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# eHealth Suisse

# eMedication in the context of the Electronic Patient Record

Implementation Concept

Approved version of the working group

Bern, March 23, 2020

ehealthsuisse
Kompetenz- und Koordinationsstelle von Bund und Kantonen
Centre de compétences et de coordination de la Confédération et des cantons
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Zweck und Positionierung dieses Dokuments

Implementierungskonzept für einen nationalen eMedication Service: Überprüfung bestehender Lösungen, Untersuchung möglicher Architekturen in Bezug auf die EPD-Infrastruktur und Empfehlung einer Architektur, die die Anforderungen erfüllt und gleichzeitig die Auswirkungen auf die EPD-Gesetzgebung minimiert.

Im Interesse einer besseren Lesbarkeit wird auf die konsequente gemeinsame Nennung der männlichen und weiblichen Form verzichtet. Wo nicht anders angegeben, sind immer beide Geschlechter gemeint.

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# Summary


Summary

The continuity of medication is of primary importance for patient safety: indeed it is recognized that a significant percentage[1] of emergency admissions in hospitals is due to medication "problems" – wrong intake, wrong posology, incompatible medications, etc. Medication anamnesis is also a key element during the admission phase into a hospital or any other medical structure. Considering that at least two sources should be taken into account, having at disposal an as complete and accurate as possible list of current and possibly past medication is a key advantage.

While ePrescription addresses the logistic aspects related to prescription and dispense – including possible actions against falsified prescriptions - optimal medication anamnesis benefits more from medication lists (e.g. active medications, medication history).

The new EPR law addresses the problem of the access to the information by the patient and the sharing of this information with his/her healthcare providers. As such it provides key founding functionality like document sharing, access control, stakeholders' identification, logging and traceability. However high expectations are placed on value added services, considering that the full power of the EPR will be revealed by such services. Among the EPR related services is one considered often as a "killing application": the shared medication treatment plan. Indeed many care processes do need an as exhaustive as possible medication overview, with important benefits for the **quality of therapeutic processes and the patient safety**. The expectations of health professionals are high in **improving their work** with regards to medication management thanks to the EPR environment. However the current architecture of the EPR-XDS.b Infrastructure do not enable the secured and easy access of an updated, accurate patient medication list and its history. Moreover, any on-the-fly[2] consolidation of all the documents in the EPR-XDS.b Infrastructures may suffer from performance issues for bringing the actual view of the medication to the patient and his or her authorized professionals as the content may come from different communities.

Purpose

It is important to note that the purpose the eMedication tools proposed in this report is NOT to increase surveillance and traceability to blame patient or professionals or to establish some surveillance of medications prescriptions, but rather to support them for a better and safer care.

eMedication Service Concept

This eMedication Service Concept explores the feasibility of implementing a shared medication treatment plan service on top of EPR communities. The proposed service aims at supporting eMedication processes by providing a global and homogeneous access to all eMedication information (plans, prescriptions, dispenses). The service also aims at providing specific lists containing aggregated information useful for patients and healthcare providers, like e.g. a treatment card or a prescription with all related information (original planning, dispenses already occurred, etc.).


[1] Recent studies are mentioning a percentage around 8% – 10%.
[2] I.e. in real time.

Several architectures are proposed, all relying on the key components of EPR-XDS.b Infrastructures for implementing the value added service aiming at supporting eMedication including ePrescription and medication anamnesis. Advantages and drawbacks of each are presented as well as the impact on the current ordinances if one has to be implemented. Discussions of the various proposals benefitted from lessons learned from experiments realized in cantons of Geneva and Vaud (shared medication treatment plan, feed-back from patients and healthcare professionals) and cantons St-Gallen and Aargau (eMediplan). Specific feed-back from patients used to EPR services was also collected.

Summary of Recommendations for a smooth integration and use are provided at the end of the report. A consensus was reached by the group resulting in the recommendation of one of the presented architecture. The recommended architecture has been selected for several reasons;

- It can be implemented with minor extensions of EPR-XDS.b Infrastructures;
- It fulfils the key requirements;
- It is compatible with the current ordinances;
- It scales up and may serve as a reference model for other value added services.

The selected architecture (3.2, described in section 6.3.3) introduces an eMedication Service which has the following key characteristics:

- The eMedication Service is split into two elements: the eMedication primary Aggregator and the eMedication Repository;
- The eMedication Service is patient centric, i.e. all eMedication documents of a given patient are stored into one unique eMedication Repository;
- The eMedication Repository belongs to the eMedication Service of the reference community of the patient;
- Every community offers an eMedication Service;
- The eMedication Service of a reference community implements all functionality while the eMedication Service of a community implements only part of the functionality and acts as a proxy towards eMedication Services of reference communities. There is no eMedication Repository in non-reference communities.

Considering the importance and the added value of supporting eMedication in the global healthcare process, it is proposed that the eMedication Service will become an integral part of the EPR.

Like EPR-XDS.b Infrastructures, the eMedication service stores sensitive data: it is therefore also recommended that the eMedication service is included into the EPR certification perimeter. Indeed it would not be coherent to distinguish between constraints and levels of security set for EPR-XDS.b Infrastructures' data from the constraints and levels of security set for eMedication data.

# 1 Change log

Change log

**April 4th, 2019 – version 0.1**

- Initial structure

**April 7th, 2019 – version 0.2**

- eHealth-Suisse template

**May 1st, 2019 – version 0.3**

- Initial draft chapters 2,3, 4 and 5

**May 7th, 2019 – version 0.5**

- Clarifications & complements in chapters 4 and 5

**May 14th, 2019 – version 0.6**

- Integration of FHIR description & inclusion of Oliver Egger's comments
- Integration of ABILIS description

**May 31st, 2019 – version 0.7**

- Focus on 1-n aggregator – reference community
- Include Abilis, eMediplan and Dossier pharmaceutique descriptions
- Integration of comments from Swiss Post + telco
- Major revision & refactoring

**June 30, 2019 – version 0.8**

- Restructuring of the table of content, need for inclusion of all scenarios

**July 17, 2019 – version 0.9**

- Reworked version with 4 scenarios

**August 25, 2019 – version 0.10**

- Include revision & comments from Claudine Leuthold
- Include revised text for eMediplan from Andreas Bührer
- Include contribution on Denmark from Benjamin Bugnon
- Include an additional table on pros/cons for each architecture (section 6.6)
- Replace "cache" by "local repository"

**September 11, 2019 – version 0.11**

- Include revision & comments from Daniel Notter
- Include option "1.5" (as option 3)
- Integrate comments from meetings of Sept. 3rd
- Update section 7 (recommendations)

**October 18, 2019 – version 0.12**

- Enhance description of architectures 3.1 and 3.2
- Revision of pro & cons
- Revision of recommendations

**November 14, 2019 – version 0.13**

- APPC description (Annex 8.3)
- Comments from C. Leutold + November 13th meeting

**November 18, 2019 – version 0.14**

- Side titles

**January 23, 2020 – version 0.16**

- Brief description of the selected architecture in the summary.

**January 31, 2020 – version 0.17**

- Secondary storage into patient's reference community according to final meeting of January 29, 2020.

**March 10, 2020 – version 1.0**

- Final version taking into account eHealth-Suisse comments.

**Open points to be clarified in further stage**

Open points

- Evaluate the need for locking a prescription while it is being processed at a pharmacy.
- Check if CMPD Option "Persistence of retrieved documents" is required and if yes, which documents are concerned.
- Determine when the treatment card is updated in the EPR-XDS.b Infrastructure (i.e. after each modification? when being retrieved?) and by which aggregator it is published into the secondary storage.

# 2 Introduction

Introduction

The continuity of medication is of primary importance for the quality of the therapeutic processes as well as for patient safety: indeed it is recognized that a significant percentage[3] of emergency (re)admissions in hospitals is due to medication "problems" – wrong intake, wrong posology, incompatible medications, etc. Medication anamnesis is also a key element during the admission phase into a hospital. Considering that at least two sources should be taken into account, enabling an accessible, up-to-date and accurate patient medication list is a core elements for safer health services – an ambition of the EPR policy.


Shared medication treatment plan

A *shared medication treatment plan* describes all medications a patient is taking or did take in the past. Although some implementations like the Austrian one consider the shared medication treatment plan as being the collection of prescriptions, it is far more than that: indeed when a physician "prescribes" a medication to a patient, two different actions are occurring: the first is the order or the communication of the decision "this medication has be to taken with this posology for this duration"; the second is "in order to be able to obtain this medication from the pharmacist, here is a prescription". However if the patient already has the medication at home or if the medication is freely available, the prescription is not necessary although not forbidden. Another source of difference results from a potential generic substitution during dispense: indeed it is very important to know which manufactured product is being taken by the patient. It is also important to know the reason for the prescription (diagnosis) in order to be able to check the right dose for the right patient. Restricting the shared medication treatment plan to a collection of medical prescriptions results therefore in a fairly incomplete overview of the patient's medication. This restriction is not only failing to support care (e.g. in situation of emergency), but it also hinders potential patient engagement (i.e. does not include patient-driven changes) as well as the contribution of crucial interventions such as medication reconciliation or reviews. Patient's adherence or compliance to his/her medication treatment cannot either be checked against only prescriptions: the whole medication treatment plan is required. Nevertheless it has to be noted that while these are core elements of safer health system, they will not be described in this report.

[3] Recent studies are mentioning a percentage around 8% – 10%.

eMedication Service

The EPR-XDS.b Infrastructure is designed for storing documents and enabling patients to have access to them and to grant access to healthcare professionals. This infrastructure is not designed for implementing processes – and eMedication implies processes, e.g. for computing medication lists ("current shared medication treatment plan"). An eMedication Service needs therefore to be designed in a way that it reaches the expectations of patients, health professionals, and stakeholders as gathered from past experiments as well as during workshops with patients and professionals. The eMedication Service has also to be based on the core EPR communities' features (healthcare professionals management, patient identity management, secondary storage for documents, logging) in order to leverage the founding functionality provided by EPR implementations.

Scope

The scope of this eMedication Service Concept is therefore:

- To explore the key requirements for implementing such a value added service for supporting eMedication, i.e. medication lists, e-prescription and e-dispense in community pharmacy world;
- To describe a functional architecture able to support the eMedication processes;
- To describe its use in the community or ambulatory world: indeed a hospital stay is generally considered as something "self-contained" during which most of the dispensed medications are related to the stay itself and thus less important for the shared medication treatment plan - they are anyway documented in the discharge letter. It has thus been chosen not to overload the shared medication treatment plan with every medication (and medication change) occurring during a hospitalization ;
- To describe its potential use in the hospital world. Indeed core focus of this work being community pharmacy, hospital pharmacy processes are excluded: processes related to (e-)medication performed during a hospital stay are considered as "internal processes" and need not necessarily to be described in a shared medication treatment plan (although they may be documented there). The shared medication treatment plan intervenes only at hospital admission (medication anamnesis, initialization of the stationary treatment plan) and at discharge (reconciliation with shared medication treatment plan). It may therefore serve during admission as *one of* several medication reconciliation source, enabling the initial setup of the patient's shared medication treatment plan, and will be updated at discharge time to reflect the *global* shared medication treatment plan for the patient when (s)he will be back at home;
- To make recommendations for filling possible gaps preventing the implementation of the eMedication Service Concept.

Aggregation, not reconciliation

As it will be explained in more details in following chapters, the eMedication Service will *not* perform any medication *reconciliation* but will only perform medication *aggregation* while *supporting* medication *reconciliation*. Medication reconciliation is a medical process that can only be performed by healthcare professionals – e.g. by a physician during discharge or a pharmacist during a patient's visit.

Reconciliation is basically the “intelligent” merge of two medications lists in order to create a third one representing the final result. Reconciliation occurs typically at discharge time, when the physician has to look at what the shared medication treatment plan contained before the patient’s hospitalization and at what the patient’s hospitalization medications treatment plan is at discharge time: medical decisions have to be taken in order to decide which medications have to continue or to be introduced after discharge and which ones have to be stopped. Aggregation will occur afterward when one is looking at the updated shared medication treatment plan, being given an aggregated view taking into account all actions that were performed on the plan up the “now”. The eMedication Service therefore intends to *support* the medication reconciliation process by facilitating the information sharing, being able to provide a homogeneous and as complete as possible view of the medication plan – whoever contributed to it. However the eMedication Service *does not* implement any medication reconciliation process, which is out of scope of this report. This important distinction has the important effect of avoiding to consider the eMedication Service as a medical device.

Supported processes

The architecture proposed in this eMedication Service Concept addresses in particular the following aspects:

- Process when a patient enters and leaves the system (i.e. when the patient enrols to the eMedication Service and when the patient unsubscribes[4] from the eMedication Service);
- Processes around e-prescription, especially for situations where the e-prescription is produced after dispense or provided by phone or fax, or when the patient goes to the pharmacy with a paper prescription;
- Access rights management in relation with EHR design principles and multi-communities environment;
- Indications on how such an eMedication management concept will be connected to the European Cross Border eHealth Information Service (CBeHIS) once Switzerland will be able to join again this international infrastructure;
- Hints regarding maintenance of specifications (ArtDecor based CDA-CH-EMED, FHIR forthcoming specification, eMedication aggregator specification).

The report however does *not* address legal and organizational aspects required to fully replace paper prescription by e-prescription. The narcotic drugs’ prescriptions[5] are also not addressed yet by the proposed infrastructure.

Chapter 3 summarizes existing work in the standardization field and describes as well relevant implementations in Switzerland and other European countries.

Chapter 4 describes the typical use cases intended to be covered by the eMedication Service.

[4] Indeed the eMedication Service is an optional service for the patient. He/she can freely decide to adhere as well as to leave the service.

[5] « Ordonnances à souche » in French

Chapter 5 describes the eMedication Service (i.e. the service provided to healthcare professionals and patients), while chapter 6 describes concrete architectures and integration of an eMedication Primary Aggregator implementing this eMedication Service with regards to existing EPR communities.

Finally chapter 7 summarizes the key findings resulting from the study and provides some recommendations.

## 2.1 Abbreviations

Abbreviations

The following acronyms are used throughout this document:

| Acronym | **Definition** |
|---|---|
| CDA | The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients. |
| CDA-CH-EMED | CDA-CH-EMED defines the documents for the exchange of medication information in the context of the EPR (electronic patient record) in Switzerland. The documents are based on the IHE Pharmacy Technical Framework. |
| CH:ADR | IHE Authorization Decision Request profile. ADR takes the information provided by the identity assertion of a transaction and formulates a decision request query by a description of the subject (who), action (how), resource (what) and environment (when). The response contains an access decision for each resource. |
| DIS | DISpense – a document defined by the IHE Pharmacy DIS Profile for describing the dispense (including potential substitution) of a specific medication. |
| EPR | Electronic Patient Record as specified in the EPR Law and its ordinances. |
| EPR Community | A community implementing the EPR functionality. References to EPR Communities refer to implementation of the EPR specifications as a set of services and functionalities. |
| EPR-XDS.b Infrastructure | A specific implementation of the EPR core functionality. References to EPR-XDS.b Infrastructure refer to technical implementation of core EPR services in relation with a (XDS) document repository. |
| FHIR | FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir) – is a next generation standards framework created by HL7. FHIR combines the best features of HL7's v2, HL7 v3 and CDA product lines while leveraging the latest web standards and applying a tight focus on implementability. |
| MPI | Master Patient Index – component used to identify patients in a cross enterprise context. The MPI stores patient identities. |
| MTP | Medication Treatment Plan – a document defined by the IHE Pharmacy MTP Profile for describing a planned medication. |
| PADV | Pharmaceutical ADVice – a document defined by the IHE Pharmacy PADV profile for describing a change or a comment on one of the other IHE Pharmacy documents (MTP, PRE, DIS). |
| PEP | Policy Enforcement Point – Actor granting access to documents by enforcing the policies defined in the EPR for a patient. |
| PML | Pharmacy Medication List – a document defined by the IHE Pharmacy PML profile for grouping a list of items coming from the other IHE Pharmacy documents (MTP, PRE, DIS, PADV). The PML document is an on-demand document created on-the-fly when being retrieved. |
| PRE | PREscription – a document defined by the IHE Pharmacy PRE Profile for describing a prescription / ordinance (which may contain several prescribed medications). |

| | |
|---|---|
| Profile | Term used by IHE (Integrating the Healthcare Enterprise) for designating a specification for solving a specific use case. The Profile describes the flows, actors, transactions and messages potentially necessary for implementing an interoperable solution. |
| SAML 2.0 | Security Assertion Markup Language 2.0 (SAML 2.0): XML-based protocol that uses security tokens containing assertions to pass information about a principal (usually an end user) between a SAML authority, named an Identity Provider, and a SAML consumer, named a Service Provider. In XUA profile SAML 2 is used for exchanging assertions also between other parties (X Assertion Provider, X Service User. |
| SOAP | Simple Object Access Protocol – a XML-based protocol for exchanging structure information |
| WebServices | Technology for implementing services provided by a server to a client |

**Table 1: Acronyms and Definitions**

## 2.2 Complementary documents

Complementary documents

The following documents contain complementary information useful for the understanding of this eMedication Service Concept:

- Art Decor specification of CDA-CH-EMED;
- Implementation guide for primary systems interconnection: 160918_Umsetzungshilfe_Primaersysteme_V1-1_f, September 16, 2018.

The following IHE Profiles and complementary standards are referenced throughout the document:

- IHE ITI: Infrastructure profile
  - Advanced Patient Privacy Consents (APPC);
  - Document management (XDS, XDS-MU, XCDR, RMU);
  - Healthcare Provider Directory (HPD);
  - Mobile access to Health Documents (MHD);
  - Node authentication and logging (ATNA, CH:ATNA, CT, CH:CT);
  - Patient identity management (PIXV3, PDQV3, CH:PIXV3, CH:PDQV3);
  - Policies access and decision (CH:ADR, CH:PPQ);
  - Sharing value sets (SVS);
  - User assertions (XUA, CH:XUA);
- IHE Pharmacy profiles (MTP, PRE, DIS, PADV, PML, CMPD);
- SAML V2: Authentication and authorization;
- CDA-CH-EMED ART-DÉCOR Specification: https://art-decor.org/art-decor/decor-project--cdachemed-.

A comprehensive list of referenced profiles is available on the eHealth-Suisse web site: https://www.e-health-suisse.ch/fr/technique-semantique/projectathon-dep/aides-a-programmer-dep/specifications-pertinentes.html.

# 3 Review of existing work

## 3.1 IHE Pharmacy Profiles

IHE Pharmacy Profiles

IHE Pharmacy Profiles contain 6 profiles relevant to this work:

- MTP – Medication Treatment Plan profile[6], for describing the introduction of a medication into the medications treatment plan. A MTP document contains only 1 medication;
- PRE – Prescription, for describing a prescription (similar to a paper prescription, i.e. may contain several items);
- DIS – Dispense, for describing the dispense of one medication, including possible substitution;
- PADV – Pharmaceutical advice, used for approving a prescription or modifying one of the above document (e.g. dose modification, comment, etc.);
- PML – Pharmacy Medication List, used for grouping a set of entries from the above profiles into one single document;
- CMPD – Community Medication Prescription and Dispense, which defines an actor able to create medication lists out of instances of the above documents.

The CMA – Community Medication Administration, used for documenting the administration of a medication, is not yet part of the process described in this eMedication Service Concept.

CMPD Profile

While the other IHE Pharmacy profiles are content profiles (describing documents), the CMPD profile illustrates the relation between the individual documents along the treatment path of the patient. It also describes the IHE actor able to produce medication lists - instantiations of the PML (Pharmacy Medication List) document. While this document is an on-demand document, it is not forbidden to store it into the EHR in order to record a specific state / view of the eMedication of the patient. The PML document is also the IHE way to represent the Medication Card Document.

Replacement policy

IHE Pharmacy MTP, PRE, DIS and PADV documents should not be superseded – modifications are to be done by issuing a PADV document that will modify the content or the status of an information contained in another existing document. At the opposite, a PML being a view at a certain point in time is by essence subject to replacement, which in pure IHE world is not a problem as it is by default not foreseen to be stored at all. Introducing the storage of PML documents would then introduce a need for being able to supersede a PML document.

[6] Indeed the eMedication Service is an optional service for the patient. He/she can freely decide to adhere as well as to leave the service.

[6] « Ordonnances à souche » in French

t Plan elements. In general, IHE MTP elements will be referenced as *MTP Document*(s).

The CMPD workflow is defined as follows:

CMPD Workflow

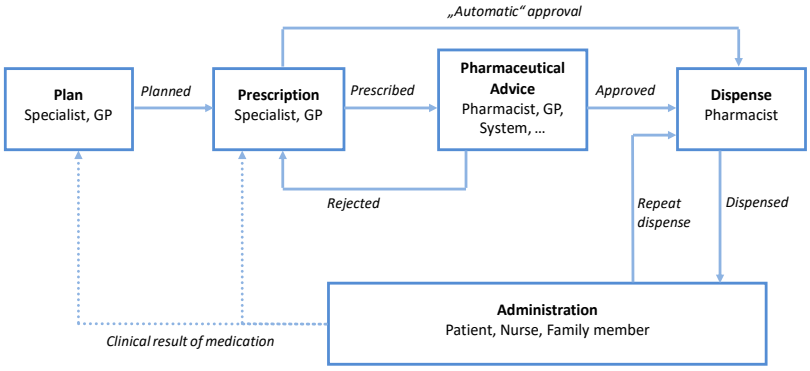



**Figure 1: CMPD Workflow**

The CMPD profile foresees two workflows:

1. Once a prescription is documented, it needs first to be "approved" by a Pharmaceutical Adviser before being allowed to be dispensed;
2. Once a prescription is documented, it can be immediately dispensed.

Although both workflows have to be supported by a CMPD implementation, one default operating mode has to be selected: the eMedication Primary Aggregator described in this eMedication Service Concept is based on the first workflow as in Switzerland in practice, every prescription is validated by a pharmacist before being dispensed[7].

Provisional prescription

However each rule has its exception – introduced in version 2019 of PRE and CMPD profiles[8] – and is related to the handling of "provisional prescriptions": indeed it occurs that the patient is going to the pharmacy asking for dispense on a prescription "that will be issued tomorrow". The fact that the PRE document is not present prevents from making links between the DIS (dispense) document and its related PRE (prescription) document. In order to provide an elegant solution to this problem, it will be possible for the pharmacist to issue a PRE document with an explicit "To be approved" marker. Prescription containing this marker will then be mandatorily considered as "to be approved" by the CMPD actor even if it is working in workflow 2 (which is anyway not the case for our implementation). In addition, in case a medication to be included in the provisional prescription is not already in the medication plan, an MTP will have to be issued before the PRE in order to properly document the medication in the plan. This operation being similar to introducing Over The Counter (OTC) medication in the plan, no approval of the MTP is required.

[7] Rules defining who can validate what are out of scope of IHE Pharmacy CMPD profile. They have to be defined for each implementation.
[8] Change proposal to be issued by June 2019 for ballot during August 2019.

## 3.2 CDA-CH-EMED National Specification

CDA-CH-EMED

A first proposal for a national specification for eMedication documents was written by HUG under the name “CDA-CH-MTPS” – Medications Treatment Plan Sharing in 2015. In 2014 an eMedication workgroup within IPAG (“Interprofessionelle Arbeitsgruppe Elektronisches Patientendossier”) was created. The final document of the IPAG issued in 2017 was called “eMedikation als Teil des elektronischen Patientendossiers”) and served along with the CDA-CH-MTPS specification as a basis for eHealth Suisse / BAG to develop CDA-CH-EMED specification in 2018.

CDA-CH-EMED Documents

The national specification defines 6 documents:

- **Medication Treatment Plan document**, documenting the introduction of one medication For every new medication, one Medication Treatment Plan document with one single Medication Treatment Plan item has to be issued. It is based on IHE Pharmacy MTP profile;
- **Medication Prescription document**, representing a prescription. It is based on IHE Pharmacy PRE profile;
- **Medication Dispense document**, representing a dispensation of one medication. It is based on IHE Pharmacy DIS document;
- **Pharmaceutical Advice document**, documenting comments and changes of existing medication or prescription. It is based on IHE Pharmacy PADV profile;
- **Medication Card document**, representing the medications treatment plan. It is based on IHE Pharmacy PML profile (containing only IHE Pharmacy MTP profile entries);
- **Medication List documen**t, representing a (subset of a) all information contained in a shared medications treatment plan. It is based on IHE Pharmacy PML profile and may include all IHE Pharmacy content profiles entries (IHE Pharmacy MTP, PRE, DIS and PADV profile entries for the moment).

Detailed specification is available in ART-DECOR environment.

Information exchanged and managed by the eMedication Primary Aggregator is based on this exchange format.

## 3.3 HL7 FHIR and Swiss Core Implementation Guide/eMedication

### 3.3.1 HL7 FHIR Release 4

HL7 FHIR

HL7 FHIR is a next generation standards framework that leverages the latest web standards and applies a tight focus on implementation. FHIR includes a RESTful API, which is an approach based on modern internet conventions and widely used in other industries. The standard represents a significant advance in accessing and delivering data while offering enormous flexibility and ease of development. For patients and providers, its versatility can be applied to mobile devices, web-based applications, cloud communications and EHR data-sharing using modular components. FHIR is already widely used in hundreds of applications across the globe for the benefit of providers, patients and payers.

The most significant change in HL7 FHIR Release 4 (R4) is that the base platform of the standard has passed a normative ballot and will be submitted to the American National Standards Institute (ANSI) as a normative standard. This means that future changes should be backward compatible so applications that implement the normative sections of R4 no longer risk being non conformant to the standard. The following portions of the standard are now normative:

- The RESTful API, the XML and JSON formats, and the basic datatypes;
- The Terminology Layer (CodeSystem and ValueSet);
- The Conformance Framework (StructureDefinition and CapabilityStatement);
- The key resources Patient and Observation[9].

FHIR Medications Resources

FHIR defines in the Medications Module six different resources:

- MedicationRequest: Represents an instruction for the administration of medication to a patient - both in the inpatient (hospital) and community setting.
- MedicationDispense: The provision of a supply of a medication with the intention that it is subsequently consumed by a patient (usually in response to a prescription).
- MedicationAdministration: A record of a patient actually consuming a medicine, or if it has otherwise been administered to them
- MedicationStatement: This is a record indicating that a patient may be taking a medication now, has taken the medication in the past, or will be taking the medication in the future
- Medication: The medication resource represents an actual medication that can be given to a patient.
- MedicationKnowledge: The MedicationKnowledge resource is draft and is included for comment purposes.

The FHIR Medication resources are not yet normative, current Maturity Levels[10] are between 2 and 3 which can be compared to the IHE Trial Implementation state of an IHE content profile (except MedicationKnowledge which has a Maturitylevel 0).

[9] http://blog.hl7.org/hl7-publishes-fhir-release-4
[10] http://hl7.org/fhir/versions.html#maturity

The difference between the Medication resources and the IHE Pharmacy Profiles is that the IHE Pharmacy profiles describe documents. Further work has to be done to define equivalent document profiles for the FHIR resources to correspond with the IHE Pharmacy Content Profile.

The same approach (developing FHIR document profiles and CDA content profiles) is currently done within the International Patient Summary[11] and for the German Prescription[12] where a CDA and FHIR guides are developed in parallel to facilitate mapping between both standards.

### 3.3.2 Swiss Core Implementation Guide (CH-Core)

Swiss Core Implementation Guide

HL7 Switzerland, eHealth Suisse and other stakeholders in Switzerland are profiling the core FHIR resources which are necessary for interoperability in Switzerland.[13] The project CH-Core[14] has been started in December 2018 and the plan is to go for a ballot of the CH-Core Implementation Guide by end or this year.

The different FHIR medication resources will be profiled that they correspond to the definitions made in CDA-CH EMED. In parallel eMedication FHIR documents will be defined to have the possibility to map between FHIR documents and CDA-CH EMED content profiles. The goal is to have the maps between the FHIR and CDA-CH EMED content profile public available so that is independent of a programming language resp. implementation.

### 3.3.3 Summary

All new standards development from HL7 are now based on the FHIR standard, the CDA standard will be still supported but without updates or new version. With the approach of defining FHIR document profiles for the CDA-CH EMED content profiles and profiles on Medication resources past development can be leveraged and implementers can take advantage of the additional features of the FHIR standard and IHE mobile profiles.

## 3.4 CARA eMedication Primary Aggregator

CARA eMedication Primary Aggregator

A shared medication treatment plan has been implemented in MonDossierMedical.ch platform since 2012 by Canton of Geneva. The Canton of Vaud also used this functionality in its own platform since 2013 for several projects. This initial version of shared medication treatment plan is deeply integrated into Swiss Post's Vivates platform, i.e. user interface is part of healthcare professional's portal and document management is part of the core Vivates platform. Only the business logic is externalized.Experiments and evaluations with healthcare professionals and patients were conducted during several years and served as significant input for the redesign of the new application for CARA[15].

[11] http://international-patient-summary.net/

[12] https://wiki.hl7.de/index.php?title=IG:ERezept

[13] https://www.fhir.ch/

[14] http://build.fhir.org/ig/hl7ch/ch-core/index.html

[15] See e.g. https://www.vd.ch/toutes-les-autorites/departements/departement-de-la-sante-et-de-laction-sociale-dsas/direction-generale-de-la-sante-dgs/projets/news/apporter-une-vue-globale-de-la-medication-dun-patient-1545057126/

With the establishment of CARA community and the end of service of the Vivates platform, a new implementation has been designed in order to implement the shared medication treatment plan as a value added service of the EPR-XDS.b Infrastructure (the “CARA eMedication Primary Aggregator”). This value added service is implemented as a component independent from the EPR-XDS.b Infrastructure but using key EPR-XDS.b Infrastructure’s functionality like patient identity management or logging. It will act as an intermediate between primary systems and the EPR-XDS.b Infrastructure as shown in the figure below.

Architecture

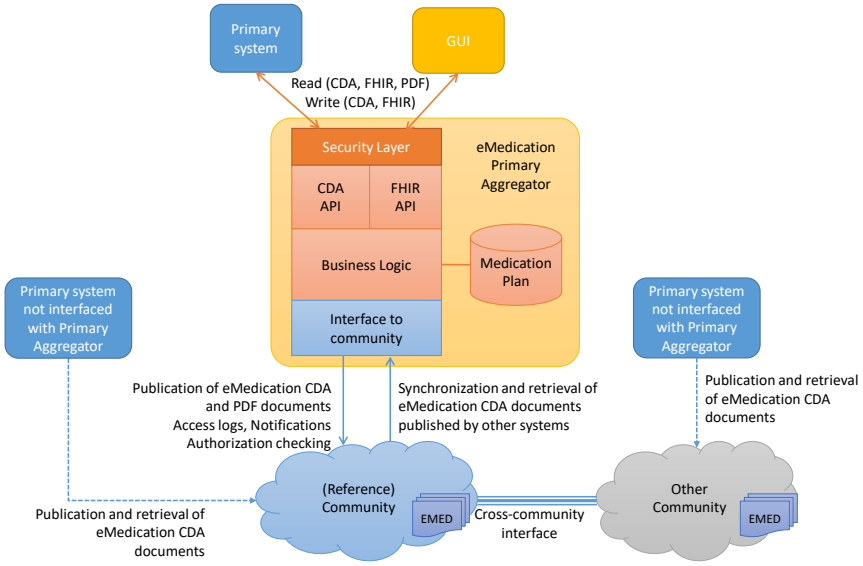



**Figure 2: CARA eMedication Primary Aggregator Provisional Architecture**

Design

The design of the new value added service takes into account results of Geneva and Vaud experiments as well as the new requirements for the Swiss EPR-XDS.b Infrastructure. It implements the IHE Pharmacy CMPD profile.

As shown in Figure 2, the new value added service is expected to have a user interface and will store documents (either submitted by primary systems or by the user interface) inside an internal repository. Storage has two objectives: it serves as primary storage for the GUI and it accelerates the access to the information, acting thus as a primary repository. It will also aggregate contributions from several providers. These two aspects led to its naming: eMedication Primary Aggregator as it will be seen like a primary system by the EPR-XDS.b Infrastructure.

The CARA eMedication Primary Aggregator will evolve in order to follow recommendations established in this report as its development started in 2019 and is ongoing.

## 3.5 eMediplan Treatment Card

eMediplan Treatment Card

The basis for the eMediplan is the complete, up-to-date overview of a patient's medication, independently from the prescriptions each is coming from. This medication plan is of central importance for each individual patient, his relatives as well as for the health professionals of this patient. Such a complete, up-to-date medication plan is often not available today. The focus of eMediplan is not on prescription or drug delivery.

### 3.5.1 Requirements and Benefits

Requirements and Benefits

| Requirements for eMediplan | Benefits |
|---|---|
| Patients and/or their relatives know their current, complete medication. | Drug therapy safety, adherence |
| The medication must be up-to-date and fully known to every healthcare professional who prescribes, substitutes or provides medication for the patient | Drug therapy safety, differential diagnostics |
| The complete medication must be documented in the own information system. (primary system) | Documentation obligation, efficiency |
| Communication between health care providers must be improved. Patient confidentiality and data protection must be respected. | Optimization of the treatment chain, drug therapy safety respect for patient rights |
| The target solution must be compatible with the electronic patient dossier (eHealthSuisse). | Promote the electronic patient dossier and its associated benefits. |
| It must be possible to introduce the desired solution gradually and it must be affordable. | Important for feasibility and successful implementation |

**Table 2: Concept eMediplan: requirements and benefits**

### 3.5.2 Process Aspects of the eMediplan

Processes

The eMediplan is geared to the needs of patients and health professionals. The core of the medication process can be divided into three phases: Medication anamnesis, new medication planning, and communication of the new plan. This applies not only to doctors' practices, outpatient centres and hospitals, but also to pharmacies, spitex, nursing homes and other health care providers.

**Medication Anamnesis**

Without a good medication anamnesis, differential diagnostic and diagnostic considerations are rarely target-oriented. As a consequence, the therapeutic considerations based on this are also questionable. This applies analogously to situations in pharmacies, spitex and nursing homes.

The medication anamnesis is considerably simplified by a complete, up-to-date medication plan. However, it should be noted that even the most perfect medication plan does not necessarily reflect what the patient is effectively doing or taking. A medication anamnesis can in no case be replaced by the automatic reading of digitally available medication information.

**New Medication Planning (New medication plan is defined)**

When a new medication plan is developed or reviewed, validations are necessary, not just to identify interactions. This requires minimal medical information. This is the only way to assess the choice of drugs and their dosages. The most important information in this regard is therefore part of the eMediplan. See below for details.

For the necessary validation of the planned medication, computer-aided options are also available today, such as interaction checks. However, only if the complete, current medication and the necessary medical information is also available in digital form.

Finally, the actual prescription (order) of the new medication, which must also be documented in the own documents, typically follows in the primary information system of the health care provider. A copy of the information is placed in the patient's EPD if the patient has one and the healthcare provider is able to do so.

**Communication of the new plan to patient and healthcare providers**

After the therapy decision, this must be discussed with the patient for various reasons. The eMediplan is helpful for this. It contains, for example, the trade name and a picture of the corresponding tablet. Both are central in everyday patient life. This also means that a new medication plan must be created after generic substitution in the pharmacy.

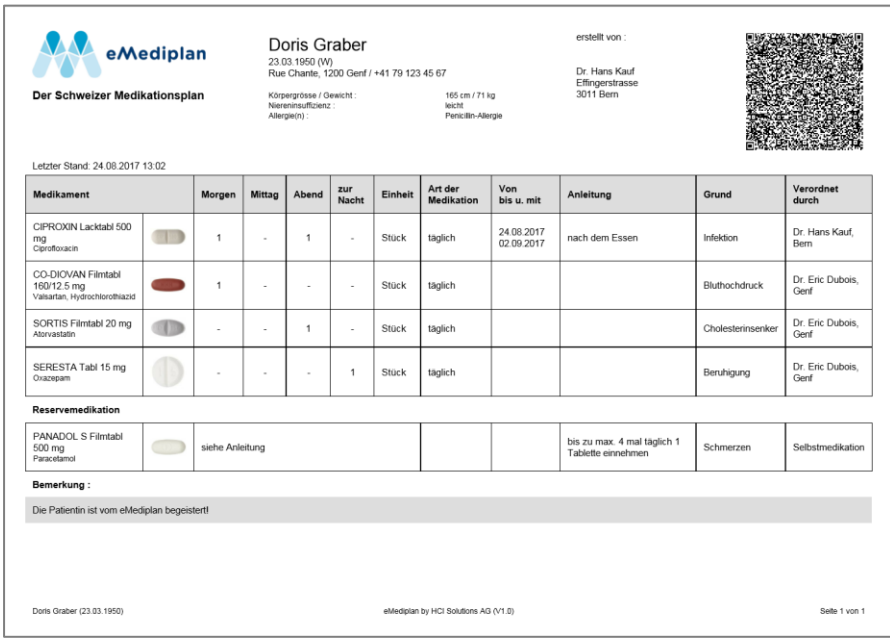
In addition to informing the patient, it is also important to inform the healthcare providers involved and those to be involved in the future. As today, this is done along the treatment chain or now via EPD. The eMediplan is also suitable for this.

Finally, the eMediplan information is an excellent basis for the simple and rapid creation of a prescription.

### 3.5.3 The eMediplan dataset

The eMediplan dataset is visualized below as a paper/PDF variant with 2D barcode. Dataset

eMediplan data set



eMediplan
Der Schweizer Medikationsplan

Doris Graber
23.03.1950 (W)
Rue Chante, 1200 Genf / +41 79 123 45 67

Körpergrösse / Gewicht : 165 cm / 71 kg
Niereninsuffizienz : leicht
Allergie(n) : Penicillin-Allergie

erstellt von :
Dr. Hans Kauf
Effingerstrasse
3011 Bern

Letzter Stand: 24.08.2017 13:02

| Medikament | | Morgen | Mittag | Abend | zur Nacht | Einheit | Art der Medikation | Von bis u. mit | Anleitung | Grund | Verordnet durch |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CIPROXIN Lacktabl 500 mg<br>Ciprofloxacin | | 1 | - | 1 | - | Stück | täglich | 24.08.2017<br>02.09.2017 | nach dem Essen | Infektion | Dr. Hans Kauf, Bern |
| CO-DIOVAN Filmtabl 160/12.5 mg<br>Valsartan, Hydrochlorothiazid | | 1 | - | - | - | Stück | täglich | | | Bluthochdruck | Dr. Eric Dubois, Genf |
| SORTIS Filmtabl 20 mg<br>Atorvastatin | | - | - | 1 | - | Stück | täglich | | | Cholesterinsenker | Dr. Eric Dubois, Genf |
| SERESTA Tabl 15 mg<br>Oxazepam | | - | - | - | 1 | Stück | täglich | | | Beruhigung | Dr. Eric Dubois, Genf |

**Reservemedikation**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PANADOL S Filmtabl 500 mg<br>Paracetamol | | siehe Anleitung | | | | | | | bis zu max. 4 mal täglich 1 Tablette einnehmen | Schmerzen | Selbstmedikation |

**Bemerkung :**

Die Patientin ist vom eMediplan begeistert!

Doris Graber (23.03.1950) eMediplan by HCI Solutions AG (V1.0) Seite 1 von 1

**Figure 3: eMediplan data set visualized as paper/PDF variant with 2D barcode**

The eMediplan dataset contains the following information:

| Information block | Content |
|---|---|
| To the document eMediplan | creation time (dateTime), author, organization, comment, document ID |
| Patient identity | Name, first name, date of birth, gender, patient IDs |
| Medical information<br>(in the context of medication) | Body size, weight<br>risks such as allergies, kidney or liver insufficiency, pregnancy, athletes (doping), motorists |
| Medication<br>(list of drugs) | Trade name of the drug incl. dosage strength/concentration, active ingredient, picture of the tablet<br>Dosage (morning, noon, evening, night), Unit or free text<br>Type of medication (intake rhythm), from - to<br>Application, Reason (for patient), Prescribed by |

**Table 3: Information of the eMediplan dataset**

### 3.5.4 Variants and Transport Routes of the eMediplan

Variants and Transport Routes

The standardized eMediplan data set in the primary system of the health care provider forms the core of eMediplan. This data set can be displayed or converted in various forms:

- Paper version or PDF, both versions with 2D barcode containing the complete, *structured* eMediplan data set;
- Exchange format, especially according to standards promoted by eHealthSuisse, without or with additional fields according to the pharmacy medication list (PML).

Transport routes are defined:

A. Patient as messenger
   → eMediplan as paper or PDF version, both with 2D barcode, also electronic transport via the patient's mobile phone, e-mail or web
   → the eMediplan dataset is completely contained in the 2D barcode, no central storage (data privacy!)

B. Along the treatment chain
   → Already established paths along the treatment chain
   → Paper / PDF with 2D barcode or exchange formats, each with structured eMediplan data set
   → Secure e-mail, collaboration platforms (e.g. PalliaCare, letter mail

C. Electronic patient dossier
   → eMediplan as an eDocument (CDA), exchange format according to eHealthSuisse approved exchange formats without or with additional fields to the pharmacy medication list (PML)
   → Storage as a PDF document with 2D barcode, also by patients
   → For patient: eMediplan as a PDF document with 2D barcode or through a standardised visualisation tool on the basis of CDA documents, e.g. with the help of an eMedication aggregator or an application on a patient's device (mobile).

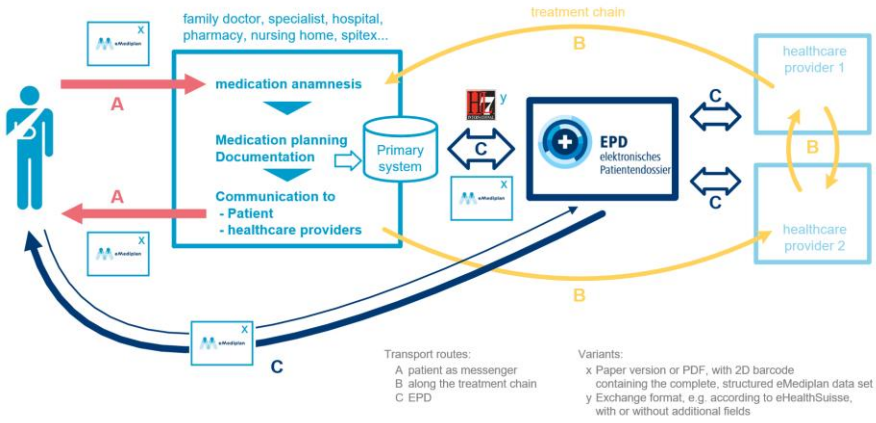



**Figure 4: Variants and transport routes of the eMediplan**

### 3.5.5 CHMED16AF (eMediplan)

CHMED16AF is a FHIR based definition for the eMediplan CHMED16A format[16]. This format was defined in FHIR STU3 version and is now updated to Release 4. A mapping will be done to convert to the respective CH-Core EMED documents.

CHMED16AF

[16] http://chmed16af.emediplan.ch/

## 3.6 ABILIS

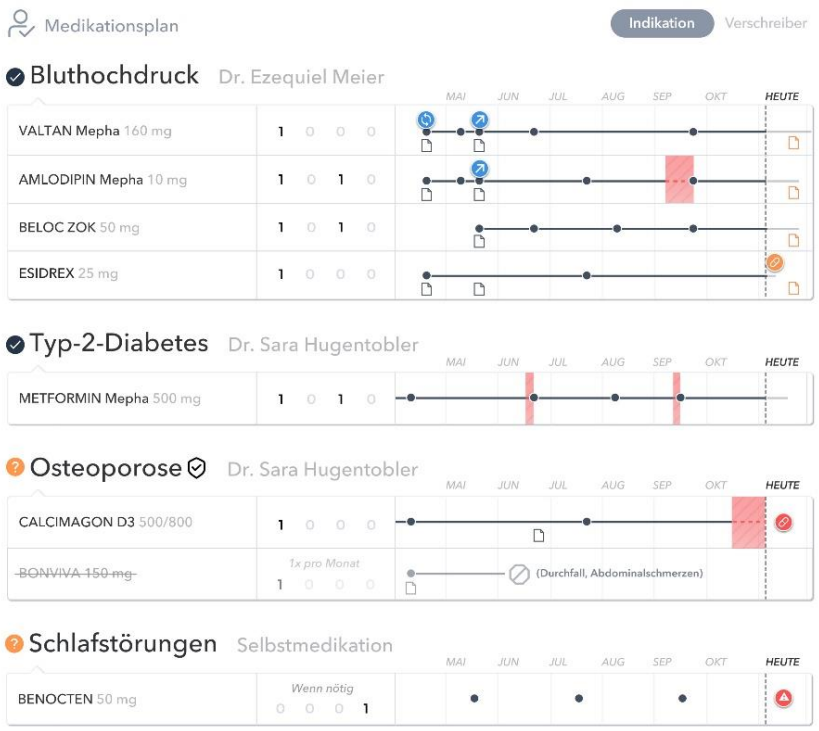
ABILIS

An overview of a patients medication (called “Dossier Pharmaceutique Partagé”) has been established by Ofac in 2005 and is used (among others) in the Canton of Fribourg and in the hospital in Morges until today. It already allows access from pharmacists as well as patients.

Ofac has done further developments on this service and will roll-out in November 2019 a new digital health platform called Abilis. Core function of this platform will be a so called “Patient View 360” with an integrated, completely new Abilis Medication Plan (Figure 5) in the B2B-Portal for health professionals. Around these medication data, a bunch of other services will be offered to health professionals. A first version (v1) of Abilis focus on services around medication information, a second version (v2) will integrate general medical information (e.g. allergies, history of illnesses) as well as patient data from connected devices. For further versions, services around continuous patient care and monitoring will be developed and integrated into Abilis.

The “Patient View 360”, the services for health professionals as well as the Abilis Medication Plan will be offered slightly different for other health professionals in order to fit their specific needs. A simplified version of the Abilis Medication Plan will be available for the patient in his B2C-Portal as well.

With the introduction of the Electronic Patient Dossier (EPD) by the Swiss Federation in April 2020, Abilis will offer an access to EPD for both, health professionals and patients. Patient-onboarding and getting an electronic ID will be possible in a one-step process in pharmacies. Of course, the access to the EPD will also be available as Web-portals for people not using Abilis digital health platform.




Draft of Abilis Medication Plan

**Figure 5: Draft of Abilis Medication Plan, pharmacists' version**

For creating these services, medication data have to be imported in a structured form from the IT-Systems (primary systems) of the health professionals into the Abilis Medication Pool by an xHealth process. In a next step, these data will be processed and can then be shared as PDF or in a CDA-CH-EMED format with other aggregators as well as being stored in the Abilis affinity domain for publishing in EPD. Figure 6 presents a simplified architecture for collecting medication information from primary systems of health professionals, sharing information with other aggregators and storing it within the affinity domain for publication in EPD.

Simplified architecture of data flows

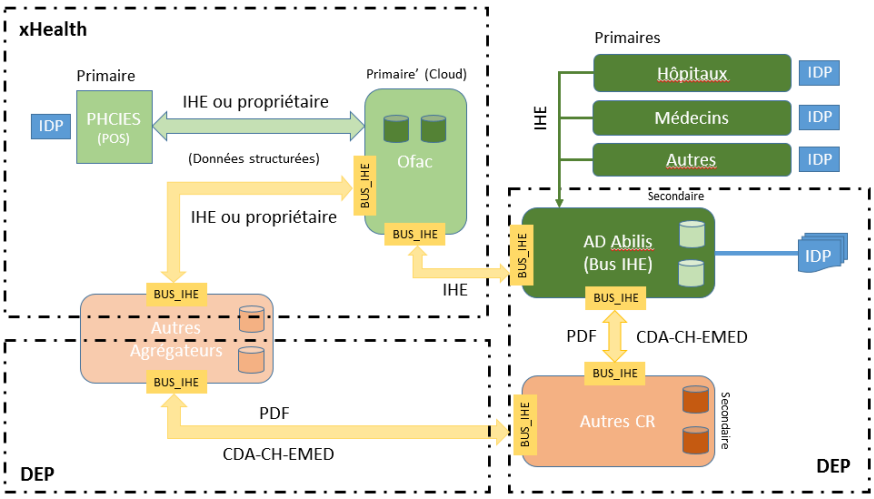



**Figure 6: Simplified architecture of data flows**

## 3.7 Austrian e-Medication Approach

Austrian e-Medication Approach

Austria implemented an e-Medication application as part of ELGA central components as shown in the figure below.

The goal of the Austrian implementation is to support community ePrescription and eDispense, offering for that a value added service called "e-Medication application" in the Austrian National Health Record (ELGA).

The service is compliant with IHE-based National e-Health strategy and infrastructure. It benefits from a seamless integration within existing client systems (physician, hospital, pharmacy).

The e-Medication application shall contain all dispenses of last year[17] and all unfilled prescriptions. It does not replace the paper prescription but acts as a "shadow" ePrescription/eDispense system (paper overrules ePrescription).

The e-Medication application is based on the following key principles:

- Interoperability specifications are based on IHE Pharmacy CMPD profile;
- National content definitions are based on IHE Pharmacy content profiles (PRE, DIS, PADV, PML);

[17] Previous dispenses are archived and not more visible.

- There is a central database for ePrescriptions and eDispenses;
- The central database keeps documents only for one year (limited by law). Law should be changed in the future in order to store documents up to 18 months or possibly 3 years;
- The central e-Medication application is situated in its own Affinity Domain („ELGA Area“);
- When the physician (or his own system respectively) creates a prescription document, it forwards it directly to the central e-Medication application[18]. A similar process routes the dispensation documents from pharmacies to the central e-Medication application;
- The patient cannot add or change information stored in the eMedication application. He/she can only empty the database (i.e. restart with an empty e-Medication repository).

ELGA Overall Architecture

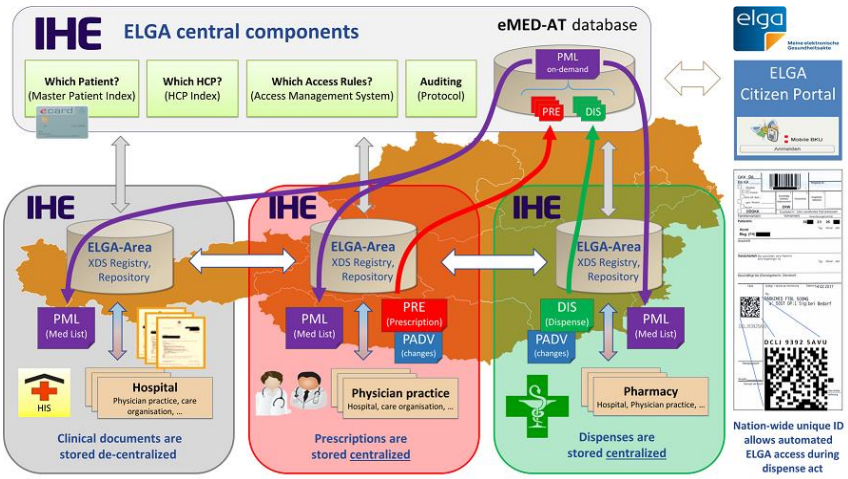



**Figure 7: ELGA Overall Architecture**

Overview of the entire medication process

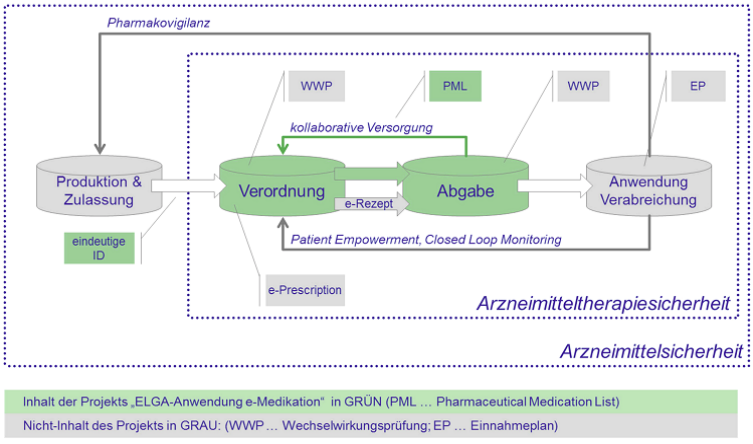



**Figure 8: Overview of the entire medication process and scope of the "e-Medication" project[19]**

[18] This works via a logic in the AGW (application gateway, over which all transactions pass). The AGW directly routes the eMedication documents directly to the Affinity Domain of eMedication and not to the “normal” Affinity Domain.

[19] Source : Kollmann A, Hameed AS, Sabutsch SW. Die Entwicklung der e-Medikation als

Main application of e-Medication

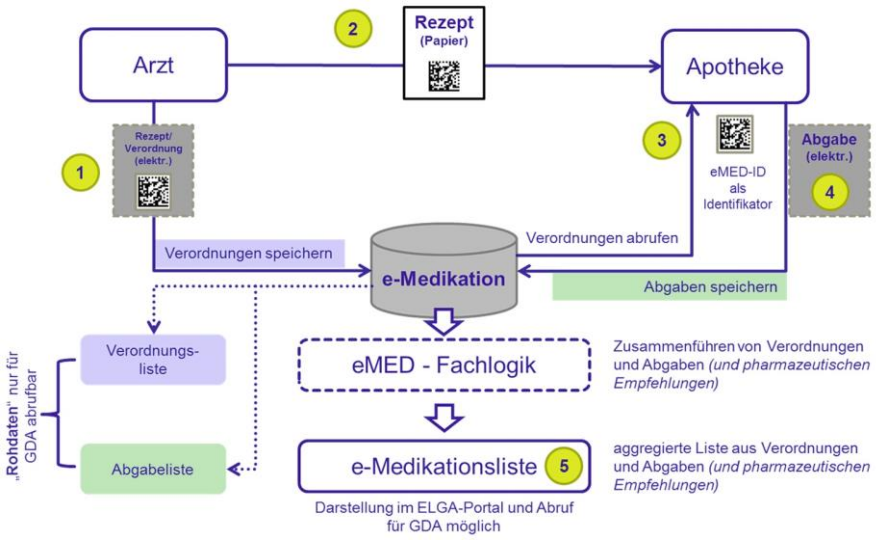



**Figure 9: Main application of e-Medication[20]**

In the figure above, the patient is given a prescription containing the indicated medications. The ePrescription is sent to the e-Medication application. The patient takes the paper prescription to the pharmacy, where the corresponding medications are dispensed. eDispense documents are published into the e-Medication application. The e-Medication application specialized logic summarizes the data of prescriptions and dispenses and compile these into the medication list.

## 3.8 Danish eMedication Approach: the shared medicine record

### 3.8.1 Summary

Danish eMedication Approach

In 2007, the Danish Health Data Authority set out to establish a nationwide *Shared Medication Record* (SMR). The political vision claimed for:

- "One patient – one national medication record" containing up-to-date information on every citizen in Denmark;
- Its purpose is to reduce possible medication errors;
- It shall be use trough local systems giving an easy access to the information for the relevant healthcare professionals.

The SMR gives an overview of the actual use of medications by the citizens – as well as giving an easy access to the information to the relevant healthcare professionals. The widespread solution is aimed to not only benefits Danish citizens, but also healthcare professionals and society overall. Along with reducing the number of medication errors that arise due to lack of information about a patient's medical history, the solution improves the working conditions for healthcare practitioners by enabling them with full online access to patients' medical files.

ELGA-Anwendung in Österreich. GMS Med Inform Biom Epidemiol. 2017;13(2):Doc10. DOI: 10.3205/mibe000177, URN: urn:nbn:de:0183-mibe0001778. Artikel available at : http://www.egms.de/en/journals/mibe/2017-13/mibe000177.shtml

[20] Source : Kollmann A, Hameed AS, Sabutsch SW. Die Entwicklung der e-Medikation als ELGA-Anwendung in Österreich. GMS Med Inform Biom Epidemiol. 2017;13(2):Doc10. DOI: 10.3205/mibe000177, URN: urn:nbn:de:0183-mibe0001778. Available from : http://www.egms.de/en/journals/mibe/2017-13/mibe000177.shtml

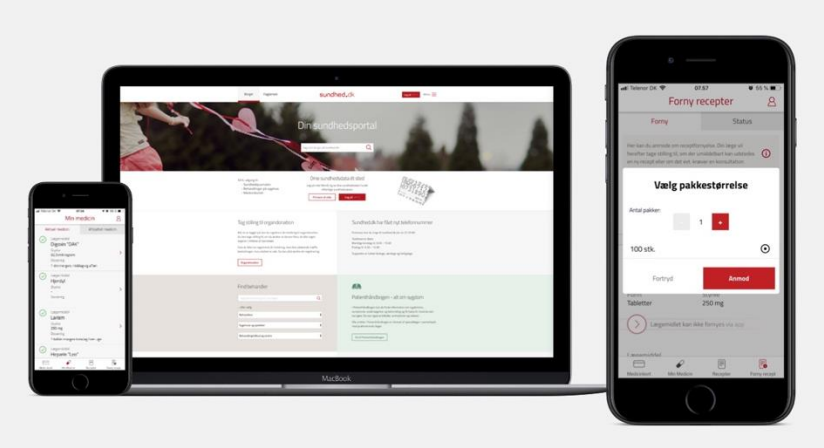
Thereby, reducing time spent in clarifying current medical information and risk of malpractice and re-admissions. The need is that all relevant patient information must be readily available when needed while ensuring data security and confidentiality.

The medication reconciliation at the admission and discharge of the hospital has been a key policy focus for patient safety. The integration of information on individuals' medication from a national SMR into a hospital EMR has been showed to be feasible and useful, and it did not increase time expenditure for medication reconciliation. The pilot was unanimously supported by patients, physicians, and pharmacists.

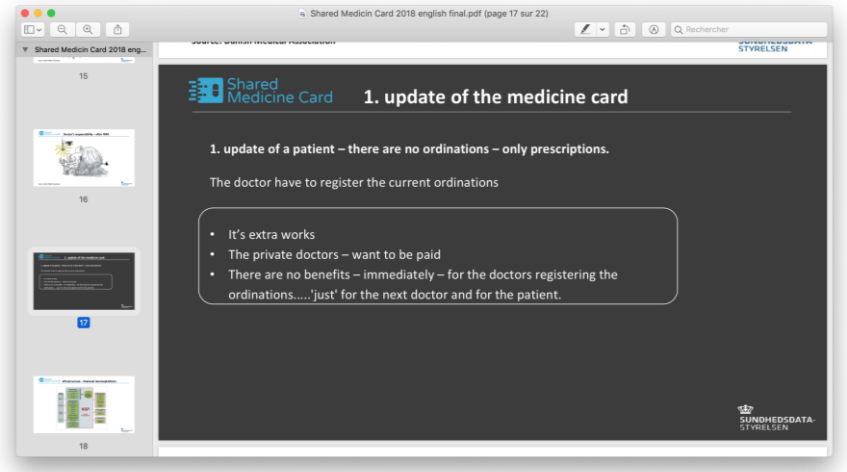
### 3.8.2 Architecture

Architecture

The Danish ePrescription system and the SMR are closely linked but are not dependent one of each other. This means that patients with a manual prescription will have data about prescribed medicine registered in the SMR, and that patients without a SMR (e.g. a person visiting Denmark as a tourist) in principle cannot make use of ePrescriptions. However, when ePrescriptions are used, it facilitates the procedure in keeping the SMR updated.[21]




Denmark also has the notion of Medication Card:




[21] https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_denmark_en.pdf

### 3.8.3 Some insights learned by the Danish experience

Insights

- High complexity of setting up such a system because of multiple dependences with the law, shared infrastructure, organization for cooperation with vendors integration management, change in practice, cultural barriers, among many others;
- Strong political commitment and ambition was necessary as well a secured funding;
- Several organizational evolutions have been necessary for enabling the cooperation among the authorities, the main vendor in charge of the SMR and the multiple vendors which were required to integrate the solution, as well as for managing the successive roll outs;
- The SMR has stimulated the patient safety awareness of the professionals by highlighting the full picture of the patient medication. The greater transparency has also raised debate about responsibilities, roles and good practices;
- Critical mass of users was necessary for getting the value out of the system, but it was hard to get there because it required:
    - systems integration;
    - changing work processes and reaching a shared understanding of the domain data.

Over time, this has succeeded immensely, and is now seen as an essential component across the Danish health sector. The SMR has dramatically reduced risk of erroneous medication and has saved lives by improving the safety and effect of treatment. Nevertheless, the setup of a SMR is an iterative and collective process that needs to be accompanied by continuous health services safety and quality evaluations to overcome sociotechnical unintended issues.

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## 3.9 French “Dossier pharmaceutique”[22]

French “Dossier pharmaceutique”

The French “Dossier pharmaceutique” (DP) is a professional tool for pharmacists (pharmacies and hospitals) accessible also to the patient. The DP is created by the health insurance for each beneficiary with an opt-out option. The law[23] sets out the content of the Dossier Médical Partagé (DMP) and the DP. The DP is part of the DMP and includes data on the beneficiary of health insurance with the dispensing of medicines and vaccines. It aims at securing the dispensing of medicines for the benefit of patients' health. The creation of a pharmaceutical file is done in a pharmacy. The creation can only be done in principle with the express consent of the patient or his legal representative. It is free of charge. It has three main objectives:

**Avoid iatrogenesis by globalizing the history of dispensing dispensaries**

The DP lists all drugs dispensed to a patient in the last four months in any pharmacy connected to the system. By consulting it, the pharmacist can identify the risks of drug interactions or redundant treatments. Unless the patient objects during the dispensing process (which occurs only occasionally), the DP contains all the drugs dispensed over the past four months, whether or not they are reimbursable, prescribed by a doctor or recommended by a pharmacist. The DP lists these drugs with their identification code, number of boxes and date of delivery. Neither the name of the prescriber, nor the selling price, nor the name of the pharmacy or its location are indicated.

**Respect professional secrecy**

None of the pharmaceutical data is written on the patient’s health card (“Carte Vitale”). They are all hosted by a “personal health data hosting provider” chosen by the Conseil national de l'ordre des pharmaciens (CNOP) after a European call for tenders. The data is encrypted and the exchanges between the pharmacies and the national host are made in SSL secure mode. They can only be used to secure the dispensation.

The pharmaceutical file stores the history over 32 months, allowing to find the batches sold to the patient and whose dangerousness was discovered after the fact. After 36 months of inactivity, a patient's pharmaceutical dossier is deleted.

There were three key objectives for the project, as described below.

**Enable the monitoring of drugs in the population**

Due to the mass of information that passes through it, the DP makes it possible to extract anonymized data on drug consumption. Thus, the “Agence nationale de sécurité du médicament et des produits de santé” (ANSM) used this tool to monitor the change introduced by the de-reimbursement of so-called third and fourth generation pills.

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[22] Sources: https://fr.wikipedia.org/wiki/Dossier_pharmaceutique (May 27, 2019); Journal de l’Ordre national des pharmaciens, #29, October 2013; https://www.service-public.fr/particuliers/vosdroits/F16033, May 27, 2019

[23] https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000020890580&dateText

In addition, the pharmaceutical dossier has evolved to allow faster withdrawal of drugs or batches of drugs from pharmacies. Finally, it serves as a channel for the transmission of health alerts, allowing authorities to reach pharmacists in a very short period of time, thus avoiding them from being warned by their patients.

The main modules included in the "Dossier Pharmaceutique" tool are:

- DP-Break, to report supply disruptions;

- DP-Sanitary monitoring, for sanitary monitoring;

- DP-Recall / withdrawal, to manage recall and batch withdrawal procedures;

- DP-Alerte, to send urgent messages to pharmacies;

- DP-Health facilities, for access through indoor pharmacies (PUI);

- DP-Suivi vaccination monitoring, for monitoring vaccination coverage;

- DP-Counterfeiting, to fight against counterfeiting.

The DP is fully independent from the national Dossier Médical Partagé. Interfaces are a priori proprietary as no reference to standards is made in the various available descriptions.

A pilot study on the e-pharmaceutical record (ePR) contribution in the medication reconciliation process during admission at the hospital has been conducted (diabetology unit of academic hospital in Toulouse in 2015). 42% of admitted patients had an ePR: among those patients, the ePR contributed in 38% of the medication anamnesis (mostly drug omission). The ePR is therefore considered as a good source of information in the process.

Most information exchange systems face major challenges in adoption and the normalization of the routine use is often hampered. The ePR may likely face such issues: indeed the study results showed that users encountered a benefit by using the ePR in about 1 checked patient on 10, and the clinical impact of the contribution was significant in 17% of the cases. In other words, doctors may consider the tool as decisive in 2% of cases, assuming they have accessed the ePR properly each time the patient has one.

The accuracy of the current medication list of the record was not assessed. The ePR does not allow information sharing from other healthcare professionals about the treatment plan, and its content is not updated during a patient interview which would enable an additional screening and foster engagement as it is the case in Denmark. Similar issues are encountered in Ireland and in Canada were the system is based on dispensations only.

## 3.10 Swedish eMedication Approach

Swedish eMedication Approach

Sweden already has an implemented national eMedication approach: indeed all pharmacies in Sweden must have access to information about e-prescriptions in the registers at the Swedish eHealth Agency in order to be a certified pharmacy. The access is authorized after an approval process at the Swedish eHealth Agency.

Registers

The architecture is based on four registers that handle personal information in the system. They have their own laws that regulate for what purposes the information can be used and by whom. The four registers are:

**The e-prescription repository**

Patients must consent to have their prescriptions stored electronically, but there is no consent needed from the patients for the prescriptions to be sent to the e-prescription repository.

All regions have functionality to send prescriptions electronically from their systems. If a patient doesn´t want his/her prescriptions to be stored electronically, he/she will use paper prescriptions instead. It is only pharmacists and the patient themselves that can have access to the information.

Currently, 99% of all prescriptions are e-prescriptions.

The Swedish Ministry of Health and Social Affairs has commissioned the Swedish Medical Products Agency to introduce electronic prescription as the main rule. The Agency is to report back to the Ministry in March 31, 2020.

**The high-cost database**

Another register that is based on consent is the high-cost database, which contains information on how much individuals have paid for prescribed pharmaceuticals within the national reimbursement scheme.

The patients themselves have access to the information as well as a pharmacist who needs the information when dispensing a prescription to charge the patient the right cost.

**Register of dispensed drugs**

A register that is not based on consent is the register of dispensed medicinal products, which contains information about all medical products a patient has had from any pharmacy regardless of it being an e-prescription or a paper prescription. For anyone but the patient to access this information, a consent must be given by the patient to the physician or the pharmacist.

A new law, the National Medication List, was passed in June 2018. The new law will allow healthcare professionals, pharmacists and patients to share nationally stored information about prescribed and dispensed medicinal products, which is not possible with the current laws. The new law will come in full effect on June 1, 2020 and will replace current laws described above. The registers and IT-services needed to access the National Medication List are being built by the Swedish eHealth Agency and they will be mandatory to use by all healthcare providers and pharmacies. It will also be mandatory for the patient, consent for storing the information above is no longer required.

**Statistics**

All pharmacies in Sweden report back to the Swedish eHealth Agency when they dispense the prescriptions as well as every other medication sold over the counter. Other sellers of OTC medicines, like supermarkets, also report their sales to the Swedish eHealth Agency. This is the basics for the national statistics on pharmaceuticals in Sweden.

**The e-prescription repository for animals**

e-Prescriptions for animals

Pet owners must consent to have their animals' prescriptions stored electronically, but there is no consent needed from pet owners for the prescriptions to be sent to the e-prescription repository for animals. If pet owners' don´t want their animals' prescriptions to be stored electronically, he/she will get paper prescriptions instead.

It is only pharmacists and the pet owners themselves that can have access to the information.

75% of all animal prescriptions are electronic.

# 4 Use of a tool supporting eMedication

Representative set of situations

This chapter describes the various steps occurring during a representative set of situations if a software tool implementing an eMedication service would be available (called “eMedication service” in the description below):

- A visit of a patient to his/her general practitioner, during which the medications of the patient is modified;
- Admission of a patient in a hospital;
- Discharge of a patient after a hospital stay or any discharge with a transfer in another care institution;
- Dispense of medications by a pharmacist;
- Home care nurse visiting her patient and documenting some problems encountered by the patient.

## 4.1 Patient visit to his/her GP

Patient visit to a GP

The following exchanges should typically occur when a patient is visiting his/her GP and that the physician adapts the medication treatment plan of the patient:

1. The GP logs in into the EPR-XDS.b Infrastructure (two factors authentication);
2. The GP[24] retrieves the current medication list in a structured form from the eMedication Service;
3. In case the GP software manages its own list of medications for the patient, both lists (local list and current medication list) are presented. If not, only the current medication list is presented;
4. If the GP decides to add a medication, a new Medication Treatment Plan document is created and published towards the eMedication Service;
5. If the GP decides to modify or stop an existing medication, a new Pharmaceutical Advice document is created and published towards the eMedication Service;
6. If the GP decides to make a new prescription, a new eMedication Prescription document is created and published towards the eMedication Service;
7. If the GP decides to dispense medication directly, a new eMedication Dispense document is created and published towards the eMedication Service;
8. The GP retrieves the up-to-date current medication list either as a structured document to be formatted or as a PDF document[25] from the eMedication Service, prints it and give it to the patient along with the prescription required to obtain the new medications from the pharmacy.

[24] No distinction is made in the text between the « GP » and his/her « primary system ».

[25] Although not formally part of the CDA-CH-EMED specification, it is considered useful that the eMedication Service is able to provide a ready-to-print version of the current medication list.

## 4.2 Patient admission in a hospital

Patient admission in a hospital

The following exchanges should typically occur when a patient is being hospitalized and the physician in charge of the patient initiates his/her medication treatment plan:

1. The physician logs in into the Clinical Information System (CIS);
2. The CIS retrieves the current medication list in a structured form from the eMedication Service;
3. The physician considers the list as one source of medication information necessary for performing the admission's medication anamnesis;
4. The physician decides which medications are being continued during hospitalization and copies those into the CIS' medication treatment plan in order to create the initial medication treatment plan for the hospital stay. Although in many situations the medications are changed according to hospital's in-house list of medications, this possibility is considered as very useful by clinicians.

## 4.3 Patient discharge after hospital stay / Patient transferred into another care institution

Patient discharge after hospital stay

The following exchanges should typically occur when a patient is being discharged or transferred into another care institution:

1. The physician logs in into the CIS;
2. The CIS retrieves the "current medication list" of the date the patient entered the hospital in a structured form from the eMedication Service;
3. The system displays the current medication list (from the hospital information system) along with the one retrieved from the eMedication Service (pre-hospitalization medication treatment plan);
4. The healthcare professional realizes the medication reconciliation in order to produce the updated medication treatment plan for the patient once (s)he left the hospital. This step is crucial as many post-hospitalization medication-related problems occur due to the fact that this reconciliation is not completely performed, resulting in the patient making his/her own mix between the medications (s)he was taking before hospitalization and medications of the discharge prescription;
5. The CIS publishes the corresponding Medication Treatment Plan, Pharmaceutical Advice and Prescription documents towards the eMedication Service;
6. In case the hospital directly dispenses the medications, the CIS publishes the corresponding eMedication Dispense documents towards the eMedication Service;

7. The physician retrieves the up-to-date current medication list either as a structured document to be formatted or as a PDF document from the eMedication Service, prints it and give it to the patient along with the printed prescription necessary to get the new medications from the pharmacy.

## 4.4 Dispense of medication at the pharmacy

Dispense at the pharmacy

The following exchanges should typically occur when a patient goes to a pharmacy for buying or receiving the medications listed on the prescription:

1. The patient presents his/her paper prescription to the pharmacist (or asks the pharmacist to retrieve the electronically signed prescription document from his/her EPR[26]);
2. The Pharmacy Information System (PIS) retrieves the list of prescriptions ready for dispense from the eMedication Service (i.e. list of IHE Pharmacy PRE documents);
3. The pharmacist selects the right prescription and gets its content directly in the PIS;
4. The pharmacist dispenses the medications, possibly substituting medications by generic ones, documenting in the PIS which boxes from which manufacturer are dispensed for each medication on the prescription;
5. The PIS publishes towards the eMedication Service the eMedication Dispense documents corresponding to the performed dispenses[27];
6. The pharmacist retrieves the up-to-date current medication list either as a structured document to be formatted or as a PDF document from the eMedication Service, prints it and give it to the patient.

## 4.5 Visit of the home care nurse

Visit of the home care nurse

The following exchanges should typically occur when a home care nurse visiting a patient at home gets some feedback from the patient about medications:

1. The nurse logs in into his/her nursing application;
2. The nurse retrieves the current medication list in a structured form from the eMedication Service;
3. The nurse adds patient's comment to one medication by publishing an Pharmaceutical Advice document towards the eMedication Service.

[26] Digitally signed prescription (with a qualified electronic signature) will be allowed from 2020.

[27] Generic substitution, if performed, is indicated directly in the eMedication Dispense Document.

# 5 eMedication Service

## 5.1 Founding principles & goals

Founding principles

Results of the experiments with the shared medication treatment plan as well as the adoption of the EPR national law and its related ordinances were important triggers for designing the shared medication treatment plan as a value added service to EPR communities. The service proposed here and called eMedication Primary Aggregator capitalizes on the experiments performed with the shared medication treatment plan in Geneva and Vaud while taking into account the global architecture of the national EPR:

- The eMedication Primary Aggregator is a value added service in the outskirt of the EPR-XDS.b Infrastructure core infrastructure. Indeed the Primary Aggregator implements an aggregation *process*, and therefore is generally considered to be outside of the scope of the EPR-XDS.b Infrastructure which implements basically a secondary storage for documents;
- Core functionality like patient identification, user authentication, logging/auditing and secondary storage of information are key functionality of each EPR-XDS.b Infrastructure: the Primary Aggregator should rely on them and not duplicate them.

The eMedication Primary Aggregator is therefore the “intermediate” component aware of all actions on the shared medication treatment plan of a patient.

Several integration schemes are presented in the next chapter: the goal of this chapter is thus to define the key principles governing the service, whatever the integration scheme is.

The Primary Aggregator’s behaviour is based on the IHE Pharmacy CMPD profile as in the first phase only CDA documents based on CDA-CH-EMED national profile are exchanged. Once FHIR equivalent profiles will be available, a revision of this architecture may occur in order to support also a “FHIR-based CMPD” equivalent profile.

CMPD Architecture

The CMPD architecture is given in the figure below.

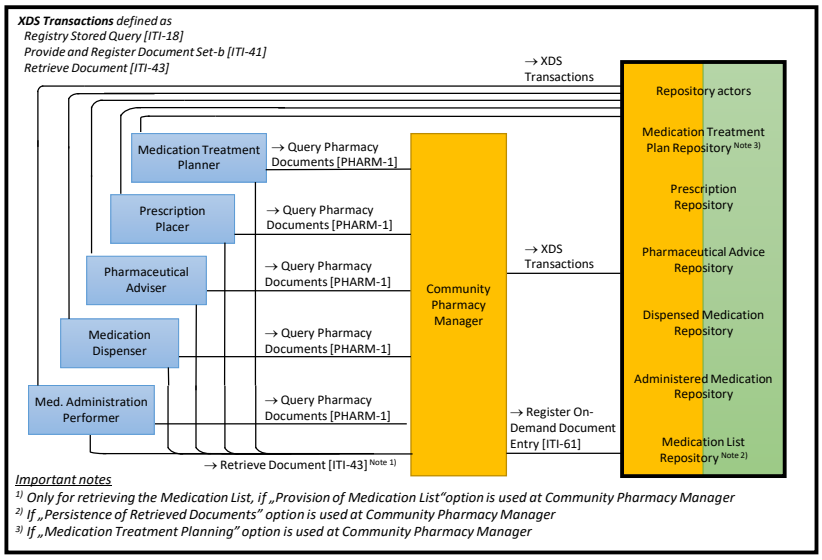


**Figure 10: CMPD and its related actors**

Notes:

- Medication Treatment Planner is in most cases a physician, but it can also be a pharmacist (e.g. for OTC) or the patient himself documenting self-medication;
- Prescription Placer is in most cases a physician, but it may also be a pharmacist documenting a provisional prescription;
- Pharmaceutical Adviser may be different actors: a pharmacist performing prescription validation, a physician validating a provisional prescription, a nurse, physician, pharmacist or even the patient himself adding a comment, etc.;
- Medication Dispenser is generally a pharmacist but may also be a dispensing physician;
- Medication Administration Dispenser is the one administering a specific medication and being able to assess that the medication has been fully taken by the patient (e.g. a nurse administering an intra-muscular medication).

In the figure above one can distinguish:

1. The primary system(s) in blue (physicians, pharmacists, nurses, etc.) comprising: Primary system(s)
    - The Medication Treatment Planner, which publishes and retrieves MTP documents (i.e. introducing new medications into the shared medication treatment plan);
    - The Prescription Placer, which publishes and retrieves PRE documents (i.e. publishing a new prescription);
    - The Pharmaceutical Adviser, which publishes and retrieves PADV documents (i.e. validating a prescription, introduction modifications or comments related to one existing document);

- The Medication Dispenser, which publishes and retrieves DIS documents (i.e. documenting a dispense);
- The Medication Administration Performer, which publishes and retrieves CMA documents (i.e. documenting medication administration). Note that CMA documents are not yet part of CDA-CH-EMED specification and therefore are not yet supported by this eMedication Service Concept although it would be easily supported;

2. The eMedication Primary Aggregator in yellow comprising: eMedication Primary Aggregator
   - The CMPD business logic;
   - Repositories for Medication Treatment Plans, Prescriptions, Pharmaceutical Advices, Dispenses, Medication Lists (if storage of on-demand produced documents is required) and (later) Administered Medications if distinct from the EPR-XDS.b Infrastructure repositories;

3. The EPR-XDS.b Infrastructure in green comprising: EPR-XDS.b Infrastructure
   - The Medication Treatment Plan Repository for storing MTP documents (secondary storage);
   - The Prescription Repository for storing PRE documents (secondary storage);
   - The Pharmaceutical Advice Repository for storing PADV documents (secondary storage);
   - The Dispense Repository for storing DIS documents (secondary storage);
   - The Administered Medication Repository for storing CMA documents (secondary storage);
   - The Medication List Repository for storing on-demand documents if required.

**CMPD Profile Options**

IHE Pharmacy CMPD profile allows a certain number of options. The following configuration applies for the described eMedication Primary Aggregator: CMPD Profile Options

1. “Provision of Medication List” Option IS supported;
2. “Persistence of Retrieved Documents” IS NOT supported;
3. “Medication Treatment Plan Planning” IS supported.
4. The Community Medication Administration document is not yet part of CDA-CH-EMED specification. As a consequence, the Medication Administration Performer is not yet supported;
5. Workflow scenario 2 is being used (i.e. no mandatory PADV for allowing dispense of every prescription). However scenario 1 is being used if a prescription is explicitly marked as “to be validated”.

It has to be noted that the eMedication Primary Aggregator is an extended implementation of the Community Medication Prescription and Dispense (CMPD) IHE Pharmacy profile: indeed it implements the transactions defined in the CMPD profile but has also business logic extensions in order to provide aggregated medication lists corresponding to classical needs of primary systems (like e.g. the treatment card). These will be described in details in the next sections.

The basic workflow of the Primary Aggregator is described in chapter 6 below.

## 5.2 Basic use cases

Basic use cases

The following use cases are the key use cases for which the eMedication Primary Aggregator is designed for. Note that these use cases are those implemented by the aggregator itself: the use cases supported by primary systems are often more complex (e.g. the reconciliation process has to be implemented at the primary system's level) but can at the end be expressed as combinations of these core use cases.

### 5.2.1 Plan (add medication)

Plan (add)

When a physician decides that the patient has to take a medication (s)he is "planning" a medication. This has not to be confused with the general expression "the physician prescribed me a medication": this common sentence is in fact the combination of two actions: the decision which results in a planning action and the (logistic) prescription which results in a prescription for the pharmacy *if required*. The prescription serves thus two purposes: a logistic purpose (being able to buy and possibly be reimbursed for a medication) and a documentation purpose for telling the patient how much and when the medication has to be taken.

Pharmacists are also performing the planning action when they perform medication dispense without a prescription (over the counter - OTC) or according to special rules (B+ lists). Those operations should therefore also result into an initial planning action.

Planning action may also be described by the patients themselves for documenting auto-medication. Indeed it is a strong demand from patients and it participates to his/her empowerment and implication in the care processes. While it may be seen as a risk for "polluting" the shared medication plan by non-professionals, it will always be clearly mentioned that a specific information has been entered by the patient himself.

In IHE Pharmacy terms, medication planning is implemented by publishing a MTP document per planned medication.

### 5.2.2 Alter plan (alter medication)

Alter

Planner[28] may decide to alter a planned medication by e.g. modifying the dosage or the administration frequency. It may also decide to add a comment to the medication – either for the professional dispensing or administering the medication of for the patient himself/herself.

[28] Term is designating the role of the actor, not his/her profession. Several healthcare providers (GPs, pharmacists, nurses …) may act as a « planner ».

Example of comments could be “Please double check intake procedure with the patient” (typically addressed to a professional) or “Drink enough water when taking this medication” (typically addressed to the patient). The type of a comment determines where it should appear (e.g. on the Medication Card document, indication for the dispenser along with a prescription, etc.).

Such operations are performed by publishing an IHE Pharmacy PADV (Pharmaceutical Advice) document referring to the original MTP document.

### 5.2.3 Stop plan (stop medication)

Stop

If a medication intake should be discontinued before the planned end of treatment defined in the original MTP document, a premature end can be introduced by issuing an IHE Pharmacy PADV document referring to the original MTP document.

### 5.2.4 Prescribe medication(s)

Prescribe

Prescriptions are issued by a prescribing physician or any healthcare professional empowered to prescribe in order to enable the patient to get the medication from the pharmacy (and subsequently to be reimbursed by the insurance). Prescription are submitted as an IHE Pharmacy PRE document. A PRE document may contain several items (prescribed medications), each referring to its corresponding MTP in the shared medication treatment plan. It is therefore the electronic version of a paper prescription. Prescription can be renewable either in terms of duration or in terms of number of renewals.

Business rules applied in Switzerland state that a prescription document is valid for at most one year (12 months) from the date of the prescription document. Renewal can be allowed up to one year, limited however by the validity period of the prescription document itself and by the total amount dispensed. It has to be noted however that rules may be change from one canton to another.

### 5.2.5 Prescribe controlled medication(s) (e.g. narcotics)

Prescribe controlled medications

Narcotics and some other specific medications have to be prescribed using specific numbered prescriptions. Such prescriptions are very specific and are using registered and individually numbered paper documents.

Such prescriptions are not yet supported by the Primary Aggregator: further work on organisational and legal aspects is required before a suitable specification can be realized.

### 5.2.6 Modify prescription

Modify prescription

Modifying a prescription can occur in several situations:

- Comments can be added;
- Posology, duration or other parameters may need to be changed;
- Prescription need to be formally approved (provisional prescription on one side or pharmaceutical adviser’s confirmation as CMPD workflow 1 is being used).

Of course modification of the prescription will never be retroactive for e.g. an already occurred dispense. However modification may be required, and thus need to be supported.

Prescription modification is performed by publishing an IHE Pharmacy PADV document linked to the initial PRE document.

Formal approval is performed by issuing an IHE Pharmacy PADV document containing for each medication a status describing the resulting state of the prescription. Status may be e.g. “OK” (approval of the prescription without any change), “REFUSE” (prescription should not be dispensed) or “CHANGE” (dispense can occur but modifications have to be taken into account. Note that “REFUSE” and “CHANGE” should be used with care on provisional prescriptions, as mentioned in IHE Pharmacy CMPD profile[29].

Substitution by a generic product during dispense is not a modification of a prescription and is documented directly in the eMedication Dispense document.

### 5.2.7 Stop prescription

Stop prescription

It may be necessary to stop dispense of a prescription – because the prescription has been superseded by another prescription, because of a mistake or because the treatment is stopped.

Stopping a prescription is performed by publishing an IHE Pharmacy PADV document referring to the concerned PRE document.

### 5.2.8 Dispense medication

Dispense medication

Dispense is performed by publishing an IHE Pharmacy DIS document. DIS document describes dispense of only one item of one PRE document and refers both to the corresponding MTP document and the corresponding PRE document. DIS document can be used to document full or partial dispense of the medication. Four dispense states can be documented:

- First fill – Complete: meaning everything dispensed at once;
- First fill – Part fill: meaning first but partial dispense;
- Refill – Part fill: meaning partial dispense (continuing);
- Refill – Complete: meaning everything dispensed.

It can also document medication substitution occurring at dispense time.

### 5.2.9 Dispense before prescription

Dispense before prescription

Dispense of medication subject to a future prescription may lead to dispenses not linked to their corresponding prescription (dispense linked only to planning (MTP) information). As this may result in lack of information on already dispensed medication, a possibility for a pharmacist to pre-document the prescription has been introduced: the pharmacist can issue a provisional prescription document referring to the physician as the author of the medical decision and containing the intended prescriptions. The document is an IHE Pharmacy PRE document but with each medication marked as “To be approved”, requiring a formal approval by a physician in order to formally validate the prescription. The approval will have to be performed through IHE Pharmacy PADV documents (one per pre-prescribed medication).

[29] From version 2019, which supports provisional prescriptions.

The process therefore implies that in such a situation, the pharmacist first issues an MTP for introducing the medication into the shared medication treatment plan if necessary (i.e. if the medication is not already present in the shared medication plan), then issues a to-be-validated PRE document (linked to the MTP document) and finally performing the dispense on the to-be-validated prescription the same way (s)he would perform a classical dispense (the DIS document being linked to the MTP and the PRE documents).

### 5.2.10 Dispense on prescription received by phone/fax

If the responsible physician has not the possibility to publish the PRE document before dispense will occur, dispense on prescription received by phone or fax may be handled the same way than dispense before prescription.

In case the physician has no access to EPR, the prescription will remain in the “To-be-validated” status except if another physician is willing to take the responsibility to validate it on behalf of the prescriber. This is not considered as a problem in itself, but forces the pharmacist to perform additional controls when accessing a “to-be-validated” prescription in order to decide if (s)he can dispense or not (e.g. calling the mentioned prescriber). MTP documents possibly created to support the provisional prescription are not provisional and therefore do not require such a validation step.

Archival of a faxed prescription may be performed by the receiver depending on regulatory requirements.

### 5.2.11 Dispense on paper prescription

Dispense on paper prescription

In case the patient comes with a paper prescription while the patient has a shared medication treatment plan, it would be useful that the pharmacist documents the prescription into the shared medication treatment plan. The same workflow as the one for dispense before prescription may therefore be used.

In case the physician has no access to EPR, the prescription will remain in the “To-be-validated” status except if another physician is willing to take the responsibility to validate it on behalf of the prescriber. This is not considered as a problem in itself, but forces the pharmacist to perform additional controls when accessing a “to-be-validated” prescription in order to decide if (s)he can dispense or not (e.g. calling the mentioned prescriber). MTP documents possibly created to support the provisional prescription are not provisional and therefore do not require such a validation step.

### 5.2.12 Get documents list

Get Documents List

The CMPD profile foresees requests for retrieving a list of documents corresponding to some criteria defined in IHE XDS profile specifications. Each returned list contains the identifiers of the documents corresponding to the selection criteria (content of selected document(s) is not returned). The following lists of documents can be requested (the ad-hoc query name is given in the parenthesis):

- MTP documents (FindMedicationTreatmentPlans):

  This list contains corresponding medication treatment plan document identifiers along with the PADV, PRE and DIS document identifiers of the documents containing references to the selected MTP documents. PADV document identifiers of documents containing references to PADV, PRE and DIS documents additionally selected are also included.

- PRE documents (FindPrescriptions):

  This list contains corresponding prescription document identifiers along with the PADV, MTP and DIS document identifiers of the documents containing references to the selected PRE documents or being referenced by selected PRE documents. PADV document identifiers of documents containing references to PADV, MTP and DIS documents additionally selected are also included.

- DIS documents (FindDispenses):

  This list contains corresponding medication treatment plan document identifiers along with the PADV, MTP and PRE document identifiers of the documents containing references to the selected DIS documents or referenced to by selected DIS documents. PADV document identifiers of documents containing references to PADV, MTP and PRE documents additionally selected are also included.

- CMA documents:

  This list is not yet supported (would be empty);

- PRE documents for validation (FindPrescriptionsForValidation):

  As the Primary Aggregator is using workflow 2 from CMPD (i.e. prescriptions are validated by default), this list will only contains PRE document identifiers containing at least one entry marked explicitly as “To be validated” and that has not yet been validated by an ad-hoc PADV entry. It also contains the PADV, MTP and PRE document identifiers of the documents containing references to or being referenced by the selected PRE documents as well as PADV document identifiers of documents containing references to PADV, MTP and DIS documents additionally selected.
  It has to be noted that the Primary Aggregator does not check the amount of possibly already dispensed medications against the number of prescribed medications. It is indeed the role of the healthcare professional to estimate if a prescription can still be dispensed or not, in case dispense on a non-validated prescription already occurred.

- PRE documents for dispense (FindPrescriptionsForDispense):

  As the Primary Aggregator is using workflow 2 from CMPD (i.e. prescriptions are validated by default), this list will only contains PRE document identifiers containing at least one entry not marked explicitly as “To be validated” or at least one entry that has already been validated by an ad-hoc PADV entry.

It also contains the PADV, MTP and PRE document identifiers of the documents containing references to or being referenced by the selected PRE documents and PADV document identifiers of documents containing references to PADV, MTP and DIS documents additionally selected.
It has to be noted that the Primary Aggregator does not check the amount of dispensed medications against the number of prescribed medications. It is indeed the role of the healthcare professional to appreciate if a prescription can still be dispensed or not.
In case a dispense document linked to a specific prescription exists and has the status “Final dispense”, the specific prescription is not considered as “dispensable” anymore.

Processes governing the selection of the returned document identifiers is described in details in section 8.2 Appendix B – PHARM-1 selection criteria.

### 5.2.13 Get medication list

Get medication list

Creation of aggregated medication lists is one key role of the Primary Aggregator, and is also the role of the CMPD Actor. At the opposite of the previous function – get documents list, this request returns one single IHE Pharmacy PML document identifier that will contain all content entries of the selected documents.

Several medication lists are provided by the Primary Aggregator through the “FindMedicationList” query:

- Current list of active medications[30] (i.e. Medication Card document containing the aggregated list of active medications);
- Current treatment card in PDF[31];
- List of all consolidated medications (i.e. treatment card including stopped or completed medications);
- List of medications with full history;
- Full raw history of shared medication treatment plan.

Other medication lists may be made available depending on the needs of primary systems.

Processes governing the selection of the returned document identifiers is described in details in section 8.2 Appendix B – PHARM-1 selection criteria.

## 5.3 Pre-loading shared medication treatment plan from an existing source

Import from an existing source

In some situation the patient may already have an existing medication plan. This is in particular the case when e.g. an eMediplan instance or another medication plan do exists.

[30] Active medications are medication having an “open” MTP entry (i.e. “starting date” before “now”, “ending date” after “now”, and no PADV stopping the MTP).

[31] This document is primarily for the patient, enabling him/her to print his/her medication treatment plan. Exact representation may be standardised.

In order not to have to re-enter all medications, publication towards the eMedication Primary Aggregator of a CDA-CH-EMED Medication Card document is supported. Such a publication triggers the following actions from the eMedication Primary Aggregator:

- Each entry of the document is extracted and a CDA-CH-EMED MTP document is created accordingly, with same authoring information than the CDA-CH-EMED Medication Card document;
- Each MTP document is processed like any other MTP submission.

In case a shared medication treatment plan do exist and is not empty, new entries will be added to the shared medication treatment plan. It is indeed the responsibility of the healthcare provider submitting the Medication Card document to be aware of the impact to add simultaneously several medications to the existing shared medication treatment plan, e.g.to avoid a medication being entered twice in the shared medication plan.

## 5.4 Patient enrolment / unsubscribe

Enrolment / Unsubscribe

Patients deciding to become “owner” of a shared medication treatment plan have to make a specific enrolment. Indeed it is foreseen that the shared medication treatment plan is optional for the patient: it should be a free decision from the patient to adhere – or not – to this service. **Subscription will however require that the patient already has an active EPR**. Implementation of patient subscription will be described in section 6.6.

Patients are free to adhere to the shared medication treatment plan: likewise patients can also decide to unsubscribe from the shared medication treatment plan service. Patient unsubscribe will lead to the removal of all information stored by the eMedication Primary Aggregator. Implementation of patient unsubscribe will be described in section 6.6.

## 5.5 Documenting events occurring outside eMedication environment

External events

It is clear that not every healthcare provider will be connected to an EPR Community from the beginning and that completeness of the shared medication treatment plan cannot be guaranteed. Moreover a certain number of healthcare providers connected to an EPR Community may not have eMedication system. It is therefore certain that a certain number of medication-related actions (prescriptions, dispenses, etc.) will not be documented in the EPR.

Such a situation has to be admitted and is anyway not unusual for healthcare providers: indeed patients may not remember some medications they are taking or did take in the past, or the exact name or posology of some medications. This is one reason among others why e.g. medication anamnesis during hospital’s admission has to be based on more than one source (three independent sources are even recommended).

Nevertheless in order to make the shared medication treatment plan as complete as possible, any healthcare provider may document acts performed by another healthcare professional and not included in the EPR.

Documentation is introduced by creating corresponding CDA-CH-EMED documents out of available information and by publishing them towards the eMedication Primary Aggregator. Responsibility is preserved as each CDA-CH-EMED document makes a clear distinction between the author of the medical decision (i.e. the one who made a decision without documenting it in the EPR) and the author publishing the information towards the eMedication Primary Aggregator. A healthcare provider documenting something another healthcare provider decided will therefore not bear the responsibility of the medical decision but only the responsibility of having made it available in the EPR.

## 5.6 Coherence of the shared medication treatment plan

Coherence of the plan

One advantage of having an eMedication Service is to guarantee the coherence of the medication plan. Indeed incoherencies may occur after several events, like among others:

- Deprecating or hiding a document referred to by others: e.g. deprecation of a prescription that was already dispensed;
- When confirming a provisional prescription that has already been dispensed, changing the name or the dosage of the medication;
- Refusing the dispense of a provisional prescription (e.g. by issuing a Pharmaceutical Advice document containing a “REFUSE” code) that has already been dispensed;
- Prescribing a medication for a duration exceeding the duration defined in the plan (MTP Item).

Instead of detecting such problems at the time of e.g. the creation of the Medication Card document or the current medication list, application of coherence rules at the time the potentially problematic request is sent and rejecting it if it breaks the coherence avoids future problems.

It is indeed not the role of the eMedication Service to apply coherence rules related to medical decisions, e.g. prescription or dispense of a medication that is not associated to a documented medical problem of the patient. Implemented rules only avoid to have incoherencies in the workflow related to the eMedication service (planning, prescription, dispensation including changes at every stage).

## 5.7 Vectors of information

Vectors of information

Current standards supporting all functions of the eMedication Primary Aggregator currently only exist based on CDA document format. Moreover EPR-XDS.b Infrastructures are currently designed for working with CDA-CH based documents and FHIR support will come only later. The current eMedication Service Concept therefore only supports communication based on CDA-CH-EMED documents and possibly IHE Advanced Patient Privacy Consents (APPC) document as discussed in the access rights management section.

It is however expected to have in the future FHIR-based CDA-CH equivalent resources[32] to CDA-CH-EMED documents as well as clear processes for implementing the CMPD functionality though FHIR resources in a multi-communities environment. This will lead to an extension of the current eMedication Service Concept.

[32] Active medications are medication having an “open” MTP entry (i.e. “starting date” before “now”, “ending date” after “now”, and no PADV stopping the MTP).
[32] This document is primarily for the patient, en

# 6 eMedication Primary Aggregator Architecture

eMedication Primary Aggregator Architecture

Several architectures can be considered in terms of number of primary aggregators and their relationships / interconnection with EPR communities. This chapter considers the most relevant architectures with their advantages and drawbacks as well as potential impact on EPR regulations for supporting its behaviour.

Architectures 1 to 4 describe an eMedication Primary Aggregator implemented as an independent component from the EPR implementations while Architecture 5 considers an integrated solution.

EPR is by definition a secondary system, i.e. it should contain only copies of documents, the original being kept by the primary system. However this definition may be considered as too simple when considering:

- the upload of information (documents) by the patient into his/her own EPR;
- Graphical user interfaces (GUI) acting directly either with the EPR-XDS.b Infrastructure (e.g. integrated into the patient's or healthcare professional's portals) or with the eMedication Primary Aggregator;
- Conversion of a medication list into a set of unitary documents (Medication Treatment Plan documents) created by the eMedication Primary Aggregator.

While in the first use case one may make the patient aware of the fact that he/she has to keep a copy of the uploaded document, the second use case has no other original (document) than what is entered though the GUI while in the third use case documents are created by the eMedication Primary Aggregator.

Primary Aggregator as a Primary System

These facts leads to the statement that the eMedication Primary Aggregator described below has to be considered as a Primary System, and that as such it makes use of the EPR core services for archiving a (secondary) copy of the information into the EPR-XDS.b Infrastructure. The eMedication Primary Aggregator is therefore a primary system between a healthcare provider's primary system and the EPR-XDS.b Infrastructure secondary system. It may also be a primary system accessed through specific GUIs for documenting eMedication information, which itself benefits from a secondary storage in the EPR-XDS.b Infrastructure.

## 6.1 Architecture 1: Single National Aggregator (external service)

Architecture 1: Single National Aggregator

With this configuration, only one national eMedication Primary Aggregator exists, offering the eMedication service to every primary system. Primary systems are interacting both with the community they are affiliated to (non eMedication related requests) and with the national Primary Aggregator for eMedication related requests.

Figure 11 below shows the global architecture of this configuration.

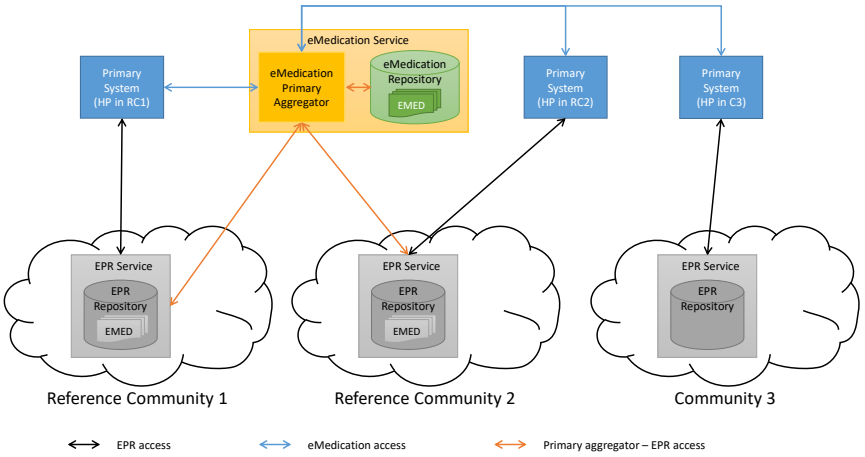


**Figure 11: eMedication Primary Aggregator versus communities (Architecture 1)**

This architecture is based on a central eMedication Primary Aggregator to which every primary system is connected to. Each community operates its own Affinity Domain, so do the eMedication Primary Aggregator.

Primary systems have two connections: one to their “home” community for regular EPR-XDS.b Infrastructure access (read and publish) and one to the eMedication Primary Aggregator for eMedication documents access (read and publish).

In order to avoid that primary systems have to publish each eMedication document twice (once to the primary aggregator, once directly into the EPR-XDS.b Infrastructure), the primary aggregator publishes every accepted document into the reference community of the patient.

The primary aggregator may also maintain a primary-level repository of every published eMedication document.

Internal architecture

The primary aggregator’s internal architecture is drawn in the figure below. It has to be noted that the modules drawn in the figure are used to represent key functionality and are not normative. They are nevertheless useful for the detailed functional description.

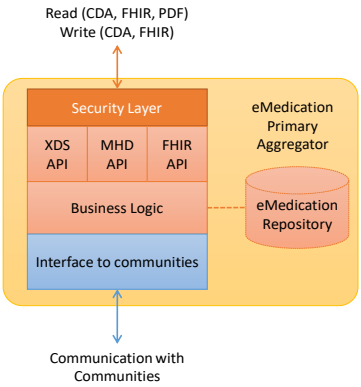


**Figure 12: eMedication Primary Aggregator Environment**

As mentioned earlier, it is expected that in the future a FHIR-based API is made available. However this will be specified in details once FHIR-based IHE Profiles (offering an equivalent functionality to MTP-, PRE-, DIS-, PADV, PML-content profiles and CMPD-workflow profile) are available. The "FHIR API" in the drawing has therefore to be considered as a placeholder for the moment. As an interim solution it may be possible to use IHE MHD (Mobile access to Health Documents) Profile for implementing the document access. However extensions of this profile will be needed in order to support document deprecation and possibly additional selection criteria for documents retrieval in order to be able to access the whole functionality of the CMPD implementation. Further descriptions in this chapter are therefore assuming the use of a XDS-based interface.

### 6.1.1 Technical architecture

Technical architecture

The eMedication Primary Aggregator is exposing a XDS-based API towards primary systems: indeed in order to minimize the added interfacing complexity for primary systems, the eMedication Primary Aggregator interface is basically the same as the one each EPR-XDS.b Infrastructure has to provide for primary systems. Hopefully this is fully in line with IHE Pharmacy CMPD profile which foresees the use of the "classical" document access transactions from IHE ITI Profile.

The same strategy is being applied for what concerns the interface between the Primary Aggregator and the communities it is connected to: in order to preserve the possibility to act as a proxy between the primary system and the EPR-XDS.b Infrastructure, the same API that is exposed to primary systems is being used by the Primary Aggregator.

Transactions to be supported

The Figure 13 below shows the transactions that have to be supported by the Primary Aggregator and the transactions that are being used by the Primary Aggregator for accessing the EPR-XDS.b Infrastructure.

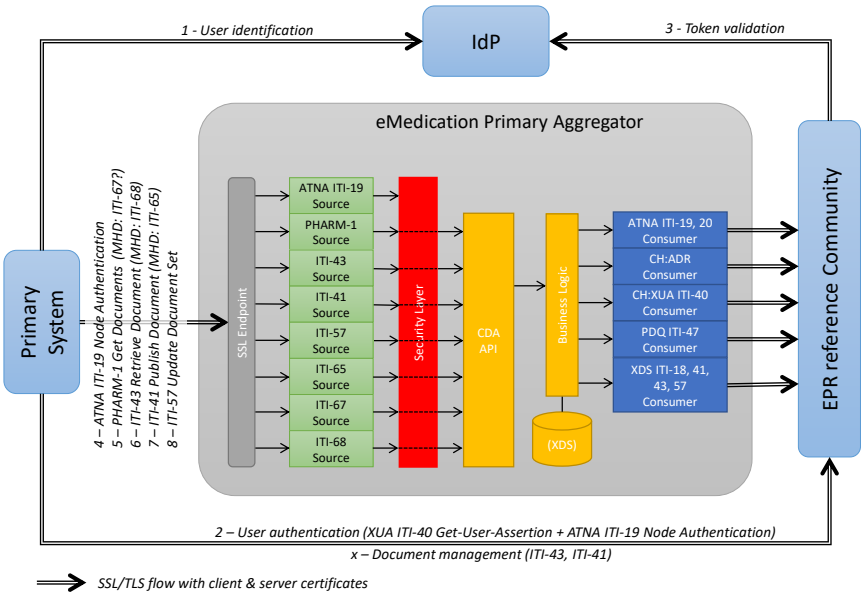


**Figure 13: eMedication Primary Aggregator Transactions**

Transactions in green boxes are transactions "offered" to primary systems,

i.e. where the Primary Aggregator acts as a server. Transactions in blue boxes are IHE transactions used by the Primary Aggregator for retrieving information from the EPR-XDS.b Infrastructure (Primary Aggregator acting as a client). It has to be noted that some transactions in blue boxes may not be necessary / useful depending on the workflows implemented (in particular ITI-18 and ITI-43). This is discussed in more details below.

### 6.1.2 Interactions with primary systems

Interactions with primary systems

As mentioned before, the interface to the Primary Aggregator is designed in a way not to add additional complexity to primary systems: it is using the same workflows and the same transactions than the “classical” interface to an EPR-XDS.b Infrastructure – except of course the PHARM-1 transactions introduced by IHE Pharmacy CMPD profile.

The following transactions are therefore supported by the Primary Aggregator (acting as source, the primary system being the consumer):

- PHARM-1: Document(s) list retrieval (“Query Pharmacy Documents”);
- ITI-43: Document(s) content retrieval (“Retrieve Document Set”);
- ITI-41: Publication of a document (“Provide and Register Document Set-b”);
- ITI-57: Document update and deprecate (“Update Document Set”).
- If MHD Profile is supported:
    - ITI-65: Publication of a document (MHD “Provide Document Bundle”);
    - ITI-67: Documents content retrieval (MHD “Find Document References”)[33];
    - ITI-68: Documents content retrieval (MHD “Retrieve Document”).

In addition, transaction ITI-19: ATNA “Authenticate Node” has to be supported in order to establish the communication between the primary system and the Primary Aggregator as well as ITI-40 carrying the XUA assertion grouped with the previous ones.

This architecture does not require to support cross-community XDS transactions (ITI-55, ITI-38 and ITI-39) as primary systems will always use intra-community services.

Patients are identified by the primary system through the EPR-SPID, which is required anyway from primary systems when interacting directly with the EPR-XDS.b Infrastructure through the same transactions (part of the XUA token).

Actions performed upon receiving one of the above mentioned request is described in the subsections below. Note that for completeness reasons

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abling him/her to print his/her medication treatment plan. Exact representation may be standardised.

on to ITI-18 search criteria.

description also takes into account transactions carrying an IHE Advanced Privacy Policy Consents document. This will be further described in the section describing implementation of access rights management (section 6.6.3 below).

Figure 20 shows the actions performed by the primary system before interacting with the Primary Aggregator, including e.g. a first “Get Medication Card document” by a physician. Indeed a primary system should first synchronize with existing data before allowing the healthcare provider to modify the shared medication treatment plan. This also allows the primary system to be aware of the existence or not of a shared medication treatment plan.

#### 6.1.2.1 Workflow “Get Documents List” (PHARM-1, “Document(s) list retrieval”)

Workflow for documents list retrieval (PHARM-1)

Primary systems can retrieve lists of documents identifiers through the use of the CMPD transaction called PHARM-1, which is based on ITI-18 “Registry Stored Query” transaction.

PHARM-1 transaction supports several queries:

- FindMedicationTreatmentPlans: search for planned medication documents and their related documents. Result is a set of document identifiers;
- FindPrescriptions: search for prescription documents and their related documents. Result is a set of document identifiers;
- FindDispenses: search for dispense documents and their related documents. Result is a set of document identifiers;
- FindMedicationAdministrations: search for administered medication documents and their related documents. Result is a set of document identifiers;
- FindPrescriptionsForValidation: search for prescriptions and their related documents containing Prescription Items ready to be validated. Result is a set of document identifiers;
- FindPrescriptionsForDispense: search for prescriptions and their related documents containing Prescription Items ready to be dispensed. Result is a set of document identifiers;
- FindMedicationList: search for the Medication List corresponding to the provided criteria. This transaction behaves differently from the other queries above: rather than returning an identifier of an existing document, it creates a new “on-demand” document containing the search criteria and returns this newly created document identifier. The true content is only assembled when an ITI-43 Document retrieve transaction is called.

The following steps are performed by the Primary Aggregator upon receiving a PHARM-1 request:

- When a list of documents is requested by the primary system (first 6 queries above), the following actions are performed:
    - Validation of the authentication (XUA) token of the primary user;
    - Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to

by the primary aggregator;
    - Verification that a shared medication treatment plan do exist. If not, the request has to be rejected as PHARM does not belong to the transactions set implemented by the community XDS provider;
    - If required, synchronization with EPR-XDS.b Infrastructure's content is performed (see 6.6.1 below);
    - If required, validation of access policies (see 6.6.1 below);
    - Compilation of the list of documents corresponding to the search criteria;
    - Return of the produced list of document identifiers.
- When a medication list or medication card document is requested by a primary system, the following actions are performed:
    - Validation of the authentication (XUA) token of the primary user;
    - Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;
    - Verification that a shared medication treatment plan do exist. If not, the request has to be rejected as PHARM does not belong to the transactions set implemented by the community XDS provider;
    - If required, synchronization with EPR-XDS.b Infrastructure's content is performed (see 6.6.1 below);
    - If required, validation of access policies (see 6.6.1 below);
    - Registration of the requested medication list (search criteria) as an on-demand document;
    - Return of the newly created document identifier.

Diagram with actors is given in Figure 21: Retrieve Document(s) List (PHARM-1) interaction diagram in 8.1 Appendix A – Interaction Diagrams.

Diagram with internal interactions is given in Figure 25: eMedication Primary Aggregator internal modules interaction diagram – PHARM-1 in 8.1 Appendix A – Interaction Diagrams.

Search criteria supported by PHARM-1 are described in 8.2 Appendix B – PHARM-1 selection criteria.

#### 6.1.2.2 Workflow "Documents content retrieval" (ITI-43)

Workflow for content retrieval (ITI-43)

The following steps are performed by the Primary Aggregator upon receiving a retrieval request:

- Validation of the authentication (XUA) token of the primary user;
- Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;

- Verification that a shared medication treatment plan do exist. If not,

the request is rejected[34];

- If required, synchronization with EPR-XDS.b Infrastructure's content is performed (see 6.6.1 below);
    - If required, validation of access policies (see 6.6.1 below);
- If the referenced document is an on-demand document:
    - Creation of its content according to its specification;
    - Publication or update of its copy in the EPR-XDS.b Infrastructure (secondary storage) if it is an Medication Card document;
- Return of the content of selected document(s).

Diagram with actors is given in Figure 22: Retrieve Document(s) Content (ITI-43) interaction diagram in 8.1 Appendix A – Interaction Diagrams.

Diagram with internal interactions is given in Figure 26: eMedication Primary Aggregator internal modules interaction diagram – ITI-43 in 8.1 Appendix A – Interaction Diagrams.

#### 6.1.2.3 Workflow "Publication of a document" (ITI-41)

Workflow for publication (ITI-41)

The following steps are performed by the Primary Aggregator upon receiving a new document:

- When receiving a new MTP, PRE, DIS or PADV document from primary system, the following actions are performed:
    - Validation of the authentication (XUA) token of the primary user;
    - Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;
    - Verification that a shared medication treatments plan do exist. If not, the request is rejected;
    - If required, synchronization with EPR-XDS.b Infrastructure's content is performed (see 6.6.1 below);
    - If required, validation of access policies (see 6.6.1 below);
    - Verification of completeness of the document;
    - Verification of coherence (see section 5.6 for what "validation of coherence" means) with the existing shared medication treatment plan;
    - Integration of the document into the shared medication treatment plan;
    - Publication of the document into the EPR-XDS.b Infrastructure (single community or reference community of the patient) by the technical user associated to the Primary Aggregator;
- When receiving an update for an existing MTP, PRE, DIS or PADV

[34] The Primary Aggregator could work as a proxy, forwarding the request to the reference community of the patient. However this would mean either implementing differentiated requests depending from the community to which the healthcare provider is connected to (use of either same community IHE transactions or cross-community IHE transactions) or having the knowledge of the community of the healthcare provider in order to forward the request to it. Moreover routing all requests to the patient's reference community may even prevent deprecation of documents as the relevant IHE profile (RMU) does not support cross-community deprecation.

document from primary system, the following actions are performed:

- Validation of the authentication (XUA) token of the primary user;
- Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;
- Verification that a shared medication treatment plan do exist. If not, the request is rejected;
- If required, synchronization with EPR-XDS.b Infra-structure's content is performed (see 6.6.1 below);
- If required, validation of access policies (see 6.6.1 below);
- Verification of completeness of the document;
- Verification of existence of the previous version;
- Verification of coherence with the existing shared medication treatment plan: if update leads to incoherence of the shared medication treatment plan, the request is rejected;
- Integration of the document into the shared medication treatment plan;
- Publication of the document into the EPR-XDS.b Infrastructure (single community or reference community of the patient) by the technical user associated to the Primary Aggregator;

- When receiving a PML/Medication Card document[35] from a primary system, the following actions are performed:
  - Validation of the authentication (XUA) token of the primary user;
  - Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;
  - Verification that a shared medication treatment plan do exist. If not, the request is rejected;
  - If required, synchronization with EPR-XDS.b Infra-structure's content is performed (see 6.6.1 below);
  - If required, validation of access policies (see 6.6.1 below);
  - Verification of completeness of the document;
  - Option: Verification that there is no existing shared medication treatment plan: if a plan do exists and is not empty, the request is rejected. If this option is not selected, any Medication Card document content will be merged with (i.e. added to) the existing shared medication treatment plan;
  - Integration of each medication into the shared medication treatment plan;
  - Publication of each medication as single MTP documents

[35] E.g. an eMediplan document.

into the EPR-XDS.b Infrastructure (single community or reference community of the patient) by the technical user associated to the Primary Aggregator;
    - Publication of the Medication Card document into the EPR-XDS.b Infrastructure (single community or reference community of the patient) by the technical user associated to the Primary Aggregator;
- When receiving an Advanced Patient Privacy Consents document from a primary system[36], the following actions are performed:
    - Validation of authentication (XUA) token of the primary user, who has to be the concerned patient;
    - Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;
    - Integration of the new consent, possibly instantiating the shared medications treatments plan in case it does not yet exists;
    - Publication of the APPC document into the EPR-XDS.b Infrastructure (single community or reference community of the patient) by the Primary Aggregator.

Diagram with actors is given in Figure 23: Publish Document (ITI-41) interaction diagram in in 8.1 Appendix A – Interaction Diagrams.

Diagram with internal interactions is given in Figure 27: eMedication Primary Aggregator internal modules interaction diagram – ITI-41 in in 8.1 Appendix A – Interaction Diagrams.

#### 6.1.2.4 Workflow "Document Update and Deprecate" (ITI-57)

Workflow for update and deprecate (ITI-57)

The following steps are performed by the Primary Aggregator upon receiving a deprecate request:

- When a deprecate request concerning a CDA-CH-EMED document is received from a primary system, the following actions are performed:
    - Validation of the authentication (XUA) token of the primary user;
    - Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;
    - If required, synchronization with EPR-XDS.b Infrastructure's content is performed (see 6.6.1 below);
    - If required, validation of access policies (see 6.6.1 below);
    - Verification that a shared medication treatment plan do exist. If not, the request is rejected;
    - Verification of the existence of the document as well as the possibility to deprecate it (business process);
    - Deprecation of the document;
    - Deprecation of the document in the EPR-XDS.b

[36] See discussion in section 6.6.3 below.

Infrastructure community (single community or reference community of the patient) by the technical user associated to the Primary Aggregator;

- When receiving an Advanced Patient Privacy Consents document deprecate request from a primary system[37], the following actions are performed:
    - Validation of authentication (XUA) token of the primary user, who has to be the concerned patient;
    - Retrieval of the MPI ID of the patient (ITI-45 PIX query) from the community to which documents are published to by the primary aggregator;
    - Deprecation of the consent document;
    - Deprecation of the document in the EPR-XDS.b Infrastructure (single community or reference community of the patient) by the Primary Aggregator;
    - Removal of the shared medication treatment plan and its content.

Diagram with actors is given in Figure 24: Deprecate Document (ITI-57) interaction diagram in in 8.1 Appendix A – Interaction Diagrams.

Diagram with internal interactions is given in Figure 28: eMedication Primary Aggregator internal modules interaction diagram – ITI-57 in in 8.1 Appendix A – Interaction Diagrams.

### 6.1.3 Key design assumptions

Several rules and constraints are associated with this architecture depending on key founding assumptions (Ax.y):

Key design assumptions

**A1.1: The eMedication Primary Aggregator maintains a primary-level repository containing all published documents**

A primary-level repository containing all published eMedication documents at the eMedication Primary Aggregator level relaxes the eMedication Primary Aggregator from the need to fetch the documents from the patient's EPR-XDS.b Infrastructures. It also have performance impacts and strongly enhance resilience of the eMedication Primary Aggregator regarding temporarily unavailability of any of the EPR-XDS.b Infrastructures where patient's eMedication documents may be stored. Note that this works only if the primary-level repository is exhaustive, which implies Assumption 1.2 to be also true.

Assumption: primary-level repository

**A1.2: Every eMedication document is published through the eMedication Primary Aggregator**

Forcing every publication of eMedication documents through the primary aggregator allows:

- The verification of the coherence of the requested change with regards to the current content of the shared medication treatment plan;
- Completeness of the primary-level repository in case such a

Assumption: flow through the primary aggregator

[37] See discussion in section 6.6.3 below.

repository is maintained at the primary aggregator level.

Allowing a primary system to publish eMedication documents directly into the EPR-XDS.b Infrastructure (i.e. without publishing it through the eMedication Primary Aggregator) will let the primary system to create incoherence in the shared medication treatment plan and voids the primary-level repository mechanism of the eMedication Primary Aggregator if implemented.

**A1.3: The eMedication Primary Aggregator manages access rights**

Distinguishing between accessing medical documents from accessing eMedication information is a request formulated by patients. Implementation of an exhaustive primary-level repository at the eMedication Primary Aggregator level makes it possible to implement also specific access rules (implementation of a Policy Enforcement Point – PEP), avoiding to implement in EPR-XDS.b Infrastructures rules specific to each value added service.

Assumption: access rights management

**A1.4: Secondary storage of eMedication documents is implemented by one single community**

The eMedication Primary Aggregator may use secondary storage from one single community or from multiple communities depending either on the patient concerned or the healthcare provider submitting the document.

Assumption: single storage location

If the eMedication Primary Aggregator has to select to which community among several ones secondary storage of eMedication documents has to be requested from (instead of publishing every received document into one unique community), a functionality allowing the primary aggregator to query which community has to be contacted based either on the patient (e.g. reference community of the patient) or on the healthcare provider (e.g. community of the healthcare provider) has to be implemented in the EPR-XDS.b Infrastructure.

## 6.2 Architecture 2: One Aggregator per Reference Community (external service)

With this configuration, one eMedication Primary Aggregator is implemented for each reference community. Each Primary Aggregator therefore “serves” the patients affiliated to the reference community it is bound to. Primary systems are interacting both with the community they are affiliated to (non eMedication related requests) and with the Primary Aggregator of the reference community of the patient for eMedication related requests.

Architecture 2: One Aggregator per Reference Community

Figure 14 below shows the global architecture of this configuration. Architecture

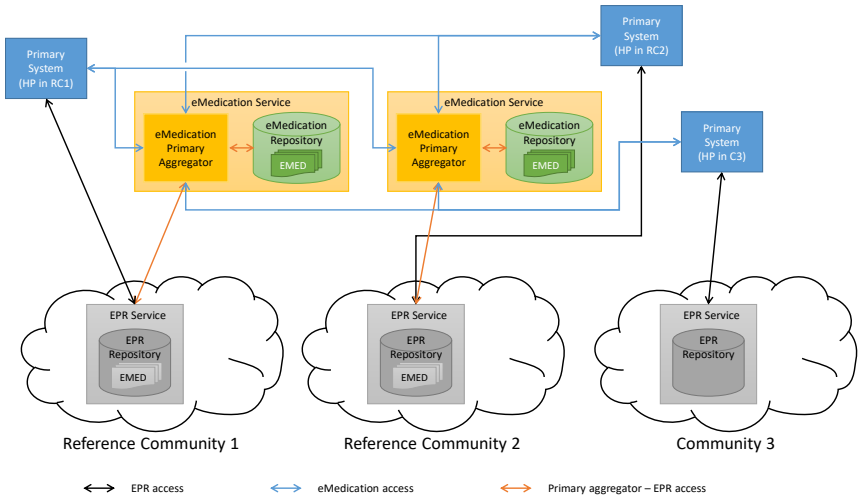


**Figure 14: eMedication Primary Aggregator versus communities (Architecture 2)**

This architecture is based on several eMedication Primary Aggregators, one per reference community. Each community operates its own Affinity Domain, so do the eMedication Primary Aggregators.

Primary systems have two connections: one to their “home” community for regular EPR-XDS.b Infrastructure access and one to each eMedication Primary Aggregator for eMedication documents retrieval.

In order to avoid that primary systems have to publish each eMedication document twice (once to the primary aggregator, once directly into the EPR-XDS.b Infrastructure), the primary aggregator publishes every accepted document into the EPR-XDS.b Infrastructure of the reference community it is connected to.

Each primary aggregator may also maintain a repository of every published eMedication document. In this case, as each eMedication Primary Aggregator is only managing patients from the reference community it is connected to, documents of a specific patient are stored only into one single primary-level repository and no inter-eMedication Primary Aggregators is required.

The primary aggregator’s internal architecture is the same as the one presented in Architecture 1.

### 6.2.1 Technical architecture

The technical architecture of the eMedication Primary Aggregator is the same as the one presented in Architecture 1. Technical architecture

### 6.2.2 Interactions with primary systems

Apart from the fact that primary systems have to contact the eMedication primary aggregator of the reference community of the patient, interactions with primary systems are the same as those described for Architecture 1. Documents are published further by the eMedication Primary Aggregator towards the reference community of the patient. Interactions with primary systems

### 6.2.3 Key design assumptions

**A2.1: The eMedication Primary Aggregator maintains a primary-level repository containing all published documents**

Key design assumptions

A primary-level repository containing all published eMedication documents at the eMedication Primary Aggregator level relaxes the eMedication Primary Aggregator from the need to fetch the documents from the patient's EPR-XDS.b Infrastructure. It also have performance impacts and strongly enhance resilience of the eMedication Primary Aggregator regarding temporarily unavailability of any of the EPR-XDS.b Infrastructures where patient's eMedication documents may be stored. Note that this works only if the primary-level repository is exhaustive, which implies assumption 2.2 to be true.

Assumption: primary-level repository

Impact on EPR regulations is summarized in section 6.6 below.

**A2.2: Every eMedication document is published through the eMedication Primary Aggregator**

Forcing every publication of eMedication documents through the primary aggregator allows:

- The verification of the coherence of the requested change with regards to the current content of the shared medication treatment plan;
- Completeness of the primary-level repository in case a repository is maintained at the primary aggregator level.

Assumption: flow through the primary aggregator

Allowing a primary system to publish eMedication documents directly into the EPR-XDS.b Infrastructure (i.e. without publishing it through the eMedication Primary Aggregator) will let the primary system to create incoherence in the shared medication treatment plan and voids the primary-level repository mechanism of the eMedication Primary Aggregator if implemented.

**A2.3: The eMedication Primary Aggregator manages access rights**

Distinguishing between accessing medical documents from accessing eMedication information is a request formulated by patients. Implementation of an exhaustive primary-level repository at the eMedication Primary Aggregator level makes it possible to implement also specific access rules (implementation of a Policy Enforcement Point – PEP), avoiding to implement in EPR-XDS.b Infrastructures rules specific to each value added service.

Assumption: management of access rights

**A2.4: Primary Systems connects to eMedication Primary Aggregator from patient's Reference Community**

As primary systems have to call the right eMedication Primary Aggregator, they need to be able to determine to which reference community the patient is enrolled to.

Assumption: selection of the primary aggregator

**A2.5: One eMedication Primary Aggregator may serve several Reference Communities**

If one eMedication Primary Aggregator is offering the service to more than one Reference Community, it has to be able to know which community to call for secondary storage.

Assumption: one aggregator, multiple reference communities

## 6.3 Architectures 3.1 and 3.2: Aggregator with Distributed Storage (external service)

Architectures 3.1 and 3.2: Distributed storage

The third configuration, initially named “Architecture 1.5”, is a mix of the two previous ones and has been declined into two versions: a single national aggregator is considered but the eMedication Repository is distributed over each reference community or one aggregator per community and an eMedication Repository distributed over each reference community.

Figure 15 below shows the global architecture of the first configuration while Figure 16 shows the second configuration.

Architecture 3.1

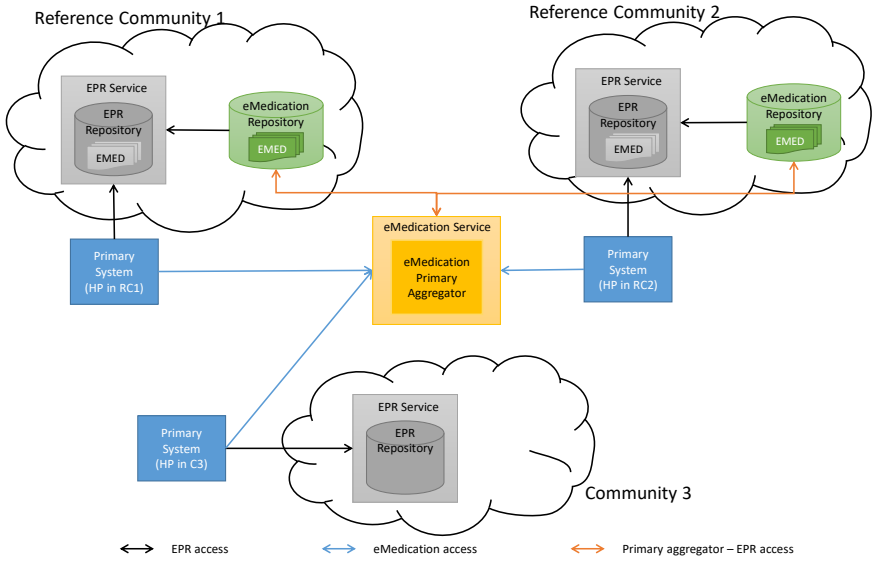


**Figure 15: eMedication Primary Aggregator versus communities (Architecture 3.1)**

Architecture 3.2

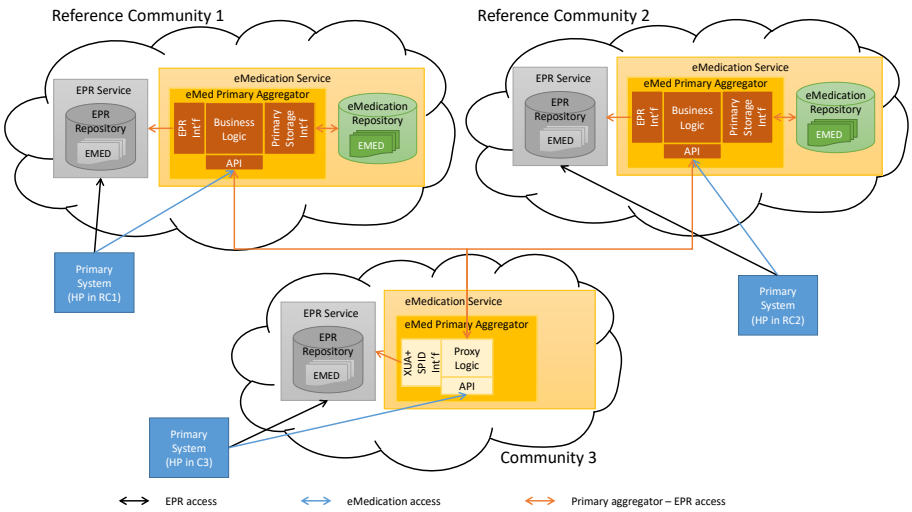


**Figure 16: eMedication Primary Aggregator versus communities (Architecture 3.2)**

In both architectures, there is a decoupling of the eMedication Primary Aggregator and the eMedication Repository. Architecture 3.1 is based on a central eMedication Primary Aggregator to which every primary system is connected to, while Architecture 3.2 is based on an aggregator in each community (reference community or community). Architecture 3.2 has the following key characteristics:

- Every eMedication Service implements the following capabilities:
  - Reception and validation of a request;
  - Validation of the user by using own community's services ("XUA+SPID Int'f" in Community 3, "EPR Int'f" in Communities 1 and 2);
  - Mapping between local patient ID and EPR-SPID by using own community's services ("XUA+SPID Int'f" in Community 3, "EPR Int'f" in Communities 1 and 2);
  - Determination of the reference community of the patient, by using community's own services.
- In addition, eMedication Services not connected to a reference community implement the following additional capability:
  - Proxy functionality for transferring the request towards the eMedication Service of the reference community of the patient.
- eMedication Services connected to a reference community implement the following additional capabilities:
  - Business logic for implementing the request;
  - Management of patient's consent;
  - Local eMedication Repository for keeping a local copy of all eMedication documents and Consent documents of the patient;
  - Publication of eMedication documents into the patient's reference community (secondary storage).

The additional concept introduced by this scenario is the notion of Local eMedication Repository: this repository implements a primary storage for eMedication documents for a patient, i.e. one given eMedication Repository concentrates all eMedication data of a given *patient* (while an EPR-XDS.b Infrastructure generally concentrates all documents produced by a given *healthcare provider*). There is one eMedication Repository per reference community.

Primary systems have two connections: one to their "home" community for regular EPR-XDS.b Infrastructure access (read and publish) and one to the eMedication Primary Aggregator for eMedication documents access (read and publish).

In order to avoid that primary systems have to publish each eMedication document twice (once to the primary aggregator, once directly into the EPR-XDS.b Infrastructure), each local eMedication Repository publishes every accepted document into its associated EPR-XDS.b Infrastructure in Architecture 3.1 while each eMedication Primary Aggregator may perform the publication either into its own community or the patient's reference community in Architecture 3.2[38].

[38] This point is further discussed in section XXX.

### 6.3.1 Technical architecture

Technical architecture

Services offered by the eMedication Primary Aggregator are the same as those described for Architecture 1.

### 6.3.2 Interactions with primary systems – Architecture 3.1

Architecture 3.1: Interactions with primary systems

Interactions with primary systems are basically the same as those described for Architecture 1 with the following differences;

- The eMedication Primary Aggregator does not call directly the reference communities but calls the eMedication Repository component;
- No synchronization with EPR-XDS.b Infrastructures is required as the eMedication Repositories have the full content of the shared medication treatment plan;
- On Demand documents are handled by the eMedication Primary Aggregator and not by the eMedication Repository as it implies aggregation business logic.

Documents are published further by the relevant eMedication Repository into the reference community of the patient.

### 6.3.3 Interactions with primary systems – Architecture 3.2

Architecture 3.2: Interactions with primary systems

Interactions with primary systems are basically the same as those described for Architecture 1 with the following differences;

- The eMedication Primary Aggregator called by the primary system validates patient's identity and healthcare professional's identity against its own community;
- Two options are available for the secondary storage: either the eMedication Primary Aggregator called by the primary system publishes itself the documents into the community of the healthcare professional for secondary storage (ensuring that secondary storage stays healthcare-professional centric) or the eMedication Primary Aggregator processing the request publishes the document into the patient's reference community. Pros and cons of both options are discussed later;
- An eMedication Primary Aggregator from a non-reference community acts as a proxy between the primary system and the eMedication Primary Aggregator of the reference community of the patient. This ensures that it is always the same eMedication Primary Aggregator that handles queries concerning one specific patient. The two eMedication Primary Aggregators being in different communities, use of cross-community transactions is required between the two:
    - ITI-18 becomes ITI-38 between the two aggregators;
    - ITI-41 becomes ITI-80 between the two aggregators;
    - ITI-43 becomes ITI-39 between the two aggregators;
    - ITI-57 does not have yet a cross-community equivalent (see ad-hoc recommendation);
    - PHARM-1 does not have yet a cross-community equivalent – see ad-hoc recommendation);
- No synchronization with EPR-XDS.b Infrastructures is required as the eMedication Repositories have the full content of the shared medication treatment plan;

- On Demand documents are handled by the eMedication Primary Aggregator and not by the eMedication Repository as it implies aggregation business logic.

Split of tasks between the eMedication Primary Aggregator called by the primary system and the eMedication Primary Aggregator performing the service is described in Figure 17 below.

Master and proxy primary aggregators

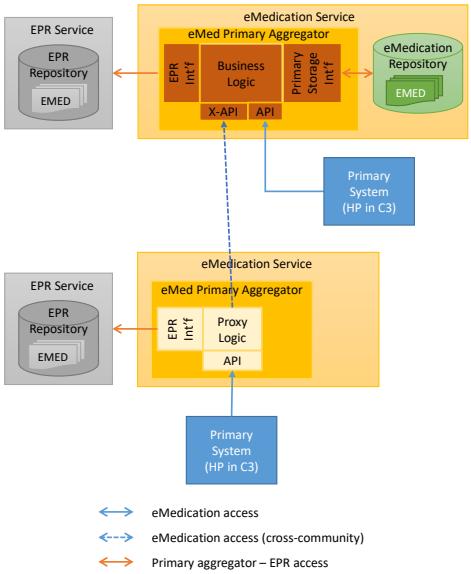


**Figure 17: Internal architecture of the two eMedication Services**

Basic diagram showing internal workflow of an eMedication Primary Aggregator of the patient's reference community is given in Figure 29: Reference Community eMedication Primary Aggregator interaction in 8.1 Appendix A – Interaction Diagrams. Basic diagram showing internal workflow of an eMedication Primary Aggregator acting as a proxy to the patient's reference community eMedication Primary Aggregator is giving in Figure 30: Proxy eMedication Primary Aggregator interaction diagram in 8.1 Appendix A – Interaction Diagrams.

### 6.3.4 Key design assumptions

**A3.1: Reference Communities implement a eMedication Repository**

Key design assumptions

In order to support the eMedication Service, a Reference Community has to implement an eMedication Repository acting as a primary-level repository for all published eMedication documents. Reference Communities not implementing an eMedication Repository cannot provide eMedication Service.

Assumption: eMedication repository in each reference community

Impact on EPR regulations is summarized in section 6.6 below.

**A3.2: The eMedication Primary Aggregator relies on eMedication Repositories for the primary storage of eMedication Documents**

Primary-level repositories containing all published eMedication documents at each Reference Community level relaxes the eMedication Primary Aggregator from the need to fetch the documents from the patient's EPR-XDS.b Infrastructure.

Assumption: eMedication repositories

It also have performance impacts and strongly enhance resilience of the eMedication Primary Aggregator regarding temporarily unavailability of any of the EPR-XDS.b Infrastructures where patient's eMedication documents may be stored. Note that this works only if the primary-level repositories are exhaustive, which implies Assumption 3.3 to be also true.

In Architecture 3.1, the eMedication Primary Aggregator selects the right eMedication Repository into which eMedication documents have to be requested from / stored to according to the Reference Community the patient is enrolled into.

In Architecture 3.2, the eMedication Primary Aggregator may have to forward the request to the eMedication Primary Aggregator of the reference community of the patient.

**A3.3: Every eMedication document is published through the eMedication Primary Aggregator**

Forcing every publication of eMedication documents through the primary aggregator allows:

- The verification of the coherence of the requested change with regards to the current content of the shared medication treatment plan;
- Completeness of the primary-level repositories.

Assumption: flow through the primary aggregator

Allowing a primary system to publish eMedication documents directly into the EPR-XDS.b Infrastructure (i.e. without publishing it through the eMedication Primary Aggregator) will let the primary system to create incoherence in the shared medication treatment plan and voids the primary-level repository mechanism supporting the eMedication Primary Aggregator.

**A3.4: The eMedication Primary Aggregator manages access rights**

Distinguishing between accessing medical documents from accessing eMedication information is a request formulated by patients. Implementation of exhaustive primary-level repositories accessible by the eMedication Primary Aggregator makes it possible to implement also specific access rules (implementation of a Policy Enforcement Point – PEP), avoiding to implement in EPR-XDS.b Infrastructures rules specific to each value added service.

Assumption: management of access rights

## 6.4 Architecture 4: One Aggregator per Community (external service)

With this configuration, one eMedication Primary Aggregator is implemented for each community. Each Primary Aggregator therefore "serves" the healthcare providers or patients affiliated to the community it is bound to. Primary systems are interacting both with the community they are affiliated to (non eMedication related requests) and with the Primary Aggregator of the community they are affiliated to for eMedication related requests.

Architecture 4: one aggregator per community

Figure 18 below shows the global architecture of this configuration.

Architecture

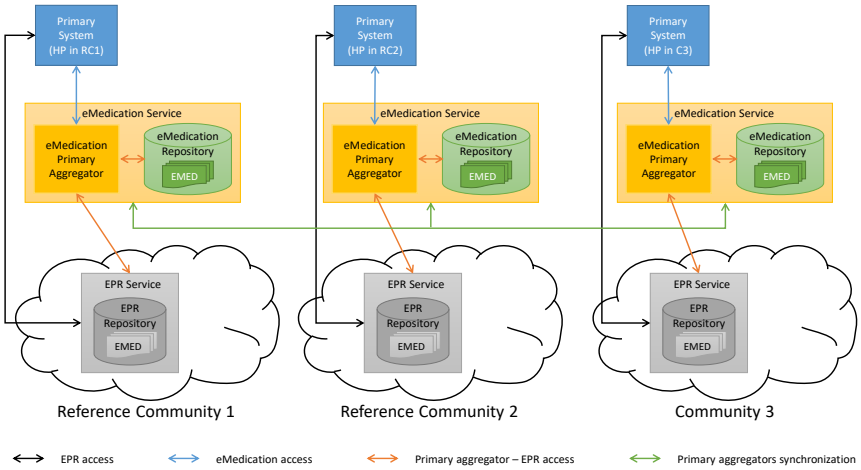


**Figure 18: eMedication Primary Aggregator Environment (Architecture 4)**

This architecture is based on several eMedication Primary Aggregators, one per community. Each community operates its own Affinity Domain, so do the eMedication Primary Aggregators.

Primary systems have two connections: one to their “home” (of the healthcare provider) community for regular EPR-XDS.b Infrastructure access and one to the eMedication Primary Aggregator of their “home” (of the healthcare provider) community.

In order to avoid that primary systems have to publish each eMedication document twice (once to the primary aggregator, once directly into the EPR-XDS.b Infrastructure), the primary aggregator publishes every accepted document into the EPR-XDS.b Infrastructure it is connected to.

Each primary aggregator may also maintain a primary-level repository of every published eMedication document. In this case, a synchronization process is mandatory as documents for one specific patient may have been published through another primary aggregator.

The primary aggregator’s internal architecture is the same as the one presented in Architecture 1.

### 6.4.1 Technical architecture

The technical architecture of the eMedication Primary Aggregator is the same as the one presented in Architecture 1.

Technical architecture

### 6.4.2 Interactions with primary systems

Apart from the fact that primary systems have to contact the eMedication primary aggregator of the “home” community of the healthcare professional, interactions with primary systems are the same as those described for Architecture 1. Documents will be published by the eMedication Primary Aggregator into the community it is associated.

Interactions with primary systems

### 6.4.3 Key design assumptions

Key design

**A4.1: The eMedication Primary Aggregator synchronizes with each other eMedication Primary Aggregator**

assumptions

Each time a request is made to the eMedication Primary Aggregator, a synchronization with all other eMedication Primary Aggregators' content has to be performed. Availability of every other eMedication Primary Aggregator at the time of the request will therefore be critical for completeness of the shared medication treatment plan. Request may be performed under caller's identity (healthcare provider or patient calling the eMedication Primary Aggregator) or under a technical user's identity assigned to the eMedication Primary Aggregator.

Assumption: EPR synchronization

**A4.2: Update of Current medication list in EPR-XDS.b Infrastructure**

Update of the current medication list in the EPR-XDS.b Infrastructure may be performed into another community than the one holding the previous version. This requires thus a remote metadata update with deprecation of a document from another community.

Assumption: update of current medication list

## 6.5 Architecture 5: One Aggregator per Community (internal service)

With this configuration, one eMedication Primary Aggregator is implemented for each community as an internal service. Each Primary Aggregator therefore "serves" the healthcare providers or patients affiliated to the community it is bound to. However at the opposite of Architecture 4, primary systems do not call directly the Primary Aggregator but the latter is being called only by community's internal services for fulfilling primary system's request if needed.

Architecture 5: one aggregator per community

Figure 19 below shows the global architecture of this configuration.

Architecture

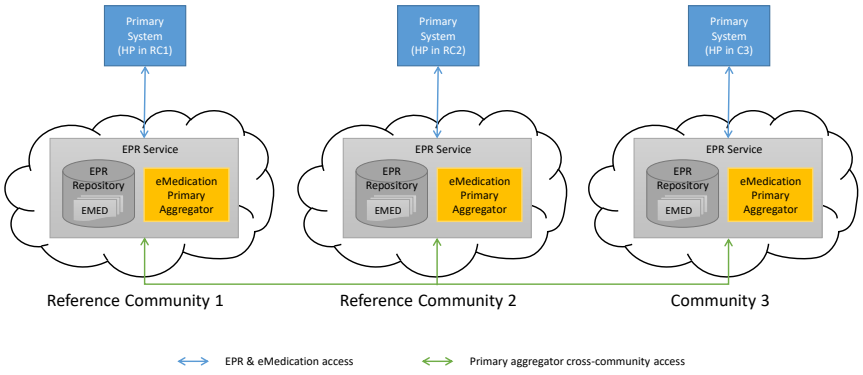


**Figure 19: eMedication Primary Aggregator Environment (Architecture 5)**

This architecture is based on internalization of the eMedication Primary Aggregator functionality within each community. The eMedication Service is becoming part of the core functionality of each EPR-XDS.b Infrastructure.

Primary systems have one single connection to their "home" (of the healthcare provider) community.

Internal architecture of the eMedication service depends on the architecture

of the EPR-XDS.b Infrastructure implementation. No description is given here as it is product dependent.

### 6.5.1 Technical architecture

Technical architecture

The eMedication service being completely internalized into the EPR implementation, interfaces to be provided depend in the way it is implemented by the EPR-XDS.b Infrastructure. No description can therefore be given here.

### 6.5.2 Interactions with primary systems

Interactions with primary systems

The following transactions have to be supported by the EPR-XDS.b Infrastructure for the eMedication Service:

- PHARM-1: Document(s) list retrieval ("Query Pharmacy Documents");
- ITI-43: Document(s) content retrieval ("Retrieve Document Set");
- ITI-41: Publication of a document ("Provide and Register Document Set-b");
- ITI-57: Document update and deprecate ("Update Document Set").
- If MHD Profile is supported:
    - ITI-65: Publication of a document (MHD "Provide Document Bundle");
    - ITI-67: Documents content retrieval (MHD "Find Document References")[39];
    - ITI-68: Documents content retrieval (MHD "Retrieve Document").

Additional transactions like ITI-19: ATNA "Authenticate Node" or ITI-40 carrying the XUA assertion are also used but not referenced here as it is part of the core functionality of any EPR-XDS.b Infrastructure.

Actions performed upon receiving one of the above mentioned request is described in the subsections below.

#### 6.5.2.1 Workflow "Get Documents List" (PHARM-1, "Document(s) list retrieval")

Workflow for get documents list (PHARM-1)

Primary systems can retrieve lists of documents identifiers through the use of the CMPD transaction called PHARM-1, which is based on ITI-18 "Registry Stored Query" transaction.

PHARM-1 transaction supports several queries:

- FindMedicationTreatmentPlans: search for planned medication documents and their related documents. Result is a set of document identifiers;
- FindPrescriptions: search for prescription documents and their related documents. Result is a set of document identifiers;
- FindDispenses: search for dispense documents and their related documents. Result is a set of document identifiers;
- FindMedicationAdministrations: search for administered medication documents and their related documents. Result is a set

---

abling him/her to print his/her medication treatment plan. Exact representation may be standardised.
on to ITI-18 search criteria.

of document identifiers;
- FindPrescriptionsForValidation: search for prescriptions and their related documents containing Prescription Items ready to be validated. Result is a set of document identifiers;
- FindPrescriptionsForDispense: search for prescriptions and their related documents containing Prescription Items ready to be dispensed. Result is a set of document identifiers;
- FindMedicationList: search for the Medication List corresponding to the provided criteria. This transaction behaves differently from the other queries above: rather than returning an identifier of an existing document, it creates a new “on-demand” document containing the search criteria and returns this newly created document identifier. The true content is only assembled when an ITI-43 Document retrieve transaction is called.

The following steps are performed by the EPR-XDS.b Infrastructure upon receiving a PARM-1 request. Note that initial steps (token validation, extraction of MPI ID, etc.) are not mentioned here as they are part of the behaviour the platform has to implement for all existing supported document-related requests.

- When a list of documents is requested by the primary system (first 6 queries above), the following actions are performed:
    - Verification that eMedication Service is available. If not, the request has to be rejected as PHARM does not belong to the core transactions set implemented by the community XDS provider;
    - If required, validation of access policies (see 6.6.1 below);
    - Compilation of the list of documents corresponding to the search criteria by querying all communities;
    - Return of the produced list of document identifiers.
- When a medication list or medication card document is requested by a primary system, the following actions are performed:
    - Verification that eMedication Service is available. If not, the request has to be rejected as PHARM does not belong to the core transactions set implemented by the community XDS provider;
    - If required, validation of access policies (see 6.6.1 below);
    - Registration of the requested medication list (search criteria) as an on-demand document;
    - Return of the newly created document identifier.

Search criteria supported by PHARM-1 are described in 8.2 Appendix B – PHARM-1 selection criteria.

#### 6.5.2.2 Workflow “Documents content retrieval” (ITI-43)

Workflow for content retrieval (ITI-43)

The following steps are performed by the Primary Aggregator upon receiving a retrieval request:

- If required, validation of access policies (see 6.6.1 below);
- If the referenced document is an on-demand document:

- Retrieval of the list and content of documents required to fulfil the request;
- Creation of its content according to its specification;
- Publication or update of its copy in the EPR-XDS.b Infrastructure (secondary storage) if it is an Medication Card Document;

- Return of the content of selected document(s).

#### 6.5.2.3 Workflow "Publication of a document" (ITI-41)

Workflow for publication (ITI-41)

The following steps are performed by the Primary Aggregator upon receiving a new document:

- When receiving a new MTP, PRE, DIS or PADV document from primary system, the following actions are performed by the eMedication Service:
  - If required, validation of access policies (see 6.6.1 below);
  - Verification of completeness of the document;
  - Verification of coherence (see section 5.6 for what "validation of coherence" means) with the existing eMedication documents;
  - Storage of the document into the EPR-XDS.b Infrastructure;
- When receiving an update for an existing MTP, PRE, DIS or PADV document from primary system, the following actions are performed by the eMedication Service:
  - If required, validation of access policies (see 6.6.1 below);
  - Retrieval of the list and content of documents required to validate the request;
  - Verification of completeness of the document;
  - Verification of existence of the previous version;
  - Verification of coherence with the existing eMedication documents: if update leads to incoherence of the shared medication treatment plan, the request is rejected;
  - Storage of the document into the EPR-XDS.b Infrastructure;
- When receiving a PML/Medication Card document[40] from a primary system, the following actions are performed:
  - If required, validation of access policies (see 6.6.1 below);
  - Verification of completeness of the document;
  - Option: Verification that there is no existing shared medication treatment plan: if a plan do exists and is not empty, the request is rejected. If this option is not selected, any Medication Card document content will be merged with (i.e. added to) the existing shared medication treatment plan;
  - Integration of each medication into the shared medication treatment plan;

[40] The Primary Aggregator could

- Publication of each medication as single MTP documents into the EPR-XDS.b Infrastructure (reference community of the patient) by the technical user associated to the Primary Aggregator;
- Publication of the Medication Card document into the EPR-XDS.b Infrastructure (reference community of the patient) by the technical user associated to the Primary Aggregator;

#### 6.5.2.4 Workflow "Document Update and Deprecate" (ITI-57)

Workflow for update and deprecate

The following steps are performed by the Primary Aggregator upon receiving a deprecate request:

- When a deprecate request concerning a CDA-CH-EMED document is received from a primary system, the following actions are performed:
  - If required, validation of access policies (see 6.6.1 below);
  - Verification of the existence of the document as well as the possibility to deprecate it (business process);
  - Deprecation of the document.

### 6.5.3 Key design assumptions

Key design assumptions

**A5.1: Support of PHARM-1 transaction by EPR-XDS.b Infrastructures**

Support for PHARM-1

EPR-XDS.b Infrastructures have to support PHARM-1 transaction in order to implement IHE Pharmacy CMPD profile.

**A5.2: The eMedication Service applies specific document access rules**

Assumption: specific document access rules

The eMedication Service has to be able to retrieve all eMedication documents in order to perform properly, applying therefore specific rules distinct from the currently defined EPR-XDS.b Infrastructure's access rules. A distinction within the EPR-XDS.b Infrastructure has therefore to be implemented in order to distinguish service implemented by the patient record functionality (core services) from the service implemented by the eMedication functionality.

**A5.3: The eMedication Service synchronizes with EPR-XDS.b Infrastructures**

Assumption: synchronization with other communities

Each time a request is made to the eMedication Service, a synchronization with all EPR-XDS.b Infrastructures has to be performed. Availability of every EPR-XDS.b Infrastructure at the time of the request will therefore be critical for completeness of the shared medication treatment plan. Request will be performed under caller's identity.

**A5.4: Update of Current medication list in EPR-XDS.b Infrastructure**

Assumption: update of current medication list

Update of the current medication list in the EPR-XDS.b Infrastructure may be performed into another community than the one holding the previous version. This requires thus a remote metadata update with deprecation of a document from another community.

## 6.6 Impact on EPR Regulations and EPR-XDS.b Infrastructure Implementations

### 6.6.1 Support for the different architectures

Impact on EPR Regulations and EPR-XDS.b Infrastructure Implementations

In order to support the key design assumptions (Ax.y) of each architecture described above, a set of requirements or additional functionalities can be identified:

1. Synchronization with EPR-XDS.b Infrastructures

   Synchronization with EPR-XDS.b Infrastructures

   Real-time synchronization with every EPR-XDS.b Infrastructure implies permanent availability of all communities in order to avoid in particular corrupted shared medication treatment plan or wrong or multiple dispense of the same prescription. Indeed not having the whole eMedication content in an internal primary-level repository forces the eMedication Primary Aggregator to fetch the whole content from the EPR-XDS.b Infrastructures before each request from primary systems can be processed. Availability of every EPR-XDS.b Infrastructure at the time of the request will be therefore critical.

2. Management of specific eMedication-related PEP rules inside each EPR-XDS.b Infrastructure

   Management of specific eMedication-related PEP rules inside each EPR-XDS.b Infrastructure

   Implementation of this functionality requires the distinction between access rules on “classical” medical documents (as defined by EPR current ordinances) and access rules on eMedication documents. Indeed as already explained before, patients are requesting to be able to distinguish between access requests to eMedication from access requests to other medical documents. Typical situation requiring this distinction is granting their pharmacist full access right to their shared medication treatment plan while not granting (full) access right to other medical documents in their EPR. Discussions with patients also show that not being able to hide part of the shared medication treatment plan is seen as a reasonable restriction contributing to their own safety.

3. Management of specific eMedication PEP rules inside the eMedication Primary Aggregator

   Management of specific eMedication PEP rules inside the eMedication Primary Aggregator

   Implementation of this functionality requires the implementation of access rules based on the healthcare provider calling the service. This extension is an alternative to the previous one. Implications are further described in section 6.6.3.

4. Knowledge of patient’s reference community

   Knowledge of patient’s reference community

   Implementation of this functionality requires the design and implementation of a new service enabling an EPR-XDS.b Infrastructure client to obtain the OID of the reference community a patient is affiliated to.

5. IHE Pharmacy CMPD support by EPR-XDS.b Infrastructures

   Implementation of this functionality means that every EPR-XDS.b Infrastructure has to implement the IHE Pharmacy CMPD profile as an additional profile.

IHE Pharmacy CMPD support by EPR-XDS.b Infrastructures

6. Documents in Healthcare Professional's Community

   This functionality is more a "nice to have" than a strong requirement. It however may enhance the acceptance the system as eMedication documents published by a specific healthcare provider will have their secondary storage in the community the healthcare professional is affiliated to (like other published documents).

Documents in Healthcare Professional's Community

The table below shows which requirement or new functionality is necessary for implementing each architecture, distinguishing for Architectures 1 and 2 implementation with a fully functional primary-level repository (i.e. primary-level repository + all requests through the primary aggregator) or not.

Requirements and functionality for each architecture

| Architecture: | A.1 | | A.2 | | A.3 | | A.4 | A.5 |
|---|---|---|---|---|---|---|---|---|
| Requirement / Functionality | with primary-level repository (A1.1 + A1.2) | without primary-level repository | with primary-level repository (A1.1 + A1.2) | without primary-level repository | single national aggregator | one aggregator per community | | |
| 1 - Synchronization | | X | | X | | | X | X |
| 2 – Extended EPR-XDS.b Infrastructure PEP | | X | | X | | | | X |
| 3 – Aggregator PEP | X | | X | | X | X | | |
| 4 – Know reference community | (X) | (X) | X | X | X | X | | |
| 5 – CMPD in EPR-XDS.b Infrastructure | | | | | | | | X |
| 6 – Documents in HP's community | | | | | | X | X | X |

**Table 4: Extensions vs Architectures**

According to this table, impacts on EPR ordinances and EPR-XDS.b Infrastructures' implementation coming from one or another architecture can be grouped into 3 key aspects each resulting in change requests (numbered CR*x*):

**Extended EPR-XDS.b Infrastructure PEP (required for synchronization)**

Current access rights matrix defined in the EPR ordinances does not enable the patient to grant specific access rights related to certain types of documents. Implementing requirements of the eMedication Service therefor implies the following extensions to EPR regulations (and as a consequence to EPR-XDS.b Infrastructure implementations):

Extended EPR-XDS.b Infrastructure PEP

| | |
|---|---|
| CR1.1 | Identification within EPR-XDS.b Infrastructure of groups of document types to which specific access rights may then be granted to. For the eMedication Service the group contains eMedication documents **(**Medication Treatment Plan document**,** Medication Prescription document**,** Medication Dispense document**,** Pharmaceutical Advice document**,** Medication Card document**,** Medication List document). |

Change request 1.1: Identification of groups of document types

| | |
|---|---|
| CR1.2 | Possibility for a patient to distinguish between the access granted to a specific group of documents (e.g. eMedication documents) and the access granted to all other documents contained into his/her EPR-XDS.b Infrastructure. |

Change request 1.2: Access rights

| | |
|---|---|
| CR1.3 | Confidentiality levels should be ignored by the EPR-XDS.b Infrastructure PEP when being called by the eMedication Service as the possibility of hiding some documents will lead to wrong or inconsistent information. Information hidden by the patient may also result in the same dispense being performed several times by no knowing it was already dispensed. |

Change request 1.3: Ignore confidentiality levels

In case the eMedication Primary Aggregator is using a specific user (technical user) for retrieving documents from the EPR-XDS.b Infrastructure (thus simplifying the identification by the EPR-XDS.b Infrastructure PEP of requests coming from the eMedication Service from requests coming from any other primary system), a third extension is required:

| | |
|---|---|
| CR1.4 | Patient has to be able to grant access to his/her eMedication documents to a technical user. |

Change request 1.4: Content access by technical users

**Service for getting the Reference Community of a Patient**

If using Architecture 2, Primary Systems need to be able to identify into which the Reference Community a patient is enrolled. This service may also be required by Architecture 1 if the eMedication Primary Aggregator has to publish the eMedication documents into the Reference Community of each patient. Such a service is not yet supported by the ordinances specifying the functionality of the EPR-XDS.b Infrastructure and will need to be added.

Identify the reference community of a patient

| | |
|---|---|
| CR2 | Service enabling a primary system to identify to which Reference Community the patient belongs to.[41] |

Change request 2: Service for getting the reference community of the patient

**Inclusion of IHE Pharmacy CMPD Profile in list of core profiles**

Architecture 5 implies the support of IHE Pharmacy CMPD Profile by the core EPR-XDS.b Infrastructure. The profile become part of the minimal set of profiles to be supported by each platform (instead of being supported by a value-added service).

IHE Pharmacy CMPD Profile

| | |
|---|---|
| CR3 | IHE Pharmacy CMPD Profile becomes part of the core set of profiles to be supported by each EPR-XDS.b Infrastructure implementation. |

Change request 3: IHE Pharmacy CMD profile is mandatory

Work as a proxy, forwarding the request to the reference community of the patient. However this would mean either implementing differentiated requests depending

### 6.6.2 Access Rights Management – Extended EPR-XDS.b Infrastructure PEP solution

Access rights management covers three phases: initial enrolment, proper access rights management when having a shared medication treatment plan and unsubscribing when the patient decides to quit the service.

Access rights management

**Patient enrolment**

Patient enrolment may be implemented either asking the patient to create and store in the eMedication Primary Aggregator with a possible copy in the EPR-XDS.b Infrastructure a consent document (see strategy proposed if the PEP is implemented at the eMedication Primary Aggregator level) or by asking the patient to instantiate access rights dedicated to the eMedication domain.

Patient enrolment

**Access Rights Management**

As mentioned before, patient has to be provided with a mean to define who may access his/her shared medication treatment plan – separately from access to other EPR-XDS.b Infrastructures' documents.

Access right management

As EPR-XDS.b Infrastructure PEP is using policies defined by the access rights management module provided to the patient through the patient's portal, an extension for managing eMedication Documents' access rules may be implemented at this level.

**Patient unsubscribing**

Patient unsubscribing may be implemented either by deprecating the consent document if this approach is used or by removing all access rights related to the eMedication domain. Unsubscribe has however no impact on the content of the EPR-XDS.b Infrastructures (eMedication documents): it will only prevent eMedication Service to operate.

Patient unsubscribing

### 6.6.3 Access Rights Management – eMedication Service's PEP solution

The eMedication Primary Aggregator is a value-added service for applications: as such it does not include any user interface for managing access rights. IHE offers several mechanisms for establishing and updating access policies that can be enforced by a PEP: the most common one is based either on IHE BPPC (Basic Privacy Policy Consents) or on IHE APPC (Advanced Privacy Policy Consents). A proposal based on the second is described in section 8.3 Appendix D – APPC Consent document. An alternative would be to manage the rules definition process inside the EPR-XDS.b Infrastructure as described in the previous section and to provide new functionality to enable the eMedication Primary Aggregator to have access to these rules. Such a strategy is not described yet in this report.

Access rights management by eMedication service

**Patient enrolment**

Patient enrolment – IHE APPC profile

Patient's enrolment is implemented through the use of an IHE Consent document: IHE Advanced Patient Privacy Consents (APPC). Presence of such a document in the eMedication Primary Aggregator repository means that the patient is enrolled. Indeed its submission by the patient himself/herself can be considered as an explicit consent.

This IHE APPC document will be kept by the eMedication Primary Aggregator and published for traceability into the EPR-XDS.b Infrastructure. A side effect of the publication into the EPR-XDS.b Infrastructure enables primary systems to 1) know that the patient has a shared medication treatment plan and 2) possibly know the reference community of the patient (derived from the OID of the repository containing the IHE APPC document).

The choice of the Advanced Patient Privacy Consents instead of the IHE Basic Patient Privacy Consents (BPPC) comes from the fact that the basic consent document does not enable the definition of access rules associated to specific healthcare providers, which is required by the eMedication Primary Aggregator.

**Access Rights Management**

Access rights management

The eMedication Service's PEP is a rule-based engine able to interpret rules defined in the IHE APPC Consent document. The following rules are supported in the Consent document:

- Grant access to a specific healthcare provider;
- Grant access to a specific group of healthcare providers or organization;
- Deny access to a specific healthcare provider.

Detailed specification of the APPC document is available in section 8.3.

In case several rules applies for a specific healthcare provider, a Grant access rule will take over any Deny access rule.

Delegations and representatives is not supported yet – however implementers may choose to implement it.

There is no need for distinguishing between read and write access: a healthcare professional having access to the shared medication treatment plan can retrieve information as well as add information to the plan.

Patient may of course republish at any time a new version of the IHE APPC document in order to update the rules applicable to his/her shared medication treatment plan.

**Patient unsubscribing**

Patient unsubscribing

Patient unsubscribing is implemented by deprecating the IHE APPC document.

It has to be noted that deprecating the Consent document also means removing the content of the shared medication treatment plan. This operation has however no impact on the content of the EPR-XDS.b Infrastructure (eMedication documents): only information stored by the eMedication Primary Aggregator is removed.

In case an eMedication Repository is being used, it may be useful either to ask the patient to copy all data before deprecating the consent or to provide the patient with an archive of the content of the eMedication Repository.

## 6.7 Summary of PROs and CONs of each architecture

Summary of PROs and CONs of each architecture

Each architecture has advantages and disadvantages. The table below summarizes the key PROs and CONs of each solution.

| Solution | PROs | CONs |
|---|---|---|
| A1 with primary-level repository | Simple topology, similar to what is implemented in other countries<br>No need for synchronization<br>Guarantee to have access to all available information (available in the local repository)<br>Single eMedication point of contact for primary systems<br>Clear separation between EPR-XDS.b Infrastructure's services and Value-Added services<br>Possibly no change on exiting EPR-XDS.b Infrastructure related regulations & implementations<br>Primary storage for patient-generated eMedication data as well as data generated through an ad-hoc portal | Central system<br>Centralized eMedication data<br>Primary repository containing a copy of all eMedication data<br>Secondary storage only in reference communities |
| A1 w/o primary-level repository | Simple topology, similar to what is implemented in other countries<br>Single eMedication point of contact for primary systems<br>Partial separation between EPR-XDS.b Infrastructure's services and Value-Added services | Central system<br>Centralized eMedication data<br>Need for synchronization<br>Important changes in the way access rules on documents stored in EPR-XDS.b Infrastructures are defined and implemented<br>Fails if one community cannot be reached<br>Scalability of approach if several domains / value added services are to be implemented<br>Lack of primary storage for patient-generated eMedication data and data generated through an ad-hoc HP Portal<br>Secondary storage only in reference communities |

Architecture 1 with primary level repository

Architecture 1 without primary level repository

| | | | |
|---|---|---|---|
| A2 with primary-level repository | No centralized eMedication data<br>No need for synchronization<br>Guarantee to have access to all available information (available in the local repository)<br>Clear separation between EPR-XDS.b Infrastructures' services and Value-Added services<br>Possibly no change on exiting EPR-XDS.b Infrastructure's related regulations & implementations<br>Primary storage for patient-generated eMedication data as well as data generated through an ad-hoc portal | Primary systems have to contact the "right" eMedication Primary Aggregator<br>Primary repositories containing a copy of all eMedication data<br>Secondary storage only in reference communities | Architecture 2 with primary level repository |
| A2 w/o primary-level repository | No centralized eMedication data<br>Partial separation between EPR-XDS.b Infrastructures services and Value-Added services | Primary systems have to contact the "right" eMedication Primary Aggregator<br>Need for synchronization<br>Fails if one community cannot be reached<br>Important changes in the way access rules on documents stored in EPR-XDS.b Infrastructures are defined and implemented<br>Scalability of approach if several domains / value added services are to be implemented<br>Lack of primary storage for patient-generated eMedication data and data generated through an ad-hoc HP Portal<br>Secondary storage only in reference communities | Architecture 2 without primary level repository |
| A3.1 | Simple topology, similar to what is implemented in other countries<br>No centralized eMedication data<br>No need for synchronization<br>Guarantee to have access to all available information (available in the local repository)<br>Single eMedication point of contact for primary systems<br>Clear separation between EPR-XDS.b Infrastructure services and Value-Added services<br>Possibly no change on exiting EPR-XDS.b Infrastructure related regulations & implementations<br>Primary storage for patient-generated eMedication data as well as data generated through an ad-hoc portal | Central service<br>Primary repositories containing a copy of all eMedication data<br>Secondary storage only in reference communities | Architecture 3.1 (central service, distributed repositories) |
| A3.2 | No centralized eMedication data<br>No need for synchronization<br>Guarantee to have access to all available information (available in the local repository) | | Architecture 3.2 (distributed service, distributed repositories) |

| | | |
|---|---|---|
| | Single eMedication point of contact for primary systems<br>Clear separation between EPR-XDS.b Infrastructure services and Value-Added services<br>Possibly no change on exiting EPR-XDS.b Infrastructure related regulations & implementations<br>Primary storage for patient-generated eMedication data as well as data generated through an ad-hoc portal<br>Secondary storage in HP's community or patient's reference commununity | |
| A4 | No centralized eMedication data<br>Single eMedication point of contact for primary systems<br>Partial separation between EPR-XDS.b Infrastructure services and Value-Added services<br>No additional copy of eMedication data | Need for synchronization<br>Fails if one community cannot be reached<br>Scalability of approach if several domains / value added services are to be implemented |
| A5 | Deep integration into EPR-XDS.b Infrastructures<br>Single point of contact for primary systems<br>Unified management for patients | Need for synchronization<br>Fails if one community cannot be reached<br>Important changes in the way access rules on documents stored in EPR-XDS.b Infrastructures are defined and implemented<br>Scalability of approach if several domains / value added services are to be implemented<br>Lack of primary storage for patient-generated eMedication data and data generated through an ad-hoc HP Portal |

Architecture 4 (distributed service)

Architecture 5 (embedded service)

It has to be noted that the fact that the advantage for the patient to be able to distinguish between access rights to the eMedication from the access rights to all other medical documents is not mentioned as it is a "PRO" for each configuration. Similarly the potential added complexity of access rights management for the patient is a "CON" for each configuration and will need a well-designed GUI enabling the definition of access rights for the EPR-XDS.b Infrastructure as well as for value added services.

The following table summarizes the impact of each architecture on the current regulations, the advantages and disadvantages of each architecture as well as how disadvantages may be mitigated.

Impact on regulation, advantages, disadvantages of each architecture

| Architecture | Impact on regulation | Advantages | Disadvantages | Mitigation of disadvantages | |
|---|---|---|---|---|---|
| A1<br>Primary repository | Mandatory use of aggregator for eMedication interactions | Simplest architecture, similar to MesVaccins.ch<br>Similar to what is implemented in other countries<br>Single PoC for eMedication interactions<br>No change in existing EPR-XDS.b Infrastructures (regulations and implementations)<br>Clear separation between value-added services (aggregator) and core services (EPR)<br>Performances<br>Primary storage for patient-generated eMedication data as well as data generated though an ad-hoc portal | Central repository with all eMedication documents of all patients<br>No eMedication documents in non-reference communities (secondary storage of eMedication documents only in reference communities)<br>Specific PoC for eMedication<br>Higher risk in case of hacking tentative as there is one central repository for all patients | Clear and strict governance rules for the central repository (e.g. through an ad-hoc foundation)<br>Same technology / interface for EPR-XDS.b Infrastructure PoC and eMedication PoC | Architecture 1 with primary level repository |
| A1<br>No primary repository | Primary aggregator technical user has to be able to retrieve documents from EPR-XDS.b Infrastructure<br>Specific access rules to be designed and implemented in EPR-XDS.b Infrastructures for eMedication context | Single PoC for medication lists<br>Separation between value-added services (aggregator) and core services (EPR-XDS.b Infrastructure)<br>Possibility for primary systems to publish eMedication documents into their own community<br>Possibility for primary systems to retrieve raw eMedication documents from their own community | Need for the primary aggregator to retrieve eMedication documents from EPR-XDS.b Infrastructures<br>Need for EPR-XDS.b Infrastructures to implement ad-hoc access rules on eMedication documents (e.g. no hidden document)<br>Specific PoC for eMedication<br>Only part of eMedication functionality (access to medication lists) possibly implemented by the aggregator | This architecture should not be considered as it is a “half-way” solution with high risks of not being able to provide the required service level in terms of performances and functionality when moving towards full ePrescription/eDispense | Architecture 1 without primary level repository |

| | | | | | |
|---|---|---|---|---|---|
| | | | High risk of not being able to reach level of performances expected by healthcare professionals (due to required synchronization with every community)<br>Risk of missing parts of the eMedication acts due to failure to access one community during synchronization<br>Architecture does not scale with future additional services<br>No eMedication documents in non-reference communities (secondary storage of eMedication documents only in reference communities) | | |
| A2<br>Primary repository | Mandatory use of aggregator for eMedication interactions<br>Need to be able to determine which aggregator is for which patient (based on reference community of patient) | Distributed architecture<br>No change in existing EPR-XDS.b Infrastructures (regulations and implementations)<br>Clear separation between value-added services (aggregator) and core services (EPR-XDS.b Infrastructure)<br>Primary storage for patient-generated eMedication data as well as data generated though an ad-hoc portal | Multiple eMedication PoCs for primary systems (to be determined from the reference community of the patient)<br>Specific PoC for eMedication (vs other documents)<br>No eMedication documents in non-reference communities (secondary storage of eMedication documents only in reference communities)<br>Complexity for managing the configuration between primary systems and aggregators (secure nodes) | Need for a directory or service returning the eMedication PoC for a specific patient<br>Same technology / interface for EPR-XDS.b Infrastructure PoC and eMedication PoC | Architecture 2 with primary level repository |
| A2<br>No primary repository | Need to be able to determine which aggregator is for which patient (based on reference community of | Distributed architecture<br>Separation between value-added services (aggregator) and core services (EPR-XDS.b Infrastructure) | Multiple eMedication PoCs for primary systems (to be determined from the reference community of the patient) | This architecture should not be considered as it is a “half-way” solution with high risks of not being able to provide the required service level in terms | Architecture 2 without primary level repository |

| | | | | |
|---|---|---|---|---|
| | patient)<br>Primary aggregator technical user has to be able to retrieve documents from EPR-XDS.b Infrastructures<br>Specific access rules to be designed and implemented in EPR-XDS.b Infrastructures for eMedication context | Possibility for primary systems to publish eMedication documents into their own community<br>Possibility for primary systems to retrieve raw eMedication documents from their own community | Specific PoC for eMedication<br>Need for EPR-XDS.b Infrastructures to implement ad-hoc access rules on eMedication documents (e.g. no hidden document)<br>Only part of eMedication functionality (access to medication lists) possibly implemented by the aggregator<br>High risk of not being able to reach level of performances expected by healthcare professionals (due to required synchronization with every community)<br>Risk of missing parts of the eMedication acts due to failure to access one community during synchronization<br>Architecture does not scale with future additional services<br>Complexity for managing the configuration between primary systems and aggregators (secure nodes)<br>No eMedication documents in non-reference communities (secondary storage of eMedication documents only in reference communities) | of performances and functionality when moving towards full ePrescription/eDispense |
| A3.1 | Mandatory use of aggregator for eMedication interactions | Simplest architecture, similar to MesVaccins.ch<br>Similar to what is implemented in other countries but with a distributed storage | Specific PoC for eMedication<br>Single national eMedication service | Same technology / interface for EPR-XDS.b Infrastructure's PoC and eMedication PoC |

Architecture 3.1 (central service, distributed repositories)

| | | | | | |
|---|---|---|---|---|---|
| | Need to be able to determine which eMedication Repository is for which patient (based on reference community of patient) | Single PoC for eMedication interactions<br>No change in existing EPR-XDS.b Infrastructures (regulations and implementations)<br>Clear separation between value-added services (aggregator) and core services (EPR-XDS.b Infrastructure)<br>Performances<br>Primary storage for patient-generated eMedication data as well as data generated though an ad-hoc portal<br>Potential attacks on the eMedication Primary Aggregator will not lead to data discovery as data is not stored at the level of the eMedication Primary Aggregator | No eMedication documents in non-reference communities (secondary storage of eMedication documents only in reference communities) | | |
| A3.2 | Mandatory use of aggregator for eMedication interactions<br>Need to be able to determine which Local eMedication Repository is for which patient (based on reference community of patient) | No central component<br>Distributed primary storage<br>Secondary storage in HP's community if selected<br>Single PoC for eMedication interactions<br>No change in existing EPR-XDS.b Infrastructure (regulations and implementations)<br>Clear separation between value-added services (aggregator and possibly its eMedication repository) and core services (EPR-XDS.b Infrastructure)<br>Performances | Specific PoC for eMedication | Same technology / interface for EPR-XDS.b Infrastructure's PoC and eMedication PoC | Architecture 3.2 (distributed service, distributed repositories) |

| | | | | | |
|---|---|---|---|---|---|
| | | Primary storage for patient-generated eMedication data as well as data generated though an ad-hoc portal<br>eMedication Primary Aggregator protected at the same level than the community | | | |
| A4 | Mandatory use of aggregator for eMedication interactions | Distributed architecture<br>Separation between value-added services (aggregator) and core services (EPR-XDS.b Infrastructure)<br>Possibility for primary systems to publish eMedication documents into their own community<br>Possibility for primary systems to retrieve raw eMedication documents from their own community<br>Single PoC for primary systems | Specific PoC for eMedication<br>Only part of eMedication functionality (access to medication lists) possibly implemented by the aggregator<br>High risk of not being able to reach level of performances expected by healthcare professionals (due to required synchronization with every community)<br>Risk of missing parts of the eMedication acts due to failure to access one community during synchronization<br>Architecture does not scale with future additional services | No easy solution to mitigate the risk of not being able to provide the required service level in terms of performances and functionality when moving towards full ePrescription/eDispense | Architecture 4 (distributed service) |
| A5 | Aggregator has to be able to retrieve documents from EPR-XDS.b Infrastructures<br>Specific access rules to be designed and implemented in EPR-XDS.b Infrastructures for eMedication context<br>IHE Pharmacy CMPD has to be supported by every EPR-XDS.b Infrastructure implementation | Distributed architecture<br>Single PoC for primary systems (eMedication and other documents)<br>Primary systems publish eMedication documents into their own community | Need for EPR-XDS.b Infrastructures to implement ad-hoc access rules on eMedication documents (e.g. no hidden document)<br>High risk of not being able to reach level of performances expected by healthcare professionals (due to required synchronization with every community) | No easy solution to mitigate the risk of not being able to provide the required service level in terms of performances and functionality when moving towards full ePrescription/eDispense | Architecture 5 (embedded service) |

| | | | | |
|---|---|---|---|---|
| | | | Risk of missing parts of the eMedication acts due to failure to access one community during synchronization<br>Architecture does not scale with future additional services | |

# 7 Recommendations

Recommendations

This chapter summarizes the key point stated in this eMedication Concept and identifies complementary work necessary for the implementation of the eMedication Service.

## 7.1 Architecture

Recommendation: Architecture

Several architectures have been described and analysed. Other countries' implementations have also been reviewed, leading to the findings that firstly no country is currently using the full power of the medication *plan* (deducting a plan from prescriptions and/or dispenses only, which leads to incomplete information) and secondly all are based on a central service and a central repository of eMedication information. One country addresses the potential performance aspect related to the amount of information by simply removing everything that is older than (currently) one year, which is considered by the group as not satisfactory in terms of clinical process.

Scalability of the implementation is also an important aspect, as it is expected that a high percentage of patients as well as healthcare providers will at term use the service, leading to a high number of requests over an increasing number of documents per patient.

Architecture 3.2 is the recommended one

The working group is clearly in favour of solution 3.2 for the following reasons:

- Architecture 1 without a local repository should be rejected as it has major drawbacks in terms of extensions to be implemented in the EPR-XDS.b Infrastructures, especially the management of specific access rules for eMedication documents;
- Architecture 1 with a local repository should be rejected as it has the major drawback of having centralized medication data for all enrolled patients: this is considered as a "killing argument" as firstly is may be considered as a major security risk and secondly it is against the EPR law (distribution of data);
- Architecture 2 without a local repositories should be rejected as it has major drawbacks in terms of extensions to be implemented in the EPR-XDS.b Infrastructures, especially the management of specific access rules for eMedication documents;
- Architecture 2 with local repositories should be rejected as it has the major drawback of forcing the primary systems to connect to many different eMedication Primary Aggregators according to the reference community of the patient (high deployment complexity);
- Architecture 3.1 should be rejected as it requires a central national eMedication aggregator which is unlikely to be accepted at a political level (against the overall philosophy of the EPR promoting distributed services);
- Architecture 4 should be rejected as it is unlikely to be able to offer the performance required by its primary users (physicians, pharmacists): indeed each request requiring synchronization with every community is considered as a killing argument in terms of performance;

- Architecture 5 should be rejected as it is unlikely to be able to offer the performance required by its primary users (physicians, pharmacists): indeed each request requiring synchronization with every community is considered as a killing argument in terms of performance;
- Architectures 1 without local repository, 2 without local repository, 4 and 5 do not support properly the possibility for a patient to benefit from the shared medication treatment plan without having all eMedication documents available in the EPR-XDS.b Infrastructures. This can be seen as not respecting the right for the patient not to have certain documents in the EPR-XDS.b Infrastructure;

Architecture 3.2 is considered the right compromise for many reasons:

- Clear separation between EPR-XDS.b Infrastructure's service and eMedication Service;
- The architecture is suitable for being applied to other future value added services;
- No central component, no central storage – distributed eMedication Repositories and communities' storage;
- Clear separation of the responsibilities between what has to be performed within HP's community (patient and healthcare professional identity verification) and within patient's reference community (aggregation, eMedication repository).

Considering Architecture 3.2, and in order to cope with EPR law and ordinances, a set of additional rules are necessary for a working implementation of an eMedication Primary Aggregator. Those are rules are formalized into the following recommendations:

Recommendations for implementing architecture 3.2

| | | |
|---|---|---|
| R1 | An eMedication Service implements an eMedication Primary Aggregator and in case it is connected to a Reference Community an eMedication Repository. | eMedication Service |

| | | |
|---|---|---|
| R2 | The eMedication Service becomes an integral part of EPR. As such, Reference Communities have to implement a full eMedication Service which includes an eMedication Repository and Communities have to implement a limited eMedication Service without the eMedication Repository. | Full eMedication service for reference communities. Proxy for other communities |

| | | |
|---|---|---|
| R3 | Primary systems willing to contribute to or access the shared medication treatment plan shall interact with the eMedication Primary Aggregator of their community. | Mandatory use of eMedication service for eMedication |

| | | |
|---|---|---|
| R4 | An eMedication Primary Aggregator owns a Technical User (TCU) identity for accessing the community it is integrated in. | TCU for eMedication Primary Aggregator |

| | | |
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| R5 | The eMedication Repository is patient centric, i.e. all eMedication documents of one specific patient are stored into the eMedication Repository of the reference community (s)he is affiliated to. | Repository is patient centric |

| | | |
|---|---|---|
| R6 | The processing (aggregation and related verifications and validations) of eMedication requests is performed by the eMedication Primary Aggregator of the reference community of the patient. | Business logic in the primary aggregator of the reference community of the patient |

Architecture 3.2 offers the possibility to use either community (HP's community or patient's reference community) for the secondary storage. Rules governing the secondary storage (which Community (HP's or patient's) will have the secondary storage, which documents have a secondary copy) will be defined within the detailed specifications document.

| | | |
|---|---|---|
| R7 | A secondary storage for eMedication documents may be implemented. The detailed specifications of the eMedication Service will describe which documents are published into the EPR-XDS.b infrastructure and by which eMedication Service. | Secondary storage for eMedication Documents |

Documents produced in relation with eMedication may be numerous and are not easily readable without at least a style sheet if not a viewer. Moreover several documents have to be aggregated in order to get an up-to-date view of the information. Their value in the EPR-XDS.b Infrastructure is therefore limited for the users of the portals (healthcare professionals as well as patient). It may be useful not to present them by default.

| | | |
|---|---|---|
| R8 | eMedication documents (except current medication list document and prescriptions documents) available in the EPR-XDS.b Infrastructure should not be listed by default by the portals but only if the user explicitly asks for getting them. Current medication list document has to be listed by default. | Visibility by default in the EPR-XDS.b Infrastructure for eMedication documents |

In order to respect the patient's right of not having eMedication documents in his/her EPR-XDS.b Infrastructure, a mechanism disabling an automatic copy of all eMedication documents into the EPR-XDS.b Infrastructure has to be provided. This may be implemented in relation with the implementation of the consent or definition of the access rights.

| | | |
|---|---|---|
| R9 | Patient must have the possibility to block the automatic publication of eMedication documents into his/her EPR-XDS.b Infrastructure (secondary storage). | Non publication of eMedication documents in the EPR-XDS.b Infrastructure |

## 7.2 Mixed electronic / paper world

Recommendation : Mixed electronic / paper world

At this stage, it is not expected to fully replace paper prescriptions but rather to implement processes and tools necessary to implement a shared medication treatment plan supporting the *care process* – and thus not particularly designed for supporting the reimbursement process.

Regulatory process is however already moving, as since the 1st of January, 2020 electronic prescriptions signed with a qualified signature (or equivalent technology guarantying the same level of authenticity, integrity and confidentiality) will have the same level of recognition that paper prescriptions with a wet signature, opening thus the use of electronic prescriptions. A full electronic ePrescription / eDispense will therefore be possible with such prescriptions under the following conditions:

- No *signed* paper version of these prescription are produced;
- Dispense is documented along with the prescription;
- No dispense can be hidden;
- A verification of the digital signature (or equivalent) is performed by the pharmacy.

Beside these electronic prescriptions, paper prescriptions will continue for many years. Indeed the use of EPR and electronic prescription applications is not mandatory and the move towards electronic prescription systems will take a certain number of years as not all healthcare providers are equipped or are willing to be equipped. Moreover it is unlikely that every use case will be supported – at least in the first versions of the eMedication Service and primary systems interfaces. This has the consequence that paper prescriptions will coexists for a while with electronic prescriptions. However for patient safety reasons, it is recommended that as much information as possible is available in the eMedication Service, even if it means that "someone" has to enter the information manually.

| | | |
|---|---|---|
| R10 | Some mechanisms for entering information available outside of the eMedication Service should be established. This means documenting the available information through a primary system connected to the eMedication Service. | Documentation of information produced by non-connected system |

## 7.3 Responsibilities

Recommendation: Responsibilities

Responsibility is a key element for the acceptance of the shared medication treatment plan. Several aspects are linked to responsibilities, mainly:

- Responsibility of the aggregation performed by the eMedication Primary Aggregator (i.e. does the primary aggregator aggregate correctly the information?);
- Responsibility against the information published into the shared medication treatment plan (e.g. when documenting third party contributions);
- Responsibility of the content of the shared medication treatment plan;
- Responsibility for marking a prescription as “dispensable”;
- Responsibility for approving a provisional prescription.

| | | |
|---|---|---|
| R11 | When a healthcare professional is documenting eMedication information on behalf of another healthcare professional, it shall be documented properly in the published document (author of the medical information versus the person who entered the information into the system) so that the two authors can be clearly identified and distinguished. | Documenting information produced by another healthcare professional |

| | | |
|---|---|---|
| R12 | Responsibility of a healthcare professional with regard to medications documented in the shared medication treatment plan by other healthcare professionals shall be clarified in order to establish a safe legal environment for the use of such a collaborative tool. | Responsibility when documenting other’s information |

| | | |
|---|---|---|
| R13 | Rules establishing who can approve (i.e. make dispensable) a prescription as well as rules establishing who can approve respectively dispense a provisional prescription have to be defined. | Approval of a pre-prescription |

## 7.4 Access rights management

Recommendation: Access rights management by the patient

Discussions with patients demonstrate that access right management should be differentiated between the different information domains. The eMedication Concept presented in this document is one domain – but several others are expected to come in the future. This will also be an indicator of the success of EPR communities as an enabling environment for health-related applications. However leaving or forcing each service to implement its own access rights mechanism will introduce a high burden for patient and be counterproductive. An extension of the access rights management system of the EPR-XDS.b Infrastructure in order to support third party applications would for sure help patients to take over the control of the access to their data managed by third party applications. The way access rights associated to third party applications are stored has to be further specified.

| | | |
|---|---|---|
| R14 | Extend the user interface for the access rights management available in the EPR-XDS.b Infrastructure in order to support the possibility for the patient to define access rights associated to the users of an external application or service. Access rights definitions are then dispatched to and stored by each responsible component (EPR-XDS.b Infrastructure for EPR-XDS.b Infrastructure access rights, eMedication Service for eMedication access rights, etc.). | Extended access rights management |

## 7.5 Cross-Community PHARM-1

The selected architecture – 3.2 – requires the use of cross-community services between the proxy eMedication Primary Aggregator and the eMedication Primary Aggregator of the reference community. This means that an extension of PHARM-1 is required for implementing the request of an ITI-38 instead of an ITI-18.

Recommendation : Cross-Community PHARM-1

| | | |
|---|---|---|
| R15 | Cross-community PHARM-1 is required by Architecture 3.2. A Change Request to IHE Pharmacy Domain should be submitted. | Implement PHARM-1 over ITI-38 |

## 7.6 RMU requirements

The mandate requested to analyse if current version of the Remote Metadata Update IHE Profile (RMU) is sufficient or not, aka if there is a requirement for being able to deprecate a document published in another community (cross-community deprecate).

Recommendation: Remote Metadata Update

The selected architecture – 3.2 – requires the use of cross-community services between the proxy eMedication Primary Aggregator and the eMedication Primary Aggregator of the reference community. This means that an extension of ITI-57 is required for implementing the deprecation of an existing eMedication document in the eMedication Local Repository.

The situation is similar for the eMediplan approach, where healthcare professionals in any community could publish a new eMediplan for a patient from any community. Considering that the eMediplan document has its own document code, it may be possible to safely detect a previous version and to replace it with the new version – even if the replaced version is in another community.

| | | |
|---|---|---|
| R16 | Remote deprecation of a document is required by Architecture 3.2. A Change Request to IHE ITI Domain should be sent to the committee. | Implement Cross-community Deprectae |

## 7.7 Maintenance of specifications

Most of the standards do evolve – or are replaced after a certain time! The same applies for specifications, CDA-CH-EMED in particular. While it may not be necessary to implement immediately every change, some changes will have to be integrated in order to support progressively more and more use cases. This is in particular the case for the notion of "provisional prescription", which is a very important notion in order to be able to properly document the chain of actions "plan → prescribe → dispense". Indeed it is relatively common that the patient comes to the pharmacy and tells the pharmacist that "(s)he will get the prescription tomorrow". Allowing the "pre-prescription" mechanism will therefore be of valuable help from the beginning.

Recommendation: Maintenance of specifications

| | |
|---|---|
| R17 | Implement the IHE Pharmacy PRE and PADV profiles changes released in summer 2019 for supporting provisional prescription into CDA-CH-EMED model. |

Update CDA-CH-EMED with 2019 profiles

As described in the implementation chapter, primary systems will have to be able to retrieve specific medication lists created on the fly like the Medication Card document or Medication treatment card as a PDF document. This need to add two document types to the list of EPR-XDS.b Infrastructure supported document types.

| | |
|---|---|
| R18 | Add the following two Document Format Code to the list of EPR-XDS.b Infrastructure supported Document Format Codes (DocumentEntry.formatCode (OID: 2.16.756.5.30.1.127.3.10.1.9)):<br>▪ urn:ch:cda-ch-emed:medication-card:2018<br>▪ urn:ch:cda-ch-emed:pdf-medication-card:2018 |

Add document format codes for medication card

The introduction of FHIR specifications (HL7v4) provides not only a new syntax for content and messages but also new communication protocols. The IHE Mobile Health Document (MHD) profile is part of this second group. Its intention is to support FHIR-based communication interface for publishing and retrieving documents. However it does not yet have enough functionality to be an alternative to each transaction used between primary systems and the eMedication Primary Aggregator. Promoting its wide use within EPR environment requires therefore some extensions to the profile.

| | |
|---|---|
| R19 | Design and propose to ITI IHE Committee extensions to MHD profile in order to support:<br>▪ Document update and deprecation<br>▪ Extended search criteria for supporting extended transactions like PHARM-1 (based on ITI-18) |

Extend MHD

## 7.8 CBeHIS impact

Recommendation: CBeHIS impact

Switzerland participated to the Cross-Border eHealth Information System promoted by the European Commission until end of 2018 and expects to join it again in a near future.

The eHealth Information System is built on top of National Contact Points for eHealth (NCPeH), which national nodes establishing the link between remote countries (aka the NCPeH of each remote country) and the national infrastructure.

The two key scenarios of this infrastructure are based on the exchange of:

- The Patient Summary document, which contains a section documenting current medication;
- The Prescription and Dispense documents.

The Prescription and Dispense documents are clearly falling under those managed by the eMedication Primary Aggregator. Connecting the Swiss NCPeH to the eMedication Service will make possible the technical implementation of the ePrescription and eDispense scenarios. Indeed work on the legal aspects will also be necessary in order to multiple dispense of the same prescription – based on the paper copy and on the electronic copy.

# 8 Appendices

## 8.1 Appendix A – Interaction Diagrams

Basic interactions with primary system

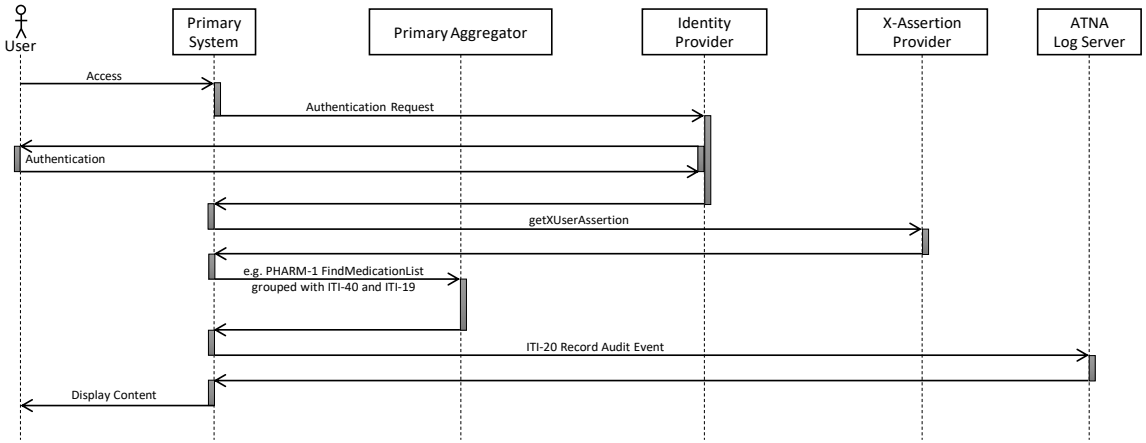



**Figure 20: Primary System basic diagram**

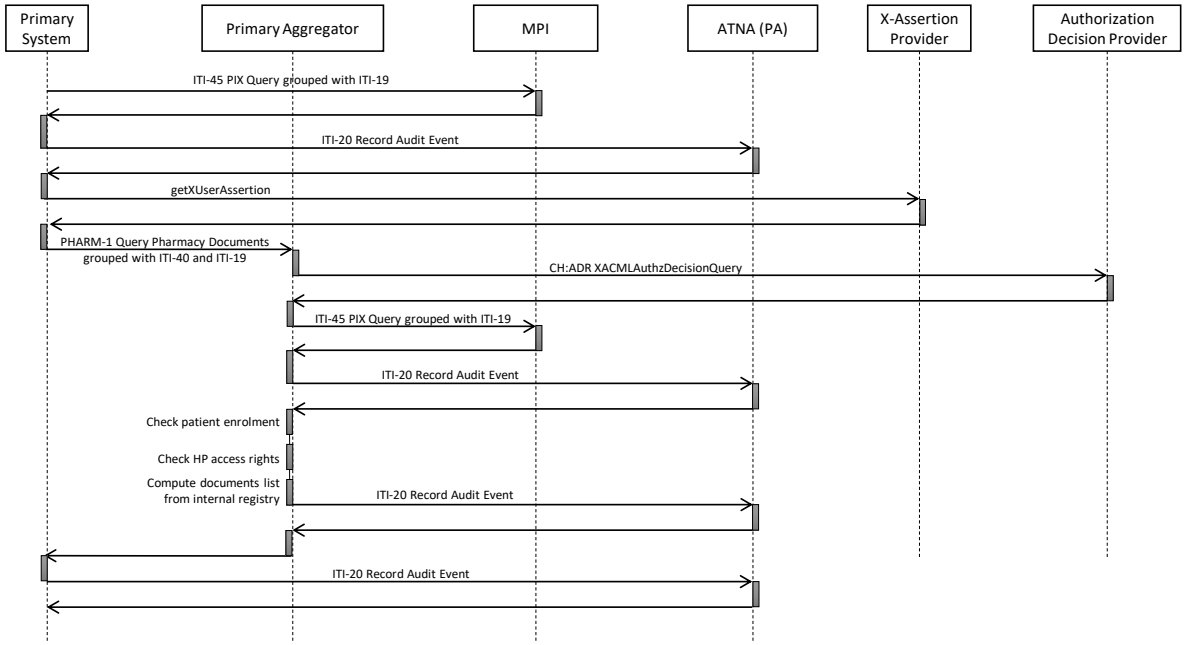



**Figure 21: Retrieve Document(s) List (PHARM-1) interaction diagram**

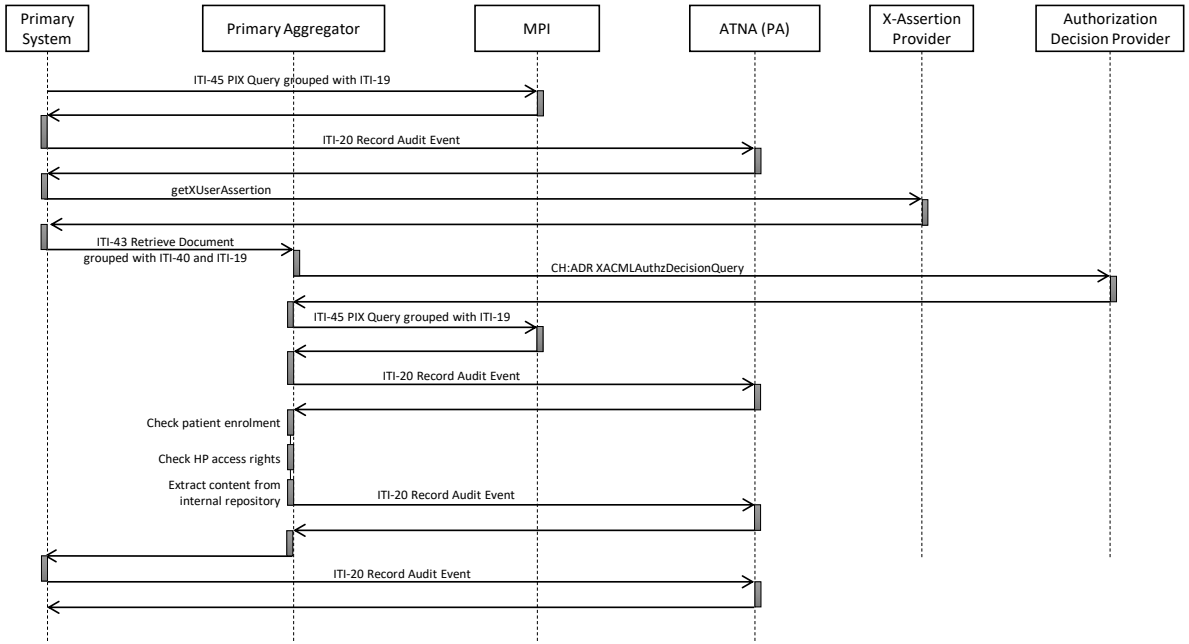



**Figure 22: Retrieve Document(s) Content (ITI-43) interaction diagram**

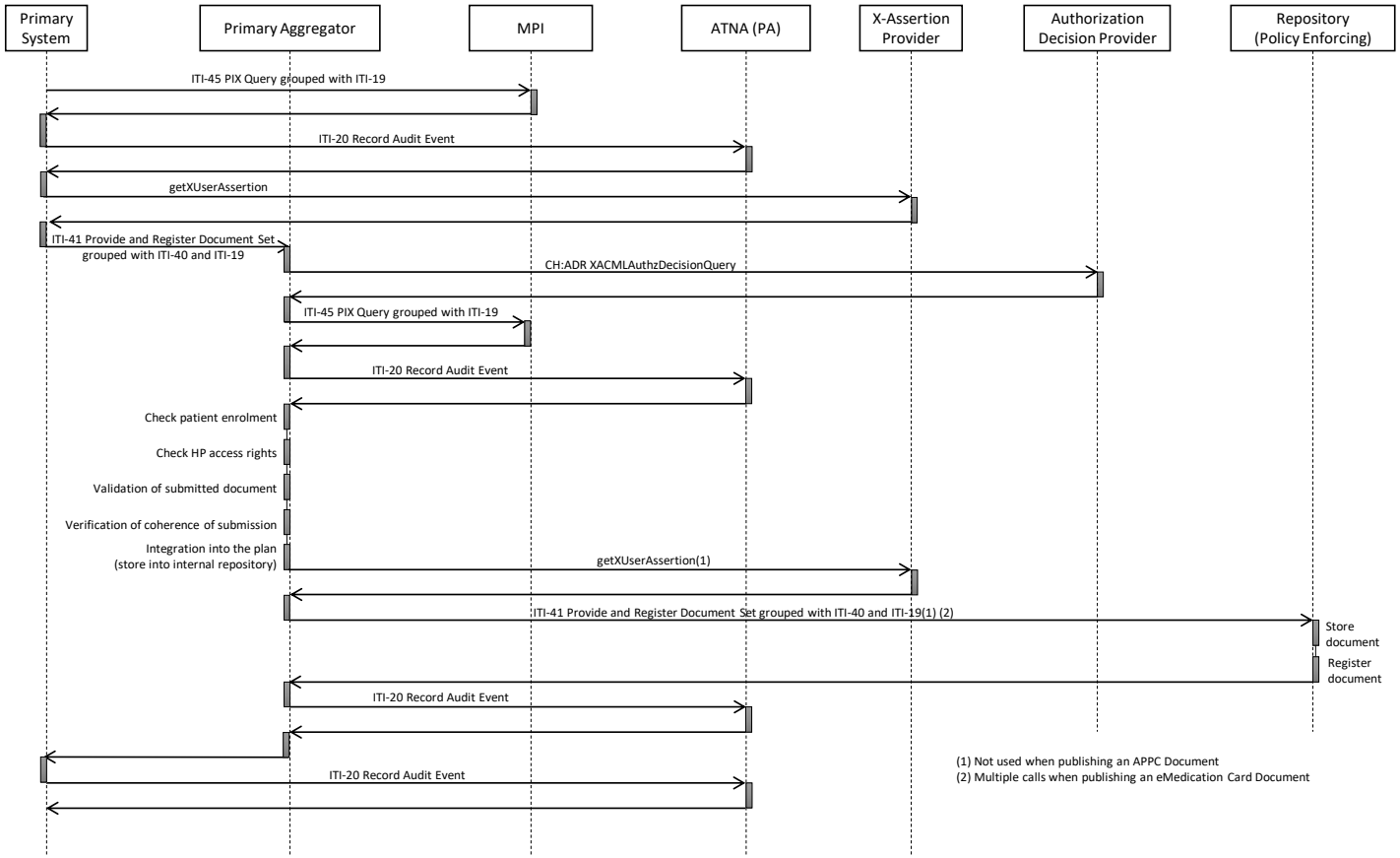



**Figure 23: Publish Document (ITI-41) interaction diagram**

Deprecate document (ITI-57)

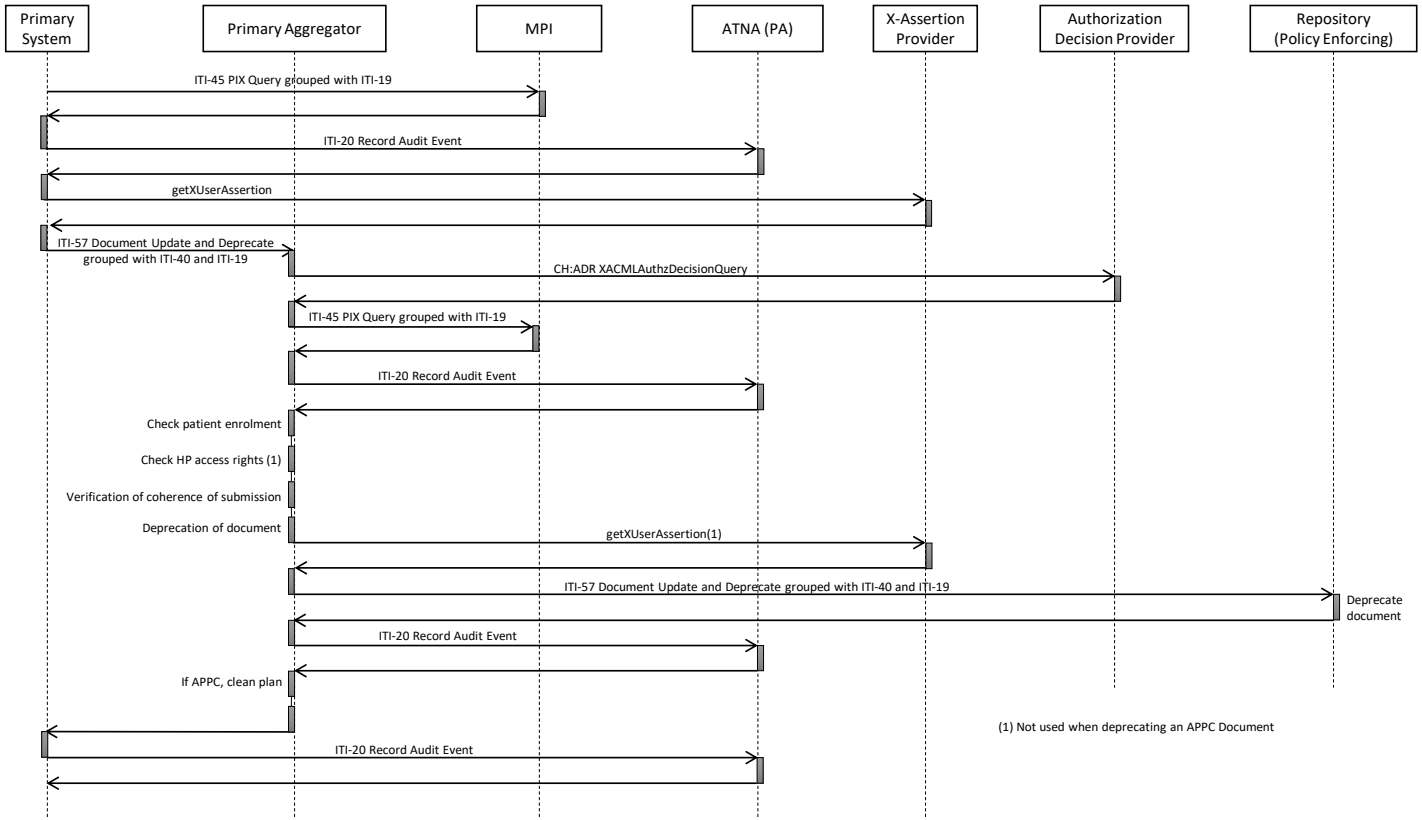
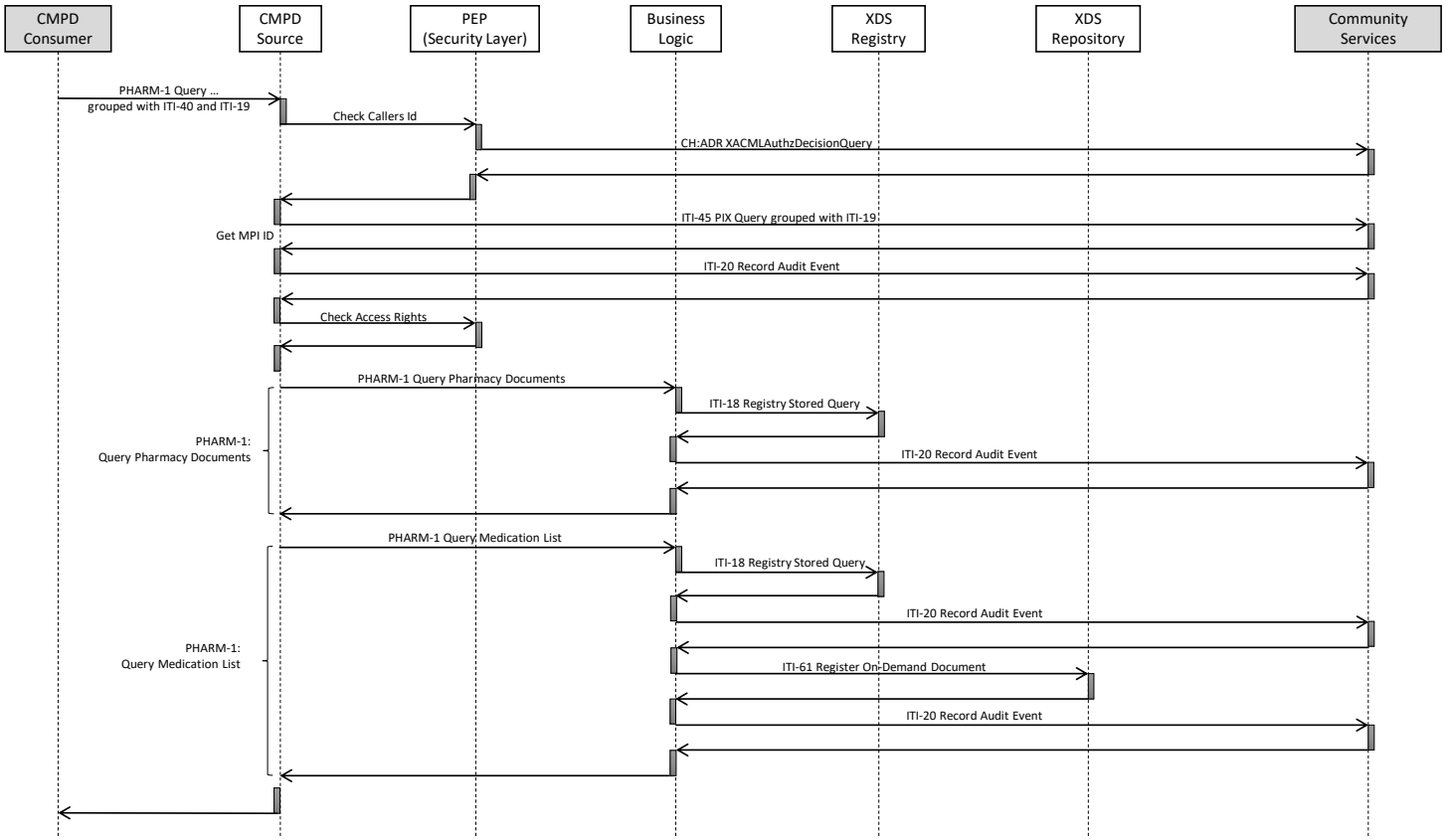


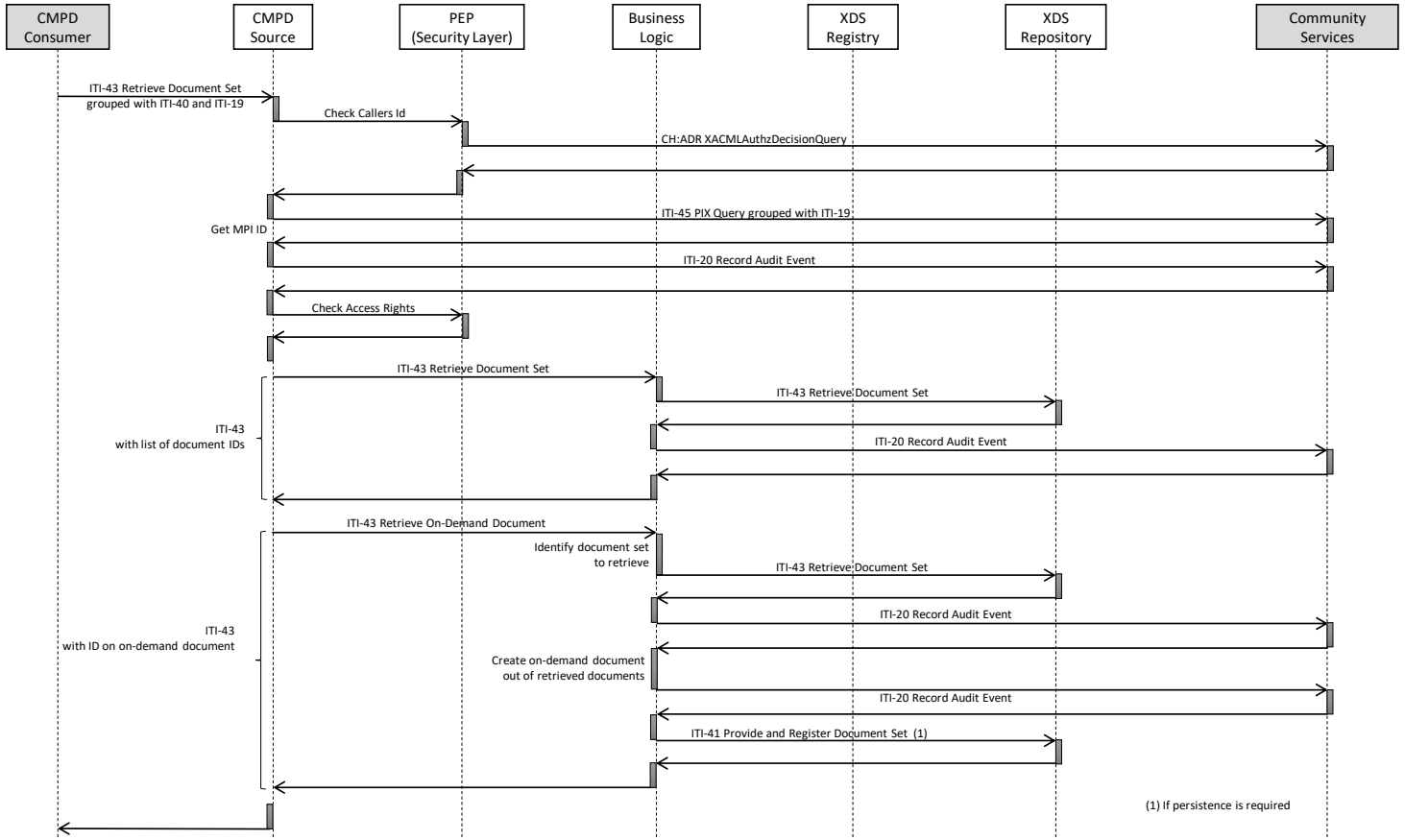

**Figure 24: Deprecate Document (ITI-57) interaction diagram**




eMedication Primary Aggregator internal modules interactions for PHARM-1

**Figure 25: eMedication Primary Aggregator internal modules interaction diagram – PHARM-1**

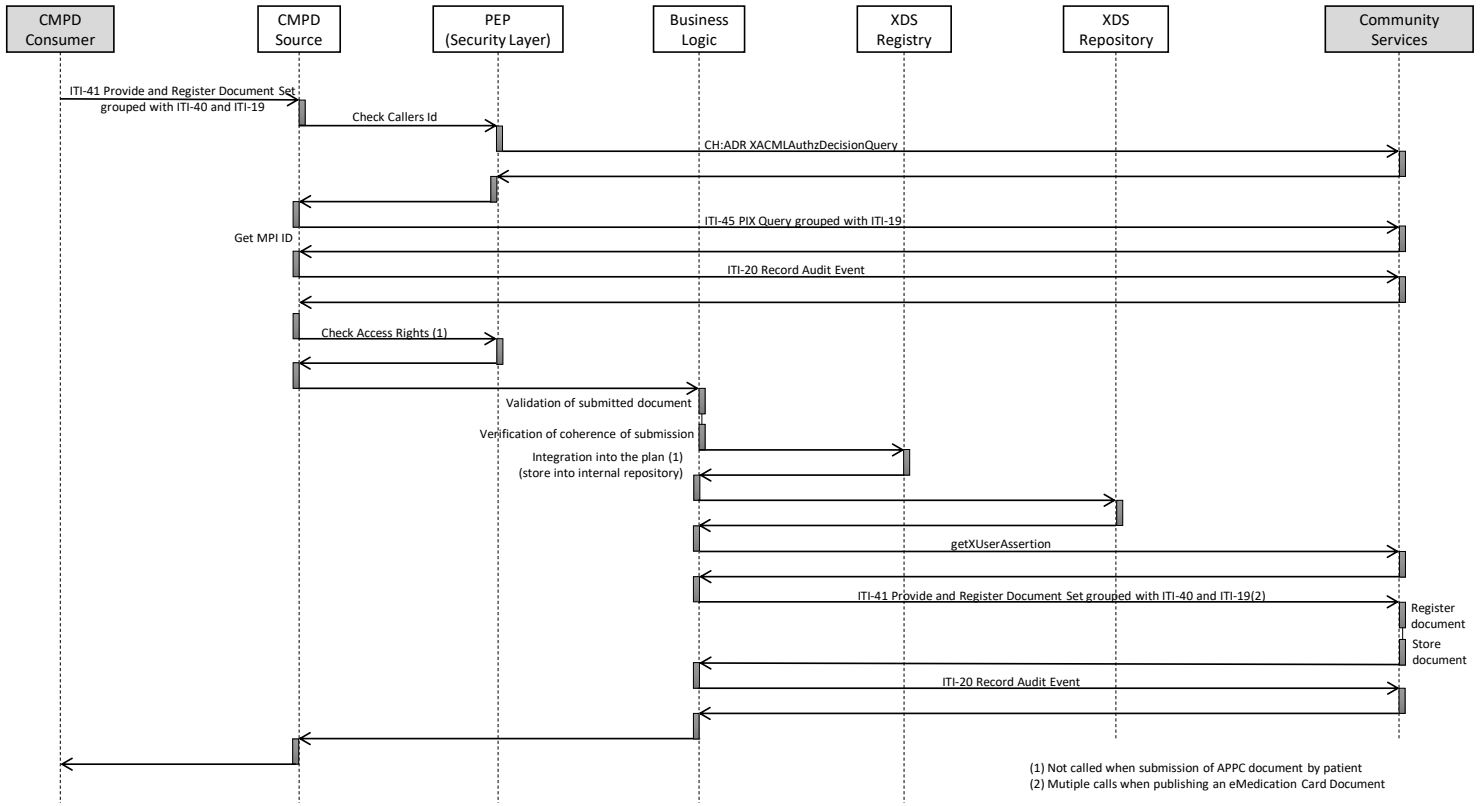
Note: Internal transactions show an implementation based on ITI transactions. Internal modules may be implemented differently.




eMedication Primary Aggregator internal modules interactions for ITI-43

**Figure 26: eMedication Primary Aggregator internal modules interaction diagram – ITI-43**

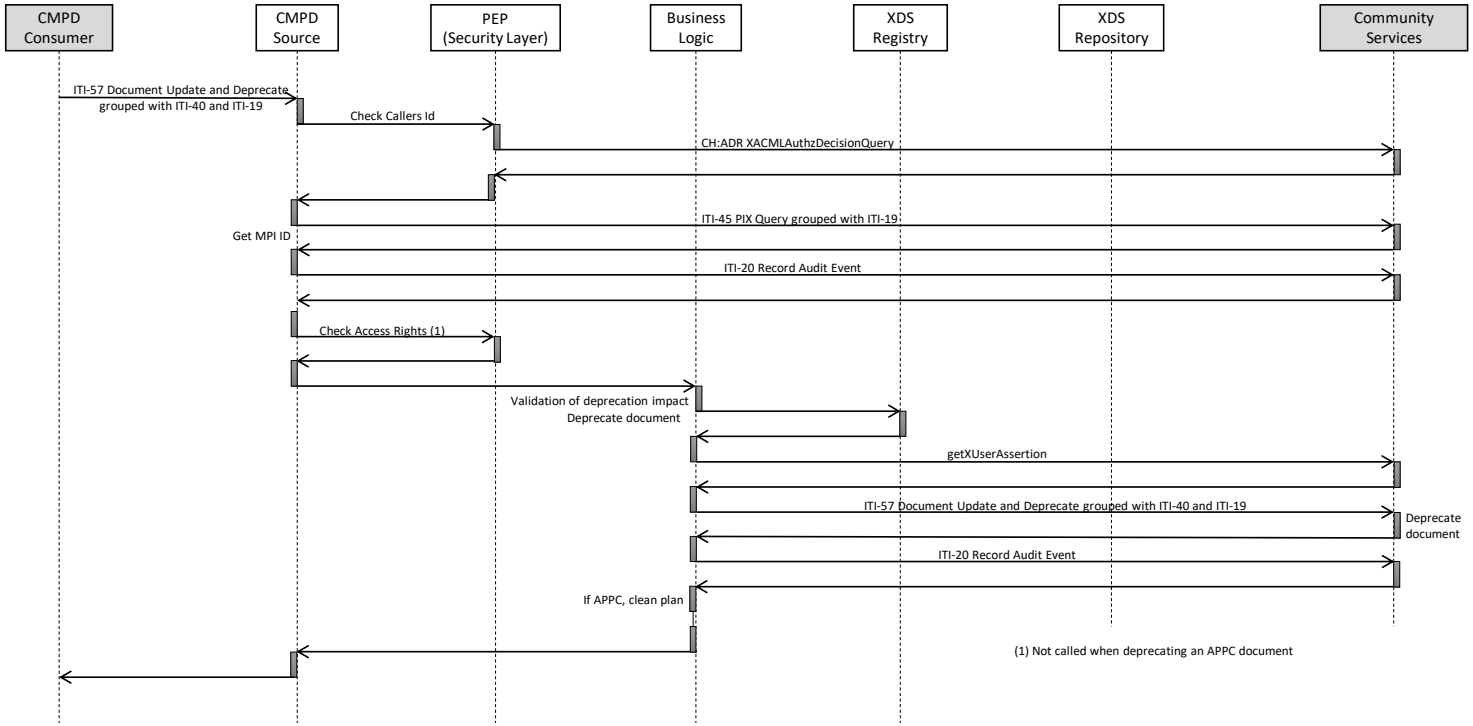
Note: Internal transactions show an implementation based on ITI transactions. Internal modules may be implemented differently.




eMedication Primary Aggregator internal modules interactions for ITI-41

**Figure 27: eMedication Primary Aggregator internal modules interaction diagram – ITI-41**

Note: Internal transactions show on an implementation based on ITI transactions. Internal modules may be implemented differently.




eMedication Primary Aggregator internal modules interactions for ITI-57

**Figure 28: eMedication Primary Aggregator internal modules interaction diagram – ITI-57**

Reference community eMedication Primary Aggregator interaction diagram

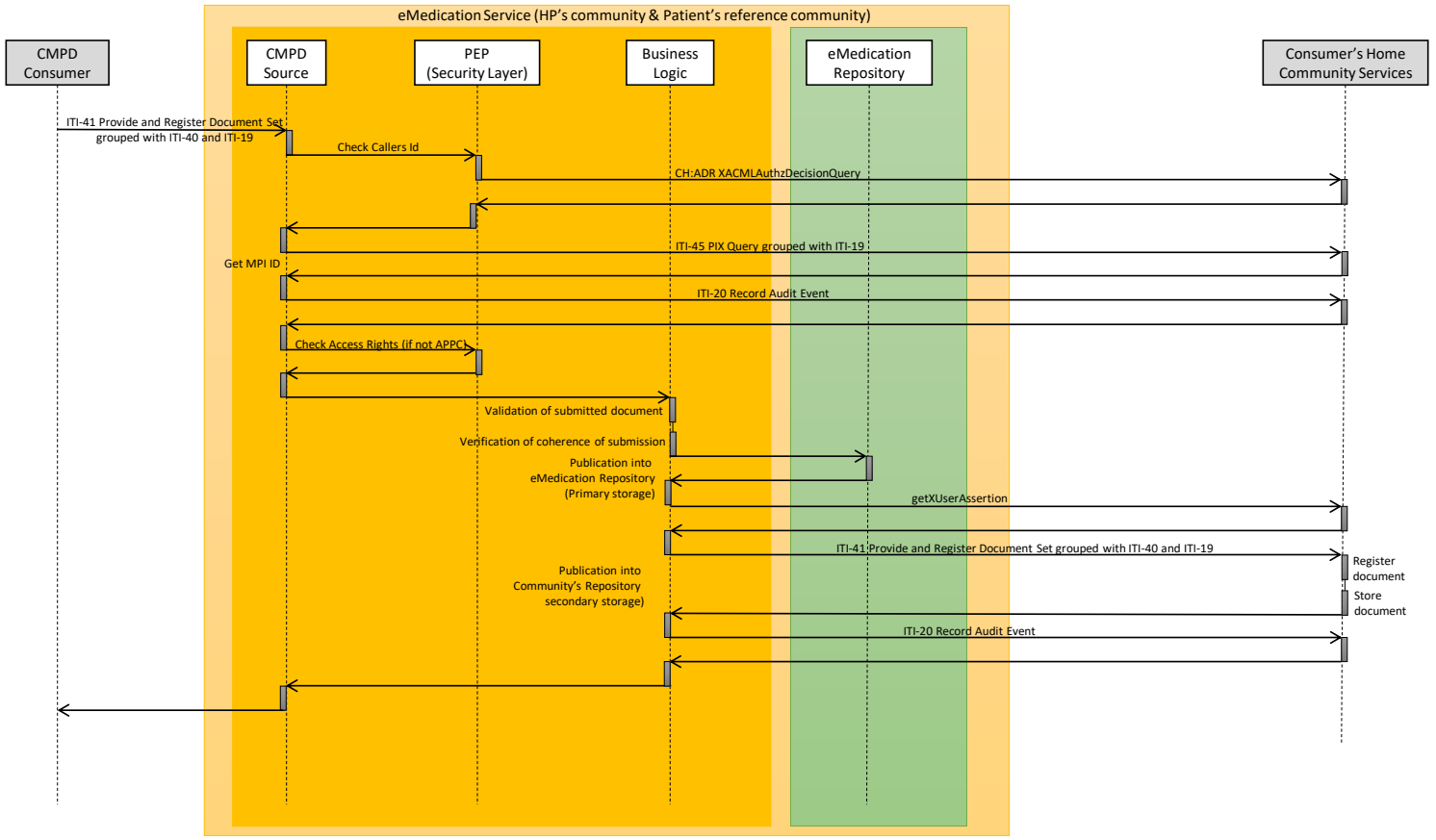



**Figure 29: Reference Community eMedication Primary Aggregator interaction diagram (patient and healthcare professional affiliated to the same reference community)**

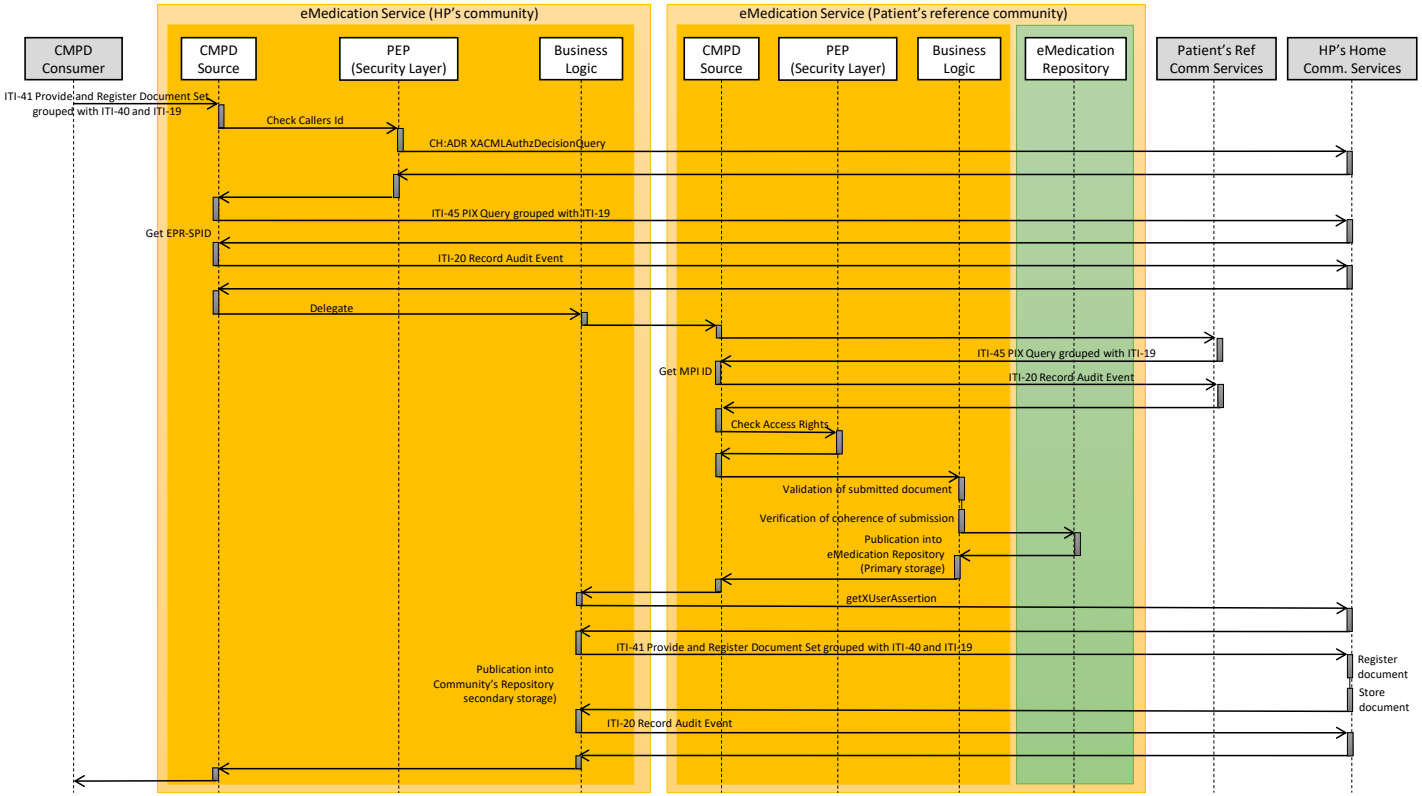



**Figure 30: Proxy eMedication Primary Aggregator interaction diagram**

Non-reference community eMedication Primary Aggregator interaction diagram

## 8.2 Appendix B – PHARM-1 selection criteria

### 8.2.1 Processing of Basic PHARM-1 "Find" Queries

PHARM-1 Selection criteria

Basic "Find" queries

Basic Find* queries of PHARM-1 are intended to retrieve raw documents according to some search criteria. The purpose of theses queries is to help the user to get a coherent set of documents according to a basic search criteria, e.g. a specific prescription will include the relevant plans (MTP items), the already performed dispenses (DIS items) as well as comments and modifications (PADV items).

These queries do not transform nor create any document: they result in an "intelligent" selection of documents from MTP, PRE, DIS and PADV CMPD repositories according to the query and the parameters provided.

The behaviour of each query is described below.

**FindMedicationTreatmentPlans**

FindMedicationTreatmentPlans Query

This query is used to select specific Medication Treatment Plan documents. In addition to returning the found MTP document IDs, it also returns:

- PADV document IDs of pharmaceutical advices referring to the selected MTP documents;
- PRE document IDs of prescriptions referring to the selected MTP documents;
- DIS document IDs of dispenses referring to the selected MTP documents;

PADV document IDs of pharmaceutical advices referring to all selected documents from steps 2 and 3.

**FindPrescriptions**

FindPrescriptions Query

This query is used to select specific Prescription documents. In addition to returning the found PRE document IDs, it also returns:

- PADV document IDs of pharmaceutical advices referring to the selected PRE documents;
- MTP document IDs of medication treatment plans referred to by the selected PRE documents;
- DIS document IDs of dispenses referring to the selected PRE documents;
- PADV document IDs of pharmaceutical advices referring to all selected documents from steps 2 and 3.

**FindDispenses**

FindDispenses Query

This query is used to select specific Dispense documents. In addition to returning the found DIS document IDs, it also returns:

- PADV document IDs of pharmaceutical advices referring to the selected DIS documents;

- MTP document IDs of medication treatment plans referred to by the selected DIS documents;
- PRE document IDs of prescriptions referred to by the selected DIS documents;
- PADV document IDs of pharmaceutical advices referring to all selected documents from steps 2 and 3.

**FindMedicationAdministrations**

FindMedicationAdministrations Query

This query is not yet supported as CMA documents are not supported.

**FindPrescriptionsForValidation**

FindPrescriptionsForValidation Query

The CMPD Manager in Switzerland is working according to scenario 2, i.e. not using a mandatory validation step for prescriptions. Prescriptions are therefore validated by default.

However with the introduction of pre-prescriptions (i.e. prescriptions established by another healthcare provider than the responsible physician), prescriptions for validation may exist. This request will thus return all prescriptions which have at least one item requiring a confirmation[42] and for which no confirmation pharmaceutical advice is present.

**FindPrescriptionsForDispense**

FindPrescriptionsForDispense Query

This query is used to select specific Prescription documents. In addition to the selection parameters, a check is performed to filter only “dispensable” prescriptions, i.e.:

- If the aggregator is configured with a mandatory pharmaceutical advice validation of prescriptions:

  Only PRE documents containing at least one Prescription Item ready to be dispensed are selected. A Prescription Item is ready to be dispensed if the last Pharmaceutical Advice Item related to it has a “statusCode” set to “completed” and an “Observation Code” set to either OK or CHANGE[43];

- If the aggregator is configured without mandatory pharmaceutical advice validation of prescriptions:

  Only PRE documents containing at least one Prescription Item ready to be dispensed are selected. A Prescription Item is ready to be dispensed if either the item has a moodCode=”int” and no Pharmaceutical Advice Item related to it exists or the last Pharmaceutical Advice Item related to it has a “statusCode” set to “completed” and an “Observation Code” set to either OK or CHANGE.

---

From the community to which the healthcare provider is connected to (use of either same community IHE transactions or cross-community IHE transactions) or having the knowledge of the community of the healthcare provider in order to forward the request to it. Moreover routing all requests to the patient’s reference community may even prevent deprecation of documents as the relevant IHE profile (RMU) does not support cross-community deprecation.

In addition to returning the found PRE document IDs, it also returns:

- PADV document IDs of pharmaceutical advices referring to the selected PRE documents;
- MTP document IDs of medication treatment plans referred to by the selected PRE documents;
- DIS document IDs of dispenses referring to the selected PRE documents;
- PADV document IDs of pharmaceutical advices referring to all selected documents from steps 2 and 3.

When requesting one of these lists, it is also possible to limit the primary set of selected entries according to:

- The creation date of the primarily selected entries by using the XDSDocumentEntryCreationTimeFrom and XDSDocumentEntryCreationTimeTo parameters. This parameter is compared to the creation date of each document;
- PracticeSettingCode[44]: this optional parameter is not taken into consideration by the Primary Aggregator;
- HealthcareFacilityTypeCode[45]: this optional parameter is not taken into consideration by the Primary Aggregator;
- EventCodeList[46]: this optional parameter is not taken into consideration by the Primary Aggregator;
- ConfidentialityCode: this optional parameter is not taken into consideration by the Primary Aggregator;
- AuthorPerson: this optional parameter is not taken into consideration by the Primary Aggregator;
- EntryStatus: by default, only “Approved” documents are returned.

Filtering can also be specified by the parameters XDSDocumentEntryServiceStartTimeFrom, XDSDocumentEntryServiceStartTimeTo, XDSDocumentEntryServiceEndTimeFrom, XDSDocumentEntryServiceEndTimeTo. These parameters are compared to several date elements as shown in the following drawing (note that renewal period can only be specified in MTP and PRE entries):

Filtering by date (XDSDocumentEntryServiceStartTimeFrom, XDSDocumentEntryServiceStart-TimeTo, XDSDocumentEntryServiceEndTimeFrom, XDSDocumen-tEntryServiceEndTimeTo)

44

E.g. an eMediplan document.

45 See discussion in section REF _Ref 14178504 \r \h 6.6.3 below.

46 See discussion in section REF _Ref14178504 \r

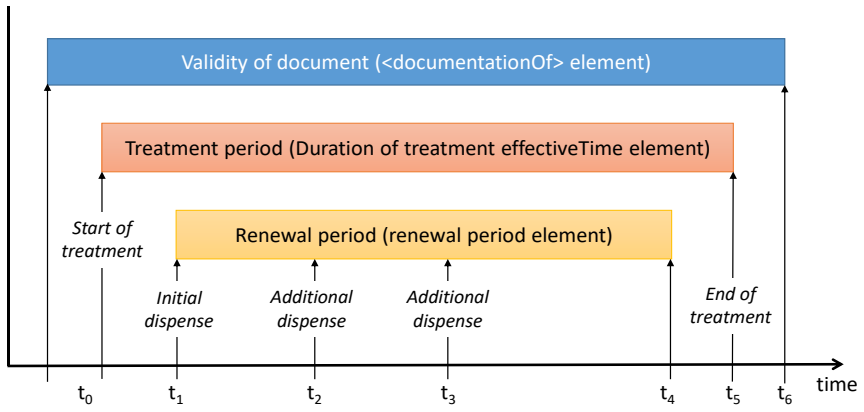



**Figure 31: Dates relevant for MTP and PRE entries**

Searching for MTP and PRE entries

The following rules apply when searching for MTP and PRE entries:

- In case a starting date is not specified, the date of publication of the document is considered;
- Validity of PRE document is at most 1 year: in case the ending date is not specified, start date + 1 year is considered. Validity of MTP document is not bound if no ending date is specified;
- Treatment period starting date (if specified) cannot be before document validity starting date;
- Treatment period ending date (if specified) cannot be after document validity ending date;
- Renewal period (if specified) is calculated once the first dispense occurred. Before first dispense, renewal period is considered to start at the same time than the treatment period. Renewal period is bound to document validity ending date;
- Service start time is specified as the first known from:
    - Renewal period start time;
    - Treatment period start time;
    - Document validity start time.
- Service end time is specified as the first known from:
    - Renewal period end time;
    - Treatment period end time;
    - Document validity end time.

Searching for DIS entries

The following rules apply when searching for DIS entries:

- Service start time is specified as the first known from:
    - Treatment period start time from DIS entry;
    - Treatment period start time from PRE entry (according to PRE entry rules);
    - Document validity start time;
    - Document publication time.

- Service end time is specified as the first known from:
  - Treatment period end time;
  - Treatment period end time from PRE entry (according to PRE entry rules);;
  - Document validity end time:
  - Document publication time.

### 8.2.2 Processing of PHARM-1 "FindMedicationList" Query (On-Demand document)

"FindMedicationList" Query

While the other PHARM-1 queries perform the selection of relevant documents at the time of the query, the FindMedicationList is only creating an On Demand document entry with the given specification. The real processing work will be performed only when the ITI-43 (document retrieval) is issued.

Query parameters for "FindMedicationList"

The query parameters defined in the CMPD profile for the "FindMedicationList" are the following:

| Parameter Name | Attribute | Opt | Multiple |
|---|---|---|---|
| $XDSDocumentEntryPatientId | XDSDocumentEntry.patientId | R | -- |
| The following yellow parameters are parameters to parameterize the business logic for assembling of the resulting Community Medication List document:[47] | | | |
| $XDSDocumentEntryServiceStartFrom | For the meaning of these parameters see explanation below. | O | -- |
| $XDSDocumentEntryServiceStartTo | | O | -- |
| $XDSDocumentEntryServiceEndFrom | | O | -- |
| $XDSDocumentEntryServiceEndTo | | O | -- |
| $XDSDocumentEntryFormatCode | | O[48] | M |
| $XDSDocumentEntryType | | O[49] | M |
| $XDSDocumentEntryStatus | XDSDocumentEntry.Status | R | M |

**Table 5: FindMedicationList query parameters**

The parameters in yellow are the interesting ones for tuning the results:

- $XDSDocumentEntryServiceStartFrom/To

  XDSDocumentEntryServiceStartFrom/To

  This query parameter is used to find all medication treatments that were started during the interval specified by the requester. The treatment starting date is given by the first "effectiveTime" element of the Dosage Instructions Content Module of the MTP Item Entry. This has the side effect that only entries linked to a MTP Item can be filtered using these parameters. Note that a PADV may be used to alter this date.

\h 6.6.3 below.

coming from IHE Pharmacy CMPD profile.

[48] Note: Omitting this parameter means that no filtering according to format code takes place, so "all" available data types will be returned.

[49] Note: Omitting this parameter means that "all" available types of Medication List documents (on-demand created or previously persisted snapshots) are returned.

- $XDSDocumentEntryServiceEndFrom/To

  This query parameter is used to find all medication treatments that were finished / completed in the interval specified by the requester. The treatment ending date is given by the first “effectiveTime” element of the Dosage Instructions Content Module of the MTP Item Entry. This has the side effect that only entries linked to a MTP Item can be filtered using these parameters. Note that a PADV may be used to alter this date.

  XDSDocumentEntryServiceEndFrom/To

- $XDSDocumentEntryFormatCode

  If this parameter is given just the given type of information shall be returned in the Medication List.

  XDSDocumentEntryFormatCode

| Parameter | Meaning |
|---|---|
| urn:ihe:pharm:mtp:2015 | Medication Treatment Plan Items shall be returned (and optional the related Community Pharmaceutical Advice documents related to them). |
| urn:ihe:pharm:pre:2010 | Prescription Items shall be returned (and optional the related Community Pharmaceutical Advice documents related to them). |
| urn:ihe:pharm:dis:2010 | Dispense Items shall be returned (and optional the related Community Pharmaceutical Advice documents related to them). |
| urn:ihe:pharm:cma:2017 | Medication Administration Items shall be returned (and optional the related Community Pharmaceutical Advice documents related to them). |

**Table 6: FindMedicationList query Format Code values**

The CDA-CH-EMED specification defines a specific document based on medication list format: the Medication Card. This specific content can be requested though an extension of the XSDDocumentEntryFormatCode value set as indicated below. A specific content type is also added for being able to retrieve a PDF version of the treatment card.

XSDDocumentEntryFormatCode

| Parameter | Meaning |
|---|---|
| urn:ch:cda-ch-emed:medication-card:2018 | The content of the treatment card shall be returned as a set of consolidated Medication Treatment Plan Items. No other items should be returned as e.g. a possible Pharmaceutical Advice item should have been merged with the original Medication Treatment Plan item.<br>Note that this Format Code is exclusive with the others. |
| urn:ch:cda-ch-emed:pdf-medication-card:2018 | The content of the treatment card shall be returned as a CDA Level 1 with a PDF content. This document is intended to be given to the patient. |

**Table 7: FindMedicationList query Additional Format Code values**

- $XDSDocumentEntryType

  If this parameter is given documents of just the provided document entry type (on-demand or stable) shall be returned.

XDSDocumentEntryType

| Parameter | Meaning |
|---|---|
| urn:uuid:34268e47-fdf5-41a6-ba33-82133c465248 | On-Demand document entry types are returned.<br>This is the on-demand created Community Medication List document. |
| urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1<br>See note [50] | Stable document entry types are returned.<br>Previously persisted snapshots of on-demand created Community Medication List document. |

**Table 8: FindMedicationList query Entry Type values**

The above parameters may be used as follows for retrieving specific medication lists fulfilling needs of primary systems:

- Current list of active medications (i.e. Medication Card Document)

  The list of active medications can be retrieved by selecting “ch:cda-ch-emed:medication-card:2018” as XSDDocumentEntryFormatCode[51] with ServiceEndTimeFrom set to “now”;

Current list of active medications

- Current treatment card in PDF format

  This version of the treatment card can be retrieved by setting the XSDDocumentEntryFormatCode parameter to “urn:ch:cda-ch-emed:pdf-medication-card:2018” and including a XDSDocumentEntryServiceEndFrom date set to “now”. PDF is produced according to PDF/A-2[52] format;

Current treatment card in PDF format

- List of all consolidated medications (i.e. treatment card including stopped or completed medications)

  This list can be retrieved by selecting “ch:cda-ch-emed:medication-card:2018” as XSDDocumentEntryFormatCode with no ServiceStartTime or ServiceEndTime;

List of all consolidated medications

- List of medications with full history

  This result is obtained by querying for all document types (i.e. not specifying any XSDDocumentEntryFormatCode), possibly limiting the timeframe by using XDSDocumentEntryServiceStart and XDSDocumentEntryServiceEnd parameters;

List of medications with full history

- Full raw history of shared medication treatment plan

  This complete list can be retrieved by selecting all format codes in XSDDocumentEntryFormatCode, i.e. “urn:ihe:pharm:mtp:2015” + “urn:ihe:pharm:pre:2010” + “urn:ihe:pharm:dis:2010”. PADV entries are always returned along with their parent entry. History period can be limited by using the XDSDocumentEntryCreationTimeFrom and possibly XDSDocumentEntryCreationTimeTo parameters. No ServiceStartTime or ServiceEndTime should be specified.

Full raw history of shared medication treatment plan

[50] Note: This parameter is applicable only if the “Persistence of Retrieved Documents” Option is supported.

[51] IHE CMPD Profile explicitly allows the use of project-specific format codes.

[52] EPR law accepts only PDF/A-1 and PDF/A-2 versions.

## 8.3 Appendix D – APPC Consent document

APPC Consent Document

The patient has to be able to define who can access his/her shared medication treatment plan. In order to use standard methods and formalism for establishing access rules, an IHE APPC Document (Advanced Patient Privacy Consents Document) is being used.

Purpose of the APPC document

The APPC document serves two purposes:

- Its existence means that the patient is enrolled in the eMedication Service;
- Its content defines who can access what by setting up rules defining who can access to what.

Rules

Rules are a combination of:

- "Who", designating a user (healthcare professional or organization). Note that the "break-the-glass" functionality is implemented through a special "who" which is "Healthcare professional asking for emergency access";
- "What", designating the patient through his/her EPR-SPID id (fixed);
- "Until when", possibility limiting the validity period of the policy;
- "How", defining the allowed actions by referring to EPR policies.

Policies

A limited set of policies (building blocks) are available for describing the access rules ("How"):

- Granting someone read access on the shared medication treatment plan, allowing the retrieval of the content of the plan ("urn:e-health-suisse:2015:policies:permit-reading-normal" policy);
- Granting someone write access on the shared medication treatment plan, allowing the publication of new information into the plan (this includes e.g. the modification of an existing medication through the publication of an update (IHE Pharmacy PADV document) ("urn:e-health-suisse:2015:policies:permit-writing-normal" policy);
- Granting someone update/deprecate access on the shared medication treatment plan, allowing the replacement or deprecation of an existing document (prerequisite: the user requesting the update/deprecate is the same as the one who published the document). Note that it is not possible to change confidentiality level of a document ("urn:e-health-suisse:2015:policies:update-metadata" policy);
- Allowing a representative to update the consent document ("urn:e-health-suisse:2015:policies:access-level:delegation-and-normal" policy)

Where "someone" can be either a healthcare professional, an organisation (or a sub-organisation / group of professionals) or a representative of the patient.

Update policy

The APPC Document can only be updated by the patient himsef/herself or by a representative having the right to amend the consent. Only the patient is allowed to remove the consent document (meaning opting out of the eMedication Service). The patient has a permanent read and write access on the consent document.

### 8.3.1 Format of the IHE APPC Document

Format of the APPC Document

The APPC Document contains one single “PolicySet” object which in turn contains:

- A “Description” section for free text description of the Policy Set;
- A “Target” section containing:
    - A “Subjects” section containing itself “Subject” entries each defining one “Who” (i.e. all “Subject” are included in the group);
    - A “Resources” section containing one “Resource” object pointing to the patient;
    - An optional “Environments” section containing one “Environment” object limiting the validity period of the policy (required if at least one “Subject” refers to an organization or group). This section will not be used within this context;
- A list of “PolicyIdReference” or “PolicySetIdReference” defining the level of access granted to the users identified by the “Subjects” section;

The root “PolicySet” may also contain a set of “PolicySet” objects instead of the above objects (useful for establishing different access rules to different users groups).

The example below shows the syntax of the various sections and objects. It should not be used as such but should serve as example for the possible building blocks.

APPC Example

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- PolicySetId to be replaced by a unique value -->
<PolicySet  PolicySetId="urn:uuid:e3585197-9e3d-4ca3-9583-4540a3a5b64b"
        PolicyCombiningAlgId="urn:oasis:names:tc:xacml:1.0:policy-combining-algorithm:deny-overrides"
        xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
        xmlns:hl7="urn:hl7-org:v3"
        xmlns="urn:oasis:names:tc:xacml:2.0:policy:schema:os"
        xsi:schemaLocation="urn:oasis:names:tc:xacml:2.0:policy:schema:os ihe-appc-xacml-combined-schema-1.0.xsd">

    <Description>
        The patient grants access to the identified healthcare professionals or groups of professionals or representative.
    </Description>

    <Target>

        <Subjects>

            <!-- Granting access right to a HCP through his GLN ("gln-of-HCP-goes-here") -->
            <Subject>
                <SubjectMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal">
                    <!-- GLN of the health professional or ID of a custodian to be authorized -->
                    <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">gln-of-HCP-goes-here</AttributeValue>
                    <SubjectAttributeDesignator
                        AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id" DataType="http://www.w3.org/2001/XMLSchema#string"/>
                </SubjectMatch>
                <SubjectMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal">
                    <!-- According to the EPD SAML 2.0 Assertions Subject element: @NameQualifier=”urn:gs1:gln” in case of a professional -->
                    <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">urn:gs1:gln</AttributeValue>
                    <SubjectAttributeDesignator
                        AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id-qualifier" DataType="http://www.w3.org/2001/XMLSchema#string"/>
                </SubjectMatch>
                <SubjectMatch MatchId="urn:hl7-org:v3:function:CV-equal">
                    <AttributeValue DataType="urn:hl7-org:v3#CV">
                        <hl7:CodedValue code="HCP" codeSystem="2.16.756.5.30.1.127.3.10.6"/>
                    </AttributeValue>
                    <SubjectAttributeDesignator DataType="urn:hl7-org:v3#CV" AttributeId="urn:oasis:names:tc:xacml:2.0:subject:role"/>
                </SubjectMatch>
            </Subject>

            <!-- OR -->

            <!-- Granting access right to a group (i.e. organization) through his GLN ("gln-of-org-goes-here") -->
            <Subject>
                <!-- GLN of a group of professionals to be authorized -->
                <SubjectMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:anyURI-equal">
```

```
            <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#anyURI">urn:oid:gln-of-org-goes-here</AttributeValue>
            <SubjectAttributeDesignator
                AttributeId="urn:oasis:names:tc:xspa:1.0:subject:organization-id" DataType="http://www.w3.org/2001/XMLSchema#anyURI"/>
        </SubjectMatch>
        <SubjectMatch MatchId="urn:hl7-org:v3:function:CV-equal">
            <AttributeValue DataType="urn:hl7-org:v3#CV">
                <hl7:CodedValue code="HCP" codeSystem="2.16.756.5.30.1.127.3.10.6"/>
            </AttributeValue>
            <SubjectAttributeDesignator DataType="urn:hl7-org:v3#CV" AttributeId="urn:oasis:names:tc:xacml:2.0:subject:role"/>
        </SubjectMatch>
    </Subject>

    <!-- OR -->

    <!-- Granting access right to a representative of the patient through his id ("representative-id-goes-here") -->
    <Subject>
        <SubjectMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal">
            <!-- ID of a representative to be authorized -->
            <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">representative-id-goes-here</AttributeValue>
            <SubjectAttributeDesignator
                AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id" DataType="http://www.w3.org/2001/XMLSchema#string"/>
        </SubjectMatch>
        <SubjectMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal">
            <!-- According to the EPD SAML 2.0 Assertions Subject element:
                @NameQualifier=”urn:e-health-suisse:representative-id” in case of a custodian/guardian/representative, who’s been assigned to
                manage a patient’s Health Record.
            -->
            <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">urn:e-health-suisse:representative-id</AttributeValue>
            <SubjectAttributeDesignator
                AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id-qualifier" DataType="http://www.w3.org/2001/XMLSchema#string"/>
        </SubjectMatch>
        <SubjectMatch MatchId="urn:hl7-org:v3:function:CV-equal">
            <AttributeValue DataType="urn:hl7-org:v3#CV">
                <hl7:CodedValue code="REP" codeSystem="2.16.756.5.30.1.127.3.10.6"/>
            </AttributeValue>
            <SubjectAttributeDesignator DataType="urn:hl7-org:v3#CV" AttributeId="urn:oasis:names:tc:xacml:2.0:subject:role"/>
        </SubjectMatch>
    </Subject>

    <!-- OR -->

    <!-- Granting emergency access rights to healthcare professionnals -->
    <Subject>
        <SubjectMatch MatchId="urn:hl7-org:v3:function:CV-equal">
            <AttributeValue DataType="urn:hl7-org:v3#CV">
```

```
                    <hl7:CodedValue code="HCP" codeSystem="2.16.756.5.30.1.127.3.10.6"/>
                </AttributeValue>
                <SubjectAttributeDesignator DataType="urn:hl7-org:v3#CV" AttributeId="urn:oasis:names:tc:xacml:2.0:subject:role"/>
            </SubjectMatch>
            <SubjectMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal">
                <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">
                    urn:gs1:gln
                </AttributeValue>
                <SubjectAttributeDesignator
                    AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id-qualifier" DataType="http://www.w3.org/2001/XMLSchema#string"/>
            </SubjectMatch>
            <SubjectMatch MatchId="urn:hl7-org:v3:function:CV-equal">
                <AttributeValue DataType="urn:hl7-org:v3#CV">
                    <hl7:CodedValue code="EMER" codeSystem="2.16.756.5.30.1.127.3.10.5"/>
                </AttributeValue>
                <SubjectAttributeDesignator DataType="urn:hl7-org:v3#CV" AttributeId="urn:oasis:names:tc:xspa:1.0:subject:purposeofuse"/>
            </SubjectMatch>
        </Subject>

    </Subjects>

    <Resources>

        <!-- Patient, designated by his EPR-SPID ("epd-spid-goes-here") -->
        <Resource>
            <ResourceMatch MatchId="urn:hl7-org:v3:function:II-equal">
                <AttributeValue DataType="urn:hl7-org:v3#II">
                    <hl7:InstanceIdentifier root="2.16.756.5.30.1.127.3.10.3" extension="epr-spid-goes-here"/>
                </AttributeValue>
                <ResourceAttributeDesignator DataType="urn:hl7-org:v3#II" AttributeId="urn:e-health-suisse:2015:epr-spid"/>
            </ResourceMatch>
        </Resource>

    </Resources>

    <Environments>

        <!-- Valid to / Mandatory only for group assignments: value ("end-date-goes-here", YYYY-MM-DD) must be greater than current date -->
        <Environment>
            <EnvironmentMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:date-greater-than-or-equal">
                <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#date">end-date-goes-here</AttributeValue>
                <EnvironmentAttributeDesignator
                    AttributeId="urn:oasis:names:tc:xacml:1.0:environment:current-date" DataType="http://www.w3.org/2001/XMLSchema#date"/>
            </EnvironmentMatch>
        </Environment>
```

```
            </Environments>

        </Target>

        <!-- Available PolicySetIdRefences - keep the required ones -->

        <!-- Read documents -->
        <PolicyIdReference>
            urn:e-health-suisse:2015:policies:permit-reading-normal
        </PolicyIdReference>

        <!-- Register new documents (RegisterDocumentSet-b + ProvideAndRegisterDocumentSet-b) -->
        <PolicyIdReference>
            urn:e-health-suisse:2015:policies:permit-writing-normal
        </PolicyIdReference>

        <!-- Update metadata (urn:ihe:iti:2010:UpdateDocumentSet) -->
        <PolicyIdReference>
            urn:e-health-suisse:2015:policies:update-metadata
        </PolicyIdReference>

        <!-- Allow a representative to forward his own access rights (requires a policies:access-level:normal) -->
        <PolicySetIdReference>
            urn:e-health-suisse:2015:policies:access-level:delegation-and-normal
        </PolicySetIdReference>

    </PolicySet>
```

# 9 Figures and Tables

## 9.1 Figures

Figures

## 9.2 Tables

Tables