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Bilateral Agreement on cross-border exchange of ePrescriptions

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 Parties, wishing to arrange the mutual relations between the two States in the field of cross-border healthcare, have agreed as follows:

PREAMBLE

The introduction of e-health solutions is one of the most important factors for modern, patient-centered and effective health care. Finland and Sweden participated 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 cross-border exchange during this phase achieved its' aim for a short period of time. The Contracting Parties will through this Agreement 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 Contracting Parties agree on applying the following principles for the exchange.

The cross-border exchange will be based on applicable national legislation and EU legislation supplemented by this Agreement.

Unless otherwise specified, this Agreement shall apply
for all inhabitants with the right to social security of either of the Contracting Party,
All healthcare treatments, including dispensation will be performed in accordance with the legislation of the country of care.

Methods for compensation for medical negligence or erroneous treatment are fully applicable for all participating patients.

Reimbursement for medicinal products will not be included in this Agreement. Purchase at 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.

Intentional actions with criminal intent will be dealt with in accordance with applicable criminal law.

The Contracting Parties will continue using the technical solution which was set up for cross-border exchange during LSP epSOS.

The Contracting Parties will use a system of legal entities functioning as national contact points (NCP) for the channeling of personal data. Each Contracting Party will appoint one legal entity to act as a NCP.

Definitions
for the purpose of this Agreement

Any term not defined in these definitions have the meaning assigned to it in the applicable legislation.

Agreement	This Agreement including all its annexes.
Anonymous data	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 "Anatomical Therapeutic Chemical Classification"	A system for classifying medicinal products
Authentication	Process for verifying 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	The country where an e-prescription is being prescribed, usually the country of affiliation
Country B	Contracting State of treatment, i.e., where cross-border healthcare is provided when the patient is seeking care abroad.
Competent authority	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
Competent institution	As regards Finland: …, and as regards Sweden: the institution or institutions responsible for the implementation of the legislation specified in Article X
Cross-border healthcare	Healthcare provided or prescribed in a Contracting Party other than the Contracting Party of Affiliation
Data Controller	A 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	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	The prescribing of medicinal products 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	A prescription for medicinal products 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	Large Scale Pilot "epSOS Smart Open Services – Open eHealth initiative for a European large scale pilot of patient summary and electronic prescriptions
Healthcare	Health service provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.
Health Professional,	A person professionally qualified to deliver health

HP	care within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the member State of treatment.
Health Care Provider	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
Insured person	As in article 3 Directive 2011/24/EU
Legislation	Applicable laws and regulations specified in Article x
Legal entity	An individual or organization which is legally permitted to enter into a contract, and be sued if it fails to meet its contractual obligations
Medicinal records	All documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process (article 3, 2011/24/EU)
Medicinal product	A medical product as defined by Directive 2001/83/EC
Medical device	A medical device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC
Medication Summary	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.
Member state of Affiliation	As defined in Article 3 in Directive 2011/24/EU
Member state of treatment	The Contracting Party on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established (Article 3, Directive 2011/24/EU)
National Contact Point (NCP)	A legal entity delegated by each Contracting Party to act as a bidirectional technical, organisational

	and legal interface between the existing different national functions and infrastructures.
Patient	Any natural person who seeks to receive or receives healthcare in a Contracting Party.
Patient consent	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	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].
Prescription	A prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so on the member State in which the prescription is issued (Directive 2011/24/EU)
Processing of personal data	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	Reimbursement of costs for medicinal product
Semantic	System for coding identifiable data used for interoperability
Value set	

Abbreviations
for the purpose of this Agreement

DPC	Data Protection and Confidentiality
DPD	Personal Data Protection Directive (95/46/EC)
EC	European Commission

EHR	Electronic Health Record
epSOS	Smart Open Services for European Patients
EU	European Union
HCO	Health Care Organization
HP	Health Professional
LSP	Large Scale Pilot
NA	National Authority
NCP	National Contact Point
WP29	Article 29 Data Protection Working Party

Applicable legislation

Unless otherwise provided in this Agreement the legal requirements for the cross-border exchange will be based on EU legislation and the national legislation of the Contracting Parties. 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.

The jurisdiction of NCP/A is applicable for a transmission of e-prescription 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

Participating patient must give their general consent for the exchange of their sensitive personal data to be used in the cross-border exchange of e-prescriptions.

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

Participating patents must also give their specific consent for the use of their sensitive personal data for each particular health care situation.

Patients' general consent must be given in accordance with national legislation of the country of affiliation.

Patients' specific consent must be given in accordance with national legislation of the country of treatment.

All consent must be given freely, specific and based on information in accordance with national law of the country of consent.

Before giving any consent the patient must be given information on the legal meaning of the exchange of personal data. This information shall also include information on possible differences between the Contracting Parties in their processing of personal data.

Liability

In a case of liability the following principles applies for establishing he applicable jurisdiction:

- Liability for prescribing medicinal products is covered by the jurisdiction of country of prescription (country A).
- Liability for translation is covered by the jurisdiction of the country of translation (country A).
- Liability for dispensation is covered by the jurisdiction of the country of dispensation (country/B).
- Liability for transmission is determined by the formal acceptance of the transmission by NCP/B. For any acts occurred before the formal acceptance the liability is covered by the jurisdiction of country A. Once the NCP/B has formally accepted the transmission of data the liability is covered by 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.

Until the fulfilment of the formal acceptance the jurisdiction of NCP/A is in force.

Insurance

Insurance or any other systems for compensation for medical negligence or wrongful medical care covers which are used by a Contracting State must also include foreign patients.

Formal requirements

Each Contracting Party is responsible for the legality of its own e-prescriptions used in the cross-border exchange.

Each Contracting Party is responsible is for the fulfilment of all formal requirements for the entire process of transmission within its' own borders.

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

Special drugs

Special drugs as defined in Annex XX are not included in the cross-border exchange.

National Contact Point

All cross-border exchange of personal data will be channelled through legal entities acting as national contact points (NCP), one NCP per Contracting Party.

Each Contracting Party will appoint a legal entity to uphold the function as NCP.

The NCP of the country of prescription is responsible that e-prescriptions used in the cross-border exchange comply with all its' formal requirements.

The NCP of the country of dispensation is responsible that the dispensation comply with all its' formal requirements.

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 personal data processed within its' own the borders. The function as data controller passes from NCP/A to NCP/B with the formal acceptance of a transmission of data.

Identification of patients

The Contracting parties ...

Agents for patients will be accepted if requirements stated in Annex xx are fulfilled.

Technical system

The data exchange is regulated by common security- and communication standards supported by central services and directories as specified in Annex XX.

Requirements for Security of technical systems, audit and semantics are specified in Annex xx

Annex 1

General consent online

Information before giving consent must contain …

The information has to be given by ….

Specification on

1. Requirements for valid e-prescriptions
2. limitations,
3. number of expeditions
4. packets size,

- The original prescription will always be available as a PDF at the dispensing pharmacy.
- reiteration
- prescribing physician has to be … in accordance with..
- other prescribing healthcare professional
- dispensing pharmacist
- dispensing pharmacies

identification of patients and possibility of agents for patients

- Electronic signatures

Special extra 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 (information security)

Semantics