Integrating the Healthcare Enterprise

Hospital Pharmacy and Community Pharmacy
Use Cases and Standards
White Paper

Version 1.0

Integrating the Healthcare Enterprise

Pharmacie hospitalière et pharmacie de ville
Cas d'utilisation et standards
Livre blanc

Version 1.0.fr.20

Traduction partielle en français : Phast

Document version	Editor	Remarks
1.0	N. Canu, PHAST G. Claeys, Agfa Healthcare T. de Jong, HL7 A. Estelrich, GIP/DMP I. Gibaud, SIB S. Juvin, GIP/DMP F. Macary, GMSIH V. Mary, SIB J. Nuñez Suarez, INDRA C. Rica, GIP/DMP A. Slee, NHS M. Sprenger, NICTIZ S. Thun, DIMDI L. Tzimis, EAHP	Version for Public Comment

[Notes du traducteur :

Eventuellement revenir sur les traductions des expressions suivantes :

- Workflow : workflow ?
- Time flow diagram
- Monitoring : monitoring ?
- Query and Retrieve
- Repository : entrepôt ? serveur ?

]

Version du document	Rédacteurs	Remarques
1.0	N. Canu, PHAST G. Claeys, Agfa Healthcare T. de Jong, HL7 A. Estelrich, GIP/DMP I. Gibaud, SIB S. Juvin, GIP/DMP F. Macary, GMSIH V. Mary, SIB J. Nuñez Suarez, INDRA C. Rica, GIP/DMP A. Slee, NHS M. Sprenger, NICTIZ S. Thun, DIMDI L. Tzimis, EAHP	Version soumise à commentaires

[Notes du traducteur :

Cette traduction partielle est publiée sous forme d'un document bilingue. La version partiellement traduite en français occupe les pages paires (pages de droite), la version originale les pages impaires (pages de gauche).

Pour imprimer le document, même si vous disposez d'une imprimante recto-verso :

- Imprimez tout, mais en spécifiant dans le dialogue d'impression « pages impaires » : vous obtenez les 68 pages numérotées de 2 à 136, qui constituent la version partiellement traduite en français.
- Vous pouvez remettre le paquet de feuilles dans l'imprimante pour imprimer la version originale au verso.
- Si l'impression commence par la fin (cas le plus fréquent), il faut enlever la page 136 du paquet : la page 135 doit être au verso de la page 134.
- Vous pouvez ignorer la première page.

Pour visualiser le document, si vous disposez d'un écran large, vous pouvez afficher deux pages côte à côte. Le sommaire en français n'est pas « actif ». Vous pouvez néanmoins trouver pratique de passer par les liens de la version originale (Contents, page 5) pour circuler dans le texte.

Dans le sommaire, les parties qui n'ont pas encore été traduite sont surlignées en jaune.

Aucune traduction n'est parfaite. En plus des observations sur le fond, vous pouvez formuler des remarques au sujet de la traduction.]

Contents

Sommaire

1 Introduction

The Pharmacy domain is increasingly adopting Information & Communication Technologies to support their main activities like prescription and medication dispense. In order to guarantee interoperability among the different ICT systems in the Pharmacy domain, it is important that all stakeholders (users, vendors, payers) agree on a set of common communication standards.

The purpose of this White Paper is to identify the critical interoperability needs in the Pharmacy domain, describe the corresponding interoperability Use Cases and propose a set of communication standards to implement these Use Cases.

The White Paper can serve as basis for the development of one or more IHE Pharmacy Integration Profiles.

The document starts with an overview of the main business processes in the pharmacy domain, describing the workflow and the information flows. These business processes are the basis for describing the various Interoperability Use Cases. The most critical Use Cases are then described in more detail, identifying the actors and interactions. Starting from these Use Cases, high level reference architecture is proposed. Finally, some possible implementations of the reference architecture are described.

1 Introduction

Dans le domaine de la pharmacie, les technologies de l'information et de la communication sont de plus en plus utilisées pour des tâches essentielles comme la prescription et la dispensation de médicaments. Pour assurer l'interopérabilité des différents systèmes informatiques utilisés dans le domaine de la pharmacie, il faut que toutes les parties concernées (utilisateurs, fournisseurs, financeurs) se mettent d'accord sur un ensemble de standards d'échange.

Ce livre blanc vise à identifier les besoins les plus criants dans le domaine de la pharmacie, décrire les cas d'utilisation qui s'y rapportent, et proposer un ensemble de standards d'échange pour implémenter ces cas d'utilisation.

Le livre blanc pourra servir de base pour le développement par IHE Pharmacie, d'un certain nombre de profils d'intégration.

Le document commence par une approche globale des principaux processus métier du domaine de la pharmacie, avec une description du circuit du médicament. Ces processus métier servent de base pour décrire les différents cas d'utilisation. Les cas d'utilisation les plus significatifs sont décrits en détail, jusqu'à l'identification des acteurs et des interactions. A partir de ces cas d'utilisation, une architecture de référence est proposée. Le document s'achève par une description de quelques implémentations possibles de cette architecture de référence.

2 Glossary

- **Treatment or medication regime:** a treatment or medication regime is a series of medications intended to heal the patient or to improve the health status or to diagnose a disease.
- **Prescription**: a prescription is an order given by a clinician (usually physicians and in some particular cases pharmacists, nurses), for a medication to be dispensed to the patient according to an established pattern. The prescription includes the dosage, instructions to the patient for the intake, etc.
- **Dispensed medication**: to dispense is the act of giving out a medication to the patient as indicated in the corresponding prescription. Since prescriptions can span long periods of time, a single prescription may result medicines dispensed several times.
- **Medication record**: medication already dispensed to the patient. This can also include the medication still not given out to the patient, prescriptions not fulfilled yet.
- **Pharmaceutical analysis**: the action performed by a pharmacist to approve/modify or reject a prescription before it is given out to the patient.
- **Pharmaceutical advice :** the outcome of the pharmaceutical analysis;
- **Healthcare Professional (HCP) :** individual that provides healthcare services like a GP, specialist, nurse and pharmacist.
- **System actor:** information system that supports a particular function in the pharmacy domain.
- **Human actor**: individual (physician, pharmacist, etc.) that usually makes use of a system actor to perform an activity in the e-pharmacy domain

2 Glossaire

- **Traitement médicamenteux :** un traitement médicamenteux est une liste de médicaments prescrits dans l'intention de guérir le patient ou d'améliorer sa santé ou de diagnostiquer une maladie.
- **Prescription** : une prescription est une demande formulée par un professionnel de santé (habituellement un médecin et dans certains cas particuliers un pharmacien, ou une infirmière), de dispenser un médicament au patient, dans le respect d'un ensemble de règles. La prescription inclut la posologie, les instructions d'administration, etc.
- **Délivrance**[1] : la délivrance est l'acte de mettre le médicament à disposition du patient comme indiqué dans la prescription. Du fait que les prescriptions peuvent avoir une durée de validité relativement longue, une même prescription peut induire plusieurs délivrances de médicaments.
- **Dossier pharmaceutique** : les délivrances dont le patient a déjà bénéficié. Ce dossier peut aussi inclure les médicaments qui restent à délivrer, les prescriptions qui restent à satisfaire.
- **Analyse pharmaceutique** : l'activité exercée par un pharmacien qui approuve, modifie ou rejette une prescription avant de délivrer des médicaments.
- **Avis pharmaceutique :** le résultat (typiquement sous la forme d'un document), de l'analyse pharmaceutique.
- **Professionnel de santé (PS) :** un individu qui participe à la production de soins, comme un médecin généraliste, un spécialiste, une infirmière ou un médecin.
- **Acteur système :** dans un système informatique, la partie qui supporte une fonction particulière du domaine de la pharmacie.
- **Acteur humain** : un individu (médecin, pharmacien, etc.) qui utilise de façon habituelle un acteur système pour accomplir une tâche dans le domaine de la pharmacie.

[1] [En français la notion de dispensation associe l'avis pharmaceutique et la délivrance. Le verbe anglais « to dispense » est un faux ami : en général il ne désigne pas la dispensation, mais seulement la délivrance, sans y associer l'avis pharmaceutique qui est considéré comme un acte distinct, complémentaire de la délivrance].

3 Scope

The White Paper focuses on the interoperability needs of information sharing systems and workflow systems existing in the pharmacy domain, respecting the patient's privacy.

More specific, the scope of the document is:

- Managing the medication dispenses of a patient in a community and hospital
- Transfer of the electronic prescriptions in a hospital and community
- Managing the interactions between community pharmacist and hospital pharmacist (e.g. admission – discharge prescription/dispense)
- The interoperability between pharmacy systems and other ICT systems on hospital and community level (e.g. EPR, EHR)
- ICA : Drug interaction checking, contra-indications, allergies

The following items are out of scope:

- OTC (Over the Counter) medication dispense and medication samples
- Creation of the electronic Prescription
- Access to patient's medical record by prescriber, validator, …
- Order and delivery of chemicals, reagents, sterilized medical supplies
- Approval of prescriptions for administrative purposes
- Individual Case Safety Report for secondary use applications like bio-surveillance, clinical trials
- Supply chain of ordering and delivering medication, stock management
- Administrative validation for expensive drugs (e.g. indications)
- Billing

3 Couverture fonctionnelle

Le livre blanc porte sur les besoins à satisfaire pour assurer l'interopérabilité de systèmes de partage de l'information dans le domaine de la pharmacie, ou de systèmes de gestion du circuit du médicament, dans le respect des droits des patients et notamment de la confidentialité.

Plus précisément, sont inclus dans la couverture fonctionnelle :

- La gestion des délivrances de médicaments en ville et à l'hôpital
- La prescription électronique à l'hôpital et pour la pharmacie de ville
- La gestion des échanges d'information entre la pharmacie de ville et la pharmacie hospitalière (comme la prescription de sortie)
- L'interopérabilité entre les systèmes de gestion de la pharmacie hospitalière, ou les autres systèmes informatiques dans l'hôpital, et les solutions extérieures (comme les dossiers médicaux partagés)
- La vérification des interactions, des contre-indications, des allergies.

Sont exclus de la couverture fonctionnelle:

- Les médicaments délivrés sans ordonnance ou distribués comme échantillons
- La création de la prescription électronique
- L'accès au dossier médical du patient, que ce soit par le médecin pour prescrire ou par le pharmacien pour faire l'analyse pharmaceutique
- La commande et la fourniture de produits chimiques, de réactifs, de dispositifs médicaux stériles
- L'approbation de prescriptions pour des raisons administratives
- Les signalements d'effets indésirables, les essais cliniques
- La chaîne logistique des commandes et des livraisons de médicaments, la gestion des stocks
- La validation administrative pour les médicaments coûteux (par exemple en fonction des indications)
- La facturation et le remboursement.

4 Pharmacy domain business process

In this section we describe, from a high level perspective, the processes of the Pharmacy domain, focusing on interoperability among systems that belong to one or more institutions.

4.1 General medication process

In general, the medication business process consists of three distinct processes, which have to be connected through interactions that transfer information and/or guide the workflow. Figure 4.1 shows this flow.

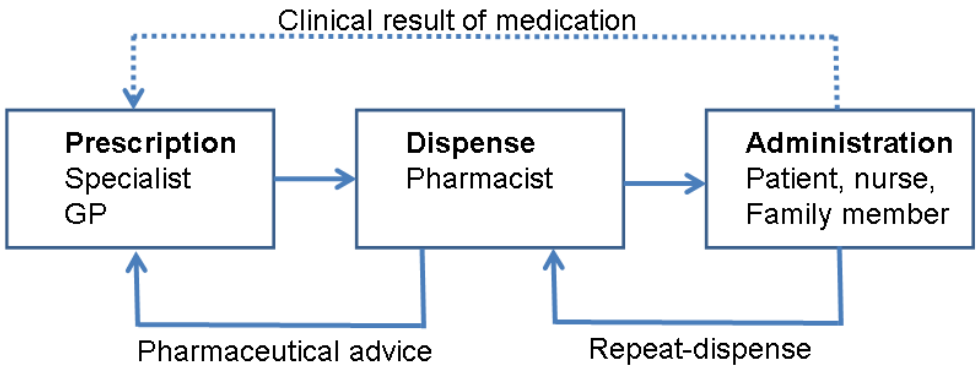


Figure 4.1: Time flow diagram showing the main elements in the general medication process

The three main processes are:

1. **Prescription of medication**: the process in which a health care professional (HCP: in most cases, but not necessarily always, a medical specialist or a general practitioner) decides that the patient needs medication. The HCP produces a prescription, an entity that can be seen as an order to anyone entitled to dispense (prepare and hand out) medication to the patient.

2. **Dispense of medication**: the process in which an HCP (typically a different HCP than the prescriber, in most cases, but not necessarily always, a pharmacist) takes in the prescription and validates the prescription against pharmaceutical knowledge and regulations. On positive outcome of the validation the pharmacist decides to what specific medication the prescription will lead, and makes that medication available to the patient. Record is kept then of the specificities of the dispensed medication (brand, type, form, quantity, etc). In many cases the dispenser is entitled to make changes to the prescription (e.g. change the brand of the medication), or reject the prescription and inform the prescriber on this rejection. The information from the dispenser to the prescriber about the validation is called the pharmaceutical advice. Variations here can exist from health care system to health care system, depending on legislation and/or the role of the pharmacist.
   In many cases one prescription can lead to more than one dispense action, like with repeat prescriptions for chronic diseases. Also here differences may exist between health care systems, in some systems repeat dispenses require repeat prescriptions, yielding a 1:1

4 Circuit du médicament

Dans ce chapitre on décrit, à une échelle macroscopique, les processus du domaine de la pharmacie [le circuit du médicament], en s'intéressant spécialement aux problèmes d'interopérabilité entre systèmes appartenant à des organisations différentes.

4.1 Cas général

En général, le circuit du médicament est constitué de trois processus distincts, qui doivent être connectés via des interactions qui transfèrent de l'information et/ou qui régulent le « workflow ». La figure 4.1 montre ce circuit.

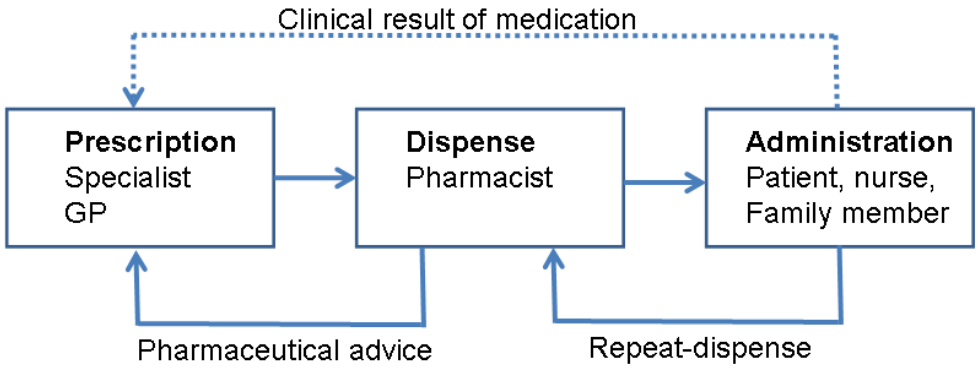


Figure 4.1: Diagramme de temps montrant les principaux éléments du circuit du médicament

Les trois principaux processus sont :

1. **Prescription de médicament** : le processus dans lequel un professionnel de santé (PS : dans la plupart des cas, mais pas nécessairement toujours, un médecin généraliste ou spécialiste) décide que le patient a besoin de médicaments. Le PS produit une prescription, une entité qui peut être vue comme une demande destinée à quiconque est habilité à délivrer (préparer et mettre à disposition) des médicaments au patient.

2. **Dispensation de médicament** : le processus dans lequel un PS (typiquement un PS différent du prescripteur : dans la plupart des cas, mais pas nécessairement toujours, un pharmacien) prend la prescription et la valide au regard du savoir pharmaceutique et de la réglementation. En cas de validation positive le pharmacien décide quelle spécialité pharmaceutique va découler de la prescription, et la met à disposition du patient. Les spécificités des médicaments délivrés sont enregistrées : marque, type, forme, quantité, etc. Dans de nombreux cas la personne qui fait la délivrance est habilitée à faire certaines modifications à la prescription (comme de changer de marque de médicaments), ou à rejeter la prescription et d'en informer le prescripteur. L'information transmise par la personne qui fait la délivrance au prescripteur est appelée avis pharmaceutique. Il peut y avoir là des différences entre les systèmes de santé, en fonction de la législation et/ou du rôle du pharmacien.
   Dans de nombreux cas une même prescription peut impliquer plusieurs dispensations, comme les prescriptions renouvelables pour les maladies chroniques. Là aussi il peut y avoir des différences entre les systèmes de santé : dans certains systèmes de santé, à chaque

relationship between prescriptions and dispenses, in some health care systems multiple dispenses per prescription are allowed.

3. **Administration of medication**: the process in which the medication is actually administered to the patient. Here, the human actor typically is the patient, a family member or a nurse.

The loop is finally closed (in the most general case) by the fact that the prescriber takes notice of the result of the medication, and yes or no decides on further action. This clinical process is outside the scope of this white paper, as is the clinical process leading to the prescription at the start.

As stated before, the emphasis of this white paper is on the medication specific interoperability aspects. These occur in this domain because of the fact that GP's and pharmacies are in general different institutions. The other intra-pharmacy processes, like preparation, stock-keeping, buying of medication are not included in the scope of this white paper.

A further source of interoperability problems lies in the fact that in the prescription process as well as in the dispense process knowledge needs to be available on the total medication regime of the patient, in order to avoid unwanted drug interactions. Since in most health care systems patients can be on medication from different pharmacies, originating from different prescribers, simultaneously, complete knowledge of all recent dispenses from all possible pharmacies is needed. For similar reasons complete knowledge of recent prescriptions might be necessary as well in some health care systems.

4.2 Subdomains

For this white paper, and for subsequent development of integration profiles, it is necessary to distinguish two subdomains. The distinction is made because there are clear differences for the mediation process between these subdomains. The subdomains are named by the pharmacy that is involved

4.2.1 Community Pharmacy subdomain

- The patient is not hospitalized
- The prescriber is in most cases a GP or a medical specialist, the latter in an outpatient clinic or in a private practice environment.
- The dispenser in most cases is a community pharmacist.
- The medication administrator in most cases is the patient or someone from the family.

4.2.2 Hospital Pharmacy subdomain

- The patient is hospitalized
- The prescriber in most cases is a medical specialist in the clinical environment
- The dispenser in most cases is the hospital pharmacist
- The medication administrator in most cases is a nurse or the patient

dispensation doit correspondre une prescription, dans d'autres systèmes de santé les dispensations multiples pour une même prescription sont autorisées.

3. **Administration de médicament** : le processus dans lequel les médicaments sont effectivement administrés au patient. Là, l'acteur humain est typiquement le patient, un membre de sa famille ou une infirmière.

La boucle est finalement bouclée (dans le cas le plus général) quand le prescripteur prend note du résultat du traitement médicamenteux, et décide ou non d'une autre action. Ce processus clinique n'est pas dans la couverture fonctionnelle de ce livre blanc, pas plus que le processus clinique à l'origine de la prescription.

Comme cela a déjà été dit, ce livre blanc met l'accent sur les problèmes d'interopérabilité qui sont spécifiques au circuit du médicament. Ces problèmes viennent du fait que les médecins et les pharmaciens travaillent généralement dans des organisations différentes. Les autres processus internes à la pharmacie, comme la préparation, la gestion des stocks, les achats de médicaments, ne sont pas inclus dans la couverture fonctionnelle de ce livre blanc.

Une source supplémentaire de problèmes d'interopérabilité vient du fait qu'une connaissance complète du processus de prescription, ainsi que du processus de dispensation, serait nécessaire pour éviter les interactions indésirables. Dans la plupart des systèmes de santé les patients peuvent prendre simultanément des médicaments venant de plusieurs pharmacies, prescrits par plusieurs médecins, et on a besoin de savoir tout ce qui a été dispensé récemment dans toutes les pharmacies possibles. Pour des raisons similaires dans certains systèmes de santé on peut avoir besoin de savoir tout ce qui a été prescrit.

4.2 Sous-domaines

Pour ce livre blanc, et pour le développement de profils d'intégration qui en résultera, il est nécessaire de distinguer deux sous-domaines. On fait cette distinction parce que le circuit du médicament n'est pas le même dans ces sous-domaines. On nomme ces sous-domaines en fonction de la pharmacie concernée.

4.2.1 Sous-domaine de la pharmacie de ville

- Le patient n'est pas hospitalisé.
- Dans la plupart des cas le prescripteur est un généraliste ou un spécialiste, ce dernier étant à son cabinet ou dans un service de consultation externe.
- La dispensation est généralement faite par une pharmacie de ville.
- L'administration des médicaments est généralement faite par le patient ou par sa famille.

4.2.2 Sous-domaine de la pharmacie hospitalière

- Le patient est hospitalisé.
- Dans la plupart des cas le prescripteur est un médecin hospitalier.
- La dispensation est généralement faite par la pharmacie de l'hôpital.
- L'administration des médicaments est généralement faite par une infirmière, ou sinon par le patient.

4.2.3 Rationale

The reason for this distinction lies in the following:

- Medication regime:
  - In the community pharmacy subdomain the relation between patients and prescribers and patients and dispensers is not unique. That means, a patient can be under a medication regime with different prescribers simultaneously, e.g. a GP and a psychiatrist. Moreover, in many countries the patient is free to choose a different pharmacist for every other prescription.
  - In the hospital pharmacy subdomain, however, a patient is brought under one medication regime (for safety and clinical control reasons mainly). In most countries all dispenses are executed over by the hospital pharmacy.

- Coupling to other processes:
  - In the community environment the medication process is in most cases only loosely coupled to other processes.
  - In the hospital environment the medication process is very closely linked to other processes of diagnostic and/or therapeutic nature. Most hospitals see prescription as a clinical order comparable with the ordering of laboratory investigations and/or radiological investigations. This close linkage is necessary for the close monitoring of clinical conditions, in which medication is an important factor.

- Administration of medication:
  - In the community environment the administration process is generally not recorded in any computer system at all.
  - In the hospital environment in many cases the administration of medication is supervised by a nurse, who, in many cases, also records the administration event in a computer system. In some cases, typically with the use of “lighter” medication, the administration is not recorded explicitly.
  - As a consequence of the fact that the human actors for administration are different in both subdomains (patient in community, nurse in hospital) there is a difference in the dispense process: in the community pharmacy subdomain the dispense is from pharmacist to patient (or family member), in the hospital pharmacy subdomains the dispense process is from pharmacy to the nursing ward, typically.

It is important to note, that these subdomains cannot be treated totally independently, because there are transitions between the subdomains. As a standard, every patient is in the community pharmacy subdomain, and when the patient needs to be admitted to the hospital he or she changes to the hospital pharmacy subdomain, and vice versa on discharge from the hospital. Figure 4.2 shows this in a scheme.

4.2.3 Explications

Voici les raisons pour lesquelles on fait cette distinction :

- Traitement médicamenteux :
  - Dans le sous-domaine de la pharmacie de ville les relations entre le patient le prescripteur et la personne qui fait la délivrance ne sont pas exclusives. Cela veut dire qu'un patient peut être sous plusieurs traitements médicamenteux simultanés, prescrits par exemple par un généraliste et un psychiatre. De plus, dans beaucoup de pays le patient est libre de choisir une pharmacie différente pour chaque prescription.
  - Dans le sous-domaine de la pharmacie hospitalière, par contre, le patient est soumis à un seul traitement médicamenteux (principalement pour des raisons médicales et de sécurité). Dans la plupart des pays toutes les dispensations sont faites par la pharmacie de l'hôpital.

- Couplage avec les autres processus de soins :
  - Dans le cadre de la ville le circuit du médicament est en général faiblement couplé avec les autres processus de soins.
  - A l'hôpital le circuit du médicament est étroitement couplé avec d'autres processus thérapeutiques ou de diagnostic. La plupart des hôpitaux considèrent la prescription de médicaments comme une demande comparable aux demandes d'analyses de laboratoire ou d'examens radiologiques. Ce couplage étroit est nécessaire pour le suivi de l'état du patient, dont le traitement médicamenteux est un facteur important.

- Administration de médicaments :
  - Dans le cadre de la ville le processus d'administration ne fait généralement l'objet d'aucun enregistrement informatique.
  - A l'hôpital l'administration des médicaments est généralement sous la responsabilité d'une infirmière, qui, en général, enregistre le compte-rendu d'administration dans un système informatique. Dans certains cas, notamment quand il ne s'agit pas de traitements « lourds », le compte-rendu d'administration n'est pas enregistré explicitement.
  - Le fait que l'acteur humain de l'administration n'est pas le même dans chacun des sous-domaines (le patient dans le cadre de la ville, l'infirmière à l'hôpital) implique une différence dans le processus de dispensation : dans le sous-domaine de la pharmacie de ville les médicaments sont délivrés au patient (ou à un membre de sa famille), dans le sous-domaine de la pharmacie hospitalière les médicaments sont délivrés à l'unité de soins.

Il est important de noter que ces sous-domaines ne peuvent pas être traités de façon totalement indépendante, parce qu'il existe des transitions entre sous-domaines. On peut considérer comme une règle, que tout patient est dans le sous-domaine de la pharmacie de ville, et que quand il doit être hospitalisé il passe dans le sous-domaine de la pharmacie hospitalière, et vice-versa lors de sa sortie de l'hôpital.
La figure 4.2 représente cela sous la forme d'un schéma.

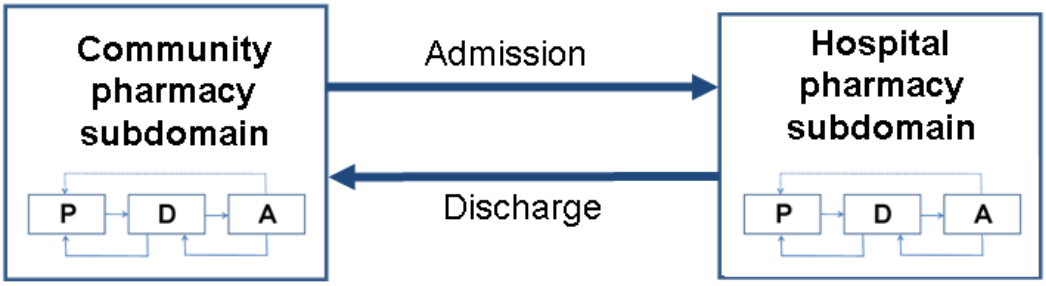


Figure 4.2: Subdivision of the pharmacy domain into two subdomains, each having the cycles prescribe-dispense-administer implemented. The transitions lie in the clinical admission and clinical discharge.

Thus, in order to be complete, the integration profiles should include:

- All relevant medication transactions in the community pharmacy subdomain;
- All relevant medication transactions in the hospital pharmacy subdomain;
- All relevant transactions needed to support the medication issues of the clinical admission process;
- All relevant transactions needed to support the medication issues of the clinical discharge process;

There are several situations where this distinction between two subdomains might be disputed. In these situations, special attention should be given, depending on the local situation. We identified the following cases:

- In hospitals the hospital pharmacy organization might also run a community-pharmacy service, mostly in the outpatient environment, as a service to their outpatients. We consider, for this white paper, then, two pharmacies to be present, a hospital pharmacy and a community pharmacy. Thus, actors of both subdomains will need to be implemented.
- In some special cases the hospital pharmacy will deliver drugs to ambulatory patients. The most common examples are the administration of (expensive) cancer drugs and narcotics. Typical for these situations is the fact that, although in an outpatient setting, the administration process needs close monitoring and recording. Per situation it needs to be decided whether these situations will have to be treated as being in the community pharmacy subdomain or in the hospital pharmacy subdomain.
- Day-care surgery: in these situations patients do not always undergo the total clinical admission process. No clinical bed is assigned, there is no nursing ward involved. Nevertheless the medication processes being involved here in most cases should be considered to be of clinical nature, because the anesthesiologist will always want to “take over” the medication regime, or, at least, be informed on all medication. Medication needed during or around the day-care surgery will come from the hospital pharmacy.

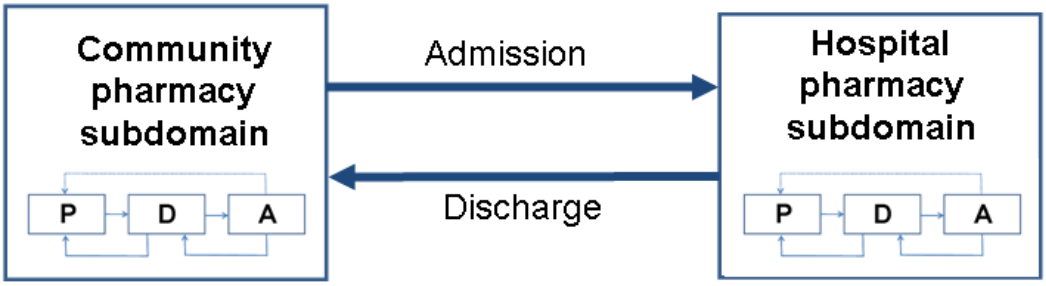


Figure 4.2 : Subdivision du domaine de la pharmacie en deux sous-domaines, chacun d'eux implémentant le circuit prescription-dispensation-administration. L'admission à l'hôpital et la sortie de l'hôpital constituent les transitions.

Donc, pour être complets, les profils d'intégration devraient inclure :

- Tous les échanges concernant les médicaments dans le sous-domaine de la pharmacie de ville ;
- Tous les échanges concernant les médicaments dans le sous-domaine de la pharmacie hospitalière ;
- Tous les échanges nécessaires pour résoudre les problèmes liés au traitement médicamenteux lors de l'admission à l'hôpital ;
- Tous les échanges nécessaires pour résoudre les problèmes liés au traitement médicamenteux lors de la sortie de l'hôpital.

Il y a différentes situations où cette distinction entre deux sous-domaines serait discutable. Dans ces situations, il faut faire attention, et tenir compte de la réalité locale. Nous avons identifié les cas suivants :

- Dans les hôpitaux, la pharmacie hospitalière peut aussi s'occuper d'un service de pharmacie de ville [les rétrocessions], généralement dans le même cadre et pour les mêmes patients que les consultations externes. Nous considérons, pour ce livre blanc, qu'il y a alors dans l'hôpital deux pharmacies distinctes, une pharmacie hospitalière et une pharmacie de ville. Il faudra donc implémenter les acteurs des deux sous-domaines.
- Dans certains cas particuliers la pharmacie hospitalière va délivrer des médicaments à des patients ambulatoires. Les exemples les plus fréquents sont les chimiothérapies et la délivrance de narcotiques. Ce qui caractérise ces situations c'est que, bien qu'on soit dans un service ambulatoire, le processus d'administration nécessite un suivi et un enregistrement. Pour chaque situation précise il faut décider si cette situation doit être traitée comme étant dans le sous-domaine hospitalier ou dans le sous-domaine de la pharmacie de ville.
- La chirurgie en hôpital de jour : dans ces situations, les patients ne font pas toujours l'objet d'une véritable admission à l'hôpital. Il n'ya a pas de lit d'hôpital, ni d'unité d'hébergement. Néanmoins ces cas impliquent un circuit du médicament de type hospitalier, parce l'anesthésiste voudra toujours prendre le contrôle du traitement médicamenteux, ou, au moins, être informé de tous les médicaments en cours. Les médicaments dont on aura besoin à l'occasion d'une opération chirurgicale en hôpital de jour, viendront de la pharmacie hospitalière.

- Nursing homes: here many different mixtures of the subdomain model might occur, varying from country to country. Some nursing homes might closely resemble the hospital situation, in other cases it might resemble the community model, in most cases with administration monitoring added. Also, the role of the prescriber might vary (the visiting GP in some cases, a specialized nursing home doctor in other cases) and the pharmacy might be a regular community pharmacy, a pharmacy belonging to the nursing home (or chain of nursing homes) or the hospital pharmacy of a near-by hospital. Here, always careful consideration is needed in order to choose the right set of domain actors.
- Hospital-hospital transfers require special precaution in the implementation. In some health care systems the process might be a discharge followed by an admission, but also direct couplings between hospitals might be conceived.

4.3 Information elements

In this section we briefly describe the main information elements involved in the various processes. The next chapter describes them in more detail. These four elements are:

- Prescription: describes the medication that the prescriber (in most cases a doctor) wants to be taken by the patient. It is input to the dispense process. Prescriptions are also used as input for the patient or the nurse on how to use the medication. Variations in the content of the prescriptions can occur, varying from country to country, depending upon habits, responsibilities, and standards.
- Dispensed medication information: describes the medication that actually has been dispensed. Recorded within this process for later reference, and in order to follow up on repeat-medication. Again, depending on the local situation in different counties, dispenses might or might not show significant differences with the prescriptions they originate from. The dispensed medication information needs to be linked to the prescriptions it originates from. There can be, in general, more dispenses originating from one prescription.
- Administration of medication: describes the administration event (only in hospitals for the time being). These events need to be linked to the prescription.
- Pharmaceutical advice: when a prescription is received by a pharmacist three steps might follow:
  - The pharmacist dispenses the prescribed medication.
  - The pharmacist decides to dispense medication different from the prescription, though still serving the same clinical goal as the original prescription. The situations where pharmacists are allowed to do so might differ from health care system to health care system.
  - The pharmacist decides that it is not valid to dispense the medication prescribed to the patient. No dispense is done.

  The pharmaceutical advice is the information element that contains the observations and actions of the pharmacist in this validation process. In situation a. in most cases no explicit advice is generated, in situations b. and c. an explicit pharmaceutical advice is generated, communicated and saved.

- Les soins de suite et de réadaptation et l'hospitalisation à domicile : on peut avoir toutes sortes de façons différentes de mélanger les sous-domaines, et cela change d'un pays à l'autre. Certaines pratiques peuvent ressembler à ce qui se passe à l'hôpital, et dans d'autres cas cela peut ressembler à la médecine de ville, avec souvent du « monitoring » en plus. De plus, le rôle du prescripteur peut varier (dans certains cas c'est le généraliste qui fait les visites, dans d'autres cas c'est un médecin hospitalier) et la pharmacie peut être une pharmacie de ville, la pharmacie du service de soins concerné (appartenant éventuellement à un réseau), ou la pharmacie hospitalière d'un hôpital des environs. Là, il faut faire très attention à bien choisir le bon ensemble d'acteurs du domaine.
- Le transfert d'un hôpital à un autre requiert des précautions particulières. Dans certains systèmes de santé le processus peut être considéré comme une sortie suivie d'une admission, mais on peut aussi concevoir un couplage direct entre les hôpitaux.

4.3 Eléments d'information

Dans cette section on décrit brièvement les principaux éléments d'information impliqués dans les différents processus. Dans le chapitre suivant ils sont décrits plus en détail. Ces quatre éléments sont :

- La prescription : elle décrit les médicaments que le prescripteur (généralement un médecin) veut que le patient prenne. C'est l'*input* du processus de dispensation. Les prescriptions sont aussi considérées comme un *input* destiné au patient ou à l'infirmière à propos de la façon d'utiliser les médicaments. Il peut y avoir des variantes dans le contenu de la prescription, en fonction des habitudes, des responsabilités, et des règles applicables.
- Le compte-rendu de délivrance : il décrit les médicaments qui ont été effectivement délivrés. Enregistré dans le cadre de ce processus pour qu'on puisse s'y reporter, et aussi pour le suivi des délivrances multiples. Encore une fois, suivant les pays, les délivrances peuvent ou ne peuvent pas montrer des différences significatives avec les prescriptions dont elles découlent. Il peut y avoir, en général, plusieurs délivrances découlant d'une même prescription.
- Le compte-rendu d'administration : il décrit un événement d'administration (seulement dans les hôpitaux pour le moment). On a besoin de relier ces événements à la prescription.
- L'avis pharmaceutique : quand une prescription est reçue par le pharmacien, trois situations différentes peuvent s'ensuivre :
  a. Le pharmacien délivre les médicaments prescrits.
  b. Le pharmacien décide de délivrer des médicaments différents de ceux prescrits, tout en ayant pour objectif le même effet clinique que la prescription originale. Les situations où les pharmaciens sont habilités à faire cela peuvent différer d'un système de soins à un autre.
  c. Le pharmacien décide qu'il n'est pas approprié de délivrer le médicament prescrit. Il n'y a pas de délivrance.

  L'avis pharmaceutique est l'élément d'information qui contient les observations et les actions faites par le pharmacien dans ce processus de validation. Dans la situation a. en général il n'y a pas émission d'un avis pharmaceutique explicite, dans les situations b. et c. un avis pharmaceutique explicite est généré, communiqué et sauvegardé.

It should be noted that there is a distinct need for use of these information elements outside the direct reach of the current medication process that generates them. The most important examples of this are:

- HCP's prescribing in other processes need all dispensed medication information of recent nature in order to check on drug-incompatibilities. In some cases they might need previous prescriptions as well, this varies from country to country.
- Pharmacists dispensing medication might also be checking on incompatibilities through insight in recently dispensed medication.
- Any HCP treating or diagnosing a patient might be needing to see recently dispensed medication in order to make correct interpretations of clinical observations, lab results, etc, or to avoid adverse effects in treatment in general (other than only treatment by medication). Here it might be considered to be important to see the recent prescriptions as well.

Il faut noter qu'il existe un usage distinct de ces éléments d'information à l'extérieur du cercle immédiat du circuit du médicament qui les produit. Les exemples les plus importants sont :

- Les PS qui prescrivent dans le cadre d'autres processus ont besoin d'être informés de toutes les délivrances de médicaments récentes, pour pouvoir vérifier les interactions. Dans certains cas ils peuvent aussi avoir besoin des prescriptions, cela dépend des pays.
- Les pharmaciens qui délivrent des médicaments peuvent aussi avoir à vérifier les interactions, en regardant les médicaments délivrés récemment.
- N'importe quel PS qui soigne un patient ou qui doit poser un diagnostic peut avoir besoin de voir les dernières délivrances de médicaments, afin d'interpréter correctement les observations cliniques, les résultats de laboratoire, etc., ou pour éviter les effets indésirables dans le traitement en général (pas seulement dans le traitement médicamenteux). Pour cela il peut être considéré comme important de voir également les dernières prescriptions.

5 Real World Information Model

The properties of the information objects listed in this section may be mandatory or optional depending on the contextual workflow. These optional/required characteristics will be refined later on, at profile building time.

5.1 Common elements

This section introduces the common external elements leveraged by medication workflows.

5.1.1 Healthcare Professional

The healthcare professional who has prescribed the medication, the pharmacist who issues a pharmaceutical advice, the technician who dispenses the medication, the nurse who administers the medication to the patient

- Identification(s)
  - national/regional/local healthcare professional ID(s)
- Person
  - Full name
  - Address
  - Tel
  - Profession (e.g. physician, dentist, midwife, pharmacist, assistant, nurse...)
  - Specialty of a physician (e.g. general practitioner, cardiologist, gynecologist...)
- Represented Organization (hospital, primary care structure, pharmacy...)
  - Organization Id(s)
  - Organization name, address, tel
  - Organization department, care unit…

5.1.2 Patient

- Identification(s)
  - national/regional/local healthcare patient ID(s)
  - national/regional health insurance patient ID
  - healthcare facility patient ID
- Person
  - Full name
  - Gender
  - Date of birth, place of birth
  - Address
  - Tel
  - Physical metrics: weight, height…

5.1.3 Encounter in the healthcare institution

- Encounter ID
- Hospital information
  - Organization ID(s), name, address...
  - Organization department, care unit in charge with the patient (with care responsibility,

5 Modèle d'information (du monde réel)

The properties of the information objects listed in this section may be mandatory or optional depending on the contextual workflow. These optional/required characteristics will be refined later on, at profile building time.

5.1 Eléments communs

This section introduces the common external elements leveraged by medication workflows.

5.1.1 Professionnel de santé

The healthcare professional who has prescribed the medication, the pharmacist who issues a pharmaceutical advice, the technician who dispenses the medication, the nurse who administers the medication to the patient

- Identification(s)
  - national/regional/local healthcare professional ID(s)
- Person
  - Full name
  - Address
  - Tel
  - Profession (e.g. physician, dentist, midwife, pharmacist, assistant, nurse...)
  - Specialty of a physician (e.g. general practitioner, cardiologist, gynecologist...)
- Represented Organization (hospital, primary care structure, pharmacy...)
  - Organization Id(s)
  - Organization name, address, tel
  - Organization department, care unit…

5.1.2 Patient

- Identification(s)
  - national/regional/local healthcare patient ID(s)
  - national/regional health insurance patient ID
  - healthcare facility patient ID
- Person
  - Full name
  - Gender
  - Date of birth, place of birth
  - Address
  - Tel
  - Physical metrics: weight, height…

5.1.3 Séjour ou consultation dans un établissement de soins

- Encounter ID
- Hospital information
  - Organization ID(s), name, address...
  - Organization department, care unit in charge with the patient (with care responsibility,

medical responsibility, hosting responsibility)
- Date/time of encounter (start, end)
- Geographic location inside the hospital

5.1.4 Medication

Most of the time, prescribers can opt for the prescription of active substances or brand-name products.

A medication has the following properties:

- Brand name or generic name
- Name of the producing laboratory
- National/regional drug code(s)
- Active substance(s) denomination(s) (International Non-proprietary Name - INN)
- Codification of active substance(s)
- Pharmaceutical form (tab, syrup…)
- Unit dosage/Strength
- Packaging, type of container, number of units
- Agreed price of the medicine

5.2 Prescription

A prescription is issued by one ordering healthcare professional for one patient, in the context of zero or one encounter (between the patient and the ordering physician and/or the healthcare institution).

Medications dispensed or administered (by a nurse or another care provider) outside the context of any prescription are considered as self-prescribed by the professional who dispenses or administers. Thus they are still attached to a pseudo-prescription, with the same properties.

A prescription may contain one or more prescription items (lines on a paper prescription). Each line relates to one medication.

A prescription may refer to another former prescription that it supersedes or renew.

An electronic prescription has the following internal properties:

- Prescription ID
- Date/Time of prescription
- Reason for prescribing (e.g. diagnostic, prognostic, protocol, clinical assessment …)
- Additional comment
- Prescriber's signature
- Status (see the "Relevant Standards" chapter)

5.3 Prescription Item

A prescription item belongs to one prescription and represents one prescribed medication. It may be associated with one or more observations.
A prescription item has the following properties:
- Prescription Item ID

medical responsibility, hosting responsibility)
- Date/time of encounter (start, end)
- Geographic location inside the hospital

5.1.4 Médicament

Most of the time, prescribers can opt for the prescription of active substances or brand-name products.

A medication has the following properties:

- Brand name or generic name
- Name of the producing laboratory
- National/regional drug code(s)
- Active substance(s) denomination(s) (International Non-proprietary Name - INN)
- Codification of active substance(s)
- Pharmaceutical form (tab, syrup…)
- Unit dosage/Strength
- Packaging, type of container, number of units
- Agreed price of the medicine

5.2 Prescription

A prescription is issued by one ordering healthcare professional for one patient, in the context of zero or one encounter (between the patient and the ordering physician and/or the healthcare institution).

Medications dispensed or administered (by a nurse or another care provider) outside the context of any prescription are considered as self-prescribed by the professional who dispenses or administers. Thus they are still attached to a pseudo-prescription, with the same properties.

A prescription may contain one or more prescription items (lines on a paper prescription). Each line relates to one medication.

A prescription may refer to another former prescription that it supersedes or renew.

An electronic prescription has the following internal properties:

- Prescription ID
- Date/Time of prescription
- Reason for prescribing (e.g. diagnostic, prognostic, protocol, clinical assessment …)
- Additional comment
- Prescriber's signature
- Status (see the "Relevant Standards" chapter)

5.3 Ligne de prescription

A prescription item belongs to one prescription and represents one prescribed medication. It may be associated with one or more observations.
A prescription item has the following properties:
- Prescription Item ID

- Beginning date of treatment / length of treatment / End of treatment date (the date the treatment is due to end) and/or number of renewals
- Frequency
- Substitution allowed or not (can the pharmacist do a substitution of medication?)
- Route of administration
- Dosage
- Intake pattern for the medication
- Medical instructions
- Diagnosis or reason for prescribing
- Alert about prescribing restrictions
- Related to a chronic disease or not (listed or unlisted)
- Prescribing restrictions (e.g. required specialty for the prescriber, limited time length …)
- Dispensing restrictions (e.g. to be delivered only at hospital)
- Specific follow-up elements
- Economic information: price, reimbursement data, conditions …
- Additional comment
- Prescriber's signature
- Status (see the "Relevant Standards" chapter)

5.4 Pharmaceutical Advice

A pharmaceutical advice relates to one or more prescription items of one prescription. . It is issued by one pharmacist. It may be associated with one or more observations.

A pharmaceutical advice has the following properties:

- Pharmaceutical advice ID
- Date/Time of advice
- Zero, one or more detected problems
  A problem can be a supply problem (suspended medication, out-of-stock...) or a medical issue (redundancy, interaction, contra-indication, overdose, adverse effect...)
- Summary of physician/pharmacist discussion (by phone, mail, messages…)
- Status: (Open | Closed)
- Decision (i.e. dispense without change | dispense with changes | refusal to dispense until further discussion with prescriber | definite cancellation of the prescription item)
- Date/Time of decision
- Pharmacist's signature

5.5 Medication Dispense

A medication dispense relates to one prescription item of one prescription.

Medications dispensed outside the context of any prescription are considered as self-prescribed by the professional who dispenses. Thus they are still attached to a pseudo-prescription.

A medication dispense is issued by one pharmacy staff. It is related to zero (community use case) or one (hospital use case) encounter of care.

- A medication dispense has the following properties:

- Beginning date of treatment / length of treatment / End of treatment date (the date the treatment is due to end) and/or number of renewals
- Frequency
- Substitution allowed or not (can the pharmacist do a substitution of medication?)
- Route of administration
- Dosage
- Intake pattern for the medication
- Medical instructions
- Diagnosis or reason for prescribing
- Alert about prescribing restrictions
- Related to a chronic disease or not (listed or unlisted)
- Prescribing restrictions (e.g. required specialty for the prescriber, limited time length …)
- Dispensing restrictions (e.g. to be delivered only at hospital)
- Specific follow-up elements
- Economic information: price, reimbursement data, conditions …
- Additional comment
- Prescriber's signature
- Status (see the "Relevant Standards" chapter)

5.4 Avis pharmaceutique

A pharmaceutical advice relates to one or more prescription items of one prescription. . It is issued by one pharmacist. It may be associated with one or more observations.

A pharmaceutical advice has the following properties:

- Pharmaceutical advice ID
- Date/Time of advice
- Zero, one or more detected problems
  A problem can be a supply problem (suspended medication, out-of-stock...) or a medical issue (redundancy, interaction, contra-indication, overdose, adverse effect...)
- Summary of physician/pharmacist discussion (by phone, mail, messages…)
- Status: (Open | Closed)
- Decision (i.e. dispense without change | dispense with changes | refusal to dispense until further discussion with prescriber | definite cancellation of the prescription item)
- Date/Time of decision
- Pharmacist's signature

5.5 Compte-rendu de délivrance

A medication dispense relates to one prescription item of one prescription.

Medications dispensed outside the context of any prescription are considered as self-prescribed by the professional who dispenses. Thus they are still attached to a pseudo-prescription.

A medication dispense is issued by one pharmacy staff. It is related to zero (community use case) or one (hospital use case) encounter of care.

A medication dispense has the following properties:

- Dispense ID
- Refill number
- Date/Time of dispensing
- Location (in the hospital)
- Expected quantity (number of packs/number of units)
- Quantity delivered (number of packs/number of units)
- Batch number
- Expiration date
- Pharmaceutical instructions
- Price paid by the patient
- Pharmacy staff's signature

5.6 Administered Medication (generally in hospital workflow)

An administered medication relates to one prescription item of one prescription. Medications administered (by a nurse or another care provider) outside the context of any prescription are considered as self-prescribed by the professional who administers. Thus they are still attached to a pseudo-prescription.

An administered medication is issued by one ward staff (e.g. a nurse). It is related to one encounter of care. It may be associated with one or more observations.

An administered medication has the following properties:

- Effective date/time of administration (start, end)
- Planned date/time of administration (start, end)
- Location
- Expiration date
- Batch number
- Quantity administered
- Ward staff's signature (e.g. nurse, physician, internist, midwife ….)
- Administration comments

5.7 Entity-relationship model

The entities described above and their relationships are synthesized in the simplified entity-relation diagram next page. The diagram is simplified because some entities have not been considered at this stage ; in particular: prescription protocol, posology item, medication component, consolidated administration report.
It is expected to refine this model while building the integration profiles that will come out of this white paper.

- Dispense ID
- Refill number
- Date/Time of dispensing
- Location (in the hospital)
- Expected quantity (number of packs/number of units)
- Quantity delivered (number of packs/number of units)
- Batch number
- Expiration date
- Pharmaceutical instructions
- Price paid by the patient
- Pharmacy staff's signature

5.6 Compte-rendu d'administration (généralement dans le circuit du médicament intrahospitalier)

An administered medication relates to one prescription item of one prescription. Medications administered (by a nurse or another care provider) outside the context of any prescription are considered as self-prescribed by the professional who administers. Thus they are still attached to a pseudo-prescription.

An administered medication is issued by one ward staff (e.g. a nurse). It is related to one encounter of care. It may be associated with one or more observations.

An administered medication has the following properties:

- Effective date/time of administration (start, end)
- Planned date/time of administration (start, end)
- Location
- Expiration date
- Batch number
- Quantity administered
- Ward staff's signature (e.g. nurse, physician, internist, midwife ….)
- Administration comments

5.7 Modèle entités-relations

The entities described above and their relationships are synthesized in the simplified entity-relation diagram next page. The diagram is simplified because some entities have not been considered at this stage ; in particular: prescription protocol, posology item, medication component, consolidated administration report.
It is expected to refine this model while building the integration profiles that will come out of this white paper.

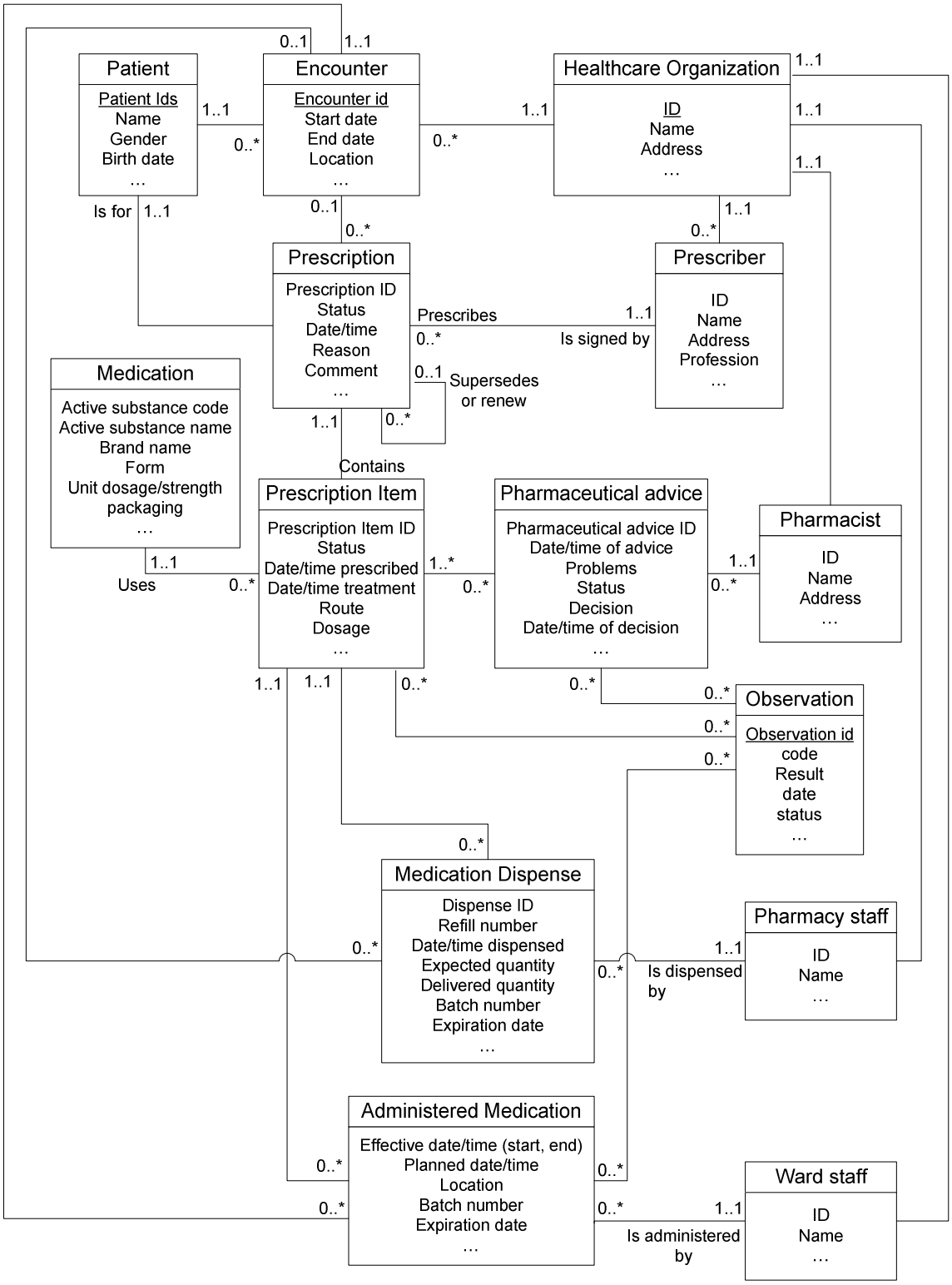


Figure 5.1: Entity-relationship model for hospital and community pharmacy

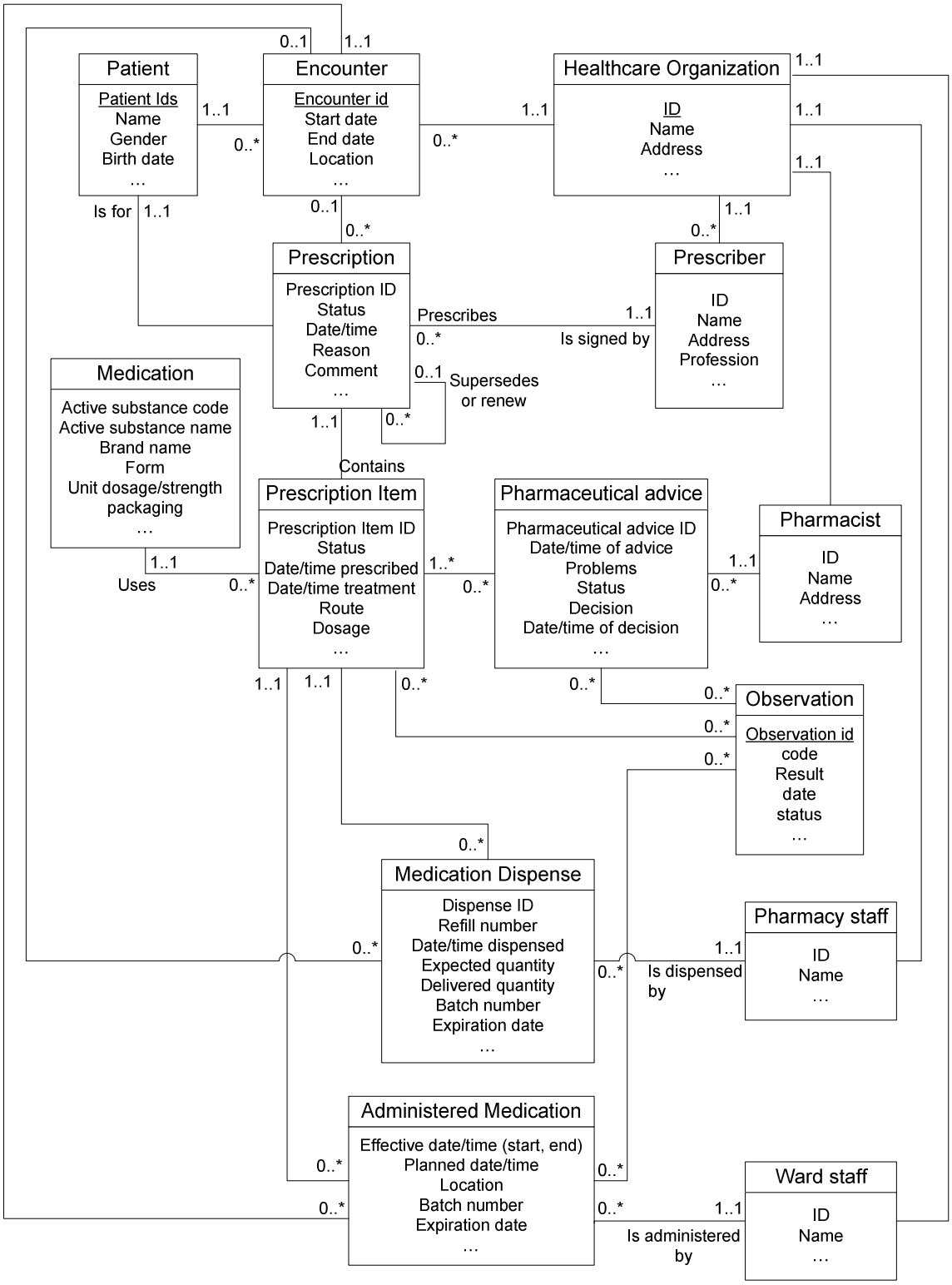


Figure 5.1: Modèle entités-relations pour la pharmacie hospitalière et la pharmacie de ville

6 Interoperability Use cases

This section describes the Interoperability Use Cases in the Pharmacy Domain. They are derived from the Businesses Processes (section 4 Pharmacy domain business process) by identifying the interactions between the Business Processes and the external world.

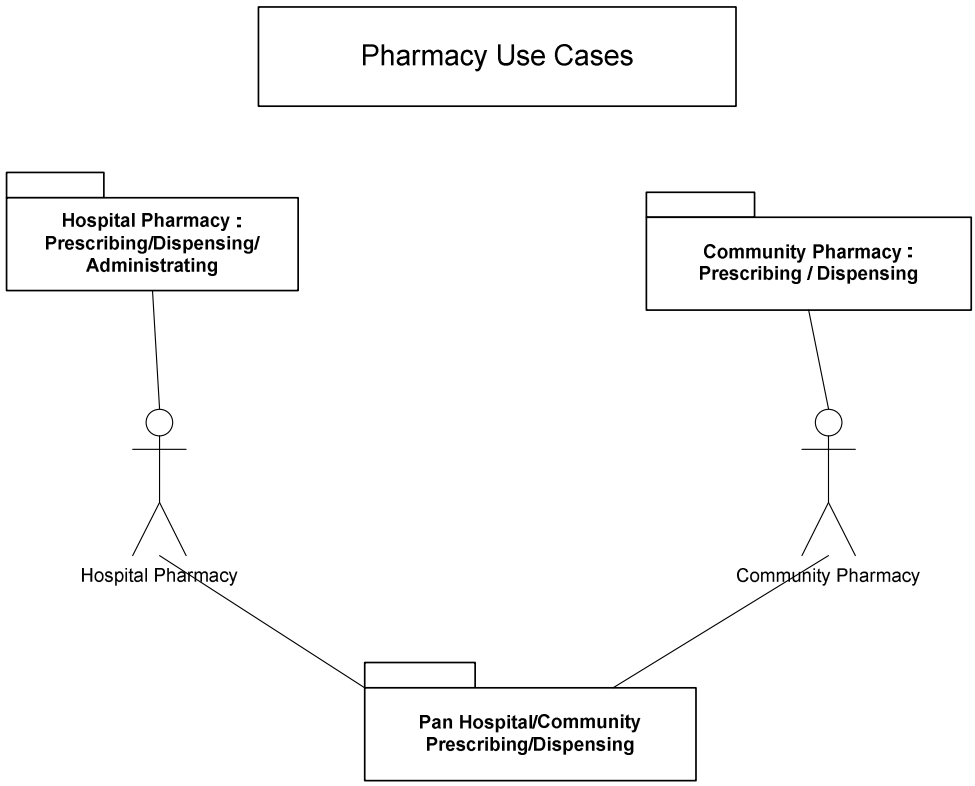


Figure 6.1: Pharmacy Use Cases

The Interoperability Use Cases can be grouped in the following categories:

- Hospital Pharmacy Use Cases : focus on Prescriptions, Dispense and Administration activities in a hospital
- Community Pharmacy Use Cases : focus on Prescriptions and Dispense activities in a community (between GPs and Pharmacist)
- Pan Hospital/Community Pharmacy Use Cases : focus on Prescriptions and Medication activities that result from Admission/Discharge of a patient from a community to a hospital (and vice versa)

The following figures give an overview of the different Use Cases. Section 7 describe the different Actors; Section 11 and 12 describe the different Use Cases in more detail.

6 Cas d'utilisation

This section describes the Interoperability Use Cases in the Pharmacy Domain. They are derived from the Businesses Processes (section 4 Pharmacy domain business process) by identifying the interactions between the Business Processes and the external world.

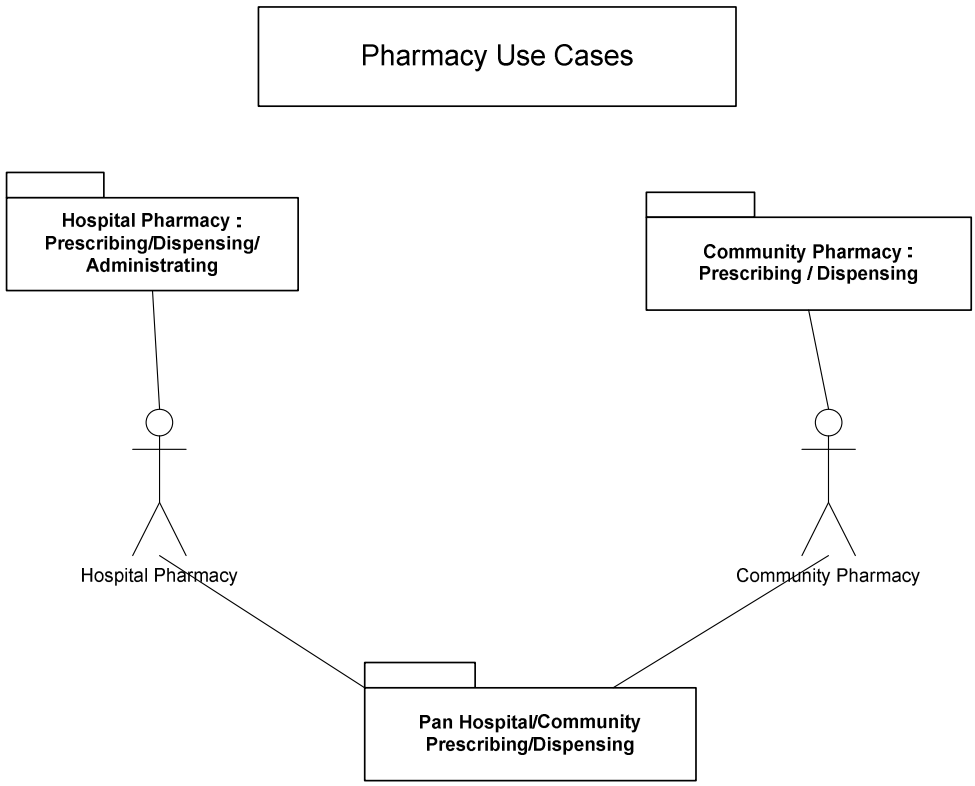


Figure 6.1: Cas d'utilisation

The Interoperability Use Cases can be grouped in the following categories :

- Hospital Pharmacy Use Cases : focus on Prescriptions, Dispense and Administration activities in a hospital
- Community Pharmacy Use Cases : focus on Prescriptions and Dispense activities in a community (between GPs and Pharmacist)
- Pan Hospital/Community Pharmacy Use Cases : focus on Prescriptions and Medication activities that result from Admission/Discharge of a patient from a community to a hospital (and vice versa)

The following figures give an overview of the different Use Cases. Section 7 describe the different Actors; Section 11 and 12 describe the different Use Cases in more detail.

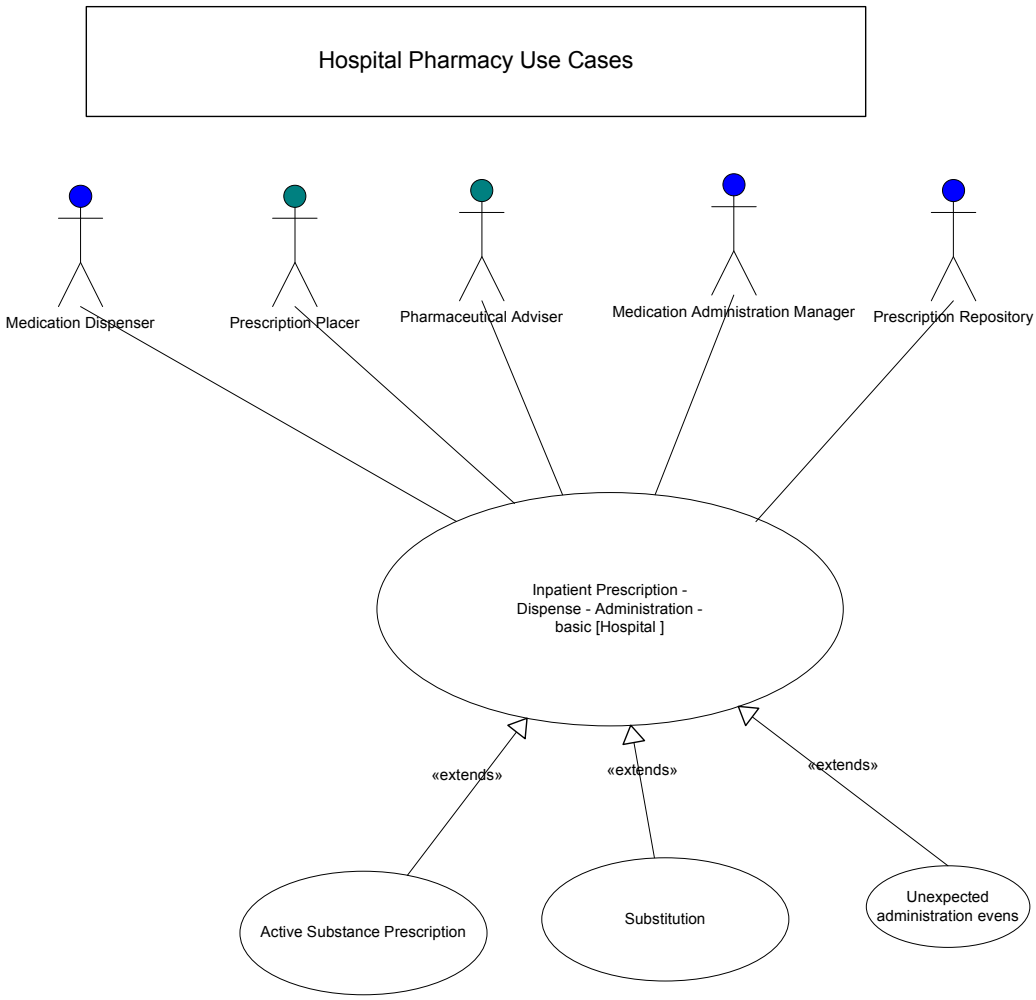


Figure 6.2: Hospital Pharmacy Use Cases

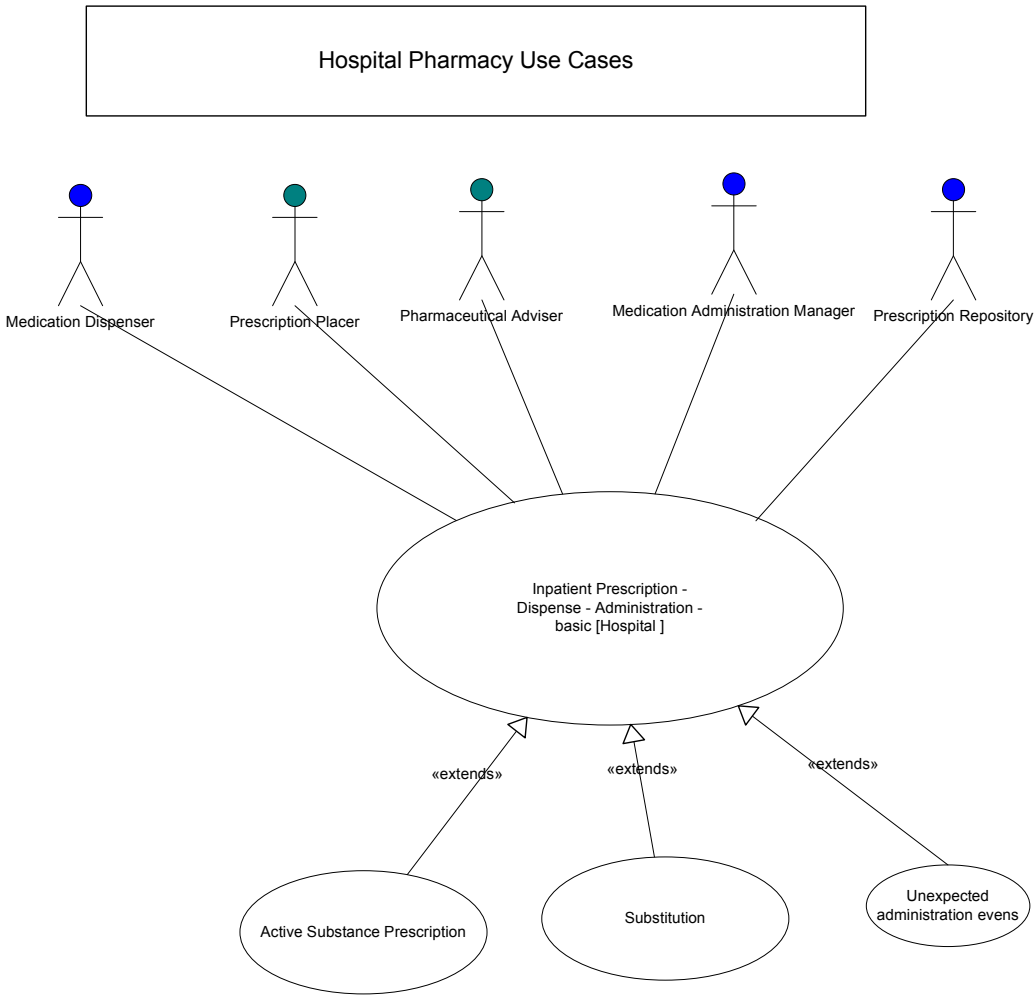


Figure 6.2 : Cas d'utilisation, pharmacie hospitalière

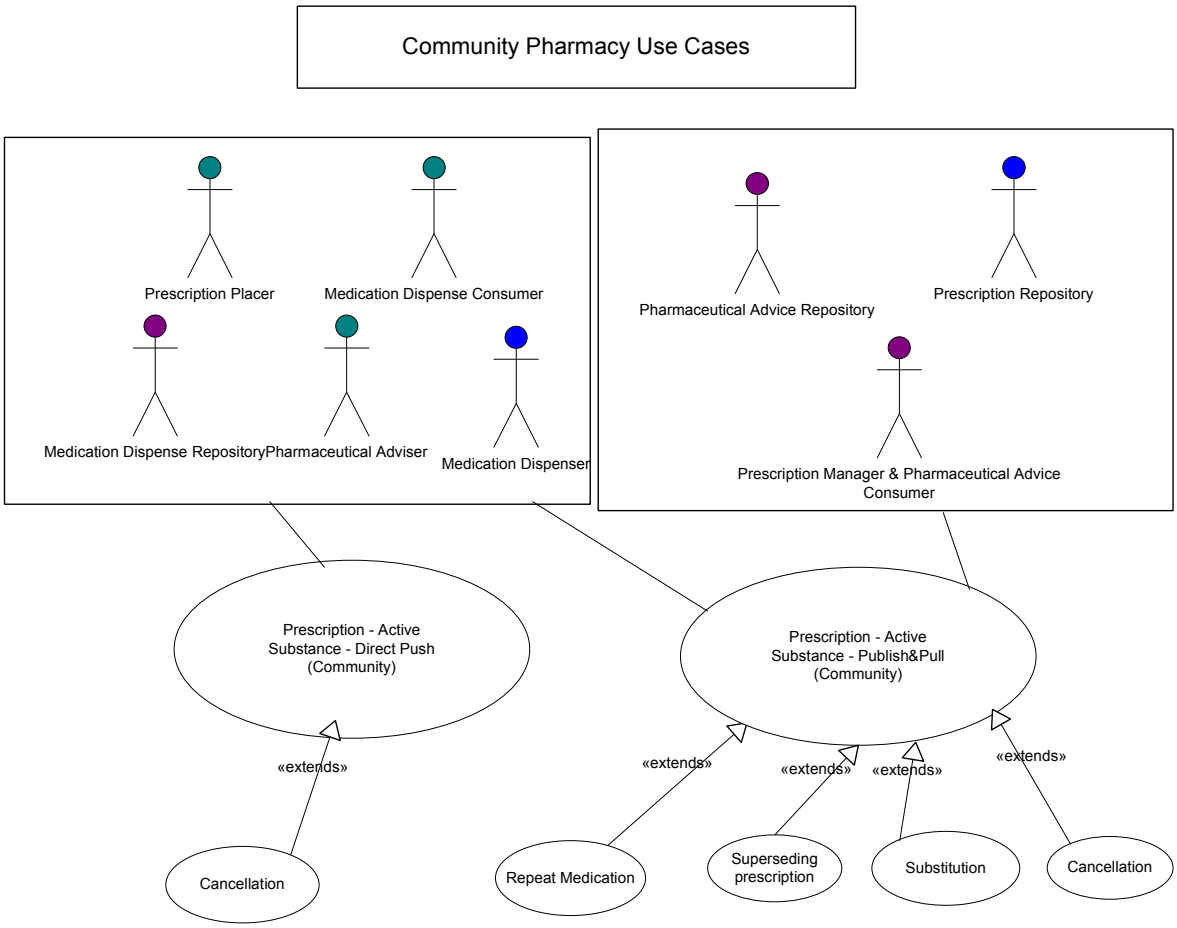


Figure 6.3: Community Pharmacy Use Cases

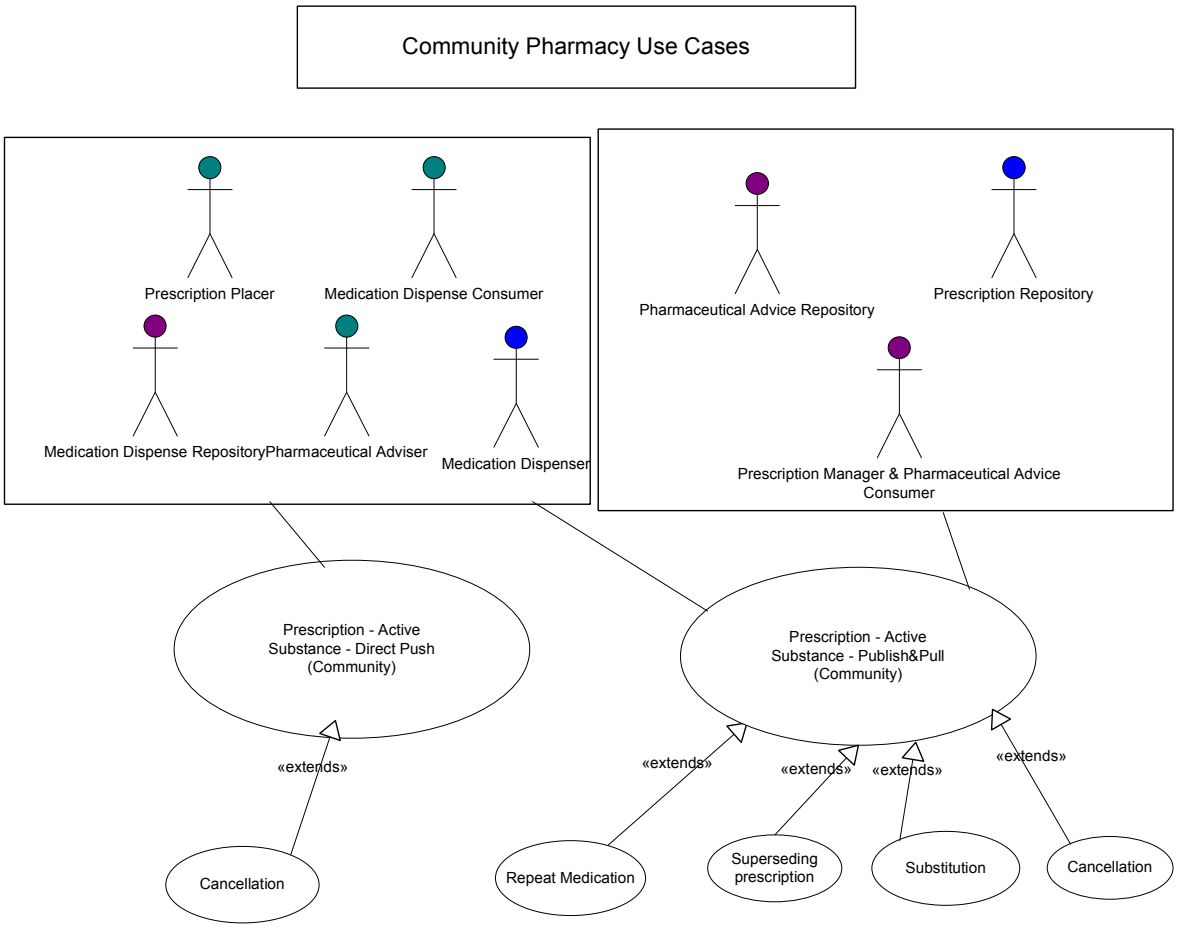


Figure 6.3 : Cas d'utilisation, pharmacie de ville

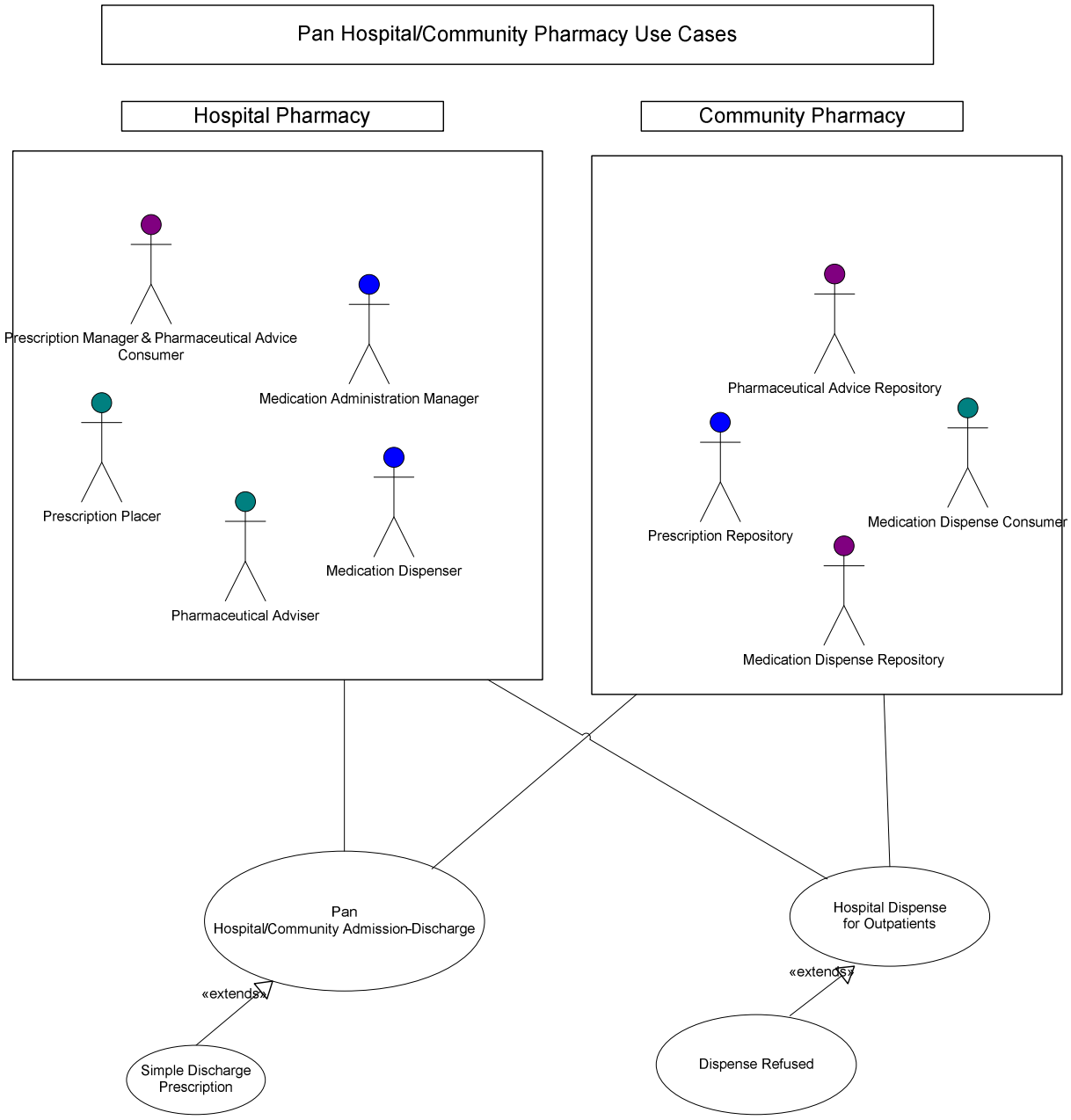


Figure 6.4: Pan Hospital/Community Pharmacy Use Cases

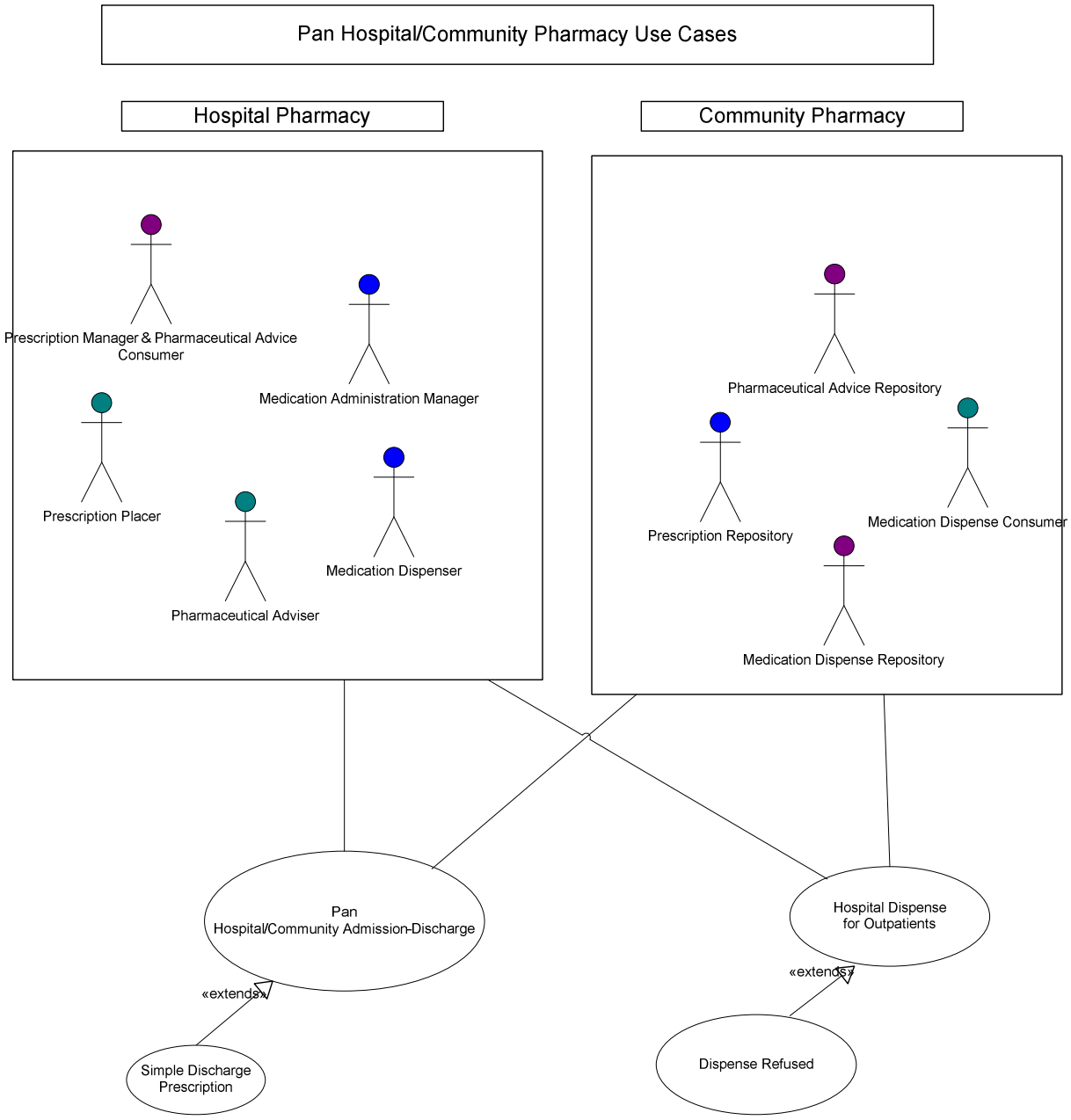


Figure 6.4 : Cas d'utilisation, échanges ville-hôpital

7 Use Case Actors

7.1 Introduction

In this section we will define the actors involved in the prescription-dispense process by specifying their main responsibility. These are the so-called system actors, i.e., they represent computer software running in facilities such as physicians' offices, hospitals, health systems' datacenters and community pharmacies.

The actors listed below represent the computer software usually found in settings taking part in the prescription-dispensation process. This comprise a variety of information systems such as hospitals information systems (HIS), electronic health records, electronic medical records, CPOE software, pharmacy's point of sale software, or health system's (central) databases.

Actual implementations of the model defined in this white paper may consist in pieces of software implementing more than one actor. As an example of this, the prescription producer may also provide the medication consumption feature in the hospital environment.

In order to standardize the naming of actors, the following conventions have been adopted:

- The actors producing a key piece of information (a prescription, a dispense, an administration report) and consuming some other piece of information are named after the main action taken by the care professional using this actor.

- Repository: under this name we will find those actors whose main responsibility consists in providing data either by hosting it (such as a central database) or by providing the means to reach it (such as a dispatcher or registry linked to multiple databases). Prescription and dispensed medication repositories are examples of this kind of actor. Both can be implemented as a standalone database or by means of a dispatcher linked to multiple databases actually running in hospitals, physicians and pharmacies' settings.

- Consumer: under this naming we will find actors whose main responsibility consists in querying and retrieving information from repositories. The prescription and dispensed medication consumers are examples of this kind of actor.

The following table lists the actors in the prescription-dispense process, grouped by type and use in the hospital and community environments:

Data	Type	Community	Hospital
Prescription	Placer	x	x
Medication Administration	Informer		x
Pharmaceutical	Adviser	x	x
Medication	Dispenser	x	x
Prescription	Repository	x	x

7 Acteurs des cas d'utilisation

7.1 Introduction

Dans cette section on va définir les acteurs impliqués dans le circuit du médicament, en spécifiant les responsabilités essentielles. Il s'agit ici de ce qu'on appelle des acteurs systèmes : ce sont des logiciels qui tournent dans des organisations telles que des cabinets médicaux, des hôpitaux, des grands systèmes d'information institutionnels, ou des pharmacies de ville.

Les acteurs qui sont listés ci-dessous représentent des logiciels que l'on peut trouver dans les organisations impliquées dans le circuit du médicament. Cela inclut toutes sortes de systèmes d'information, comme les systèmes d'information hospitaliers (SIH), les dossiers patients électroniques, les logiciels de saisie de prescription, les gestions de pharmacies de ville, ou les bases de données (centrales) des institutions du secteur de la santé.

Les implémentations effectives du modèle décrit dans ce livre blanc peuvent se traduire par des programmes qui implémentent plus d'un acteur. Par exemple, le logiciel qui produit la prescription peut aussi être celui qui gère la consommation de médicaments en milieu hospitalier.

Afin de standardiser le nommage des acteurs, les conventions suivantes ont été adoptées :

- Les acteurs qui produisent des éléments d'information essentiels (une prescription, un compte-rendu de délivrance, un compte-rendu d'administration) et qui consomment d'autres éléments d'information, sont nommés en fonction de l'action principale effectuée par le professionnel de santé qui utilise cet acteur.

- Repository (entrepôt) : sous ce nom on trouve ces acteurs dont la responsabilité principale consiste à fournir des données, soit en les hébergeant (comme une base de données centrale), soit en fournissant les moyens de les récupérer (comme un logiciel qui dispatche de l'information ou donne des liens vers des bases de données multiples). Les entrepôts de prescriptions ou de comptes-rendus de délivrance sont des exemples d'acteurs de ce genre. Ils peuvent être implémentés sous la forme d'une seule base de données, ou en passant par un dispatcheur en lien avec de multiples bases de données qui tournent dans des hôpitaux, des cabinets médicaux ou des pharmacies.

- Consumer (client d'entrepôt) : sous ce nom on trouve des acteurs dont la responsabilité principale consiste à faire des requêtes pour récupérer de l'information en provenance des entrepôts des données. Les clients des entrepôts de prescriptions ou de comptes-rendus de délivrance sont des exemples de ce genre d'acteur.

La table suivante donne la liste des acteurs du circuit du médicament, groupés par type, en indiquant s'ils sont utilisés dans les environnements hospitalier et/ou de ville :

Donnée	Type	Ville	Hôpital
Prescription	Placer	x	x
Medication Administration	Informer		x
Pharmaceutical	Adviser	x	x
Medication	Dispenser	x	x
Prescription	Repository	x	x

Data	Type	Community	Hospital
Medication Dispense	Repository	x	x
Pharmaceutical advice	Repository	x	x
Prescription & Pharmaceutical Advice	Consumer	x	x
Medication Dispense	Consumer	x	x

7.2 Link between system actors and human actors

In order to emphasize the relationship between human actors and system actors, the following table depicts the link between both types of actors:

System actor	Human actor
Prescription Placer	Prescriber such as physician (GP or specialist), nurse, pharmacist, etc.
Medication Administration Informer	Nurse
Pharmaceutical Adviser	Pharmacist
Medication Dispenser	Pharmacist
Prescription Repository	n.a.
Medication Dispense Repository	n.a.
Pharmaceutical Advice Repository	n.a.
Prescription & Pharmaceutical Advice Consumer	Pharmacist, physician, etc.
Medication Dispense Consumer	Pharmacist, physician, etc.

7.3 Prescription placer

The main role of this actor consists in placing the prescription (initial or modified in case of a substitution of invalidation, for example). It sends the cancellation of the prescription or its discontinuation, as well. In order to fulfill this task, the prescription placer retrieves the current treatment of the patient and medication already dispensed recently.

The prescription placer receives the pharmaceutical validation and status tracking information such as substitution, availability, administration plan and reports and cancellation. The corresponding human actor is a prescriber.

Donnée	Type	Ville	Hôpital
Medication Dispense	Repository	x	x
Pharmaceutical advice	Repository	x	x
Prescription & Pharmaceutical Advice	Consumer	x	x
Medication Dispense	Consumer	x	x

7.2 Relations entre les acteurs systèmes et les acteurs humains

De façon à bien faire comprendre les relations entre les acteurs humains et les acteurs système, le tableau suivant décrit les liens entre ces deux types d'acteurs :

Acteur système	Acteur humain
Prescription Placer	Un prescripteur comme un médecin (généraliste ou spécialiste), une infirmière, un pharmacien, etc.
Medication Administration Informer	Une infirmière
Pharmaceutical Adviser	Un pharmacien
Medication Dispenser	Un pharmacien
Prescription Repository	n.a. (non applicabble)
Medication Dispense Repository	n.a.
Pharmaceutical Advice Repository	n.a.
Prescription & Pharmaceutical Advice Consumer	Un pharmacien, un médecin, etc.
Medication Dispense Consumer	Un pharmacien, un médecin, etc.

7.3 Prescription placer (émetteur de prescription)

Le rôle principal de cet acteur consiste à émettre la prescription (initiale, ou modifiée dans le cas où elle remplace une prescription invalidée par exemple). C'est aussi lui qui peut émettre l'annulation de la prescription, ou son interruption. Pour accomplir cette tâche, l'émetteur de la prescription récupère les informations sur le traitement courant du patient et sur les dernières délivrances de médicaments.

L'émetteur de la prescription reçoit la validation pharmaceutique, ainsi que les informations de suivi de la prescription comme une substitution, la disponibilité, le plan et les comptes-rendus d'administration, une annulation. L'acteur humain correspondant est le prescripteur.

7.4 Medication administration Informer

The medication administration producer's main responsibility consists in creating and placing the medication administration plan and the corresponding administration reports. In order to achieve this, it receives the initial prescription, the pharmaceutical validation or a "simple" substitution. It also receives the confirmation of drug availability for administration.

Through administration reports, the Medication Administration Manager actor reports, among others:

- The replacements (e.g. the 1g tablet by two 500 mg single dose packets).
- The follow-up (e.g. injectable follow-up).

7.5 Prescription repository

This repository contains the medication prescribed to the patient from the prescription producer and may receive updates to the current treatment (cancellations, changes, etc.). It also provides the current treatment to other actors such as the prescription consumer.

7.6 Dispensed medication repository

This repository contains the medication actually dispensed to the patient; this information is received from the medication dispenser. The dispensed medication repository provides the medication record of the patient to other actors such as the dispensed medication consumer.

7.7 Pharmaceutical advice repository

This repository contains the pharmaceutical advice issued by the pharmaceutical adviser (typically a pharmacist). It provides this information to the prescription & pharmaceutical advice consumer.

7.8 Prescription & pharmaceutical advice consumer

This actor allows for the retrieval of current prescriptions and pharmaceutical advice from the prescription repository. This information may be required to dispense medication or to check the current treatment when prescribing further medication.

7.9 Dispensed medication consumer

This actor obtains information on medication already dispensed to the patient, aggregates it and provides it to the human actor (e.g. direct check of the medication record of the patient) or to other (information system) actors such as the prescription producer. This information is received from the dispensed medication repository. The human actor behind this system actor may be a pharmacist, a prescriber or other healthcare professional authorized to access the medication record.

7.10 Pharmaceutical adviser

This actor is responsible for the validation of prescriptions from a pharmacist's perspective. Therefore, it receives the initial prescription, validates it and sends it back (accepted, cancelled, modified, substitution of pharmaceutical product); therefore it provides the pharmaceutical advice. To perform this task it checks the current treatment.

7.4 Medication administration informer (émetteur de CR d'administration)

La responsabilité principale de cet acteur consiste à créer et émettre le plan d'administration et les comptes-rendus d'administration correspondants. Pour accomplir cette tâche, il reçoit la prescription initiale, la validation pharmaceutique ou une substitution « simple ». Il reçoit aussi la confirmation que les médicaments sont disponibles en vue de leur administration.

Au travers des comptes-rendus d'administration, l'émetteur du CR d'administration rapporte aussi, entre autres :

- Les remplacements (par exemple d'un comprimé de 1g par deux sachets de 500 mg).
- Le suivi (par exemple le suivi des perfusions [qui n'est pas dans la couverture fonctionnelle de ce livre blanc])

7.5 Prescription repository (entrepôt de prescriptions)

Cet entrepôt stocke les informations sur les médicaments prescrits au patient, fournies par l'émetteur de prescription, et peut recevoir des mises à jour du traitement courant (annulations, modifications, etc.). Il met aussi le traitement courant à disposition d'autres acteurs comme le client des entrepôts de prescriptions.

7.6 Dispensed medication repository (entrepôt de CR de délivrance)

Cet entrepôt stocke les informations sur les médicaments effectivement délivrés au patient, fournies par l'émetteur de comptes-rendus de délivrance. L'entrepôt de CR de délivrance met ces informations à disposition d'autres acteurs comme le client des entrepôts de CR de délivrance.

7.7 Pharmaceutical advice repository (entrepôt d'avis pharmaceutiques)

Cet entrepôt stocke les avis pharmaceutiques émis par l'émetteur d'avis pharmaceutiques (typiquement un pharmacien). Il met ces informations à disposition du client des entrepôts de prescriptions et d'avis pharmaceutiques.

7.8 Prescription & pharmaceutical advice consumer (client des entrepôts de prescriptions et d'avis pharmaceutiques)

Cet acteur permet de récupérer les informations sur les prescriptions en cours et les avis pharmaceutiques, à partir de l'entrepôt de prescriptions [et de l'entrepôt d'avis pharmaceutiques]. Ces informations peuvent être nécessaires pour dispenser les médicaments ou pour vérifier le traitement courant avant de prescrire de nouveaux médicaments.

7.9 Dispensed medication consumer (client des entrepôts de CR de délivrance)

Cet acteur obtient des informations sur les médicaments déjà délivrés au patient, et les agrège avant de les fournir à l'acteur humain (consultation directe du dossier pharmaceutique du patient) ou à d'autres acteurs système comme l'émetteur de prescriptions. Ces informations viennent de l'entrepôt de CR de délivrance. L'acteur humain derrière cet acteur système peut être un pharmacien, un prescripteur, ou tout autre professionnel de santé autorisé à accéder au dossier pharmaceutique.

7.10 Pharmaceutical adviser (émetteur d'avis pharmaceutiques)

Cet acteur est responsable de la validation de la prescription, de la part d'un pharmacien. Pour ce faire, il reçoit la prescription initiale, la valide et la renvoie (acceptée, annulée, modifiée, ou avec une substitution de spécialité pharmaceutique) : il fournit l'avis pharmaceutique. Pour accomplir cette tâche, il prend connaissance du traitement courant.

This actor may be implemented in the hospital pharmacy module of a hospital information system or the point of sale software of the pharmacy. The corresponding human actor is typically a pharmacist (or pharmacist assistant).

7.11 Medication dispenser

This actor is responsible for the process of dispensing medication to the patient, fulfilling the prescription. Therefore it produces the information on the medication dispensed to the patient. In order to achieve this, it receives prescriptions already validated. It also confirms drug availability for administration and it receives the administration plan and administration reports.
This actor may be implemented as the point of sale software of a community pharmacy or the hospital pharmacy module of a hospital information system. The human actor behind this system actor is usually a pharmacist or a pharmacist assistant.

Cet acteur peut être implémenté dans le module de gestion de la pharmacie d'un système d'information hospitalier ou dans le logiciel de vente d'une pharmacie de ville. L'acteur humain correspondant est typiquement un pharmacien (ou un préparateur en pharmacie).

7.11 Medication dispenser (émetteur de CR de délivrance)

Cet acteur est responsable du processus de délivrance des médicaments au patient, pour satisfaire la prescription : il produit les informations sur les médicaments délivrés au patient. Pour accomplir cette tâche, il reçoit des prescriptions déjà validées [à commenter]. Il doit aussi confirmer si les médicaments sont disponibles, et recevoir le plan et les comptes-rendus d'administration.
Cet acteur peut être implémenté en tant que logiciel de point de vente d'une pharmacie de ville, ou comme module de gestion de la pharmacie d'un système d'information hospitalier. L'acteur humain derrière cet acteur système est habituellement un pharmacien ou un préparateur en pharmacie.

8 Use cases for Community Pharmacy

8.1 Models

Current implementations of the community pharmacy process (prescribe & dispense medication) may be categorized in two different alternatives.

The first alternative is the so-called publish & pull which corresponds to a rather centralized approach. In this model, generally speaking, information is generated by a placer type actor (prescriber or dispenser) and stored by means of a central repository type actor. Other actors retrieve data by pulling it from repositories. This approach may apply to health systems where information is accessed on a centralized basis and, therefore, is made available to a collective of potential users (such as prescriptions available for dispense in any community pharmacy).

The alternative approach is the direct push model where information is sent directly to the actor intended to use it (e.g. prescriptions sent directly to the pharmacy named by the patient) and therefore no information is stored on a centralized basis. This model focuses on direct communication instead of availability to (more) potential users.

Generally speaking, the use cases defined in this document do not cover the process of prescribing a medicine since it is considered out of the scope of the white paper. Therefore, use cases focus on the transfer of prescriptions to pharmacies.

8.2 Use Case community pharmacy-active substance, publish & pull

8.2.4 Purpose

The purpose of this use case is to illustrate the prescription-dispense process in community pharmacy when the prescriber orders an active-substance (generic) medicine in the publish & pull model.

8.2.5 Story Board

John Doe attends a consultation to his general practitioner, GP, because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance “Fenoterol” in his “prescription placer” software. The prescription is electronically sent to the “prescription repository”. Since prescriptions are available to a wide range of pharmacies, John picks the pharmacy closest to his office. The pharmacist asks for John’s health card in order to retrieve the patient’s active prescriptions (from the “prescription repository”) and recent dispensed medication (from the “dispensed medication repository”). Since John also suffers from arthritis he was prescribed ibuprofen. The pharmacists checks for interactions and finds nothing outstanding. He consults his inventory and picks Berotec which is in the range of prices approved by the health system. He gives out this medicine to the patient and records the transaction in the “medication dispenser”. The information on the medication dispensed is electronically sent to the “dispensed medication repository”.

8 Cas d'utilisation pour la pharmacie de ville

8.1 Modèles

Current implementations of the community pharmacy process (prescribe & dispense medication) may be categorized in two different alternatives.

The first alternative is the so-called publish & pull which corresponds to a rather centralized approach. In this model, generally speaking, information is generated by a placer type actor (prescriber or dispenser) and stored by means of a central repository type actor. Other actors retrieve data by pulling it from repositories. This approach may apply to health systems where information is accessed on a centralized basis and, therefore, is made available to a collective of potential users (such as prescriptions available for dispense in any community pharmacy).

The alternative approach is the direct push model where information is sent directly to the actor intended to use it (e.g. prescriptions sent directly to the pharmacy named by the patient) and therefore no information is stored on a centralized basis. This model focuses on direct communication instead of availability to (more) potential users.

Generally speaking, the use cases defined in this document do not cover the process of prescribing a medicine since it is considered out of the scope of the white paper. Therefore, use cases focus on the transfer of prescriptions to pharmacies.

8.2 Cas d'utilisation pour la pharmacie de ville – substance active, publier et extraire

8.2.4 Finalité

The purpose of this use case is to illustrate the prescription-dispense process in community pharmacy when the prescriber orders an active-substance (generic) medicine in the publish & pull model.

8.2.5 Story Board

John Doe attends a consultation to his general practitioner, GP, because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance "Fenoterol" in his "prescription placer" software. The prescription is electronically sent to the "prescription repository". Since prescriptions are available to a wide range of pharmacies, John picks the pharmacy closest to his office. The pharmacist asks for John's health card in order to retrieve the patient's active prescriptions (from the "prescription repository") and recent dispensed medication (from the "dispensed medication repository"). Since John also suffers from arthritis he was prescribed ibuprofen. The pharmacists checks for interactions and finds nothing outstanding. He consults his inventory and picks Berotec which is in the range of prices approved by the health system. He gives out this medicine to the patient and records the transaction in the "medication dispenser". The information on the medication dispensed is electronically sent to the "dispensed medication repository".

8.2.6 Sequence Diagram

The following diagram represents the sequence of data exchanged between "system actors" involved in this use case.

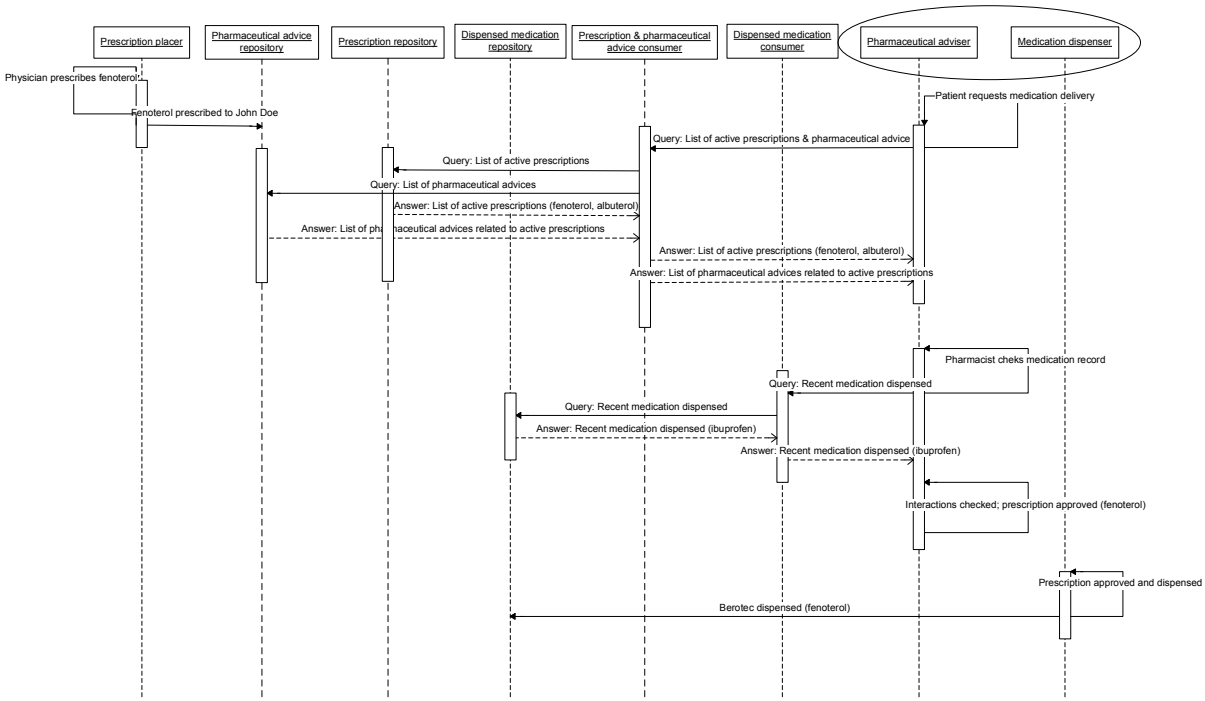


Figure 8.1:Use Case community pharmacy-active substance, publish & pull

This diagram illustrates the sharing of pharmaceutical advice among pharmacists which is done by querying the pharmaceutical advice repository when requesting the list of current prescriptions. For simplicity, this checking of pharmaceutical advice is not repeated in further diagrams.

8.3 Use Case community pharmacy-repeat medication

8.3.4 Purpose

The purpose of this use case is to illustrate a base version of the prescription-dispense process in case of a repeat medication.

8.3.5 Story Board

Since John Doe has a mild breathing condition, his GP prescribed him Fenoterol for five months. The most common presentation of this medicine lasts one month; therefore John goes to the pharmacy every month for refills.

8.2.6 Sequence Diagram

The following diagram represents the sequence of data exchanged between "system actors" involved in this use case.

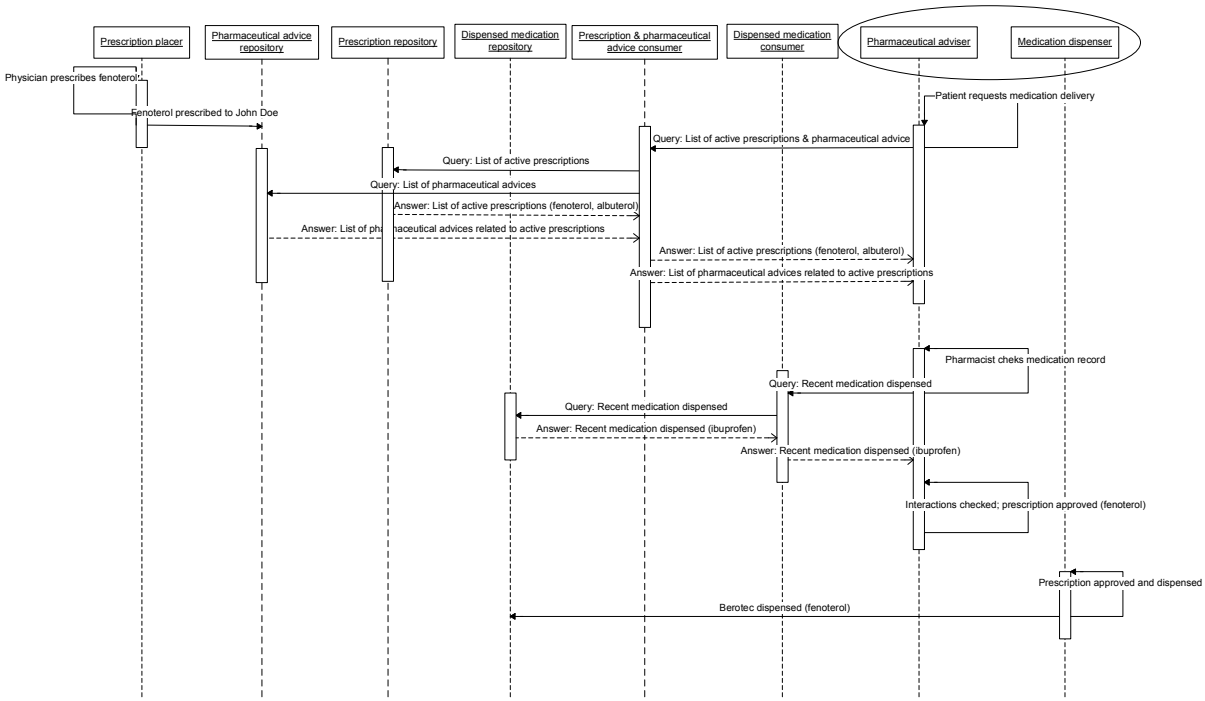


Figure 8.1:Use Case community pharmacy-active substance, publish & pull

This diagram illustrates the sharing of pharmaceutical advice among pharmacists which is done by querying the pharmaceutical advice repository when requesting the list of current prescriptions. For simplicity, this checking of pharmaceutical advice is not repeated in further diagrams.

8.3 Cas d'utilisation pour la pharmacie de ville – renouvellements

8.3.4 Purpose

The purpose of this use case is to illustrate a base version of the prescription-dispense process in case of a repeat medication.

8.3.5 Story Board

Since John Doe has a mild breathing condition, his GP prescribed him Fenoterol for five months. The most common presentation of this medicine lasts one month; therefore John goes to the pharmacy every month for refills.

At the pharmacy, the pharmacist requests John's health card in order to retrieve the active prescriptions and verifies that he has refills left. The pharmacist gives out Berotec to John and records the transaction in the "medication dispenser". The medication just dispensed is sent to the dispensed medication repository where the number of refills is adjusted accordingly.

The prescription repository contains the number of containers prescribed to John Doe whilst the dispensed medication repository hosts the number of containers already dispensed; therefore, both repositories have to be consulted prior to dispensing refills to John Doe. Additionally, the initial prescription is not modified by the fact of refills given out to John Doe, the initial number of container remaining static as long as the process lasts. What is updated is the number of container dispensed.

8.3.6 Sequence Diagram

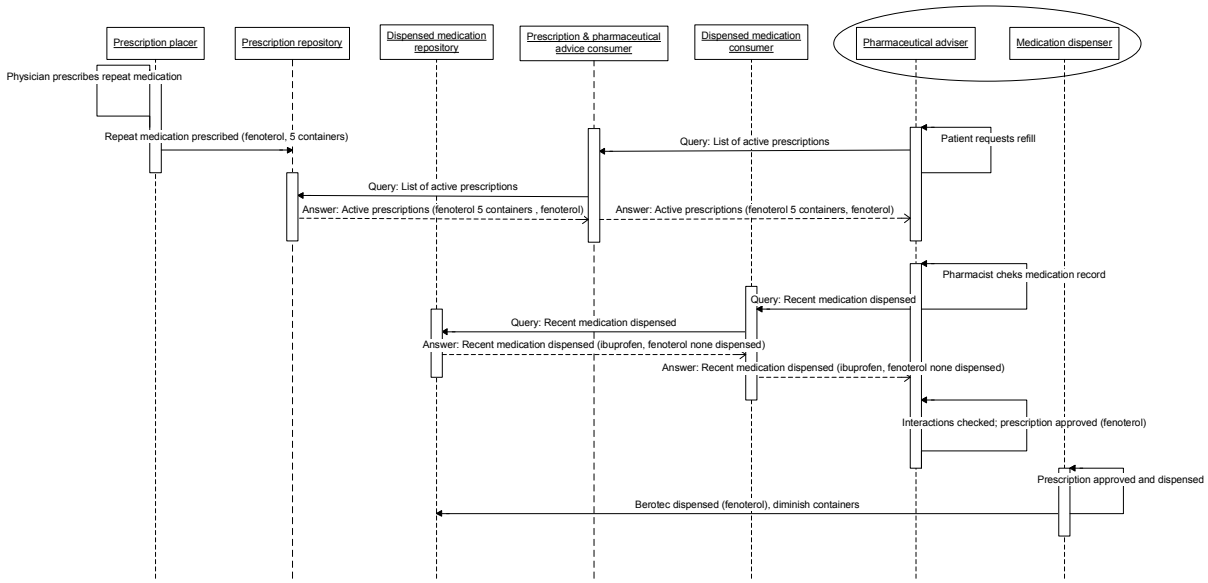


Figure 8.2:Use Case community pharmacy-repeat medication

The previous diagram illustrates the first loop of the repeat medication process where no container was yet dispensed to the patient. In subsequent loops, the number of containers dispensed would reflect the medication already given out to the patient, being the potential number of loops equal to the number of containers initially prescribed (5 in this example).

8.4 Use Case Community pharmacy-cancellation proposed

8.4.4 Purpose

The purpose of this use case is to illustrate the prescription-dispense process in community pharmacy when the prescriber orders a medicine which interacts with a recently dispensed drug

At the pharmacy, the pharmacist requests John's health card in order to retrieve the active prescriptions and verifies that he has refills left. The pharmacist gives out Berotec to John and records the transaction in the "medication dispenser". The medication just dispensed is sent to the dispensed medication repository where the number of refills is adjusted accordingly.

The prescription repository contains the number of containers prescribed to John Doe whilst the dispensed medication repository hosts the number of containers already dispensed; therefore, both repositories have to be consulted prior to dispensing refills to John Doe. Additionally, the initial prescription is not modified by the fact of refills given out to John Doe, the initial number of container remaining static as long as the process lasts. What is updated is the number of container dispensed.

8.3.6 Sequence Diagram

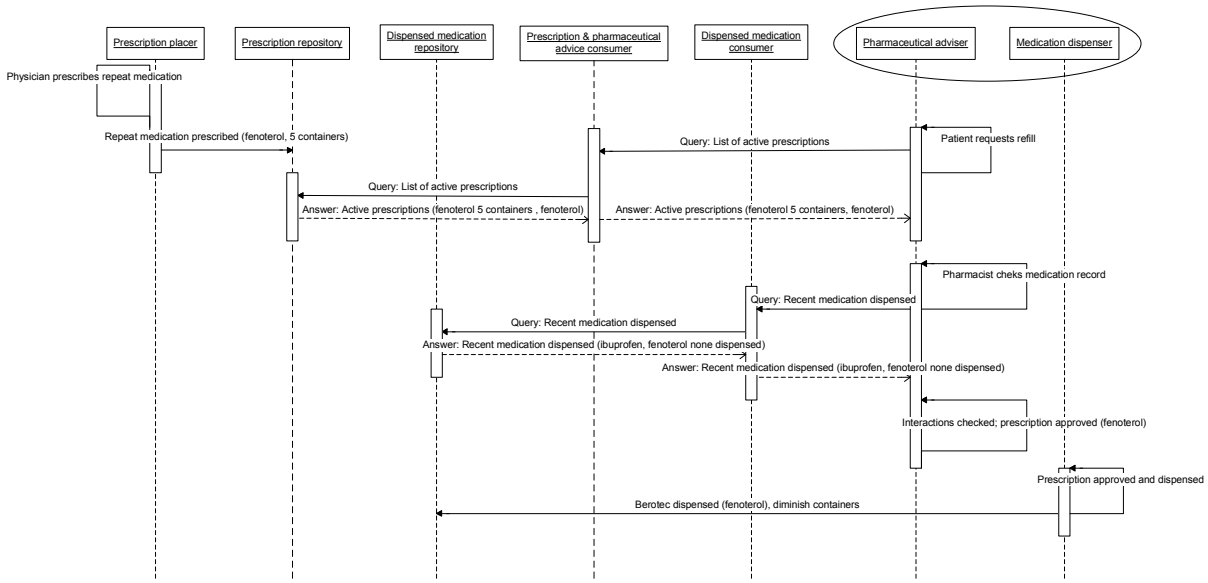


Figure 8.2:Use Case community pharmacy-repeat medication

The previous diagram illustrates the first loop of the repeat medication process where no container was yet dispensed to the patient. In subsequent loops, the number of containers dispensed would reflect the medication already given out to the patient, being the potential number of loops equal to the number of containers initially prescribed (5 in this example).

8.4 Cas d'utilisation pour la pharmacie de ville – annulation recommandée

8.4.4 Purpose

The purpose of this use case is to illustrate the prescription-dispense process in community pharmacy when the prescriber orders a medicine which interacts with a recently dispensed drug

and the pharmacist proposes a cancellation; this cancellation can be considered as pharmaceutical advice.

8.4.5 Story Board

At the pharmacy, the pharmacist checks for interactions and notices that the patient has been given recently Ketoconazole which may increase the level of Fenoterol in blood. The pharmacist considers this potentially harmful to the patient and decides to propose a cancellation of the prescription to the GP. Therefore, the medicine Fenoterol is not dispensed to the patient and the pharmacist's proposal is recorded in the "pharmaceutical adviser".
This cancellation proposal is sent electronically to the "pharmaceutical advice repository" and the patient is advised to consult his GP in order to address this issue. The following day, John Doe attends a consultation to his GP who checks the "pharmaceutical advice repository" and reads the cancellation proposal sent by the pharmacist. The GP may accept the cancellation proposal and prescribe another medicine or confirm the original prescription provided that the benefits surpass the potential harm.

8.4.6 Sequence Diagram

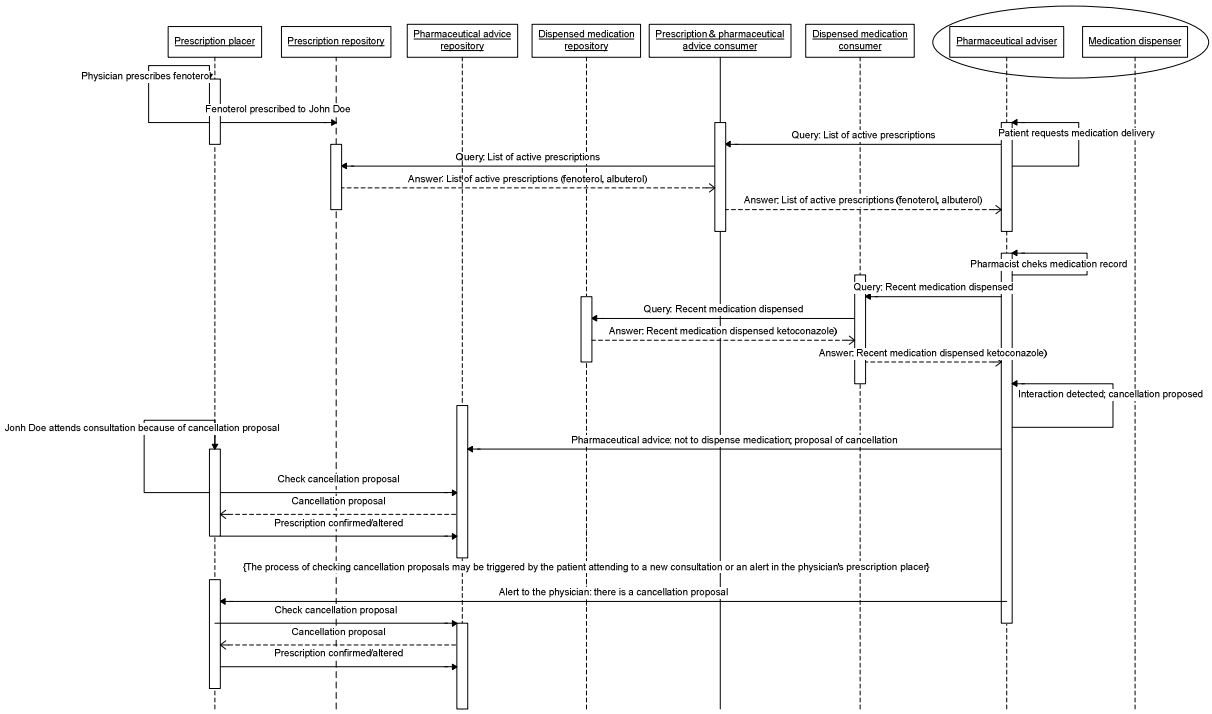


Figure 8.3 : Use Case Community pharmacy-cancellation proposed

This diagram portrays the process from the prescription act to the confirmation/amendment of the prescription. From this point on, the process is similar to the one illustrated in the first community pharmacy use case.

and the pharmacist proposes a cancellation; this cancellation can be considered as pharmaceutical advice.

8.4.5 Story Board

At the pharmacy, the pharmacist checks for interactions and notices that the patient has been given recently Ketoconazole which may increase the level of Fenoterol in blood. The pharmacist considers this potentially harmful to the patient and decides to propose a cancellation of the prescription to the GP. Therefore, the medicine Fenoterol is not dispensed to the patient and the pharmacist's proposal is recorded in the "pharmaceutical adviser".
This cancellation proposal is sent electronically to the "pharmaceutical advice repository" and the patient is advised to consult his GP in order to address this issue. The following day, John Doe attends a consultation to his GP who checks the "pharmaceutical advice repository" and reads the cancellation proposal sent by the pharmacist. The GP may accept the cancellation proposal and prescribe another medicine or confirm the original prescription provided that the benefits surpass the potential harm.

8.4.6 Sequence Diagram

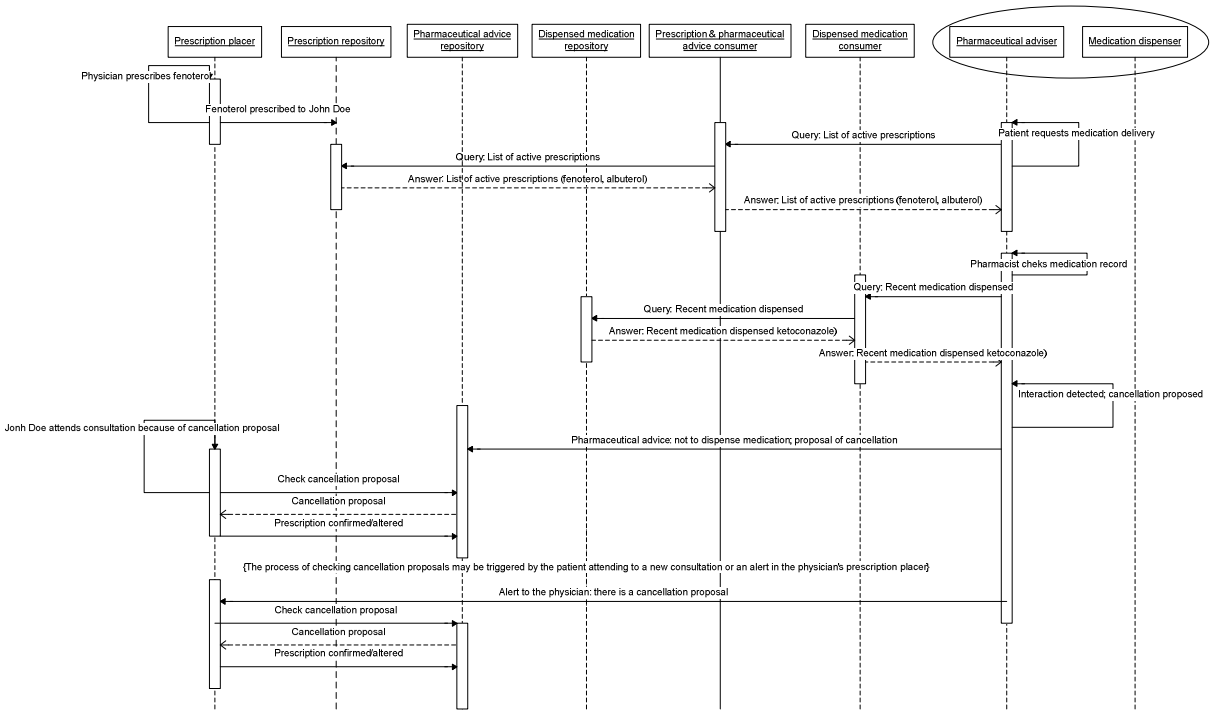


Figure 8.3 : Use Case Community pharmacy-cancellation proposed

This diagram portrays the process from the prescription act to the confirmation/amendment of the prescription. From this point on, the process is similar to the one illustrated in the first community pharmacy use case.

The physician checking the cancellation proposal may be triggered by the patient attending consultation or by an alert sent by the pharmaceutical adviser actor of the pharmacist's system to the prescription placer actor of the physician's system.

Finally, this use case also represents the scenario where the substitution of a commercial brand medicine has to be approved by the prescriber.

8.5 Use Case community pharmacy-substitution of medicine

8.5.1 Purpose

The purpose of this use case is to illustrate the substitution of a medicine when a particular brand is not available at the pharmacy.

8.5.2 Story Board

At the pharmacy the particular commercial brand (Ventolin) prescribed by the GP has run out of stock. The pharmacist proposes a substitution (generic medicine with active substance Albuterol) to John Doe who agrees since both medicines have the same active substance (Albuterol). The new dispensed medication is recorded in the "medication dispenser" and the related information is sent to the "dispensed medication repository".

8.5.3 Sequence Diagram

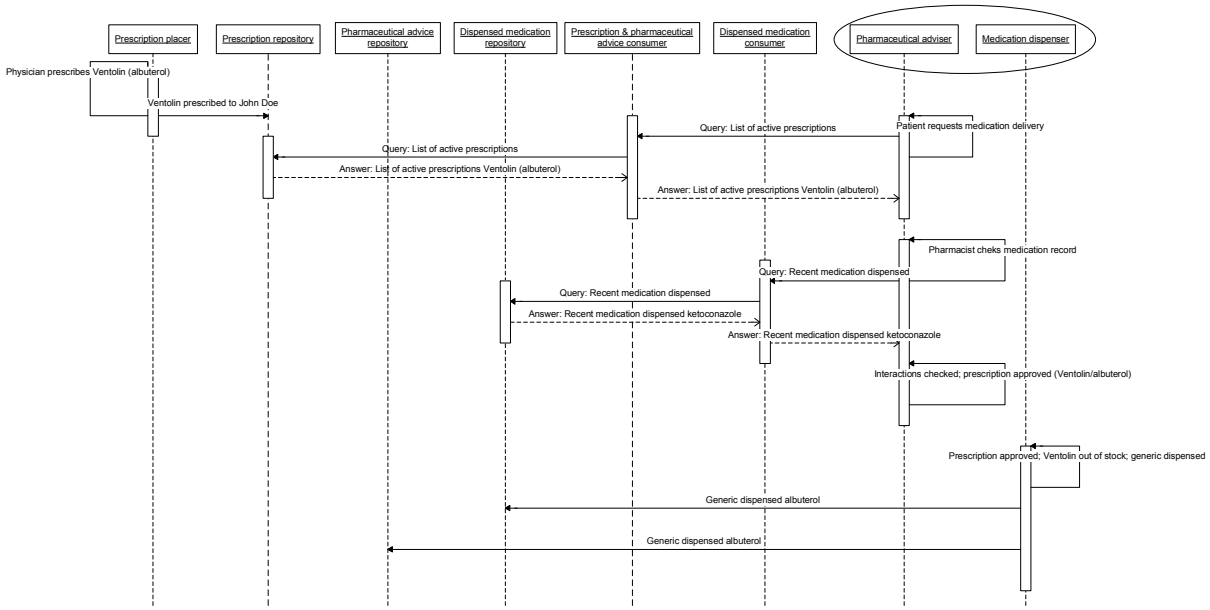


Figure 8.4: Use Case community pharmacy-substitution of medicine

The physician checking the cancellation proposal may be triggered by the patient attending consultation or by an alert sent by the pharmaceutical adviser actor of the pharmacist's system to the prescription placer actor of the physician's system.

Finally, this use case also represents the scenario where the substitution of a commercial brand medicine has to be approved by the prescriber.

8.5 Cas d'utilisation pour la pharmacie de ville – substitution

8.5.1 Purpose

The purpose of this use case is to illustrate the substitution of a medicine when a particular brand is not available at the pharmacy.

8.5.2 Story Board

At the pharmacy the particular commercial brand (Ventolin) prescribed by the GP has run out of stock. The pharmacist proposes a substitution (generic medicine with active substance Albuterol) to John Doe who agrees since both medicines have the same active substance (Albuterol). The new dispensed medication is recorded in the "medication dispenser" and the related information is sent to the "dispensed medication repository".

8.5.3 Sequence Diagram

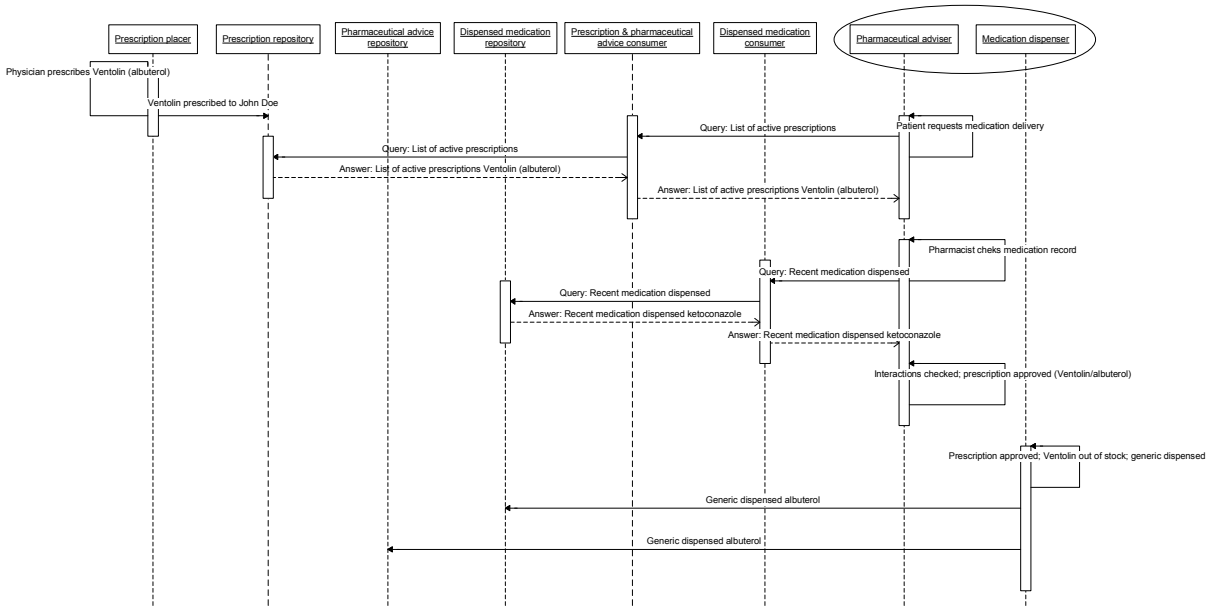


Figure 8.4: Use Case community pharmacy-substitution of medicine

8.6 Use Case Community pharmacy-superseding a prescription

8.6.1 Purpose

The purpose of this use case is to illustrate de process of a specialist (hospital) superseding a repeat prescription made by a general practitioner (community).

8.6.2 Story Board

John Doe attends a consultation to his general practitioner because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance "Fenoterol" as a repeat medication.

Additionally, the GP refers John Doe to a specialist (pneumologist) for a thorough diagnostic. Since the appointment with the specialist will take place in one week's time, John Doe requests the delivery of the medication (Fenoterol) at a pharmacy nearby. As usual, the medication record is checked for interactions and the medicine (Berotec) is given out to John.

One week later, John Doe attends the consultation to the pneumologist who checks for John's medication record (medicines already dispensed such as Fenoterol) and active prescriptions. The exploration conducted by the specialists leads to a precise diagnosis: chronic bronchitis. Therefore, the specialist cancels the prescription done by the GP and prescribes a new active substance: Ipratropium (whose corresponding commercial brand may be Atrovent inhaler). In terms of information systems this cancellation is sent to the prescription repository.

John Doe requests the new medication at a different pharmacy where interactions are checked and the new medicine is dispensed (Atrovent). Since the previous prescription (Fenoterol) was superseded, it cannot be dispensed any more.

8.6 Cas d'utilisation pour la pharmacie de ville – annulation et remplacement d'une prescription

8.6.1 Purpose

The purpose of this use case is to illustrate de process of a specialist (hospital) superseding a repeat prescription made by a general practitioner (community).

8.6.2 Story Board

John Doe attends a consultation to his general practitioner because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance "Fenoterol" as a repeat medication.

Additionally, the GP refers John Doe to a specialist (pneumologist) for a thorough diagnostic. Since the appointment with the specialist will take place in one week's time, John Doe requests the delivery of the medication (Fenoterol) at a pharmacy nearby. As usual, the medication record is checked for interactions and the medicine (Berotec) is given out to John.

One week later, John Doe attends the consultation to the pneumologist who checks for John's medication record (medicines already dispensed such as Fenoterol) and active prescriptions. The exploration conducted by the specialists leads to a precise diagnosis: chronic bronchitis. Therefore, the specialist cancels the prescription done by the GP and prescribes a new active substance: Ipratropium (whose corresponding commercial brand may be Atrovent inhaler). In terms of information systems this cancellation is sent to the prescription repository.

John Doe requests the new medication at a different pharmacy where interactions are checked and the new medicine is dispensed (Atrovent). Since the previous prescription (Fenoterol) was superseded, it cannot be dispensed any more.

8.6.3 Sequence Diagram

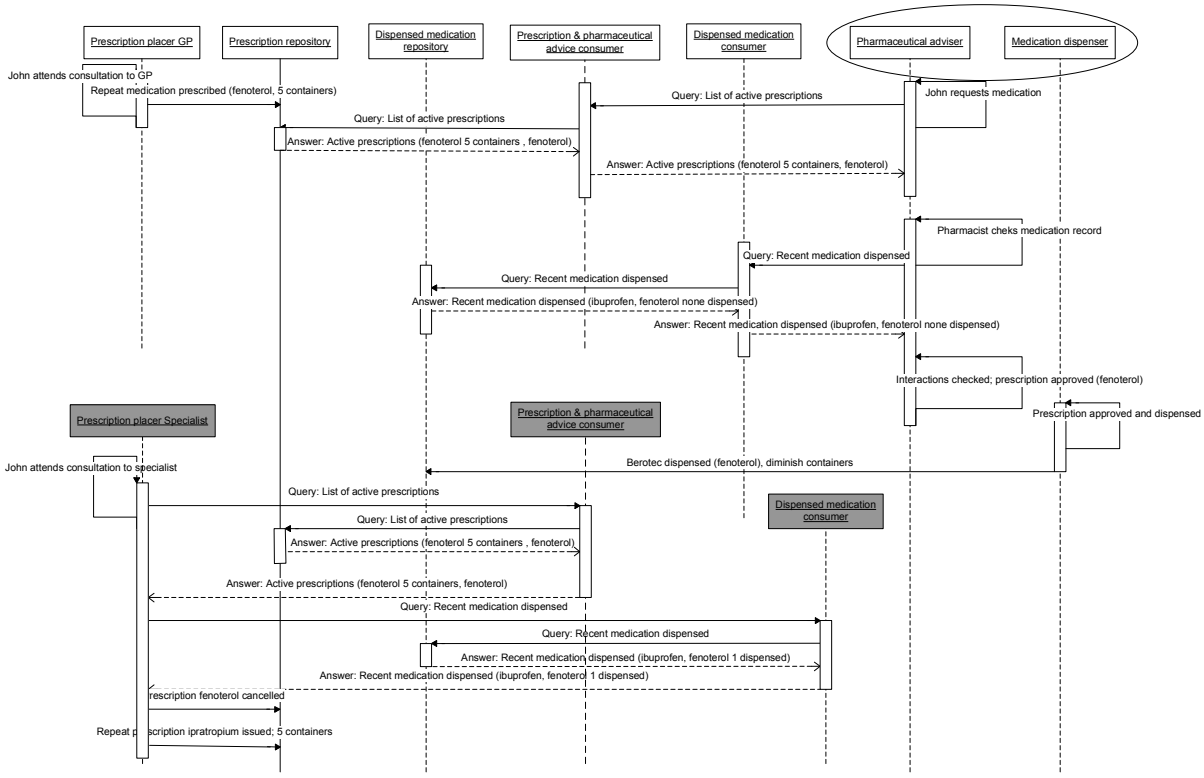


Figure 8.5: Use Case Community pharmacy-superseding a prescription

This diagram illustrates the process from the initial prescription, medication dispensed and new prescription issued superseding the initial one. Since two prescribers intervene in this process, a GP and a specialist, two instances of the prescription placer are depicted. The same applies to the prescription &pharmaceutical advice consumer and dispensed medication consumer. This example also illustrates how the prescriber learns the number of refills left, by comparing the initial prescription with the medication already dispensed of that particular prescription; in order to achieve this, it queries the prescription repository and the dispensed medication repository.

From this point on, the process follows the common path already described in previous use cases.

8.7 Use Case community pharmacy-active substance, direct push

8.7.1 Purpose

The purpose of this use case is to illustrate the prescription-dispense process in community pharmacy when the prescriber orders an active-substance (generic) medicine in the direct push model.

8.6.3 Sequence Diagram

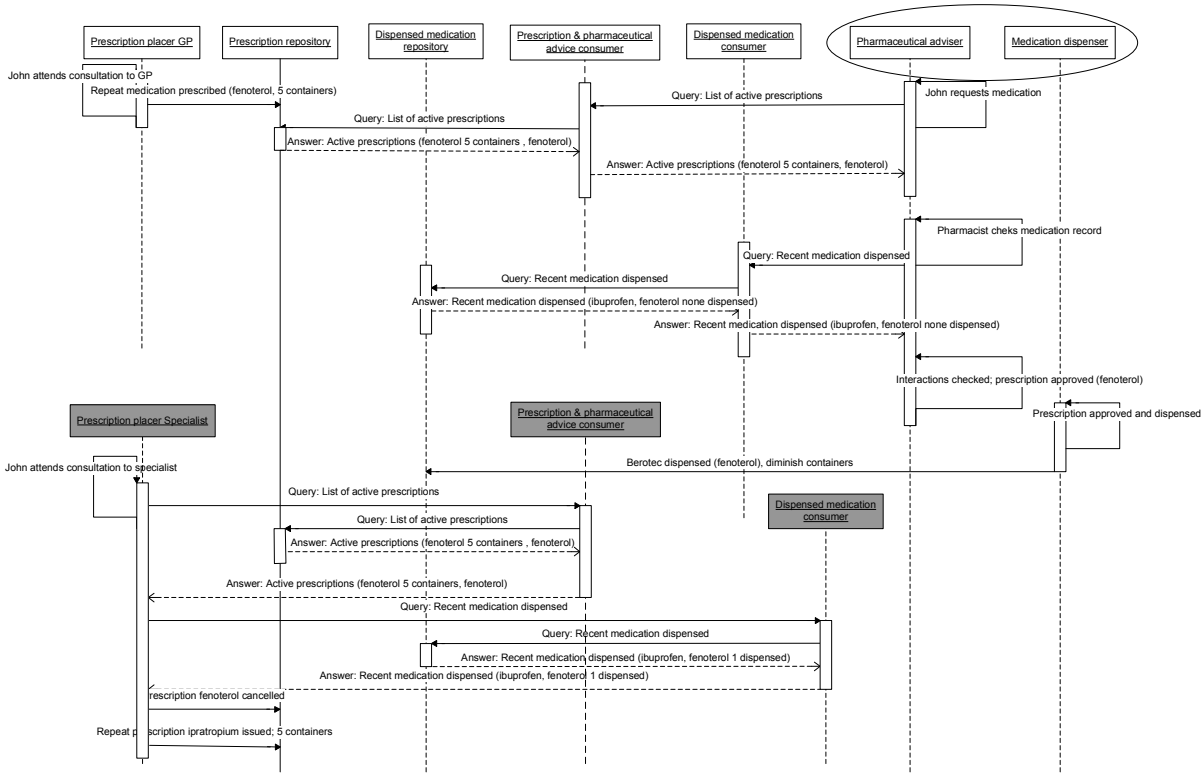


Figure 8.5: Use Case Community pharmacy-superseding a prescription

This diagram illustrates the process from the initial prescription, medication dispensed and new prescription issued superseding the initial one. Since two prescribers intervene in this process, a GP and a specialist, two instances of the prescription placer are depicted. The same applies to the prescription &pharmaceutical advice consumer and dispensed medication consumer. This example also illustrates how the prescriber learns the number of refills left, by comparing the initial prescription with the medication already dispensed of that particular prescription; in order to achieve this, it queries the prescription repository and the dispensed medication repository.

From this point on, the process follows the common path already described in previous use cases.

8.7 Cas d'utilisation pour la pharmacie de ville – substance active, transmission directe

8.7.1 Purpose

The purpose of this use case is to illustrate the prescription-dispense process in community pharmacy when the prescriber orders an active-substance (generic) medicine in the direct push model.

8.7.2 Story Board

John Doe attends a consultation to his general practitioner, GP, because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance "Fenoterol" in his "prescription placer" software. The GP asks John for his preferred pharmacy which is the one closest to his house, Farmaxia. John indicates this to the GP who electronically sends the prescription to the pharmacy.
At the pharmacy, John authenticates himself by means of this health or ID card; the pharmacist gets the prescription from the "medication dispenser" embedded in his pharmacy's software and gives out Berotec (which besides having the active substance also fits in the price range agreed with the health system) to John. The transaction is recorded in the "medication dispenser" and electronically sent to the "dispensed medication repository" and "prescription placer" for the GP to be updated on the medication actually dispensed to John Doe.

A possible implementation of this use case may use the health card as the means to convey the prescription to the pharmacy.

The following diagram portrays the exchange of data between in this case.

8.7.3 Sequence Diagram

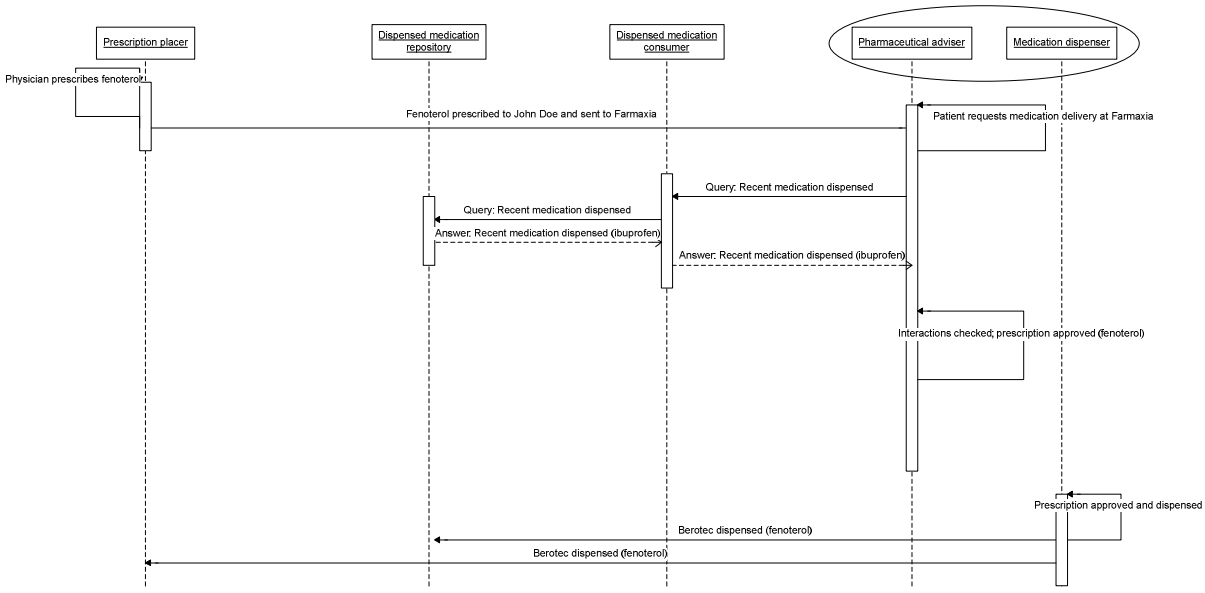


Figure 8.6: Use Case community pharmacy-active substance, direct push

8.7.2 Story Board

John Doe attends a consultation to his general practitioner, GP, because he is experiencing some breathing difficulty. The practitioner examines John and prescribes the active substance "Fenoterol" in his "prescription placer" software. The GP asks John for his preferred pharmacy which is the one closest to his house, Farmaxia. John indicates this to the GP who electronically sends the prescription to the pharmacy.
At the pharmacy, John authenticates himself by means of this health or ID card; the pharmacist gets the prescription from the "medication dispenser" embedded in his pharmacy's software and gives out Berotec (which besides having the active substance also fits in the price range agreed with the health system) to John. The transaction is recorded in the "medication dispenser" and electronically sent to the "dispensed medication repository" and "prescription placer" for the GP to be updated on the medication actually dispensed to John Doe.

A possible implementation of this use case may use the health card as the means to convey the prescription to the pharmacy.

The following diagram portrays the exchange of data between in this case.

8.7.3 Sequence Diagram

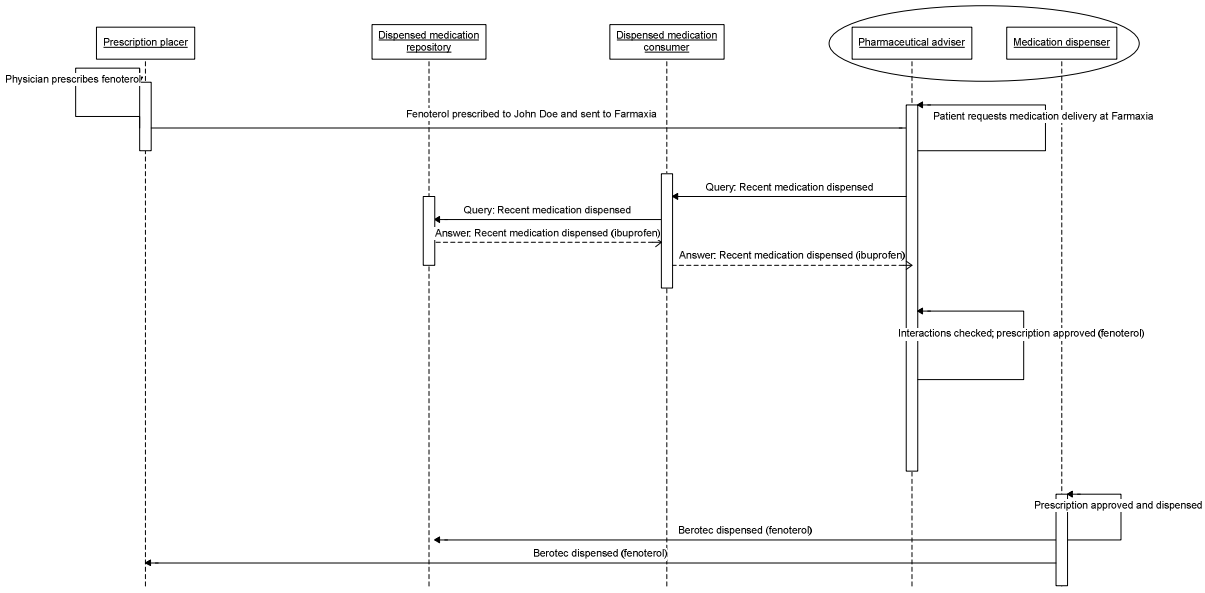


Figure 8.6: Use Case community pharmacy-active substance, direct push

8.8 Use Case community pharmacy-cancellation proposal, direct push

8.8.1 Purpose

The purpose of this use case is to illustrate the prescription-dispense process in the direct push model when the prescriber orders a medicine which interacts with a recently dispensed medicine and the pharmacist proposes a cancellation.

8.8.2 Story Board

At the pharmacy, the pharmacist checks for interactions and notices that the patient has been given recently Ketoconazole which may increase the level of Fenoterol in blood. The pharmacist considers this potentially harmful to the patient and decides to propose a cancellation of the prescription to the GP. Therefore, the medicine Fenoterol is not dispensed to the patient and the pharmacist's proposal is recorded in the "pharmaceutical adviser".
This cancellation proposal is sent electronically to the "prescription placer" and the patient is advised to consult his GP in order to address this issue. The following day, John Doe attends a consultation to his GP who checks the "prescription placer" and reads the cancellation proposal sent by the pharmacist. The GP may accept the cancellation proposal and prescribe another medicine or confirm the original prescription provided that the benefits surpass the potential harm.

Sequence Diagram

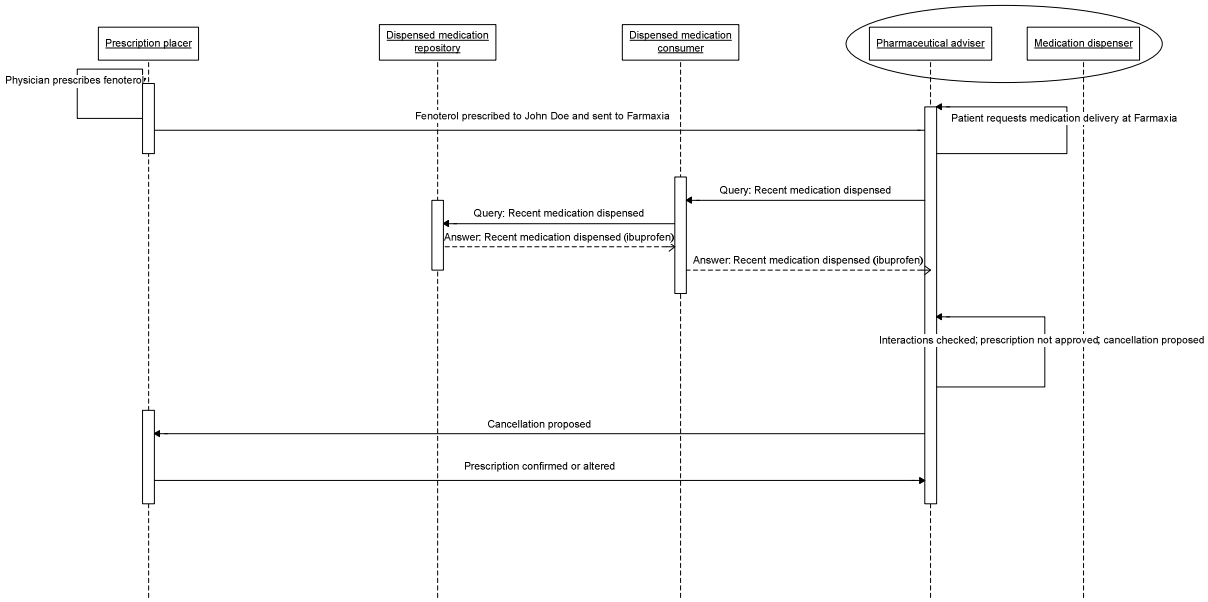


Figure 8.7: Use Case community pharmacy-cancellation proposal, direct push

The previous diagram depicts the process until the prescription is confirmed or amended by the prescriber. From this point on, the process is similar to the regular dispensing one detailed in the precedent use case.

8.8 Cas d'utilisation pour la pharmacie de ville – annulation recommandée, transmission directe

8.8.1 Purpose

The purpose of this use case is to illustrate the prescription-dispense process in the direct push model when the prescriber orders a medicine which interacts with a recently dispensed medicine and the pharmacist proposes a cancellation.

8.8.2 Story Board

At the pharmacy, the pharmacist checks for interactions and notices that the patient has been given recently Ketoconazole which may increase the level of Fenoterol in blood. The pharmacist considers this potentially harmful to the patient and decides to propose a cancellation of the prescription to the GP. Therefore, the medicine Fenoterol is not dispensed to the patient and the pharmacist's proposal is recorded in the "pharmaceutical adviser".
This cancellation proposal is sent electronically to the "prescription placer" and the patient is advised to consult his GP in order to address this issue. The following day, John Doe attends a consultation to his GP who checks the "prescription placer" and reads the cancellation proposal sent by the pharmacist. The GP may accept the cancellation proposal and prescribe another medicine or confirm the original prescription provided that the benefits surpass the potential harm.

Sequence Diagram

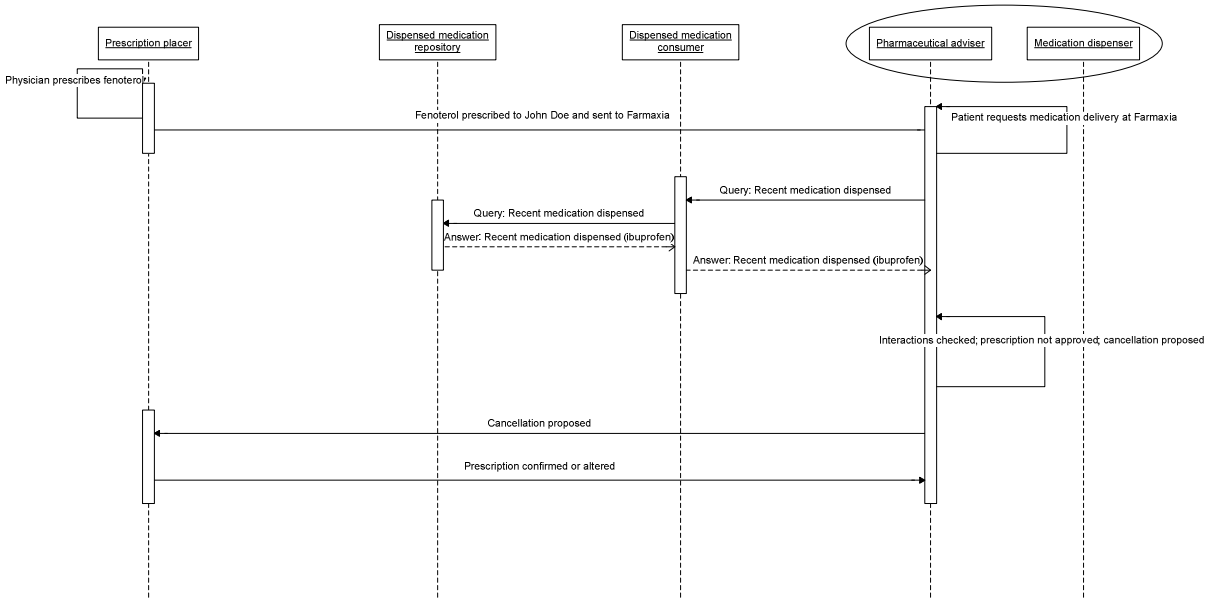


Figure 8.7: Use Case community pharmacy-cancellation proposal, direct push

The previous diagram depicts the process until the prescription is confirmed or amended by the prescriber. From this point on, the process is similar to the regular dispensing one detailed in the precedent use case.

9 Use Cases for Hospital Pharmacy

9.1 Flow Chart

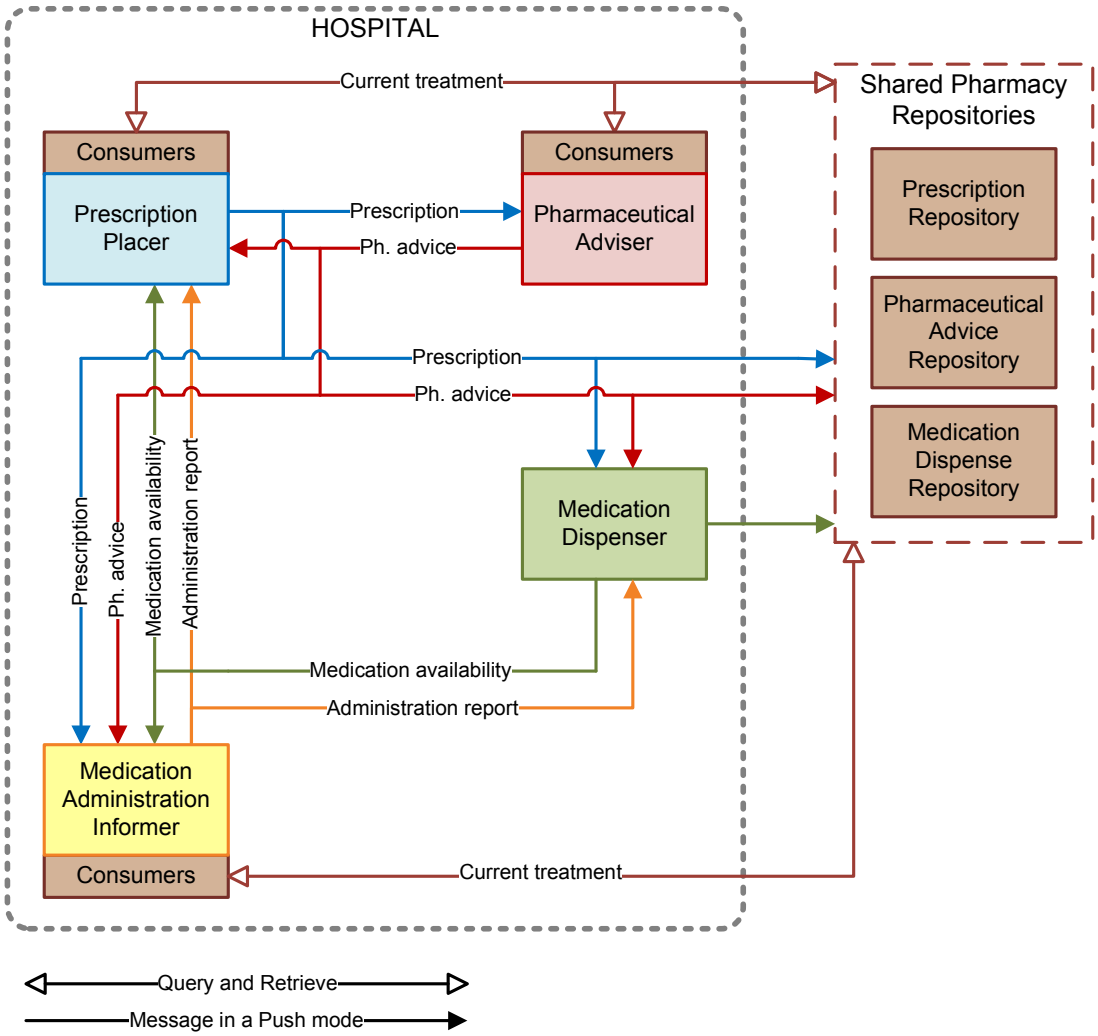


Figure 9.1: Flow Chart Hospital Pharmacy

“Consumers” = Prescription & Pharmaceutical Advice Consumer + Medication Dispense Consumer, both integrated with a Hospital Pharmacy Actor.

Some flows are optional, depending on the use cases. In many circumstances, the Prescription Repository does not have to be updated by the Hospital Pharmacy.

9 Cas d'utilisation pour la pharmacie hospitalière

9.1 Diagramme de flux

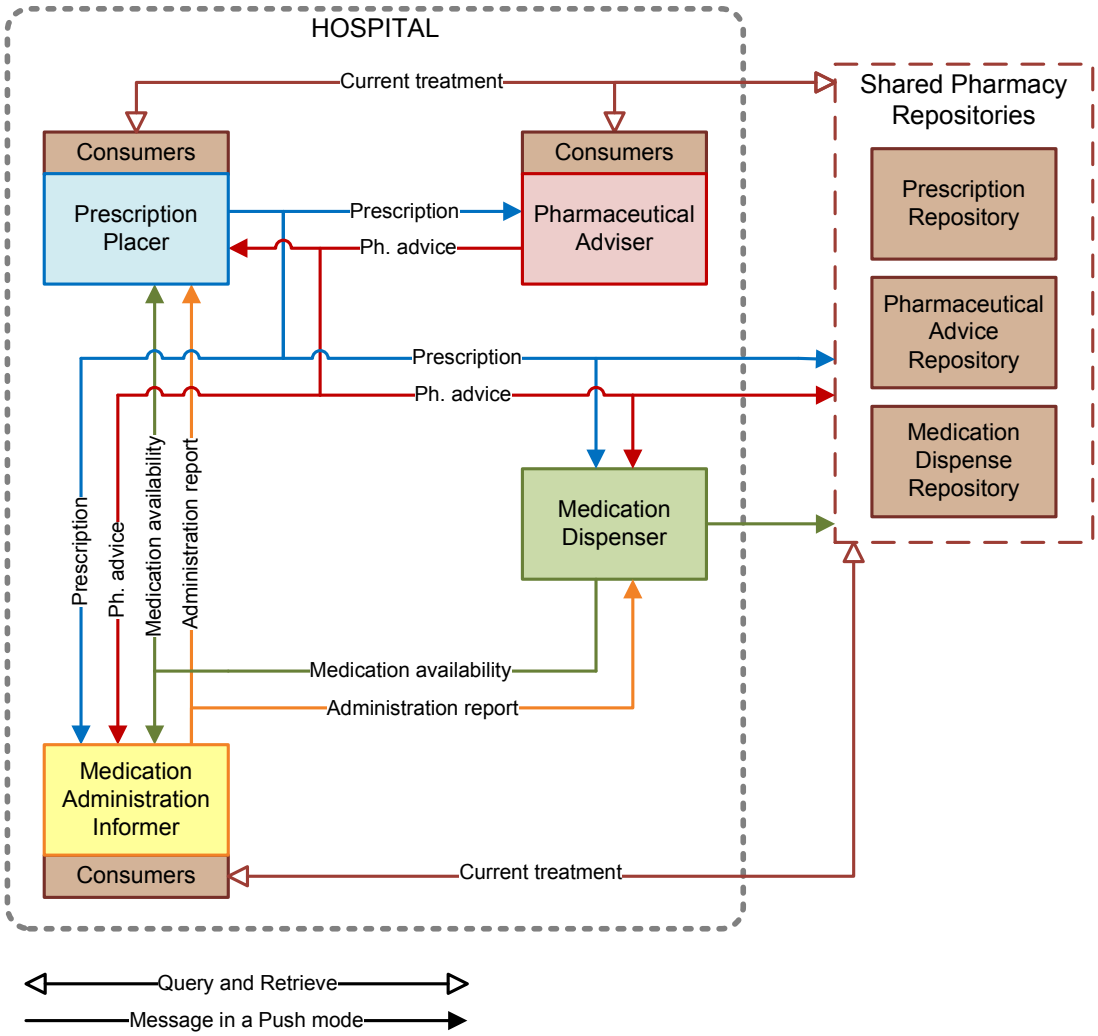


Figure 9.1 : Diagramme de flux de la pharmacie hospitalière

« Consumers » = Prescription & Pharmaceutical Advice Consumer + Medication Dispense Consumer, tous les deux intégrés avec un acteur de la pharmacie hospitalière.

Certains flux sont optionnels, cela dépend des cas d'utilisation. Dans de nombreuses circonstances, il n'y a pas lieu que le Prescription Repository soit mis à jour par la pharmacie hospitalière.

9.2 Use Case hospital pharmacy - inpatient, basic scenario

9.2.1 Storyboard

Adam Everyman was admitted to Good Health Hospital. Dr. Hippocrates, after having reviewed current treatment, prescribes Doliprane 1000 mg tablets, 1 orally three times a day for the duration of the inpatient admission. Susie Supply, a hospital pharmacist, reviews the medication order, the current treatment, and local pharmacotherapy guidelines as well as the appropriateness of the medicine, form, strength, route and dose. She authorizes the dispensing of this medication. The order is then scheduled for administration. Florence Nightingale, a nurse, does the drug administration round next morning and checks the physician's order, electronic signature and the patient's identity. She opens the appropriate container, visually checks the medication, scans its barcode and administers it to Adam Everyman. Shared information about Adam Everyman's current treatment does not have to be updated.

There are use cases which are more or less similar, but with different medications, where shared information about patient's current treatment would have to be updated. Example: chemotherapy.

9.2 Cas d'utilisation pour la pharmacie hospitalière – patient hospitalisé, scenario de base

9.2.1 Scénario

Adam Everyman a été admis à l'hôpital Good Health. Le Dr Hippocrates, après avoir pris connaissance du traitement en cours, prescrit du Doliprane en comprimés de 1000 mg. Susie Supply, une pharmacienne de l'hôpital, vérifie la prescription et le traitement en cours en prenant en compte les règles locales concernant le bon usage des médicaments. Elle vérifie aussi le caractère approprié de la spécialité pharmaceutique, de la forme, de la force, de la voie d'administration et de la posologie. Elle autorise la délivrance de ce médicament. La demande fait ensuite l'objet d'un plan d'administration. Florence Nightingale, une infirmière, procède à l'administration le lendemain matin : elle vérifie la prescription du médecin, la signature électronique et l'identité du patient. Elle ouvre la boîte qui convient, vérifie visuellement le médicament, douche son code-barre avant de l'administrer au patient. Il n'y a pas lieu de mettre à jour les informations partagées [entre la ville et l'hôpital] concernant le traitement médicamenteux d'Adam Evreyman.

Il y a des cas d'utilisation plus ou moins similaires, mais, avec des médicaments différents, où l'information partagée concernant le traitement du patient doit être mise à jour. Exemple : la chimiothérapie.

9.2.2 Sequence Diagram

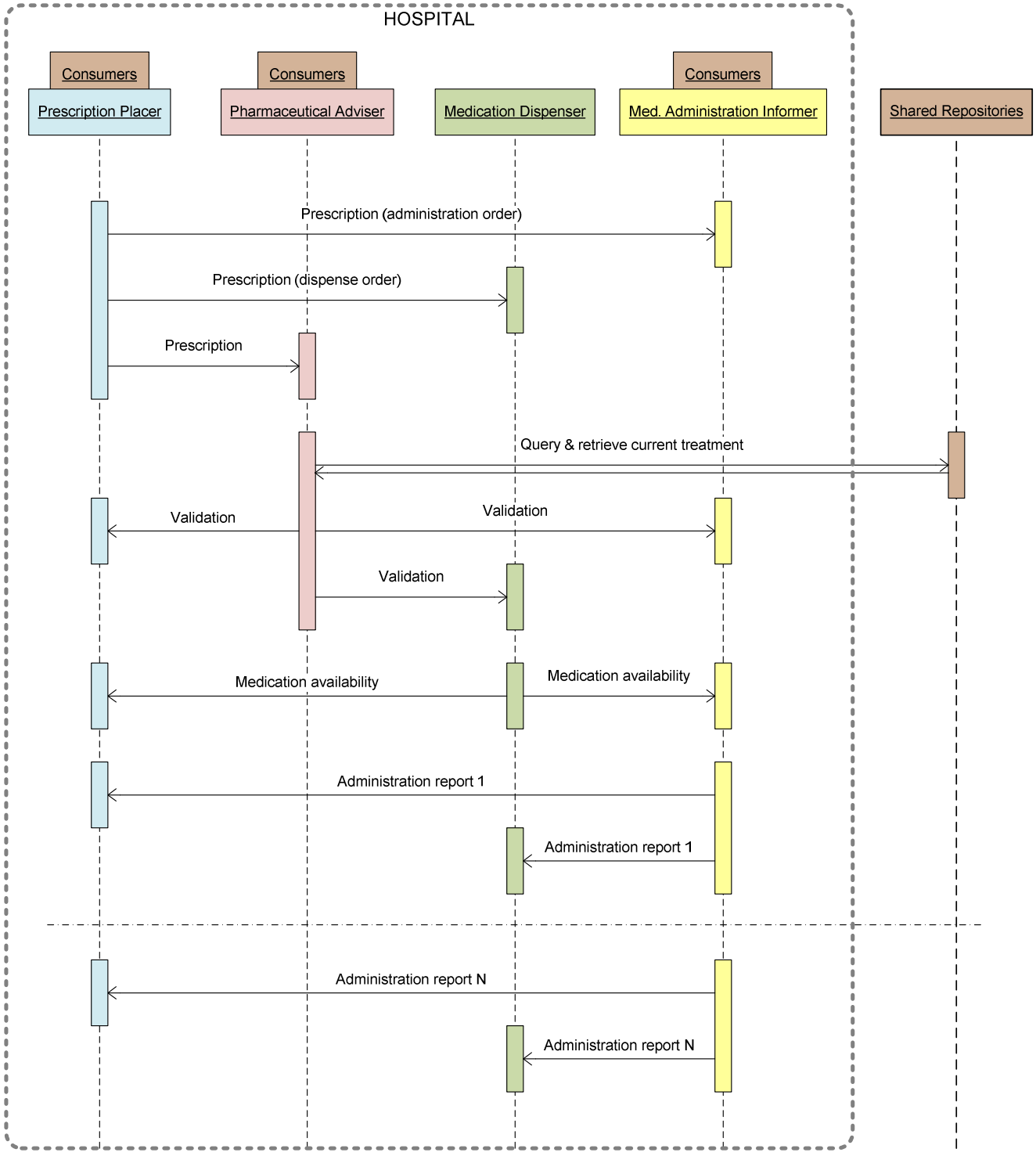


Figure 9.2: Use Case hospital pharmacy - inpatient, basic scenario

9.2.2 Diagramme de séquence

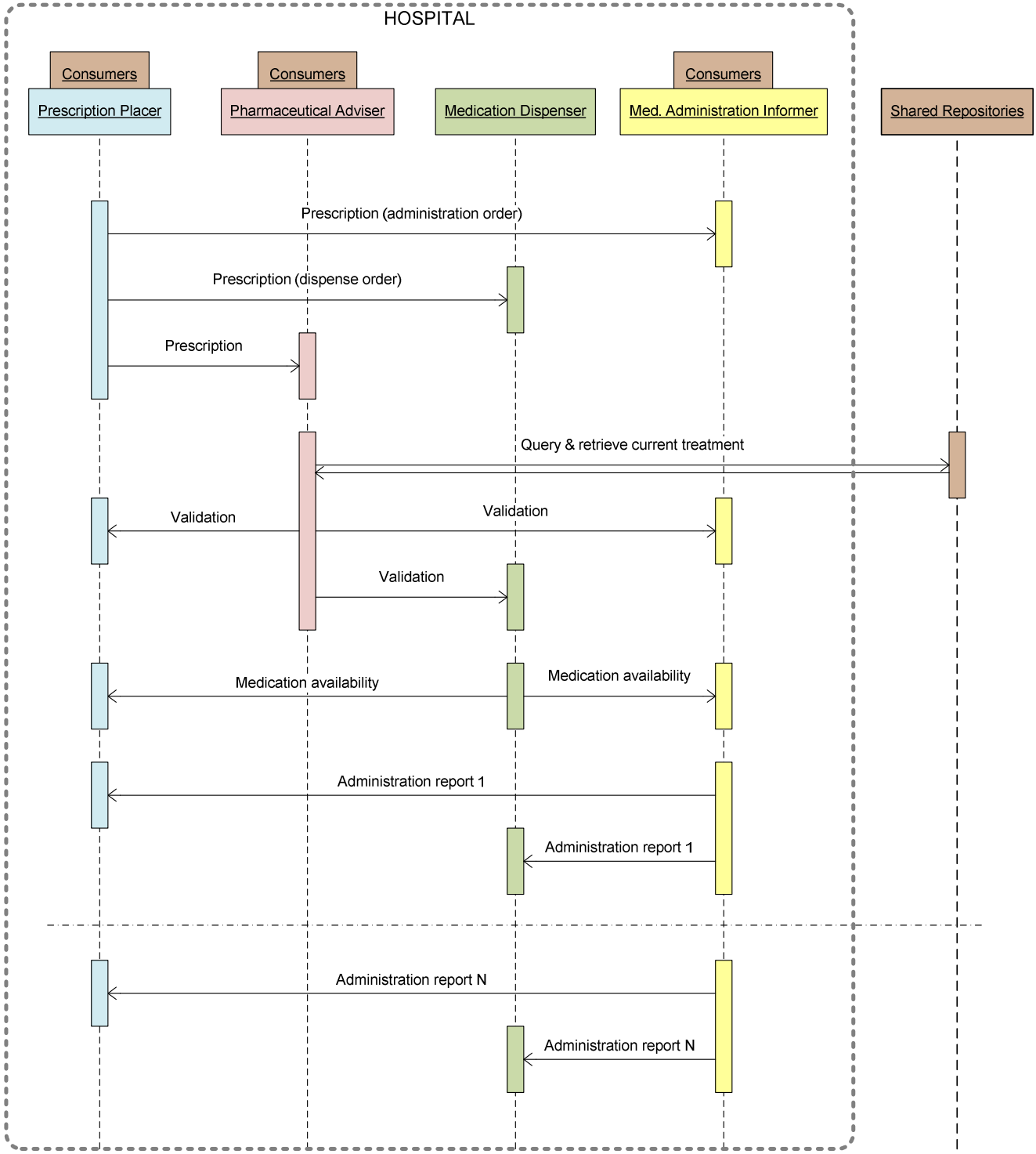


Figure 9.2 : Cas d'utilisation pour la pharmacie hospitalière – patient hospitalisé, scenario de base

The sequence diagram begins when the prescription is ready to send. The Query and Retrieve which was necessary for the prescriber to review the current treatment, is not represented.

The drug prescription has two purposes at the same time, namely:

- It is the order to administer for the care unit and/or;
- An order to the pharmacy to make a supply.

Both messages could be the same. But in some cases, each could contain complementary information, specifically intended for the care unit and/or for the pharmacy.

In real life, many circumstances may lead to situations where the set of administration reports will not conform exactly to the scheduled administration plan.

9.3 Use Case hospital pharmacy – inpatient, unexpected administration events

9.3.2 Storyboard

This use case is the same as use case #1, except that:

- The second day, Adam Everyman, the patient, has to be fasting for a hepatic (ultrasound) scan. Florence Nightingale, the nurse, does not administer the medication to the patient.
- The third day, there are no more 1g tablets left on the ward for administration.
- Florence Nightingale, the nurse, therefore substitutes the 1g tablet for two 500 mg single dose packets in lieu of the resupply of 1g tablets being available.

The sequence diagram is the same as for use case #1.

Among 9 administration reports, two of them will therefore contain more specific information:

- The second day, one of the reports points out the medicine has not been administered and explains why.
- The third day, one of the reports indicates that the 1g tablet has been replaced by two 500 mg single dose packets.

Le diagramme de séquence commence quand la prescription est prête à envoyer. Le « Query and Retrieve » qui a permis au prescripteur de prendre connaissance du traitement courant, n'est pas représenté.

La prescription de médicaments sert à deux choses à la fois, plus précisément :

- C'est la demande d'administrer adressée à l'unité de soins;
- C'est la demande de mettre à disposition adressée à la pharmacie.

Les deux messages peuvent être identiques. Mais dans certains cas, l'un ou l'autre peuvent contenir des informations complémentaires destinées soit à l'unité de soins soit à la pharmacie.

Sur le terrain, il survient souvent des circonstances qui conduisent à des situations où la liste des comptes-rendus d'administration ne va pas correspondre exactement au plan d'administration initialement prévu.

9.3 Cas d'utilisation pour la pharmacie hospitalière – patient hospitalisé, circonstances imprévues lors de l'administration

9.3.2 Scénario

Ce cas d'utilisation est le même que le cas d'utilisation N° 1, sauf que :

- Le deuxième jour, Adam Everyman, le patient, doit être à jeun pour une échographie hépatique. Florence Nightingale, l'infirmière, n'administre pas le médicament au patient.
- Le troisième jour, il n'y a plus de comprimés de 1g dans le service au moment de l'administration.
- En conséquence, Florence Nightingale, l'infirmière, remplace le comprimé de 1g par deux sachets de 500 mg, sans attendre le réapprovisionnement en comprimés de 1g.

Le diagramme de séquence est le même que pour le cas d'utilisation N° 1.

Parmi les 9 comptes-rendus d'administration, deux vont par conséquent contenir des informations spécifiques :

- Le deuxième jour, un des comptes-rendus rapporte que le médicament n'a pas été administré, et explique pourquoi.
- Le troisième jour, un des comptes-rendus indique que le comprimé de 1g a été remplacé par deux sachets de 500 mg.

9.4 Use Case hospital pharmacy - inpatient, simple case of substitution

9.4.1 Storyboard

This use case is the same as use case #1, except that:

- Susie Supply, the hospital pharmacist, decides that Doliprane 1000 mg, effervescent tablet, will be substituted by Efferalgan 1 g, effervescent tablet.

9.4.2 Sequence Diagram

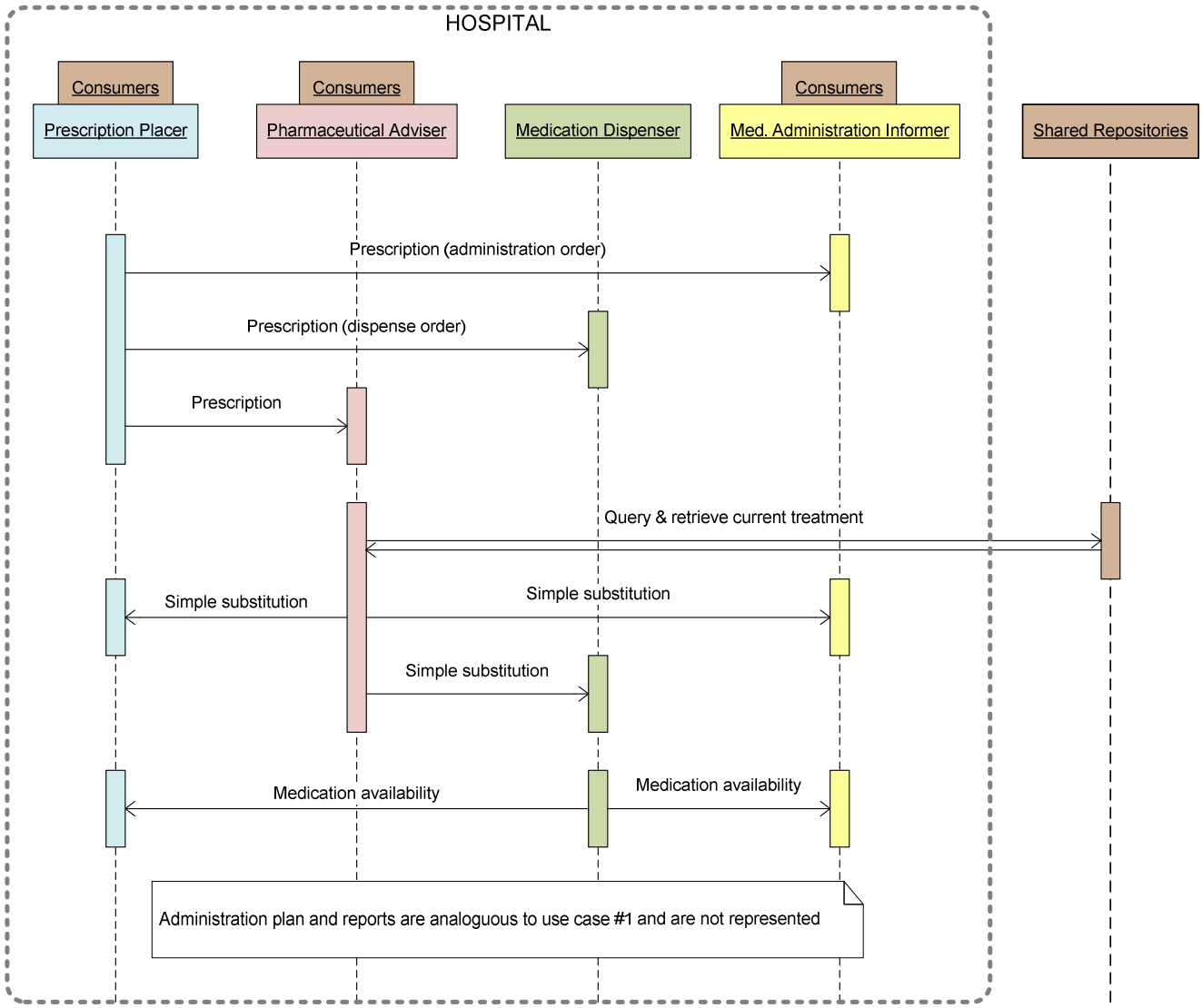


Figure 9.3: Use Case hospital pharmacy – inpatient, unexpected administration events

9.4 Cas d'utilisation pour la pharmacie hospitalière – patient hospitalisé, substitution simple

9.4.1 Scénario

Ce cas d'utilisation est le même que le cas d'utilisation N° 1, sauf que :

- Susie Supply, la pharmacienne, décide de substituer au Doliprane 1000 mg, en comprimés effervescents, de l'Efferalgan 1 g, en comprimés effervescents.

9.4.2 Diagramme de séquence

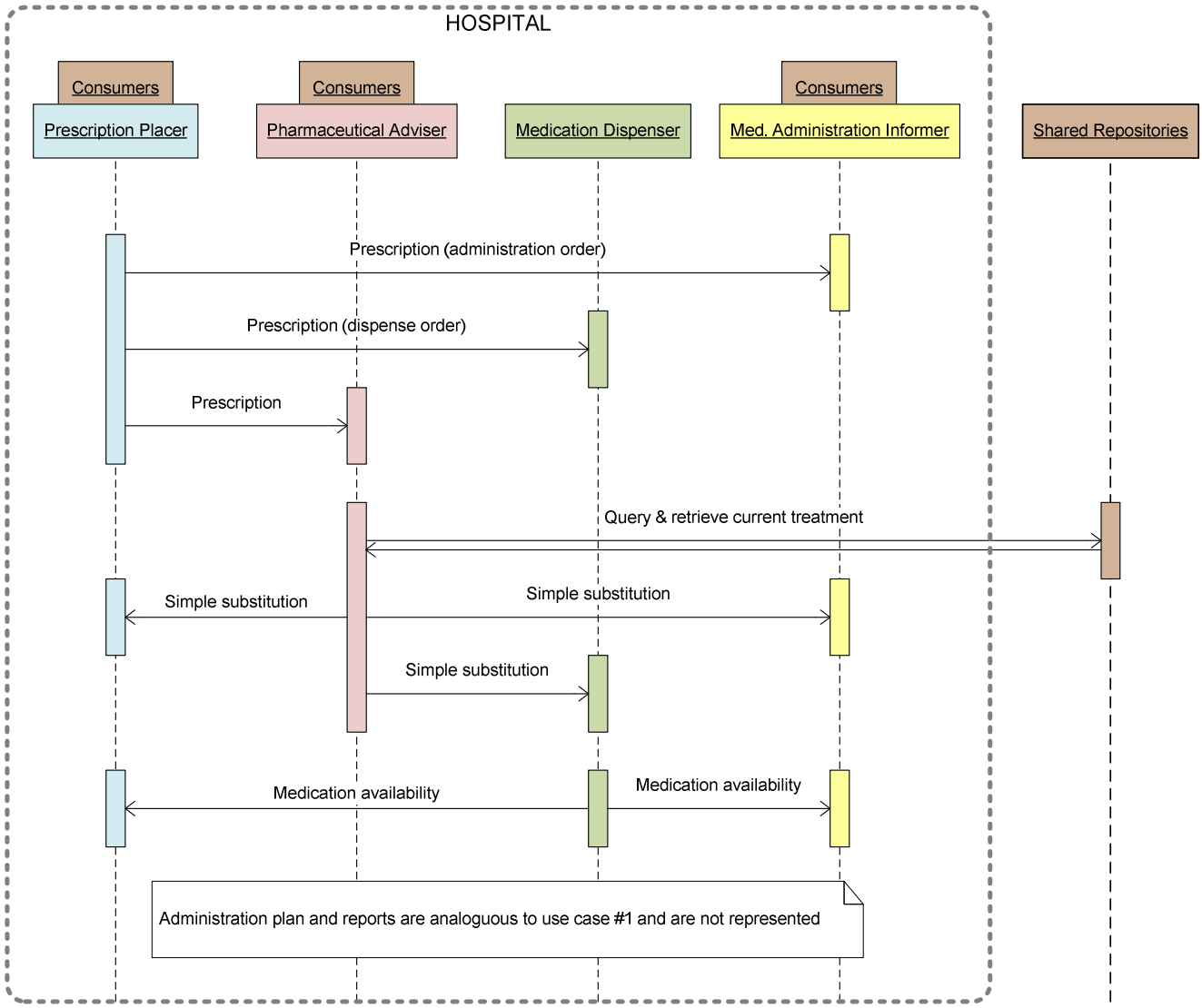


Figure 9.3 : Cas d'utilisation pour la pharmacie hospitalière – patient hospitalisé, substitution simple

A simple substitution rule repository is defined at the hospital level to support situations as described above i.e. where appropriate alternatives may be administered to patients without the intervention of a prescriber or pharmacist being required per dose. This repository is implemented by the Pharmaceutical Adviser actor (software or human user). This process allows for the identification of any situation which results in a "simple substitution" interaction with the concerned actors. No explicit back-validation is required from the Prescription Placer, the physician agreeing in principle to the rule applied by the pharmacist.

A simple substitution remains a type of validation. The hospital pharmacist is supposed to check the current treatment.

Note #1: Any complex substitution proposed by a pharmacist proposal will need validation by the Prescription Placer actor. Complex substitution will be addressed in a specific use case, which is not in the scope of this proposal.

Note #2: This simple substitution should not be confused with an INN (International Nonproprietary Names) or an active substance prescription. Active substance prescription is addressed in the next use case.

Un référentiel de règles de substitution simple est défini au niveau de l'hôpital. Il supporte les situations telles que celle décrite ci-dessus, où il existe des médicaments équivalents qui peuvent être administrés au patient sans que cela nécessite à chaque fois une intervention du prescripteur ou du pharmacien. Ce référentiel est implémenté par l'acteur Pharmaceutical Adviser (automatisme ou utilisateur humain). Ce processus permet d'identifier toute situation qui doit induire une interaction « substitution simple » avec les acteurs concernés. Il n'est pas attendu, en retour, une validation explicite par l'acteur Prescription Placer, le médecin acceptant a priori la règle appliquée par le pharmacien.

Une substitution simple reste une forme de validation. Le pharmacien hospitalier est censé vérifier le traitement courant.

Remarque 1 : Toute substitution complexe proposée par le pharmacien impliquera une validation explicite par l’acteur Prescription Placer. La substitution complexe sera traitée dans un cas d’utilisation spécifique, qui n’est pas dans la couverture fonctionnelle de ce livre blanc.

Remarque 2 : La substitution simple ne doit pas être confondue avec la prescription en DCI (Dénomination Commune Internationale), ni avec une prescription en substance active. La prescription en substance active est traitée dans le cas d’utilisation qui suit.

9.5 Use Case hospital pharmacy - inpatient, active substance prescription

9.5.1 Storyboard

This use case is the same as use case #1, except that:

- Dr. Hippocrates prescribed Paracetamol, which is the active substance of either Doliprane or Efferalgan, without specifying the form.
- Susie Supply, the hospital pharmacist, chooses Doliprane 1000 mg, effervescent tablet, to fulfill the active substance prescription.

9.5.2 Sequence Diagram

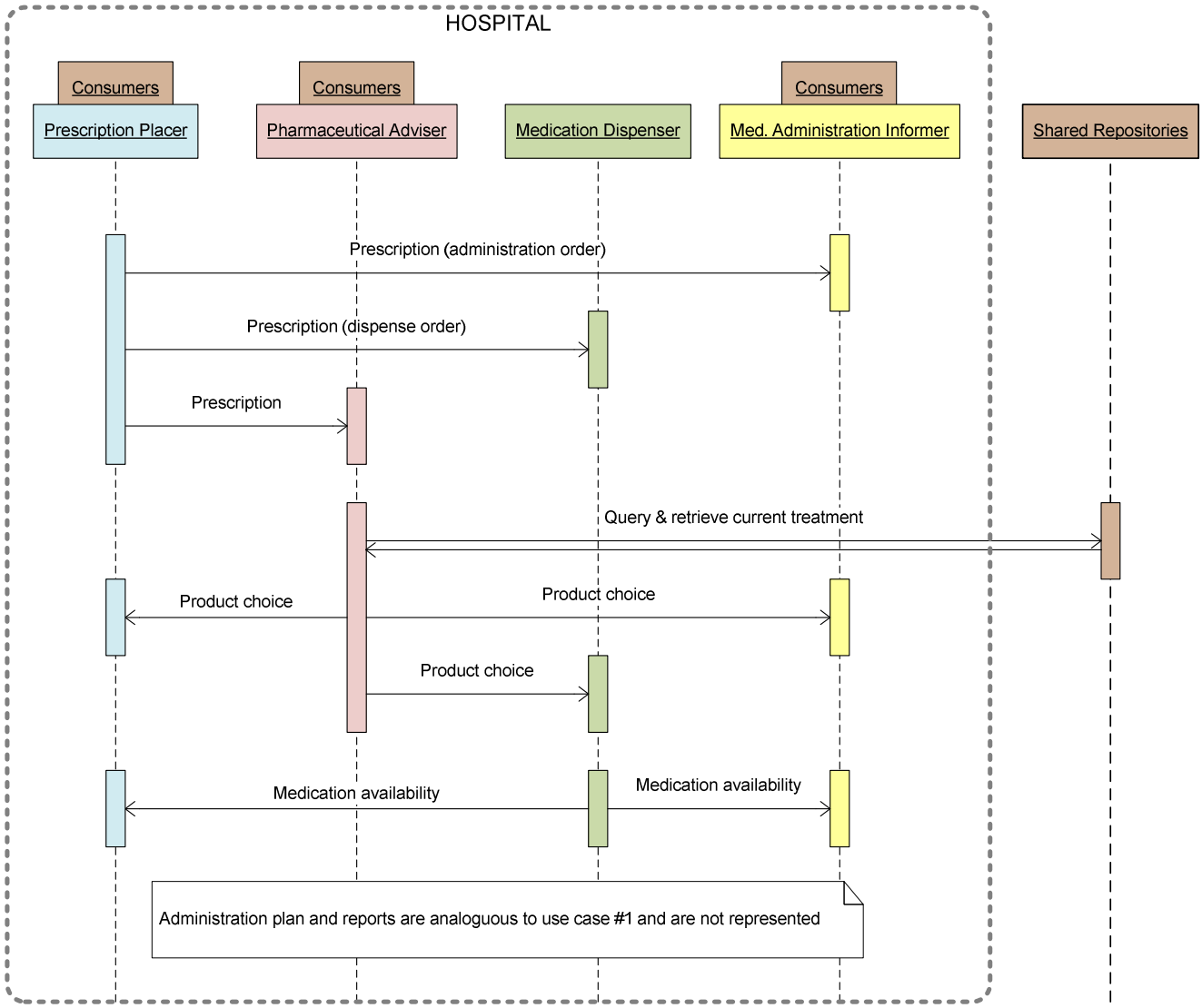


Figure 9.4: Use Case hospital pharmacy - inpatient, active substance prescription

9.5 Cas d'utilisation pour la pharmacie hospitalière – patient hospitalisé, prescription en substance active

9.5.1 Scénario

Ce cas d'utilisation est le même que le cas d'utilisation N° 1, sauf que :

- Le Dr Hippocrates avait prescrit du Paracetamol, qui est la substance active à la fois du Doliprane et de l'Efferalgan, et n'avait pas précisé la forme.
- Susie Supply, la pharmacienne de l'hôpital, choisit le Doliprane 1000 en comprimés effervescents de 1000 mg, pour satisfaire la prescription en substance active.

9.5.2 Sequence Diagram

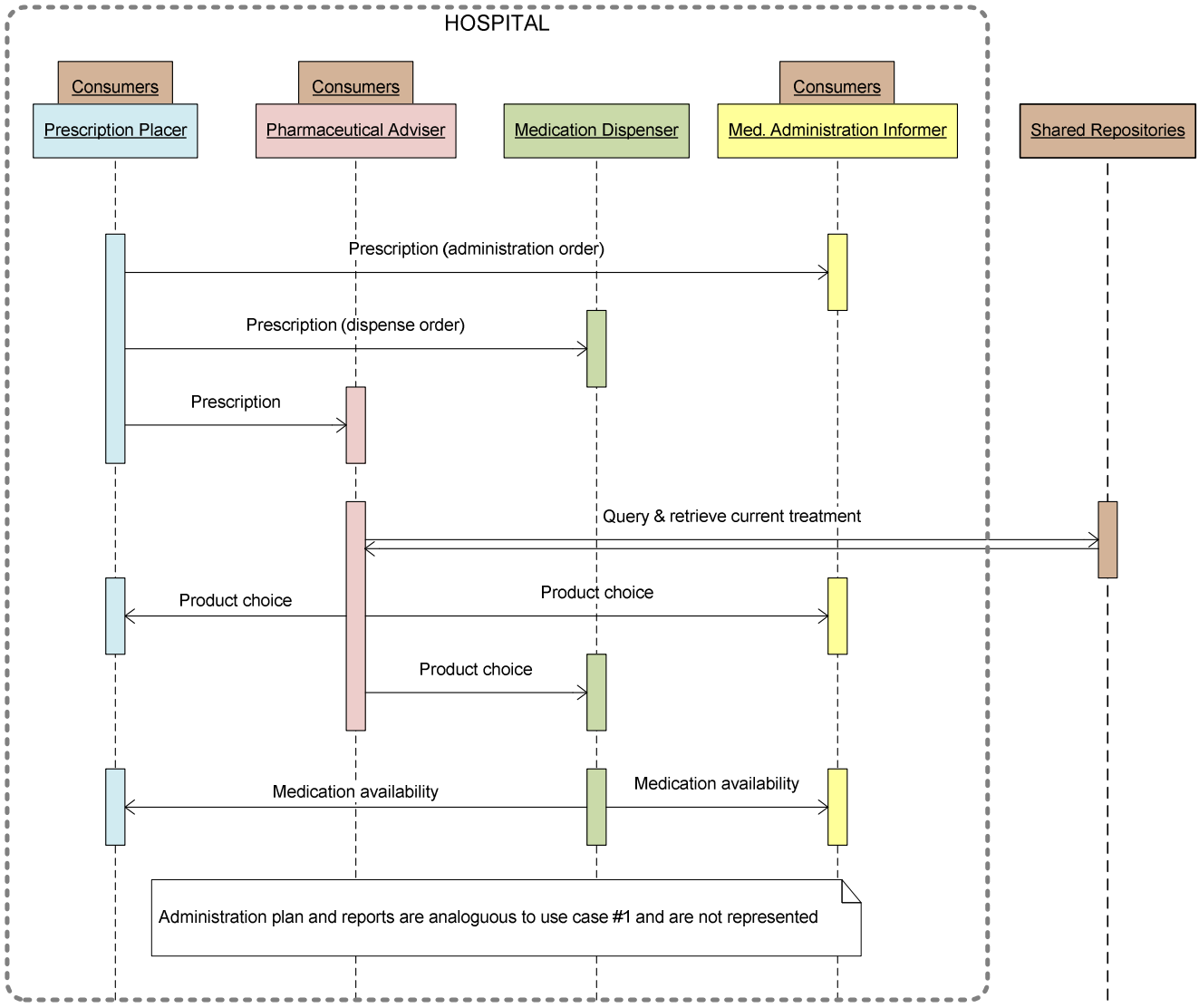


Figure 9.4 : Cas d'utilisation pour la pharmacie hospitalière – patient hospitalisé, prescription en substance active

The relationship between medicinal, branded products to active substances is defined at a national level. A simple repository is available or accessible at the hospital level. This repository is implemented by the Pharmaceutical Adviser actor (software or human user). No explicit back-validation is awaited from the Prescription Placer, the physician agreeing in principle to the relationships defined/applied by the pharmacist.

The choice of a product for fulfilling an active substance prescription remains a kind of validation. The hospital pharmacist is supposed to check the current treatment.

Les relations entre les spécialités pharmaceutiques et les substances actives sont définies à un niveau national. Un référentiel est disponible ou accessible au niveau de l’hôpital. Ce référentiel est implémenté par l'acteur Pharmaceutical Adviser (automatisme ou utilisateur humain). Il n'est pas attendu, en retour, une validation explicite par l'acteur Prescription Placer, le médecin acceptant a priori les relations définies et/ou appliquées par le pharmacien.

Le choix d’un produit pour satisfaire une prescription en substance active reste une forme de validation. Le pharmacien hospitalier est censé vérifier le traitement courant.

10 Pan Hospital/Community Pharmacy Use Cases

These Use Cases focus on the interactions between hospital and community in order to create a Continuity of Treatment context.

10.1 Admission-Discharge with Continuity of Treatment

10.1.1 Purpose

This use case illustrates an organization that ensures continuity of current medications between the community space and the hospital space, as is often the case with hospitals in United Kingdom.

10.1.2 Storyboard

A patient is to be admitted at hospital, coming from home. His initial inpatient prescription remains identical to the medicines that he has been taking at home.

His prescription is written up (1) and the medicines that he has brought in with him assessed by a pharmacy technician to confirm that they are appropriate to be used during his stay (2). A pharmacist verifies that the medicines are appropriate for the patient and annotates the prescription to identify that the check has occurred.

Of the four medicines that he has been taking three have sufficient supply and can be used. He does not have sufficient of his fourth medicine which the pharmacy technician re-dispenses from pharmacy. The pharmacy supplies a one month pack of medicines labeled ready for him to take home (3). All of his medicines are stored in a locked box at the side of his bed and used during his stay.

Two days later a new medicine is prescribed late at night (4). The ward staff uses a ward stock box of the medicine to administer the first three doses (5) until an original pack of medicines labeled for the patient (including discharge instructions) is supplied by pharmacy (6).

The following day the patient is discharged – his discharge prescription is the same as his inpatient one. It is recorded in the hospital information system as well as in the community prescription repository (7). His ‘take-home’ medicines are supplied from the locked box at the side of his bed (8). The delivery is published into the shared medication dispense repository (8).

10 Cas d'utilisation ville-hôpital

Ces cas d'utilisation portent sur les interactions ville-hôpital, afin de créer un contexte pour la continuité des soins.

10.1 Séjour en hôpital avec continuité du traitement

10.1.1 Finalité

Ce cas d'utilisation est l'illustration d'une organisation qui préserve la continuité du traitement médicamenteux entre les univers de la ville et de l'hôpital, comme c'est souvent le cas pour les hôpitaux du Royaume Uni.

10.1.2 Scénario

Un patient doit être admis à l'hôpital, en provenance de son domicile. La prescription initiale pour son séjour à l'hôpital reste identique aux médicaments qu'il prenait chez lui.

Sa prescription est transcrite (1) et les médicaments qu'il a apportés avec lui sont vérifiés par un préparateur en pharmacie qui s'assure qu'ils peuvent être utilisés pendant son séjour (2). Un pharmacien vérifie que les médicaments sont appropriés pour le patient et annote la prescription pour certifier que cette vérification a été faite.

Sur les quatre médicaments que le patient prenait, trois sont en quantité suffisante. Il n'a pas suffisamment de son quatrième médicament, et le préparateur en pharmacie procède à une délivrance complémentaire. La pharmacie fournit un paquet de médicaments pour un mois, et mentionne sur l'étiquette qu'il pourra les emporter chez lui (3). Tous ces médicaments sont stockés dans une boîte fermée à clef à côté de son lit, et sont utilisés pendant le séjour à l'hôpital.

Deux jours plus tard un nouveau médicament est prescrit tard le soir (4). Le personnel du service prend les médicaments dans une armoire de service pour administrer les trois premières doses (5) jusqu'au moment où un paquet de médicament spécialement étiqueté pour le patient (avec les instructions à suivre quand il sortira de l'hôpital) est fourni par la pharmacie (6).

Le jour suivant le patient sort de l'hôpital – sa prescription de sortie est la même que pour son hospitalisation. Elle est enregistrée dans le système d'information de l'hôpital ainsi que dans l'entrepôt de prescriptions de la ville (7). Ses médicaments « à prendre à la maison » viennent de la boîte fermée à clef à côté de son lit (8). La délivrance est enregistrée dans l'entrepôt partagé de comptes-rendus de délivrance (8).

10.1.3 Sequence Diagram

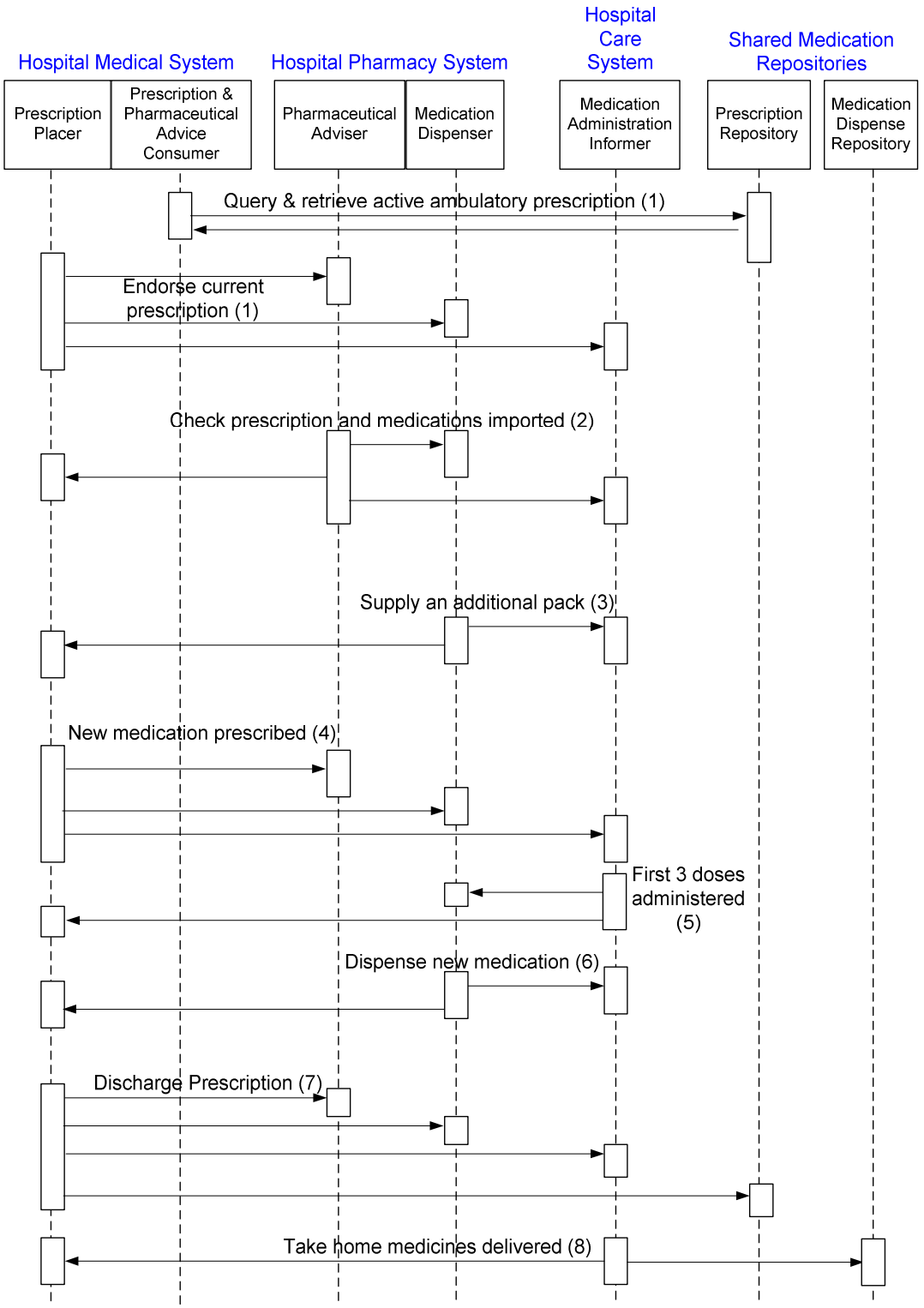


Figure 10.1: Use Case Admission-Discharge with Continuity of Treatment

10.1.3 Diagramme de séquence

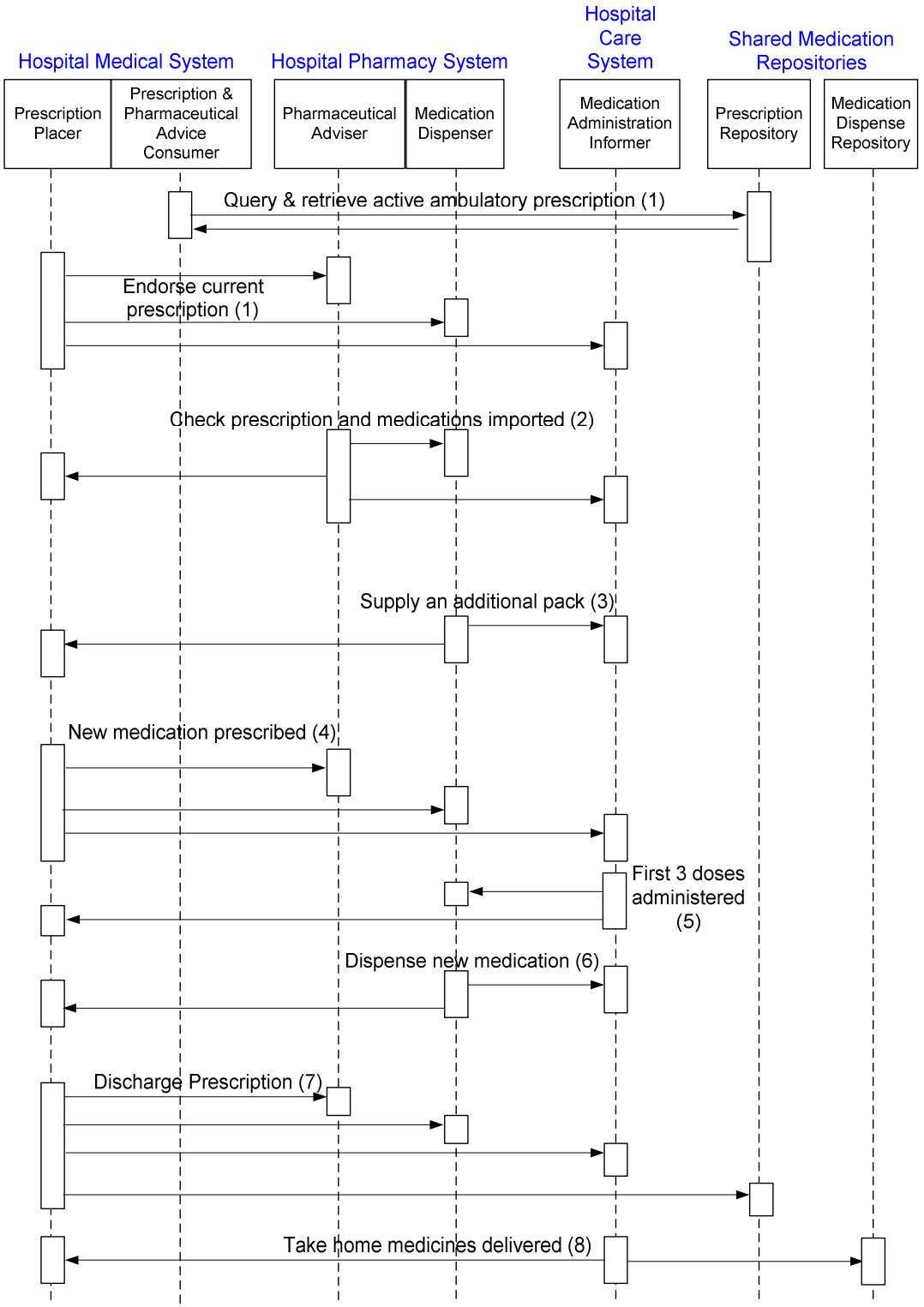


Figure 10.1 : Séjour en hôpital avec continuité du traitement

10.2 Admission/discharge with hospital taking over medications during stay

10.2.1 Purpose

This use case illustrates the admission process with the hospital taking over the control on all medications to be administered to the patient during their stay. The medications that the patient may have brought with them are discarded and replaced by medications exclusively delivered by the hospital pharmacy. Conversely, at discharge time the hospital prescribes medications to the patient but does not dispense them. This is a common organization in most European countries.

10.2.2 Storyboard

A patient is admitted at hospital. The admitting physician checks any medications that the patient used to intake while at home, and recognizes that one – Digoxin - has to be pursued during the patient stay. None of the medications that the patient brought with them is kept. The physician writes a new prescription, which includes the Digoxin (1). After pharmaceutical analysis by the pharmacist (2), the pharmacy dispenses the prescribed medications (3), which are daily administered by the nurse (4).

Finally, the patient is discharged. The physician discharging the patient prescribes medications that the patient will have to get delivered from a community pharmacy. The patient is given a paper prescription describing the medicine prescribed containing all the intake instructions (posology, starting date, end date…). At the same time, the electronic prescription is published by the hospital medical system into the regional prescription repository (5).

Later on, the patient goes to a community pharmacy to obtain the medications. The pharmacy system queries the regional prescription repository together with the dispense repository to look up for the prescription and check that no other dispenses have already been performed (6). The pharmacist analyses the prescription (7), and then dispenses the medicines to the patient. The dispense is registered into the shared repository (8).

10.2 Séjour en hôpital avec rupture de continuité du traitement

10.2.1 Finalité

Ce cas d'utilisation est l'illustration du processus d'admission qui implique une prise de contrôle par l'hôpital de la totalité des médicaments qui vont être administrés au patient pendant son séjour. Les médicaments que le patient peut avoir apportés avec lui sont mis de côté et remplacés exclusivement par des médicaments délivrés par la pharmacie de l'hôpital. Inversement, au moment de la sortie l'hôpital prescrit des médicaments au patient mais ne les délivre pas. C'est l'organisation la plus répandue dans la plupart des pays européens.

10.2.2 Scénario

Un patient est admis à l'hôpital. Le médecin qui fait l'admission vérifie les médicaments que le patient avait l'habitude de prendre quand il était chez lui, et note que l'un d'eux – la Digoxin – doit être poursuivi pendant la durée du séjour. Aucun des médicaments que le patient a apportés avec lui n'est utilisé. Le médecin établit une nouvelle prescription, qui inclut la Digoxin (1). Après analyse pharmaceutique par le pharmacien (2), la pharmacie délivre les médicaments prescrits (3), qui sont administrés quotidiennement par l'infirmière (4).
Le patient finit par sortir de l'hôpital. On donne au patient une prescription papier qui décrit les médicaments prescrits avec toutes les instructions pour les prendre (posologie, date de début, date de fin…). En même temps, une prescription électronique produite par le système d'information de l'hôpital est publiée sur l'entrepôt régional de prescriptions (5).
Un peu plus tard, le patient va dans une pharmacie de ville pour avoir ses médicaments. Le logiciel de la pharmacie fait des requêtes sur l'entrepôt de prescriptions et sur l'entrepôt de comptes-rendus d'administration et s'assure qu'il n'y a pas encore eu de délivrance (6). Le pharmacien analyse la prescription (7), et délivre ensuite les médicaments au patient. La délivrance est enregistrée dans l'entrepôt partagé (8).

10.2.3 Sequence Diagram

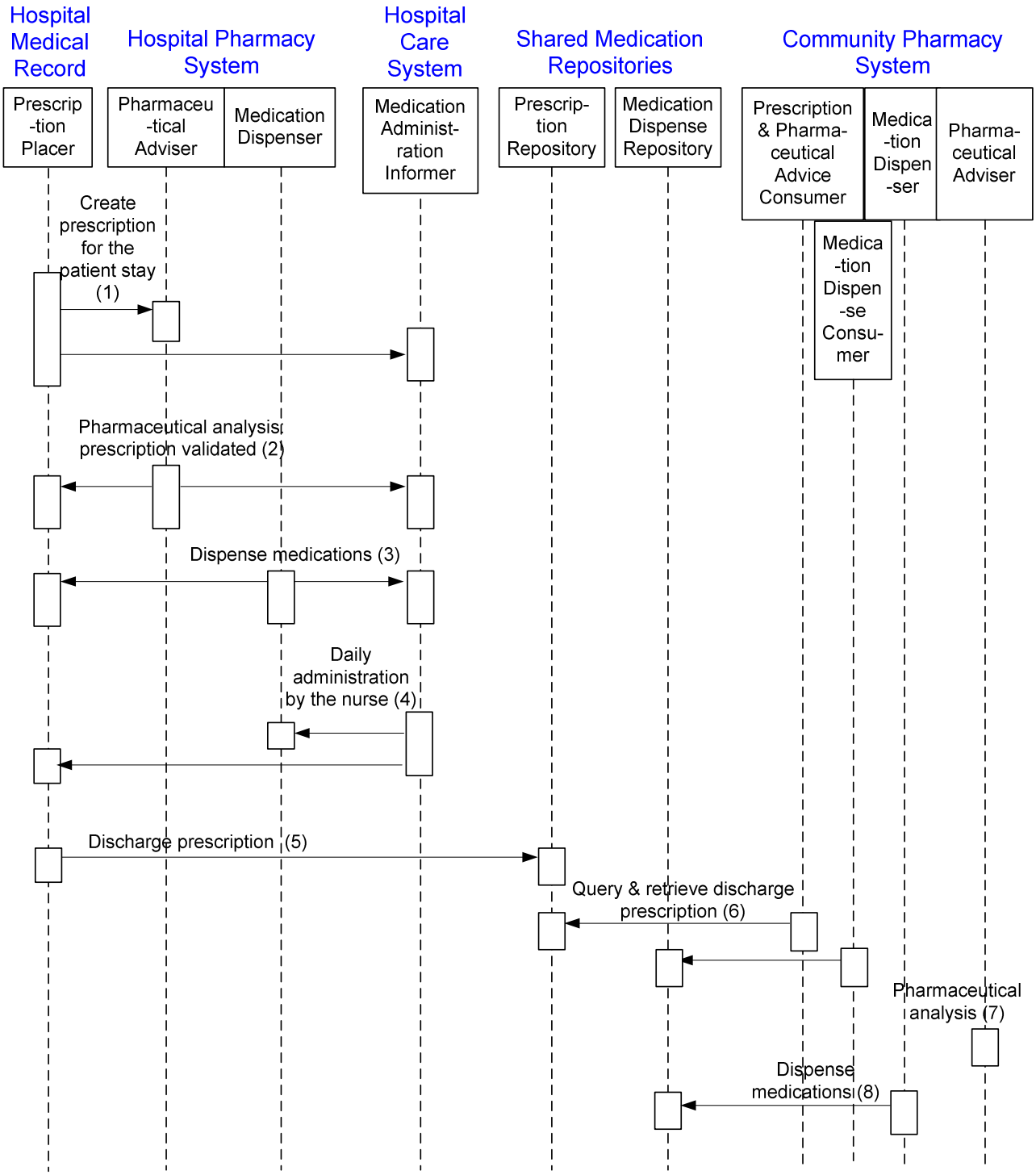


Figure 10.2: Use Case Admission-Discharge with hospital taking over medications during stay

10.2.3 Diagramme de séquence

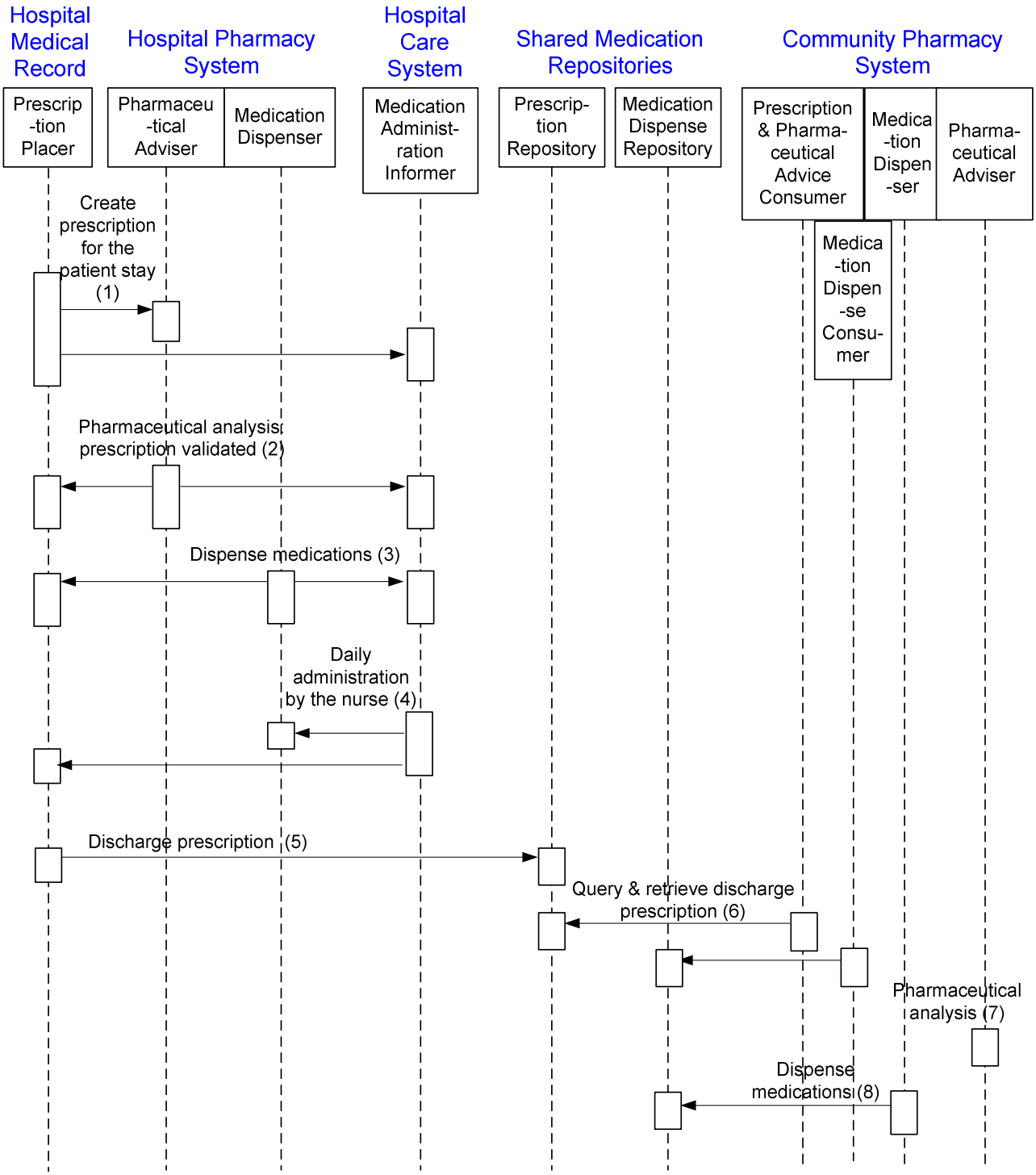


Figure 10.2 : Séjour en hôpital avec rupture de continuité du traitement

10.3 Hospital Dispense for Outpatients

10.3.1 Purpose

This use case shows the hospital dispensing specific medications to outpatient, in fulfillment of a prescription that has been produced in the community space. This category of hospital dispense for outpatients is called “retrocession” in France. The official list of medications that can only be dispensed by hospitals is regularly updated by the ministry of health.

10.3.2 Storyboard

A patient was hospitalized for a resistant schizophrenia, and then discharged by the neurologist with a renewable prescription of cocaine. Since then, the patient is regularly checked by his psychiatrist in town. The psychiatrists renews the initial Clozapine prescription as needed. This particular medication is to be obtained at a hospital pharmacy. The prescription is published into the national prescription repository.

(1) The patient goes to a hospital pharmacy in order to retrieve his medication. The patient brings the initial prescription by the neurologist as well as the renewal ordered by the psychiatrist. The hospital pharmacist queries the national prescription repository and retrieves the prescription.

(2) The hospital pharmacist queries the national dispense repository for current dispenses. The pharmacist checks that no dispense have already been performed for the current prescription and that it does not interact with any other current medications dispensed to the patient.

(3) No interaction being detected, the pharmacist accepts the prescription, dispenses the medication and records it into the national dispense repository.

(3 bis) Variation of (3): An interaction is detected. The pharmacist refuses the prescription. His pharmaceutical advice is recorded into the pharmaceutical advice repository. The prescriber is notified.

10.3 Rétrocession

10.3.1 Finalité

Ce cas d'utilisation montre l'hôpital qui délivre des médicaments spécifiques à un patient ambulatoire, pour satisfaire une prescription qui a été produite dans l'univers de la ville. Cette catégorie de délivrance à des patients ambulatoires est appelée « rétrocession » en France. La liste officielle des médicaments qui ne peuvent être délivrés que par les hôpitaux est régulièrement mise à jour par le Ministère de la Santé.

10.3.2 Scénario

Un patient a été hospitalisé pour schizophrénie chronique, et le neurologiste l'a fait sortir de l'hôpital avec une prescription renouvelable de cocaïne. Depuis lors, le patient doit voir régulièrement son psychiatre en ville. Le psychiatre renouvelle la prescription initiale de Clozapine au fur et à mesure des besoins. Ce médicament particulier ne peut être obtenu qu'auprès d'une pharmacie d'hôpital. La prescription est publiée dans l'entrepôt national de prescriptions.

(1) Le patient va à la pharmacie de l'hôpital pour avoir ses médicaments. Le patient apporte la prescription initiale du neurologiste, ainsi que le renouvellement prescrit par le psychiatre. Le pharmacien de l'hôpital consulte l'entrepôt national de prescriptions et récupère les informations.

(2) Le pharmacien de l'hôpital consulte l'entrepôt national de comptes-rendus de délivrance pour avoir la liste des délivrances. Le pharmacien vérifie qu'il n'y a pas déjà eu de délivrance pour la prescription en cours, et qu'il n'y a pas d'interaction avec d'autres médicaments délivrés récemment.

(3) Comme on n'a pas détecté d'interaction, le pharmacien accepte la prescription, procède à la délivrance du médicament et l'enregistre dans l'entrepôt national de comptes-rendus de délivrance.

(3 bis) Variante du point (3) : Une interaction été détectée. Le pharmacien refuse la prescription. Son avis pharmaceutique est enregistré dans l'entrepôt national d'avis pharmaceutiques. Le prescripteur reçoit une notification.

10.3.3 Sequence Diagram: Normal dispense

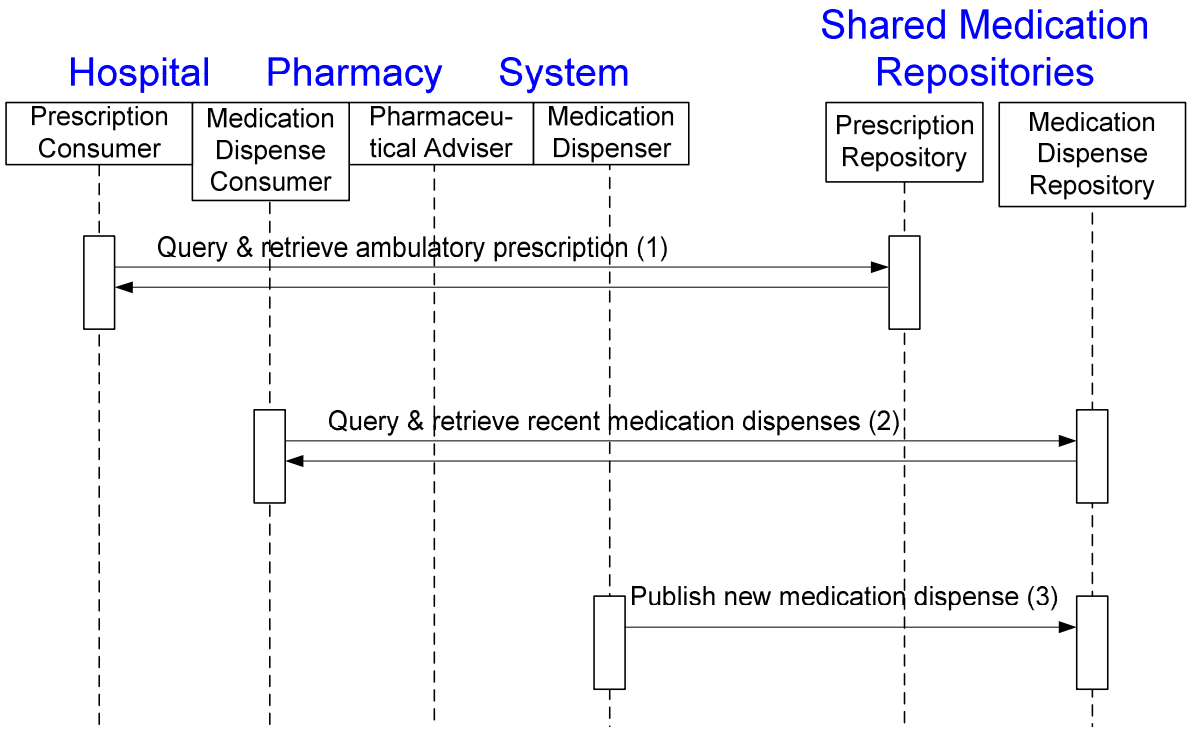


Figure 10.3: Use Case Hospital Dispense for Outpatients – normal

10.3.3 Diagramme de séquence : délivrance normale

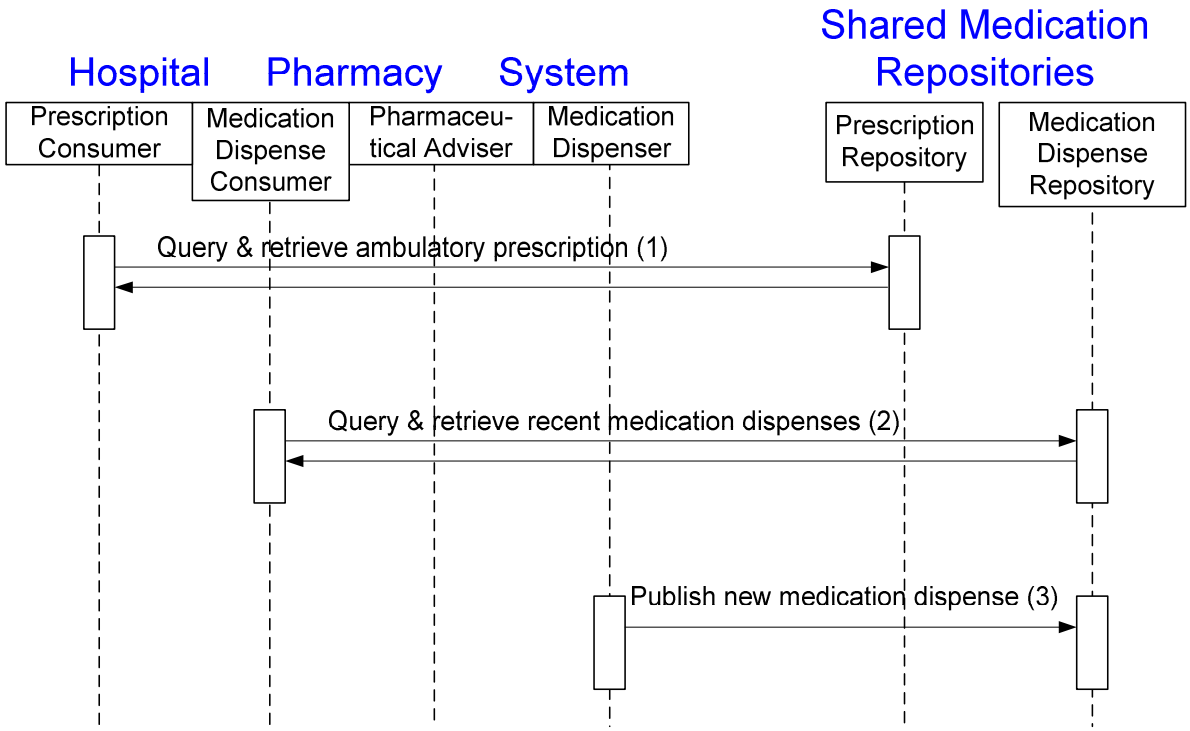


Figure 10.3 : Rétrocession – normale

10.3.4 Sequence Diagram with Interaction detected and dispense refused

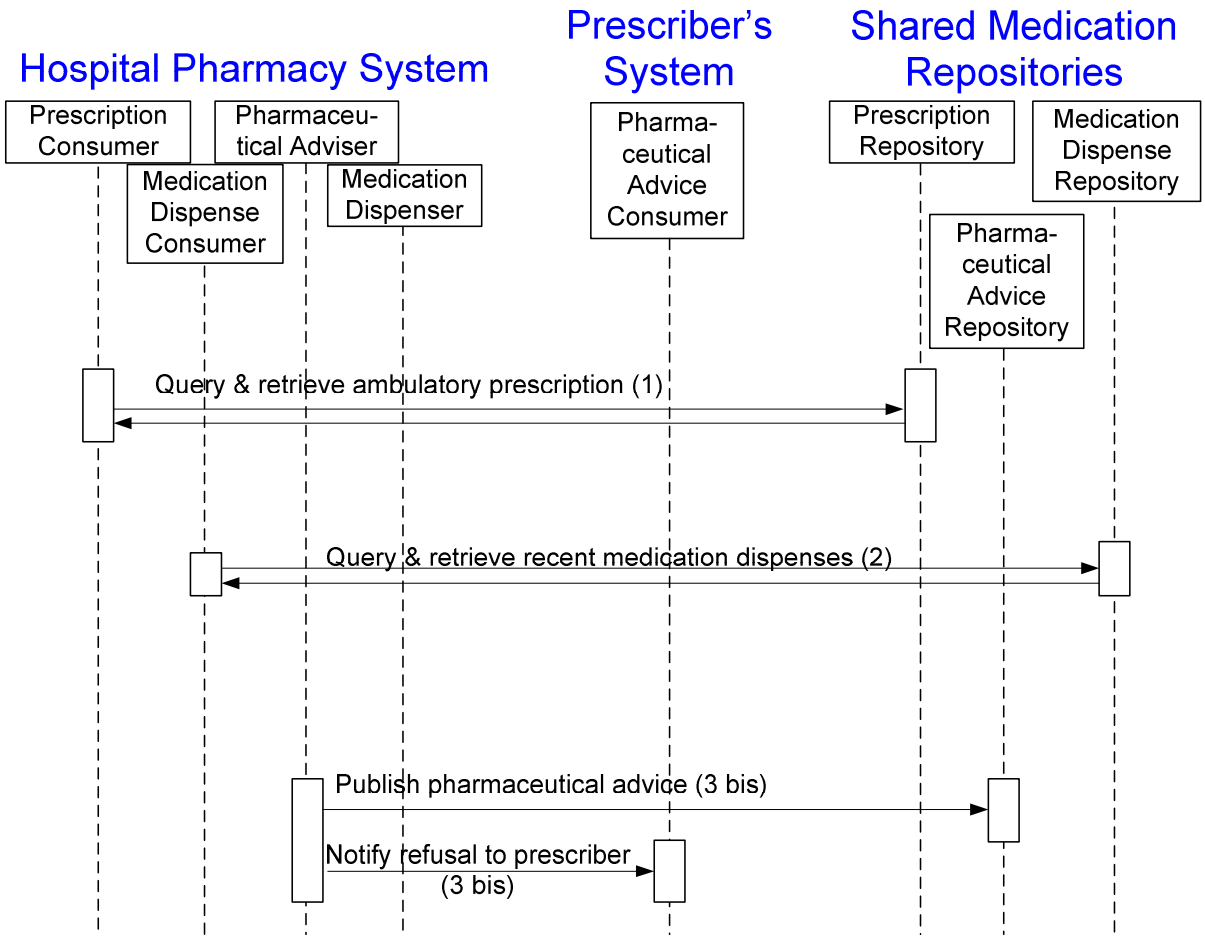


Figure 10.4: Use Case Hospital Dispense for Outpatients – with Interaction detected and dispense refused

10.3.4 Diagramme de séquence avec une interaction détectée et la délivrance refusée

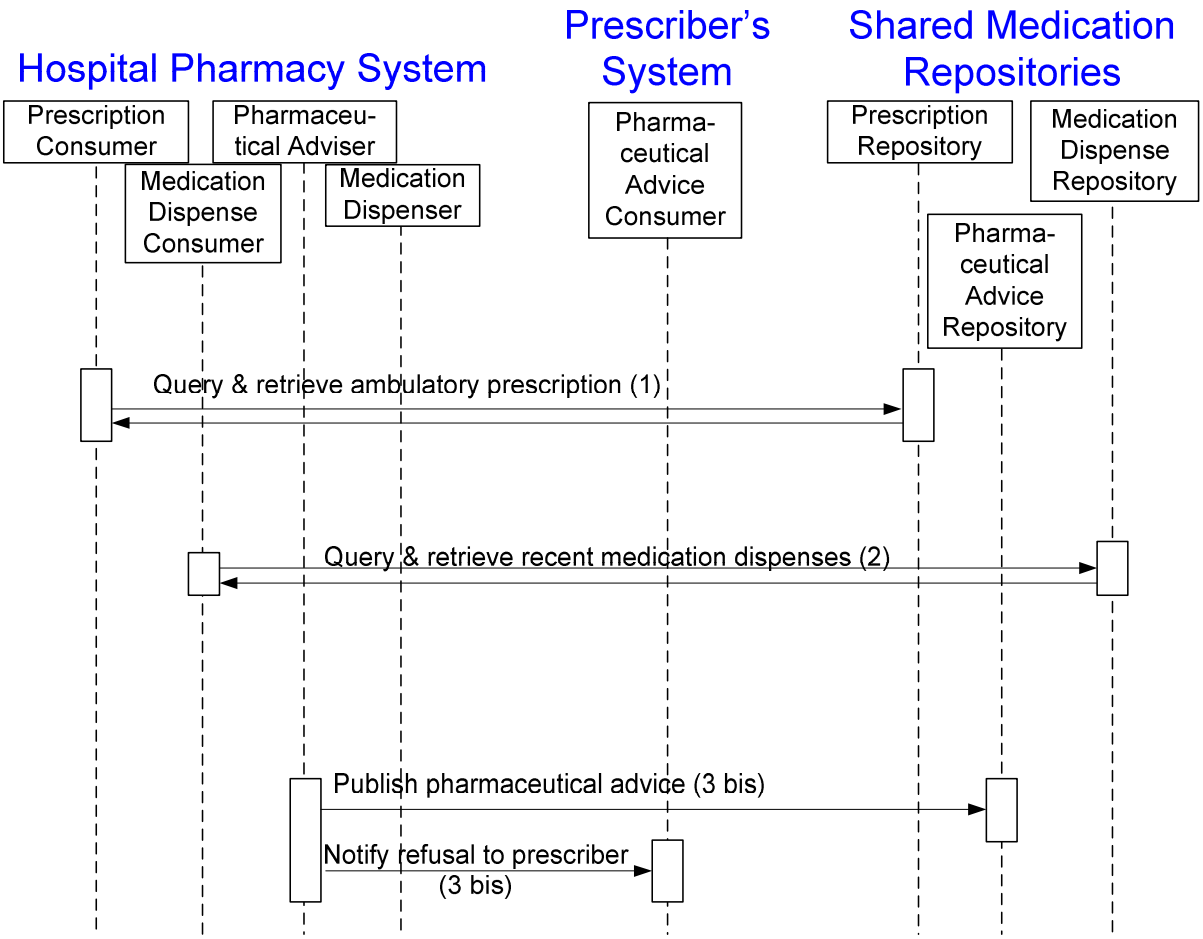


Figure 10.4 : Rétrocession – avec une interaction détectée et la délivrance refusée

11 Relevant standards for the pharmacy domain

11.1 HL7 V2

HL7 v2 messages supporting the pharmacy workflow have been in play for a long time.
These messages support the intra hospital workflow as well as the community workflow, and some real implementations exist in both subdomains.
These messages and their content (data segments and fields) are described in chapter 4"Order Entry" of HL7 2.5.1 or 2.6. The messages relevant to the pharmacy hospital sub domain use cases described earlier in this document are listed below:

Main process	Message	Actions	Sender	Receiver
Prescription	OMP^O09	prescription created, cancelled or updated	Prescription Placer	Pharmaceutical Adviser Medication Dispenser Medication Administration Informer
	ORP^O10	Ack		
Pharmaceutical analysis	RDE^O11	prescription accepted and encoded, changed, or refused	Pharmaceutical Adviser	Prescription Placer Medication Dispenser Medication Administration Informer
	RRE^O12	Ack		
Dispense	RDS^O13	Dispensed medication	Medication Dispenser	Prescription Placer Medication Administration Informer
	RRD^O14	Ack		
Medication Administration	RAS^O17	Medication administered	Medication Administration Informer	Prescription Placer Medication Dispenser
	RRA^O18	Ack		

For all messages listed in the table above, the real action requested is coded in field ORC-1 "Order Control", which is the 1st field of each "Common Order" segment in the message. For instance, when placing a new order the Prescription Placer will populate this field with the value "NW" ("new order placed"). When accepting a new order and deciding a substitution, the Pharmaceutical Adviser will populate this field with the value "RU" ("replaced unsolicited").
These messages use a set of common segments (e.g. PID for patient, OBX to provide clinical observations) and some other segments dedicated to the pharmacy domain: RXO (order), RXR (route), RXE (encoding), RXD (dispense), RXA (administration).

11 Normes et standards pour le domaine de la pharmacie

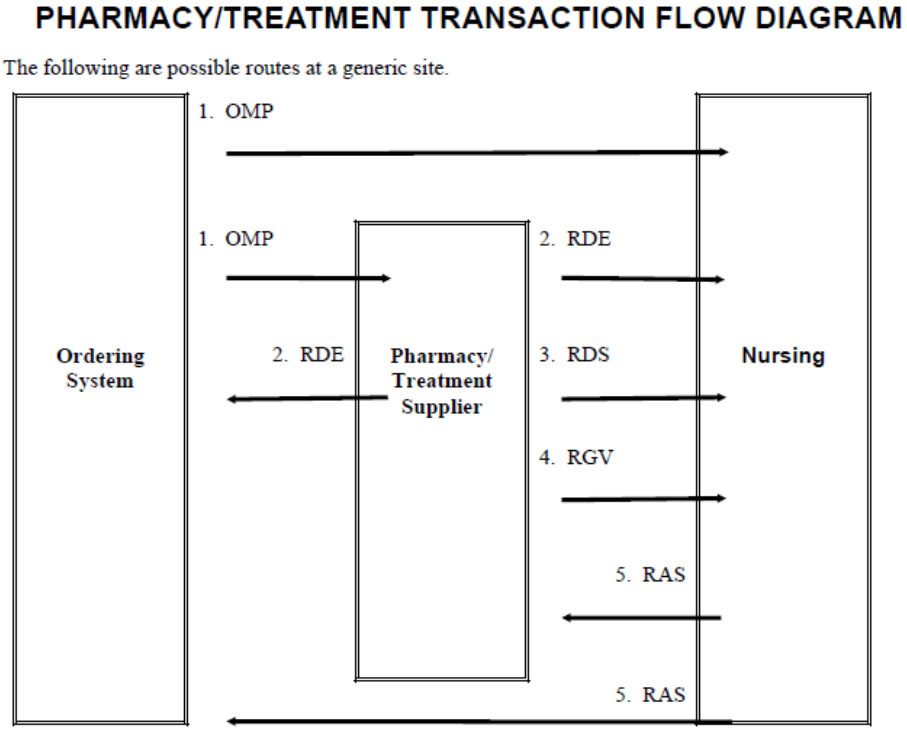
11.1 HL7 V2

HL7 v2 messages supporting the pharmacy workflow have been in play for a long time.
These messages support the intra hospital workflow as well as the community workflow, and some real implementations exist in both subdomains.
These messages and their content (data segments and fields) are described in chapter 4"Order Entry" of HL7 2.5.1 or 2.6. The messages relevant to the pharmacy hospital sub domain use cases described earlier in this document are listed below:

Main process	Message	Actions	Sender	Receiver
Prescription	OMP^O09	prescription created, cancelled or updated	Prescription Placer	Pharmaceutical Adviser Medication Dispenser Medication Administration Informer
	ORP^O10	Ack		
Pharmaceutical analysis	RDE^O11	prescription accepted and encoded, changed, or refused	Pharmaceutical Adviser	Prescription Placer Medication Dispenser Medication Administration Informer
	RRE^O12	Ack		
Dispense	RDS^O13	Dispensed medication	Medication Dispenser	Prescription Placer Medication Administration Informer
	RRD^O14	Ack		
Medication Administration	RAS^O17	Medication administered	Medication Administration Informer	Prescription Placer Medication Dispenser
	RRA^O18	Ack		

For all messages listed in the table above, the real action requested is coded in field ORC-1 "Order Control", which is the 1st field of each "Common Order" segment in the message. For instance, when placing a new order the Prescription Placer will populate this field with the value "NW" ("new order placed"). When accepting a new order and deciding a substitution, the Pharmaceutical Adviser will populate this field with the value "RU" ("replaced unsolicited").
These messages use a set of common segments (e.g. PID for patient, OBX to provide clinical observations) and some other segments dedicated to the pharmacy domain: RXO (order), RXR (route), RXE (encoding), RXD (dispense), RXA (administration).

Chapter 4 of HL7 v2.5 standard diagrams an example of intra hospital workflow based on these messages:



11.2 HL7 v3 messages

HL7 v3 is providing messages, which are built per domain. The v3 messages for the Pharmacy domain are still in the building process. After normalizing the medication model, HL7 has moved forward again with messages, starting with the community space. The Medication Order message is about to become normative, after May 2009 ballot. The Medication Dispense message will enter ballot process in May 2009 and should become normative early 2010. Messages for hospital pharmacy are a distinct project, yet to be started. They're unlikely to be ready in the same time frame.

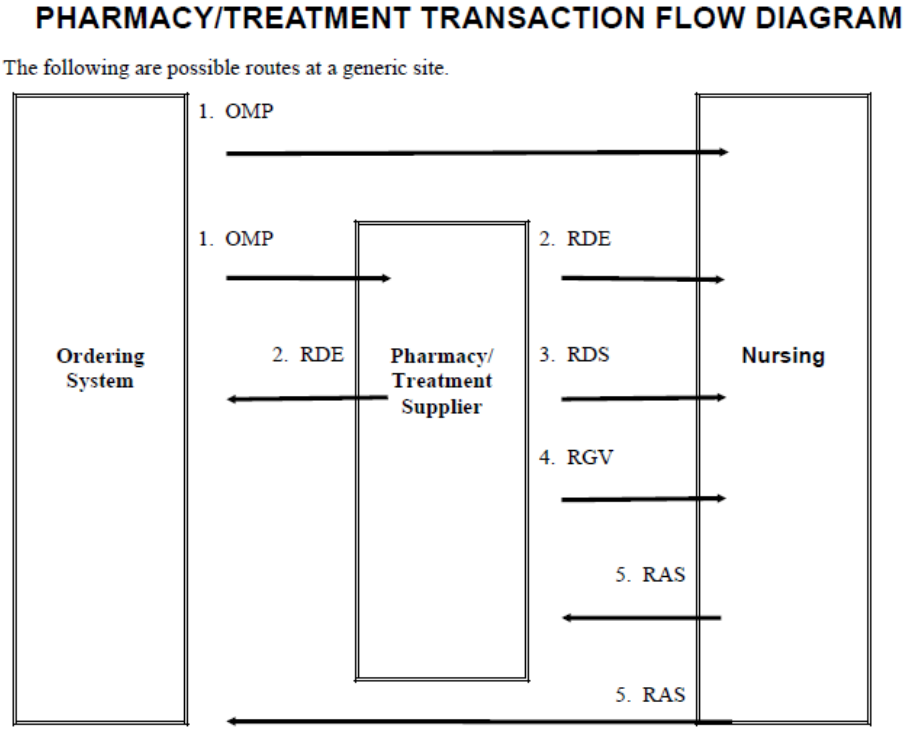
11.3 HL7 v3 documents

On the other hand HL7 v3 offers a standard for clinical documents: CDAr2, which is normative, stable, and widely adopted for the sharing of clinical documents such as referrals, medical summaries, consultation reports…
This section tries to assess the appropriateness of CDAr2 for pharmacy objects appearing in the pharmacy use cases

11.3.1 Act Moods

The objects described in this white paper (prescription, pharmaceutical advice, dispense …) represent acts, and are represented in HL7 v3 as specialization of the Act class.

Chapter 4 of HL7 v2.5 standard diagrams an example of intra hospital workflow based on these messages:



11.2 Messages HL7 v3

HL7 v3 is providing messages, which are built per domain. The v3 messages for the Pharmacy domain are still in the building process. After normalizing the medication model, HL7 has moved forward again with messages, starting with the community space. The Medication Order message is about to become normative, after May 2009 ballot. The Medication Dispense message will enter ballot process in May 2009 and should become normative early 2010. Messages for hospital pharmacy are a distinct project, yet to be started. They're unlikely to be ready in the same time frame.

11.3 Documents HL7 v3

On the other hand HL7 v3 offers a standard for clinical documents: CDAr2, which is normative, stable, and widely adopted for the sharing of clinical documents such as referrals, medical summaries, consultation reports…
This section tries to assess the appropriateness of CDAr2 for pharmacy objects appearing in the pharmacy use cases

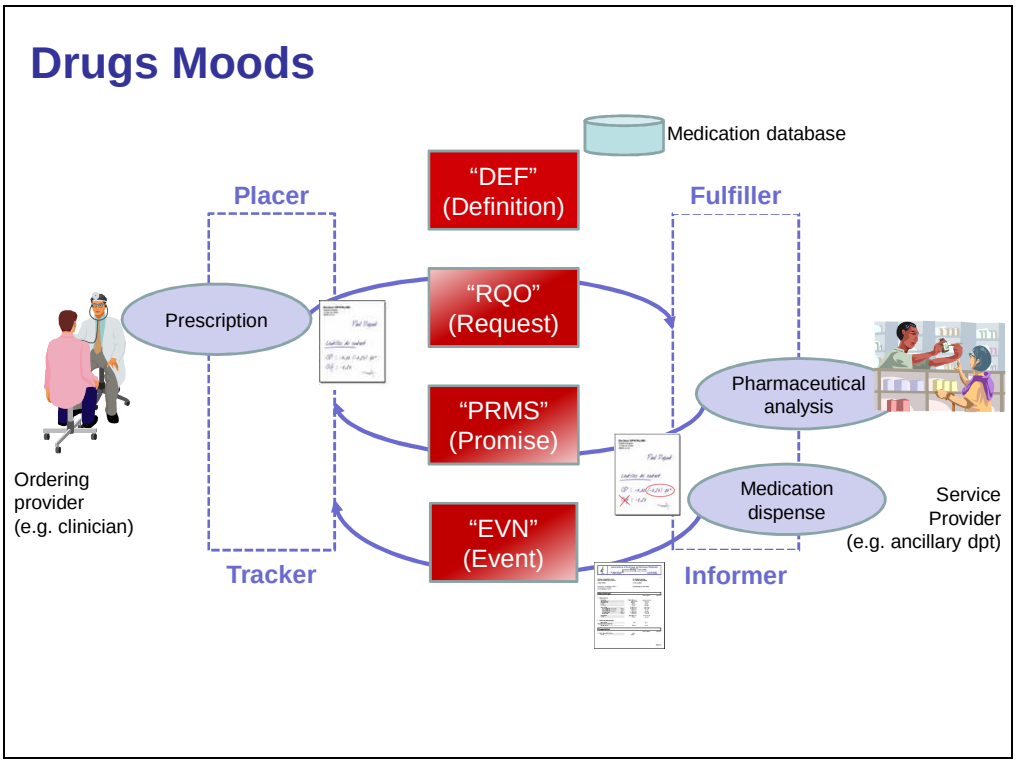
11.3.1 Act Moods

The objects described in this white paper (prescription, pharmaceutical advice, dispense …) represent acts, and are represented in HL7 v3 as specialization of the Act class.

V3 models acts in various “moods”:

- “Definition” (when the act is represented in a catalogue)
- “Request” when the act is prescribed
- “Promise” when the performer (the fulfiller) has accepted to perform this act.
- “Event” when the act has actually been performed (or cancelled, or aborted).

The prescription is a “request” from the ordering provider to the pharmacist for dispense, and intra-hospital, to the nurse for administration of the drug.
The pharmaceutical advice can be considered as a “promise” from the pharmacist.
The dispense is an event: The requested service has been performed (unless it was cancelled). So is the medication administration by the nurse.



Each object has its own life cycle, keeping its own mood:
The prescription may evolve over time, with new drugs added or replacing others. But this object only belongs to the ordering physician. The pharmacist cannot update it.

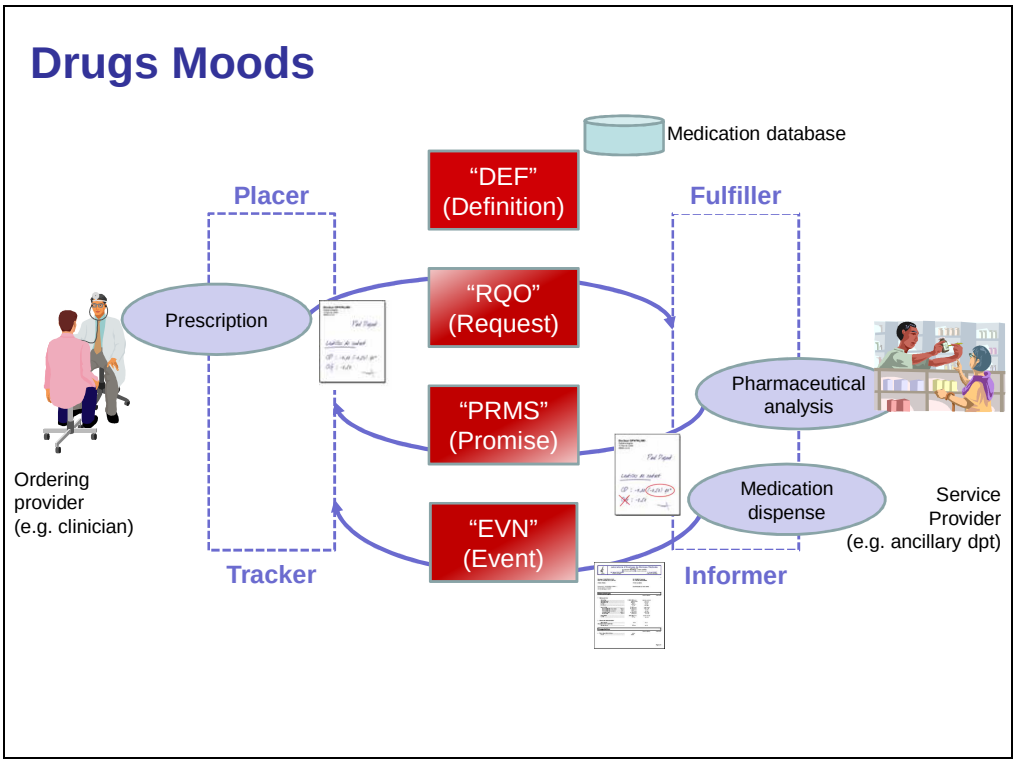
The pharmacist may require replacements of a drug by a new one. This takes place in the “promise” object, coming from the pharmaceutical analysis process. This object belongs to the pharmacy and cannot be updated by anyone outside the pharmacy.

Similarly, the dispense event is produced by the pharmacist or his assistant. This dispense belongs to the pharmacy.

V3 models acts in various "moods":

- "Definition" (when the act is represented in a catalogue)
- "Request" when the act is prescribed
- "Promise" when the performer (the fulfiller) has accepted to perform this act.
- "Event" when the act has actually been performed (or cancelled, or aborted).

The prescription is a "request" from the ordering provider to the pharmacist for dispense, and intra-hospital, to the nurse for administration of the drug.
The pharmaceutical advice can be considered as a "promise" from the pharmacist.
The dispense is an event: The requested service has been performed (unless it was cancelled). So is the medication administration by the nurse.



Each object has its own life cycle, keeping its own mood:
The prescription may evolve over time, with new drugs added or replacing others. But this object only belongs to the ordering physician. The pharmacist cannot update it.

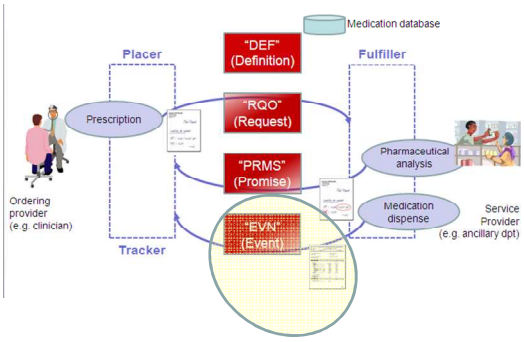
The pharmacist may require replacements of a drug by a new one. This takes place in the "promise" object, coming from the pharmaceutical analysis process. This object belongs to the pharmacy and cannot be updated by anyone outside the pharmacy.

Similarly, the dispense event is produced by the pharmacist or his assistant. This dispense belongs to the pharmacy.

11.3.2 What kind of documents CDA was designed for

What content CDA is meant for?

```
<ClinicalDocument>
   …
  <recordTarget>
     <!-- … the patient -->
  </recordTarget>
  …
  <inFulfillmentOf>
      <!-- … references of the order  fulfilled -->
  </inFulfillmentOf>
 …
  <documentationOf>
     <serviceEvent  moodCode= "EVN" >
        <!-- … the documented service event -->
     </serviceEvent>
  </documentationOf>
  …
  <component>
     <structuredBody>
          <!-- … body of the document
                carrying the output of the
                service event -->
```



CDA represents clinical documents describing a service event performed for a patient, possibly in fulfillment of an order.

CDA is convenient for dispenses.
CDA does not seem appropriate for a prescription or a pharmaceutical validation

The CDA schema is suitable for representing the dispense as a document. A CDA dispense shall reference the prescription it fulfils in the <inFulfillmentOf> element of the CDA header. Conversely, the CDA standard was not really designed to represent orders (prescriptions) or promises (pharmaceutical advice). However it still can represent these objects if one considers the act of prescribing as an event in itself, that needs to be recorded and kept over time as it was at prescription time.

The other decision factors that have to be considered regarding CDA are the key factors that favor the choice of a document standard versus a message standard:

11.3.3 Persistency

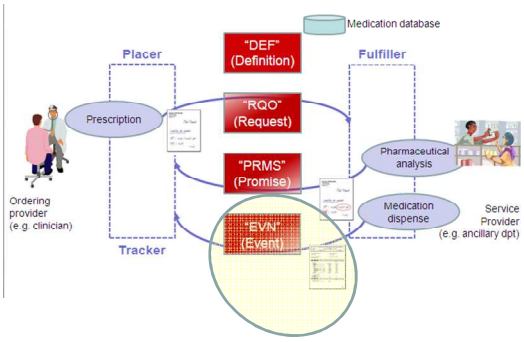
How long do the objects represented in the workflows of this white paper have to persist, and be available for use by the various human actors and their system actors?

- The use cases of the community sub domain (including the exchanges between hospital and community) clearly need prescriptions, pharmaceutical advices and dispenses to persist as they were produced by their authors (physician, pharmacist), and be accessible over time by the actors, for checking against new prescriptions, and also for liability purpose.
- Conversely, the intra hospital use cases need not that prescriptions, validations, dispenses and administration reports persist as shared objects. The intra hospital use cases need real time exchange between all system actors, with fine grained status change notifications, ensuring that all systems involved keep at all time the same knowledge of the ongoing process and the last status of its structured data. Liability in this sub domain is ensured

11.3.2 What kind of documents CDA was designed for

What content CDA is meant for?

```
<ClinicalDocument>
   …
  <recordTarget>
     <!-- … the patient -->
  </recordTarget>
  …
  <inFulfillmentOf>
      <!-- … references of the order  fulfilled -->
  </inFulfillmentOf>
 …
  <documentationOf>
     <serviceEvent  moodCode= "EVN" >
        <!-- … the documented service event -->
     </serviceEvent>
  </documentationOf>
  …
  <component>
     <structuredBody>
          <!-- … body of the document
                carrying the output of the
                service event -->
```



CDA represents clinical documents describing a service event performed for a patient, possibly in fulfillment of an order.

CDA is convenient for dispenses.
CDA does not seem appropriate for a prescription or a pharmaceutical validation

The CDA schema is suitable for representing the dispense as a document. A CDA dispense shall reference the prescription it fulfils in the <inFulfillmentOf> element of the CDA header. Conversely, the CDA standard was not really designed to represent orders (prescriptions) or promises (pharmaceutical advice). However it still can represent these objects if one considers the act of prescribing as an event in itself, that needs to be recorded and kept over time as it was at prescription time.

The other decision factors that have to be considered regarding CDA are the key factors that favor the choice of a document standard versus a message standard:

11.3.3 Persistency

How long do the objects represented in the workflows of this white paper have to persist, and be available for use by the various human actors and their system actors?

- The use cases of the community sub domain (including the exchanges between hospital and community) clearly need prescriptions, pharmaceutical advices and dispenses to persist as they were produced by their authors (physician, pharmacist), and be accessible over time by the actors, for checking against new prescriptions, and also for liability purpose.
- Conversely, the intra hospital use cases need not that prescriptions, validations, dispenses and administration reports persist as shared objects. The intra hospital use cases need real time exchange between all system actors, with fine grained status change notifications, ensuring that all systems involved keep at all time the same knowledge of the ongoing process and the last status of its structured data. Liability in this sub domain is ensured

by a tighter coupling of the systems within one unique organization, with precise policies regulating the workflow, and common tools supporting these policies.

11.3.4 Stewardship

A CDA document is authored and issued by a healthcare professional or organization who wants to share its content with other actors. The professional or organization source of the document is liable for its content and is entitled to administrate this document, that is:

- Deprecate it when comes a time it's no longer relevant.
- Replace it in case an error in this content has been detected and needs to be corrected.
- Complement it with addenda (documents appended to it) when needed.

The key point here is that stewardship is a role assumed by the source of the document, and no-one else. For instance a prescription issued by a GP will never be updated by a pharmacist (wanting to substitute a medication) or another physician (wanting to add a medication) or a nurse (wanting to change the dose packaging).

11.3.5 Degree of interactivity of the workflow

The more real-time oriented and interactive the workflow is the less suitable documents are. For instance, the hospital workflow surely cannot be handled with documents, which does not preclude this workflow to produce some persistent documents to be shared within the institution and/or with the community.

11.3.6 Workflow requirements that cannot be handled only with documents

The requirements presented in this section come from the use cases presented earlier in this document. These requirements need other artifacts than documents (e.g. messages or services)

- **Prescription Status Management**

A prescription or a prescription item can take one of these statuses

ORDERED	The prescription has been produced by the ordering provider and published, but is not yet assigned to or retrieved by any pharmacy. This status is mainly used by the Community subdomain in the "publish and pull" mode.
PLACED	The prescription is produced and placed to a pharmacy that has received it or retrieved it from a repository, but has not accepted it yet. Either the pharmaceutical analysis is not performed yet Or it has detected an issue and reported it in a pharmaceutical advice, which is awaiting resolution through further interactions/dialog between the pharmacist and the prescriber.
IN PROGRESS	A pharmacy has checked that the prescription is free of potential adverse issues (e.g. interactions, overdose) and has accepted to dispense the medications (which may need time for preparation or stock provision). Some of the prescribed medications may have been dispensed. Further dispenses are expected in the future.
COMPLETED	The prescription is completely dispensed. No more action is expected on this prescription.
CANCELLED	The prescription, which was ORDERED has been cancelled by the ordering provider, or has expired because the patient never showed up to any pharmacy.

by a tighter coupling of the systems within one unique organization, with precise policies regulating the workflow, and common tools supporting these policies.

11.3.4 Stewardship

A CDA document is authored and issued by a healthcare professional or organization who wants to share its content with other actors. The professional or organization source of the document is liable for its content and is entitled to administrate this document, that is:

- Deprecate it when comes a time it's no longer relevant.
- Replace it in case an error in this content has been detected and needs to be corrected.
- Complement it with addenda (documents appended to it) when needed.

The key point here is that stewardship is a role assumed by the source of the document, and no-one else. For instance a prescription issued by a GP will never be updated by a pharmacist (wanting to substitute a medication) or another physician (wanting to add a medication) or a nurse (wanting to change the dose packaging).

11.3.5 Degree of interactivity of the workflow

The more real-time oriented and interactive the workflow is the less suitable documents are. For instance, the hospital workflow surely cannot be handled with documents, which does not preclude this workflow to produce some persistent documents to be shared within the institution and/or with the community.

11.3.6 Workflow requirements that cannot be handled only with documents

The requirements presented in this section come from the use cases presented earlier in this document. These requirements need other artifacts than documents (e.g. messages or services)

- **Prescription Status Management**

A prescription or a prescription item can take one of these statuses

ORDERED	The prescription has been produced by the ordering provider and published, but is not yet assigned to or retrieved by any pharmacy. This status is mainly used by the Community subdomain in the "publish and pull" mode.
PLACED	The prescription is produced and placed to a pharmacy that has received it or retrieved it from a repository, but has not accepted it yet. Either the pharmaceutical analysis is not performed yet Or it has detected an issue and reported it in a pharmaceutical advice, which is awaiting resolution through further interactions/dialog between the pharmacist and the prescriber.
IN PROGRESS	A pharmacy has checked that the prescription is free of potential adverse issues (e.g. interactions, overdose) and has accepted to dispense the medications (which may need time for preparation or stock provision). Some of the prescribed medications may have been dispensed. Further dispenses are expected in the future.
COMPLETED	The prescription is completely dispensed. No more action is expected on this prescription.
CANCELLED	The prescription, which was ORDERED has been cancelled by the ordering provider, or has expired because the patient never showed up to any pharmacy.

DISCONTINUED	The prescription is not carried out by the pharmacy for some specific reason. (e.g. after detection of an adverse issue by the pharmacist, and dialog with the prescriber, the final decision is made to abort this prescription, and possibly issue a new different one in replacement)
SUSPENDED	This status may be useful in the hospital workflow: The prescription which was IN PROGRESS is held for a period of time, for some clinical (surgical procedure) or physical (patient temporary leave) reason. Dispense and administration of the medication to the patient are suspended, and are expected to be resumed at a later point.

The following diagrams show the major status transitions of a prescription in hospital and community subdomains:

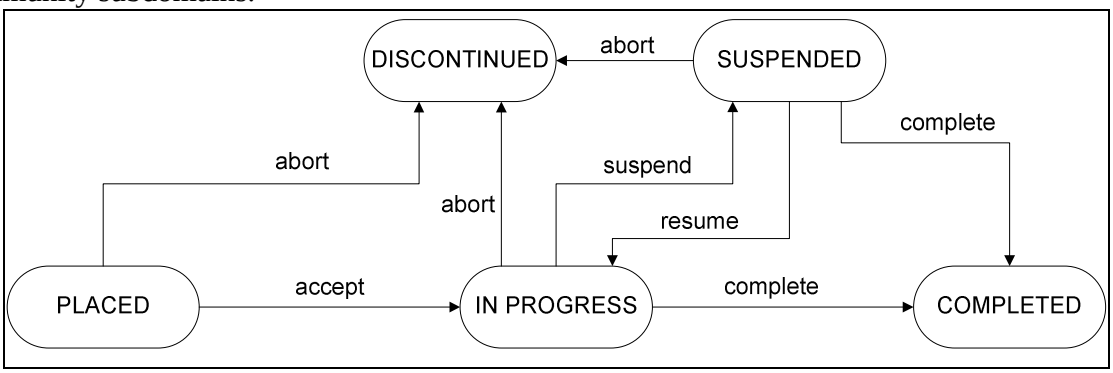


Figure 11-1: State transitions of Medication Prescription (Item) in the Hospital subdomain

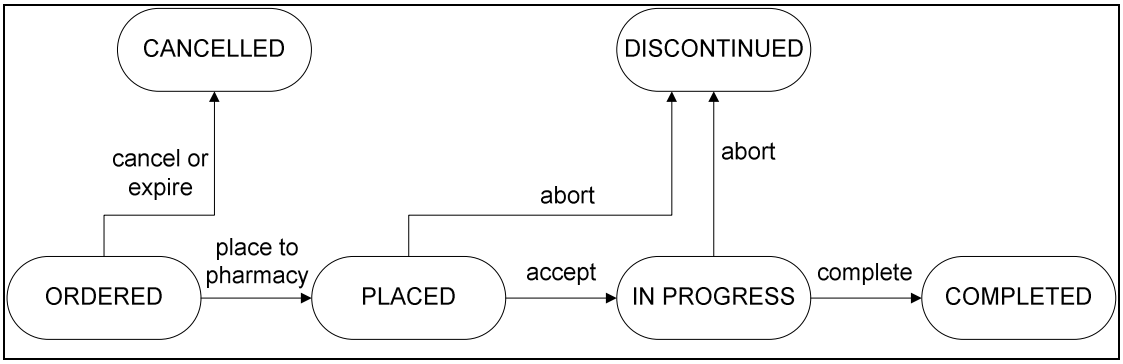


Figure 11-2: State transitions of Medication Prescription (Item) in Community subdomain

The management of these status transitions and the presentation of the prescription current status to the healthcare professional cannot be handled with documents. This management needs a service layer around the prescription document. Conversely, if the prescription is a message, the message carries this status.

- **Linking the pharmaceutical advice and the dispenses to their prescription**

When a prescription is retrieved from a repository by a system used by a healthcare professional, the retrieval must always bring back the prescription along with the existing pharmaceutical

DISCONTINUED	The prescription is not carried out by the pharmacy for some specific reason. (e.g. after detection of an adverse issue by the pharmacist, and dialog with the prescriber, the final decision is made to abort this prescription, and possibly issue a new different one in replacement)
SUSPENDED	This status may be useful in the hospital workflow: The prescription which was IN PROGRESS is held for a period of time, for some clinical (surgical procedure) or physical (patient temporary leave) reason. Dispense and administration of the medication to the patient are suspended, and are expected to be resumed at a later point.

The following diagrams show the major status transitions of a prescription in hospital and community subdomains:

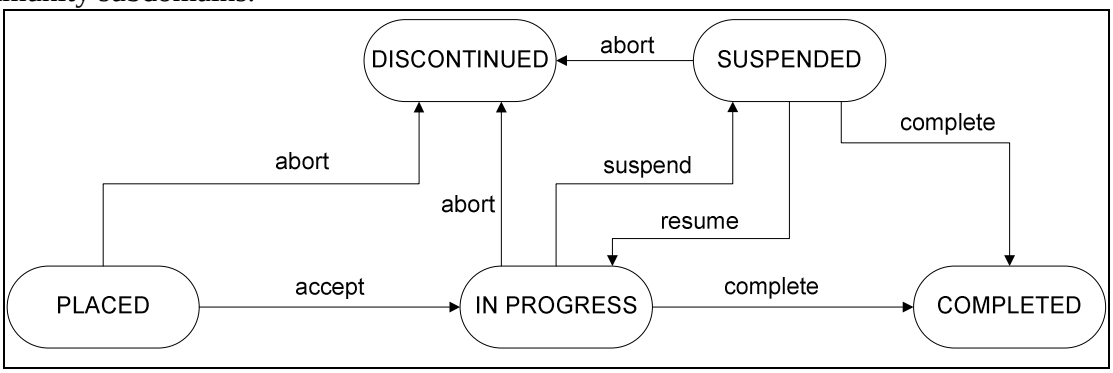


Figure 11-1: State transitions of Medication Prescription (Item) in the Hospital subdomain

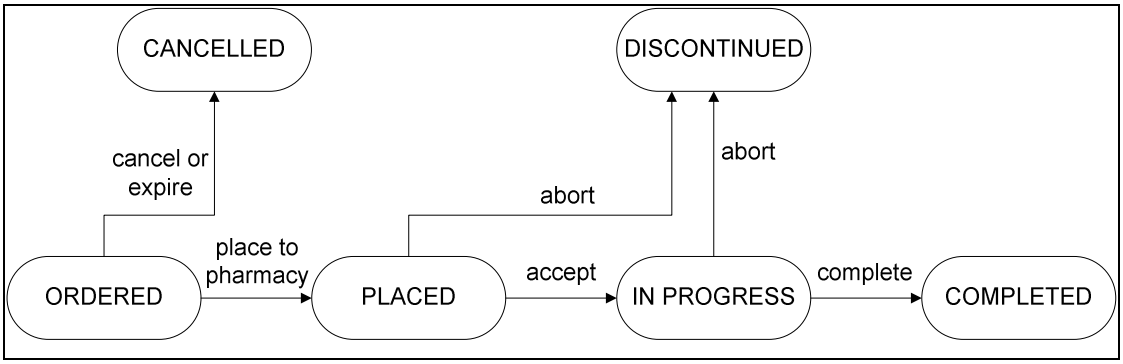


Figure 11-2: State transitions of Medication Prescription (Item) in Community subdomain

The management of these status transitions and the presentation of the prescription current status to the healthcare professional cannot be handled with documents. This management needs a service layer around the prescription document. Conversely, if the prescription is a message, the message carries this status.

- **Linking the pharmaceutical advice and the dispenses to their prescription**

When a prescription is retrieved from a repository by a system used by a healthcare professional, the retrieval must always bring back the prescription along with the existing pharmaceutical

advices and/or dispenses related to that prescription, in order to present a coherent view of the prescription to the professional, detailing what was prescribed, what was accepted, what was substituted, what was refused, what was dispensed.
This management needs two or three additional features:

- A new type of external link between documents: This link should be carried in the "parentDocumentId" metadata associated to a document, with a new type of association "SUCC" for successor. (e.g. a dispense document is a successor to the prescription document if the dispense was performed in fulfillment of this prescription)
- A new type of internal link between CDA documents: The "relatedDocument" element of the CDA schema should provide a new possible value for its "typeCode" attribute, which would be something like "SUCC" (successor, e.g. a pharmaceutical advice is a successor to the prescription it advises on)
- A service layer over the document infrastructure holding the prescription, pharmaceutical advice and dispense as documents, that will encapsulate the query and retrieval of documents by the Consumer actors, and will process these links.

- **Notification of acceptance/refusal by the pharmacist to the ordering provider**

If the prescription and pharmaceutical advice are documents in repositories, the pharmacist needs an additional notification service over the document infrastructure to notify their decision on the prescription directly to the system of the ordering provider.

- **A prescription supersedes a former prescription issued by another physician**

As shown in the Community Use Case chapter, it may happen that a specialist prescribes new medications superseding an in progress renewable prescription formerly ordered by the GP for the treatment of a chronic disease. This brings a particular relationship between prescriptions considered as documents: Prescription 2 issued by physician B puts prescription 1 formerly issued by physician A in DISCONTINUED status.
This case also needs a service layer over the document sharing infrastructure.

11.4 The XDS family of IHE profiles to support documents

The IT Infrastructure domain of IHE has produced a number of profiles that can prove useful for the sharing or the exchange of pharmacy objects as documents.
Some countries may choose to build on these infrastructure profiles. Other countries may choose to rely on a different non-IHE infrastructure, using for instance the Medical Records message set of HL7 v3.

11.4.1 XDS-b – Cross Enterprise Document Sharing

This profile provides an infrastructure for the storage/query/retrieval of prescriptions, pharmaceutical advices and dispenses as clinical documents. If a country or a region decides to rely on this profile, the repositories actors defined in this white paper will be represented in XDS by:

- One single Registry Actor: that will handle the metadata associated with all types of documents (prescriptions, pharmaceutical advices, dispenses)
- A set of Repository Actors that can be distributed or centralized, specialized per type of document or not.

advices and/or dispenses related to that prescription, in order to present a coherent view of the prescription to the professional, detailing what was prescribed, what was accepted, what was substituted, what was refused, what was dispensed.
This management needs two or three additional features:

- A new type of external link between documents: This link should be carried in the "parentDocumentId" metadata associated to a document, with a new type of association "SUCC" for successor. (e.g. a dispense document is a successor to the prescription document if the dispense was performed in fulfillment of this prescription)
- A new type of internal link between CDA documents: The "relatedDocument" element of the CDA schema should provide a new possible value for its "typeCode" attribute, which would be something like "SUCC" (successor, e.g. a pharmaceutical advice is a successor to the prescription it advises on)
- A service layer over the document infrastructure holding the prescription, pharmaceutical advice and dispense as documents, that will encapsulate the query and retrieval of documents by the Consumer actors, and will process these links.

- **Notification of acceptance/refusal by the pharmacist to the ordering provider**

If the prescription and pharmaceutical advice are documents in repositories, the pharmacist needs an additional notification service over the document infrastructure to notify their decision on the prescription directly to the system of the ordering provider.

- **A prescription supersedes a former prescription issued by another physician**

As shown in the Community Use Case chapter, it may happen that a specialist prescribes new medications superseding an in progress renewable prescription formerly ordered by the GP for the treatment of a chronic disease. This brings a particular relationship between prescriptions considered as documents: Prescription 2 issued by physician B puts prescription 1 formerly issued by physician A in DISCONTINUED status.
This case also needs a service layer over the document sharing infrastructure.

11.4 La famille de profils IHE XDS pour les documents

The IT Infrastructure domain of IHE has produced a number of profiles that can prove useful for the sharing or the exchange of pharmacy objects as documents.
Some countries may choose to build on these infrastructure profiles. Other countries may choose to rely on a different non-IHE infrastructure, using for instance the Medical Records message set of HL7 v3.

11.4.1 XDS-b – Cross Enterprise Document Sharing

This profile provides an infrastructure for the storage/query/retrieval of prescriptions, pharmaceutical advices and dispenses as clinical documents. If a country or a region decides to rely on this profile, the repositories actors defined in this white paper will be represented in XDS by:

- One single Registry Actor: that will handle the metadata associated with all types of documents (prescriptions, pharmaceutical advices, dispenses)
- A set of Repository Actors that can be distributed or centralized, specialized per type of document or not.

The consumer actors presented in this white paper will be represented in XDS by as many Document Consumer Actors.
The "Prescription Placer", "Medication Dispenser", "Pharmaceutical Adviser" actors presented in this white paper will be combined with "Document Source" Actors.

11.4.2 XDM – Cross Enterprise Document Media Interchange

This profile may be useful for direct exchanges of documents in the community space. The profile supports both the exchange on a medium such as a CD or a USB key (carried by the patient to the care provider), or attached to an email (sent by one care provider to another).

11.4.3 NAV – Notification of Document Availability

This profile enables a system having published a document in a repository, to notify an intended recipient of the document availability. This could be used for instance by the pharmacist to notify the ordering physician with the pharmaceutical advice.

11.4.4 ebRIM and ebRS from ebXML OASIS standard

The XDS family profile leverages and constrains ebRIM and ebRS. These standards offer also capabilities to encode workflow behavior (e.g. status management), which might support some of the workflow requirements listed above.

11.5 Relevant semantic standards

- ICSR Framework Reference Model (prEN ISO 27953-1)
- ICSR Human pharmaceuticals (prEN ISO 27953-2)
  The standard specifies the data elements for transmission of Individual Case Safety Reports of adverse events/reactions that may occur upon the administration of one or more medicinal products to a patient, regardless of source and destination

- prEN ISO 11615: Data Elements and Structures for the Exchange of Regulated Medicinal Product Information for Drug Dictionaries (MPID)
  This standard provides a single structure for the data elements required for the exchange of information that uniquely and certainly identifies a medicinal product, wherever authorized for marketing. The project will further provide references to other standards and external terminological resources required to populate the data elements defined in this standard.

- prEN ISO 11616: Structures and Controlled Vocabularies for Pharmaceutical Product Identifiers (PhPIDs)

- prEN ISO 11238: Structures and Controlled Vocabularies for Ingredients (substances)
  This standard will adapt and adopt, or if necessary, develop structures and content of controlled vocabularies for ingredients that are used worldwide in medicinal products. Each ingredient will be defined at the molecular level and then assigned a randomly generated unique identifier. When an ingredient cannot be defined at the molecular level because of insufficient molecular information (e.g., polymers and botanicals), then it will be defined at the non-molecular level by a set of criteria that is deemed by experts to be

The consumer actors presented in this white paper will be represented in XDS by as many Document Consumer Actors.
The "Prescription Placer", "Medication Dispenser", "Pharmaceutical Adviser" actors presented in this white paper will be combined with "Document Source" Actors.

11.4.2 XDM – Cross Enterprise Document Media Interchange

This profile may be useful for direct exchanges of documents in the community space. The profile supports both the exchange on a medium such as a CD or a USB key (carried by the patient to the care provider), or attached to an email (sent by one care provider to another).

11.4.3 NAV – Notification of Document Availability

This profile enables a system having published a document in a repository, to notify an intended recipient of the document availability. This could be used for instance by the pharmacist to notify the ordering physician with the pharmaceutical advice.

11.4.4 ebRIM and ebRS from ebXML OASIS standard

The XDS family profile leverages and constrains ebRIM and ebRS. These standards offer also capabilities to encode workflow behavior (e.g. status management), which might support some of the workflow requirements listed above.

11.5 Normes et standards pour l'interopérabilité sémantique

- ICSR Framework Reference Model (prEN ISO 27953-1)
- ICSR Human pharmaceuticals (prEN ISO 27953-2)
  The standard specifies the data elements for transmission of Individual Case Safety Reports of adverse events/reactions that may occur upon the administration of one or more medicinal products to a patient, regardless of source and destination

- prEN ISO 11615: Data Elements and Structures for the Exchange of Regulated Medicinal Product Information for Drug Dictionaries (MPID)
  This standard provides a single structure for the data elements required for the exchange of information that uniquely and certainly identifies a medicinal product, wherever authorized for marketing. The project will further provide references to other standards and external terminological resources required to populate the data elements defined in this standard.

- prEN ISO 11616: Structures and Controlled Vocabularies for Pharmaceutical Product Identifiers (PhPIDs)

- prEN ISO 11238: Structures and Controlled Vocabularies for Ingredients (substances)
  This standard will adapt and adopt, or if necessary, develop structures and content of controlled vocabularies for ingredients that are used worldwide in medicinal products. Each ingredient will be defined at the molecular level and then assigned a randomly generated unique identifier. When an ingredient cannot be defined at the molecular level because of insufficient molecular information (e.g., polymers and botanicals), then it will be defined at the non-molecular level by a set of criteria that is deemed by experts to be

sufficient. Ingredients include, but are not necessarily limited to, chemicals, biologics (including vaccines, allergenic extracts, and botanicals), and select foods that are known to interact with drugs. Ingredients will include both the active ingredients and the inactive ingredients (excipients).

- prEN ISO 11239: Structures and Controlled Vocabularies for Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration
  This standard defines a controlled vocabulary of dosage forms, units of presentation and routes of administration in the specified domains. The controlled vocabulary is made available in a specified form.

- prEN ISO 11240: Structures and Controlled Vocabularies for Units of Measurement
  This international standard specifies information structures and a set of terms and term identifiers that can be used to communicate the units of strength for identification of medicinal products as well as structures and units as parts of medication dosing information, also called posology. This information is necessary to convey the amount of a medicinal product that has been taken or prescribed to be taken in a certain time interval. This Standard thus includes measurements of dose units and relevant dosing time information including intervals. This Standard is applicable for the pharmacovigilance reporting of Individual Case Safety Reports, but may also be applicable to other use cases within the regulatory and clinical areas. The scope includes both the vocabulary structure(s) and the content i.e. controlled terms themselves.

- prEN ISO 11595: Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results
  This controlled vocabulary will operate at the level of internationally recognized controlled vocabularies for laboratory test information for the reporting of laboratory results.

- ISO - Common glossary
  http://www2.dev.cred.ca/skmt_isowg8_dev/index.asp

- SNOMED CT published by IHTSDO
- LOINC, Regenstrief Institute
- NWIP Metadata Model and XML-interface specification for OID registries in healthcare
- NWIP Guidance for maintenance of object identifiers
- EMEA – EUTCT/Eudrapharm
- WHO-Terminologies (ATC, ICD-10, INN)
- HL7 vocabulary domains and value sets
- Most countries impose national standards or code sets for dispensable medications. The profiles built in the IHE Pharmacy domain will have to support these national code sets. Example : German Drug Codes, e.g. ASK, PZN

Note: The prefix prEN points ISO pre-standards for the EU, that do not have yet the normative status.

sufficient. Ingredients include, but are not necessarily limited to, chemicals, biologics (including vaccines, allergenic extracts, and botanicals), and select foods that are known to interact with drugs. Ingredients will include both the active ingredients and the inactive ingredients (excipients).

- prEN ISO 11239: Structures and Controlled Vocabularies for Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration
  This standard defines a controlled vocabulary of dosage forms, units of presentation and routes of administration in the specified domains. The controlled vocabulary is made available in a specified form.

- prEN ISO 11240: Structures and Controlled Vocabularies for Units of Measurement
  This international standard specifies information structures and a set of terms and term identifiers that can be used to communicate the units of strength for identification of medicinal products as well as structures and units as parts of medication dosing information, also called posology. This information is necessary to convey the amount of a medicinal product that has been taken or prescribed to be taken in a certain time interval. This Standard thus includes measurements of dose units and relevant dosing time information including intervals. This Standard is applicable for the pharmacovigilance reporting of Individual Case Safety Reports, but may also be applicable to other use cases within the regulatory and clinical areas. The scope includes both the vocabulary structure(s) and the content i.e. controlled terms themselves.

- prEN ISO 11595: Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results
  This controlled vocabulary will operate at the level of internationally recognized controlled vocabularies for laboratory test information for the reporting of laboratory results.

- ISO - Common glossary
  http://www2.dev.cred.ca/skmt_isowg8_dev/index.asp

- SNOMED CT published by IHTSDO
- LOINC, Regenstrief Institute
- NWIP Metadata Model and XML-interface specification for OID registries in healthcare
- NWIP Guidance for maintenance of object identifiers
- EMEA – EUTCT/Eudrapharm
- WHO-Terminologies (ATC, ICD-10, INN)
- HL7 vocabulary domains and value sets
- Most countries impose national standards or code sets for dispensable medications. The profiles built in the IHE Pharmacy domain will have to support these national code sets. Example : German Drug Codes, e.g. ASK, PZN

Note: The prefix prEN points ISO pre-standards for the EU, that do not have yet the normative status.

11.6 NCPDP

http://www.ncpdp.org/
Local standard designed for the community pharmacy workflow in the USA.

11.7 PN13 – SIPh2_v2

Local standard designed for hospital pharmacy workflow in France. This standard specifies a set of 6 xml encoded messages:

- Prescription
- Pharmaceutical analysis report
- 3 flavors of Dispense (dispense for one patient, grouped dispense, non-patient related distribution)
- Medication administration report

The documentation in French is made available to the editors members of the SIPh community.

11.8 Recommendations

Given the use cases presented in this white paper, the following statements can be made:

- The hospital pharmacy workflow needs messages or services. In 2009, and probably in 2010, the only international standard available for this workflow is HL7 v2.x.

- In case messages are chosen to handle the community workflow, the two candidates are HL7 v2 and HL7 v3 messages. The V2.x message pharmacy treatment message set is available and stable. The V3 Pharmacy message set is expected to reach normative status by January 2010. It is explicitly developed for the community space in the rigorous frame of the HL7 Development Framework, and has captured international use cases refined by early adopters such as Canada, NL and UK. It is therefore likely to offer the best coverage for the requirements of the community use cases.

- A number of countries have expressed a requirement for persistency of pharmacy treatment content, legally authenticated in community shared repositories. One way to fulfill such requirements is to publish these contents as electronic documents, based on the HL7 CDA standard. The document sharing infrastructure can leverage IHE XDS or other standards such as the Medical Records HL7 v3 message set, depending upon national infrastructure choices.

- If a document infrastructure is in place, the community pharmacy workflow could also leverage it. For that purpose, a number of additional features (e.g. status management, document linking) need messages or services around the document repositories. ebXML is one of the standards to investigate for these additional features.

11.6 NCPDP

http://www.ncpdp.org/
Local standard designed for the community pharmacy workflow in the USA.

11.7 PN13 SIPh2 v2

Local standard designed for hospital pharmacy workflow in France. This standard specifies a set of 6 xml encoded messages:

- Prescription
- Pharmaceutical analysis report
- 3 flavors of Dispense (dispense for one patient, grouped dispense, non-patient related distribution)
- Medication administration report

The documentation in French is made available to the editors members of the SIPh community.

11.8 Recommendations

Given the use cases presented in this white paper, the following statements can be made:

- The hospital pharmacy workflow needs messages or services. In 2009, and probably in 2010, the only international standard available for this workflow is HL7 v2.x.

- In case messages are chosen to handle the community workflow, the two candidates are HL7 v2 and HL7 v3 messages. The V2.x message pharmacy treatment message set is available and stable. The V3 Pharmacy message set is expected to reach normative status by January 2010. It is explicitly developed for the community space in the rigorous frame of the HL7 Development Framework, and has captured international use cases refined by early adopters such as Canada, NL and UK. It is therefore likely to offer the best coverage for the requirements of the community use cases.

- A number of countries have expressed a requirement for persistency of pharmacy treatment content, legally authenticated in community shared repositories. One way to fulfill such requirements is to publish these contents as electronic documents, based on the HL7 CDA standard. The document sharing infrastructure can leverage IHE XDS or other standards such as the Medical Records HL7 v3 message set, depending upon national infrastructure choices.

- If a document infrastructure is in place, the community pharmacy workflow could also leverage it. For that purpose, a number of additional features (e.g. status management, document linking) need messages or services around the document repositories. ebXML is one of the standards to investigate for these additional features.

12 Examples of deployment architecture in Pharmacy domain

12.1 Community Pharmacy

12.1.1 Publish & pull model

In the publish & pull architecture prescriptions and dispensed medication are managed by central repositories. These repositories cover the whole jurisdiction of the health system, either nationally or regionally. This means that the health system itself is the main responsible for providing access to prescriptions and dispensed medication.

Thanks to this feature, any practitioner and pharmacist working for the health system and serving the patient can connect to these repositories to retrieve and update data according to their user profiles. Therefore, patients may choose any community pharmacy for their medication to be dispensed.

The information on the dispensed medication is managed centrally so that pharmacists can always retrieve the comprehensive medication record of the patient which contains medicines (recently) dispensed to the patient and check for interactions with active prescriptions.

Approaches

Providing that the point of sale software of the pharmacy (medication dispenser and pharmaceutical adviser) is not directly connected with the aforementioned repositories (prescription repository, pharmaceutical advice repository and dispensed medication repository), the regional health system provides the means for pharmacists and physicians to get prescriptions and dispensed medication and pharmaceutical advice by means of the “prescription & pharmaceutical advice consumer” and “dispensed medication consumer”.

The following scheme represents an implementation based on this alternative where repositories and consumers are provided by the health system and, therefore, are centralized applications and databases:

- Prescription repository
- Dispensed medication repository
- Pharmaceutical advice repository
- Prescription & pharmaceutical advice consumer
- Dispensed medication consumer

12 Exemples d'architectures possibles pour les déploiements

12.1 Community Pharmacy

12.1.1 Publish & pull model

In the publish & pull architecture prescriptions and dispensed medication are managed by central repositories. These repositories cover the whole jurisdiction of the health system, either nationally or regionally. This means that the health system itself is the main responsible for providing access to prescriptions and dispensed medication.

Thanks to this feature, any practitioner and pharmacist working for the health system and serving the patient can connect to these repositories to retrieve and update data according to their user profiles. Therefore, patients may choose any community pharmacy for their medication to be dispensed.

The information on the dispensed medication is managed centrally so that pharmacists can always retrieve the comprehensive medication record of the patient which contains medicines (recently) dispensed to the patient and check for interactions with active prescriptions.

Approaches

Providing that the point of sale software of the pharmacy (medication dispenser and pharmaceutical adviser) is not directly connected with the aforementioned repositories (prescription repository, pharmaceutical advice repository and dispensed medication repository), the regional health system provides the means for pharmacists and physicians to get prescriptions and dispensed medication and pharmaceutical advice by means of the "prescription & pharmaceutical advice consumer" and "dispensed medication consumer".

The following scheme represents an implementation based on this alternative where repositories and consumers are provided by the health system and, therefore, are centralized applications and databases:

- Prescription repository
- Dispensed medication repository
- Pharmaceutical advice repository
- Prescription & pharmaceutical advice consumer
- Dispensed medication consumer

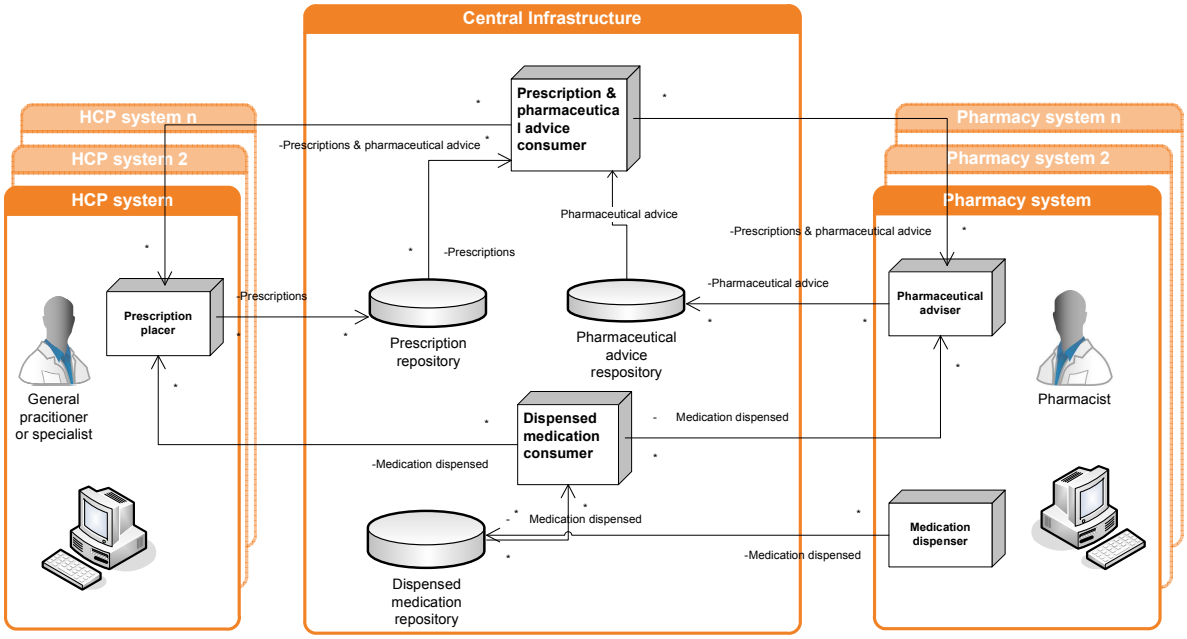


Figure 12.1: Community Pharmacy – Publish & pull model – centralized model

The prescription placer may be implemented in a regional/national electronic health record, a hospital information system (for outpatient practitioners) or the clinicians' electronic medical record of a health centre/clinic. Usually, the medication dispenser is implemented in the point of sale software of a pharmacy which may provide also the features for pharmaceutical advice.

The prescription repository, pharmaceutical advice repository and dispensed medication repository are centralized and are managed by the health system itself and are accessible from any pharmacy, health centre and hospital of the health system. Prescriptions and medication already dispensed are, therefore, centrally accessed.

In this model it is assumed that pharmacies use a middleware to convey dispensed medication information and pharmaceutical advice to repositories. Since this middleware only reroutes and does not transform data, is not considered an actor in the e-pharmacy domain.

An alternative to the previous model is an architecture where the physician's software and pharmacist's software is directly linked to repositories so that the so-called consumer actors are integrated in other information systems.

The following diagram depicts this alternative implementation where consumers are embedded into the practitioner's and pharmacist's software.

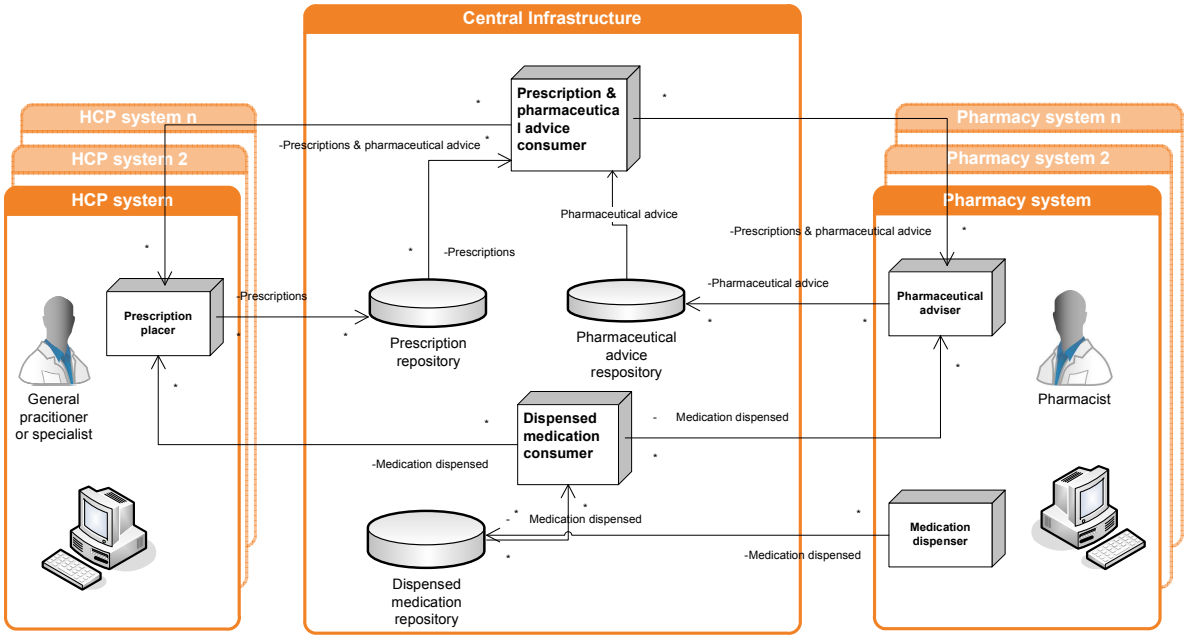


Figure 12.1: Community Pharmacy – Publish & pull model – centralized model

The prescription placer may be implemented in a regional/national electronic health record, a hospital information system (for outpatient practitioners) or the clinicians' electronic medical record of a health centre/clinic. Usually, the medication dispenser is implemented in the point of sale software of a pharmacy which may provide also the features for pharmaceutical advice.

The prescription repository, pharmaceutical advice repository and dispensed medication repository are centralized and are managed by the health system itself and are accessible from any pharmacy, health centre and hospital of the health system. Prescriptions and medication already dispensed are, therefore, centrally accessed.

In this model it is assumed that pharmacies use a middleware to convey dispensed medication information and pharmaceutical advice to repositories. Since this middleware only reroutes and does not transform data, is not considered an actor in the e-pharmacy domain.

An alternative to the previous model is an architecture where the physician's software and pharmacist's software is directly linked to repositories so that the so-called consumer actors are integrated in other information systems.

The following diagram depicts this alternative implementation where consumers are embedded into the practitioner's and pharmacist's software.

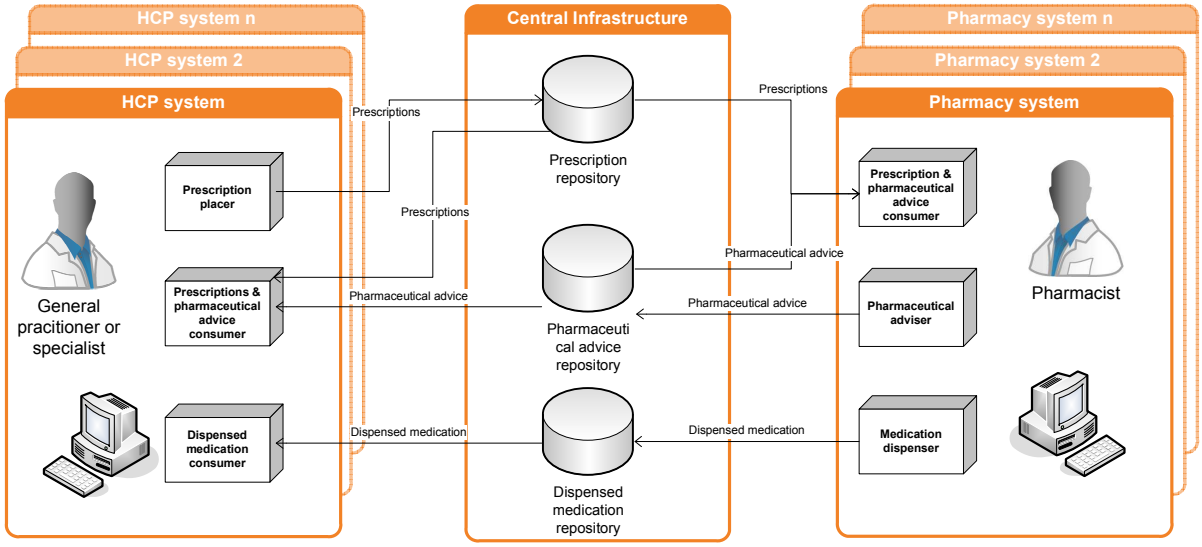


Figure 12.2: Community Pharmacy – Publish & pull model – federated model

12.1.2 Decentralized architecture

In a decentralized architecture prescriptions and dispense data are stored in the database of the system that generates and/or registers them. These databases cover the business process of the department, organization, or group of organizations that use the system. Each (healthcare) organization is responsible for the management of its own prescriptions and dispense data.

This means that practitioners and pharmacists will need to have a way to access the data in other systems, and that they need to make their data available to those other systems. To this end, there needs to be an infrastructure that connects the systems, either on a regional, national, or international scale. This infrastructure may contain a central component (hub, broker) that acts as an index and/or intermediary. This component does not store (copies of) data, but might store references to data, being informed by the decentral systems on the existence of data as they are produced.

The mechanism for retrieving medication history is based on queries to the source systems. These queries might be routed or combined by an intermediary component, but the result set is always drawn (in real time) from the source database(s) and presented to the querying user.

The scheme functionally is equivalent to the schemes in the previous paragraph, with the only exception that the central repositories (prescription, dispense and pharmaceutical advice) are now

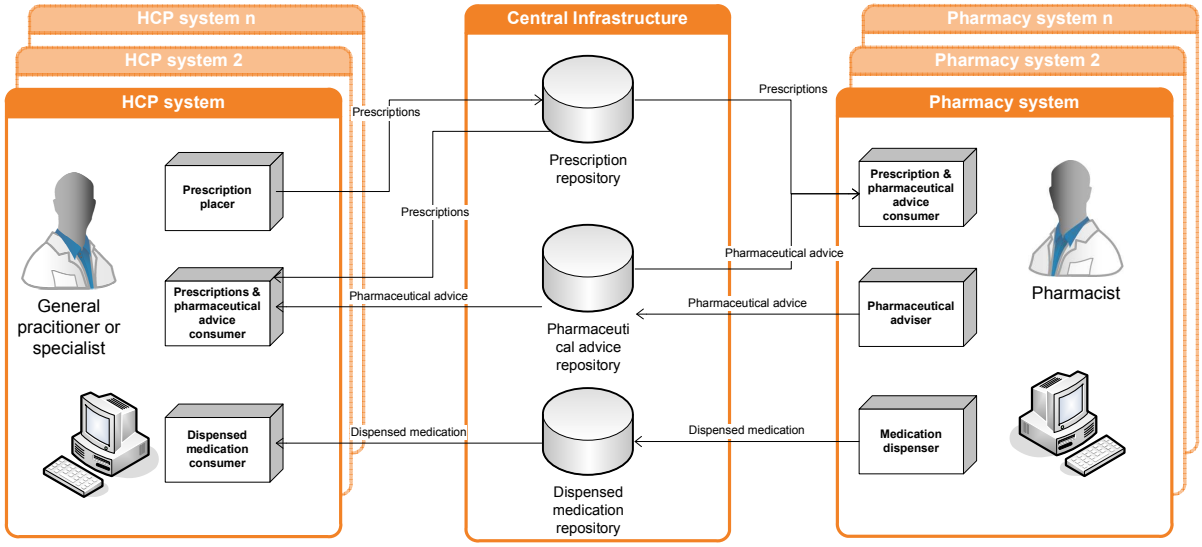


Figure 12.2: Community Pharmacy – Publish & pull model – federated model

12.1.2 Decentralized architecture

In a decentralized architecture prescriptions and dispense data are stored in the database of the system that generates and/or registers them. These databases cover the business process of the department, organization, or group of organizations that use the system. Each (healthcare) organization is responsible for the management of its own prescriptions and dispense data.

This means that practitioners and pharmacists will need to have a way to access the data in other systems, and that they need to make their data available to those other systems. To this end, there needs to be an infrastructure that connects the systems, either on a regional, national, or international scale. This infrastructure may contain a central component (hub, broker) that acts as an index and/or intermediary. This component does not store (copies of) data, but might store references to data, being informed by the decentral systems on the existence of data as they are produced.

The mechanism for retrieving medication history is based on queries to the source systems. These queries might be routed or combined by an intermediary component, but the result set is always drawn (in real time) from the source database(s) and presented to the querying user.

The scheme functionally is equivalent to the schemes in the previous paragraph, with the only exception that the central repositories (prescription, dispense and pharmaceutical advice) are now

central registries (or elements in a central registry) that act as brokers to give access to the decentralized repositories, which are within the systems of the connected HCP's (pharmacy, GP, specialist).

As a matter of fact, the repositories in the previous paragraph contain a registry function and a repository function combined, and the only difference in the decentralized approach as compared to the centralized approach lies in the fact that registry and repository functions are split, allowing more repositories under one registry.

Figure 12.3 below shows an example of such a decentralized architecture. In this example the repositories are decentral, one central registry exists for all information elements (prescription, pharmaceutical advice and dispensed medication information) and the clients (consumers) are decentral as well.

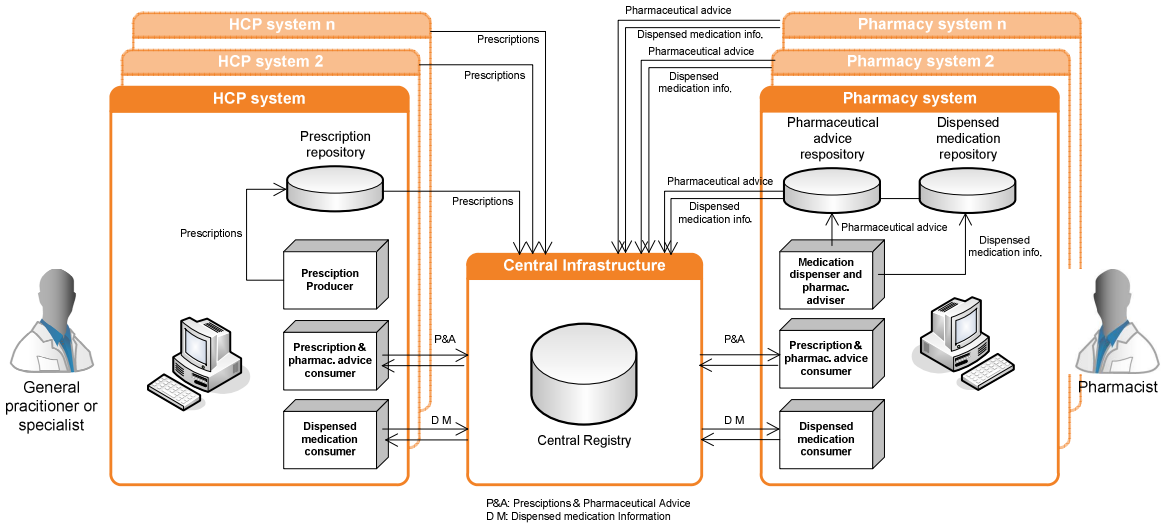


Figure 12.3: Community Pharmacy – Publish & pull model – de-centralised model

12.2 Hospital

The intra-hospital medication workflow involves the information systems used by:

a. The clinicians in the wards who prescribe medications and record the effects of treatments: The system implements the hospital's Electronic Medical Record (EMR)
b. The nurses in the wards who plan and perform the administration of medications to their patients. The system implements the hospital's Electronic Care Record (ECR).
c. The pharmacists who analyze new prescriptions, notify their pharmaceutical advices to the prescribers, manage medication dispenses and track medication administration. Their system is the pharmacy information system.

These 3 systems: EMR, ECR, pharmacy information system, may be independent or combined in any of the following combinations:

a. 3 independent systems EMR, ECR, Pharmacy system, exchanging data with one another.

central registries (or elements in a central registry) that act as brokers to give access to the decentralized repositories, which are within the systems of the connected HCP's (pharmacy, GP, specialist).

As a matter of fact, the repositories in the previous paragraph contain a registry function and a repository function combined, and the only difference in the decentralized approach as compared to the centralized approach lies in the fact that registry and repository functions are split, allowing more repositories under one registry.

Figure 12.3 below shows an example of such a decentralized architecture. In this example the repositories are decentral, one central registry exists for all information elements (prescription, pharmaceutical advice and dispensed medication information) and the clients (consumers) are decentral as well.

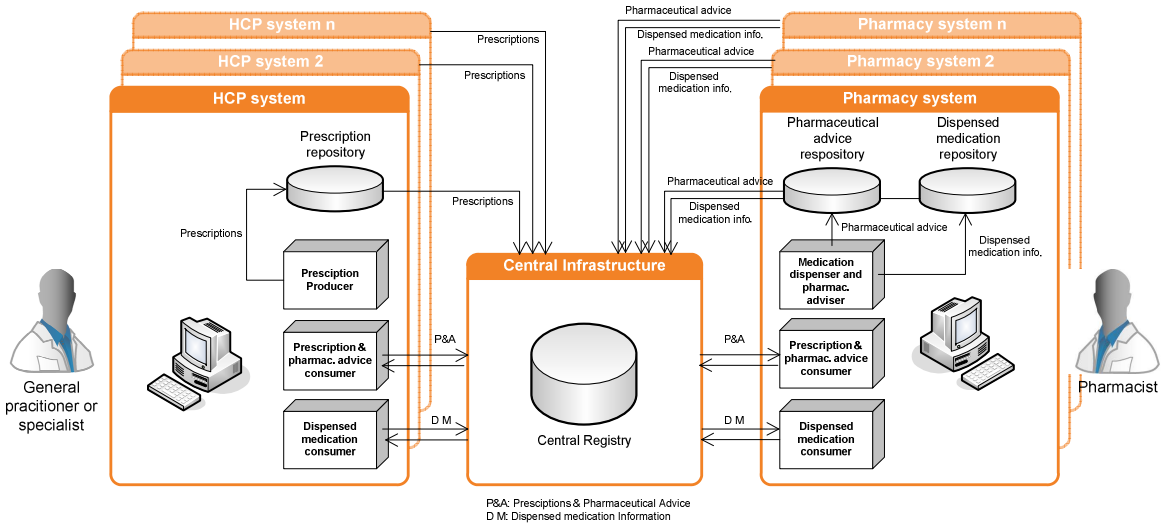


Figure 12.3: Community Pharmacy – Publish & pull model – de-centralised model

12.2 Hôpital

Dans le circuit du médicament intrahospitalier, sont impliquée les solutions informatiques utilisées par :

a. Les médecins dans les services qui prescrivent des médicaments et qui enregistrent les effets des traitements : la solution implémente le dossier patient.
b. Les infirmières dans les services qui font les plans d'administration et qui administrent les médicaments à leurs patients. La solution implémente la gestion des soins.
c. Les pharmaciens qui analysent les nouvelles prescriptions, notifient les avis pharmaceutiques aux prescripteurs, assurent la délivrance des médicaments et le suivi de l'administration des médicaments. Leur solution est la gestion de la pharmacie.

Ces 3 solutions : dossier patient, gestion des soins, gestion de la pharmacie, peuvent être indépendantes ou combinées de différentes manières :

a. 3 solutions indépendantes de dossier patient, gestion des soins, et gestion de la pharmacie qui échangent des données entre elles.

b. One Patient Record combining EMR+ECR, exchanging data with the pharmacy system.
c. One holistic hospital care system combining EMR+ECR+Pharmacy system.

In any of the above combinations, the hospital professionals (physicians, nurses, clinicians, pharmacists, technicians) are assumed to have a common access through their system, to the hospital master data (e.g. Patient identification, patient encounters and movements, personnel directory, organization directory (building, ward, care unit), medications catalog, clinical terminologies, diseases classifications…)

Moreover, in any of the above combinations, the hospital prescribers and pharmacists are assumed to have access to the community shared medication repositories (prescriptions, pharmaceutical advices, medication dispenses), to be able to fulfill community prescriptions and register the corresponding dispenses, as well as to publish discharge prescriptions to be fulfilled by the community.

Another variation is induced by the increasing cooperation between the hospitals of a territory around a reference facility, and the sharing of some of its resources. For instance in a territory, the pharmacy of a reference hospital might serve the physicians, clinicians and nurses of a set of related satellite hospitals.

The architectures supporting the above combinations are depicted in the figures below, which all assume a common repository for community, containing prescriptions, advices and dispenses.

12.2.2 Standalone hospital with 3 independent systems

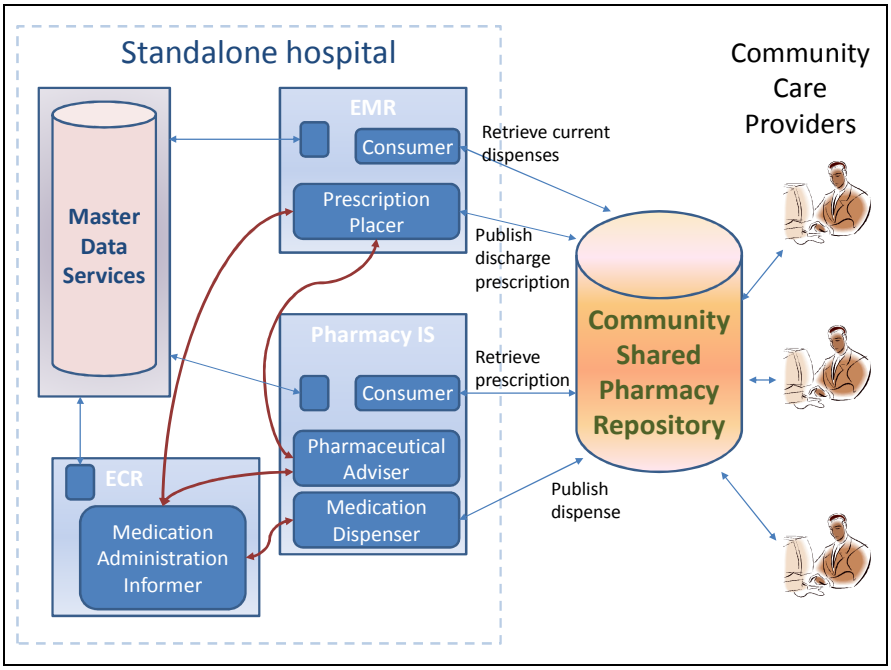


Figure 12.4: Standalone hospital with 3 independent systems

b. Un dossier patient qui intègre la gestion des soins et qui échange des données avec la gestion de la pharmacie.
c. Un système d'information hospitalier totalement intégré qui combine le dossier patient, la gestion des soins et la gestion de la pharmacie.

Quelle que soit la manière de combiner les solutions, les hospitaliers (médecins, infirmières, cliniciens, pharmaciens, préparateurs) sont censés avoir tous un accès commun, au travers des solutions qu'ils utilisent, aux données de référence de l'hôpital (comme l'identification des patients, la gestion des mouvements, le serveur de structures (bâtiments, services, unités de soins), la codification des médicaments, les terminologies médicales, la codification des diagnostics…).

En outre, quelle que soit la manière de combiner les solutions, les prescripteurs et les pharmaciens de l'hôpital sont censés avoir accès aux entrepôts de données partagés de la médecine de ville (prescriptions, avis pharmaceutiques, comptes-rendus de délivrance), pour pouvoir satisfaire des prescriptions de ville et enregistrer les délivrances correspondantes, ainsi que pour pouvoir publier des prescriptions de sortie qui seront satisfaites par les pharmacies de ville.

Une autre variante est induite par le développement de la coopération entre les hôpitaux au sein d'un territoire autour d'un établissement de référence, et le partage de certaines de ses ressources. Par exemple au sein d'un territoire la pharmacie d'un hôpital de référence peut servir les médecins et les soignants d'un ensemble d'hôpitaux satellites.

Les différentes architectures qui supportent les différentes manières de combiner les solutions sont décrites dans les figures ci-dessous, qui toutes supposent un entrepôt commun pour la médecine de ville, avec les prescriptions, les avis pharmaceutiques et les comptes-rendus de délivrance.

12.2.2 Un seul hôpital avec trois solutions indépendantes

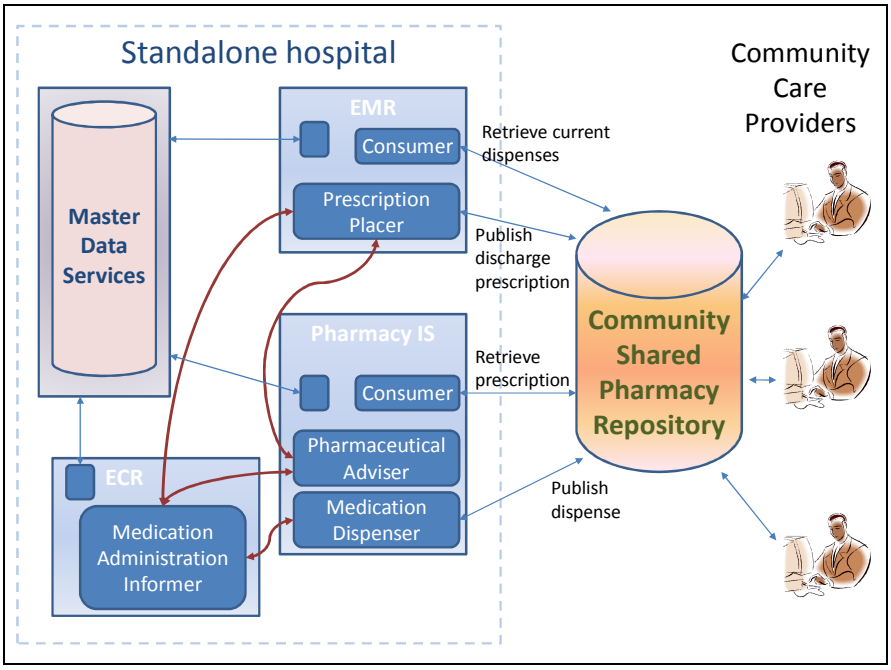


Figure 12.4 : Un seul hôpital avec trois solutions indépendantes

Comments:

The dark red bidirectional arrows represent the message flows between the hospital systems, supporting prescription, pharmaceutical analysis, dispense and administration.

One drawback of this architecture is that the pharmacy system performing the pharmaceutical analysis does not have direct access to the patient EMR, and therefore can miss some piece of information critical to that process. To eliminate this drawback the prescription message must provide rich clinical information extracted from the EMR (e.g. allergies, lab results, history, family history …)

Another drawback is the heaviness of the message flows: Each system has to synchronize its steps in the workflow through message exchanges with the two others.

12.2.3 Standalone hospital with combined EMR+ECR

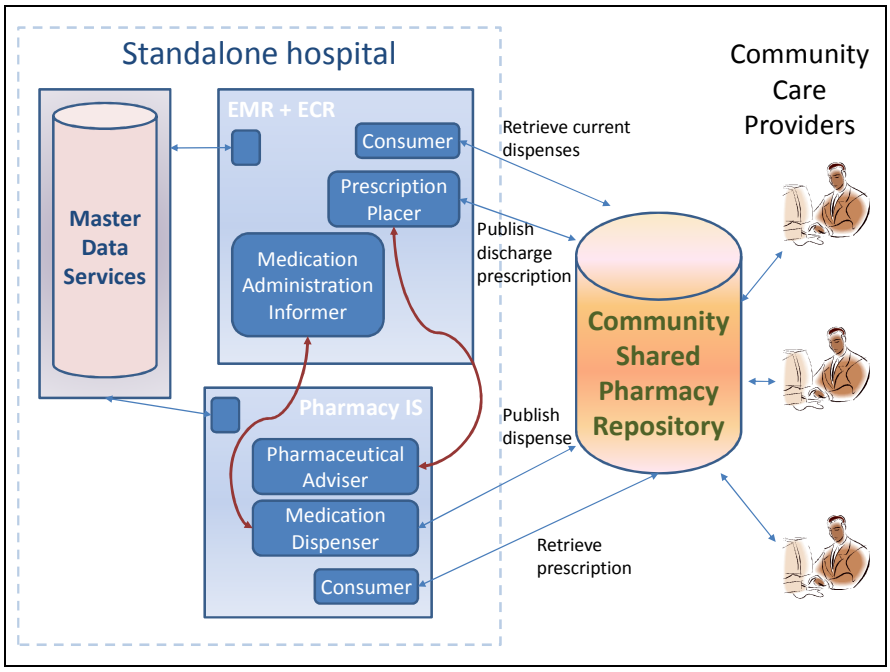


Figure 12.5: Standalone hospital with combined EMR+ECR

Comments:

The dark red bidirectional arrows represent the message flows between the hospital systems, supporting prescription, pharmaceutical analysis, dispense and administration.

In this architecture also, the pharmacy system performing the pharmaceutical analysis does not have direct access to the patient EMR, and therefore can miss some piece of information critical to that process. To eliminate this drawback the prescription message must provide rich clinical information extracted from the EMR (e.g. allergies, lab results, history, family history …)

Remarques :

Les flèches bidirectionnelles rouge foncé représentent les échanges de messages entre les solutions déployées dans l'hôpital, qui supportent la prescription, l'analyse pharmaceutique, la délivrance et l'administration des médicaments.

Un inconvénient de cette architecture est que la gestion de la pharmacie dans laquelle on fait l'analyse pharmaceutique n'a pas d'accès direct au dossier patient : certains éléments d'information essentiels pour ce processus peuvent manquer. Pour éliminer cet inconvénient le message de prescription doit fournir des informations cliniques riches, extraites du dossier patient (comme les allergies, les résultats de laboratoire, l'historique du patient, les antécédents familiaux…).

Un autre inconvénient est la lourdeur des échanges de messages : à chaque étape du workflow chacune des solutions doit échanger des messages avec les deux autres pour se synchroniser.

12.2.3 Un seul hôpital où le dossier patient intègre la gestion des soins

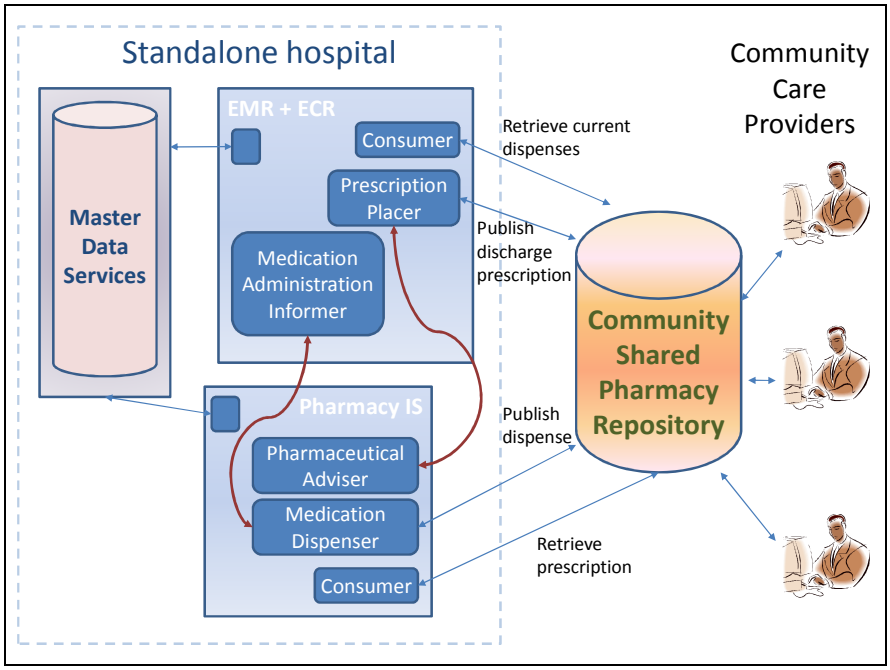


Figure 12.5 : Un seul hôpital où le dossier patient intègre la gestion des soins

Remarques :

Les flèches bidirectionnelles rouge foncé représentent les échanges de messages entre les solutions déployées dans l'hôpital, qui supportent la prescription, l'analyse pharmaceutique, la délivrance et l'administration des médicaments.

Dans cette architecture aussi, la gestion de la pharmacie dans laquelle on fait l'analyse pharmaceutique n'a pas d'accès direct au dossier patient : certains éléments d'information essentiels pour ce processus peuvent manquer. Pour éliminer cet inconvénient le message de prescription doit fournir des informations cliniques riches, extraites du dossier patient (comme les allergies, les résultats de laboratoire, l'historique du patient, les antécédents familiaux…).

12.2.3 Standalone hospital with holistic information system

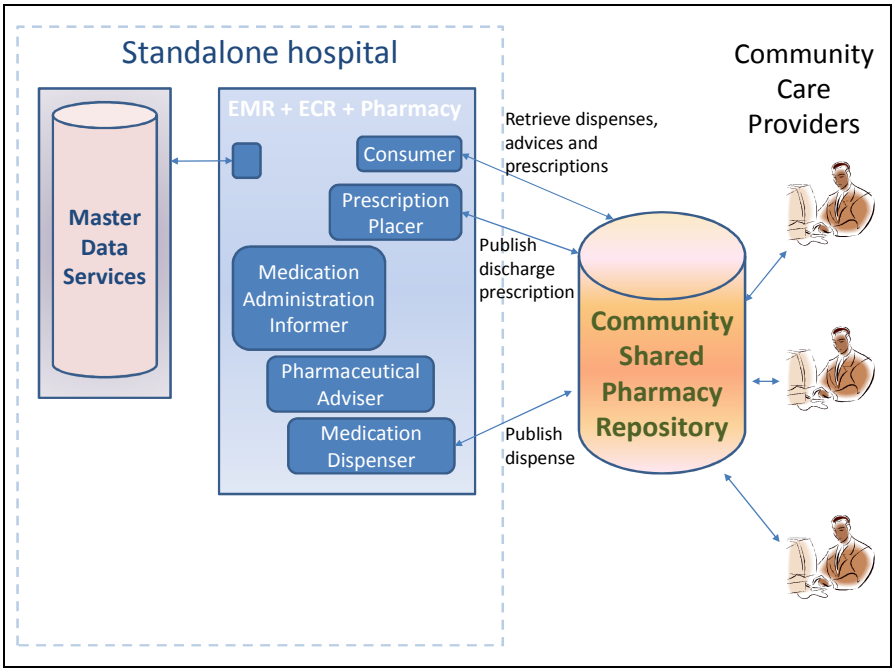


Figure 12.6: Standalone hospital with holistic information system

Comments:

In this architecture one single systems holds all hospital actors, therefore no messages are needed to support the internal hospital pharmacy workflow. The flows that persist are the exchanges with the community repositories.

12.2.3 Un seul hôpital avec un système d'information intégré

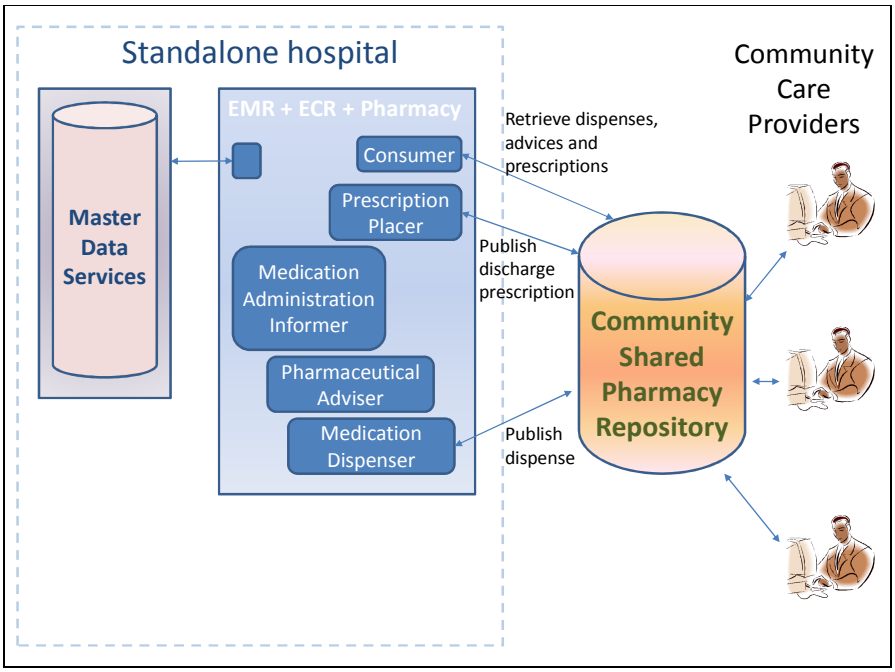


Figure 12.6 : Un seul hôpital avec un système d'information intégré

Remarques :

Dans cette architecture, une solution unique rassemble tous les acteurs de l'hôpital : il n'y a pas besoin de messages pour supporter le circuit du médicament intrahospitalier. Seuls persistent les échanges avec les entrepôts de données de la médecine de ville.

12.2.4 Central pharmacy shared by a set of hospitals

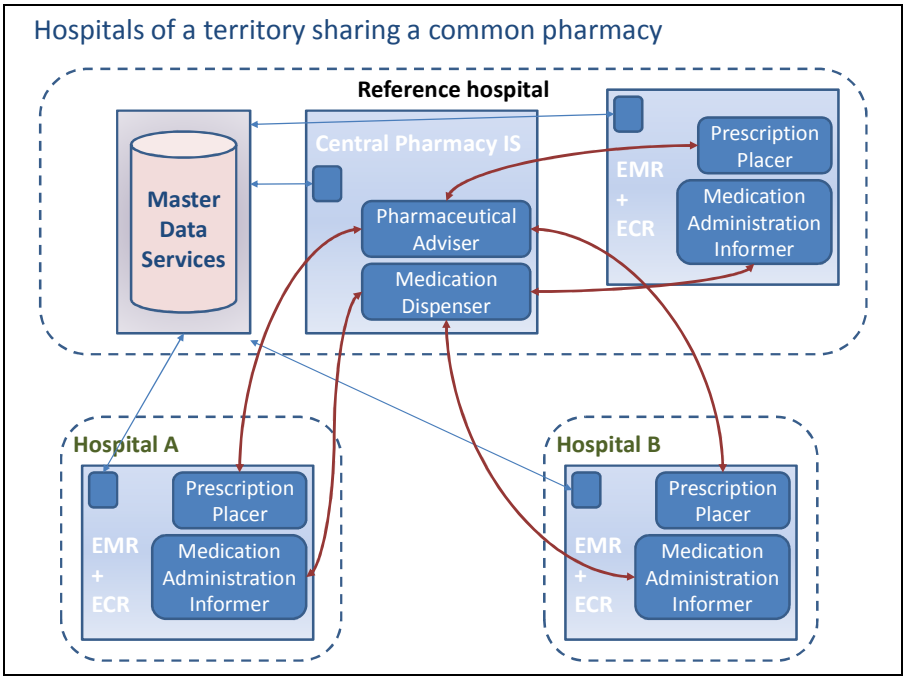


Figure 12.7: Central pharmacy shared by a set of hospitals

Comments:

The reference hospital holding the common pharmacy is also assumed to hold the common master data shared by the hospital of the territory.

The exchanges with the community outside the territory are not shown.

12.2.4 Une pharmacie centrale partagée par un ensemble d'hôpitaux

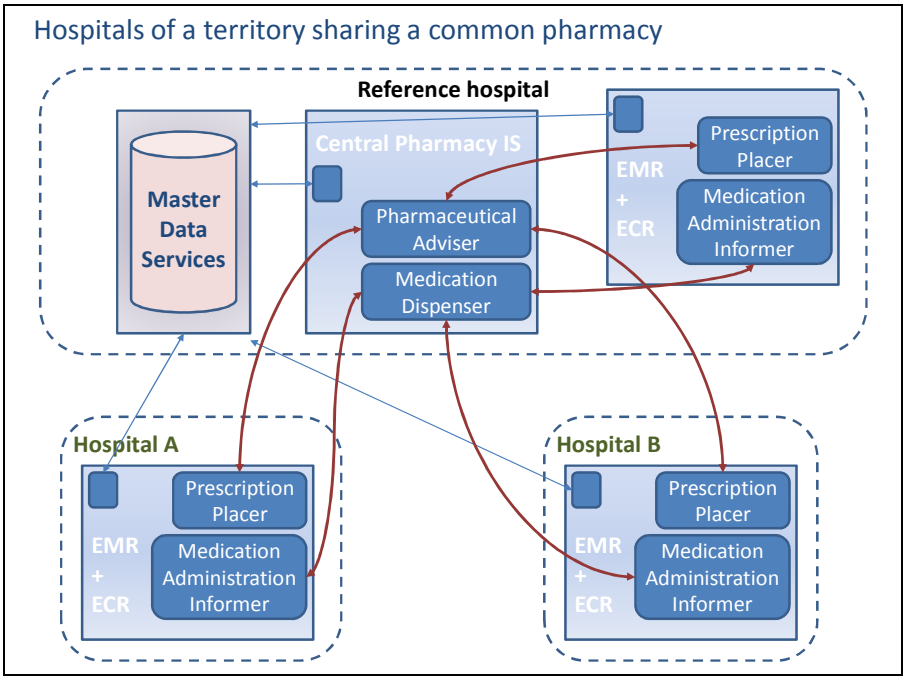


Figure 12.7 : Une pharmacie centrale partagée par un ensemble d'hôpitaux

Remarques :

L'hôpital de référence qui tient la pharmacie commune est aussi censé tenir les données de référence communes partagées par les hôpitaux du territoire.

Les échanges avec la médecine de ville au-delà du territoire ne sont pas représentés.

13 References

- IHE ITI Technical Framework vol1: http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_4_0_Vol1_FT_2007_08_22.pdf
- Laboratory Technical Framework: http://www.ihe.net/Technical_Framework/upload/ihe_lab_TF_rel2_1-Vol-3_FT_2008-08-08.pdf
- XDS Metadata versioning- white paper: ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr6-2008-2009/Technical_Cmte/Whitepaper_Work/Metadata_Versioning/metadata_versioning_05.doc

13 References

- IHE ITI Technical Framework vol1: http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_4_0_Vol1_FT_2007_08_22.pdf
- Laboratory Technical Framework: http://www.ihe.net/Technical_Framework/upload/ihe_lab_TF_rel2_1-Vol-3_FT_2008-08-08.pdf
- XDS Metadata versioning- white paper: ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr6-2008-2009/Technical_Cmte/Whitepaper_Work/Metadata_Versioning/metadata_versioning_05.doc