Smart Open Services for European Patients

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

D3.1.2 Final definition of functional service requirements – ePrescription

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ABSTRACT

This document describes the uses cases to be found on the epSOS LSP, identifying the needed requirements, information to be exchanged and possible issues from the users' point of view.

History of Alteration

Version	Date	Status Changes	From	Review
0	18/07/2009	First Draft	ANDA	Participants of 21/07/2009 Paris f2f
0 1	21/07/2009	Input from Paris meeting and 'Storyboards' working document	ANDA	WP3.1
0 2	07/09/2009	Working version to incorporate the changes as a result of the comments made by WP3.1	WP3.1	ANDA
1	28/09/2009	It incorporate the final results of Tcon of 11/09/2009. Final version before Quality review	ANDA	Quality review
1.1	27/10/2009	It includes the results from the QR	ANDA	Technical WPs
1.2	26/03/2010	Some changes have been made after feedback from the technical groups	ANDA	

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1 FOREWORD

epSOS LSP project operates within a complex policy background and focuses on electronic patient record systems, with its initial focus on two cross border services, i.e. Patient Summary and e-Prescribing/e-Dispensing. The aim of the pilot is to demonstrate that it is feasible for any Member State (MS) that already provides these eHealth services to its residents, to create the conditions that will allow it to also offer these services to them when they travel abroad to other Member States taking part in the epSOS LSP.

It is important to note that the epSOS services involving Patient Summaries and e-Prescribing/e-Dispensing will be offered on a pilot basis and the intention is to gather data and learn from this pilot operation to accelerate deployment of these services. The pilots will test the feasibility and acceptance of the overall technical and legal interoperability of the proposed solutions.

It is also important to clarify that it is a basic principle of epSOS LSP that the proposed implementation will build technical interoperability into current national solutions. In the same way it is the objective of the project to develop a modus operandi of interoperability between existing legal and regulatory frameworks, rather than to propose new ones or amendments to existing legislation.

Concepts paper epSOS LSP

2 EXECUTIVE SUMMARY

Based on the principles stated in the Foreword, the goal of this deliverable has been to identify, once the common understanding of the ePrescription service within the epSOS LSP framework has been agreed and the use cases identified, the requirements from the point of view of the HCP necessary to implement a feasible service considering the level of maturity of the solutions within the Member State (MS) and the lack of an European framework, always considering patient safety as a paramount. In consequence, the aim has been to focus on strictly necessary requirements in order to achieve a minimum but secure and safe service and also identify desirable ones that would improve the service but that might be difficult to implement in this LSP for all MSs.

The discussion and the content regarding this deliverable starts from the concepts, ideas and description contained in the previous deliverable, D3.1.1 'Draft definition of functional service requirements - ePrescription' and the inputs from WP2.1 'Analysis and comparison of legal and regulatory issues'. If D3.1.1 was focused on the analysis of the ePrescription service, identifying possible alternatives and issues, this deliverable, D3.1.2 'Final definition of functional service requirements - ePrescription' describes the service based on the preferred solution or alternative, applies the solutions of the issues that have been solved and sets out conclusions and issues that will be encountered during the pilot phase.

The major business decision agreed after the development of the draft deliverable is that prescriptions, as orders, must be the responsibility of the country that generates them. This means that at this stage, any prescription written in a foreign country will not be sent to the patient's home country to be managed as an order in that country. This decision is based on the yet immature European framework regarding the ePrescription service, such as legislation or processes, as reflected in the issues identified in this document.

The two use cases identified, use case 1 'Medicine already prescribed in country A' and use case 2 'Medicine newly prescribed in country B', have been carefully analysed and all possible issues and requirements have been identified. Also, possible exceptions[1] in the processes are explained and an assistance service is described. Use case 1 has been described in more detail and prioritised due to a higher perceived benefit to the patient while use case 2 has been considered as an experimental use case not to be implemented in this LSP (see Annex I of D3.1.2).

[1] Possible situations to be faced different than the successful use case

The main issue that affects use case 1 -namely medicine already prescribed in country A being dispensed in Country B- is the potential problem associated with semantics. Prescriptions are not all described in a similar manner across different European countries leading to concerns around patient safety in ensuring that the right information and medicine is received. Other important issues are related to the different processes and concepts for ePrescription in all countries. Hence the way in which the European service is defined must be as transparent and neutral as possible to these processes and concepts. Last but not least, legislation represents a potential major challenge in supporting the dispensing of a prescription across borders. The legislation pertaining to the country in which the prescription is written may be very different to that across a border. Suggestions are included to support identifying the validity of a prescription as it crosses borders and how these challenges might be addressed.

Other important issues that affect both use cases are those related to patient identification and patient consent[2] and management of data originated in another country and how to include the data into the systems whilst being compliant with the relevant legislation.

The functional requirements identified to fulfil the use cases:

- assure the security of the service, like identification, authentication or patient consent
- ensure access the information from/to another country
- support the right interpretation of the information (semantics, right identification of the medicine…)
- define the minimum information needed to fulfil all steps of the service (prescribe, dispense and inform on the dispense)
- make transparent a country's processes (including legislation) to the other countries

In addition to the functional requirements, non functional requirements have been identified as they are needed to fulfil the functional ones and are directly related to the HCP experience and to the security of the process (from the functional point of view).

Regarding the different sets of information needed for the services to be exchanged, the whole ePrescription service has been analyzed from the country where the information is generated to the country that receives that information and semantically processes it. The datasets described in the deliverable reflect the information in the country where it is needed and after the semantic processing.

[2] Both topics will be solved in WP3.6 'Identity management'

A classification of the different datasets of information identified has been developed based on their degree of relevance in the process:

- Minimum or essential data items for the dispenser to dispense, those that are considered essential from the pharmaceutical point of view to identify the medicine, those that must be present in a prescription by law and those needed to update the relevant prescription once the medicine has been dispensed.
- Maximum or additional data items such that, even if not received, the dispenser can still safely dispense regardless of this information or once the medicine has been dispensed, the related prescription can be identified and updated. If a country has that information, it can make it available to another country to use that information in the process (the fields exist and make sense in that other country)

As recommendations for the other WPs, apart from those derived from the functional requirements that affect other WPs like Semantics, Identification or Security, the main ones are:

- the semantic transformation of the medicine based on the active ingredient and not on brand name,
- the need for contractual agreements to create a secure legal framework but without jeopardising the services, and
- it is essential that during the pilot phase, the exceptions, either functional or technical are clearly reported, analysed and a procedure needs to be put in place in order to evaluate and to solve them (change management). Also the potential patients and all the actors involved in the process need to be informed of the services, their rights and duties.

In summary, although currently most of the identified issues already happen in the common practice when patients travel abroad with paper prescriptions, the epSOS LSP should overcome these barriers by taking advantage of the technologies to improve the services to the cross-border patients. However, action at European level is also needed:

- to prevent current legal restrictions that can seriously jeopardise the ePrescription services and hence the benefits already achieved for the patients in their countries.
- to assure the patient safety avoiding issues like substitution due to the differences between medicines across Europe. Not only a common medicines nomenclature or language is needed but also a common criteria for the semantic description of the different medicine elements maintained and updated at European level.

3 INTRODUCTION

The aim of this document is to identify and describe the service requirements necessary to achieve the general and specific objectives defined in Annex I in relation with the ePrescription service.

This deliverable is not a self-contained document, which means that is part of the work of the epSOS Large Scale Pilot (LSP) project and is based on the outputs of the previous deliverable, D3.1.1 'Draft definition of functional service requirements - ePrescription', WP1.1 ' Analysis and comparison of national plans/solutions', WT5.2.1 'Initial Scope', 'Concepts paper epSOS LSP' and WP2.1 'Analysis and comparison of legal and regulatory issues'.

All concepts used in the document are taken from either trusted sources like EMEA, ISO, European directives…or have been explicitly defined within the WP or within the project.

3.1 Goal of WP 3.1

As stated in Annex I, *"a definition of the functional service requirements for the epSOS System (initial scope) is to be drawn up. The definition is to be based on use cases and to describe system outputs, not processes. Additional requirements and necessary constraints may be incorporated into the specification as appropriate (e.g. data protection requirements). Best practice in NHS Connecting for Health output-oriented specification is to be taken as the starting point. This approach is to be scaled down to ePrescription Services as delimited in the initial scope. - Variants / alternatives are documented in Initial Scope of the previous deliverable (i.e. D3.1.1), submitted for board decision and the decision implemented in this final version (i.e. D3.1.2) of the deliverable".*

This goal must be achieved fulfilling the overarching goal of this project, which 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 services, between European health care systems. As a result, not only a European infrastructure must be created but also all participating country systems will need to be updated to be able to communicate and handle the epSOS LSP services.

4 CONTEXT

The starting point for the work to be performed in this WP, as stated in WP1.1, 'Analysis and comparison of national plans/solutions', is that all countries have major differences regarding the language, the level of deployment of the ePrescription services and the eHealth processes, concepts and legislation. The challenge for this WP is to define a common service, as non intrusive as possible, that provides a safe and minimum added value for the patient, with unified and common understandable concepts and within the current Health and eHealth legislations (European and national). This implies that this WP must have a clear understanding of the concepts, the processes and legislation of all countries participating in the LSP.

4.1 Basic definition of the ePrescription service

The concept of the ePrescription service is understood as the ordering of a prescription in software, the electronic transmission of that prescription from the Prescription provider to a Dispense provider, the electronic dispensing of the medicine and the electronic transmission of the dispensed medicine information from the dispenser provider to the prescription provider.

The ePrescription service is made up of **electronic prescribing** and **electronic dispensing**:

- ePrescribing is defined as prescribing of medicines in software by a health care professional legally authorized to do so, for dispensing once it has been electronically transmitted, at the pharmacy.
- eDispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medicine(s).

For the purposes of this document, prescribing and dispensing are referred to electronic prescribing and dispensing or ePrescribing and eDispensing.

4.2 Antecedents and scope

In this section, a definition of the antecedents and the real scope of WP3.1 within the epSOS LSP project is given, specifying both inputs and outputs. The boundaries between this deliverable and other deliverables in the project are also specified (e.g. only information

necessary for ePrescription is identified, no data modelling). Requirements and assumptions, on which the analysis of this document will be based, are also stated.

The proposals described in this section have as their main antecedents the use cases defined in the Initial Scope elaborated in the WT5.2.1 ‘Initial Scope’, the recommendations made by WP1.1 ‘Analysis and comparison of national plans/solutions’, the legal and regulatory requirements and constraints identified in WP2.1 ‘Analysis and comparison of legal and regulatory issues’, the ‘Concept paper epSOS LSP’ and the previous deliverable of this WP, D3.1.1 ‘Draft definition of functional service requirements - ePrescription’.

It is important to consider both the theoretical and practical experience of the distinct regions and countries for the ePrescription service development and implementation to be able to identify the best practices. However, this document does not analyse the individual processes of each region to prescribe and dispense, such as clinical decision support, registry in EHRs, rules of each region or legislation, authentication of health professionals…

The functional requirements necessary to be fulfilled by the Use Cases and the datasets (structure and fields) that are going to be exchanged in the cross border scenario (information related to the ePrescription service) within the epSOS LSP are identified. An agreement on the minimum datasets to be exchanged (those necessary to fulfil the WP3.1 goal and the functional requirements and Use Cases defined) has been reached. Maximum datasets have also been defined, meaning those datasets that are not essential to fulfil WP3.1 goal but they give additional information.

The prescriptions considered for the epSOS LSP are medicinal products intended for human use, elaborated from an industrial process, prescribed for out-patients (not to be dispensed in the Hospital), and dispensed in Community Pharmacies. These medicinal products must be produced by a registered pharmaceutical manufacturer and hold a current 'marketing authorisation' (licence).

The following scenarios or functionalities (including types of medicinal products) are out of the scope of the functional description:

- Sealed prescriptions (or information): The decision of a patient to hide information (e.g. prescriptions or diagnosis related to HIV) is part of each country’s process. This document will not cover or solve the scenario where the patient goes to country B and decides to authorise the HCP in that country to consult the hidden information.

- Precautionary cancellation: the dispenser might decide he is unable to safely dispense a medicine and cancel the prescription temporarily until the prescriber revises the prescription. As this is a process not implemented in every country, it is out of the scope.
- Pharmaceutical care: It can not be assured that for the epSOS LSP all the information needed for correct or proper Pharmaceutical care will be available. It is assumed that medication surveillance, as part of the pharmaceutical care, will be covered by other processes in the country where health care within the context of epSOS LSP is given. Anyway, it is recommended that the current prescriptions could be accessed by the pharmacist.
- Narcotics: they have specific legislation and are too complicated to deal with at this stage.
- Substitution of active ingredient, strength and/or pharmaceutical dose form: as countries have different legislation regarding this topic and it is a complicated matter to solve for the epSOS LSP, substitution will include the simplest possibilities with the lowest impact for patient safety namely brand name and package size.
- Medicinal products which are prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the 'magistral formula' or extemporaneous preparations) or those prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy (commonly known as the officinal formula or extemporaneous preparations).

Interdependencies between WP3.1 and WP3.2 'Definition of PS Services'.

- The structure of the data contained in the Medication Summary (within the PS), is consistent across both WPs to show coherent information. The definition of this structure is in the scope of WP3.1 (e.g. medicinal product description), but the content is in the scope of WP3.2 where WP3.1 recommend a minimum content.
- The Prescriber is a role covered in the HCP described in WP3.2 'Definition of Patient Summary Services' in order to access to the PS. Thus, the access of the prescriber to the PS is covered in the description of the Use Cases of WP3.2 'Definition of Patient Summary Services'.

Interdependencies between WP3.1 and WP3.3 'System Architecture'

- Data modelling must be done in WP3.3 but the functional definitions and the human understandable description of the data model must be made in WP3.1.

Interdependencies between WP3.1 and WP3.5 ‘Semantic Services’

- In this deliverable, the fields that the Prescription and Dispensed medicine datasets must contain will be defined as well as the definitions or meanings of these fields but not the possible contents (e.g. the field ‘substance’ will be described but the different value sets or library as amoxicillin, acetylcysteine…will not be identified).
- If in WP3.1 an international standard coding system is identified and agreed on, it will be recommended to WP3.5.

5 DESCRIPTION OF THE USE CASES AND REQUIREMENTS IDENTIFICATION

5.1 Description of the ePrescription service

The purpose of this section is to describe the overall procedure of the ePrescription service in the epSOS LSP scenario at a high level, describing key concepts and identifying the actors (both human and technical) and their functional relationship. The description is based on the information from WP1.1 ‘Analysis and comparison of nation plan/solutions’ and from the work carried out in parallel within WP3.2 ‘Definition of PS Services’ and the scope of use cases defined in WT5.2.1 ‘Initial Scope’.

5.1.1 Key concepts

In order to describe the service some key concepts, that are different for the countries, need to be explained:

- Prescription Item

A prescription can contain a single item or medicine (e.g. Spain), or several items or medicines (e.g. Italy). In the case of several items, they refer to different medicines and they can be dispensed separately.

E.g. a patient with strong muscle pain is prescribed non-steroids anti-inflammatory and a stomach protector.

Spain	Italy
• Prescription 1: Ibuprofen… • Prescription 2: Omeprazol…	Prescription 1: • Item 1: Ibuprofen… • Item 2: Omeprazol…

- Time Valid Prescription

It is the time during which the prescription can be dispensed (see Terminology in section 11).

E.g. In Andalusia the time validity means that the patient can withdraw the medicine from the pharmacy until the date of the end of treatment while in other countries, like the UK, the patient can withdraw the medicine up to a maximum number of days from the date of issue, e.g. 6 months.

- ‘Available’ prescription

It is the one that the patient can withdraw from the pharmacy at that specific moment (see Terminology in section 11).

E.g. In Andalusia, you can write a prescription for 1 year treatment (that would mean a lot of boxes of the same medicine) but the law does not allow that it be collected in one go, but 1 by 1 (except some specific medicines). In order to do this, the dispense provider controls the specific slots of times (that are also regulated by law) where the boxes can be collected, i.e. it calculates the 'available' prescriptions. In Sweden, on the contrary, the patient can collect a number of boxes (up to 3 months according to the posology) in one go. So this means that if the patient were going to the pharmacy the day after the prescription was made, in Spain the 'available' prescriptions would be 1 and in Sweden, x number of boxes up to 3 months.

- Current prescriptions

For the epSOS LSP it has been defined as *all medicines that the prescriber has prescribed and patient is supposed to be taking at that moment* (see Terminology in section 11).

- Prescription dataset

It is the data (elements) that the dispenser will receive in the epSOS LSP in order to dispense.

- Dispensed medicine dataset

It is the data (elements) that the country that ordered the prescription will receive when the medicine related to that prescription has been dispensed.

- Medicinal product, brand name, generic and active ingredient

Medicinal product description			
Active ingredient or Brand Name	Strength (dose/unit)	Package	Pharmaceutical dose form
Active ingredient: Paracetamol	500 mg	30	capsules
Brand name: Efferalgan	500 mg	30	capsules
Generic name: Paracetamol Tesco	500 mg	30	capsules

5.1.2 Use cases identification

Generally speaking, the ePrescription service in the epSOS LSP scenario consists of a series of steps that leads to the dispensing of medicine(s) to a patient in a cross border

environment. In order to achieve this objective, a series of requisites and steps that are described in the next sections, have to be fulfilled.

In order to identify the uses cases, an analysis of the different possibilities have been made. The following table shows all possible use cases depending on the different roles of the MS and their expected frequency.

The roles that a country can play in the ePrescription service are:

1. Country that is the home-country of the patient. Here, patient identification can be verified, and the country ID, together with the patient ID and any other data defined in WP 3.6, uniquely identifies the patient in the epSOS LSP. This is known as country A.
2. Country where a prescriber issues or writes a prescription.
3. Country where a dispenser dispenses the medicine(s).

These roles can be spread over one to three countries in the following 5 scenarios or use cases:

UC	Home	Prescribing	Dispensing	Comment
0	A	A	A	Regular situation, no special epSOS actions upfront
1	A	A	B	“Medication already prescribed in country A” use case
2	A	B	B	“Medication newly prescribed in country B” use case
3	A	B	A	Medication prescribed in country B and dispensed in home country
4	A	B	C	Two foreign countries involved

- Use case 0 is the regular situation, where everything occurs in the home country. It is not an interoperability scenario.
- Use case 1 is the most common scenario in interoperability between ePrescription services, where the patient has been already prescribed in his home country. The different possibilities will be analysed in detail along this document.
- Use case 2: Prescription is written in country B and dispensed in country B.
  This scenario is, although not a pure interoperability case of the ePrescription service (as defined in this deliverable), is very common and is similar to use case 0 but identification of patient and patient consent are handled in a different way. Besides, information from country A might be accessible to help the different HCPs to provide the right care (to prescribe and dispense) and information about the events in country B could be sent to

country A. This use case has also been described in Annex I of this document but as an experimental use case[3], not to be implemented in this phase of the epSOS LSP.

- Use case 3 is the same as use case 1 where the roles of countries are changed (except for the role of Home country). For this reason, use case 3 will not be analysed in this document as it is almost redundant.
- Use case 4 represents an unlikely situation. The chances of a patient being prescribed in country B and dispensed in another country are low as we assume that the care attention in country B is up to the time the patient is in country B. For this reason, the use cases are limited to interoperability between just 2 countries, A and B.

In conclusion, the scenario within the scope of this document is use case 1, a patient from country A with a prescription issued in country A and dispensed in country B, as it is the most common interoperability scenario between ePrescription services, where:

Country A: This is the country where the patient can be univocally identified and his data may be accessed.

Country B: This is the country the patient is visiting and in which information about this patient is needed in case the patient needs health care.

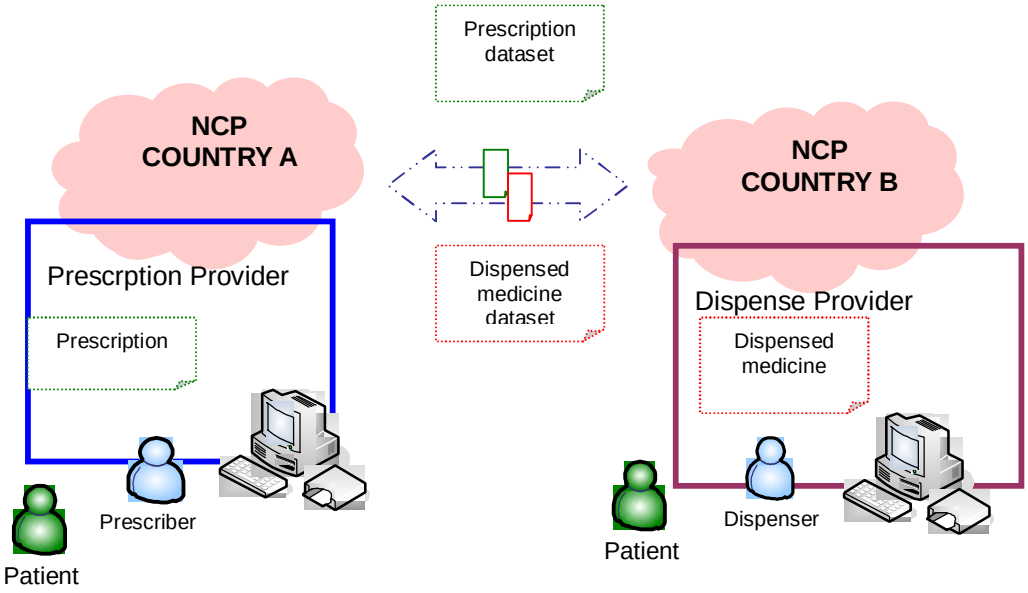


Figure 1. Use case 1 of ePrescription Service

[3] The scope of the services has been reduced and use case 2 has been described to be implemented in a future expansion of the epSOS LSP. At this stage, two countries have expressed their willingness to pilot it as an experimental use case and, as a result, its description may be modified in a second phase of the epSOS LSP.

5.1.3 Summary actors description

This section is a summary of the responsibilities and actions that are needed per actor (technical and human) involved in the ePrescription service. Basically, these actors may be categorized as (please refer to Figure 1 above):

Human actors (individuals):

- Patient: individual for whom the HCP decides to prescribe a medicine or who requires dispensing of medicine(s) prescribed in a country participating in the epSOS LSP.
- Prescriber: legally authorised health care professional who orders medicine(s) to be dispensed to the patient, by means of his/her prescription provider.
- Dispenser: legally authorised health care professional who dispenses medicine(s) to the patient fulfilling a prescription ordered by a prescriber.

System actors (information system or provider such as those used to prescribe, dispense, process or convey information across borders):

- Prescription provider: information provider used by the prescriber to identify himself and to order prescriptions. This system (not physical but logical) also handles and processes all the information about the Patient Summary, medication summary and other health information. This actor is a concept of a system that contains all health information and is not intended to match with any physical or technical implementation as in each country these functions may be implemented in a different way.
- Dispense provider: information provider used to identify the dispenser and to retrieve available and not-fulfilled prescriptions and to update information on the medicine(s) dispensed. This system is a logical entity and is not intended to match with any physical implementation.
- National Contact Point or NCP. This logical system deals with the following:
  - Semantics to solve the issues related to translation between different coding systems
  - Identification of patients and identification and authentication of HCPs
  - Conveying information to and from prescription and dispense providers and logical nodes of other countries
  - Deals with the legal aspects related to the own country and to interoperate in the epSOS LSP

  This actor is responsible for assuring security, reliability and availability of information, complying with national and international regulation and law. All the information needed for the use cases is made exchangeable by means of the National Contact Points in the countries.

The following table outlines the direct interaction between human actors and technical actors in the ePrescription service:

Table 1 Human and technical relationship

System actor	Human actor
Prescription provider	Prescriber
Dispense provider	Dispenser
NCP	NA

5.2 Description of the Use case and the requirements

The objective of this section is to describe the use case and the requirements that will need to be fulfilled to ensure a secure interoperable scenario. This includes required knowledge (not just data) and requirements about how to access and get information.

5.2.1 Use case 1: Medicine already prescribed in country A

5.2.1.1 Sequence diagram of use case

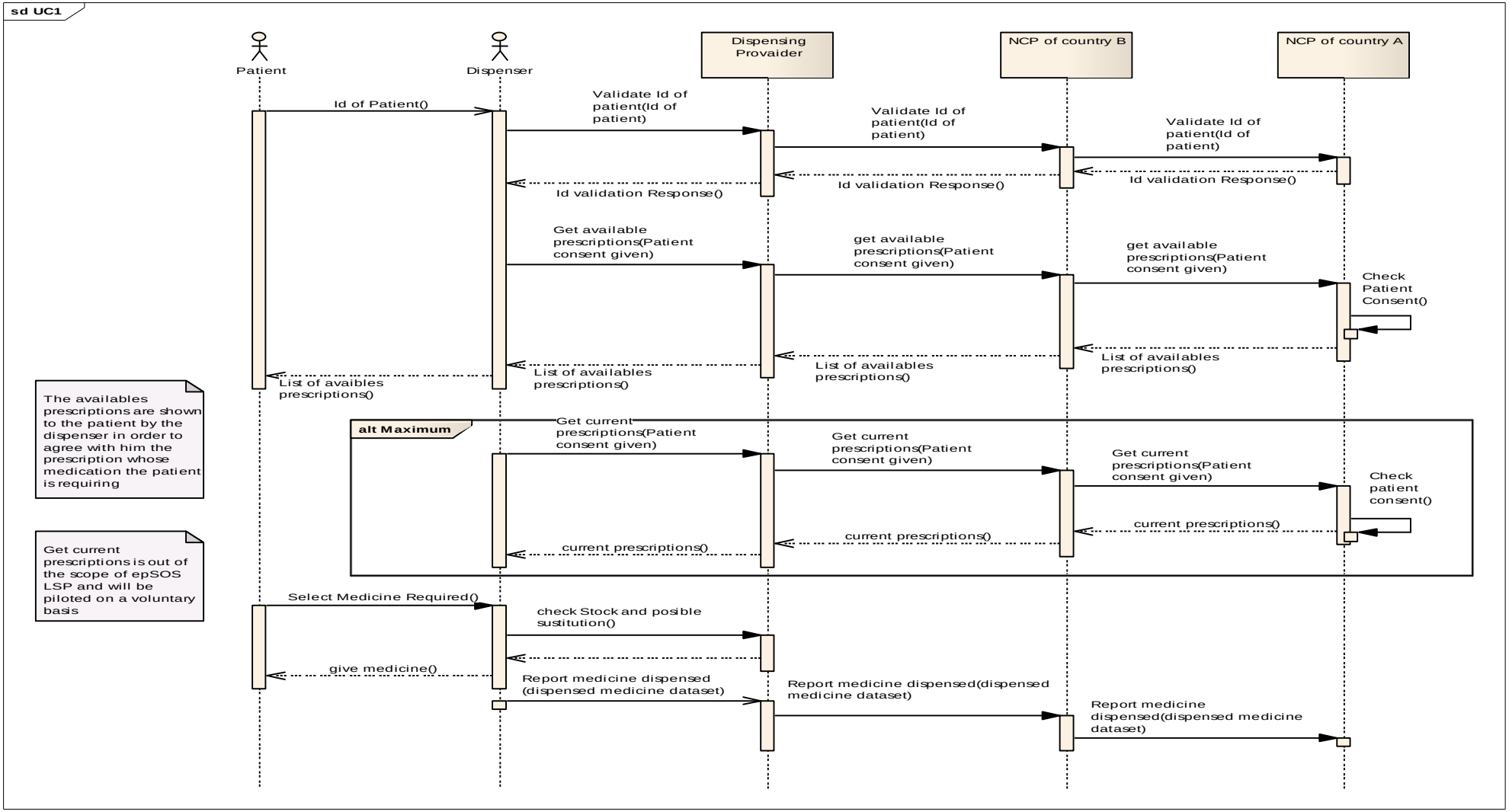


Figure 2. Sequence diagram use case 1

5.2.1.2 Description of use case

This use case describes the dispensing of medicine(s) in country B when the medicine(s) has been prescribed in a different country (country A), where the patient has a valid identification in terms of health care. Country A in this case is also the country where the patient can be univocally identified.

In order for the use case to take place, several preconditions are needed:

- The patient has already been electronically prescribed (valid prescription) by a prescriber authorised to prescribe in country A.
- In country B, a mechanism to validate the identity of the patient and to handle patient consent against country A has to be available at the pharmacy and the dispenser is a person legally authorised to dispense medicinal products.
- In order to obtain the needed information in country B, the Prescription Provider in country A must make accessible at least the 'available' prescriptions to be sent or requested by another country. This implies that country A is able to calculate the 'available' prescriptions (it has the necessary information or parameters to select the prescriptions that can be dispensed at that moment).
- Country A must provide, maintain and support a logical country node (NCP) supporting communication of the information identified in this section with country B and vice versa and that there must be a chain of trust between system actors in this process.

If these preconditions are met, the use case can take place and the first thing the patient needs to do is to identify himself to the dispenser. The dispenser has to check if this identification is valid or not through his Dispense provider before accessing any data. In order to avoid legal issues, it is imperative that the patient is univocally identified so that patient identity can be ensured. The appropriate method to achieve this will be specified in the corresponding work package (WP3.6 'Identity Management').

Once the patient has been identified, the HCP can ask for the 'available' prescriptions for that patient. The HCP could also ask to access the current prescriptions. It must be clear to the HCP and the patient what information is going to be asked for and what information is going to be presented to the HCP. Before any information is presented to the HCP, patient consent must be given (the appropriate method will be specified in WP3.6 'Identity Management).

Access to 'available' prescriptions:

In order to select the prescription requested by the patient, the list of 'available' (and thus, valid) prescriptions from country A has to be presented to the dispenser and the patient. These prescriptions are provided by country A according to the rules that apply in its health

system, meaning that only a prescription that can be dispensed in country A at that moment is available for dispensing in country B (this implies that country A is responsible for deciding which prescriptions are available to be dispensed in country B and thus, all prescriptions that pharmacists see in country B can be dispensed to the patient at that moment)[§]. This means that every time the patients go to the pharmacy, the 'available' prescriptions need to be requested again.

The prescription has to be valid and is within the correct time slot defined for collection from the pharmacy for country A (in some countries, mainly with long term treatments, the prescriptions can only be collected from pharmacies within specific date/time slots to help the patient correctly administer the medicine(s)).

If there are no 'available' prescriptions, the HCP will be informed of that.

Access to current prescriptions[**]:

Apart from the 'available' prescriptions, the dispenser in country B could also request, if permitted in country B and patient consent is given, the current prescriptions to consult the information e.g. to check possible interactions or to emergency dispense a medicine already dispensed if in that country is permitted. Depending on country A legislation, the current prescriptions might not be available to be accessed by a pharmacist in country B. If that is so, the pharmacist will be informed that he is not allowed to access such information.

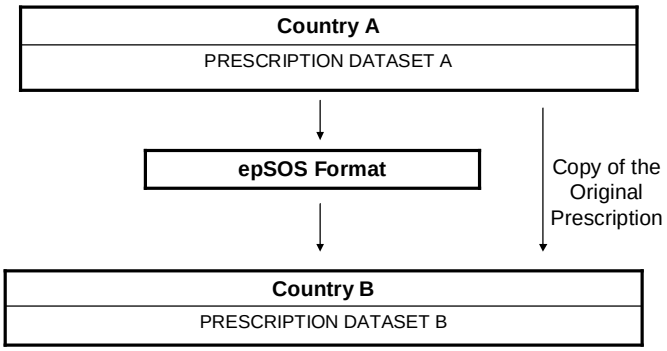
Once the information requested has been sent from country A to country B, to allow the dispenser to understand the information, this must be intelligible to him, i.e. structured, equivalent meaning and understandable (see description in section 5.2.2.1) , presented in his system as decided by country B (in order to ease the process for the HCP, it is recommended that the information is presented as it is normally) and contain all necessary information to identify the right medicine.

As the medicinal products are not the same in the different countries, to guarantee the univocal identification of a medicinal product cross border, the nomenclature to be used for the name must be the active ingredient and not the brand name. The following scenario is assumed on the process of sending the prescription dataset from country A to country B:

[§] At this point, legislation in Country B has not been taken into account yet.

[**] This service has been left out of the scope of epSOS, which means that only the countries that are able and willing to offer the service at this stage, will pilot it.

Data set interoperability



The information that country A is sending to country B will need to identify the active ingredient of the medicinal product. Then, it will be converted to a common epSOS format (to be defined by WP3.5 'Semantic Services') to be sent to country B. Country B will then receive the prescription data set of country A in this common epSOS format. This epSOS format will afterwards need to be translated in the NCP to a single concept in country B (if a single prescription is made in country A, in country B can not be several prescriptions for practical reasons) and then a brand name among all available in country B should be selected[††] (the dataset is defined in section 6.1). The reason is that normally, the same medicinal product does not exist (this document covers substitution of brand name and/or size of package) in both countries and country B will need to translate its single code into a medicinal product that exists in there[‡‡] (brand name (different from the original) + strength + pharmaceutical dose form + package size (that can be different from the original)).

In order to understand the definition of 'single concept' and the process, the following table represents the state chart of the prescription when sent to country B[§§]:

[††] the same applies to items within the prescription. Also, the selection of the brand name is an internal process of every country.

[‡‡] How the translation is done is an internal process and the 'single concept' does not represent a mapping of a Country A prescription in a single medicinal product in Country B using existing Country B data bases. It is just the information to identify medications in Country B corresponding to the medication prescribed in Country A as Country B can directly relate the epSOS format with the different brand names.

[§§] This is an example and does not necessarily match a real medicinal product.

Table 2 Semantic process of the medicinal product

Country A medicinal product	Country A single concept (identifies active ingredient)	epSOS format	Country B single concept	Country B medicinal product
Termalgin 500 mg **30** comprimidos	Paracetamol 500 mg 30 comprimidos	xxx	Paracetamolo 0,5g 30 tablets	Paracetamolo **Tesco** 0,5g **20** tablets

Some issues might arise when translating the medicine from country A to country B. The different possibilities are described:

- In country B the exact same branded medicine does exist, meaning that the exact same following elements are found: active ingredient + brand name + strength + pharmaceutical dose form + package size (according to the minimum dataset defined in section 6). The dispenser then dispenses the medicine.
- In country B the same medicine in generic form does exist, meaning that the exact same following elements are found: active ingredient + strength + pharmaceutical dose form + package size. The dispenser then dispenses the medicine and indicates to the Dispense provider that substitution (of brand name) has taken place[***]. When brand name substitution is of a product with a narrow therapeutic index and/or release, characteristics may be altered by a switch and patient safety considerations must be taken into account as alteration may result in either toxicity or under treatment.
- In country B the medicine does exist but with different package size. The dispenser might then dispense another size of package (either smaller or bigger) according to country B rules or legislation and will indicate to the Dispense provider that substitution (of package size) has taken place[***]. The consequence of changing the package size affects to the use case at different levels:
  - the patient gets less medicine than needed (if the package dispensed is smaller than the original size)
  - if the size of the package dispensed in country B does not exist in country A, this will affect to the update of the prescription (to calculate the new credit or medicine left to be taken).
  - The countries must be able to recognise or translate the original medicine independently of the Package size so it can be changed (if WP3.5 ‘Semantic Services’ decides to codify several fields –group them- in a single code (e.g. active

[***] Substitution has been defined as a data element in the Dispensed medicine dataset

ingredient + strength +…=1234), the package size can not be part of this single code to allow substitution. See section 8.2.4).

- In country B the medicine does not exist, meaning the active ingredient or strength or pharmaceutical dose form is not the same. In this case, the dispensing is not possible as substitution of any of these three elements is out of the scope of the epSOS LSP. The dispenser has to see and be aware that there is an available prescription but that can not be translated into a medicinal product in country B as the active ingredient or the strength or the pharmaceutical dose form is not the same. Some countries 'group' different pharmaceutical dose forms into one, which can be considered for other countries as a 'change' of the dose form. In Andalusia for instance, when a 'gastric-resistant tablet' is prescribed, this is converted to 'tablet' (as 'gastric-resistant tablet' belongs to the 'tablet' group). This grouping is within the scope of epSOS LSP.

In order to help prevent these issues, country B has to receive also the original prescription written in country A (no epSOS semantic transformation). This "copy" of the unchanged original prescription from country A may be used by the pharmacist in country B when accessing the 'available' prescriptions as a manual safety/security check of, for instance, the original brand name or the pharmaceutical dose form. Also a group of experts (clinicians and pharmacists) could be created that control:

- which medicines, regarding their bioavailability characteristics and their therapeutic index and/or release, can be substituted and which not (e.g. antiepileptic, cardiotonic…)
- the level of detail of description of the data elements regarding semantics (e.g. active ingredient or active ingredient + salts). It might happen that for some therapeutic groups only active ingredient is needed and for others is important to have also the salts.
- the possible grouping of pharmaceutical dose forms. As some countries group them and the criteria to group is different as the clinical criteria is also different, it would be advisable to have a common and homogenised understanding of the grouping, e.g. group the pharmaceutical dose forms based on the route of administration so countries can still group following the national criteria.

Special attention will need to be paid during the piloting phase to prevent any possible breach in the safety of the patient.

Once the patient and the dispenser agree on the prescription (in order to do that, both have to understand the information), this one is about to be dispensed. The legal principle is that country A sets the validity when prescribing and country B when dispensing which implies some legal issues that might be faced during the process:

- The first issue that will need to be solved is the country's and European's legislation regarding the legal validity of ePrescriptions (both the local and the foreign versions). If a country A ePrescription is not recognised in country B, there is no use case.
- That the prescription does not contain all necessary fields needed by law in country B. Although this issue has been considered when selecting the minimum dataset of the prescription to be sent to country B, there might be countries that are not able to provide all these fields, resulting on the pharmacist being unable to dispense. The result of this situation will need to be followed and analysed during the piloting phase.
- That substitution is performed in country B when in country A substitution of that specific medicine is not allowed. Country A must be aware of this possibility when signing up the contractual agreements for the pilot operation (e.g., when country B group the pharmaceutical dose form).
- Another important issue is the validity as an order (time valid, prescribed by an authorised person, under country A legal framework, can be dispensed at that moment to the patient –intervals between regular dispenses-…) and the veracity of data of a country A prescription in country B (country A will need to assure this two aspects of the prescriptions before sending them to country B, i.e. calculate the 'available' prescriptions). This means that pharmacists in country B could check:
  - whether the prescription is not time valid for country B. This can have a major impact on long term treatments and chronic patients as for every country the duration of these treatments is different;
  - whether it was made for instance by a nurse, where in country B nurses are not allowed to prescribe. In this case the impact is, so far, low as not in many countries nurses are, right now, allowed to prescribe, but the patient will then need to go to the prescriber to get a new prescription;
  - whether to dispense more than x boxes of the medicine, even if it is indicated in the prescription, as by law they are not permitted to dispense more than x. This will result in the patient having to go back to the pharmacy another time(s) to collect further boxes having a major impact on patients with long term conditions that are going to be present in country B for some time;
  - if the medicine can be dispensed as this medicine, when prescribed in country B, needs a special 'ok' or additional authorization before being dispensed. This will have a major impact on the patient as he will need to go to the prescriber to be prescribed as he needs the medicine;
  - whether to dispense the medicine as brand name or package size substitution is not permitted at the point of dispensing. This has a huge impact on country B as

pharmacists will not be able to dispense any medicine at all (the likelihood of requiring brand name substitution is really high);

- o whether to dispense the medicine as brand name is compulsory and the country A prescription has been made by active ingredient. This situation has a major impact for those patients coming from regions or countries that prescribe by active ingredient (e.g. Andalusia).

As county A is calculating the 'available', which means that country A decides which medicines can be dispensed to the patient (as it has been defined), country B should not question the time validity, the number of boxes to be dispensed or if the medicine needs a special authorisation when prescribed in country B of the prescription. This is already assured by country A when calculating the 'available' as it is the prescriber in country A who has established what the patient needs and when.

The conclusion from the Legal group is that "*country A will do what it does lawfully and country B will do things lawfully as well. Prescriptions that are legal in country A cannot be refused by country B, notwithstanding the right of the pharmacist to withhold dispensing if he can justify concerns about patient safety. So all the instances will need to be treated on a case by case basis".* These instances will need to be analysed during the piloting phase to be able to evaluate the real impact of legislation on the ePrescription service level.

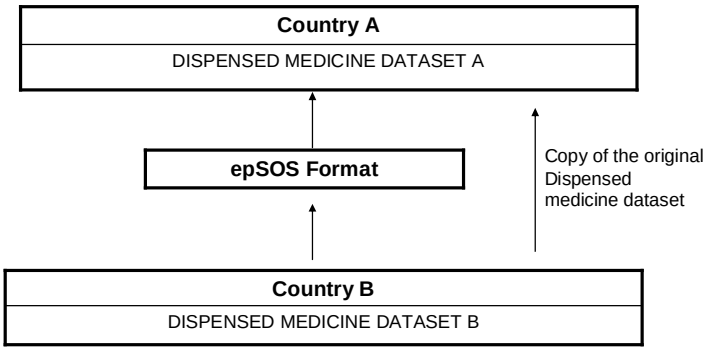
The HCP dispenses the medicine to the patient and must enter the information (defined in section 6.2) into the system to inform country A. The process in country B then ends unless the patient wants to withdraw more medicines or has further requests to the pharmacist that needs to keep the access to the patient's information, i.e. the HCP will not have access anymore to patient information unless identification and patient consent is performed again. Before the patient leaves the pharmacy, the pharmacist should inform, if possible, that the information of the event has been sent to country A. Patient data can be saved in the HCP system if the patient gives consent (consent has to be explicit, freely given and informed) and if country B can assure the proper measures to deal with clinical information according to the Data Protection Legislation. The information about the medicine(s) dispensed should be sent in real time and right after all these medicines of that patient have been dispensed. In order to guarantee the security of the patient, country B must assure that country A has successfully received the information about the medicine(s) dispensed before requesting again the 'available' prescriptions of that patient to country A[†††]..Country A must assure that

[†††] The dispenser can dispense all available prescriptions provided by country A in that request without any confirmation of successful receipt. The next time a dispenser asks for the available prescriptions, they need to have been updated so county B

the ‘available’ prescriptions have been updated with that information before informing country B of the successful receipt.

The information about the medicine dispensed that has been sent to country A must support the identification of the related prescription in country A to allow updating the original prescription and for things like brand name, package size substitution etc.
The following scenario is assumed on the process of sending the dispensed medicine information from country A to country B:

Data set interoperability



The dispensed medicine information will be converted to a common epSOS format (to be defined by WP3.5 ‘Semantic Services’) to be sent to country A. Country A will then receive a dispensed medicine data set of country B in an epSOS format. As in most cases, the same medicinal product does not exist (this document covers different brand name and/or size of package) in both countries, country A will translate the epSOS format into the single concept of the related prescription (the dataset is defined in section 6.2). In consequence, and for security and traceability reasons, also a copy of the original medicinal product dispensed in country B (the dispensed medicine data set B) has to be sent to country A so the real information of what has been dispensed is available in country A. Country A can then decide whether to include this information in its Systems or not but always assuring the proper measures to keep or to deal with clinical information according to its Data Protection Legislation.

has to have previously assured that country A has received the information about the medicine dispensed in the previous request.

The following table represents the state chart of the dispensed medicine when sent to country A:

Table 3 Semantic process of the medicine dispensed information

Country B medicinal product dispensed	**Country B single concept (identifies active ingredient of the medicine dispensed)**	**epSOS format**	**Country A single concept**
Paracetamolo **Tesco 0,**5g **20** tablets	Paracetamolo 0,5g 20 tablets	xxx	Paracetamol 500 mg 20 comprimidos

During the process, the dispenser may identify that he does not have sufficient or all necessary information required to support dispensing or considers for some reason not to dispense due to safety reasons. This has to be communicated to the patient. This situation will need to be stated and analysed during the piloting phase to understand the reasons to not dispense.

5.2.2 Requirements description

In order to fulfil the use case, the following requirements have been identified (in order of sequence):

Table 4 List of Requirements

Functional Requirements	
FR01	HCP Identification and authentication
FR02	Trust between countries
FR03	Patient identification
FR04	Patient consent
FR05	Structured information
FR06	Equivalent information
FR07	Information understandable
FR08	Information selection
FR09	Prescription presentation
FR10	‘Available’ (and thus, valid) prescription
FR11	desirable but not minimum: Access to current prescriptions by dispenser[‡‡‡]
FR12	Original prescription
FR13	Identification of the medicinal product
FR14	Substitution
FR15	Dispensed medicine data sent to country A
FR16	Identification of prescription and medicinal product dispensed
FR17	Original dispensed medicine
FR20	Information Traceability

[‡‡‡] This requirement has been left out of the scope of epSOS and will be piloted on a voluntary basis.

Non Functional Requirements

NFR01 Service availability
NFR02 Communications
NFR03 Response time
NFR04 Confidentiality
NFR05 Access control
NFR06 Audit Trail
NFR07 Integrity
NFR08 Non repudiation
NFR09 Trust between countries
NFR10 Guaranteed delivery
NFR11 Single session
NFR12 Supervision services

The FRs and NFRs with the same numbering in D3.1.2 'Final definition of functional service requirements –ePrescription' and D3.2.2 'Final definition of functional service requirements- Patient Summary' are the same but applied to the specific situations, i.e. information exchanged and actors.

The goal of these requirements have been to assure the security of the service, the accessibility of the information from/to another country, the right interpretation of the information, the information needed to fulfil the service and to make as transparent as possible the countries' processes (including legislation) in the other countries.

5.2.2.1 Functional Requirements

FR01- HCP Identification and authentication

FR01	**HCP Identification and authentication**
Description	The HCP must be univocally identified and authenticated and must be identified based on his/her role/profile.
Associated Goals	• To provide security to the process • To ensure that the HCP is legally allowed to perform the functionalities described in this document
Actors	Dispenser Dispense provider

FR02- Trust between countries

FR02	Trust between countries
Description	All the countries involved in the project are integrated into one system of trust (functional). It is necessary to have an agreed framework for creating trust, by establishing policies for critical data protection, privacy and confidentiality issues as well as mechanisms for their audit.
Associated Goals	• To enable the exchange of information between countries • To avoid having to identify all professionals and institutions from a foreign country in the country of origin. On the one hand, each HCP will be univocally identified and authenticated in his local system and must be identified based on his/her role/profile. On the other hand, Health Care Provider Organisation provides HCP a status, a function, an authentication from which the HCP trust is derived. Furthermore, Health Authorities Institutions assign and assure the status, the function, and sometime the authentication of HCP
Actors	NCPs Prescription provider and Dispense provider Prescriber and Dispenser

FR03- Patient identification

FR03	Patient identification
Description	The patient needs to be univocally identified in a reliable way (unique and unequivocal id) to allow the HCP to consult his information[§§§](after his explicit consent or authorisation). For functional and security purposes in the information usage, the univocally identification of the patient is highly relevant. One-to-one and unmistakable identification of the patient must be assured. Patient authentication will be guaranteed at national level based on the concept of mutual trust. Special attention needs to be paid to people under protection and children as they might not own an identification. The process of identification (positive or negative) must be recorded.
Associated Goals	• To have certainty of the identity of the patient
Actors	Patient Dispenser Dispense provider NCPs

FR 04- Patient consent

[§§§] the necessary datasets for the HCP

FR04	Patient consent
Description	This requirement is subject to Legal aspects defined in WP2.1 'Legal and Regulatory Issues' and the different solutions to handle it are described in WP3.6 'Identity Management'. The patient consent is considered to be the legal basis for lawfully processing their medical data by any IT system. Consent must be given in Country B per request and informed, specific and freely given. It must furthermore enforce the consent by deciding on whether a certain request for data is legitimated by the consent or not (Country A can not disclosure any information until patient consent has been given in Country B). The lifecycle of the consent must be logged in a way that the legitimacy of each request can be reconstructed in retrospect.
Associated Goals	• Manifesting the legal foundation for a lawful data processing • Granting the patient his specific rights according to data protection regulations • Deciding on whether a certain request for data is legitimated by the consent or not
Actors	Patient Dispenser Dispense provider NCPs

FR05- Structured Information

FR05	Structured Information
Description	The information sent to another country must be structured, this is in structured modular data groups (sorted under the correct nesting headlines) each of them containing related items of information with a unified meaning of fields (e.g. field 'active ingredient' is properly identified in country A and translated to country B). The information should be presented in his system as decided by country B (in order to ease the process for the HCP, it is recommended that the information is presented as it is normally done).
Associated Goals	• Safety reason • HCP and patient understand the meaning of all the fields that are going to be shown to them • To provide the HCP with the necessary information to safely dispense to the patient • Guarantee the safety of the patient through a proper understanding of the received information • Ensure safety delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs Dispense provider

There are several possibilities to deal with the unified meanings regarding medicines:

- Each data field of the minimum dataset defined in section 6 is translated into a common terminology or nomenclature.
- A subgroup of the minimum dataset (e.g. active ingredient + strength + pharmaceutical dose form) have a unique coding into the common language (this subgroup is the data that the doctor can not break up as they are defined by the commercialised products).

RF06- Equivalent information

FR06	Equivalent Information
Description	The information sent to another country must be equivalent in the Meaning, i.e. a unified meaning of the information: must be coherent with that system (e.g. the field 'active ingredient' means the same in both countries).
Associated Goals	• Safety reason • HCP and patient understand the meaning of all the fields that are going to be shown to them • To provide the HCP with the necessary information to safely dispense to the patient • Guarantee the safety of the patient through a proper understanding of the received information • Ensure safety delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs Dispense provider

FR07- Information Understandable

FR07	Information Understandable
Description	The information sent to another country must be Understandable (language) by the human actors that will make use of it.
Associated Goals	• Safety reason • HCP and patient understand the meaning of all the fields that are going to be shown to them • To provide the HCP with the necessary information to safely dispense to the patient • Guarantee the safety of the patient through a proper understanding of the received information • Ensure safety delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs Patient Dispenser Dispense provider

FR08 – Information selection

FR08	Information selection
Description	The information regarding the 'available' prescriptions and the current prescriptions must be well identified so the Dispenser knows what sort of information he is going to access or is looking at.
Goals	For safety reasons To ease the process for the dispenser
Actors	Dispenser Dispense provider

FR09- Prescription presentation

FR09	Prescription presentation
Description	The dataset identified as minimum in section 6.1 has to be available to the dispenser to dispense. If there is more than one prescription 'available', the data related to identification of patient, prescriber and prescription will be per prescription 'available'. In the case that the prescription contains several items, there will be a set of patient, prescriber and prescription data per item.
Associated Goals	• To help the dispenser to choose the right data or piece of information. • To reduce time in dispensing
Actors	Dispense provider Dispenser NCPs

FR10- 'Available' (and thus, valid) prescription

FR10	'Available' (and thus, valid) prescription
Description	The dispenser needs to see **at least** the available (and in consequence, valid for country A) prescriptions in country A of the patient, i.e. the prescriptions that can be dispensed at that specific or particular moment. This means that the patient should be able to obtain in country B what he could obtain in country A. This has some implications, already described in section 5.2.1.2, some of which can be solved in the epSOS LSP and some others not. Country A needs to be able to calculate the 'available' prescriptions. In the case of a prescription for long term treatment, this is not only the prescriptions that are time valid, but also those that can be withdrawn at that moment by the patient (that the patient has 3 packages prescribed does not necessarily mean that he can collect all at any day or the same day but at a specific slots of time).
Associated Goals	• For the dispenser to identify which prescription can be dispended for that patient at that moment under country A conditions (country B then will dispense according to his legislation –to be further described) • To avoid problems of country A and B different prescription validity periods
Actors	Dispenser Dispense provider NCPs

FR11- desirable but not minimum: Access to current prescriptions by dispenser

FR11	desirable but not minimum: Access to current prescriptions by dispenser
Description	The Dispenser could consult the current prescriptions for that patient.
Associated Goals	• check possible interactions, pharmaceutical care, 'emergency dispense' (depending on country B legislation)…safety reasons
Actors	Dispenser Dispense provider NCPs

FR12- Original prescription

FR12	Original prescription
Description	The HCP must be able to consult a copy of the original prescription (no epSOS semantic transformation) including at least the medicinal product description and the posology. In most cases, the same medicinal product does not exist (this document covers different brand name and/or size of package) in country A and B, so there will be a translation into the epSOS format.
Associated Goals	• For safety reasons as the brand name of the product is probably going to be changed
Actors	Dispenser Dispense provider NCPs

FR13- Identification of the medicinal product

FR13	Identification of the medicinal product
Description	The dispenser needs to have in the prescription all necessary information (defined in section 6.1) in order to identify the correct product (active ingredient, strength, pharmaceutical dose form…) to be safely dispensed. I.e., the medicinal product description, (e.g. paracetamol 'XXX' 500mg 12 tablets) previously translated as defined in WP3.5 'Semantic Services' and with intelligible information as described in FR05,06 and 07. Regarding the field of 'Advice to the dispenser', as it is available in the language of country A, to avoid legal and ethical issues to the dispenser, it should be wise to implement an option that allows the dispenser to decide, knowing that this data is available, if he wants to consult it.
Associated Goals	• To correctly identify the medicinal product that has to be dispensed • For safety reasons
Actors	Dispenser Dispense provider NCPs

FR14- Substitution

FR14	Substitution
Description	The dispenser will need to know if in the translation from the medicine in country A to a medicine in country B (semantic) the brand name or the package size has been modified from the original one. As the processes in each country are not in the scope of the document, it might be that the dispenser himself is the one who substitutes the medicines or it is a transparent process for him. The dispensed medicine information (dataset identified in section 6.2) should also indicate if the medicine has been substituted. The issues regarding the substitution of the medicinal product are described in section 5.2.1.2)
Associated Goals	• Security reasons • Safety reasons
Actors	Dispenser Dispense provider NCPs

FR15- Dispensed medicine information sent to country A

FR15	Dispensed medicine information sent to country A
Description	The information (minimum and maximum datasets described in section 6.2) about the dispensed medicine event must be sent to country A. If there is more than one medicine dispensed, the fields related to identification of patient, dispenser and the dispensed medicine data sets will be per medicine dispensed. In the case that the prescription contained several items, there will be a set of patient, dispenser and dispensed medicine data per item. It is a task of country B to assure the successful delivery of the dispensed medicine information to country A before country B request again the 'available' prescriptions for the same patient. This should be done in real time and right after the medicines have been dispensed . Country A must assure, before answering country B of the successful receipt of the medicine dispensed information, that the 'available' prescriptions have been updated with that information.
Associated Goals	• The prescription provider of country A must be informed about the dispensed medicine • Security reasons
Actors	Dispenser Dispense provider NCPs

FR16- Identification of original prescription and medicinal product dispensed

FR16	Identification of original prescription and medicinal product dispensed
Description	The dispensed medicine dataset must contain the necessary information to allow identification of the prescription that has been dispensed (link between dispensed medicine and prescription).
Associated Goals	• To update the status of the prescription • To link the dispensed information to the prescription
Actors	Prescription provider and Dispense provider NCPs

FR17- Original dispensed medicine

FR17	Original dispensed medicine
Description	Country A will also need to know the original dispensed medicine in country B (but not translated to a equivalent one in country A) and the one in the epSOS semantic format to verify the active ingredient dispensed (as in most cases, the same medicinal product does not exist).
Associated Goals	• For safety and security reasons as the brand name of the product is probably going to be changed. If the patient withdraws a different medicine and when taking it, he has adverse reaction, the country A HCP will be able to diagnose based on the information on what it was originally prescribed and what the patient has actually taken • Traceability reasons
Actors	Dispense provider NCPs

FR20 – Information Traceability

FR20	Information Traceability
Description	The information describing the process and the data involved in the process must be retrievable. This includes information such as the prescriber, the exact place and time where the prescription was made, the identification of the Pharmacy where the medicine was dispensed, the dispenser that dispensed, if there was substitution, the original prescription, the translation of the prescription from country A to country B, the epSOS format…Specifically, all information that has been considered as minimum and maximum in the prescription and dispensed medicine datasets. Some of this information is not necessarily contained in the datasets exchanged between countries (as they have been considered maximum datasets) but must be able to be traced and recovered.
Associated Goals	• Security reasons • Legal reasons
Actors	Prescriber and Dispenser Prescription provider and Dispense provider NCPs

5.2.2.2 Non Functional Requirements

The non functional requirements are the same as the ones identified in WP3.2 'Definition of PS Services'.

NFR01- Service availability

NFR01	Service availability
Description	Availability is the property of being accessible and usable upon demand by an authorised entity (ISO 7498-2:1989). There are different causes for technical unavailability (of communications, NCPs, local systems…) of the epSOS service as o failure o unplanned stop (bug, random error) o partial planned stop (non optimal running) o planned stop (maintenance, update) Each unpredictable service interruption will be detected as soon as possible. The origin of the failure (HCP system, NCP system...) will be explained. It will be declared which systems or types of information that cannot be reached at the present time due to circumstances or technical failures. The procedure to follow will be specified in order to come back to a normal mode. Instead of completely unavailability, the service can be degraded. This state needs to be defined and when this happens, the suitable alerts and the procedures to follow will need to be defined..
Associated Goals	The epSOS service will be continuously available

NFR02- Communications

NFR02	Communications
Description	Information has to travel from one country to another. The epSOS service requires secure communications between different local systems, situated in several countries. The information exchange between countries must be protected from random errors as well as snooping or hacking attacks. This means: • That the parties participating to the communication must be properly identified in both countries • The information exchanged must be protected • The integrity of all information exchanged during the performance of any of the use cases must be guaranteed • The session and the information exchanged must be associated with secured data allowing afterward verification
Associated Goals	To have secure communication means between National Contact Points

NFR03- Response time

NFR03	Response time
Description	As the information has to travel from one country to another it has to be accessible and available with reasonable response times. Of course, all the countries are integrated on one system of trust. The response time could vary depending on the chosen architecture; that is, whether it is centralized or distributed and whether there are multiple sources of information or just one. An acceptable response time not only applies to the receipt of the information, but also to the identification and authentication of HCP and patient. Shall be deemed an acceptable response time to load information of less than 10 seconds[****].
Associated Goals	• Information has to travel from one country to another. An acceptable time response not only applies to the receipt of information, but also to the identification and authentication of HCP and patient • The system should provide an acceptable end-to-end response time, not degrading or delaying the already existing services because the patient is waiting while the system accesses and shows the required information • The access times should be tested continually by the system to give the user some idea of what to expect

NFR04- Confidentiality

NFR04	Confidentiality
Description	Whenever identifiable medical data is communicated, stored, or processed, the confidentiality of the data must be enforced and safeguarded by the epSOS LSP services (by all actors involved). All communication of identifiable data between the epSOS LSP partners must be performed in a way that prohibits any unwanted disclosure of medical data to any third party. Furthermore, the epSOS LSP services must enforce that any data access is only possible over safeguarded, well-defined interfaces. An unwanted or unlawful disclosure to an unauthorised party must also be prohibited at all times.
Associated Goals	• Manifesting the legal foundation for a lawful data processing • Protecting and safe-guarding the patients medical information • Ensuring the involved HCP to be fully compliant with their professional code

NFR05- Access control

[****] The feasibility of this will depend on the technical group. Also, 10 seconds is not a service level agreement but a proposal of threshold

NFR05	Access control
Description	Each system (NCPs, prescription and dispense providers) must assure that only authorized persons and systems are able to access protected data. As authorisations may involve the existence of a treatment context inside a HCPO, these treatment relationships must be justificable on demand. The communication partners (origin, destination, and potential facilitators) need to be known to each other with prior positive verification that all involved partners are authentic (security features to be provided by the means of an identity (subjects, actors, objects) and access management).
Associated Goals	• For traceability reasons • For security reasons • To assure confidentiality • For Confidentiality and integrity of medical data reasons • To align to the European Data Protection Regulations

NFR06- Audit Trail

NFR06	Audit Trail
Description	Any data access or attempt to access medical data through the epSOS LSP services, must be fully transparent and traceable and reproducible e.g. by logging of “who” accessed “which” medical data from “where” at “what” time under “whose” authority. When all audit data is available, a supervision authority must be able to fully recover and reconstruct an access attempt and access path in order to verify its regulatory compliance. The collected data must be available and suitable for scheduled and unscheduled security audits. Extraordinary and/or emergency accesses must be specially marked in order to facilitate the local management of those. All data gathered by the audit services may contain identifiable personal data and must be protected accordingly. Furthermore, since the audit trail may be considered as evidence/proof in potential investigations, all protocols must be fully safeguarded in integrity and confidentiality. Access to the audit trail must be restricted and only be granted to authorised persons with concrete access necessities within epSOS LSP. The audit services of the epSOS LSP services should collect a pre-defined set of operational data in order to provide an adequate quality- and capacity-assessment. These protocols must only be used for continuous service delivery and/or service improvement and must not leave the epSOS LSP context.
Associated Goals	• Enabling a transparent and ‘able to be reconstructed’ system operation • Documenting compliance and legitimacy of data accesses • Making the epSOS LSP services auditable

NFR07- Integrity

NFR07	Integrity
Description	The integrity of the transmitted information must be guaranteed. This requirement guarantees that all transmitted data for a patient arrives at the assessing HCP in country B without any alteration from the NCP in country A. It must be identified that the transmitted data has not been damaged, reduced or altered. Any loss of integrity of the transmitted data must be recognizable by the recipient.
Goals	For safety reasons

NFR08- Non-repudiation

NFR08	Non-repudiation
Description	The issuer of the transmitted information must be held accountable for this. This requirement guarantees that medical data from a patient at the assessing HCP in country B is supported by the necessary assurance about the issuer of the information. It must remove the possibility that the issuer of information denies that the sending has taken place covering also the content.
Goals	To guarantee that the issuer of the information agreed in this deliverable to be exchanged cannot refuse that the issuance has taken place

NFR09- Trust between countries

NFR09	Trust between countries
Description	All the countries involved in the project are integrated into one system of trust (technical). It is necessary to have an agreed framework for creating trust, by establishing 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
Associated Goals	• To enable the exchange of information between countries • To avoid having to identify all professionals and institutions from a foreign country in the country of origin. On the one hand, each HCP will be univocally identified and authenticated in his local system and must be identified based on his/her role/profile. On the other hand, Health Care Provider Organisation provides HCP a status, a function, an authentication from which the HCP trust is derived. Furthermore, Health Authorities Institutions assign and assure the status, the function, and sometime the authentication of HCP

NFR10 – Guaranteed delivery

NFR10	Guaranteed delivery
Description	When information is sent from one country to another, it must be assured that the information has been properly received by the user in the receiver country
Goals	• For security reasons • To check that the ePrescription service has been properly completed

NFR11 – Single session

NFR11	Single session
Description	In order to avoid fraud, only one session can be opened for the patient at a time.
Goals	• For security reasons • To avoid a patient withdrawing the same medicine at the exact time from different pharmacies

NFR12- Supervision services

NFR12	Supervision services
Description	A service must be put in place to detect all the technical exceptions and to check and monitor the performance of the service (time response, communications…). This requirement will be further described by the technical WPs.
Goals	• To assure the availability and to avoid degradation of the service

5.2.3 Relationship between the use case and requirements

- Use case 1: 'Medicine already prescribed in country A'

Four major actions are identified for the description of the Use case:

UC 1 Action list
A: Check Patient ID
B: Get Available Prescription List
C: Dispense Medicine
D: Send information about the dispensed medicine to country A

Table 5 Use Case 1 description

UC 1	**Medicine already prescribed in country A**	
Goals	The goal of this use case is to allow a patient to retrieve medicine in country B that has been prescribed in country A	
Functional Requirements to be fulfilled by country A	FR02, Trust between countries FR03, Patient identification FR04, Patient consent FR05, Structured information FR06, Equivalent information FR20, Information traceability	
Functional Requirements to be fulfilled by country B	FR01, HCP Identification FR02, Trust between countries FR03, Patient identification FR04, Patient consent FR05, Structured information FR06, Equivalent information FR07, Information understandable FR08, Information selection FR09, Prescription presentation FR10 'Available' prescription FR11, Desirable but not minimum: Access to current prescriptions by the dispenser FR12, Original prescription FR13, Identification of medicine FR14, Substitution FR15, Dispensed medicine information sent to country A FR16, Original dispensed medicine FR17, Identification of prescription and medicinal product dispensed FR20, Information traceability	
Actors	**Human actors**	**Technical actors**

	• Patient • Dispenser	• Dispense provider • Logical node country A • Logical node country B
Pre conditions or requirements	• The patient has been already electronically prescribed by an authorised prescriber in country A • A mechanism to validate the identity of the patient at the Pharmacy against country A and to handle the patient consent has to be available (FR03, FR04) • The dispenser is a person legally authorised in country B to dispense medicinal products and is identified and authenticated in his/her dispense provider (FR01) • Country A must be able to calculate the 'available' prescriptions (FR10) • Country A must be able to make accessible at least the available prescriptions (and current prescriptions if applies) to be sent or requested by another country (FR09 and FR11) • Country A must provide, maintain and support a logical country node (NCP) supporting communication of the prescriptions and dispensed medicines datasets (identified in section 6) with country B and vice versa (FR20) • Dispense Provider must be able to obtain or get prescriptions and to send the dispensed medicine information from/to country A (FR09, FR10, FR12, FR15, FR16) • There is a chain of trust between system actors in this process (FR02) • All technical actors involved in the process must be able to retrieve all the information describing the process and the data involved in it. This includes information such as the identification of the dispenser, the Pharmacy where the medicine was dispensed, the dispenser that dispensed, if there was substitution, the original prescription, the translation of the prescription from country A to country B, the epSOS semantic format…Some of this information is not necessarily contained in the datasets exchanged between countries but must be able to be traced and recovered (FR20)	
Post conditions	• The patient has been dispensed the medicine needed and previously prescribed in country A • The (copies of) the dispensed medicine information (original in country B and the one codified into the epSOS format) linked to the prescription is sent to country A, where it is decided whether to include this information on its Systems or not, but always assuring the proper measures to keep or to deal with clinical information according to the data protection legislation in country A	

Normal sequence

Step[††††]	**Actions (or description)**	
	A: Check Patient ID[‡‡‡‡]	FRs fulfilled: FR 03
1.	A patient from country A visits a pharmacy in country B to get the medicine(s) already prescribed in country A by an authorised prescriber.	
2.	The patient identifies himself.	
3.	The dispenser requests the validation of the identity of the patient through the dispense provider.	
4.	The dispense provider conveys this request to the NCP of country B.	

[††††] The steps described do not intend to describe any technical solution. This is just a functional description
[‡‡‡‡] This step is similar to WP3.2

5.	The NCP of country B conveys this request to the NCP of country A.	
6.	The NCP of country A gets and provides to the NCP of country B the (positive or negative) patient's identification confirmation.	
7.	The NCP of country B provides the patient's identity confirmation to the dispense provider.	
	B: Get 'Available' Prescription	FRs fulfilled: FR 05, 06, 07, 08, 09, 10, 11, 12, 13
8.	Once the identity of the patient is validated, the dispenser requests, with the consent of the patient (FR04), **at least** the list of 'Available' prescriptions that can be dispensed by means of the dispense provider (he could also request, on a second step and with a specific patient consent, the current prescriptions if both countries have decided to pilot this service on a voluntary basis as this is out of epSOS LSP).	
9.	The dispense provider requests the list of 'available' prescriptions to the NCP of country B.	
10.	The NCP of country B requests the list of 'available' prescriptions to the NCP of country A.	
11.	The NCP of country A, after checking if patient consent has been provided, gets and provides to the NCP of country B the list of 'available' prescriptions on the epSOS format and also the copies of the original prescriptions. The information expected is an agreed subset of the complete content of each prescription.	
12.	The NCP of country B conveys the list of available prescriptions to the dispense provider (once they have been transformed from the epSOS format to the country B format based on a single concept[§§§§]). At this stage the prescription must be understandable in the country B's official language, the content of the prescription has to comply with the usual practice in country B (format and content, including coding mechanisms and displaying of information) and must contain at least the minimum (could be the maximum) dataset described in section 6.1. Also, the dispenser must get the original prescription.	
	C: Dispense Medicine	FRs fulfilled: FR 12, 14
13.	Once the list of 'available' prescriptions is available in the dispense provider, the dispenser agrees with the patient the prescription related to the medicine the patient is requiring. Provided there is no 'available' prescription, the use case is terminated[*****]. The original prescription must be also provided.	
14.	Then the dispenser selects the medicine to be dispensed. This activity (in the epSOS LSP scenario) includes the following: Agreement on the medicine with the patient • If the exact medicine does exist, meaning by that the same active ingredient + strength + pharmaceutical dose form + package size (according to the minimum dataset defined in section 6), the dispenser checks availability of the medicine to be dispensed (stock). • If the medicine does exist but with different package size, the dispenser checks availability of the medicine to be dispensed (stock) and selects a substitute medicine -another size (smaller or bigger)- according to country B rules.	
	D: Send dispensed medicine information to country A	FRs fulfilled: FR 15, 16, 17
15.	Once the medicine is dispensed to the patient, the dispenser reports the information (described in section 6.2) on this dispensing event through the dispense provider and the dispense provider must inform of the successful record.	
16.	The dispense provider provides the dispensed medicine information to the NCP of country B.	
17.	The NCP of country B conveys this information to the NCP of country A (the epSOS format and a copy of the original medicine dispensed).	

[§§§§] See description on section 5.2.1.2

[*****] if the dispenser could see the current prescriptions, even with no 'available' prescriptions, he could decide to dispense –if allowed- on a fulfilled prescription).

18.	The NCP in country A informs NCP of country B of the success.
19.	The use case is terminated. No more access to patient data from country A is possible.
Exceptions[††††††]	
The identity of the patient cannot be properly validated in country A	
6	The NCP of country A informs the NCP of country B of the identification failure.
7	The NCP of country B informs the dispense provider of the identification failure.
8	The dispenser informs of this failure to the patient. The validation of the identification might be requested again (number of attempts to be defined by WP3.7) and if not possible the use case is terminated. Should the validation be successful, the use case is resumed at step 6.
Denial of patient consent	
8	If patient consent is not given by the patient or it can not be recorded in country B, the use case is terminated.
Patient consent can not be checked	
11	If country A can not check that patient consent has been given, a notification is sent to country B (and the list of available prescriptions is not provided).
The medicinal product does not exist in country B	
14	If there is no medicinal product in country B with the same active ingredient + strength + pharmaceutical dose form, the dispenser has to see that there is an available prescription to be dispensed (original prescription translated to country B single code) and should be aware that there is no translation to a medicine in country B.
The prescription is not safe to dispense at the point of care (pharmacy) (the dispenser does not have the necessary information to identify the medicine or to dispense it).	
14	The dispenser informs of this issue to the patient and the use case is terminated.
The communication is breached somewhere during the process	
	The dispenser needs to be informed of the issue and its probable cause.
	The dispenser informs of this issue to the patient. The process can be repeated again as many times (to the HCP discretion) and if not possible , the dispenser informs of this issue to the patient.
The pharmacist is not able to report the medicine dispensed to the dispense provider	
15	The pharmacist must try to report the dispensed medicine as his discretion. If not possible, he has to report this issue to the Assistance service[‡‡‡‡‡].
The communication is breached at step D	
	The dispense provider or the NCP of country B must assure that the information is sent to country A before requesting again any information of that patient to country A.
Maximums	
8	The current prescriptions to be consulted by the dispenser could also be provided (FR11).

[††††††] The numbers under "Exceptions" refer to the 'steps' numbers in the 'Normal sequence' section of this table
[‡‡‡‡‡] This service is described in section 7

6 COMMON INFORMATION SETS

In order to agree on necessary common datasets to be exchanged in the ePrescription service, a questionnaire was sent to all participating countries. The objective was first to understand the processes, concepts and terms of the different countries and second to find out the data items used (or recommended for the epSOS LSP) in the different Member States for the ePrescription service. Regarding the datasets, it focused on availability of the data items in that Member State and the 'mandatory' attribute of each data item, understanding by mandatory that this data field was required by law or was considered as minimum by that Member State in order to dispense. All the responses provided by Member States were analyzed and a proposal was made regarding the mandatory requirements and the availability of the different data fields (this proposal is called 'WP3.1 Questionnaire Structure eP Results&proposal_v2' and it is an internal –not to be published- working document). The proposal was analyzed and discussed and the results are described in this section.

6.1 Common structure of prescription dataset

The objective of this section is to document what has been agreed regarding the information to be exchanged:

- The definition of items to be shared: Appellation (Long name and short name), definition, and accepted values
- A Minimum and advisable data set

In order to understand the proposed dataset, some elements need to be explained:

Minimum and maximum:

Minimum is the data that have been considered as essential for the dispenser to dispense, considered essential from the pharmaceutical point of view to identify the medicine or legally mandatory (e.g. identification of Prescriber). This information will have to be available to another country within the epSOS LSP.

Maximum is the data that, even if not received by the dispenser, he could still dispense in the normal process of the ePrescription service, i.e. when there is a prescription 'available' to be dispensed. If country A has that information, it can make it available to country B if it uses that information for other purposes like pharmaceutical care[§§§§§] (the fields exist and make sense in that other country).

[§§§§§] Pharmaceutical care is out of the scope of epSOS LSP

To understand the defined dataset, some concepts are summarised below (also please refer to section 5.2.1.2 where the semantic process is explained):

Medicinal product description:

Active ingredient or name of the medicinal product	Strength of the medicinal product (dose/unit)	Medicinal product package	Pharmaceutical dose form
Paracetamol	500 mg	30	capsules
Atropine	5 mg/ml	10ml	Eye drops

The proposed datasets are described in the following tables. **These datasets refer to the information country B is receiving after the semantic services in country B take place, once patient identification and patient consent have been performed and it will be the information on which the dispenser will base the decision of what to dispense**:

6.1.1 About Patient Identification in the ePrescription

Variable	Definitions	MS: Minimum Max: Maximum	Comments	Example
Given Name	The Name of the patient	MS	This field can contain more than one element	Marta
Family Name/Surname	The surname/s of the patient	MS	This field can contain more than one element	Español Smith
Gender	The gender of the patient	Max	This field can be empty	Male/female/ unknown
Birth date	Date of birth	MS	This field may contain only the year	01/01/2009
Regional/National Health Id	If the patient has a regional or national Health Identification	MS	This field is required by some national laws	
Social/Insurance Number		Max	If a patient has both, national/regional ID and Social/Insurance number, only the regional/national Health Id is required by law. If the only identification the patient has is the Social/insurance number, then this one is considered as the regional/national Health Id. This field is required by some national laws.	

6.1.2 About HCP Prescriber Identification in the ePrescription

Variable	Definitions	MS: Minimum Max: maximum	Comments	Example
Given Name	The Name of the Prescriber	MS	This field can contain more than one element	Marta
Family name/surname	The surname/s of the Prescriber	MS	This field can contain more than one element	Español Smith
HCP Id number	The identification of the person as HCP	MS		12345
Profession		MS		Physician
Specialist		Max		Dermatologist
Prescriber Facility Address:	The place (complete address) where the prescriber made the prescription		This is not a field but a block of information made up of the following fields. This might not be in the dataset but this information needs to be available for the process traceability (FR20)	e.g., Los Bermejales Health Care Centre. Alemania St. Seville, 41018. Spain
—Name of the Facility		Max		For instance, the name of the building: Los Berrmejales
—Street Address		Max		Alemania Street
—City		Max		Seville
—State or Province		Max		Seville
—Zip or Postal Code		Max		41018
—Telephone		Max		+34 954123123
—Contact email of the centre or of the prescriber		Max		losbermejaleshealthcentre@xxx.es
—Country	The country where the prescription was made	MS	The dispenser needs to know the country where he is consulting the information from	Spain
Prescriber Organization:			This is not a field but a block of information made up of the following fields. This might not be in the dataset but this information needs to be available for the process traceability (FR20)	
—Organization Name		Max		e.g. Andalusia Health Service
—Organization Identifier		Max	This filed can be numbers and/or letters	123458xfs

6.1.3 About the prescription data in the ePrescription

Variable	Definitions	MS/Max MS Minimum Data Set Max Maximum	Comments	Example
Prescription ID	Identification of the prescription	MS		
Prescription Item ID	Identification of the Item within the prescription	MS	One prescription might contain more than one item (or medicines). In the country where prescriptions contain just one item or medicine, then the prescription ID=Prescription ID item	Item1: medicinal product 1 description + posology Item2: Medicinal product 2 description + posology Item 1 ID:1234 Item 2 ID: 2345
Country A Cross-border/regional/national medicinal product code	Code that identifies the medicinal product description in that region/country or among some countries	Max	Some countries like Denmark and Sweden might have the same medicinal product code	
Country B Single concept	It is the translation to a single concept in country B from the epSOS semantic format. This is not a mapping to the existing medicinal products in country B		This is not a field but a block of information made up of the following fields. If a single prescription is made in country A, in country B can not be several prescriptions. It has to be one for practical reasons and then a brand name among all available in country B should be selected. Please refer to Table 2 for clarification on this concept	Paracetamolo 0,5g 30 tablets (the original medicinal product prescribed in country A is **Termalgin** 500 mg **30** comprimidos)
—Active ingredient (of country A in Country B units)	See section 11.2	MS	Country B translates (does not change) the active ingredient from country A to country B units (single concept) but it is the same active ingredient. This is part of FR 13 (Id of medicinal product)	Paracetamolo
—Strength of the medicinal product (of country A in Country B units)	See section 11.2	MS	Country B translates (does not change) the strength from country A to country B units (single concept) but it is the same strength This is part of FR 13 (Id of medicinal product)	Dose/unit. E.g. 500mg that it is what contains 1 tablet, i.e. the unit in country A, it can be 0,5g in country B
—Medicinal	See section 11.2	MS	This is the size of the package	30

product package (of country A)			prescribed in Country A. This is part of FR 13 (Id of medicinal product) and FR14 (substitution)	
— Pharmaceutical dose form (of country A in Country B units)	See section 11.2	MS	Country B translates the dose form from country A to country B units (single concept) but it is the same pharmaceutical dose form. This is part of FR 13 (Id of medicinal product)	In country A is 'comprimidos' and in country B 'tablets'
Brand name of the medicinal product prescribed in country A	See section 11.2	Max	This is a free text field and can be empty if the prescription was made by active ingredient	Termalgin
Route of Administration (of country A in Country B units**)**	See section 11.2	Max	Country B translates the route of administration from country A to country B units but it is the same route	In injectable: intramuscular In Tablet: oral
Number of packages (of country A)	Number of boxes that have been prescribed in country A	MS	This is the number of boxes prescribed in country A	2
Posology (of country A in Country B units**)**	See section 11.2	MS	Country B translates the posology from country A to country B units but it is the same posology. This field can be a single field or a block of different fields (Number of units per intake, frequency of intakes (per day/month or week) and duration of treatment)	1 unit/intake every 24 hrs for a duration of 30 days in country A can be 1unit/intake once a day during 1 month
Date of issue of the prescription	Date when the prescription was made	MS		Date
Date of onsent of treatment	Date when patient needs to start taking the medicine prescribed	Max		Date
Date of end of treatment	Date when patient has to finish taking the medicine prescribed	Max		Date
Instructions to patient	The prescriber might give to the patient instructions	Max	They must be presented in the original language.	Take only when headache
Advise to the dispenser	The prescriber might give instructions to the dispenser	Max	The information will be in the original language as automatic translation is not secure enough. To avoid legal and ethical issues to the dispenser, it should be wise to implement an option that allows the dispenser to decide, knowing that this data is available, whether he wants to consult it or not.	Watch hypertension

Apart from the previous data elements, also a copy of the original prescription has to be available in country B (this copy could be the same data elements, structured or not, but without any semantic transformation).

Although 'Route of Administration' has been considered a maximum data element as it is normally a free text, WP3.1 is concerned about the importance of this field and the impact of not having it. In some countries, route of administration is already included within the pharmaceutical dose form but if not, the only measure we can provide at this moment is that the dispenser can check a copy of the original prescription to help him with this issue among others. Also, if the semantic group describes the pharmaceutical dose form at a certain level, the route of administration is implicitly known. This issue will also need to be followed during the piloting phase.

6.2 Common structure of the dispensed medicine dataset

The objective of this section is to agree and propose:

- The definition of items to be shared: Appellation (Long name and short name), definition, and accepted values
- A Minimum and advisable data set

In order to understand the proposed dataset, some elements need to be explained:

Minimum and maximum:

Minimum is the data that has been considered as essential for the country that made the prescription (in this deliverable, country A) to identify and update the related prescription (including law implications e.g. identification of dispenser) once it has been dispensed. This information will have to be available to country A within the epSOS LSP.

Maximum is the data that, even if it is not received by country A, it could still identify and update the related prescription. If a country has that information, it can make it available to another country that use that information for other purposes (the fields exists and make sense in that other country).

The semantic process is described in section 5.2.1.2.

The proposed datasets are described in the following tables (this datasets refer to the information that country A is receiving after the semantic services in country A take place):

6.2.1 About Patient Identification

Variable	Definitions	MS Minimum Max Maximum	Comments	Example
Given Name	The Name of the patient	MS	This field can contain more than one element	Marta
Family Name/Surname	The surname/s of the patient	MS	This field can contain more than one element	Español Smith
Regional/National Health Id	If the patient has a regional or national Health Identification	MS		
Social/Insurance Number		Max	If a patient has both, national/regional ID and Social/Insurance number, only the regional/national Health Id is required by law. If the only identification the patient has is the Social/insurance number, then this one is considered as the regional/national Health Id. This field is needed by law.	

6.2.2 About HCP Dispenser Identification

Variable	Definitions	MS Minimum Max maximum	Comments	Example
Given Name	The Name of the Dispenser	MS	This field can contain more than one element	Marta
Family name/surname	The surname/s of the Dispenser	MS	This filed can contain more than one element	Español Smith
HCP (Pharmacist) Id number	The identification of the person as HCP	MS		12345
Dispenser Facility (Pharmacy) Id Number		MS	The identification of the Pharmacy is needed. This can be done either by the ID number or by the Address	
OR Dispenser Facility (Pharmacy) Address	The place where the dispenser made the dispense	Or MS	This is not a field but a block of information made up of the following fields. The identification of the Pharmacy is needed. This can be done either by the ID number or by the Address	
—Name of the facility		Max	The pharmacy might have a name that identifies it. If it has it, then it has to be sent.	
—Street Address		MS		
—City		MS		
—State or Province		MS		

—Zip or Postal Code		MS		
—Country	The country where the pharmacy is located	MS		
Pharmacy Organization		Max	This is not a field but a block of information made up of the following fields. In some countries, pharmacies are grouped in a 'College' that represent them. This might not be in the dataset but this information needs to be available for the process traceability (FR20)	
—Organization Name		Max		
— Organization Identifier		Max		

6.2.3 About the dispensed medicine data

Variable	Definitions	MS/Max MS Minimum Data Set Max Maximum	Comments	Example
Dispensed medicine Id	Identification of the dispensed medicine event in country B	MS		
Prescription ID	Identification of the related prescription (country A) of the dispensed medicine	MS	This is part of FR 16 (Id of prescription and medicine dispensed)	
Prescription Item ID	Identification of the item or medicine of the related prescription (country A) of the dispensed medicine	MS	One prescription might contain more than one item or medicine. In the country where prescriptions contain just one item, then the prescription ID=Prescription ID item. This is part of FR 16 (Id of prescription and medicine dispensed)	
Country B Cross-border/regional/national medicinal product code	Code that identifies the medicinal product description in that region/country or among some countries	Max	Some countries like Denmark and Sweden might have the same medicinal product code	
Country A	It is the	MS	If a single medicine is dispensed in	Paracetamol

Single concept	translation to a single code in country A from the epSOS semantic format		country B, in country A can not be several dispensed medicines. It has to clearly identify the active ingredient of the medicine dispensed.	500 mg 20 comprimidos
Active ingredient			This is the active ingredient of the medicine dispensed in Country B (in Country A units), that has to be the same that the one prescribed as substitution is not allowed.	Paracetamol
Strength of the medicinal product			Strength of the medicinal product of the medicine dispensed in Country B (in Country A units) that has to be the same that the one prescribed.	500 mg
Medicinal product package (of country B)			As substitution of package size is in the scope, the size of the package of the medicine dispensed may differ from the one prescribed	20
Pharmaceutical dose form			This is the pharmaceutical dose form of the medicine dispensed in Country B (in Country A units), that has to be the same that the one prescribed.	Comprimidos
Route of Administration	See section 11.2	Max	As substitution of route of administration is out of the scope, the route of administration of the medicine dispensed has to be the same than the one prescribed	In injectable: intramuscular In Tablet: oral
Number of packages	Number of boxes that have been dispensed	MS	This is part of FR 16 (Id of prescription and medicine dispensed). In principle, the number of packages dispensed should be the same than the ones prescribed for patient safety reasons but this might be subject lo legal restrictions that will need to be followed during the pilot.	2
Date of the dispensed medicine event	Date when the medicine was dispensed	MS		
Substitution	If a different brand name or package size has been dispensed	Max	It indicates if brand name or package size dispensed are different from the one prescribed. This is part of FR 14 (substitution)	YES/NO

Apart from the previous data elements, also a copy of the original medicine dispensed has to be available in country A (this is the same data elements, structured or not, but without any semantic transformation, so it includes the brand name of the medicine dispensed).

7 FUNCTIONAL RELATIONSHIP WITH PS

During the work carried out in WP3.1 'Definition of functional requirements –ePrescription' and WP3.2 'Definition of functional requirements –Patient Summary', there has been a constant process of harmonisation between the ePrescription and the Patient Summary services to build a coherent and consistent service (the whole service, Patient Summary and ePrescription). This harmonisation has been performed from different perspectives:

- The requirements identified. Some requirements are common to both services (excepting the actors involved and the information exchanged) and some others are different as the specific objectives of the services are also different.
- The information shared and who has access to it in the different scenarios.
  - The dependencies between the information exchanged in both services have been analysed in the following table:

Fields included	Medication Summary data	ePrescription data	Current prescriptions	Dispensed medicine data
Active ingredient	Yes	Yes	Yes	Yes
Active ingredient id code	Yes	No	Yes	No
Posology				
• Number of units per intake	Yes	Yes	Yes	No
• frequency of intakes	Yes	Yes	Yes	No
• duration of treatment	Yes	Yes	Yes	No
Strength	Yes	Yes	Yes	Yes
Date of onset of treatment	Yes	Yes (max)	Yes (máx)	No
Date of end of treatment	No	Yes (max)	Yes (máx)	No
Medicinal product package	No	Yes	No	Yes
Pharmaceutical dose form	Yes (max)	Yes	Yes	Yes
Brand name	No	Yes (max)	No	Yes
Route of administration	No	Yes (max)	No	Yes (max)
Number of packages	No	Yes	No	Yes
Date of issue of the prescription	No	Yes	No	No

Instructions to patient	No	Yes (max)	No	No
Advise to the dispenser	No	Yes (max)	No	No
Date of the dispense medicine event	No	No	No	Yes
Substitution	No	No	No	Yes (max)

- Who has access to what information is described in the following table and depends on the role of the health professional:

Access	Patient Summary	Medication Summary	Available prescriptions	Current prescriptions	Dispensed medicine information
HCP-physician	Yes	Yes	No	Yes, in the PS	It depends on the country
HCP_Prescriber	It depends on the country	Yes	No	Yes, in the PS	It depends on the country
Dispenser	No	No	Yes	Yes	No

- The concepts. A common understanding of the terminology used and of the definition of concepts and the data elements to be exchanged has been achieved to assure the congruence of the whole service.

It is important to understand that the information about the current prescriptions is not used for dispensing but to help the HCP to perform pharmaceutical care.

8 OTHER ISSUES AND FUNCTIONAL RECOMMENDATIONS

As result of the work carried out in this WP, a set of possible issues and recommendations based on the functional requirements specification has been delivered to other WPs.

8.1 Open issues from Initial Scope (D5.2.1)

Regarding the Open Issues stated in D5.2.1 Initial Scope to be discussed and answered in this WP, the results of the discussions are as follows:

- Are additional authorizations required for any types of prescriptions?
  In the case of an authorization needed in country A, as country A should make accessible to country B at least the 'available' prescriptions, i.e., the ones that are able to be dispensed to that patient at that particular moment, if an additional authorization is required by country A, this means that prescription is not yet available to be dispensed.
  In the case of an authorization needed in country B, then it should be up to country B to decide whether or not to dispense the medicine.

- How are multiple dispenses of one prescription to be handled? I. e. can a medicine be dispensed again due to the loss of it when a patient needs to take it due to health problems? (A medicine is dispensed according to a previous prescription where the medicine of the prescription has already been dispensed, i.e. 'emergency dispense').
  If a prescription has already been fulfilled, this means that it is not 'available' anymore. If there is no prescription available for country A, country B will not know what can be dispensed. But if country A has also sent the current prescriptions (optional), the pharmacist might be able to check that there has been a prescription already fulfilled and decide (up to country B legislation) that has enough information to make an emergency dispense of the medicine already dispensed. This procedure is implemented in just three countries but could lead to a fraud or misuse of the service as there is no way to control how many emergency boxes have been dispensed as country A does not have this process implemented. This situation will be analysed during the piloting phase.

- Dispensing of medicine without prescription in an emergency situation that might be very common when abroad.
  This is not an ePrescription service or scenario as there is no 'available' prescription. This is out of the scope of the epSOS LSP (over the counter medicines –those that do not need prescription- are out of the scope of the epSOS LSP).

8.2 Recommendations

The following recommendations are proposed.

8.2.1 epSOS

Create a group of experts (clinicians and pharmacists) that decide which medicines can be substituted, how the pharmaceutical dose forms can be homogenised to avoid issues like national grouping and to decide the level of detail of the semantic description of the different medicine elements.

8.2.2 WP1.2, WP3.3, WP3.9, WP3.10 and PD4

Exceptions to the process, either functional (e.g. the dispenser does not have the right information to safely dispense) or technical (e.g. communication problems with retrieving information from a country) have to be measured during the pilot phase and a procedure and a structure (human and technical) needs to be put in place in order to evaluate and solve these exceptions. An information procedure regarding functioning of the service, duties, rights, etc. is also needed directed to the potential patients and all the actors involved in the process. WP1.2 ‘Overall evaluation of the project’, WP3.3 ‘System architecture’, WP3.9 ‘Development of proof of concept system for pilot site’, WP3.10 ‘Proof of concept testing’ and PD4 ‘Field testing’ should collaborate in this task, that it has been partly described below in Assistance services.

As it has been stated in the document, there are several situations that will need to be followed and evaluated during the piloting as those related to legislation and to functional issues like substitution, route of administration missing or emergency dispense.

8.2.2.1 Assistance services

The objective of the Assistance services is to provide guidelines to epSOS LSP end users (HCPs) in case they need assistance or something goes wrong during the pilot phase. Possible errors may be:

- Wrong identification of a patient
- Errors in the display of the information

These assistance services should provide a way to facilitate the use of the services as well as to report possible problems that may appear during their use. In addition, these assistance services should provide recommendations to warn the HCP in case any technical problem appears.

The following assistance services are recommended:

- Help Desk:
    - Contact Telephone to provide on-line support to HCPs.

- Email address. An email address within the HCPO should be available to report errors, suggestions and complaints of the HCPs about the epSOS services.

- Frequently Asked Questions list (F.A.Q list):

A F.A.Q list should be easily reachable within the HCPO that is providing the services locally and should include answers to possible misuse, known problems or limitations of the application/services. The following are some examples:

- What countries can I access to use the epSOS services?
- Which services and where are available?
- What is in the scope of the project?
- What is out of the scope of the project?
- How do I identify a patient?
- Why information of a patient is not available? (to have into account possible restrictions because of legal issues or epSOS requirements).

- Warnings to the user.

Information about possible problems should be provided to the user during the use of the application. These are some of those problems that could be automatically detected:

- Communication problems

  A message should appear saying that information cannot be shown due to communication problems and that it should be tried later.
- Technical problems (e.g. server not working)

  A message should appear saying that information cannot be shown due to technical problems and that it should be tried later.
- Problems in the documents received.

  There might be problems in the information received (e.g. the information received is incomplete or doesn't fulfil the epSOS requirements). A warning should be displayed saying that the 'information received is not complete'.

8.2.3 WP1.2 and WP2.1

As stated by WP2.1 'Analysis and comparison of legal and regulatory issues', *country A legislation sets the validity on prescription and country B legislation on dispensing.* WP3.1 had the need to understand the impact on the epSOS LSP of this statement. For this reason, constant communication have been maintained between both WPs. As a result, WP1.2 'Overall evaluation of the project' will need to analyse the dimensions of the results about the following situations:

- Country B legislation is more restrictive than country A, meaning that the level of service normally offered to the patient will be decreased and in some cases, affecting to the patient safety.
- Country B legislation is less restrictive than country A, meaning that the patient could acquire more rights than in his home country leading to misuse, fraud and patient safety breach.

And WP2.1 will need to make sure that countries are aware of all the possible legal situations identified in this deliverable to be faced during the piloting when signing the Framework Agreement.

8.2.4 WP3.5

Regarding the semantic services:

1. Two alternatives have been identified based on the experience of some of the participants as useful in order to allow the semantic interoperability (this is not to be considered as a recommendation but as a proposal in case WP3.5 find it useful) :
   - Codify each field of the medicinal product description.
   - Group some fields and create a single coding for those (the active ingredient or name of the medicinal product + strength + pharmaceutical dose form). The codification will be reduced as 3 different fields will be codified with a single code. These fields are already determined by the medicinal product and can not be disaggregated by the prescriber or the dispenser (e.g. Amoxicillin can not be found in the Market with a strength of 10 mg but 1000mg, and it can be found in capsules but never in injectable) and thus reduce the number of possibilities.
2. From a medical point of view, a medicinal product may be identified via the active ingredient or a brand name:
   - Active ingredients are named in accordance with an international nomenclature and it is valid for every country.
   - Brand names vary from country to country. Medicines with identical active ingredients and excipients can be named differently in two countries, even if they are offered by the same company. In some (rare) cases, the same brand name is used for different active substances in different countries.

   Thus, it is imperative, for patient safety reasons, always to communicate the active ingredient to the member state (minimum data set). The brand name may be communicated for information purposes (maximum data set); a mechanism to translate a

country A brand name to a country B brand name is not recommended due to high complexity and small benefit.

3. The fields that are free text should be presented in the original language to avoid possible misunderstanding with automatic translations.
4. Standards should be used when possible. The following table shows the different standards already available and identified in this WP:

Medicinal product description	Data models	Terminologies
Substances	ICH: M5 ISOTC_215_691	Chemical (…) WHO: substances INN, Classification: ATC EphMRA: PBIRG (harmonized ATC) Others: USAN, SNOMED CT
Pharmaceutical dose forms	ICH: M5 ISOTC_215_692	EDQM: Standard Terms
Routes of administration	ICH: M5 ISOTC_215_692	EDQM: Standard Terms ICH: M5
Units of presentation	ICH: M5 ISOTC_215_692	EDQM: Standard Terms
Strength Units of measure	ICH: M5 ISOTC_215_693	ICH: M5
Medicinal products (data elements, structures & relationship): data models (brand name and generic name)	ISOTC_215_694	National list of commercialized authorised medicines

9 EXAMPLE OF USE CASE: STORYBOARDS

A patient from Andalusia (Spain) is visiting Denmark for holidays and he will stay there for one month. We are going to show different examples about several possible situations that will have two possible results, either the patient is able to retrieve the medicine prescribed in country A, or he will need to attend a prescriber to get a new prescription (this later situation is better analysed in annex I of this document where Use case 2 'Medicine newly prescribed in country B' is described):

Case	Patient	Situation in Denmark	Comments
1.1	A chronic patient with a Long term treatment. This type of patient is the most favoured regarding the ePrescription service that implements Long term treatments	The current box is finished and needs to collect a new one******	This is one of the most common patient scenarios and will benefit from the epSOS LSP
1.2	A chronic patient with a Long term treatment. This type of patient is the most favoured regarding the ePrescription service that implements Long term treatments	He loses his medicine, or forgets it…	This is one of the most common patient and to benefit from the epSOS LSP
1.3	A patient with a prescription (no Long term treatment)	He could not collect the medicine in country A and needs it.	This situation is not as frequent as the ones before as normally he would have withdrawn the medicine beforehand
1.4	A patient with a prescription (no Long treatment)	He loses his medicine, or forgets it…	This situation is frequent and depending on the availability of the current prescriptions at the pharmacy, the result will differ

****** This refers to the situation that can occur for example in Andalusia, where the patient can not collect more than 1 box of the same medicine –except for special medicines than can be collected up to 4 boxes- at the same time.

9.1 Description and analysis of the use case

- Chronic treatment (case 1.1 and 1.2 in the table above): Patient with an ePrescription of 'omeprazol capsules for a year'.

The patient is in Denmark and he goes to a pharmacy because he has ran out of boxes and needs the medicine and the dispenser consults if the omeprazol is available at this moment in the information from Andalusia or Spain ('available' prescriptions).

- No chronic treatment (case 1.3 and 1.4 in the table above): Patient with an ePrescription of amoxicillin capsules for 7 days.

The patient is in Denmark, he goes to a pharmacy because he needs the medicine and the dispenser consults if this medicine is available at this moment in the information from Andalusia or Spain.

Although the description of the situation is slightly different for Long term treatment than for a single prescription, the results are the same:

Description of the situation	Result
1.1: The current box is finished and patient needs to collect a new one. **There is an 'Available' ePrescription** 1.3: The patient needs to collect the medicine. **There is an 'Available' prescription**	There is an electronic dispensing and the patient receives the medicine. The dispensed medicine information is sent to Andalusia to update the related prescription
1.2: He has lost the current box(es), or has forgotten it (them)… **There is no 'Available' prescription.** *This situation can be caused because the patient has lost a package(s) or part of a package of medicine or he has forgotten it in Andalusia, or the patient is taking more quantity of the medicines than he needs.* 1.4: He has lost the medicine, or has forgotten it…**There is no**	Two possible situations can happen at this point: —In Andalusia is forbidden for a pharmacist to access the current prescriptions but just the 'available' prescriptions. Thus, the **current prescriptions** of the patient in Andalusia will **not** be **available** for the pharmacist in Denmark to consult. The pharmacist will need to decide with the information he has (nothing in this case) if he is able to dispense the medicine and if not, give advice to the patient for the needed steps in order to get the medicine (UC2 'Medicine newly prescribed in country B') —In Andalusia pharmacists are allowed to access the

'Available' prescription. *This situation can be caused because the patient has lost the medicine or he has forgotten it in Andalusia or the patient is using more quantity of the medicine than he needs.*	current prescriptions. Thus, the **current prescriptions will be sent to the pharmacy** in Denmark together with the available prescriptions (that in this case there is none available). The pharmacist will need to decide with this information (current prescriptions) if he is able to dispense the medicine and if not, give advice to the patient for the needed steps in order to get the medicine (UC2 'Medicine newly prescribed in country B') . **In these two situations, there is no dispensed medicine information sent to Andalusia as the dispensing is not based on an 'available' and valid ePrescription that can be updated with that medicine dispensed**

9.2 Issues when dispensing

It is assumed for this example that an ePrescription from Andalusia is recognised and it is a valid prescription, i.e. it is an order that can be dispensed in Denmark.

- **Substitution of brand name and package size** if it is different between countries or the dispenser has not this package size at that moment.

eP made in Andalusia	Single concept in country B	eP dispensed electronically in Denmark
DOLOTREN 50mg 40 tablets, 1 tablet each 8 hours during 365 days.	DICLOFENAC 50mg 40 tablets, 1 tablet each 8 hours for one year.	VOLTAREN 50mg 30 tablets, 1 tablet each 8 hours for one year.

- **Without substitution of brand name and with substitution of package size** if it is different between countries or the dispenser has not this package size in that moment.

eP made in Andalusia	Single concept in country B	eP dispensed in Denmark electronically
VOLTAREN 50mg 40 tablets gastric-resistant, 1 tablet each 8 hours during 365 days.	DICLOFENAC 50mg 40 tablets, 1 tablet each 8 hours for one year.	VOLTAREN 50mg 30 tablets, 1 tablet each 8 hours for one year.

- **Medicines that can not be substituted (law or regulation) in the country where the prescription is made.** Patient with a ePrescription of phenytoin (the brand name is EPANUTIN) capsules for a year.
  This is the same situation as the first described, but in this case, in Andalusia the dispenser is not allowed to supply or alter the brand name of phenytoin. However, the law or regulation can be different in Denmark and the most common situation is that the brand names of the medicines are different between countries so they will be substituted. When brand name substitution is of a product with a narrow therapeutic index and/or release, characteristics may be altered by a switch and patient safety considerations must be taken into account as alteration may result in either toxicity or under treatment. As previously stated, this situation needs special attention when piloting the service. This will also be analysed by the group of experts (clinicians and pharmacists) before piloting.

- Patient with an ePrescription of a medicine that can be dispensed in a community pharmacy in Andalusia (Spain), but **in Denmark it must be dispensed in a Hospital Pharmacy.**
  This situation is out of the scope as described in section 3.2 of D3.1.2.

- Patient with an ePrescription of a medicine that can be dispensed in a community pharmacy in Andalusia (Spain), but **in Denmark it is not commercialized.**
  This situation is out of the scope, because we have defined that it is not possible to change the active ingredient (or the strength or the pharmaceutical dose form).

- Patient with an **ePrescription made by a nurse** or other HCP that is not a physician in Andalusia but it is not possible to be dispensed in Denmark because prescriptions made by nurses are not legal.

- Patient with an ePrescription of **narcotics**.
  This situation is out of the scope.

- ePrescription of a **sanitary product** like glucose blood test strips.
  This situation is out of the scope. The scope includes medicinal products for human use, elaborated by or in which elaboration an industrial process has taken place.

10 CONCLUSIONS

Some of the issues described in this document already happen when patients travel abroad with paper prescriptions; often the issues are legislative. In order to encourage the countries to offer the services abroad, then irrespective of whether this is already common practice or new, a minimum level of service needs to be guaranteed which assures the safety of the patient. The definition of the services in the epSOS LSP identify the issues and propose measures to smooth the impact of these issues. However, a consistent level of service that assures the safety of the patient can not be provided within the current legal and pharmaceutical frameworks. Two actions should be taken at the European level to provide it:

- Creation of a legal framework that supports the interoperability of the ePrescription services to assure a minimum quality of these always protecting the security and safety of the patient. This will partly solve issues like substitution.
- Establishment of a group of European experts (clinicians and pharmacists) that:
    - develops a European nomenclature (common semantic language) that will allow to have a common understanding of the medicines (the different elements like active ingredients, pharmaceutical dose form, strength…) avoiding patient safety issues.
    - decides which medicines (regarding their bioavailability characteristics and their therapeutic index and/or release) can be substituted, how the pharmaceutical dose forms can be homogenised to avoid issues like national grouping and to decide the level of details of the semantic description or nomenclature of the different medicine elements.

11 TERMINOLOGY

This section summarises the standard terminology adopted in the epSOS Project and in this Work Package and contained in this Deliverable. The WT5.2.1 'Initial Scope' definitions will be used as a starting point. This section also includes terminology adopted within the WP3.1 in order to understand the description of the Use cases.

11.1 Project name

Smart Open Services for European Patients- Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription (epSOS): it identifies the name of the project.

11.2 Medical terms

Active Ingredient:
Is defined as a substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product.
NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)

Available prescription;
Is the prescription that can be retrieved for the patient in the act of dispensing (at that specific or particular moment). This implicitly means that it is a time valid prescription.
epSOS D3.1.1

Brand name or name of the medicinal product:
The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.
DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human

Current prescription:
Any prescribed medicine whose period of time indicated for the treatment has not yet expired, whether it has been dispensed or not. This mean that it might not be an 'available' prescription since the time to withdraw the medicine may have expired but the treatment is still on.
epSOS D3.1.1

Dispensed Medicine data:
In this Deliverable it is referred to as electronic dispensed medicine dataset.
epSOS D3.1.1

Dispensed Medicine:
The medicine given to a patient as indicated in the prescription ordered by a prescriber.

IHE_ePharmacy_1.0

Dispenser:
Health Care Professional who dispenses medicine(s) to the patient fulfilling a prescription order by a prescriber.
epSOS D5.2.1

Dose form:
Is defined as the physical manifestation [“entity”] that contains the active and/or inactive ingredients that deliver a dose of the medicinal product. The key defining characteristics of the Dose Form can be the state of matter, delivery method, release characteristics, and the administration site or route for which the product is formulated.
NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES
(EMEA/CHMP/ICH/168535/2005)

eHealth:
Health care practice which is supported by electronic processes and communication.
http://en.wikipedia.org/wiki/EHealth

eDispensing
It is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medicine(s).
epSOS D3.1.1

ePrescribing
It is defined as prescribing of medicines in software by a health care professional legally authorized to do so, for dispensing once it has been electronically transmitted, at the pharmacy.
epSOS D3.1.1

Generic medicinal product:
Shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product had been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives or an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy or the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriated detailed guidelines.
DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human

HCP:
Health Care Professional.
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 health care sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.
epSOS D5.2.1

HCPO:
Health Care Provider Organisation
An institution, authorized to provide health care services, univocally identified in the set of the Health Care Institutions.
epSOS D3.2.1

Long term treatment:
Refers to those treatments in which one prescription includes several dispenses of the same medicine distributed along a period of time.
epSOS D3.1.1

Medical Record:
Is a systematic documentation of a patient's medical history and care. The term 'Medical record' is used both for the physical folder for each individual patient and for the body of information which comprises the total of each patient's health history. Medical records are intensely personal documents and there are many ethical and legal issues surrounding them such as the degree of third-party access and appropriate storage and disposal. Although medical records are traditionally compiled and stored by health care providers (HCP) personal health records maintained by individual patients have become more popular in recent years.
epSOS D.2.1.1

Medication Summary:
At least, a list of current prescriptions with the following information of each one: brand name, active ingredient, pharmaceutical dose form, strength, package size, posology, onset date of treatment and end date of treatment.
epSOS D3.2.1

Medicinal Product:
(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.'
DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human

Medicinal Product Package:
Delivery unit of a medicinal product in an outer container.
NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)

Medicine:
Medicinal Product.
epSOS D3.1.1

NHS:
National Health Service.
epSOS ANNEXI

Original prescription:
The minimum data set defined but as prescribed in the origin country (e.g. the brand name of country A that it will probably be different than the one dispensed in country B).
epSOS D3.1.1

Patient:
Person or defined groups of persons receiving or registered as eligible to receive health care services or having received health care services.
ISO_CommonGlossary

Patient consent:
Provided to the data controller means any freely given specific and informed indication of his/her wishes by which the data subject signifies his agreement to personal data relating to him/her being processed.
epSOS D.2.1.1

PS:
Patient Summary
Should be understood to be a minimum set of patient's data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (e.g. emergency) and in case of planned care (e.g. citizen movement).
epSOS ANNEXI, D2.1.1 and D5.2.1

Pharmaceutical Dose form:
A Pharmaceutical Dose Form is the form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/manufacturer/distributor.
NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)

Point of Care:
Is any natural or legal person or any other subject having legal capacity that relies on the usage of personal health related data in order to fulfil tasks or business purposes notwithstanding whether those tasks have been delegated by law or not.
epSOS D.2.1.1

Posology:
Number of units per intake, frequency of intakes (per day/month or week) and duration of treatment.
Real Decreto 1910/84

Prescriber:
Health Care Professional who issues a prescription.
epSOS D5.2.1

Prescription provider:
See actors description in section 5.1.3.
epSOS D3.1.1

Prescription:
Prescribed medicine data (in this Deliverable it is referred to electronic prescription).
epSOS D3.1.1

Route of administration:
Indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. In some cases a medicinal product can be intended for more than one route and/or method of administration.
NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)

Strength:

Is the content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form.
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

Substance:
Any matter irrespective of origin which may be:
human, e.g. human blood and human blood products; animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.
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

Time valid prescription:
Prescription that has not yet expired (i.e. the patient can withdraw the medicine during the time the prescription is valid).
epSOS D3.1.1

Valid Prescription:
It is an 'official' prescription, i.e. a prescription made fulfilling the legislation and the procedures defined in that country.
epSOS D3.1.1

11.3 Technical terms

Access:
The ability to obtain certain services (health care, electronic services: patient summary, electronic prescription), as determined by factors such as the availability and affordability of goods and services.

MS:
(EU) Member State.
epSOS D5.2.1

APM:
Administrative Project Manager.
epSOS ANNEXI

Authentication:
Process to verify the claimed identity before authorising a particular action to be performed.

Authorization:
Process by which entitlement of a requester, to access or use a given service, is determined.
epSOS ANNEXI

Coding System:
A scheme for representing concepts using (usually) short concept identifiers to denote the concepts that are members of the system; defines a set of unique concept codes. Examples of coding systems are ICD-9, LOINC and SNOMED.
ISO_CommonGlossary

Concept:
Unit of knowledge constructed through combining characteristics.
ISO_CommonGlossary

Country A:
Is the Member State of affiliation i.e., the state where personal health data is stored and where the mobile patient is insured. This is the country where the patient can be univocally identified and his data may be accessed [Term from D5.2.1 adapted].
epSOS D.2.1.1

Country B:
Is the Member State of treatment i.e., where cross-border health care is actually provided when the patient is seeking care abroad. This is a country, different from country A, in which information about a patient is needed in case the patient needs health care [Term from D5.2.1, adapted].
epSOS D.2.1.1

EC:

European Commission.
epSOS ANNEXI

EMEA:
European Medicines Agency.
epSOS ANNEXI

epSOS LSP:
Smart Open Services for European Patients Large Scale Pilot - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription.
epSOS D5.2.1

epSOS Semantic Format or Code:
The format/code in which the identified datasets will be arranged to communicate among the Member States. This format/code will be defined in WP3.5 ‘Semantic Services’.
epSOS D3.1.1

epSOS Service:
The ePrescription services built on top of the NCPs (internal and external communications and processes).
epSOS D3.1.1

FORMAT:
To organize or arrange text, according to a chosen pattern.
epSOS D3.1.1

FR:
Functional Requirement.
Defines a function of a software system or its component. A function is described as a set of inputs, the behaviour and outputs.
http://en.wikipedia.org/wiki/Functional_requirements

Identification:
Assignment of a unique number or string to an entity within a registration procedure which unambiguously identifies the entity. This number or string serves thereafter as an identifier uniquely attached to this entity.
i2-Health_D3.1_1.0

ID:
Identification. An official document that shows or proves who you are.
http://dictionary.cambridge.org/

ICT:
Information and Communication Technologies.
epSOS D5.2.1

IHE:
Integrating the Health care Enterprise.
epSOS ANNEXI

ISO:
International Organization for Standardization: http://www.iso.org.
epSOS D5.2.1

LSP:
Large Scale Pilot.
Is the EU wide pilot project to implement a Patient Summary and ePrescription service to support continuity of care.
epSOS ANNEXI

L&R Issues:
Legal and Regulatory issues. Related with WP 2.1 ‘Analysis and comparison of legal and regulatory issues’.
epSOS ANNEXI

Are those issues that emerge from EU and national legal and regulatory frameworks and they directly relate to the two epSOS use cases.
epSOS D.2.1.1

NCP:
National Contact Point (see actors description in section 5.1.3).
epSOS D3.1.1

NFR:
Non-functional requirement
Requirement that specify criteria that can be used to judge the operation of a system, rather than specific behaviours.
http://en.wikipedia.org/wiki/Non-functional_requirement

Personal Data:
Is any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity [Dir 95/46/EC].
epSOS D.2.1.1

PC:
Project Coordinator.
epSOS ANNEXI

PEB:
Project Executive Board.

epSOS ANNEXI

PP:
Project place: Electronic space for the editorial and management of epSOS project.
epSOS D3.1.1 (Annex II)

PSB:
Project Steering Board.
epSOS ANNEXI

Reliability:
Ability to provide security on the veracity of the information provided.

SNOMED CT:
The Systematized Nomenclature of Medicine (SNOMED) is a multiaxial hierarchical and computer processable classification of medical terminology covering most areas of clinical information such as diseases, procedures, pharmaceuticals etc.

TOC:
Table of contents.
epSOS D3.1.1 (Annex II)

TPM:
Technical Project Manager.
Has overall responsibility for the timely completion of technical work in the project over and above responsibilities carried by WP Leaders.
epSOS ANNEXI

TCON:
Telephone Conference.
Conference Calls.
epSOS D3.1.1 (Annex II)

UC:
Use case:
Is a methodology used in systems analysis to identify, organize and describe system requirements involved in health care scenarios. Contains all system activities that have significance to the user.
epSOS D5.2.1

WP:
Work Package.
epSOS ANNEXI

WG:
Working group.
epSOS D3.1.1 (Annex II)

12 GLOSSARY

D3.1.1	Draft definition of functional service requirements- ePrescription
D3.1.2	Final definition of functional service requirements- ePrescription
EC	European Commission: **http://ec.europa.eu/index.htm**
eP	Electronic Prescription
epSOS LSP	European Patients – Smart Open Services Large Scale Pilot
FR	Functional Requirement
NFR	Non Functional Requirement
HCP	Health Care Professional
HCPO	Health Care Professional Organization
ID	Identification
IHE	Integrating the Health Care Enterprise – Europe
IHTSDO	International Health Care Terminology Standards Development Organisation
ISO	International Organization for Standardization: **http://www.iso.org**
IT	Information Technologies
L&R	Legal and regulatory
LSP	Large Scale Pilot
MS	(EU) Member State
NCP	National Contact Point or National Country Node
NFR	Non functional requirement
PC	Project coordinator
PD3	Project Domain 3
PEB	Project Executive Board
PM	Person month
PoC	Point of Care
PP	Project Place
PS	Patient Summary
PSB	Project Steering Board
SNOMED	Systematized Nomenclature of Medicine
TelCon or Tcon	Conference call
ToC	Table of contents
TPM	Technical Project Management
UC	Use case
WG	Working group
WP	Work package
WPL	Work package leader
WT	Work task

13 LIST OF FIGURES

14 LIST OF TABLES

15 Annex I: Use case 2 ‘Medicine newly prescribed in country B’

This section describes further functionalities beyond the current epSOS LSP scope that were analysed within WP3.1 with the purpose of a future scalability of the epSOS LSP solution. The aim is to profit from existing favourable cross border regional environments and present, with information purposes, possible enhancements to allow beneficiaries to implement additional functionalities on a voluntary basis and among their MSs in order to learn and prepare effectively for a possible epSOS future extension: UC2, ‘Medicine newly prescribed in country B’, is described in this annex but it will not be implemented in this epSOS LSP. Only two countries will pilot it as an experimental use case. Also, the requirements of this use case might change in a possible extension of epSOS LSP to be aligned with the new Patient Summary services defined in that extension.

15.1 Sequence diagram of use case

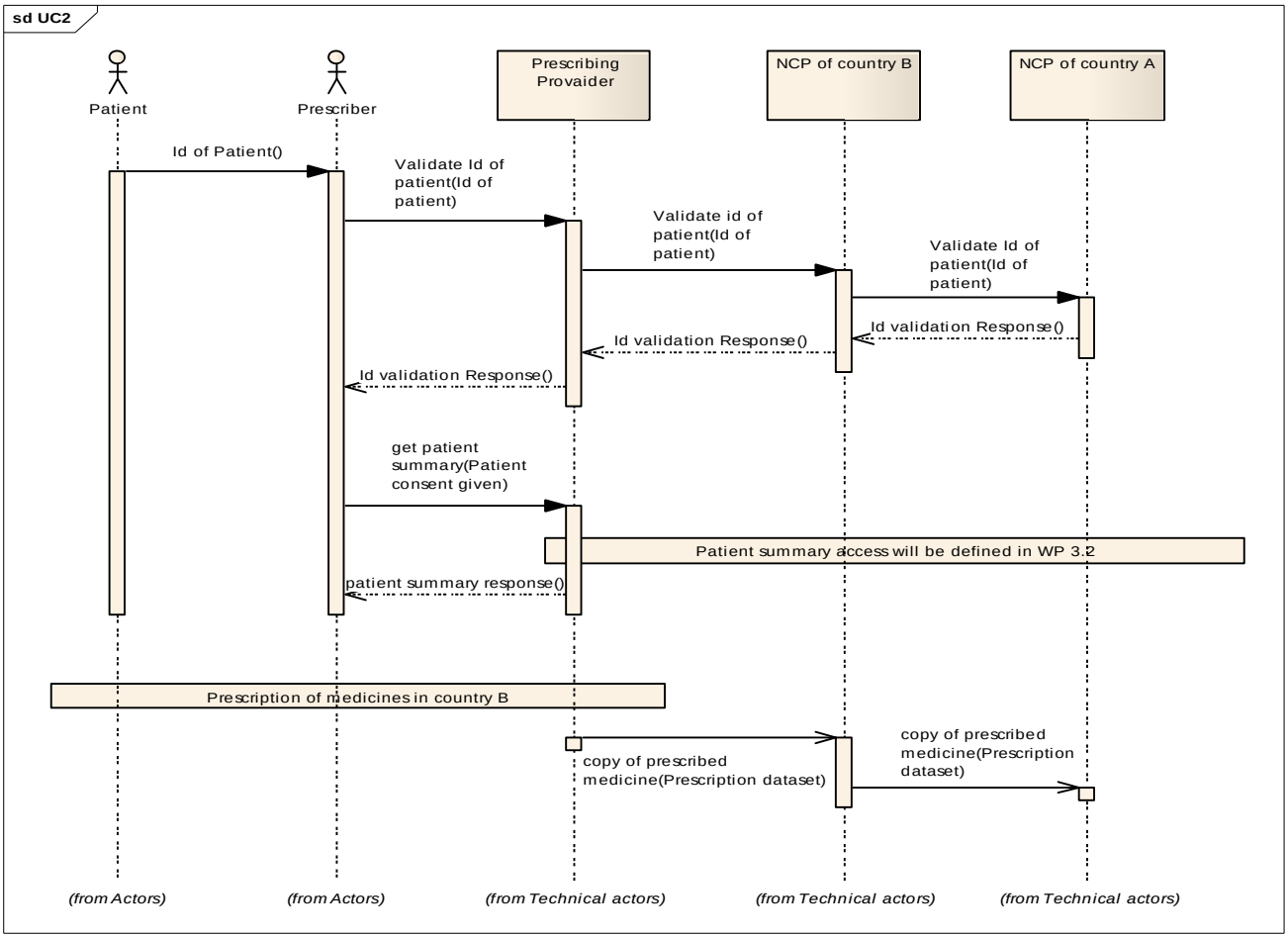


Figure 3. Sequence diagram use case 2 –prescribing

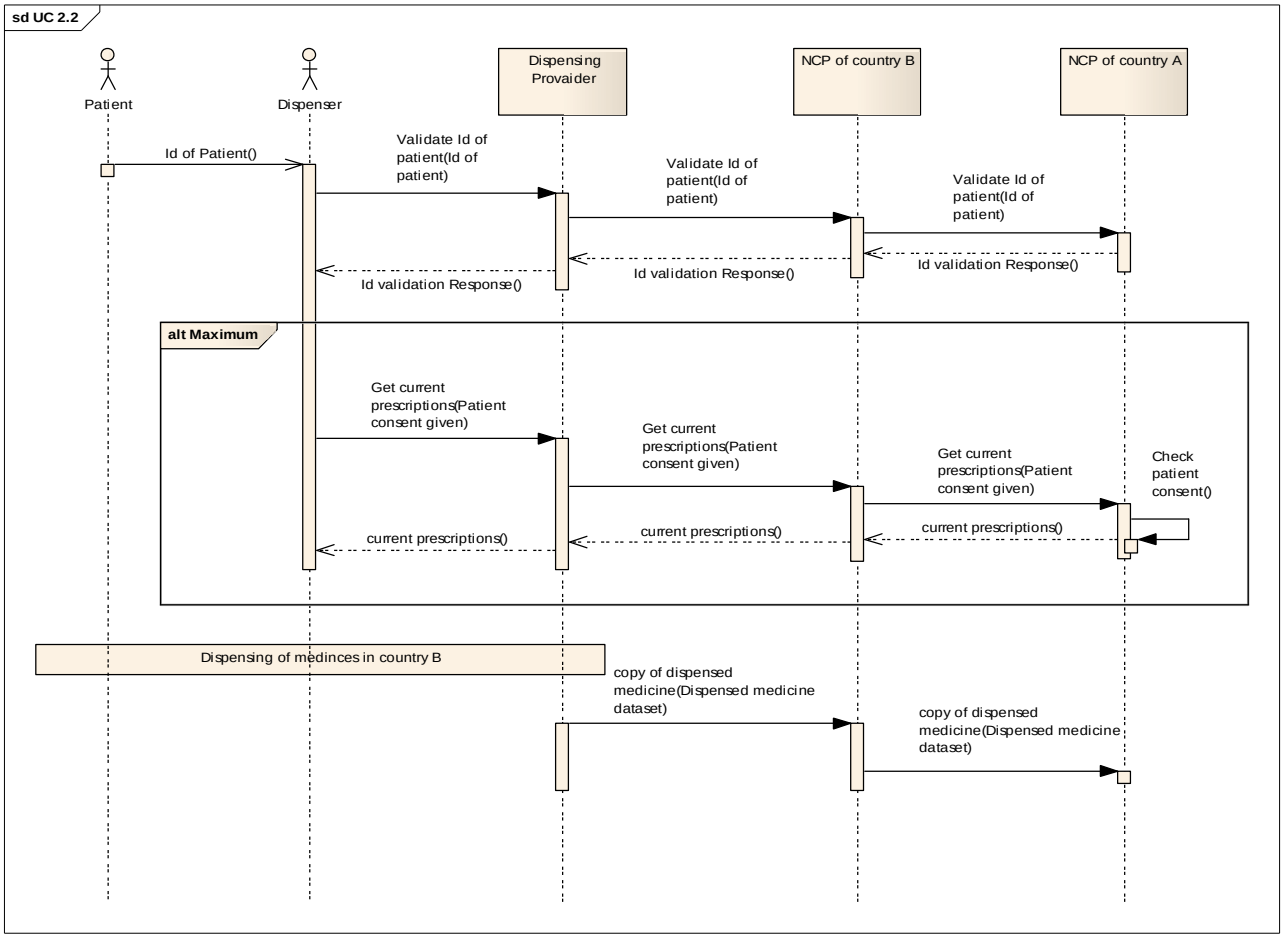


Figure 4. Sequence diagram use case 2 –dispensing

15.2 Description of use case

This use case describes the prescribing of medicine(s) in a country (B) when the patient comes from a different country (A) where he/she has a valid identification in terms of health care. It is assumed that the medicine will be dispensed in country B as it is the most probable situation.

In order for the use case to take place, several preconditions must be met:

- In country B, a mechanism to validate the identity of the patient and to obtain the patient consent has to be available[††††††]. The HCP, apart from being a person legally authorised to prescribe/dispense medicinal products also needs to be identified and authenticated in his/her prescription/dispense provider.
- Country A and B must provide, maintain and support a logical country node (NCP) supporting communication of the information identified in this section and that there must be a chain of trust between system actors in this process.

[††††††] This mechanism is the same than the one identified in WP3.2 'Definition of PS services'.

If these preconditions are met, the use case can take place. The steps and requirements to identify the patient, to get the patient consent and to obtain the Medication Summary and other data of the Patient Summary in country B, to help the prescriber to prescribe, are described in WP3.2 ‘Definition of PS Services’.

In order for the prescriber to prescribe, it should be advisable, and if patient consent is given at the request, he could access at least the Medication Summary (that contains at least the current prescriptions) and other information contained in the Patient Summary as allergies, contraindications, etc…This access is not a minimum requirement but a desirable one as it is not essential for the prescriber to prescribe.

In order to allow the prescriber to understand the information, this must be intelligible to him, i.e. structured, equivalent meaning and understandable (see section 5.2.2.1) and presented in his system as decided by country B (in order to ease the process for the HCP, it is recommended that the information is presented as it is normally done).

Once the prescription has been generated, the patient can withdraw the medicine from a pharmacy in country B. Besides, a copy of the prescription data set is sent to country A where it is decided whether to include this information in its Systems or not, always assuring the proper measures to keep or to deal with clinical information according to the Data Protection Legislation. Country A will receive the prescription data set of country B in the epSOS format (identifying active ingredient of the prescription) and a copy of the original prescription as described in section 5.2.1.2. The prescription information does not need to be sent on real time but country B needs to make sure and to be aware of the successful receipt in country A.

To dispense the medicine, the dispenser could, if patient consent is given on the request and if legally possible, access the current prescriptions of the patient in country A to help the dispenser to perform security/safety checking. The information must be intelligible to him, i.e. structured, equivalent meaning and understandable (see section 5.2.2.1) and presented in his system as decided by country B (in order to ease the process for the HCP, it is recommended that the information is presented as it is normally done). When the medicine is dispensed, a copy of the dispensed medicine is sent to country A where it is decided whether to include this information in its Systems or not, but always assuring the proper measures to keep or to deal with clinical information according to the Data Protection Legislation. Country A will receive the dispensed medicine data set of country B in the epSOS format (identifying active ingredient of the medicine dispensed) and a copy of the original medicine dispensed. The dispensed medicine information does not need to be sent in real time but country B needs to make sure and to be aware of the successful receipt in country A.

15.2.1 Requirements description

The requirements identified are:

Functional Requirements	
FR01	HCP Identification and authentication
FR02	Trust between countries
FR03	Patient identification
FR04	Patient consent
FR05	Structured information
FR06	Equivalent information
FR07	Information understandable
FR11	desirable but not minimum: Access to current prescriptions by dispenser
FR12	Original prescription
FR15	Dispensed medicine data sent to country A
FR17	Original dispensed medicine
FR18	desirable but not minimum: Access to patient summary by the prescriber
FR19	Prescribed medicine data sent to country A
FR20	Information Traceability

The non functional requirements are the same described in section 5.2.2.2 of the deliverable

15.2.1.1 Functional Requirements

This section contains only the functional requirements that have not been described in section 5.2.2.1 of the deliverable.

FR18- desirable but not minimum: Access to patient summary by the prescriber

FR18	**desirable but not minimum: Access to patient summary by the prescriber**
Description	The HCP could have access, to help him to prescribe with a minimum medical record about the patient, to the current prescriptions and other data contained in the PS. The current prescriptions need to be contained within the Medication Summary.
Associated Goals	• To safely and appropriately prescribe
Actors	Prescriber Prescription provider Country A and B NCPs

FR19- Prescribed medicine data sent to country A

FR19	desirable but not minimum: Prescribed medicine data sent to country A
Description	The information (minimum and maximum datasets described in section 6.2) about the prescribed medicine event must be sent to country A. If there is more than one medicine prescribed, the fields related to identification of patient, prescriber and theprescribed medicine data sets will be per medicine prescribed. In the case that the prescription contained several items, there will be a set of patient, prescriber and prescribed medicine data per item.
Associated Goals	• Safety reasons
Actors	Prescriber Prescription provider Country A and B NCPs

- Use case 2:'Medicine newly prescribed in country B' (and dispensed in country B)

Eight major actions are identified for the description of the Use case:

UC 2 Action list
A: Check Patient ID
B: Consult, if patient consent is given, Medication Summary with the current prescriptions (if available, it is not a minimum requirement but desirable) and other data of the PS
C: Prescribe Medicine
D: Send information about the prescribed medicine to country A
E: Check patient ID at the pharmacy
F: Consult, if patient consent is given, current prescriptions (if available, it is not a minimum requirement)
G: Dispense medicine
H: Send information about the dispensed medicine to country A

Table 6 Use Case 2 description

UC 2	Medicine newly prescribed in country B
Goals	The goal of this use case is to allow a doctor in country B to create a new prescription to a foreign patient from country A in a secure and effective manner using electronic prescribing and allow the patient to retrieve the prescribed medicine in a country B pharmacy.
Functional Requirements to be fulfilled by country A	FR02, Trust between countries FR03, Patient identification FR04, Patient consent FR20, Information traceability
Functional Requirements to be fulfilled by country B	FR01, HCP Identification FR02, Trust between countries FR03, Patient identification FR04, Patient consent FR05, Structured information FR06, Equivalent information FR07, Information understandable FR11, desirable but not minimum: Access to current prescriptions by dispenser

	FR12, Original prescription FR15, Dispensed medicine data sent to country A FR17, Original dispensed medicine FR18, desirable but not minimum: Access to Patient Summary by the prescriber FR19, desirable but not minimum: Prescribed medicine data sent to country A FR20, Information traceability	
Actors	**Human actors**	**Technical actors**
	• Patient • Prescriber • Dispenser	• Prescription provider • Dispense provider • Logical node country A • Logical node country B
Preconditions	• A mechanism to validate the identity of the patient and to handle patient consent against country A has to be available at the Prescriber and Dispenser location (FR03, FR04) • The prescriber/dispenser is a person legally authorised in country B to prescribe/dispense medicinal products and is identified and authenticated in his/her prescription/dispense provider (FR01). • Preconditions about accessing the PS are described in D3.2.2 • Country B must provide, maintain and support a logical country node (NCP) supporting communication of information with country A and vice versa (FR20) • There is a chain of trust between system actors in this process (FR02) • All technical actors involved in the process must be able to retrieve all the information describing the process and the data involved in it. This includes the information identified in the description of the use case, such as the identification of the prescriber, the organisation of the prescriber, the patient, the description of the medicinal product dispensed…all this information must be able to be traced and recovered (FR20)	
Post conditions	• The prescriber has created a Prescription and this one has been made available to the pharmacy in country B • The patient will be able to withdraw the medicine in a pharmacy in country B • Country A receives the information regarding the prescription (FR12, FR19) and the dispense (FR15, FR16) made in country B	

Normal sequence

Step	**Actions (or description)**	
	A: Check Patient ID[‡‡‡‡‡‡]	FRs fulfilled: FR 03
1.	A patient from country A visits a prescriber in country B.	
2.	The patient identifies himself.	
3.	The prescriber requests the validation of the identity of the patient through the prescription provider.	
4.	The prescription provider transfers this request to the NCP of country B.	
5.	The logical node of country B conveys the request to the NCP of country A.	

[‡‡‡‡‡‡] This step is exactly the same as in WP3.2

6.	The logical node of country A checks ID and provides to the NCP of country B the (positive or negative) patient's identification confirmation.	
7.	The NCP of country B provides the patient's identity confirmation to the prescription provider.	
	B: Consult, if patient consent is given, Medication Summary and other data of PS (desirable)§§§§§§	FRs fulfilled: FR04, FR18, 05, 06, 07
	C: Prescribe Medicine*******	
	D: Send prescription information to country A	FRs fulfilled: FR 05, 06, 07
8.	The prescription provider provides the prescription information to the NCP of country B.	
9.	The NCP of country B conveys this information to the NCP of country A (the epSOS format and a copy of the original prescription).	
	E: Check patient ID at the pharmacy	FRs fulfilled: FR 03
10.	The patient identifies himself.	
11.	The dispenser requests the validation of the identity of the patient through the dispense provider.	
12.	The dispense provider transfer this request to the NCP of country B.	
13.	The logical node of country B conveys the request to the NCP of country A.	
14.	The logical node of country A checks ID and provides to the NCP of country B the (positive or negative) patient's identification confirmation.	
15.	The NCP of country B provides the patient's identity confirmation to the dispense provider.	
	F: Consult, if patient consent is given, current prescriptions (it is a maximum requirement)	FRs fulfilled: FR 04, 05, 06, 07, 11
	G: Dispense Medicine†††††††	
	H: Send dispensed medicine information to country A	FRs fulfilled: 15, 16, 17
16.	The dispense provider provides the dispensed medicine information to the NCP of country B	
17.	The NCP of country B conveys this information to the NCP of country A (the epSOS format and a copy of the original medicine dispensed).	
	UC ends.	
Exceptions		
The identity of the patient cannot be properly validated in country A		
5	The logical node of country A informs the logical node of country B of the identification failure	
6	The logical node of country B informs the dispense provider of the identification failure.	
7	The prescriber informs of this failure to the patient. The validation of the identification might be requested again provided the number of attempts does not exceed the following figure "3". should the number of attempts exceed this figure, the use case is terminated. Should the validation be successful, the use case is resumed at step 6.	
The communication is breached somewhere during the process (steps A, B, C, F, G)		
	The prescriber or the dispenser needs to be informed of the issue and the probable cause (according to the step).	
	The prescriber or the dispenser (according to the dispenser) informs of this failure to the patient. The process might be repeated again, provided the number of attempts does not exceed the following figure "3". Should the number of attempts exceed this figure, the use case is terminated. This issue has to be logged and reported.	
The communication is breached at step D or H		

§§§§§§ The description of this step is made in WP3.2
******* How this prescription is done is a Country B process
††††††† How the dispense is done is a Country B process

	NCP of country B has to try 'x' number of attempts. If 'x' is exceeded, this failure has to be logged by the system and reported (x is to be defined by security services).
Maximums	
B	The NCP of country A, after checking if patient consent has been given, gets and provides to the NCP of country B the current prescriptions (within the medication summary) and other data of the patient summary.
F	The NCP of country A, after checking if patient consent has been given, gets and provides to the NCP of country B the current prescriptions.

15.3 Example of Use case: Storyboards

A person from Andalusia (Spain) is visiting Denmark for holidays and he will stay there during one month. We are going to show different examples about several possible situations that end up in a new prescription made in country B.

Patient with Long term treatment		
Case	**Situation in Denmark**	**Comments**
2.1	The current box is finished and the patient needs to collect a new one and the pharmacist considers he does not have enough information to safely dispense and recommends the patients to visit a prescriber	This situation should not be frequent as this is what epSOS LSP tries to solve
2.2	He loses his medicine, or forgets it…and the pharmacist considers he does not have enough information to safely dispense and recommends the patients to visit a prescriber	This situation will be very common as not all countries are allowed to make an emergency dispense (on a prescription already dispensed) and not all countries will send the current prescriptions to the pharmacists
A patient with a prescription (no Long term treatment)		
Case	**Situation in Denmark**	**Comments**
2.3	He could not collect the medicine in country A and needs it but the pharmacist considers he does not have enough information to safely dispense and recommends the patients to visit a prescriber	Normally he would have withdrawn the medicine beforehand and also this situation shouldn't be frequent as this is what epSOS LSP tries to solve
2.4	He loses his medicine, or forgets it…	Frequent situation but not as probable as patient with Long term treatment. Depending on the availability of the current

		prescriptions at the pharmacy, the result will differ
A person with no treatment		
Case	**Situation in Denmark**	**Comments**
2.5	He does not feel well and decides to visit a physician	The longer the person stays in country B, the more probable this situation is

15.3.1 Description and analysis of the use case

- Chronic treatment (cases 2.1 and 2.2 in table above): Patient with an ePrescription of 'omeprazol capsules for 1year'.

The prescriber checks how many boxes he needs while staying in Denmark and prescribes the patient 'omeprazol capsules' for the duration of time he considers.

- No chronic treatment (cases 2.3 and 2.4 in table above): Patient with an ePrescription of amoxicillin capsules for 7 days.

The prescriber checks the original prescription, consults with the patient what he needs and prescribes the patient 'amoxicillin capsules' for the duration of time he considers advisable.

Although the description of the situations is slightly different, the results are the same:

Description of the situation	**Result**
2.1: The current box is finished and patient needs to collect a new one. **There is an 'Available' ePrescription** 2.3 The patient needs to collect the medicine. **There is an 'Available' prescription**	The prescriber consults the current treatment and prescribes the patient the medicine needed. The prescription duration is up to the HCP's discretion
2.2: He has lost the current box(es), or has forgotten it (them)… **There is no 'Available' prescription.** *This situation can be caused because the patient has lost a package(s) or part of a package of medicine or he has forgotten it in Andalusia or the patient is taking more quantity of the medicines than he needs* 2.4: He has lost the medicine or has forgotten it…**There is no 'Available' prescription** *This situation can be caused because the patient has lost the medicine or he has forgotten it in Andalusia or the patient is using more quantity of the solution than he needs*	

2.5 He does not feel well and decides to visit a physician	The prescriber consult the PS and prescribes the patient a treatment for the period of time the patient is going to be in Denmark
All the boxes are going to be dispensed in Denmark and copies of these events (prescription and dispensed medicine) will be sent to Andalusia	

16 Annex II: Referring documents

Date	Type	Description	Version	Origin	Document
20/11/ 2008	Final	It establishes the scope of the epSOS LSP at a high level	0.9	epSOS WP5.1	D5.2.1 Initial Scope
27/03/ 2009	Draft	It reports on Opportunities and constraints of Participating MS architectures	0.9	epSOS WP1.1	Analysis and comparison of national plans/solutions
02/02/ 2009	Internal work document	It describes the project plan, methodology, work groups, tasks description…	0.4	epSOS WP3.1	Draft 3 1 project plan
25/02/ 2009	IHE work document	It describes IHE Hospital and Community Pharmacy Use Cases and Standards	1.0	IHE	IHE ePrescription white paper
03/02/ 2009	Internal work document	It describes the action points, next milestones and it is constantly updated	0.7	epSOS WP3.1	TASKs epSOS WP3.1
15/05/ 2009	Internal work document	It describes pros/cons of the business alternatives for Board decision	2.0	epSOS WP3.1	MSI_SSI_analysis
27/02/ 2009	Internal work document	It collects input from all MS about availability and mandatory of data elements	0.8	epSOS WP3.1	Questionnaire for the content of the national ePrescription
29/03/ 2009	Internal work document	It analyses all the inputs from all MS about the data fields used in their eP systems and proposes a dataset	0.8	epSOS WP3.1	Results & Proposal for Minimum Data Set
08/06/ 2009	Internal work document	It collects input from all MS about specific processes and concepts	0.1	epSOS WP3.1	Processes & concepts questionnaire
14/03/ 2009	Internal work document	It contains the analysis and questions from legal issues found in WP3.1 and the answers from the WP2.1	0.4	epSOS WP3.1	Request for clarification to WP2.1