REGERINGSKANSLIET

Annex I

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Ministry of Health and Social Affairs

Legal Secretariat
Legal Adviser
Aneta Blåder

Telephone +46 8 405 3487
Mobile +46 70 308 1173
E-mail aneta.blader@gov.se

National Institute for Health and Welfare Finland
Information Departement
Legal Adviser
Tanja Stormbom
Telephone +358 29524 7278
E-mail tanja.stormbom@thl.fi

Bilateral Agreement on cross-border exchange of e-prescriptions

Agreement

on cross-border exchange of e-prescriptions between the Kingdom of Sweden and the Republic of Finland

The Government of the Kingdom of Sweden and the Government of the Republic of Finland, hereinafter referred to as the Contracting States, wishing to [for final version]….:

PREAMBLE

The introduction of e-health solutions is one of the most important factors for modern, patient-centered and effective health care. Both Finland and Sweden have been participating in the large scale pilot (LSP) epSOS which aimed at creating a system for a cross-border exchange of e-prescriptions and patient summaries. The LSP epSOS ended on the 30th June 2014.

The cross-border exchange of e-prescriptions between the Contracting States during the epSOS phase has achieved at creating a workable system for a cross-border exchange. The Contracting States will therefore continue the exchange of e-prescriptions on a full nationwide scale by creating a common legal framework and a technical solution for the cross-border exchange.

The epSOS solution/system

The epSOS project was a system for international communication of national health records. The initial focus in epSOS was on the exchange of patient summary and e-prescriptions. All data was

intended to flow between national contact points, one in each participating country, which interacted with national databases for prescribers, pharmacies and other relevant systems in the interaction-chain. The system was comprised of a common set of security and communication standards supported by central services and directories.

The epSOS system worked by allowing healthcare professionals in a foreign country (country B) to receive information from a patients' medical records in his or hers country of affiliation (country A). The cross-border exchange of medical records was channeled through National Contact Point (NCP) in the countries involved.

Patients participating in the exchange needed to give two consents, a general consent for participating in the system thus making the e-prescriptions available for cross-border exchange and a specific consent for each healthcare situation.

The Finland -Sweden solution
The Contracting States will continue using the technical solution the Contracting states set up for cross-border exchange during the LSP epSOS.

The Contracting States will use the system of channeling personal data, including sensitive personal data through National Contact Point (NCP), one per each State.

The legal framework will be based on applicable EU legislation supplemented by this Agreement.

The Contracting States agree on applying the principles stated below:

- Legislation for dispensation is fully applicable for foreign inhabitants.
- Insurance systems or other systems for compensation due to medical negligence or corresponding erroneous treatment are fully applicable for foreign citizens.
- Reimbursement of medicine used in a Contracting State will not be used in the cross-border exchange.
- Intentional ... with criminal intent will be ... in accordance with applicable criminal law.

PART I
GENERAL PROVISIONS
Article1

Definitions

1. For the implementation of this Agreement:
    a) The term "legislation" means: the laws and regulations specified in Article 2;
    b) The term "competent authority" means: as regards Finland: The Government or the authority nominated by the Government, and as regards Sweden: The Government or the authority nominated by the Government;
    c) The term "competent institution" means: as regards Finland: …, and as regards Sweden: the institution responsible for the implementation of the legislation specified in Article 2;
    d) The term "reimbursement…."
    e) The term "e-prescriptions" ….
    f) Further definitions are defined in Annex xx

2. Any term not defined in paragraph 1 of this Article have the meaning assigned to it in the applicable legislation.

Article 2

Material Scope

1. This Agreement shall apply:
    a) as regards Finland, to all legislation concerning:
        i …..
        ii…..
        iii…..
    b) as regards Sweden to all legislation concerning:
        i…
        ii…
        iii…

2. This Agreement shall also apply to all legislation which will amend or extend the legislation specified in paragraph 1 of this Article.

3. It shall apply to any legislation which will extend to existing schemes to new categories of beneficiaries, unless, in this respect, the Contracting state which has amended its legislation notifies the other Contracting State within six months of the official publication of the said legislation of its objections to the inclusion of such new categories of beneficiaries.

Article 3

Personal Scope

Unless otherwise specified, this Agreement shall apply to all persons who are subjects to the legislation of either of the Contracting States.

Article 4

Equality of Treatment

Unless otherwise provided in this Agreement, in applying the legislation of a Contracting State, the persons specified in Article 3 shall receive equal treatment with nationals of that Contracting State.

Article x

PART II

Provisions concerning the applicable legislation

Article x

General Provision

Unless otherwise provided in Articles x-xx of this agreement, person covered by this Agreement shall be subject only to the legislation of the Contracting State providing health care.

Article xxx

Common legal framework

EU legislation
Unless otherwise provided in this Agreement the legal requirements for the cross-border exchange will be based on applicable EU legislation. Questions outside the scope of EU legislation are provided by this Agreement and the national legislation of the Contracting State providing health care.

Jurisdiction
The jurisdiction of each Contracting State will be applied for any occurrences within the borders of each state.

In a cross-border exchange the jurisdiction of NCP/A is applicable for the transmission until the NCP/B has received and formally accepted the transmission. The formal acceptance marks the

transition from the jurisdiction of country A to the jurisdiction of country B.

Patients' consent
The cross-border exchange of sensitive personal data is based on the participating patients consent given in accordance with national legislation of the country of affiliation.

Patients choosing to participate in the cross-border exchange will give two consents, a general consent for participating in the exchange thus making the e-prescriptions available across national borders and an additional consent at the pharmacy dispensing a requested medicine.

The consent must be given freely, specific and based on information [in accordance with national law in the country where the consent is given.

Participating patient has the possibility to give his or hers general consent on line.

Liability
Liability for prescribing medicine lies within the jurisdiction of country of prescription (country A).
Liability for translation lies within the jurisdiction of the country of translation /country/A). The original prescription will always be available as a PDF at the dispensing pharmacy.
Liability for dispensation lies within the jurisdiction of the country of dispensation (country/B).
Liability for transmission is determined by the formal acceptance of the transmission by NCP/B. Before the acceptance the liability lies within the jurisdiction of country A and after the acceptance the liability lies within the jurisdiction of country B.

Formal acceptance
The NCP/B has to formally accept a transmission of data from NCP/A. The acceptance is also the transition of the applicable jurisdiction to be used for the specific transmitted data.

Insurance
Insurances by a Contracting State for wrongful medical care covers all patients including foreign patients.

Formal requirements
Each Contracting State is responsible for the legality of its own e-prescriptions used in cross-border exchange and for all formal requirements for all parts of the process for the sending.

Each Contracting State recognizes the formal requirements applied by the other Contracting State.

Special drugs

PART III

National Contact Point

All cross-border exchange of personal data will be channelled through National Contact Points (NCP), one NCP per Contracting State.

Each Contracting State will appoint a legal entity to uphold the function as NCP. For purpose of this Agreement the NCP of the country of affiliation will generally be termed NCP/A and the NCP of the country of dispensation will be termed NCP/B.

The NCP of the country of affiliation (NCP/A) is responsible that e-prescriptions used in a cross-border exchange complies with all formal requirements in the country of affiliation until the transmission has been formally accepted by the NCP/B.

Unless otherwise provided the transmission of data from NCP/A has to be formally accepted by NCP/B.

Data controller
The NCP is the data controller for data within the borders of its country. The function as data controller passes from NCP/A to NCP/B when NCP/B formally accepts the transmission of data from NCP/A.

Technical system
The data exchange is regulated by common security- and communication standards supported by central services and directories.

Security of technical systems etc

Audit

Semantics

Identification of patients
The Contracting States ...

Part IV

Exceptions

Part .....
MISCELLANEOUS PROVISIONS

Article xxx

Administrative Arrangement

1. The competent authorities of the Contracting States shall conclude an Administrative Arrangement that sets out the measures necessary for the implementation of this Agreement.
2. The competent institutions and liaison bodies of each Contracting State shall be specified in the Administrative Arrangement.

Article xxxx

Administrative Collaboration

1. For the implementation of this Agreement, the competent authorities as well as the competent institutions of both Contracting States shall assist each other with regard to the determination of entitlement to or payment of any benefit under this Agreement as they would for the application of their own legislation. The assistance referred to in this Article shall be provided without mutual reimbursement of costs.

2. Where the legislation of on Contracting State provides that any document which is submitted to the competent authority or institution of that Contracting State shall be exempted, wholly or partly, from fees, including consular and administrative fees, the exemption shall also apply to corresponding documents which are submitted to the competent authority or institution of the other Contracting State in the application of this Agreement.

3. Documents and certificates which must be produced for the implementation of this Agreement shall be exempt from authentication by diplomatic or consular authorities. Copies of documents which are certified as true and exact copies by a competent institution of one of the Contracting States shall be accepted as true and exact copies by the competent institution of the other Contracting State without further certification.

Annex 1 (different q)

General consent online

Information before giving consent

Specification on

1. ePrescription
2. prescribing physician
3. prescribing healthcare professional
4. pharmacist
5. pharmacies
6. limitations,
7. number of expeditions,
8. packets size,
9. reiteration
10. Agents

- Purchase in a foreign pharmacy has to be paid in full at the pharmacy. Patient who want to be reimbursed for such a purchase have to apply in his/hers own country of affiliation.
- Electronic signatures used today – what is the difference (if any?)between the Fi and Swe system? Swe legal requirements – who is responsible today?
- Check limitations/time limit for patients rights to request logging made in the systems (patientsäkerhetslagen, patientdatalagen)

NCP
Tasks for the NCP

Procedure of transmission

Procedure of formal acceptance

Technical solutions, Technical details on the data system involved, security
Audit
Identification and authentication of the patient during dispensation
Authorization
Validity
Security (informations security)
Semantics

Annex

Abbreviations

DPC	Data Protection and Confidentiality
DPD	Personal Data Protection Directive (95/46/EC)
EC	European Commission
EHR	Electronic Health Record
epSOS	epSOS (Smart Open Services for European Patients)
EU	European Union
HCO	Health Care Organisation
HCP	Health Care Professional
LSP	Large Scale Pilot
NA	National Authority
NCP	National Contact Point
PoC	Point of Care
UC	Use case
WP29	Article 29 Data Protection Working Party

Annex

Definitions of concepts and key terms

Note: These set of definitions concern the usage of terms in this document. Where existing terms are considered insufficient for the purposes of this document they have been adapted accordingly. Explicit notifications to such changes have been provided.

Agreement the term means this Agreement including all its annexes.

Anonymous data in the sense of the Directive 95/46/EC can be defined as any information relating to a natural person where the person cannot be identified, whether by the data controller or by any other person, taking account of all the means likely reasonably to be used
either by the controller or by any other person to identify that individual, including access to publicly accessible data (e.g. phone books).

ATC means "Anatomical Therapeutic Chemical Classification" which is a system for classifying medicine (pharmaceuticals?).

Authentication Process to verify the claimed identity of a party 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.

Country A is the Contracting State of affiliation, i.e., the state where personal health data of a patient is stored and where he or she is insured. This is the country where the patient can be unequivocally identified and his or her data may be accessed.

Country B is the Contracting State of treatment, i.e., where cross-border healthcare is provided when the patient is seeking care abroad. This is a country, different from country A, in which information about a patient is needed to support the provision of healthcare

Data Controller shall mean the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of processing are determined by national or Community laws or regulations, the controller or the specific criteria for his nomination may be designated by national or Community law [Dir 95/46/EC].

Data Processor is a natural or legal person, public authority, agency or any other body which processes personal data on behalf of the *Data Controller* [Dir 95/46/EC].

e-prescribing 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

e-prescription means a prescription for medicines or treatments, provided in electronic format. A prescription is understood as a set of data such as drug ID, drug name, strength, form, dosage, indication.

epSOS; LSP epSOS means the Large Scale Pilot "epSOS Smart Open Services – Open eHealth initiative for a European larga scale pilot of patient summary and electronic prescriptions

Points of Care (PoC)**:** This is a location where an inhabitant of the Contracting States may seek healthcare services. It may be a hospital, a pharmacy, the practice of a registered healthcare professional or any other point of the health care system of country B, participating in the exchange.

Health Care Professional (HCP) is a person professionally qualified to deliver care; in epSOS the term is used as in Directive 2005/36/EC establishing rules for the mutual recognition of regulated professions.

Health Care Professionals are designated HCPs within the PoCs that are entitled to deliver the services.

Health Care Organisation (HCO) is any legal entity having legal capacity that relies on the usage of personal health related data in order to fulfill tasks or business purposes notwithstanding whether those tasks have been delegated by law or not. In certain cases a sole practitioner HCP may be both HCP and HCO.

Health Care Provider is an organization or person who delivers proper health care in a systematic way professionally to any individual in need of health care services.

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.

Legal entity is an individual or organization which is legally permitted to enter into a contract, and be sued if it fails to meet its contractual obligations.

Medical Record or ***Health 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 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 professionals (HCP) and health care organisations (HCO) personal health records maintained by individual patients have become more popular in recent years. All data collected in medical records shall be regarded as sensitive personal data and processed accordingly.

Medication Summary is all prescribed medicine for which the period of time indicated for the treatment has not yet expired, whether they have been dispensed or not. It's a synonymous record of current medication. It contains the following information of each one: active ingredient, strength, pharmaceutical dose form, posology, route of administration, onset date of treatment and duration of treatment.

National Contact Point (NCP) is an organization delegated by each participating country to act as a bidirectional technical, organisational and legal interface between the existing different national functions and infrastructures. The NCP is legally competent to contract with other organisations in order to provide the necessary services which are needed to fulfil the business use cases and support services and processes. The epSOS NCP is identifiable in both the epSOS domain and in its national domain, acts as a communication gateway and establishes a Circle of Trust amongst national Trusted Domains. The epSOS NCP also acts as a mediator as far as the legal and regulatory aspects are concerned.

Patient consent provided to the data controller or processor means any freely given explicit and informed indication of his/her wishes by which the data subject signifies his/her agreement to personal data relating to him/her being processed for a given purpose.

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 Personal data includes written data, images and audio data stored on any time or medium. [Dir 95/46/EC].

Processing of personal data ('processing') means any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction [Dir 95/46/EC].

Reimbursement

Semantic (identifiable data, interoperability, mapping, processing, transformation, transcoding, systems etc.

Value set

REGERINGSKANSLIET

Memorandum

22 October 2014

Ministry of Health and Social Affairs
Sweden

Legal Secretariat
Rättssakkunnig
Aneta Blåder
Telephone +46 8 405 3487
E-mail aneta.blader@regeringskansliet.se

National Institute for Health and Welfare Finland

Information Department
Legal Adviser
Tanja Stormbom
Telephone+358 29524 7278
E-mail tanja.stormbom@thl.fi

A sustainable legal basis for a cross-border exchange of of medical records/sensitive personal data within EU

Annex II

Annex II
The principles for the work on Finland – Sweden solution
The cross-border exchange during the epSOS phase was successful for testing the system as well as the possible need for an exchange on a permanent bases. The two countries therefore intend to continue the exchange of ePrescriptions on a full nationwide scale as soon as possible. The two countries are therefore now creating a common legal framework and a technical solution for the planned cross-border exchange. The Swedish-Finnish solution will continue using the epSOS technical solution as this technical set-up is working. The basic epSOS architecture with a NCP in each country is believed to help ease several legal challenges for cross-border exchange and Finland-Sweden will also adopt this system with one NCP per country as the channel for the data flow between the countries. The epSOS legal framework on the other hand is considered inadequate for use beyond the pilot phase. The legal challenges will be solved by a bilateral agreement for questions which are not met by existing EU legislation.

Basic principles

The following basic principles must apply for the exchange.

1. A common legal framework based on EU legislation supplemented with an agreement on questions outside the scope of EU legislation.
2. Patients' consent is the legal basis for the cross-border exchange of sensitive personal data.
3. Participating patient have to give a general consent for participating and a specific consent in a specific health care situation e.g. at a pharmacy.

4. The legal systems involved are fully applicable for foreign inhabitants.
5. Existing insurance systems or other systems for compensation due to e.g. medical negligence are fully applicable for foreign citizens.
6. The aim is to create a system which will, if possible, give the same security for patients in the foreign country as they have in their own country of affiliation. Therefore if, contrary to 1 & 2, there are provisions in the national legal systems that can only be used for citizens this problem has to be solved so that the aim is maintained.
7. Reimbursement or subvention by the state for medical purchase will not be part of the planned cross-border exchange, at least not in the very beginning. Purchase at a pharmacy has to be paid in full. Any demands for reimbursement will have to be solved within each national system.

The two countries have not identified legal hindrances for a cross-border exchange of ePrescriptions. Both countries are members of the EU. The legal framework will therefore be based on applicable EU legislation complemented with a bilateral agreement for legal requirements not met by the EU legislation.

Legal basis
The most important EU legislation to take into consideration is the Data Protection Directive **95/46/EC** and the Patient's Rights Directive

Jurisdiction
The jurisdiction of each country will be applied for any occurrences within the borders of each country. To simplify the question on the exact moment when the transmission of data has crossed the borders the NCP receiving the data from the country of affiliation will have to formally accept the transmission. The acceptance also marks the transition from one jurisdiction to another jurisdiction.

Patients' consent
For the cross-border exchange to function it is required for patients to give a general consent for participating in the system so that ePrescriptions can be made available across national borders. Another (*additional*) specific consent is to be given at the pharmacy dispensing the medicine (a *two-stage* consent solution). Furthermore, it will be essential that the electronic communication is encrypted, all transactions are logged and the log is made available to the subject (patient), either online or by request. It is recommended that the scope of the project and its architecture is also consulted and agreed upon with the Data Inspectorate (=DPA?) in each country.

National Contact Point for eHealth
One of the main challenges of cross-border cooperation is secure channels for the exchange of health information. The use of a NCP in each member country will be an important element for creating such a channel.

The NCP architecture as created in epSOS is to be used. A NCP is a legal entity with a control-function. Data exchange takes place through the various NCPs. The NCP will e.g. ensure that only valid prescriptions will be made available across national borders and that only authorized pharmacists / personnel can access the data.

Liability - jurisdiction between countries
In cross-border situations, the exchange itself create situations that complicates responsibilities in each Nordic country, such as errors in prescriptions from the doctor, errors related to the treatment and management [of the prescriptions] at the pharmacy, errors in, or during the translation process or errors relating to advise on how prescribed drugs should be used.

The main principles of liability can be described through some examples:

- *Liability for the proper prescribing of medications: Medications prescribed in country A for a patient from country A and dispensed in country B. The liability for prescribing in this case lies within the jurisdiction of country A.*
- *Liability for transfer/exchange: Country A is responsible for data content (data integrity) to the NCP in country B. If data is changed / modified during this phase then country A responsible. In practical terms it can be a challenge to identify where the transmission the data has changed. Logging can provide remedy.*
- *Liability for translation: The original prescription is always available as a PDF in epSOS. This is meant to reduce the risk related to translation. Each country is responsible for the translation from a common language (English) and from theirown language to the common language (English).*
- *Liability for dispensing: an error caused by the pharmacy falls within the liability rules in country B (where the action takes place). All Nordic countries have taken steps to ensure that potentially affected patients are covered by insurance-like schemes. It must however be considered whether these schemes cover foreign nationals who receive drugs prescribed*

on prescription from country B from a pharmacy in country A.

Insurance systems
In case of harm /injury/damage to a patient the jurisdiction of the country where the harm was caused (Country B) will be used for establishing damages or insurance compensation through the social security system, except when the liability is attributable to the improper prescription of medications by a prescriber residing in Country A. In this last circumstance the jurisdiction to be applied is that of Country A

Questions for national authorities
Question on matters that undergo a continuing change due to e.g. technical development will only be specified as principles in the agreement and the work on the details and the right to re-negotiate will be given to competent authorities. Such question are e.g. authorisation/authentication of health professionals, identification of patients, semantics, audit, dispensation to the patients' agent, storage of given consent, authorization, logging, cross-border identification of medicinal products, dispensing rules regarding substitution.

Technical solutions and information security
For a good cross-border exchange of prescriptions to work there is need for good technical solutions. The technical solution of the NCP can be developed by an external software company with the use of open source software ("OpenNCP").

Formal requirements
Each country of origin (country A) is responsible that ePrescriptions issued in country A are in accordance with all applicable legislation in country A.

Prescribing physicians etc.
The same principle applies for prescribing physician, pharmacist and pharmacies.

Special drugs etc
The same principle as above applies for special drugs, limitations, number of expeditions, packets size and reiteration.

Ethics etc
Every dispensation, whatever the origin of the ePrescription has to be dispensed in accordance with the legislation of the country of dispensation (country B).

Identification and authentication of the patient during dispensation

Each country has its own system of identification of its residents. Requirements for identification and authentication of patients with prescriptions from other Nordic countries should in principle be no different than for prescriptions issued in Sweden or Finland. Every country has to create systems for a secure identification of foreign patients.

ePrescriptions/Drugs asked for by an agent has to be dispensed in accordance with the legislation of the country of dispensation (country B).

Consent and access their own information

The Legal Network will in its report recommend that consent is used as the legal basis for the processing of personal data within the framework of this project as described by the Data Protection Directive 95/46/EC and the Patient Rights Directive in cross-border healthcare 2011/24/EU.

The same principle is to be used in the cross-border exchange between Finland and Sweden.

The article 29 WP recommends a two-stage consent solution. First, an explicit consent is necessary to make the information available in other countries. Such consent in country A will allow healthcare providers to develop specific data with the intent to make them available in the future to other healthcare providers in the context of epSOS, the second consent given expressly for the treatment of health information (dispensation of drugs) in country B.

It must also be made exceptions to the requirement for consent where the data subject is physically or legally incapable of giving his consent.

REGERINGSKANSLIET

Memorandum

22 October 2014

Ministry of Health and Social Affairs
Sweden

Legal Secretariat
Rättssakkunnig
Aneta Blåder
Telephone +46 8 405 3487
E-mail aneta.blader@regeringskansliet.se

National Institute for Health and Welfare Finland

Information Department
Legal Adviser
Tanja Stormbom
Telephone+358 29524 7278
E-mail tanja.stormbom@thl.fi

A sustainable legal basis for a cross-border exchange of of medical records/sensitive personal data within EU

Annex III

The Nordic Legal Network

For some European countries the epSOS exchange has to certain extent been successful. The Nordic Countries regard the eHealth solutions as one of the most important factors for modern, patient-centered and effective health care and have therefore followed the results of the epSOS pilot closely. The Nordic Council of Ministers eHealth group have established a Nordic Legal network for analyzing the legal requirements affecting cross-border exchange of ePrescriptions and the possibilities to set forth and develop a legal and technical framework for the exchange of Nordic ePrescriptions.

Legal aspects, obstacles

The Nordic countries have a comparatively similar legal approach to ePrescription particularly regarding cross-border possibilities. The Legal Network has not identified legal hindrances to cross-border ePrescription exchanges in the Nordic countries. There are however some differences that can create challenges. These could be solved through bilateral or multilateral agreements.

The joint Nordic Legal Network has given the following recommendations (summary).

1. EU legislation should be used as the legal common framework for the exchange. For EU countries this is necessary but it also affects countries outside the EU, the extent has to be set down each specific case.
2. Patients consent should be used as the legal basis for the processing of personal data.

3. Participation in the system will require a two-stage consent as recommended by the WP 29 in its recommendation to the LSP epSOS. The patient need to give a general consent for participating in the system so ePrescriptions can be made available across national borders, and one additional specific consent given at the pharmacy dispensing the medicine a *two-stage* consent solution).
4. It is essential that the electronic communication is encrypted, all transactions are logged and the log is made available to the subject (patient), either online or by request.
5. The scope of the project and its architecture should be consulted and agreed upon with the Data Inspectorate in each country.
6. Matters related to *reimbursement/subvention* will not be discussed in this phase of the project as digital cross-border reimbursement is out of scope. The matter is also financially, legally and technically complicated to solve. The possibility to apply for reimbursement from the patients' country of affiliation is for each country to decide upon e.g. in accordance with the Patients' rights directive 2011/24/EU when applicable.
7. It is essential to create secure channels for the exchange of health information. The NCP/epSOS architecture should be used with only one NCP in each participating country.
8. The NCP is a legal entity, either separate or part of another entity, with a control-function and the data exchange takes place through the various NCPs. The NCP will e.g. ensure that only valid prescriptions will be made available across national borders and that only authorized pharmacists / personnel can access the data.
9. The technical solution for the NCP is in reality just an extended service for the national solution. The premise for what can and should be exchanged and disclosed is set forth by the legal framework and the possibilities of prescription solution. The legal responsibility (liability for handling data) can be in same the establishment (legal entity) responsible for the prescription solution and for the NCP.
10. The data-exchange is regulated by decided common security- and communication-standards in epSOS and supported by central services and directories.
11. Based on *The Article 29* WP working document on the epSOS project ("*Working Document 01/2012 on epSOS* (WP189 the NCP in country A should be responsible for the *delivery* of patient data and the NCP in country B should be responsible for *retrieval* of patient data.
12. Liability - jurisdiction between countries
    In cross-border situations, the exchange itself create situations that complicates the responsibilities. The main principles of liability can be described through some examples:

- *Liability for the proper prescribing of medications: Medications prescribed in country A for a patient from country A and dispensed in country B. The liability for prescribing in this case lies within the jurisdiction of country A.*
- *Liability for transfer/exchange: Country A is responsible for data content (data integrity) to the NCP in country B. If data is changed / modified during this phase then country A responsible. In practical terms it can be a challenge to identify where the transmission the data has changed. Logging can provide remedy. Two possible solutions are either to allow forum shopping or to make the NCP/B acceptance of the transmission formal connected to the transition from one jurisdiction to the other.*
- *Liability for translation: The original prescription is always available as a PDF in epSOS. This is meant to reduce the risk related to translation. Each country is responsible for the translation from a common language (English) and from their own language to the common language (English).*
- *Liability for dispensing: an error caused by the pharmacy falls within the liability rules in country B (where the action takes place). All Nordic countries have taken steps to ensure that potentially affected patients are covered by insurance-like schemes. It must however be considered whether these schemes cover foreign nationals who receive drugs prescribed on prescription from country B from a pharmacy in country A.*

13. Formal requirements for ePrescriptions, prescribing physician, pharmacies, pharmacy personnel, special drugs. Principally, the formal requirements for a valid ePrescription must be harmonized for the solution to be effective and put to use. It is however probably not necessary that all formal requirements are harmonized to achieve a common cross-border Nordic solution. In a common solution all prescription must be valid but what makes a prescription valid does not necessarily need be identical (harmonized) in all countries. There will however be a presumption that there are no formal obstacles to counteract validity in other countries. Related and relevant is that it is also a conceivable solution where each country in addition has prescriptions that can only be dispensed / transmitted in the issuing country.
14. All data exchanged in the system must be validated.
15. Requirements for identification and authentication of patients with prescriptions from other Nordic countries should in principle be no different than for the prescriptions issued in Norway.

16. A system for translation is necessary. This means that epSOS' semantic engine must be considered. This will also include matters of liability in regards to the translation and use of such an engine. The chosen language and code must be able to be communicated between the countries.
17. It must also be made exceptions to the requirement for consent where the data subject is physically or legally incapable of giving his consent.
18. The prescriber is identified with e-ID. The control of the prescriber having valid prescribing rights and that he or she has the proper rights to prescribe the drug in question is checked against the health professional register (HPR).