need any specific approval workflows: Once it is validated in the ERP, the order is sent to the vendor. Only a notification is also sent for the financial management system, to prepare the billing processor to receive an invoice.

15.4 Supplier Order Processing

The supplier receives the order, checks product availability and informs the hospital that the order has been accepted. When shipping the 50 items to the hospital pharmacy, an electronic dispatch advice is issued, which includes all traceability information (item identification, lot/batch number, expiry date) as well the identification of the shipment. The information about the shipment is as follows:

Shipment ID: 773500538500000018
Item
Customer Order Number: MD00015
GTIN: 5012917021912
National Code: xyz123
Name: BUSCOPAN IBS RELIEF
Lot number: XYZ0009
Expiry date: 03-2017
Quantity: 50

15.5 Item Reception

Upon the arrival of the items to the hospital pharmacy, the identification of the shipment is scanned and linked to the electronic dispatch advice. Since the shipment notice has been received, the shipment ID can be matched with the received items and with the order for BUSCOPAN IBS RELIEF.

Upon scanning the shipment ID, the WMS system looks up the content of the shipment notice and since there is a match, the ERP gets updated with the received items, including their traceability data (Lot number and expiry date).

Note: In some cases, it may be decided to scan each trade item received. This can be advised in some cases. Some examples:

- When some items are suspected to be damaged, then only the ones that are in proper condition are acknowledged as received. (see Use Case 6 Cold-stored medication, resupply and return for return of products to supplier)
- When the shipment identifier cannot be read or matched.
- When any directive from each partner advises the scan - e.g., for expensive or controlled items

In short, the scanning of each item may be advised when, for any reason, it is considered that the received items may not match the inventory description

As the received items match the order issued by the pharmacy, the pharmacy inventory is updated from the shipment notice - the items described in the shipment notice are added to the stock. Use Case 6 Cold-stored medication, resupply and return describes a case of arrival of items that do not precisely match one order.

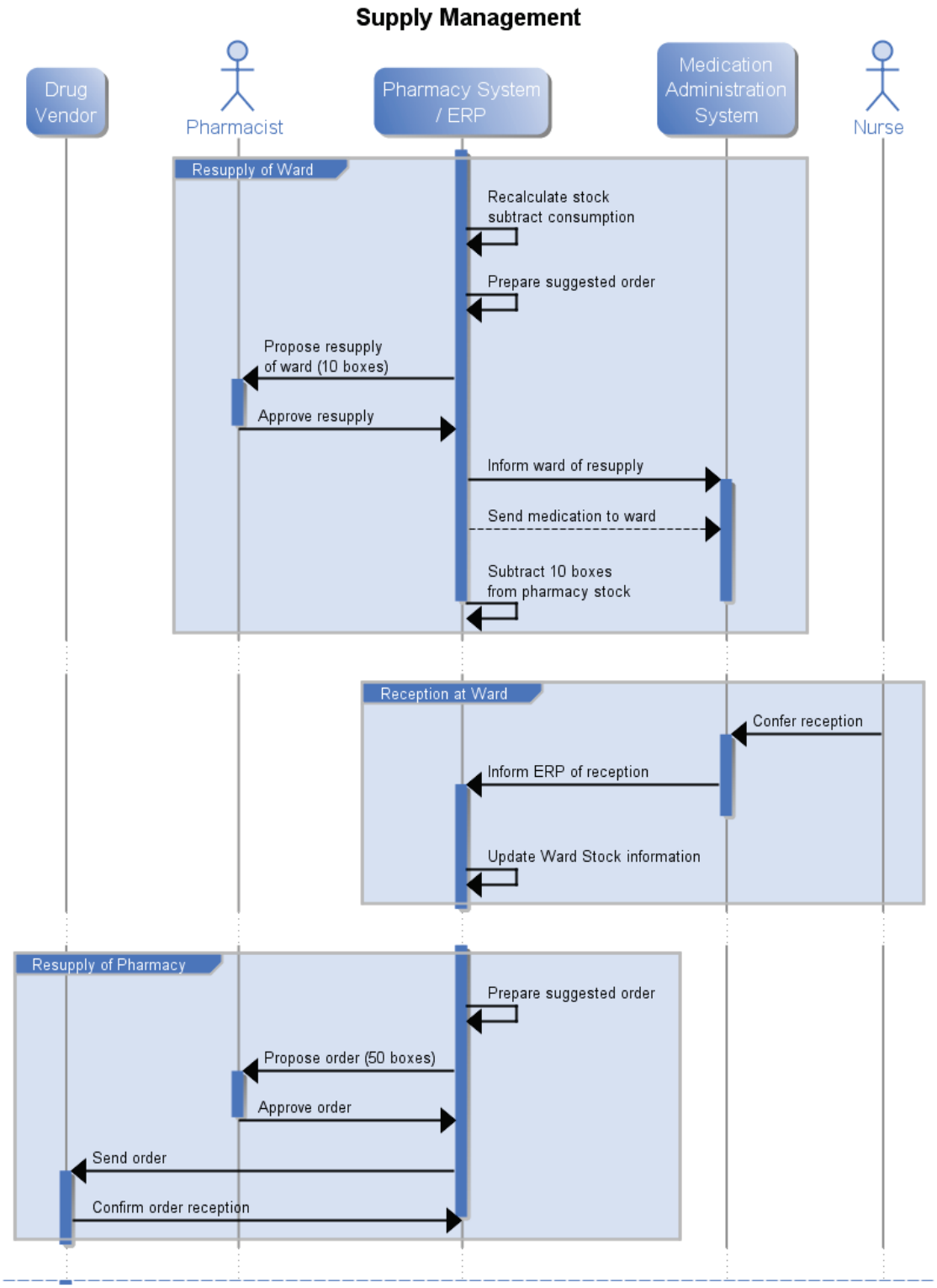
The items are then placed on the shelf in the Pharmacy, and the Warehouse Management System gets updated for the new inventory items in the reception area.

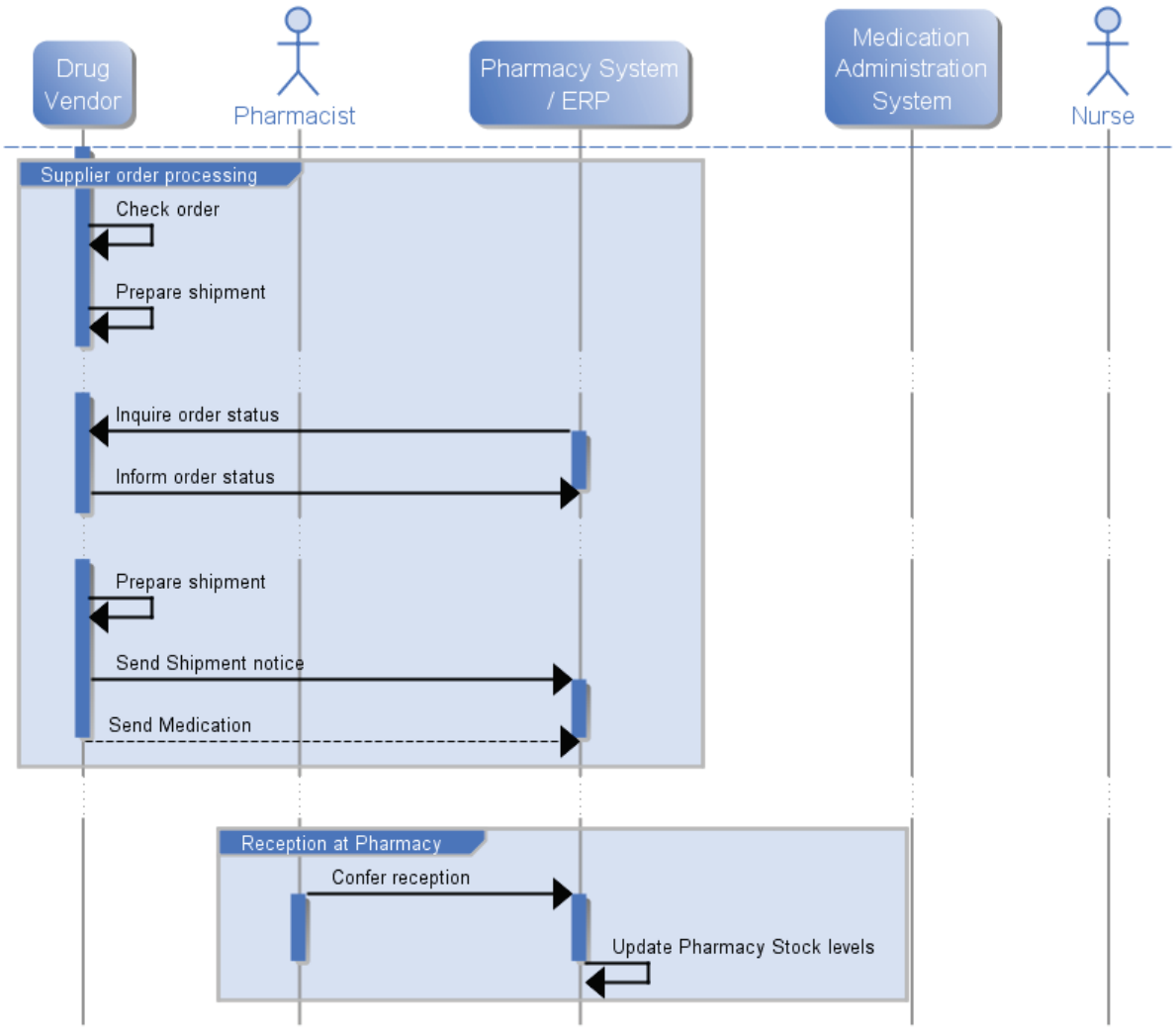
The detailed inventory status at the pharmacy is finally as follows:

Pharmacy						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
5012917021912	BUSCOPAN IBS RELIEF bx 20 tablets	ABC0001	12-2016	18		
		XYZ0009	**03-2017**	**50**		
			Total:	**68**	20	50
	...					

1645

15.6 Sequence Diagram





1650

16 Use Case 3 Inventory Count and Resupply, Product Distribution

This use case shows the checking of inventory at a specific inventory location - in this example, the satellite pharmacy must count the inventory and report to the central pharmacy.

Since the inventory must be manually checked before reporting, the initiator of this process is the satellite pharmacy.

This use case deliberately relies on some assumptions to ensure a broader functional scope, for example the Inventory application is a remote/mobile app without any previous knowledge of the current inventory.

This use case is limited to only one medication, although in practice, several items are of course expected to be at a given location.

16.1 Preconditions

The responsible for the satellite pharmacy has a recurrent task to check the current inventory level at his pharmacy. The satellite pharmacy has 2 inventory locations:

1. The normal inventory in a dedicated room (labeled "Pharmacy Stock")
2. The refrigerator where certain medication is kept in cold storage.

Besides this, the satellite pharmacy is also responsible for the ward inventory, so there are 2 more locations:

3. Ward G1
4. Ward P1

Thanks to a procurement directive that mandates lot-traceability, the product packages contain structured barcodes which contain not only the item, but also lot number and expiry date:

(01)07612345678900

(17)141231(10)LX02374834

According to the central Pharmacy System, which keeps track of the inventory at the hospital, the inventory of the satellite pharmacy is as follows:

Ward G1						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
07612345678900	XXXXXXXXXX	LL1233223	12-2016	5		
		LX02374834	03-2017	8		
			Total:	**13**	5	10
	...					

16.2 Scan Location Inventory

At the end of the year 2014, the pharmacist goes through the inventory locations, and counts the items in stock. The procedure is the same for all locations, and is as below for Ward G1.

The pharmacist starts by identifying the location that is expected to be scanned. This can be done by scanning the barcode for the location.

Since this barcode includes semantics, the inventory system automatically interprets this scanning as a location identification. The remote application requests from the central Pharmacy information about the expected inventory for that location. This will allow to display any discrepancies in real time.

When this information is received, the system notifies the user, who then proceeds to scan the barcode of each item in the same location. The scanning system contains the logic to parse the content of the barcode, obtaining the following information about the scanned products:

- 4 boxes of item 07612345678900. This box has lot LL1233223 and an expiry date 12-2016.
- 8 boxes of item 07612345678900. This box has lot LX02374834 and an expiry date 03-2017.
- 1 box of item 07612345678900. This box has lot LA00012224 and an expiry date 02-2015.

(The last item is an item that is about to expire and was not used earlier.)

After scanning all the items, the remote application displays a summary of the scan results, including the discrepancies - 4 boxes of lot LL1233223, instead of 5, and 1 unexpected box of lot LA00012224.

The pharmacist inspects the package and confirms that the item is indeed of that lot, about to expire. The remote system submits the report to the Pharmacy system, informing of the new inventory status. The Pharmacy system updates this information in its database.

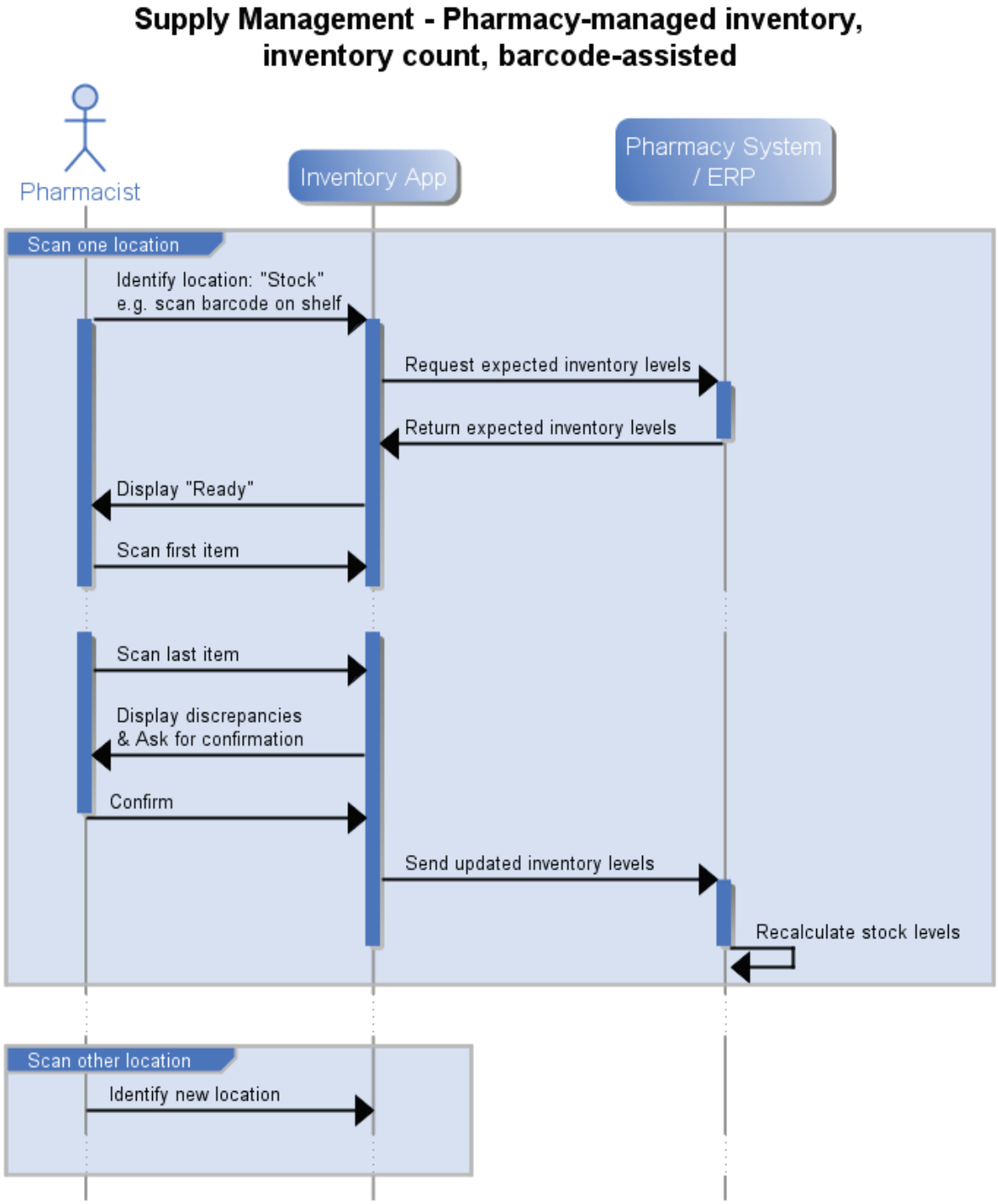
At the end, the Pharmacy System contains the information that the inventory of the satellite pharmacy is as follows:

Ward G1						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
07612345678900	XXXXXXXXXX	LL1233223	12-2016	4		
		LX02374834	03-2017	8		
		LA00012224	02-2015	1		
			Total:	**13**	5	10
	...					

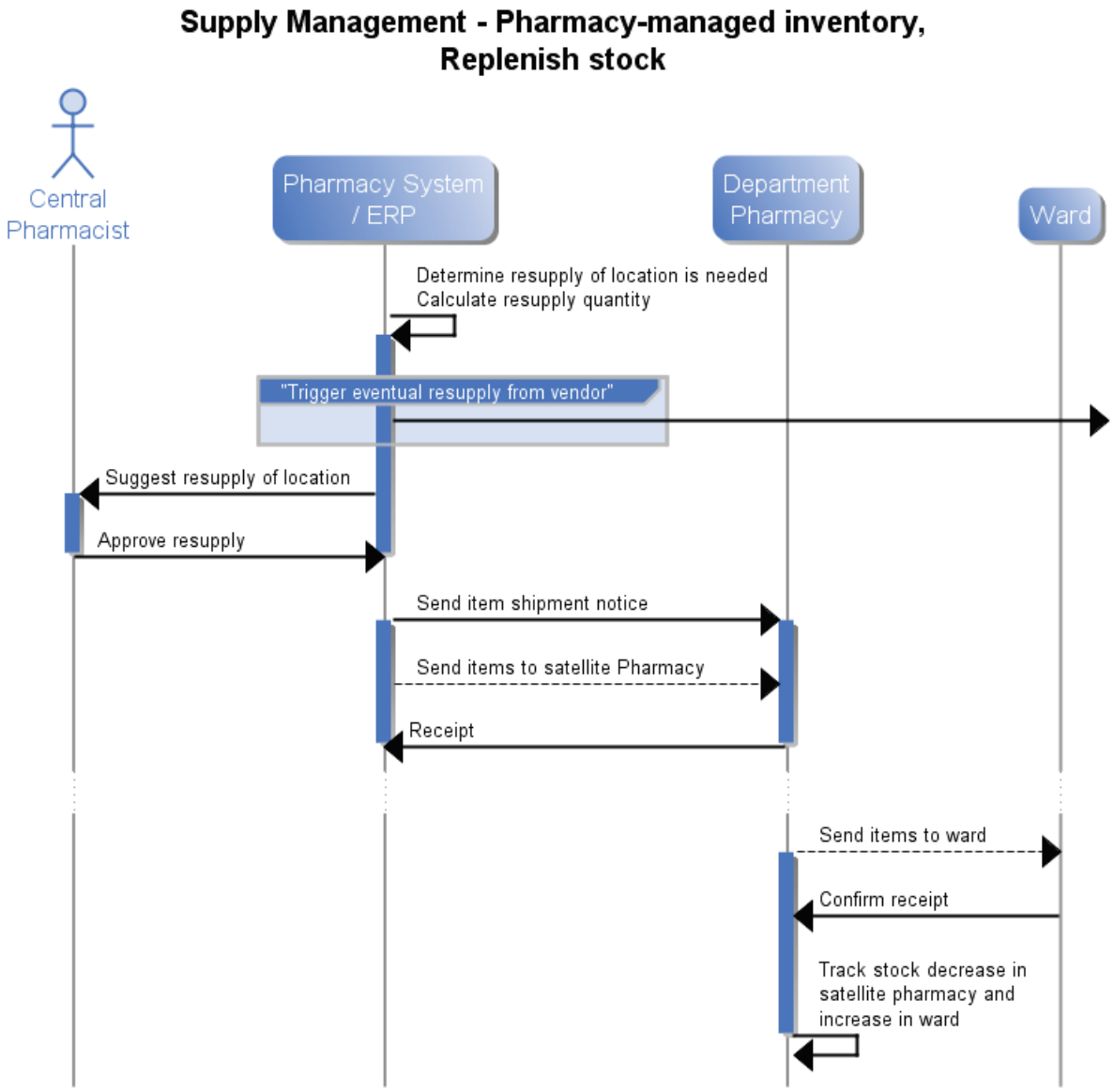
1710

This information can then be used for any of the purposes in this document, e.g., resupply, recall, etc.

16.3 Sequence Diagram



1715



17 Use Case 4 – Community Pharmacy, Stock and Consignment Items

This use case describes a situation where the pharmacy has, besides normal inventory items, an agreement with a vendor, who leaves some items to be exhibited in the pharmacy. These items are in consignment and not ordered by the pharmacy. They are under the responsibility of the vendor until sold.

17.1 Preconditions

The Pharmacy stock has recently been recounted and is considered accurate. The following items are available in the pharmacy:

Pharmacy Stock						
Item Code	Item name	Lot	Expiry Date	Available qty	Reorder level	Default order qty
	...					
05725361962471	XXXXXXXXXX	LLABC01	12-2017	10		
		LLABC03	01-2018	8		
			Total:	**18**	5	10
03582938641053	XXXXXXXXXX	383035	07-2018	3		
		383037	03-2019	7		
			Total:	**10**		
	...					

The second item is in consignment, and as such. the inventory is managed by the vendor.

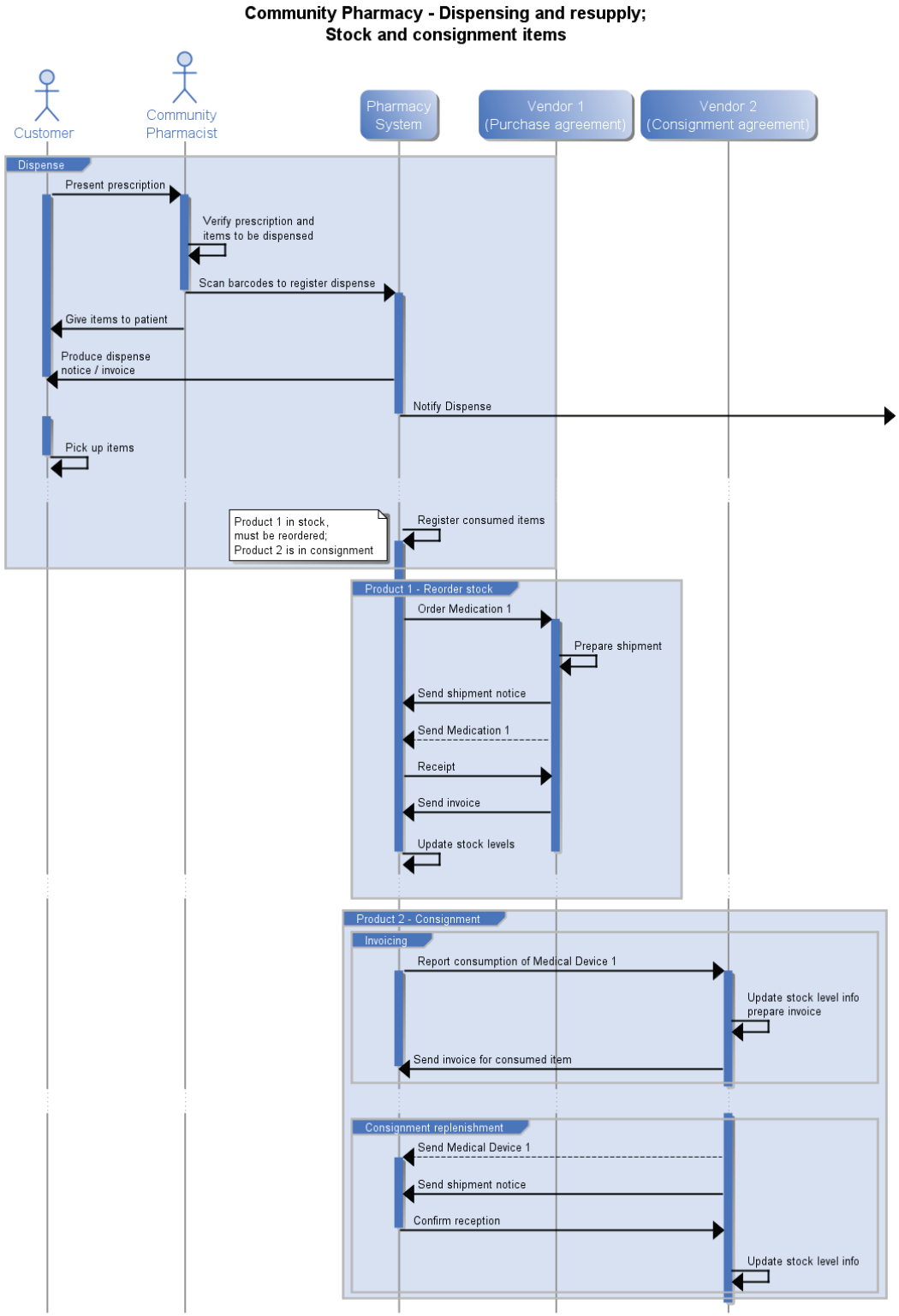
17.2 Sale of Items

A patient presents a prescription which contains two items. These items are both available in the pharmacy (one is in normal stock, another is in consignment).

After the dispense, the inventory is depleted by one unit of each. For the item that is in normal stock, this brings the product to a level below the order level. The pharmacy system proposes to the pharmacist to order more of these items to restore the inventory levels, and the pharmacist approves. The order is sent to the vendor, which will supply the item in the desired quantity.

As for the second item, the medical device, the pharmacy system does not track the inventory, but rather sends each consumption to the vendor, so that the vendor can manage the stock of these items. In this case, the consumption report is sent to the vendor, which triggers the billing of that item to the pharmacy. In addition, the vendor realizes that it is better to replenish the item at that pharmacy, so it prepares a shipment that will be delivered during a next delivery round to the pharmacy.

17.3 Sequence Diagram



17.4 Requirements

This use case introduces the following requirements:

17.4.1 Consumption Report

There is a need to indicate the consumption of an item, without that being an order for refill. It is simply an indication that one item has been consumed.

The consumption report must be able to convey information on:

- the item that was used - to the traceability level that is desired. (i.e., including lot, serial and expiry info if adequate),
- the consumer (in this case, the pharmacist, but it can also be a nurse, or a patient…),
- the consumption act (date, time, place),
- eventually the patient,
    - sometimes there are consumptions that are not associated with a patient, and sometimes the patient information is not to be conveyed for privacy or other reasons
- (any additional data deemed necessary for the concrete use)

18 Use Case 5 – Continued Care Institutions - Preparation, Dispense and Pick Up of Patient Stock

This use case describes a situation where an institution must provide medication to the patients. This medication is provided by an agreement between a hospital and the institution. The order is made in the hospital and the treatment is made in the institution, outside of the hospital.

18.1 Preconditions

In the hospital, the physician has issued a prescription for the following items:

- Paracetamol 500 mg tablets 3 times per day as needed for 3 weeks.
- Amoxicillin 500 mg capsules for 2 weeks.
- Sertraline 100 mg tablet: ZOLOFT 100 mg tablets

The following products are available:

- Paracetamol - DEPON 500 mg tablets in boxes of 20, available at an automated dispenser in the remote institution
- Amoxicillin - AMOXIL caps 500 mg in boxes of 28 capsules, available in the central pharmacy
- Sertraline - ZOLOFT 100 mg tablets in boxes of 28 tablets, available in the remote institution

Amoxicillin is a prescription-only medicinal product and must be dispensed per patient. For this medication, the Pharmacy dispenses the complete treatment in order ensure treatment continuation, e.g., that the medication will not be changed for an equivalent during the treatment.

Sertraline requires can only be dispensed by a hospital pharmacy. The pharmacy has a policy of not dispensing more than 7 tablets for a patient, for two types of reasons:

- Clinical: to monitor the adherence and therapy for the patients
- Logistics: to minimize unused or misused inventory.

Substance	Brand	Location	Stock levels	Dispense Max
…	…	…	…	…
Paracetamol 500 mg tablets	DEPON 500 mg tablets	Satellite (Aut)	60 boxes = 1200 tablets	7 days
Amoxicillin 500 mg capsules	AMOXIL caps 500 mg	C. Pharmacy	40 boxes = 1120 capsules	
Sertraline 100 mg	ZOLOFT 100 mg tablets	Satellite (Man)	24 boxes = 672 tablets	7 tablets
…	…	…	…	…

18.2 Dispensing

18.2.1 Part 1: Preparation, dispense and pickup (1st week of treatment)

When receiving the prescription, the pharmacist checks the prescription and, knowing where the preferred inventory location of the items to be dispensed are, steers a dispense request to the central pharmacy (for paracetamol and amoxicillin) and informs the remote pharmacy about the upcoming request for the sertraline.

The central pharmacy can immediately dispense the 21 paracetamol and 14 amoxicillin: A request is sent to the automated dispensing system for the paracetamol, and the amoxicillin is dispensed manually at the central pharmacy.

Since the rules for dispensing sertraline allow only dispensing for 7 days, the central pharmacy issues to the remote pharmacy a dispense request for 7 units of sertraline.

The nurse picks up the medication from the central (possibly after a transport) and from the remote pharmacies, for administering to the patient.

All of the dispense processes above can be followed by resupply or any other processes, as described in previous use cases.

18.2.2 Part 2: Updates to dispense triggered by administration, consumption report

From the continued care institution, the Pharmacy receives information about the administration and use of certain medication, to better adapt their dispense processing.

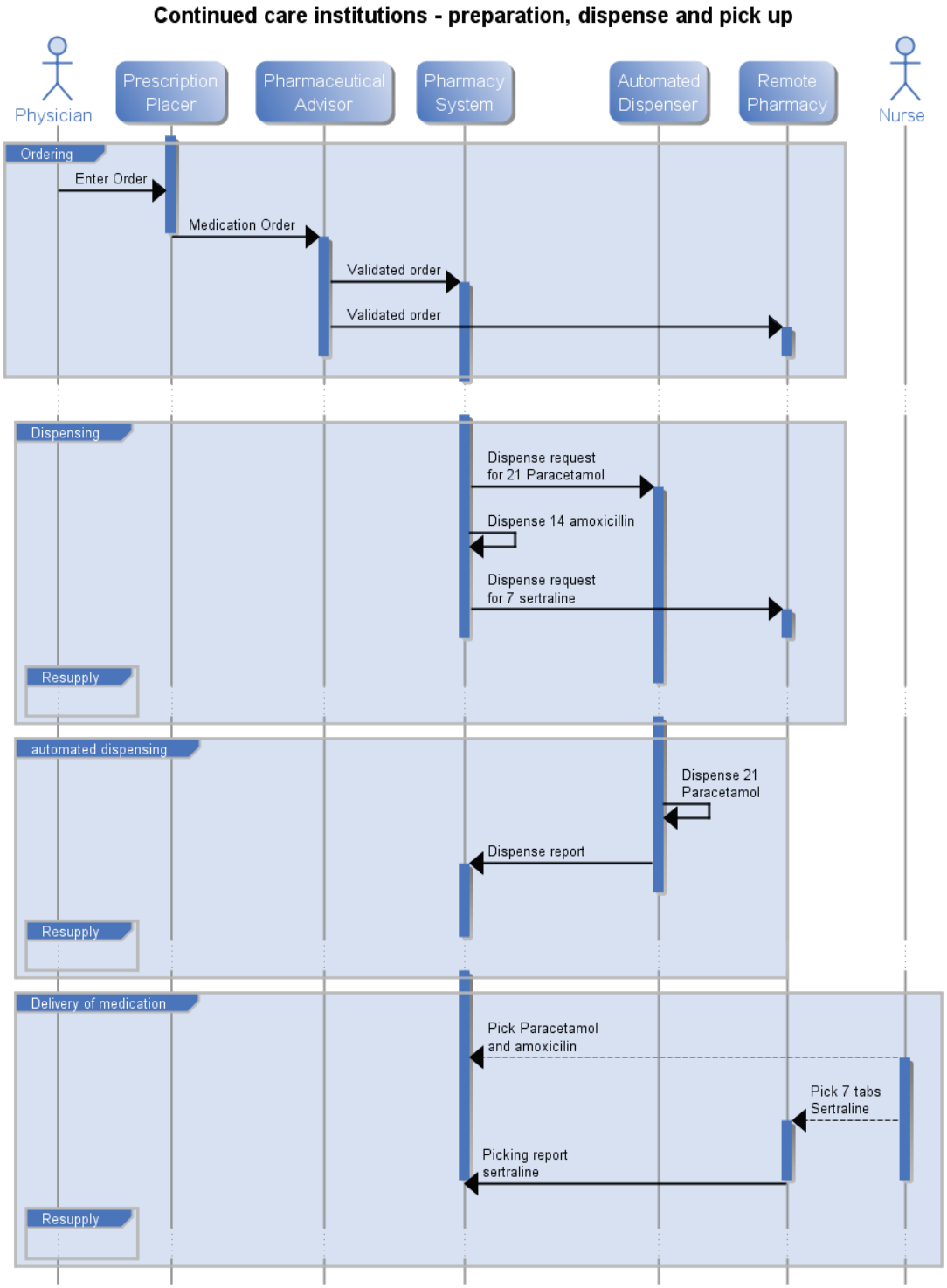
In the first day of treatment, the nurse prepares the medication. By accident, the nurse drops one of the tablets of amoxicillin and takes another from the medications that were dispensed. The medication is placed at the bed of the patient.

After 1 week, the nurse notes that the patient has not taken one of the medications - sertraline. The patient opened the medication blister given by the nurse, but only took it one day, and not the next 6 days. The nurse must report that the medication is not taken but is to be considered consumed. Since the paracetamol was supposed to be taken only when needed, the nurse informs that only 6 tablets were consumed during that week, instead of 21.

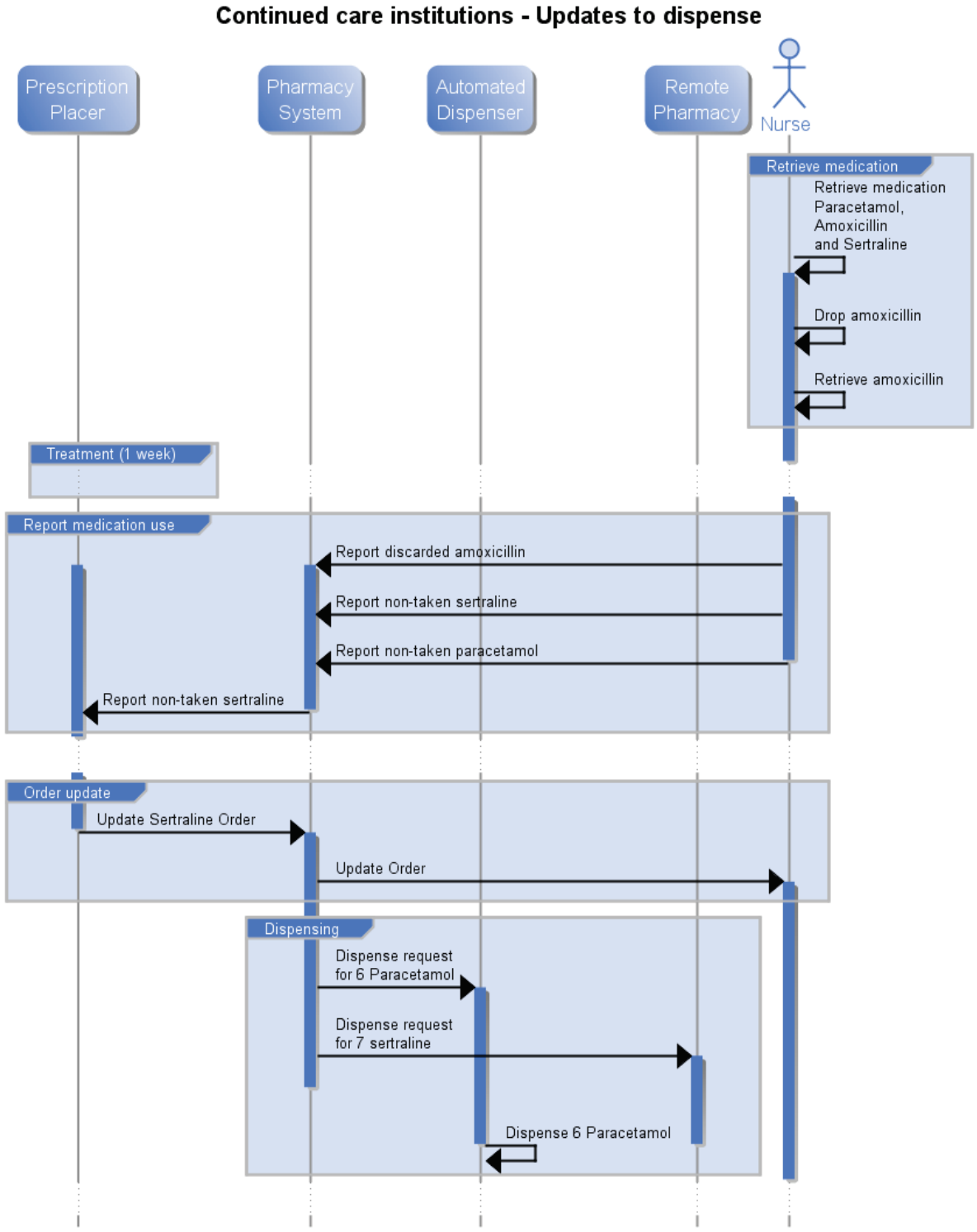
From this, the physician is notified about the sertraline and informs the pharmacy that the treatment should be restarted. The pharmacy decides to dispense the medication that the patient did not take: The pharmacy dispenses 7 more units for that week, but while this was initially supposed to be the final dispense, it has now changed and 7 more units will be expected to be dispensed in the week after.

1820 ## 18.3 Sequence Diagram

18.3.1 Part 1: Preparation, dispense and pickup (1st week of treatment)



18.3.2 Part 2: Updates to dispense



1825

18.4 Requirements

This use case underlines the need for a dispense request that is not a prescription – it is a logistics / materials order, just to provide the items that are needed for the execution of the clinical activities.

This use case introduces the following requirements:

18.4.1 Add Items to Inventory

There is a need for a mechanism to add units to inventory, i.e., register new units in the inventory. This may be an interoperability requirement for later, but for now it is considered to be a functionality that is directly in the inventory management system.

18.4.2 Return Authorization

There is a need to inform of the authorization to send items. This acts in a similar way to an inventory order (with reversed roles in this case), where one of the party's requests/allows the other party to send some items.

18.4.3 Return of Items

The return of items is similar to the delivery of items: One party informs the other about the sending of items.

19 Use Case 6 – Cold-stored medication, resupply and return

This use case shows that supply involves not only the information flow but also the materials flow, which can bring additional requirements, such as the transformation of items between actors – for example, a transport may result in unwanted alteration of the products, and the result is that what is shipped is not what is delivered, which affects inventory management.

19.1 Preconditions

A hospital has a stable stock of meningitis vaccines. After a surge of meningitis cases during summer, the hospital stock is almost depleted, and they decide to reorder medication (this is similar to the first use case in this document).

19.2 Resupply and Return

The pharmacist in the hospital requests the medication, which is prepared and shipped from the vendor. The shipment is accompanied by an electronic shipment notice, which informs the pharmacist about the pending delivery and quantities.

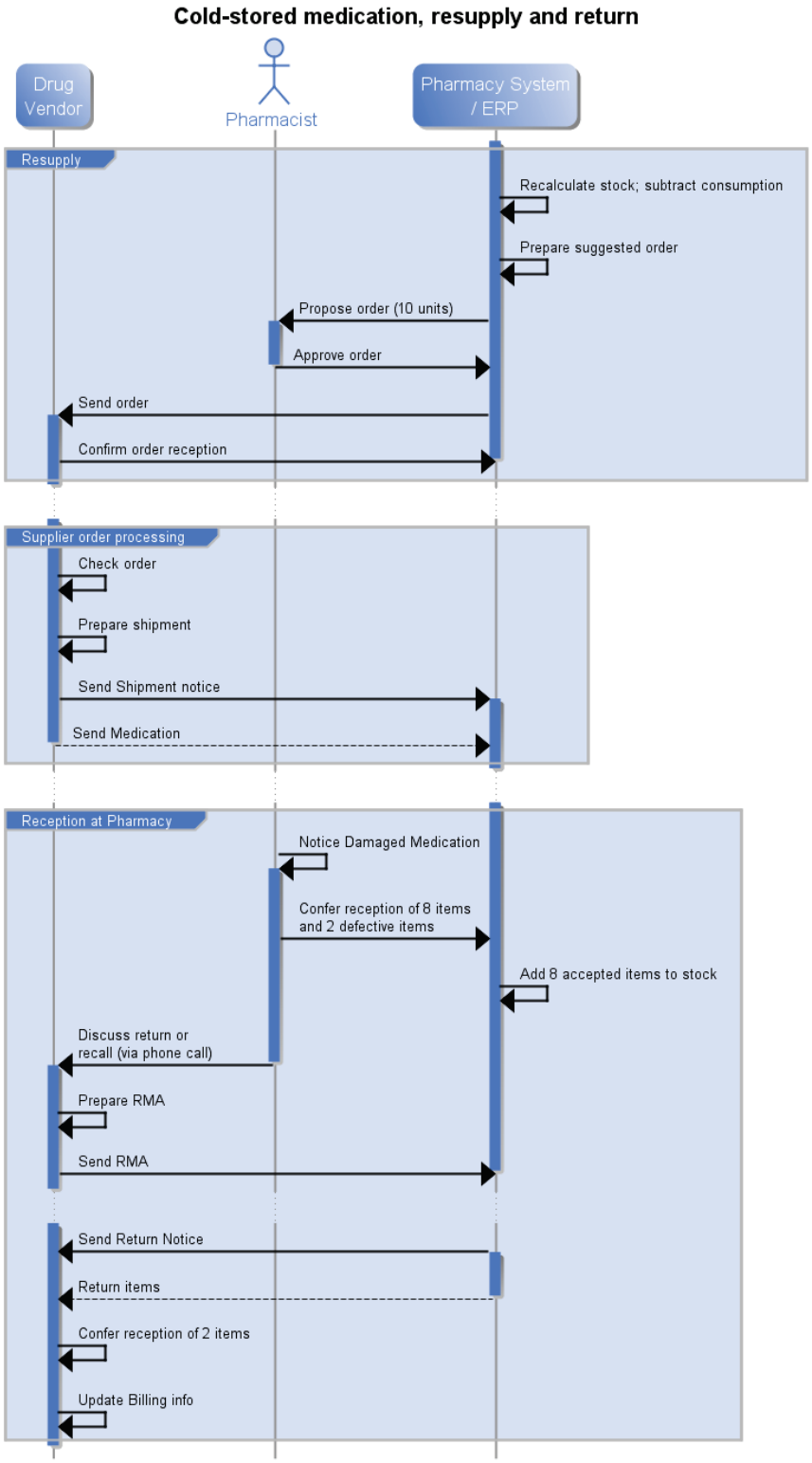
After the medication is delivered to the hospital, the pharmacist notices that some of the items appear to be damaged in transport. 8 units are in proper condition and are added to the inventory of the hospital. 2 units however are not in proper condition, and the pharmacist cannot use them.

The pharmacist decides to return the items, and during a phone call, the vendor agrees with that return. The vendor prepares an RMA (authorization to return materials).

The hospital pharmacist prepares the items for sending back to the vendor, in a process that is similar to the initial shipment: identifying which items are to be sent, preparing a shipment notice, and sending the items.

In some cases, the invoice can be paid in full and then the credit invoice is issued. In other cases, the invoice can be immediately revised… The complexity of this matter is not in the scope of this work, but the information required for billing is provided by the mechanisms discussed in this document.

19.3 Sequence Diagram



19.4 Requirements

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There is a need to inform of the authorization to send items. This acts in a similar way to an inventory order (with reversed roles in this case), where one of the party's requests allows the other party to send some items.

19.4.3 Return of Items

The return of items is similar to the delivery of items: One party informs the other about the sending of items.

20 Use Case 7 – Falsified Medication Check

This use case describes how a physical item (product package) can be checked at dispense time, according to the Falsified Medicines Directive. The dispenser retrieves the item, and when scanning it, the system performs a lookup of the item's serial and lot numbers, returning information whether the product is considered OK or not.

20.1 Preconditions

The pharmacy system adopts FMD compatibility and IHE transactions.

The pharmacist has still some items from his trusted supplier, and has received a new shipment from a new supplier.

The products delivered by the trusted supplier have been registered in the FMD Hub, as described in the IHE educational material for FMD: http://ihe.net/uploadedFiles/Documents/Pharmacy/IHE%20Pharmacy%20FMD%20Guide_Rev1.0_2017-02-08.pdf

The products delivered by the new supplier are not registered.

Both products have a label with a barcode that contains the GTIN, the lot number, serial number, and expiry date. The GTIN is the same since it is the same product, but the lot numbers, and expiry dates are different between the two products. The serial number is of course unique for each item.

20.2 Retrieval and Online Checking

The pharmacist is dispensing medication for a patient. This can be in hospital and community pharmacy[28].

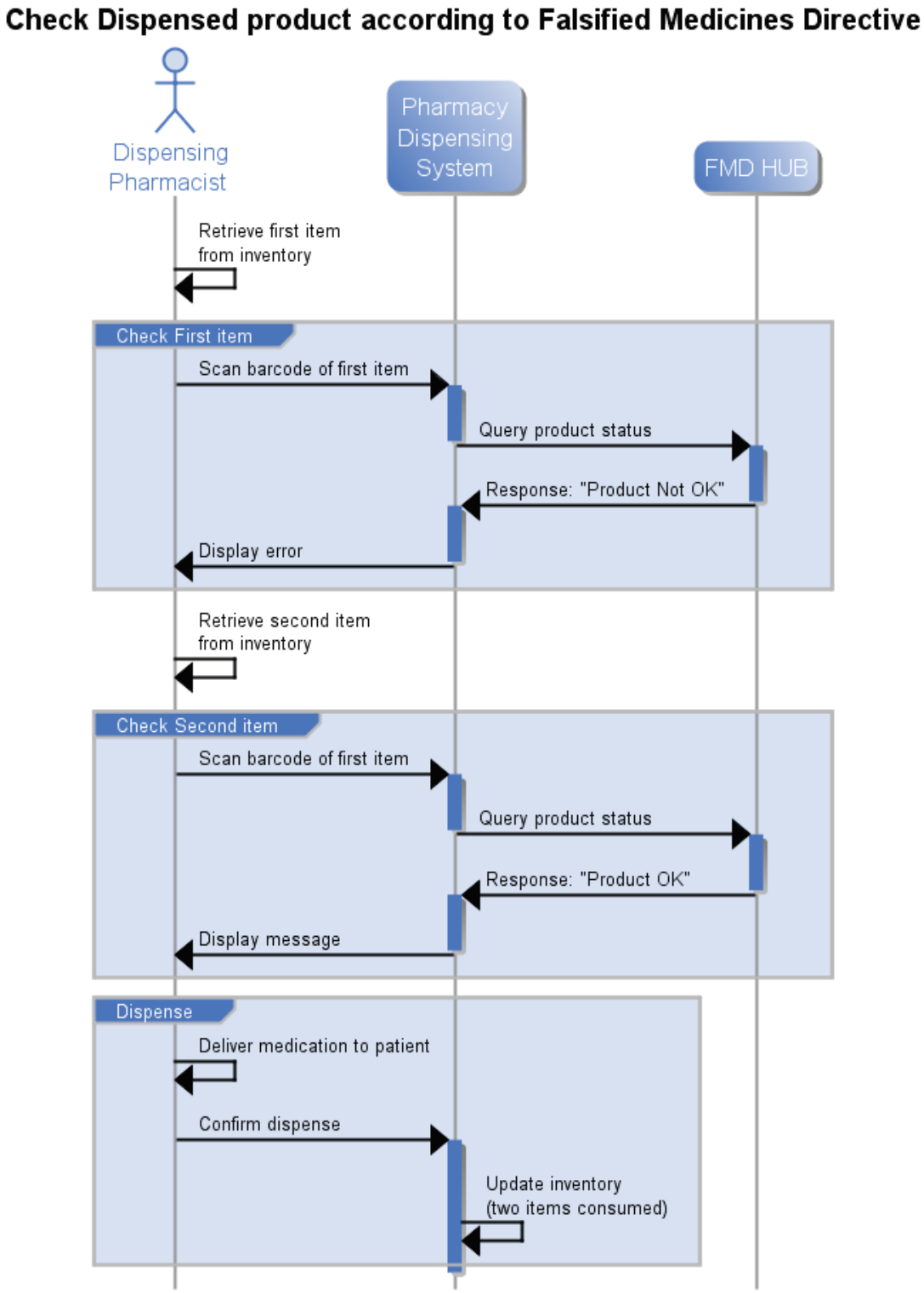
The pharmacist first gets a product from the new supplier. When retrieving the product, the barcode is scanned. The system immediately triggers a product info lookup as mandated by the FMD. Since this product has not been registered in the FMD hub, that system responds that the item is not OK.

The pharmacist quarantines or discards the suspect item, and retrieves another item from his previous supplier. The second barcode is submitted and the response is that the item is OK.

The dispenser dispenses the second item and registers it as assigned to that patient. For inventory purposes, two items have been consumed. But only one dispensed.

[28] This can happen either in hospital pharmacy central distribution, when the pharmacist prepares the dispenses for distribution to the wards, OR in a community pharmacy).

20.3 Sequence Diagram



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20.4 Requirements

This use case introduces the following requirements:

20.4.1 Inventory Item Lookup Request

There is a need to look up a specific product from another provider. This is a request which identifies the complete product information – this includes not only the product type, but also the physical product attributes – lot, expiry, serial, etc.

20.4.2 Physical Item Lookup Response

The product lookup should provide the adequate information. In this use case, the information expected can be a simple “OK”/”Not OK”. In some cases, a more complex payload could be expected, such as a traceability report. A wide variety of such cases can be expected, so it is important not to limit the possibilities.

21 Use Case 8 – Operating Theater – UDI lookup

This use case describes another type of product lookup: Not checking the status of a specific physical item, but looking up the characteristics of that kind of product in the "catalog": When preparing a device.

21.1 Preconditions

In the Operating room, a patient is receiving a lung catheter. The procedure has been scheduled 2 weeks in advance, and when preparing the patient for surgery, the team notes that patient intolerance to latex is not documented, so they decide to use latex-free materials.

In the Operating Theater stock, there are catheters in consignment. Some contain latex and others contain Liquid Silicone Rubber. All these devices are labeled with a UDI label and barcode, and are registered in the central registry for devices (in the US, the GUDID).

21.2 Scanning and Looking Up Products

21.2.1 Scanning UDI Barcode

To prepare for the surgery, the nurse retrieves the items from the local inventory. When scanning the UDI Barcode, the OR system parses the barcode, obtaining the lot number, serial number and expiry date. The expiry date is still in the future and the product is considered valid for implant.

21.2.2 Looking Up Product in the Catalog

But the OR system can also lookup the product in the local catalog, to obtain more information like the price (for charges) or any other information. The OR system submits the product GTIN and obtains the catalog information, which includes *"Device labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)"*.

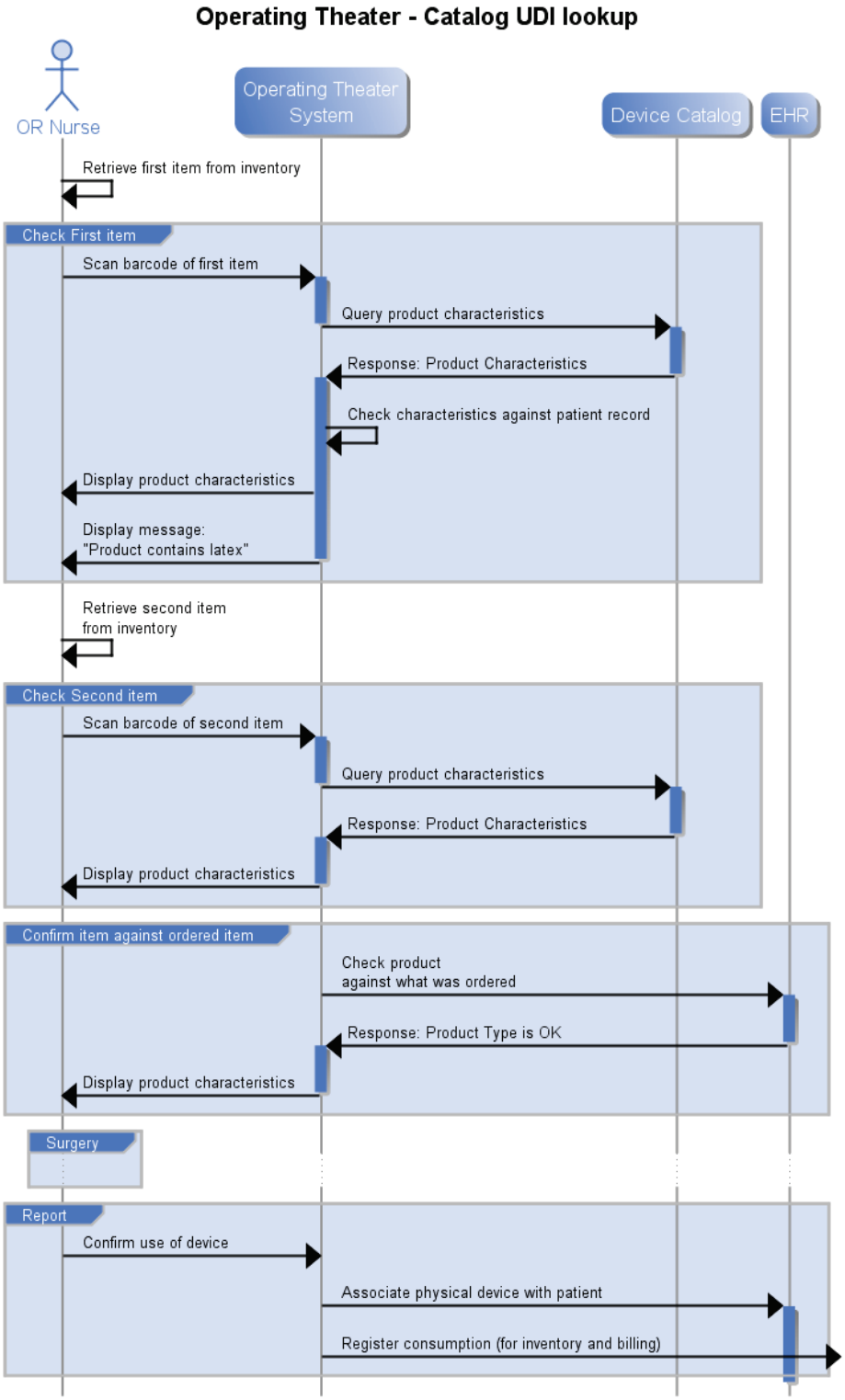
The OR system has been informed that the patient may be allergic to latex, and this immediately triggers an alert to the nurse. The nurse retrieves another device.

21.2.3 Looking Up Product Type in the EHR Order

After the product characteristics are obtained, the product is matched against what was ordered or the patient.

This is done by submitting the product information (Product ID or attributes) against the EHR which contains the order, whether for a specific product ID or containing specified characteristics. The EHR responds with the result of the matching.

21.3 Sequence Diagram



1965

21.4 Requirements

This use case introduces the following requirements:

21.4.1 Catalog Item Lookup Request

There is a need to look up one product type. This is in all aspects similar to the physical product lookup, except that the physical product attributes (lot, etc.) are not required. Since the physical product lookup contains a superset of the information in the Catalog Item Lookup request, it may be that this is not strictly a new requirement, but can be covered by the Physical Item Lookup.

21.4.2 Catalog Item Lookup Response

As a result of the Catalog Item Lookup request, the response is expected to be a descriptive set of product characteristics. In this case, it is a presence of latex or something else. It can also be a broad set of characteristics, from which the receiver can select those appropriate. These are “catalog” characteristics, so they are defined for the product type.

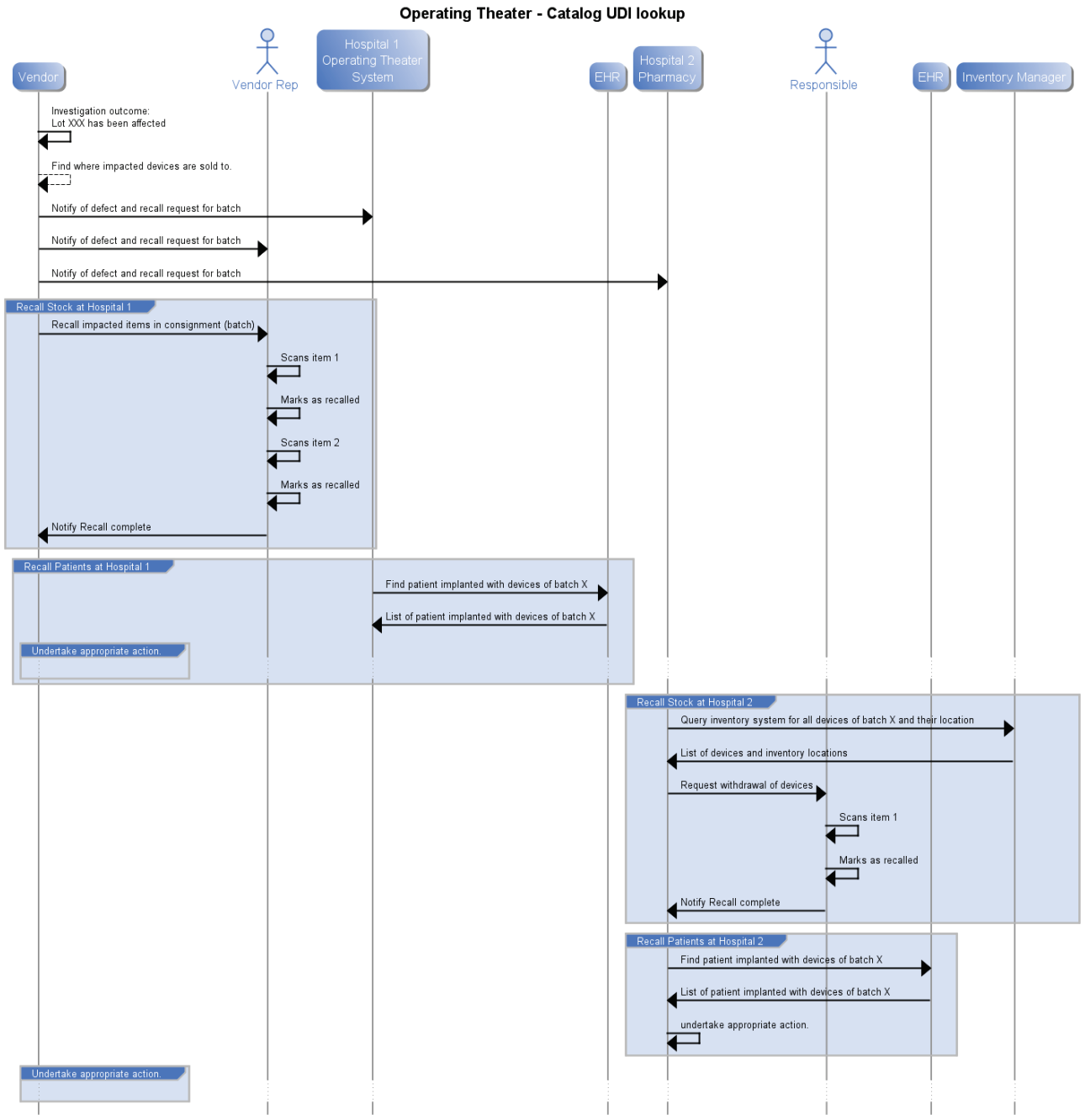
22 Use Case 9 – Recall of UDI Devices

This use case shows the use of UDI in the tracking of medical devices that are already in the supply chain.

This use case presents the following:

- After an internal investigation, the manufacturer of pacemaker discovers that some leads can detach after implantation.
- The investigation reveals that this problem applies to one batch of a specific device model.
- The manufacturer issues a recall notice to the customers AND to all the known stock locations.
- Hospital 1 has the items in consignment.
- Hospital 1 does a research and finds that one patient has received a pacemaker from the recalled batch.
- Hospital 2 has purchased three pacemakers and two of them are in their stock, and the third one is implanted.

In different countries, there are different people that will handle the device inventory. It can be a pharmacist and in some countries, it can be the Purchasing department.



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Part III – Interoperability Requirements and Scheme

23 Requirements Overview

This is an overview of the requirements needed to achieve the key use cases in the document.

In order to support the interoperability and the complexity described in the use cases, a set of reusable mechanisms should be available. The analysis in this white paper allows to create a first model that can be used.

23.1 Interoperability Mechanisms

After a prescription, some items may be dispensed in different quantities than prescribed or not dispensed at all. In other situations, the prescription must be dispensed from different locations. For each of these locations, a dispense order must be used not the original prescription.

R 1. A mechanism is needed to request dispensing a product on behalf of a prescription but not being the original prescription. This is just for the purpose of dispensing.

From the decision of ordering items to replenish stock, the requester must be able to send that request in a standard manner.

R 2. There is a need for standard a mechanism to request items from a supplier; the request may be for immediate fulfilment or for approval for later fulfilment.

In most cases, the request is to the supplier. But in other cases the request may be to an authorizing party, or another management system.

R 3. There is a need for a mechanism to inform another party (not the supplier) of a request of items.

After the order is placed, it is important that the requester can ask the supplier the status of the order.

R 4. Like other orders, it is important to inquire the status of a supply order.

In response to the request, or as an immediate response to the order, or unsolicited, the supplier may inform about the status

R 5. A mechanism is needed to inform the status of an order.

The shipment may also be informed so that both parties know that the items (ordered or not) are now in transport.

R 6. When items are sent (as a response to an order or not), there is a need to inform of the shipment and its contents.

R 7. When items are received, there is a need to check in, or report the arrival of an item (receipt).

When returning products, or otherwise sending items (whether or not as part of an order), there may be a need to authorize the shipment.

R 8. A delivery permission request is a required mechanism.

As a consequence of this permission request, the party accepting the items will inform the sender.

R 9. A delivery authorization is required.

Some items are consumed, at the point of administration

R 10. Upon administration or use of a medication or device, it is needed to inform that an item that has been administered or used.

In some cases, the device is used or consumed but not administered.

R 11. There is a need to report item consumption which is not the same as administration.

A system may need to know the status of the inventory of another.

R 12. An inventory query is a required mechanism.

Whether as a response to an inventory query or not, systems may need to inform others about the inventory status.

R 13. An inventory status is a required mechanism.

	UC1	UC2	UC2a	UC3	UC3b	UC4	UC5	UC5b	UC6	UC8	UC9a	UC9b
R1 Disp Request							X	X				
R2 ResupplyRequest		X				X						
R3 StatusQuery			X									
R4 OrderStatus		X	X			X						
R5 ShipmentNotice		X	X		X			X				
R6 ReceiptNotice		X	X		X			X				
R7 Deliv Request								X				
R8 Deliv Authoriz								X				
R9 Administration	X							X				
R10 Consumption						X	X	X				
R11 Inv Query				X								
R12 Inv Status				X								
R13 Inv Item Status												
R14 Request Scan												
R15 Request decoding												
R16 Decoding Response												
R17 Product Info Query									X	X	X	

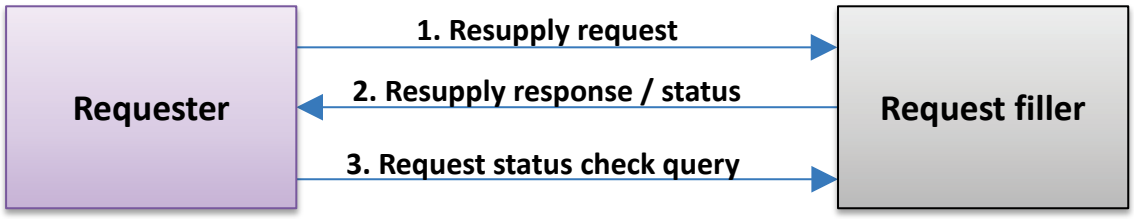
23.2 Interoperability Architecture

The mechanisms identified can be grouped in a series of stackable functions:

23.2.1 Resupply Request

These are the mechanisms used for an entity to ask another for products. The receiver of this request may be the same that will send the items (as in the case of a communication between a pharmacy and a supplier), or may be someone that approves and forwards the order (like the case between a hospital department and the purchasing department, which will then ask the supplier).

The parties can be called Requester and Request Filler

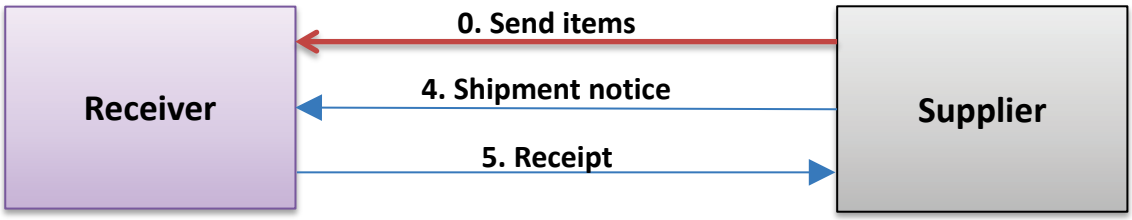


Note that the "Resupply response / status" is usually a verbal communication and we may not need to cover it with an explicit digital exchange standard.

23.2.2 Delivery

This is the information exchange about the delivery of products (which typically follows the actual physical transport). This is between the item supplier and the item receiver. The item receiver may be the same that initiated the request (as in the case of a pharmacy receiving the items they ordered from the supplier) or another entity (as when the supplier delivers directly to the ward from an order that was requested by the central purchasing department).

The parties are called Supplier and Receiver.

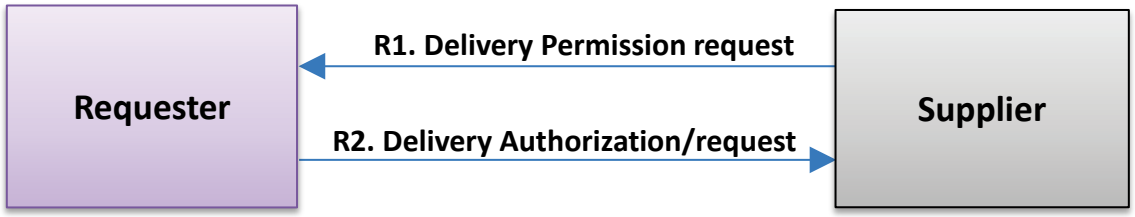


23.2.3 Return Order

These are interoperability functions to process the return orders. These are the request for permission to return/deliver products (when a hospital requests to return items that for some reason are not wanted), and the delivery or return authorization/request (the supplier's

acceptance or initiation of a return, which can also be used when a supplier initiates the recall).

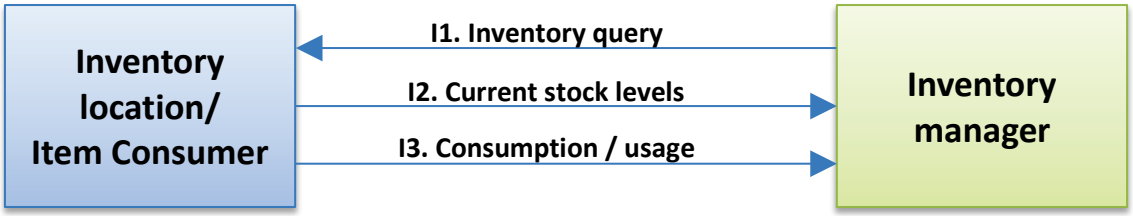
The parties are called Requester and Supplier.



23.2.4 Inventory

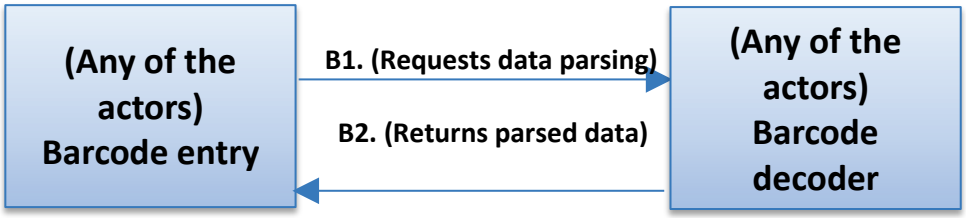
The inventory mechanisms are used to maintain and inform the status of inventory, i.e., the items available or consumed. This consists of a request for inventory status (when a central pharmacy inquires a department about its current stock), an inventory status update (when, requested or not, a department informs the pharmacy about the status of inventory) and an information of inventory consumption, e.g., when a professional or automated distribution system informs the pharmacy that a unit of a product is now consumed so that the pharmacy can keep track and recalculate the expected inventory).

The parties are the Inventory Manager and the Inventory Location / Item Consumer.



23.2.5 Barcodes

Barcodes can be used whenever physical items are present. The use of barcodes may require a system to decode information about the barcodes, and this information can then be used to initiate the functions above (e.g., inform a consumption of an item after scanning its barcode).



23.2.6 Product Lookup

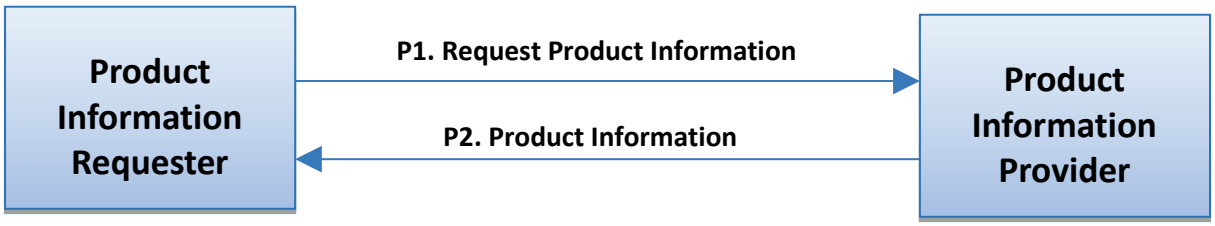
One additional information that is pertinent to the entire supply chain and will be further developed is the product lookup.

Product lookup is about querying information about a present or desired product. It can be looking up characteristics of a product in a catalog, or it can be about checking the status and traceability of a physical item instance. The information contained in both cases is rather similar, or overlapping, and it is not convenient to try to outline a difference between these cases:

- When scanning a barcode, the nurse may be looking at product catalog information such as latex information before a surgery.
- But the nurse may also be interested in receiving information that the specific item instance is marked for recall.
- Product Information can be triggered from reading a barcode or by entering a request from selecting an item in a catalog.

Other examples can be brought forward.

The transaction for "looking up a product" will commonly be used with the barcode decoding (but not necessarily so; therefore a barcode-specific transaction for product lookup is not desirable). The common use case will be that the system that scans a barcode sends unparsed data or parsed data, and this triggers the request for product information.



The Product Information Provider may be associated with other IHE actors, namely those about Product Catalog information, or any actor that may provide traceability information. For the scope of this paper, they are simply considered one functional block.

23.3 Data Requirements:

The following are the minimum requirements for the mechanisms identified, i.e., the data that is required for these mechanisms to function. There will be other data elements needed e.g., to ensure redundancy or data processing needs, or communication handshake, etc. but in this section we just identify the critical data elements for the functionalities described.

23.3.1 R1 Dispense Request

- Identification of the Patient
- Identification of the Requester
- Identification of the Request
- Requested item(s)
  - Identification
  - Quantity

  - Any traceability information if a specific item is needed – for example requesting a specific lot of a medicinal product, or requesting the return of a specific item.
- (Link to clinical order such as prescription ID)
- (workflow data, for example partial delivery count (when we need to say "this is a dispense 1 of 5")

23.3.2 R2 Resupply Request

- Identification of the Requester
- Identification of the request Filler
- Identification of the Request
- Requested item(s)
  - Identification
  - Quantity
  - Any traceability information if a specific item is needed – for example requesting a specific lot of a medicinal product, or requesting the return of a specific item.
- Location where the item should be delivered or placed
- Location or source of the item
- Data needed distribution – e.g., billing modes, etc.
- Rationale and reference for resupply, e.g., upstream requests or events, like the prescription that has to be fulfilled, or the stock depleted

23.3.3 R3 Resupply Request Notification

- Identification of the Request Filler
- Identification of the Requester
- Identification of the Request
- Identification of the Requested item(s)
- Request status

23.3.4 R4 Status Query

- Identification of the Request Filler
- Identification of the Requester
- Identification of the Request

23.3.5 R5 OrderStatus

(Same as R3 – Resupply Request Notification – may even be the same transaction type)

23.3.6 R6 Shipment Notice

- Identification of the Sending party (note that here we no longer call these Request filler, but the actual sending party – this is because "filling" a request may not imply delivery - For example it may be a request approval)
- Identification of the Receiving party
- Identification of the Shipment
- Sending party location
- Receiving party location
- Sent items
  - Identification of the item
  - Physical item characteristics e.g., lot number etc.
  - Quantity

23.3.7 R7 Receipt Notice

- Identification of the Sending party
- Identification of the Receiving party
- Identification of the Shipment
- Sending party location
- Receiving party location
- Sent items
  - Identification of the item
  - Physical item characteristics
  - Quantity

23.3.8 R8 Delivery Request

- Identification of the Sending party
- Identification of the Receiving party
- Identification of the Shipment
- Sending party location
- Receiving party location
- Sent items
  - Identification of the item
  - Physical item characteristics
  - Quantity

23.3.9 R9 Delivery Authorization

- Identification of the Sending party
- Identification of the Receiving party
- Identification of the Authorization or Authorized Shipment

23.3.10 R10 Administration

- (This is only related to supply in that it can entail a consumption)

23.3.11 R11 Consumption

- Stock Location
- Identification of the Consumption reporter
- Identification of the Patient or indication that this is for no specific patient
- Identification of the reporter
- Consumed items
  - Identification of the item
  - Physical item characteristics e.g., lot number etc.
  - Quantity

23.3.12 R12 Inventory Query

- Identification of the Requester
- Identification of the Request
- Inventory location (e.g., Operating Room 12)
- Inventory location holder/manager (e.g., Operating Room 12, managed by vendor ACME"
- Inventory status e.g., "only items in consignment"
- Additional product attributes
- Additional information about the type of response requested

Note: the Inventory query and Catalog / formulary query are often used in some combination, or with some functional overlap. For example a prescriber may query only for medication of a given type that is available in stock. This means that the inventory information (availability is somewhat "appended" to the catalog information.

In some simple systems, the same information repository handles catalog and inventory information, but as explained in the introductory sections of this document, this approach has limitations to handling traceability.

23.3.13 R13 Inventory Status

- Identification of the Request
- Date and time
- Inventory entries
  - Location
  - Content
    - Item
    - Physical attributes (lot, machine-readable content, etc.)
    - Quantity
- Identification of the reporter

23.3.14 R14 Inventory Item Status

- Item attributes
  - Item identification
  - Physical attributes (lot, machine-readable content, etc.)
  - Quantity
- Additional status info (valid, etc.)

23.3.15 R15 Request Scan

23.3.16 R16 Request decoding

- Encoded data

23.3.17 R17 Decoding Response

- Decoded data
  - Identification of the item (e.g., product code)
  - Product characteristics e.g., lot, etc.

23.3.18 R18 Product Info Query

- Item ID
- Type of information requested

Part VI – Standards

24 Overview of Standards

There are three key types of standards that apply to the use cases described here:

- Data Exchange specifications – these cover the messages between systems. Examples:
  - HL7®[29] version 2 – a message-oriented standard with wide global adoption
  - CDA®[30] and Version 3 – structured content, document-oriented with global recognition and implementations e.g., many IHE profiles
  - FHIR®[31] – multi-paradigm standard for healthcare data exchange, supporting messages, documents, and in multiple formats, e.g., XML or JSON.
  - GS1 XML – Supply-chain dedicated standard, based on XML documents, with global implementation in several industries and in the healthcare supply chain.
- Terminologies and product codes – standards that provide reference values for use by the different actors. For example, GTIN, or IDMP, or any national health product terminology.
- AIDC – standards for encoding information in computer-readable form like barcodes. Examples are GS1 barcode (traditional and 2D), HIBCC, ICCBA etc.

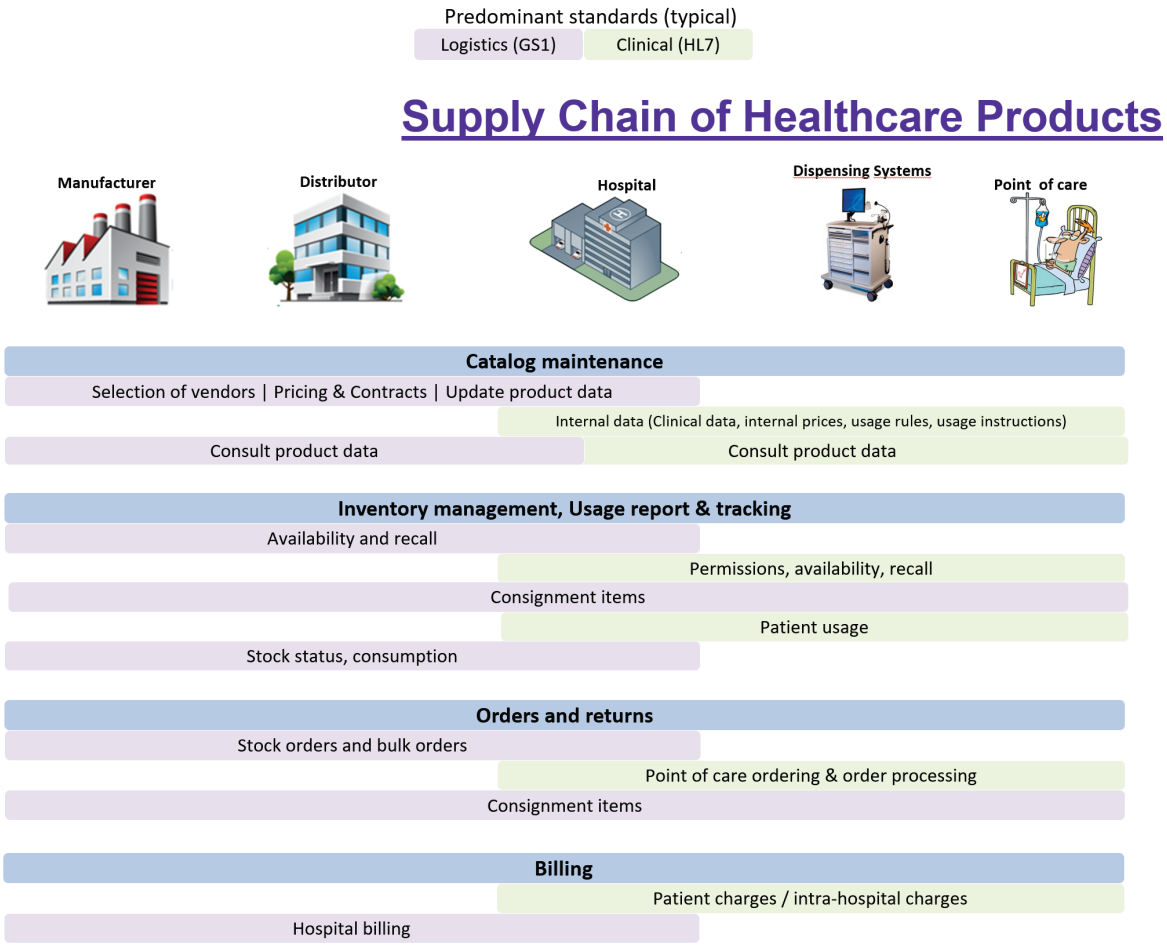
24.1 Analysis of Applicable Standards

The different standards have a preferred applicability to different purposes. For example, blood products and medical devices use different standards for barcodes; HL7 is usually more dedicated to data exchange inside an institution, while GS1 and x12 usually handle the "outside" logistics.

[29] HL7 is the registered trademark of Health Level Seven International.

[30] CDA is the registered trademark of Health Level Seven International.

[31] FHIR is the registered trademark of Health Level Seven International.



2320 The following table shows the available standards and their match to the main requirements identified. This is not an exhaustive analysis, rather an indication of maturity, coverage and adequacy.

The standards analyzed are selected from common implementations and SDOs actively working on this topic, and for the most critical transactions identified:

2325

	HL7 v2 (v2.9.x)	HL7 FHIR	GS1	x12	UBL
Supply Request	Yes	WIP[32]	Yes	Yes	
Supply Delivery	Yes	WIP[32]	Yes	Yes	
Recall	Unknown	Unknown[33]	Yes	Yes	

[32] HL7 FHIR has resources for Supply Request and Delivery. At the time of writing of this document, these resources have a Maturity Level 1, which means these resources may still evolve.

[33] There is currently no FHIR resource or recommendation covering Recall, Inventory Status, Consumption.

Inventory status	Unknown	Unknown	Yes	Yes	
Consumption	Unknown	Unknown	Yes	Not found	
Product Discovery	Yes (basic)	Partial (e.g., IHE UBP profile)	Yes	Yes	

These standards have different applicability in different areas. Traditionally, the supply chain has been focused on supply-specific aspects which are then adapted to healthcare needs – which brings a number of advantages, namely the "harmonization" of healthcare needs with common good practices for supply, like traceability, flexibility, etc.

This alignment requires collaboration by implementers and also by standards organizations. One example of such collaboration is the Memo of Understanding between GS1 and HL7, establishing the intention to contribute to the safety and integrity of the supply chain.

http://www.hl7.org/documentcenter/public_temp_AA12D9B2-1C23-BA17-0C7AC26D7769A523/pressreleases/HL7_PRESS_20131014.pdf

24.2 Recommended Standards

The list of standards in the previous table is not an exhaustive list of applicable or implemented standards. It is a shortlist with the standards that at the time of producing this paper, have been found to be mature and commonly used in the Supply of Medical products.

Standards like GS1 and X12 are commonly used industry standards.

For healthcare, HL7 v2, HL7 FHIR and GS1 have a broad acceptance by suppliers and users.

For this reason, we mention the standards in the overview but this document uses HL7 and GS1 standards to describe the use cases. This is also an indication that HL7 and GS1 standards, given their functional compatibility with the model described and with each other, are good candidates for IHE profiles where we want to maintain the continuum of information throughout the Supply Chain.