



Smart Open Services for European Patients

**Open eHealth initiative for a European large scale pilot of
patient summary and electronic prescription**

Initial Scope

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1 Objective of the document

The goal of the document is to define the Initial Scope of epSOS, in order to detail the content of the work described in Annex 1 and to provide uniform interpretation of basic concepts to be applied and understood uniformly by other WPs. Based on these to furthermore initiate a process for creating and maintaining suitable epSOS definitions.

The document is structured as follows:

- Chapter 2 will provide an introduction to epSOS, describing the political and regulatory framework in which epSOS has been defined
- Chapter 3 will define the epSOS Scope, report the basic prerequisites (general and functional) derived from Annex 1 and other EU Recommendation documents and identify the major out of scope topics (i.e. differentiation).
- Chapter 4 will provide the definition and the interpretation of key terms commonly used in epSOS. The goal is to establish a common vocabulary to avoid incorrect interpretations that may lead to incoherent choices and implementations.
- Chapter 5, starting from the basic prerequisites and the definitions, will define overall requirements and assumptions
- Chapter 6 will describe the Use Cases, derived from Annex 1, providing a careful analysis of situations and possible procedural approach.

2 Introduction of epSOS (Political framework)

The overarching goal of epSOS (Smart Open Services for European Patients) is “to develop a practical eHealth framework and ICT infrastructure that will enable secure access to patient health information, particularly with respect to a basic Patient Summary and ePrescription, between European healthcare systems.”¹

Towards that direction, the national regulatory authorities and competence centres for eHealth that are cooperating in epSOS aim to test both services in pilot applications in a range of member states. The approach, which is based on well-developed and distinct use cases, and associated infrastructural components, aims to deliver both a methodological process and durable implementations (termed ‘building blocks’). These will form the basis for a longer term, pan-European approach to building interoperable service solutions.

The large scale pilot’s main approach is to define a small set of agreed use cases and an analysis of both existing and foreseeable national solutions. They will be used to design pilot systems that are based on the principle of interconnecting the respective national solutions.

The methodology will strive to build a common architecture and core services for the identification of users and institutions, security, confidentiality and privacy aspects, and aim to enhance various semantic aspects of the systems. epSOS will cover to some extent all aspects of interoperability as defined in the EC-Recommendation². It will create conditions that will allow the execution of pilots within existing legal systems by establishing a legal interoperability layer aiming to enhance trust. The legal requirements to be taken into account should address: medical legal constraints, privacy respect, security procedures. The regulatory framework must be respected in pilot site operations.

A number of parallel projects generate results from which epSOS benefits, equally epSOS contributes to these projects:

- STORK³: It aims at implementing an EU wide interoperable system for recognition of eID and authentication that will enable businesses, citizens and government employees to use their national electronic identities in any Member State.
The project will:
 - Develop common rules and specifications to assist mutual recognition of eIDs across national borders;
 - Test, in real life environments, secure and easy-to-use eID solutions for citizens and health care providers;
 - Interact with other EU initiatives to maximize the usefulness of eID services.
- CALLIOPE⁴, which is a Thematic Network with a focus on cross-border eHealth Interoperability on organisational level. The central goal of the CALLIOPE network is to produce business benefit for decision makers for national eHealth implementations. Towards this goal, CALLIOPE comprises a dedicated forum where decision makers, implementers, professionals, patients and other stakeholders can share their views on how to establish interoperable eHealth services.
- EHEALTH INTEROP⁵, which addresses the requirements of the European Commission mandate to the European Standards Organisations (ESOs) on standardisation in the field of e-

¹ Annex I, Ch. B1.1.2.1

² The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C (2008) 3282

³ <http://www.eid-stork.eu/>

⁴ <http://www.calliope-network.eu/>

⁵ <http://www.ehealth-interop.nen.nl/>

health. This mandate (M/403) aims to provide a consistent set of standards to address the needs of this rapidly-evolving field for the benefit of future healthcare provision.

The political and regulatory framework, the goal and the scope of epSOS relates to the draft “Commission Recommendation on cross-border interoperability of electronic health record systems” and the associated “Explanatory Memorandum”⁶. It is intended to support the premise that connecting people, systems and services is vital for the provision of good healthcare in Europe insofar as it is necessary to enable the un-prevented mobility of patients as well as eHealth products and services, and hence may contribute significantly to the establishment and functioning of the internal market.

“The ultimate goal of the Recommendation is, therefore, to contribute to creating a means whereby authorised health professionals can gain managed access to essential health information about patients, subject to the patients’ consent, and with full regard for data security, privacy and confidentiality requirements. Such information could include the appropriate parts of a patient’s electronic health or medication record, patient summary, and emergency data accessible from any place in the Community.”⁷

The terms and definitions throughout the document are strictly used for the purpose of description of the processes and use cases patient summary and electronic prescription. Further analysis by the according WPs might result in alterations and/or more precise definitions of terms.

⁶ Explanatory Memorandum: Commission Recommendation of July 2nd 2008 on cross-border interoperability of electronic health record systems” and the associated (COM(2008)3282 final)

⁷ Explanatory Memorandum: Commission Recommendation of July 2nd 2008 on cross-border interoperability of electronic health record systems” and the associated (COM(2008)3282 final)

3 Scope of epSOS and initial prerequisites

3.1 epSOS scope

epSOS scope is to investigate, build and evaluate a service infrastructure to enable cross border interoperability of ePrescription and Patient Summary services, to facilitate patients' mobility, according to the Commission's recommendation⁸.

The infrastructure will demonstrate the interoperability⁹ between two or more Electronic Health Record Systems, allowing the exchange of computer interpretable data and human understandable knowledge.

epSOS will identify means of interoperability which will allow to connect services and architectures, potentially different in every Member State (MS), to provide Patient Summary (PS) and ePrescription (eP) cross-border services.

epSOS will define, develop and test services to allow a patient from country A while being in country B, to exploit eP and PS services available in country A.

Some countries of the European member states have implemented frameworks and/or solutions to exchange information between different hospitals, general practitioners, radiology institutes or laboratories, their experience and situations will be considered also in epSOS.

There are **nine specific objectives** for participating member states. These are to:¹⁰

- agree on a dataset that describes the agreed upon patient summary, as well as the minimum data set required for countries to connect to the services;
- agree similarly on a basic dataset and other requirements for ePrescription;
- agree a minimum set of requirements for the access to information taking into account the **needs of the various actors**, including specifically citizens, healthcare professionals and healthcare provider organisations;
- design, implement and test a practical technical solution to **confidentiality and security** requirements in a 'laboratory' setting;
- demonstrate the **practical implementation** of the solution, again in compliance with confidentiality and security requirements, in a number of settings in a number of participating states
- **evaluate** the results of the practical implementation;
- demonstrate the ability to access information in **compliance with relevant confidentiality and security requirements**, including in particular the content of the European Data Protection Directive and any further formally agreed amendments to this that come from the Article 29 Working Party;
- select and use relevant interoperability standards
- propose ways in which the implementation may be **replicated** in all other member states, in collaboration with those other states.

⁸ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C (2008) 3282

⁹ See 4.2.4 Interoperability

¹⁰ See Annex I, Ch. B1.1.2.2

In addition to the above reference to Annex I there are also privacy requirements to be considered in the description of processes and use cases for patient summary and electronic prescription.

It is expected that epSOS will deliver the following **Key measurable outputs**¹¹:

- an analysis of:
 - the specific constraints applying in different member states to the exchange of personal health information, including legal, regulatory, technical and operational issues
 - expected volumes of information to be accessed (e.g. numbers of travellers seeking healthcare in other member states, etc)
- an agreed framework for creating trust, by establishing policies, processes and procedures for critical data protection, privacy and confidentiality issues as well as mechanisms for their audit. Such issues include but are not limited to:
 - identification, authentication and authorisation mechanisms
 - security and trust mechanisms
 - recording and exchanging patient consent
- an agreed process for enabling semantic and syntactic interoperability between participating entities
- an agreed definition of:
 - the information to be accessed in terms of a Patient Summary
 - the information to be accessed in support of ePrescription
- an agreed set of functional user requirements in the form of an output-based specification
- an agreed set of standards for access to information
- an agreed specification for a technical solution (or set of possible technical solutions) to the user functional requirements
- a piloted technical solution
- an evaluation of the test implementation
- an evaluation of the practical implementation
- a proposed methodology for replicating the solution in other member states

3.2 Basic prerequisites

In this section the basic prerequisites that have been identified as necessary to further describe the scope of epSOS will be summarised. Some of these prerequisites have been already defined by the European Commission as recommendations or conclusions in the different E-health working groups within the i2010 initiative.

¹¹ Annex I, Ch. B1.1.2.3

3.2.1 General prerequisites

1. The primary application of electronic Patient Summary and ePrescription is to provide the HCP with a dataset of key health information at the point of care to deliver safe patient care in an unscheduled and scheduled contact.
2. The solution must be focused on the needs and wishes of citizens, patients and their carers (including wishes with respect to confidentiality and consent)¹².
3. Any access is in the context of a resident of one MS visiting another MS and seeking health-care in that MS¹².
4. The solution must maintain, and preferably enhance, patient safety¹².
5. The interchange of information between different MSs must observe the planned or already in place solutions or services and respect the regulations and laws of these MSs regarding Patient Summary and ePrescription. From this prerequisite, the following statements are deducted:
 - The solution must be capable of being supported by all member state administrations within the context of their national health regulations, strategies and eHealth implementations¹².
 - A policy of no intrusion or interference in the other MSs must be applied (e.g. the valid regulatory framework is the regulatory framework of the country where the service is provided to the patient).
 - A relationship of trust with the other MSs exists (e.g. validity of the identity of a professional in other MS).
 - Security and privacy requirements and legislations for electronic data exchange must not be weakened and must be satisfied.
6. Agreement on common standards by all EU Member States, should be reached.
7. The eHealth industry and other stakeholders must be involved.
8. Any contractual arrangements must comply with relevant national and European procurement processes.
9. National well-organised eHealth infrastructures are pre-requisite for cross-border solutions. From this statement, there should be existence/deployment, even as advanced trials of ePrescription and/or Patient Summary Services in the Countries where a pilot site will be implemented.
10. The solution must be capable of being replicated by all Member States¹³.
11. A National Contact Point per MS to interchange the information has to be established¹⁴.

3.2.2 Functional prerequisites

1. Any access to personal information will generally take place with a citizen's explicit and informed consent. This is subject of further investigation if the person is not able to express the consent.
2. The protection of personal data, privacy and confidentiality must be assured.
3. One-to-one and unmistakable identification of the patient must be assured.

¹² Annex I, Ch. B1.1.2.1

¹³ Annex 1, Ch B1.3.1.3

¹⁴ Annex 1, Ch B1.3.1.3

4. Every MS is responsible for the content of the electronic data generated in it, in particular there is NO central European database within epSOS where any patient related data is held.
5. The information interchanged must be understandable in both countries involved in the interaction.
6. If information about a patient is generated in country B, any country A decides if and how it stores that information.

3.3 Differentiations

In the light of the epSOS goal, the major elements which are not in its scope will be reported in this section.

It is out of epSOS scope to build an European integrated health information system to deal with Patient Summary and ePrescription, keeping aligned and updated the health related information of every citizen who needs health care assistance, while traveling all over Europe.

One of the basic requirements of epSOS is the non interference with the local Health Care system of a Member State. As a consequence of this assumption, it is out of epSOS scope to ask a Member State to modify the way in which it provides its Patient Summary (PS) and ePrescription (eP) services.

Since the epSOS goal is to demonstrate the cross-border interoperability, the management of any activity generated in a Member State, fully accomplished in the same Member State, without any interaction with other Member State, is out of epSOS scope.

Electronic prescriptions and Patient Summary may cover additional aspects such as reimbursement or drug safety surveillance, which are **not** considered within epSOS.¹⁵ Nevertheless epSOS will not adopt solutions which are in contradiction with already defined procedures of these additional aspects, especially reimbursement.

¹⁵ Annex I, Ch. B1.1.3.2

4 Definitions

4.1 Introduction

It has been commonly recognized that, starting from epSOS Annex I, some acronyms or some relevant elements for the identification of the services to be provided by epSOS, are referred to using different wordings.

A typical example is the acronym "HCP", sometimes referred as Health Care Professional, sometimes as Health Care Providers.

Other relevant examples are Patient Summary and Medical Summary, or ePrescription and Medication Summary.

In order to avoid misunderstandings or discrepancies and divergences, a commonly agreed vocabulary, associating a univocal meaning and contents to every item, is provided as follows.

4.2 Definitions

4.2.1 Places and Actors

Country A

This is the country which holds information about a patient, where the patient can be univocally identified and his data may be accessed.

Country B

This is the country, different from country A in which information about a patient is needed in case that the patient needs healthcare.

Health Care Professional (HCP)

"**health care professional**" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC¹⁶.

This means that a Health Care Professional is a person who delivers health care or care products professionally to any individual in need of health care services, in order to prevent, relieve or treat a medical problem. A Health Care Professional must be related to at least one HCPO (see below).

In the case of ePrescription also relevant are:

Prescriber

- **Health Care Professional** who issues a prescription. The professional person must be authorized to do so.

Dispenser, dispensing agent

- **Health Care Professional** who provides the order of a prescription. The professional person must be authorized to do so.

Health Care Provider Organization (HCPO)

¹⁶ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

Health Care Provider Organization is an institution, authorized to provide health care services, univocally identified in the set of the Health Care Institutions.

Examples: Health Center / Hospital / Medical Emergency Vehicle / Medical Practice / Pharmacy

Patient

“Patient” means any natural person who receives or wishes to receive health care in a Member State¹⁷.

Point of Care (PoC)

Any location where health care is provided.

4.2.2 Patient Summary

Patient Summary

“patient’s summary, emergency data set, medication record” mean subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription¹⁸.

A Patient Summary is a concise clinical document that makes a pre-defined patient health data set (to be defined at a later stage of the project) available for

- unexpected contacts (accident, emergency,..)
- planned contact (cross-organisational care path, citizen movement,..)

A **Patient Summary** would provide a HCP with essential information needed for health care coordination and the continuity of care in case of unexpected care, or when the patient consults a HCP other than his regular advisor (e.g. the general practitioner he/she is registered with).

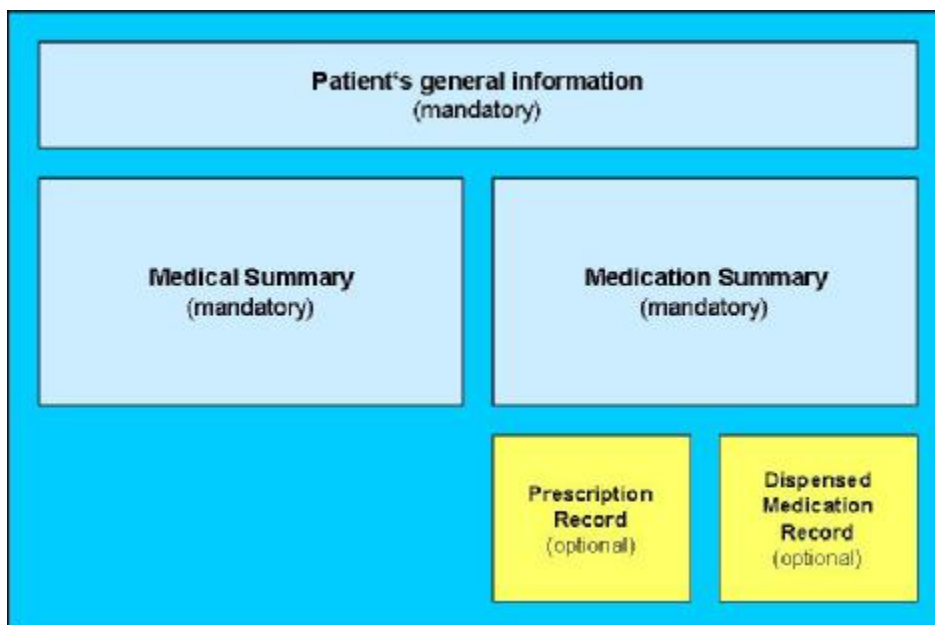


Fig. 1: Patient Summary

¹⁷ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

¹⁸ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

The **Patient Summary** might contain data such as (to be defined in detail at a later stage of the project in WP 3.2):

1. Patient's general information (mandatory):
 - demographics,
 - contact information,
 - insurance data,
2. Medical summary (mandatory):
 - existing conditions (allergies, current illness or disease, etc)
 - medical history, i.e. information on previous or current health care episodes
3. Medication summary (mandatory):
 - Contains the prescriptions and/or dispensations in order to provide a complete picture of the patient's status.
 - In addition to that it might also contain (but not mandatory):
 - Prescription Record: prescriptions with dosage and route of administration (implicit when the pharmaceutical form is known)¹⁹
 - Dispensed Medication Record: current and recent dispensed medication²⁰

The **Patient Summary** does not hold detailed medical history or details of clinical condition or the full set of the prescriptions and dispensation. Detailed and complete data are usually contained in the Electronic Health Record (see below).

Electronic Health Record (EHR)

"**electronic health record**" means a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes²¹.

Electronic Health Record System (EHRS)

"**electronic health record system**" means a system for recording, retrieving and manipulating information in electronic health records²².

4.2.3 ePrescription

Introduction:

Generally a prescription is an order given by a HCP (Prescriber) for a medicine or clinical laboratory or imaging analysis or any complementary medical care (including examination) to be dispensed to the patient according to an established pattern. The prescription may include the dosage and the route of administration.

The terms medicine and drugs are used as synonyms throughout this document.

¹⁹ Prescription with drug ID, trade name, generic name, pharmaceutical form, unit dosage will be helpful for the dispensing agent (usually a pharmacist), especially in use case 2A (Medication Dispense)

²⁰ Current and recent dispensed medication with drug ID, trade name, generic name, pharmaceutical form, unit dosage will be helpful for the prescriber (usually a doctor of medicine), especially in use case 2B (New medication prescription and dispense), to avoid drug interactions.

²¹ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

²² The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

Medicinal Prescription: Any medicinal prescription issued by a professional person qualified to do so²³.

Medicinal prescription can be referred to as drug prescription throughout this document.

ePrescription (Electronic Prescription)

"**ePrescription**" means a medicinal prescription, provided in electronic format²⁴: "A prescription is understood as a set of data like drug ID, drug name, strength, form, dosage, indication or as a list of drugs together covering the patients current medication. The dataset might differ slightly between the countries."

In the context of epSOS, this definition of ePrescription will apply²⁵

However, it is not excluded that the use of the infrastructure and the service developed in epSOS might be afterwards extended to handle ePrescriptions different from medicinal prescriptions.

4.2.4 Interoperability

The interoperability between member states is a key success factor for epSOS. To achieve and maintain cross-border interoperability the following definitions are provided as guidelines.

"interoperability of electronic health record systems" means the ability of two or more electronic health record systems to exchange both computer interpretable data and human interpretable information and knowledge²⁶.

"cross-border interoperability" means interoperability between neighbouring and non-neighbouring Member States and their entire territories²⁷.

"semantic interoperability" means ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose²⁸.

Also:

Ability of two or more systems or components to exchange information and to use the information that has been exchanged²⁹.

Health system interoperability means the ability, facilitated by ICT applications and systems to exchange, understand and act on citizens/patient and other health related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors and organizations within and across health system jurisdictions in a collaborative manner³⁰.

²³ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use - TITLE I – DEFINITIONS - Article 1

²⁴ Article 1(19) of Directive 2001/83/EC of the European Parliament and of the Council, issued and transmitted electronically The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

²⁵ Annex I, CH. B1.3.1.1.; "A prescription is understood as a set of data like drug ID, drug name, strength, form, dosage, indication or as a list of drugs together covering the patients current medication. The dataset might differ slightly between the countries."

²⁶ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

²⁷ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

²⁸ The commission of the European Communities - Commission Recommendation (2008/594/EC) of 2 July 2008 on cross-border interoperability of electronic health record systems, notified under document number C(2008) 3282

²⁹ IEEE Standard Computer Dictionary of 1990 and is used in the EU Study

³⁰ DG INFOSO project SemanticHEALTH

Some categories of interoperability were described in the ETSI White Paper, which also gives a good documentation about epSOS has to deal with³¹:

- **technical interoperability** – is usually associated with hardware/software components, systems and platforms that enable machine-to-machine communication to take place,
- **syntactical interoperability** – is usually associated with data formats. Certainly, the messages transferred by communication protocols need to have a well-defined syntax and encoding, even if it is only in the form of bit-tables. However, many protocols carry data or content, and this can be represented using high-level transfer syntaxes such as HTML, XML or ASN.1,
- **semantic interoperability** – is usually associated with the meaning of content and concerns the human and machine interpretation of the content
- **organizational interoperability** – as the name implies, is the ability of organizations to effectively communicate and transfer (meaningful) data (information) even though they may be using a variety of different information systems over widely different infrastructures, possibly across different geographic regions and cultures.

³¹ ETSI White Paper No. 3, Achieving Technical Interoperability - the ETSI Approach;
<http://www.etsi.org/Website/document/whitepapers/IOP%20whitepaper%20Edition%203%20final.pdf>

5 Overall Requirements and Assumptions

In this section, the specific requirements that epSOS should fulfil in order to achieve its goals are listed. They can be divided in general and functional requirements.

5.1 General Requirements

The services that will be set up should fulfil the following requirements:

- **Multi-laterality:** Define a distributed virtual common infrastructure to support communication among healthcare parties all over EU
- **Subsidiary :** Enforce the ownership of patient data for each health authority
- **Multi-lingual:** Have to be linguistically neutral to be comprehensible by the involved actors (HCP, Patients, ...) as for, for example pathologies, symptoms, physiological parameters, medication names,...
- **Interoperability:** Support the communication among the heterogeneity of medical systems
- **Privacy :** Assure EU citizens that only authorized HCP are able to access their data
- **Reliability:** Enable access to health data anytime and anywhere

A **National Contact Point** has to be established by each participating country, acting as a bidirectional way of interfacing between the existing different national functions provided by the national IT infrastructures and those provided by the common European infrastructure, created in epSOS. The National Contact Point takes care of external and internal national communication and functions in epSOS and the semantic mapping (if necessary) between information on either side³²:

The NCP also acts as a kind of mediator as far as the legal and regulatory aspects are concerned. The NCP creates the conditions (by supporting trust, data protection and privacy) for a trusted relationship with other countries' NCPs.

- **External cross border:** the NCP provides cross-border access to ePrescription and Patient Summary services by means of a secure communication to another NCP.
- **Internal in the country:** the NCP provides a unified mechanism for the assembly and transformation of data, formats and ID and trust mechanisms between the national IT systems and the common European infrastructure. These NCP functions are going to be developed in coordination with the specifications of the functionalities of the common services and central broker.
- Some **central information broker services** are required as a physical and organisational support node between the different National Contact Points and the common services. The role of the node is to act like a switch-board between the different services, monitor the communication and support pilot participants during implementation³³. In WP 3.3 (Architecture) the necessity for central services will be analysed and clarified.
- The solution requires to integrate heterogeneous IT systems by means of open, international standards and to demonstrate compliance with relevant national and international standards and regulations.

³² See Annex I Ch. B1.3.1.1

³³ Annex I, Ch. B1.3.1.1

- The epSOS pilot should be an open, vendor neutral infrastructure.

5.1.1 Functional Requirements

- epSOS will focus on a set of minimum requirements necessary for the implementation of the Use Cases.
- epSOS has to resolve **semantic differences** such as medication names and clinical terminologies where these differ between countries.³⁴
- A set of common services are to be set up supporting and securing the cross-border communication of ePrescription and Patient Summary.³⁵
 - Common Security Service supporting the secure transport and authorization and secure use of patient consent.
 - Common ID Service for transformation between different ID mechanisms.
 - Common Semantic Service for translation between different codes, classification and terms used in the different member states.
 - Common interfaces for interconnection with dispense services and services for contraindication and interaction checks (the dispense services and the medication check services themselves are not within the scope of the pilot)

5.2 Assumptions

The assumptions listed below aim to help the definition of criteria for the selection of pilot sites.

With respect to the existing services and infrastructures in the Member States where the pilots will be installed, the following assumptions should apply, in order to demonstrate the multilateral interoperability. :

- the services to be demonstrated,
- the network used for the interoperability demonstration,
- the security infrastructure used for the interoperability demonstration,
- the HCP identification service used for the interoperability demonstration

should exist and should be deployed or should be in an advanced testing phase.

Since the pilot trials will be performed by involving real citizen, and will not be just analogue laboratory test cases, it must be taken into account that the use of PS and eP is the use of legal medical document with possible consequences in criminal and civil case.

As a consequence the legal requirements to be taken into account should address data security, confidentiality and privacy, health system related issues and professional aspects.

The regulatory framework must be respected in pilot site operations.

³⁴ Annex I, Ch. B1.1.3.3

³⁵ Annex I, Ch. B1.3.1.1

6 Use Cases

In Annex I four different use cases are briefly described.

Based on these descriptions in combination with given definitions and overall acceptable assumptions, it is the goal of this document to give an overview about the necessary set of use cases. On the basis of WP1.1 questionnaire analysis and WP2.1 outcomes, within the epSOS timeframe WP3.1 and WP3.2 will identify the feasible cases that have to be developed for interoperability purposes.

In a first rough evaluation every use case will be analysed with focus on actors, activities and obvious sequences.

The use cases in Annex I are referred to as “Patient Summary” and “Electronic Prescription” (both hold two variations).

6.1 Patient Summary

Introduction:

The situation that needs to be considered is that a conscious or unconscious person visits an HCP and wants to make use of his/her own patient summary which is abroad. This situation can arise in an emergency or be planned.

The use cases for Patient Summary described in Annex I might be subject to different laws / regulations and may require different procedures. They will be analysed by WP 3.2.

Each Patient Summary is connected with an existing national IT infrastructure and IT systems, making it also possible to extract data on-demand from a variety of national IT systems.

6.1.1 Requirements

The goal of the epSOS Patient Summary is “to make it possible to give access to a patients own health data while abroad, supporting mobility of European patients and improve quality of health care for European citizens travelling for study, work and leisure”.³⁶

Caveat: A patient can have more than one electronic PS, in one or many countries. The handling of the different cases will be defined within the functional specification phase of the project.

Access to a Patient Summary

- The HCP’s access is subject to the patient’s explicit (earlier) consent to the access to data.

Besides, it could be generally possible to allow the patient to access his PS from abroad. The details if this will be realised as an epSOS service (within the pilot), or if already existing solutions could be used, will be defined in WP 3.2.

If however at a later stage of the project the functional and technical specification allows to also show a readable PS to the patient, this would be beneficial. Note that it would be an optional requirement. It is currently **not** a described use case and would mean the introduction of a new use case.

- The Patient Summary service may be accessed in two different ways:

³⁶ Annex I, Ch. B1.1.3.1

- a) by secure internet access where patients or authorized health professionals may read the patient data
- b) by web services providing XML document, where the Patient Summary may be requested and received as an integrated part of the participating health professionals EHR systems

The information included in the Patient summary could be provided in:

- Structured format
- Unstructured format.

Availability of a Patient Summary

It cannot be assumed that all the content of the Patient Summary will be present or available to HCPs in all circumstances because data can only be held with the patient's explicit consent, further the patient can determine whether and which HCPs can see the data.

Language of the Patient Summary

Since the HCP should be able to understand the PS, WP 2.1, 3.2, 3.5, 3.7 will define under which conditions it will be provided to him/her in his/her native language.

6.1.2 Use Cases “Occasional Visitor” and “Regular” visit to Health Care Professional in country B

The Patient Summary might be used in two distinct use cases³⁷.

From a technical point of view the difference is merely that in use case 1 the HCP does not have any records of the patient, in use case 2 there might be a record from previous visits or previous data exchange. It must be however noted that the two cases are very different in terms of regulations that are relevant to cross border care.

Patient Summary Use Case 1:

- When a person is an **occasional visitor** in country B, for example on holiday or business. In such cases the visit is irregular, infrequent and may often not be repeated. The HCP has no records from previous encounters.

³⁷ Annex I, Ch. B1.1.3.1

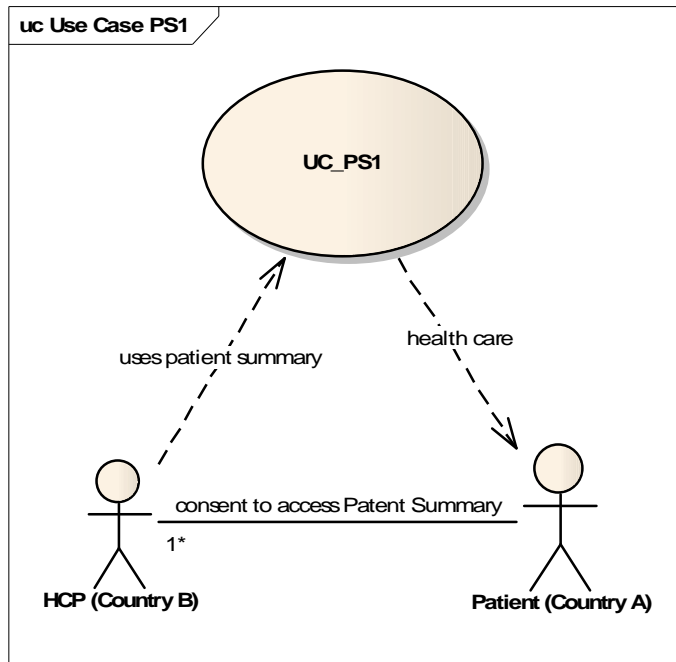


Fig. 2: Use Case Patient Summary “occasional visitor”

Patient Summary Use Case 2:

- When a person is a **regular visitor** to country B, for example working regularly in the country or living close to the border or in case of seasonal migration. In such cases the visitor may be accustomed to using health services in country B and the HCP of country B may have a record from previous encounters.

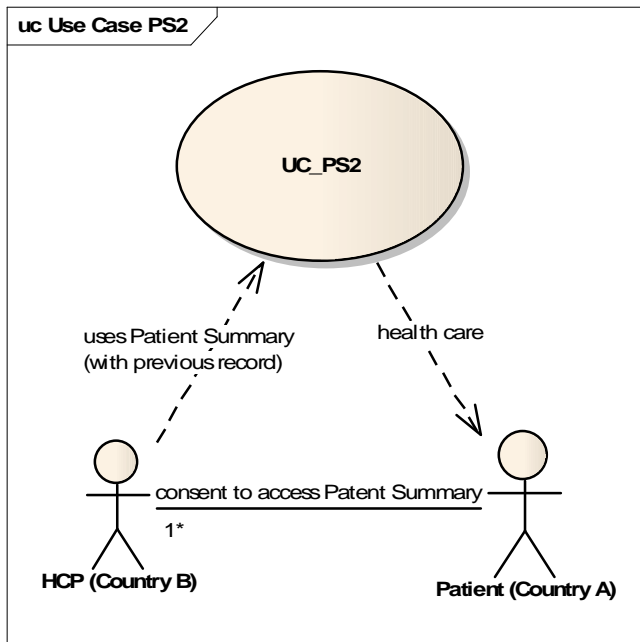


Fig. 3: Use Case Patient Summary “regular visitor”

However, both use cases generate the same technical requirements and same needed services and are therefore described together in the following. The difference is on the receiver side, where the HCP might / might not know the patient from before.

In the use case the following entities participate:

- A patient from country A in need of health care in country B.
- A Health Care Professional (HCP) in country B.
- A HCP interface in country B which serves as a communication interface to a National Contact Point (NCP) of country B.
- A NCP in country B receiving a request from HCP interface (e.g. embedded in the national IT infrastructure of country B) and connecting to the NCP of country A.
- A NCP in country A communicating with the existing national infrastructure of country A (where information about the patients summary are provided) and the NCP in country B.
- A Patient Summary (PS) Service in country A providing information for the NCP in country A.

More detailed the use cases may be illustrated in this way:

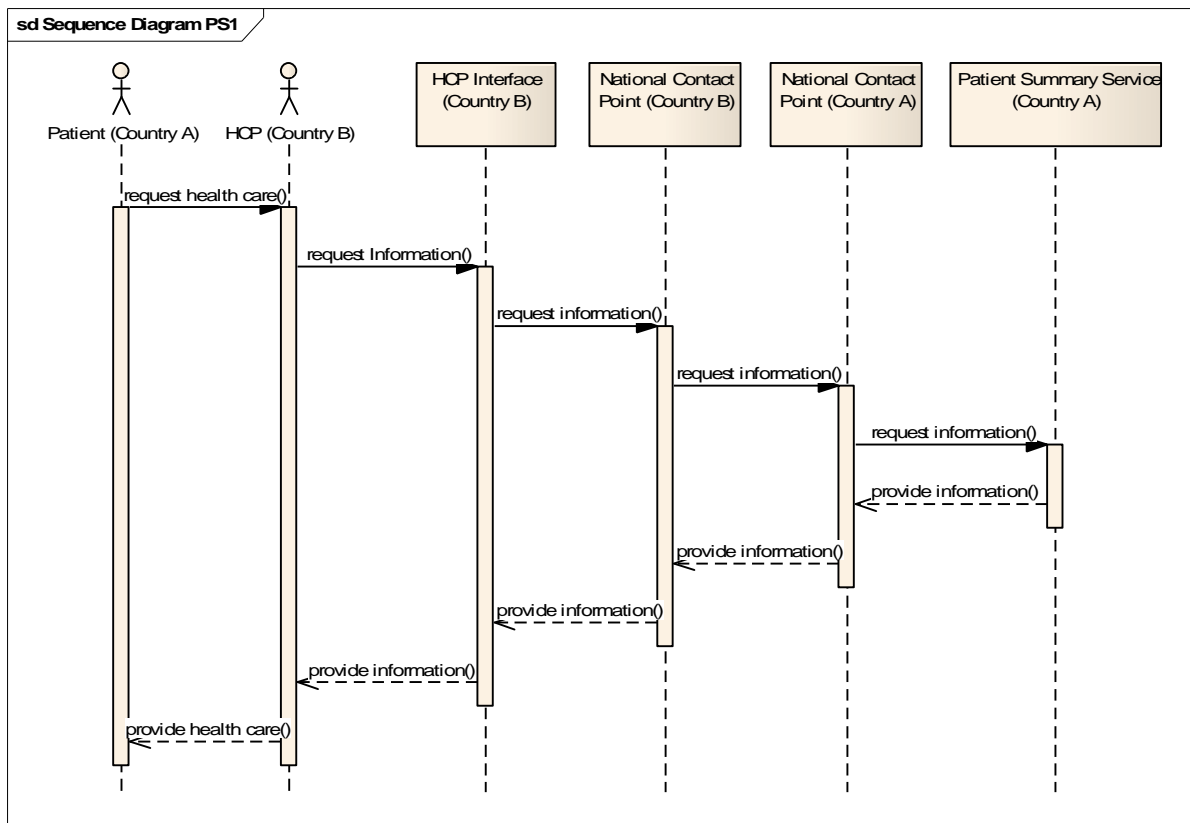


Fig. 4: Sequence Diagram Patient Summary “occasional visitor”

The transactions will be evaluated by WP 3.2 according to the scenarios listed in Section 6.1.

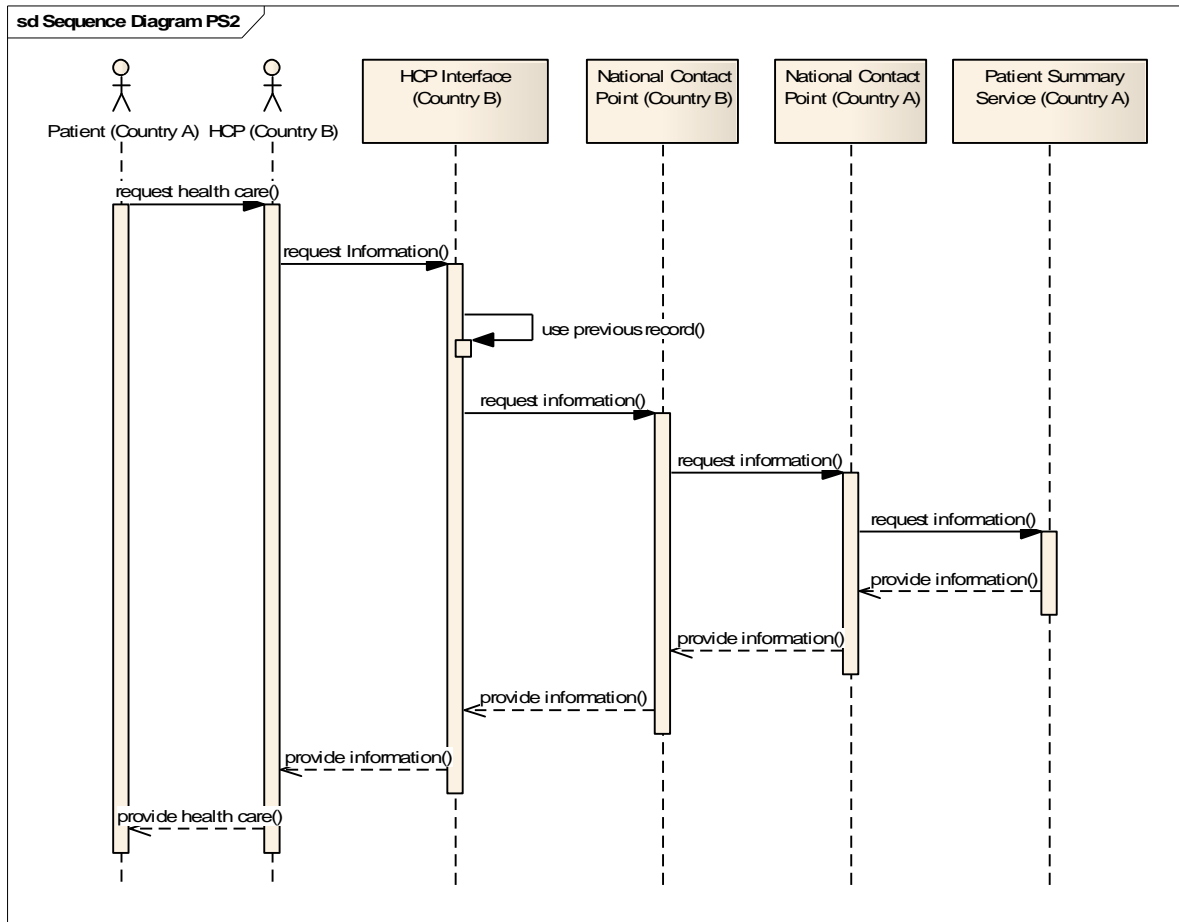


Fig. 5: Sequence Diagram Patient Summary “regular visitor”

The above diagrams contain the main steps:

Step	Name	Description	Output	Entities
1	Trigger for health care	A patient from country A requests or is in need of health care and contacts an HCP in country B.	Trigger to HCP	Patient, HCP
2	Request for information from Patient Summary	During consultation with the patient the HCP generates and sends a request to the NCP B using his/her HCP interface (depends on if the visit is regular or occasional!)	Request to NCP B	HCP, HCP interfae, NCP B
3	NCP transfer 1	NCP B transfers the request to NCP A which transfers it to the PS Service for response	Information transfer to PS Service	NCP A, NCP B, PS Service
4	NCP transfer 2	NCP A receives an response from PS Service and transfers it to NCP B	Information transfer from PS Service	NCP A, NCP B, PS Service
5	Response from Patient Summary	The NCP B transfers the response to the HCP interface.	Response to the HCP interface	NCP B, HCP interface

6	HCP uses information from Patient Summary and provides health care to the patient	The HCP finishes the consultation using the retrieved information provided in the HCP interface.	Patient receives health care with the help of information from Patient Summary	HCP, HCP interface, patient
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Tab. 1: Use Case description Patient Summary

ID for patient and HCP, security issues and semantics are managed in WP 3.5 “Semantic Services”, WP 3.6 “Identity Management” and WP 3.7 “Security Services”,.

6.2 Electronic Prescription

The typical situation to be faced might be:

- Medicine dispensation, according to a valid prescription: dispensation of the medicine of the prescription not (fully) dispensed, yet
- Medicine re-dispensation due to an emergency situation, a medicine is re-dispensed according to a previous prescription (medicine of the prescription already dispensed)
- Medicine dispensation without prescription in an emergency situation that might be very common when abroad
- Medicine prescribed and dispensed in the country B

All mentioned cases might be subject to different laws / regulations and may require different procedures. They will be analysed by WP 3.1.

In the use cases the following entities participate:

- A patient from country A in need of health care in country B
- A HCP Prescriber in country B
- A HCP Dispenser in country B
- A Patient from country A
- A HCP Prescriber interface in country B serves as a communication interface to a National Contact Point (NCP) of country B.
- A eHealth interface in country B used by an HCP Dispenser
- A NCP in country B communicating with an existing HCP interface (e.g. embedded in the national IT infrastructure of country B) and the NCP of country A.
- A NCP in country A communicating with an existing national infrastructure of country A (where information about the patients summary are provided) and the NCP in country B.
- A Patient Summary (PS) Service in country A providing information for the NCP in country A.
- A Prescription Data Service which provides information for prescribing medicine

An **ePrescription service** generally embraces the whole medicine prescribing and dispensing cycle and may cover different functionalities³⁸:

³⁸ According to Annex I - B1.1.3.2. Electronic prescription

- the **informed prescribing system**: ICT-supported decision-making system for prescription which supports HCPs in choosing the right medicine and dose appropriate to the patient's needs and warns for potential negative interactions between medicines.
- the **electronic set up and recording of a prescription** in an EHRS.
- the **electronic transmission of a prescription** from a Prescriber to a Dispenser. It might be necessary to transfer also the information on the prescribed medication, associated to the current prescription
- the electronic transmission of the dispensed medication from a Dispenser to the NCP.

These functionalities include mechanisms to guarantee:

- the identity of the Prescriber, the patient, the Dispenser.
- the authenticity and the integrity of the prescription and the dispensation.

If and which parts of such possibly existing services will become part of epSOS will be specified in WP3.1.

The Patient Summary will be supplied to the HCP to support the decision what medicine should be prescribed.

6.2.1 Requirements

In the epSOS context, the ePrescription makes it possible:

- **to access and use an existing prescription from abroad**: this is the use case “Medication dispense” (A patient needs medicine that is already prescribed in country A when in country B).
- **to prescribe and dispense** to a visiting patient from country A and send the prescription and dispensing to the NCP of country A: this is the use case “New prescription” (A HCP Prescriber in country B decides to prescribe medicine to a visiting patient from country A).

ePrescription services may be accessed in two different ways:

- by secure internet access where the selected ePrescription can be read by patients or health professionals without integrated IT systems.
- by web services providing XML document, where the selected ePrescription may be “inter-linked” (for request, reply or sending information) as an integral part of the participating health professional’s EHR systems.

The information included in the ePrescription could be provided in:

- Structured format
- Unstructured format.

The **electronic transmission of prescriptions** is considered to form a central ‘building block’ on the path towards a systematic electronic data interchange within European healthcare systems.³⁹

The case that a prescription in one country is invalid in another country (for example a patient has been prescribed a medication which may not be authorised or legal in the country the patient is visiting) must be managed.⁴⁰

The functional and technical specifications have to find solutions for the following challenges:

³⁹ Annex I, Ch. B1.1.3.2

⁴⁰ Annex I, Ch. B1.1.3.3

- Prescriptions produced in one European country should be universally directly fulfilled in another European country (in Europe currently, there are a number of legal and regulatory conditions that prevent it).⁴¹
- The semantic aspects of ePrescription are of considerable importance: different trade names, contents and packaging are used in different member states, not only do the trade names of the same active substance differ between countries, but pharmaceuticals with the same trade name may even contain different active substances in different countries).⁴²
- A case should be managed in which information available may be incomplete or restricted; if the pharmacist decides he or she is unable to safely dispense the prescription.⁴³
- Informed prescription systems offered by various vendors and institutions should work together.⁴⁴

Besides, it could be generally possible to allow the patient to access his eP from abroad. The details if this will be realised as an epSOS service (within the pilot), or if already existing solutions could be used, will be defined in WP 3.1.

6.2.2 Use Case “Medicine already prescribed in country A”

A patient needs medicine that has already been prescribed in country A when in country B. In this case the HCP Dispenser should be able to electronically access the prescription from the same eHealth interface she uses for prescriptions ordered in the local country. When medicine is dispatched, the system should notify the patient’s NCP in country A about the dispensed drugs.⁴⁵

The following figures show the use case and the sequence diagram referring to the description in Annex I.

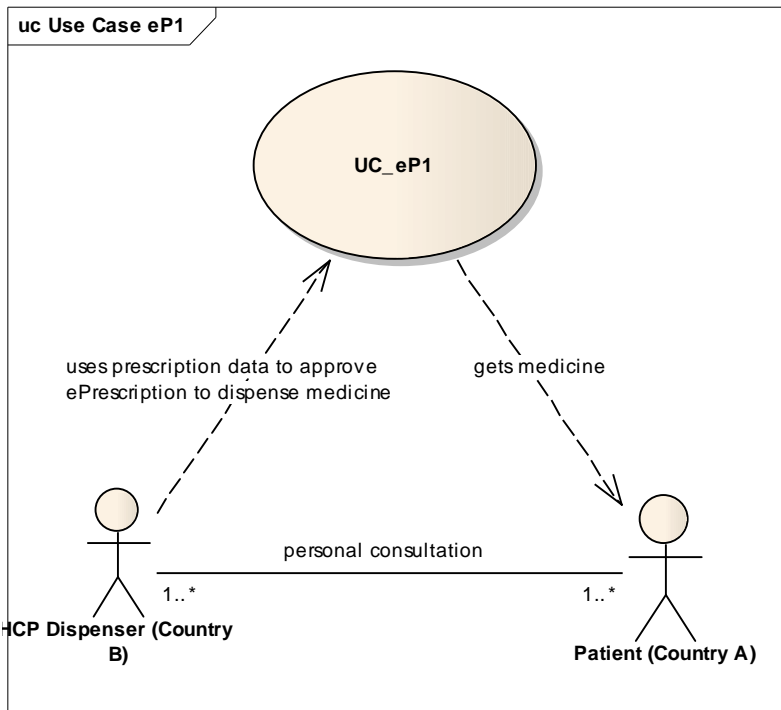


Fig. 6: Use Case ePrescription “A patient needs medicine that is already prescribed in country A when in country B”

⁴¹ Annex I, Ch. B1.1.3.3

⁴² Annex I, Ch. B1.1.3.3

⁴³ Annex I, Ch. B1.1.3.3

⁴⁴ Annex I, Ch. B1.1.3.3

⁴⁵ Annex I, Ch. B1.1.3.2

According to the use case description the HCP Dispenser (e.g. pharmacist) must know what medicine has been prescribed (e.g. through a consultation).

The HCP Dispenser accesses the necessary data to be able to dispatch the medicine. After the medicine is dispensed the system informs the NCP in country A about the dispatch.

The following figure shows the interaction between the different entities of the use case.

The information requested and provided, quoted in the sequence diagram, may differ according to the first three scenarios listed in Section 6.2. They will be analysed by WP 3.1

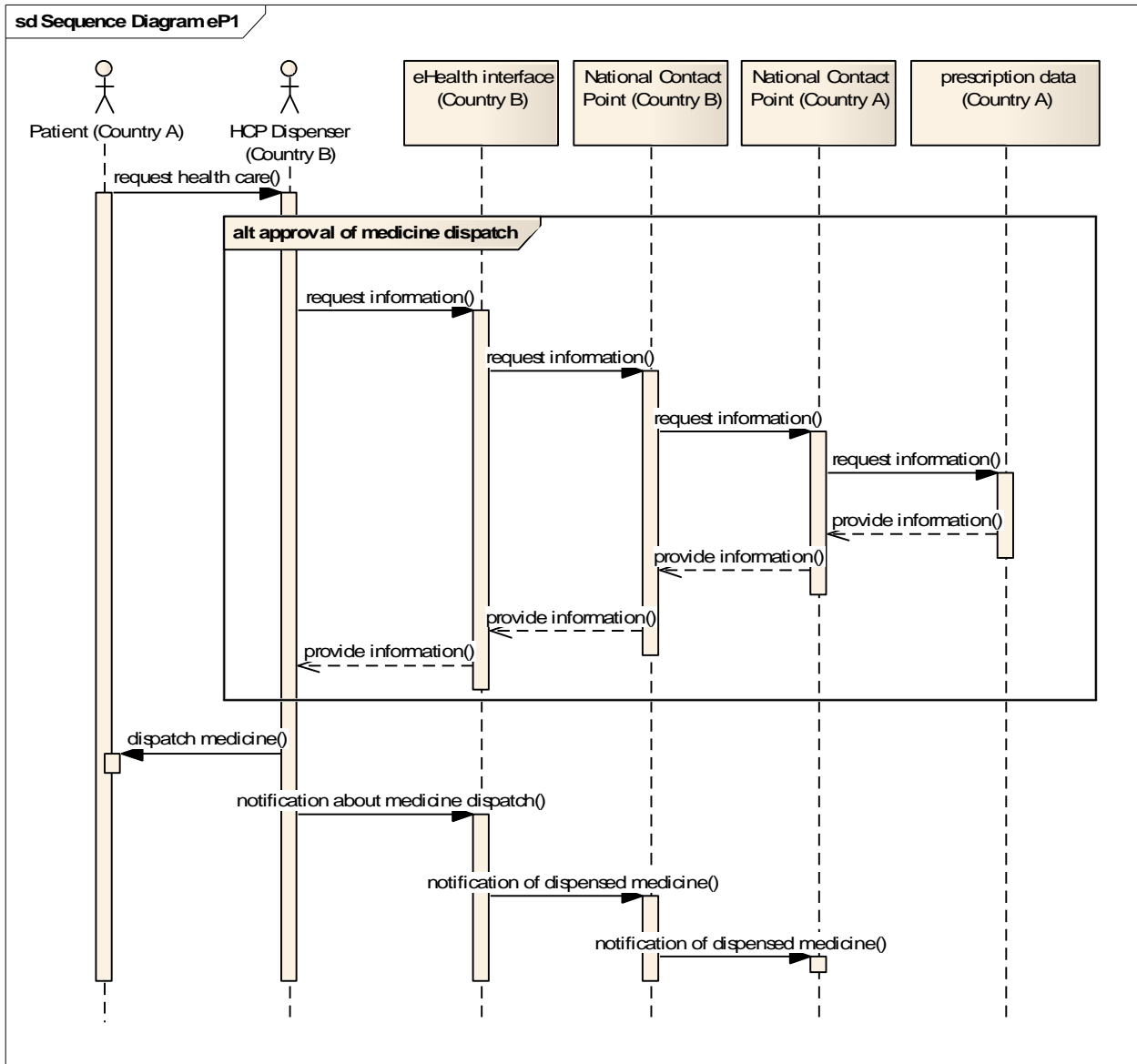


Fig. 7: Sequence Diagram ePrescription “A patient needs medicine that is already prescribed in country A when in country B”

Based on the sequence diagram the steps within this use case are shown in the following table.

Step	Name	Description	Output	Entities
1	Patient re-requests health care	A patient from country A requests health care in form of consultation from a HCP in country B.	Trigger to HCP Dispenser	Patient, HCP Dispenser
2	HCP Dispenser re-requests information	The HCP Dispenser re-requests information about a prescription via an eHealth-interface.	Information request to prescription record	HCP Dispenser, eHealth-interface
3	NCP transfer 1	The eHealth interface transfers the request via the NCP B to NCP A which transfers it to the prescription data for response	Information transfer to prescription data	eHealth interface, NCP A, NCP B, prescription data
4	NCP transfer 2	NCP A receives an response from prescription data and transfers it to NCP B	Information transfer from prescription data	NCP A, NCP B, prescription data
5	Response from prescription data	The NCP B transfers the response to the eHealth interface.	Response to the eHealth interface	NCP B, eHealth interface
6	Dispatch of medicine	With the necessary information from the prescription data the medicine can be dispatched.	Dispatch medicine	HCP Dispenser, patient
7	Notification of dispatched medicine	The NCP A is notified about the dispatched medicine through NCP B.	Message to NCP A	eHealth-interface, NCP A, NCP B

Tab. 2: Sequence diagram ePrescription “A patient needs medicine that is already prescribed in country A when in country B”

6.2.3 Use Case “Medicine newly prescribed in country B”

A HCP Prescriber decides to prescribe medicine to a visiting patient from country A. To assist the medical professional to make the best decision on the pharmaceutical strategy to be used, the patient’s medical and medication summary history from country A will be available through the Patient Summary. When the electronic prescription is finalized, a copy of the prescription will also be sent to the NCP in country A for inclusion in the medication summary.⁴⁶

The following figures show the use case and the sequence diagram referring to the description in Annex I.

⁴⁶ Annex I, Ch. B1.1.3.2

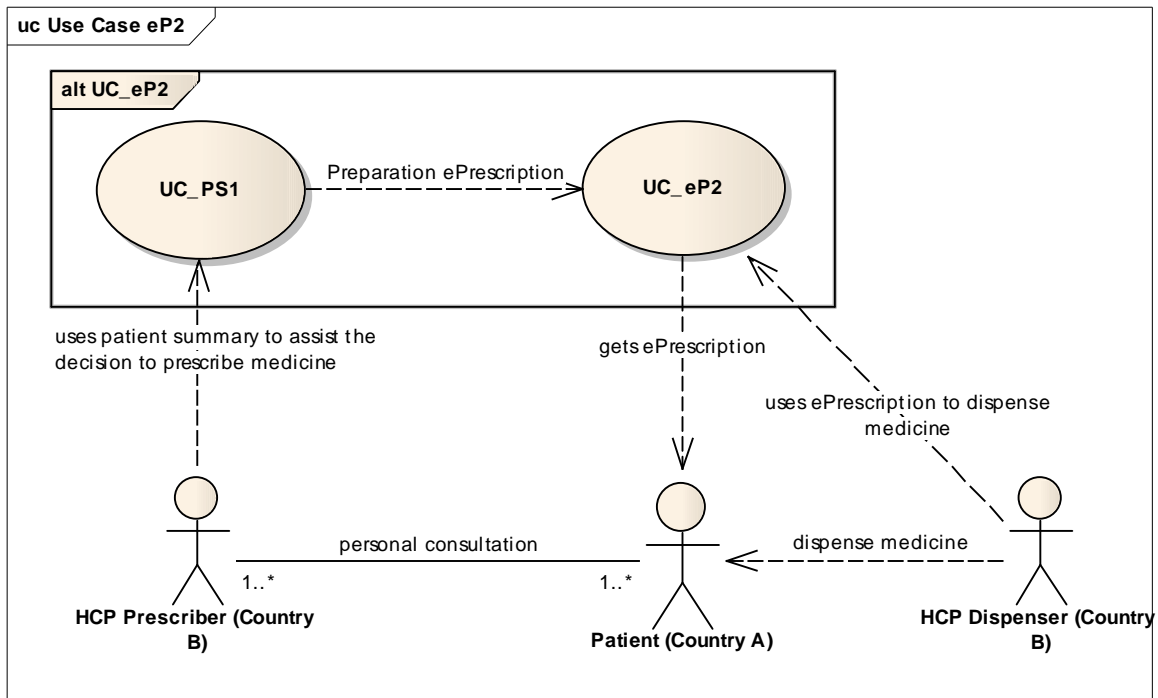


Fig. 8: Use Case ePrescription “A HCP decides to prescribe medicine to a visiting patient”

Fig. 8 shows three physical actors that are involved in the use case.

Based on the requirements and other information from Annex I the three actors interact within this use case in different ways.

The HCP Prescriber decides to prescribe medicine to a patient. That action is preceded by some kind of personal consultation (e.g. examination). As a result the patient gets an ePrescription. The HCP Dispenser uses the information in this ePrescription to dispense medicine to the patient.

The ways in which that ePrescription is processed and what information it can hold is shown in Fig. 9.

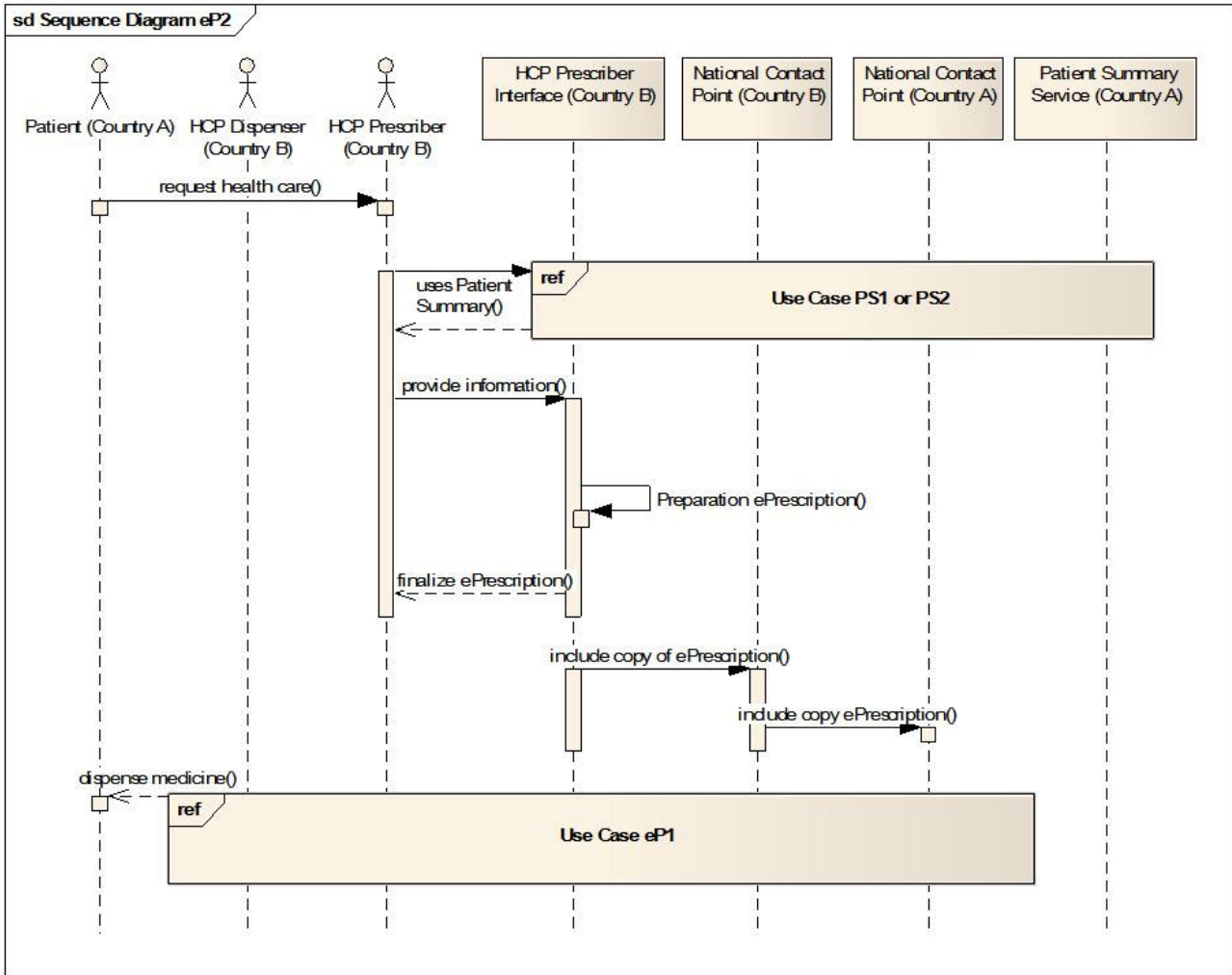


Fig. 9: Sequence Diagram ePrescription “A HCP decides to prescribe medicine to a visiting patient”

The figure shows the interaction between these entities which is also given in the following table.

Step	Name	Description	Output	Actors
1	Patient requests health care	A patient from country A requests health care in form of consultation from a HCP in country B.	Trigger to HCP Prescriber	Patient, HCP Prescriber
2	HCP Prescriber requests information	The HCP Prescriber requests information to help him to make the best decision on the pharmaceutical strategy for a patient from country A using his/her HCP Prescriber interface.	Information request to PS service	HCP Prescriber, HCP Prescriber interface
3	NCP transfer 1	The HCP Prescriber interface transfers the request via the NCP B to NCP A which transfers it to the PS service for response	Information transfer to PS service	HCP Prescriber interface, NCP A, NCP B, PS service

4	NCP transfer 2	NCP A receives an response from PS service and transfers it to NCP B	Information transfer from PS service	NCP A, NCP B, PS service
5	Response from PS service	The NCP B transfers the response to the HCP Prescriber interface.	Response to the HCP Prescriber interface	NCP B, HCP Prescriber interface
4	Preparation ePrescription	With the necessary information from the patent summary the HCP Prescriber prepares and finalizes an ePrescription based on the pharmaceutical strategy	ePrescription	HCP Prescriber, HCP Prescriber interface
5	Copy of ePrescription to NCP	A copy of the finalized ePrescription is sent via NCP B to the NCP A for inclusion	Copy of ePrescription to NCP A	HCP Prescriber interface, NCP B, NCP A
6	Patient receives dispensation of medicine	Based on the information of the ePrescription the HCP Dispenser dispenses medicine to the patient.	Dispensed medicine to patient	HCP Dispenser, patient, NCP B, NCP A, patient

Tab. 3: Sequence diagram ePrescription “A HCP decides to prescribe medicine to a visiting patient”

The sequence diagram lacks all possible technical features that might be necessary to process an ePrescription. The idea is to only use elements and more or less detailed information given in Annex I and avoid all restricting assumptions and differentiations.

7 Open Issues

While discussing and documenting the epSOS initial scope WP 5.2 identified some important issues which need further clarification and clear definitions. Since this is the scope of further analysis they are intentionally not defined in detail in this document. Rather the following list should be used as input by WP5.2 to WP2.1 and PD3 for their work. The list is not complete and therefore does not intend to cover all open issues.

- Should the patient be able to access his/her own PS?
- How to cover the case of emergency and the case of a patient being unconscious or a minor or in need of a legal representative?
- Should the PS be completely visible to the HCP of country B or just in parts?
- Are additional authorizations required for any types of prescriptions?
- How are multiple dispensations of one prescription to be handled?

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10 Glossary

CALLIOPE	DGINFSO project, Thematic Network - CALL for InterOPERability, http://www.calliope-network.eu/
CC	Competence Centre
CEN	Comité Européen de Normalisation (European Committee for Standardization): http://www.cen.eu/cenorm/index.htm
CENELEC	Comité Européen de Normalisation Electrotechnique, the European Committee for Electrotechnical Standardization: http://www.cenelec.org/
CIP	Competitiveness and Innovation framework Programme
CPOE	computerized physician order entry
CCR	Continuity of Care Record
DG INFSO	Directorate General for Information Society and Media: http://ec.europa.eu/dgs/information_society/index_en.htm
EC	European Commission: http://ec.europa.eu/index.htm
EHealth INTEROP	eHealth Interoperability
EHR	Electronic Health Record
EHRS	Electronic Health Record System
eP	Electronic Prescription
EPSOS	European Patients – Smart Open Services
ESO	European Standardization Organizations
ETSI	European Telecommunications Standards Institute: http://www.etsi.org
EU	European Union (Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark,, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom)
HCP	Health Care Professional
HCPO	Health Care Professional Organization
HL7	Health Level 7: http://www.hl7.org
ICT	Information and Communication Technologies
ICT PSP	Information and Communication Technologies Policy Support Programme
ID	Identity
IHE	Integrating the Healthcare Enterprise - Europe
ISO	International Organization for Standardization: http://www.iso.org

epSOS – Initial Scope

IT	Information Technologies
LSP	Large Scale Pilot
M/403	European Commission's mandate to the European Standardization Organizations (ESOs), CEN, CENELEC, and ETSI, to develop a coordinated work programme for standardization in health informatics
MS	(EU) Member State
NA	National Administration (e.g. ATNA for Austria National Administration, DKNA Denmark National Administration, ...)
NCP	National Contact Point
PoC	Point of Care
PS	Patient Summary
SME	Small / Medium Enterprise
STORK	Secure Identity across borders linked
UC	Use case
XML	Extended Mark-up Language