



**Ministry of Health and Social Affairs
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Legal Secretariat

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PREAMBLE

The State of [insert State name], the State of [insert State name], The State of [insert State name], the State of [insert State name], and the State of [insert State name], are Contracting parties (signatories) to this Agreement

Having regards to

- The Treaty on the Functioning of the European Union, and in particular Article 168(7) thereof as this Agreement falls under the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care, including the management of health services and medical care and the allocation of the resources assigned to them.
- Article 8 of the Charter of Fundamental Rights of the European Union which provides for the right to the protection of personal data and Directive 95/46/EC obliging Member States to protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data.
- Article 35 of the Charter of Fundamental Rights states that everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices and a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
- Article 11 of Directive 2011/24/EU obliges the Member States to recognize prescriptions issued in another Member State.

- Article 14 of Directive 2011/24/EU obliges the Union to support and facilitate cooperation and exchange of information among Member states working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States (the “eHealth Network”).
- The eHealth Network (eHN) set up by Directive 2011/24/EU is the main strategic and governance body with the task of setting up an interoperability framework for cross-border eHealth services.
- The eHN Interoperability Framework must create a sustainable legal basis for the cross-border exchange by supplementing EU law through an agreement open for any EU/EEA/EFTA Member state wishing to participate.
- The Agreement will be a multilateral voluntary contractual agreement setting the legal basis for the eHN cross-border exchange of personal health data within EU/EEA/EFTA/?.
- As the Agreement is for the exchange of personal data for cross-border healthcare, the EU law particularly important to be taken into account are Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare and Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- This Agreement is made to enable the cross-border exchange to be executed by methods stated in this agreement and its annexes.
- This Agreement is a legal agreement between its signatories.
- This Agreement does not intend to change or interfere with national legislation.
- This Agreement is open for all member states of the European Union/EEA/EFTA/?.
- All member states are free to choose whether to participate or not in the signature of the Agreement. Once a Member state has entered into the Agreement it is obliged to fulfil all the requirements stated in the Agreement.
- All parties to the Agreement have the right to choose, in accordance with their own national legislation, the method for the fulfilment of the requirements

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

THE PARTIES HAVE HERETO AGREED AS FOLLOWS**Section I
Definitions**

The herein terms printed with an initial capital letter shall have the following meanings unless the context otherwise requires:

“Agreement” means this Agreement including all its annexes.

“Authentication” means a process for verifying the claimed identity of a party before authorising a particular action to be performed

“Authorization” means a process by which entitlement of a requester, to access or use a given service, is determined.

“CBeHIS” means the Cross Border eHealth Information Services

“Country A” means the country of origin for an e-prescription or a patient summary; usually the country of affiliation

“Country B” means a Contracting State of treatment, i.e., where cross-border healthcare is provided

“Contracting party” means a party that has signed this Agreement.

“Cross-border healthcare” means healthcare provided or prescribed in a Contracting Party other than the Contracting Party of Affiliation

“Data Controller” means 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” means 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” means 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

“ePrescription” means 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.

“Patient summary” means

“Formal acceptance (by country receiving data)” means

“Guarantee for sending data” means

“NCPeH” means

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To be elaborated and coordinated with the work of other Jasehn WP

Section II

General objectives and scope

Clause 1

This Agreement is the legal basis for the processing of personal data concerning health for the purpose of cross-border healthcare.

Clause 2

This Agreement is without prejudice to EU law.

Clause 3

This Agreement supplements all applicable EU law. Of special importance for the realization of this Agreement are

- Directive 2011/24/EU by supporting a high level of human health protection across borders via electronic means, and
- Directive 95/46/EC for the protection of individuals with regards to the processing of personal data,

Clause 4

4.1

This Agreement applies to requirements for cross border health care as laid down in this Agreement.

4.2

Current cross border health care services are the ones set forth in annexes X and Y, without prejudice of the adoption of further services in accordance with the development of technological and organizational assets that can lead to the increasing of such services.

Clause 5

This Agreement applies to processing of personal data within the EU/EEA/EEA and Switzerland (EFTA/candidate countries/other third countries

Clause 6

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

Clause 7

All health care treatments, including dispensation will be performed in accordance with the legislation of the country of care.

Clause 8

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

Clause 9

State insurance systems or other systems for compensation due to medical negligence or corresponding erroneous treatment are fully applicable for foreign citizens.

Clause 10

Health care treatment including purchase of medicinal products has to be paid in full in the country of care. National systems for reimbursement will not be applied in the country of treatment. Patient who want to be reimbursed for medical cost has to apply for this in accordance with the legislation of a patients' country of affiliation.

Section III
General Obligations of the Contracting parties

Clause 11

Disclosure of data and direct access

The Contracting Parties of this Agreement shall ensure that the data mentioned in Annex XX is disclosed to another contracting party upon request according to the organizational framework and semantic and technical requirements set out in Annex Y and Z. The requesting Contracting party shall also have direct access to the same data according to Annex XX.

Clause 12

Data protection

The Contracting parties are responsible for establishing a system for lifting the prohibition of the processing of personal data concerning health, set out in Annex X, for the case situations referred to in Annex S, in accordance with Article 8 of the Directive 95/46/EC [Data Protection Regulation] as implemented by their national law,. This clause shall be without prejudice to national laws providing that the prohibition referred to in Article 8(1) may not be lifted according to Article 8(2)(a) of the same Directive/Regulation.

Clause 13

Information

The Contracting parties shall ensure that information is given to the data subject in accordance with Articles 10 and 11 of Directive 95/46/EC and Article 4 and 5 and 6 of Directive 2011/24/EU (see Annex I)

Clause 14

Governance body

The Governance body shall consist of X (should be an independent body).

The rules of procedure of the Governance body shall determine the procedure for entering the Multilateral Agreement and evaluating the implementation of the Agreement.

The Governance body shall decide when a country has fulfilled the obligations of this Agreement in order to enter the Agreement.

The Governance body shall monitor the Contracting parties implementation of this Agreement.

The Governance body shall in cooperation with the Contracting Parties decide on changes to the Annexes X, Y and Z

Section IV
Relationship between the Contracting Parties to the Agreement

Clause 15

Governing law and jurisdiction

15.1 This Agreement shall be governed by and construed in accordance with the law of the European Union complemented, where necessary, by national law.

Disputes between private parties

15.2. In civil and commercial matters, any disputes between private parties, controversy or claim arising out of or relating to this Agreement are subject to the jurisdiction established in accordance with the Regulation (EC) No 1215/2012 (Brussels I).[According to Article 4.1 the main principle of the Regulation is defendant's domicile].

15.3 The applicable law on any disputes between private parties on non-contractual matters is regulated by Regulation (EC) 593/2008 (Rome I). The law on any disputes between private parties on contractual matters is regulated by Regulation (EC) 864/3007 (Rome II). This clause concerns i.e. applicable law on tort and medical liability.

Disputes between Contracting Parties

15.4 If a dispute between Contracting Parties is not amicably resolved the dispute shall be subject to the jurisdiction of the country where the legal matter has its origin. This shall be the jurisdiction of the country of formal acceptance (c.f. definitions).

Clause 16

Term and termination

16.1 This Agreement shall subsist until it is either replaced by another Agreement or it is terminated in accordance with paragraph 2 of this Clause.

16.2 This Agreement shall only be terminated if agreed in writing unanimously by the Contracting Parties.

Clause 17

Withdrawal by a Contracting Party

Should a Contracting Party decide to withdraw from the Agreement, the Contracting Party shall notify the Governance body prior in writing.

Clause 18

Signature

18. 1 This Agreement shall be open for signature by the member States of the EU/EEA/EEA and Switzerland/candidate countries/other third countries

18.2. Should a country among those referred to in paragraph 1 decide to join the Agreement, it shall inform the Contracting Parties in writing, through the Governance body.

18.3 The signature of the Agreement by a joining country means that it accepts unconditionally all stipulations of the Agreement as well as all decisions already adopted by the Governance body [or any other relevant decision making body].

18.4 This Agreement shall be established and executed in the equally authentic linguistic versions.

18.5 The Contracting Parties shall sign one or more duplicates of each of the linguistic versions of this Agreement. Signatures on different duplicates of an authentic linguistic version shall have the same effect as if the signatures were on a single duplicate of this Agreement.

Clause 19

Entry into force

This Agreement shall enter into force 14 days following the day on which the Governance body has received a signed duplicate of this Agreement from each Contracting Party in all authentic linguistic versions, the Governance body has signed a duplicate in the same authentic linguistic versions, and one third of all Contracting Parties have submitted to the Governance body the Confirmation of completion of national procedures for the approval of this Agreement or the absence of a need for such procedures.

Clause 20

Confidentiality

Any information received by a Contracting Party under this Agreement shall be treated as confidential in the same manner as information obtained under the domestic law of that Party and may be disclosed only by persons or authorities (including courts and administrative bodies) in the jurisdiction of the Contracting Party concerned with the assessment or collection of the

Section V

Requirements for participation

Clause 21

Applicable Jurisdiction during transmission of data in cross-border exchange

21.1

The jurisdiction of each Contracting State will be applied for any legal matter that has its origin within the borders of that state.

21.2

During transmission of personal data concerning health for the purpose of cross-border healthcare the jurisdiction of Country A is in force until Country B has formally accepted the transmission. The formal acceptance marks the transition from the jurisdiction of country A to the jurisdiction of country B.

21.3

Non- repudiation (to be elaborated)

Clause 22

Secure gateway between Contracting parties

22.1

Each Contracting party must establish a secure gateway for the transmission of data between to other Contracting parties

22.2

As secure gateway for the transmission of data to other Contracting parties, each Contracting State must establish an NCPeH compliant with the OFW-NCPeH as provided for in Annex xx. Each Contracting State must establish an NCPeH compliant with the OFW-NCPeH, see Annex xx.

Clause 23

Legality of data sets

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

Clause 24

Responsibility for transmission

24.1

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

24.2

Each Contracting State must establish a system for the fulfilment of the formal requirements for transmission of data as provided for in Annex zz .

Clause 25**Consent and information**

25.1

Participating patient must give his or her valid consent in MS A for the exchange of their sensitive personal data to be used in the cross-border exchange of e-prescriptions.

25.2

Participating patients must also give their valid consent for the use of their sensitive personal data in each particular health care situation in MS B.

25.3

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

25.4

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

25.6

Participating patients will have the possibility to give his or her consent on line.

25.5

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 sensitive personal data.

Clause 26**Liability in health care relations**

26.1

Liability due to the cross-border exchange in this Agreement is covered by the jurisdiction of the country where the harm is shown to have occurred.

26.2

Jurisdiction on liability for transmission is determined by the formal acceptance of the transmission by NCPeH/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.

Clause 27**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.

Clause 28

Identification of patients

to be elaborated with group WP X ?

Clause 29

Authorisation of health care professionals

to be elaborated with group WP X during 2016?

Clause 30

Authentication of health care professionals

to be elaborated with group WP X during 2016?

Clause 31

to be elaborated with group WP X during 2016?

Clause 32

Audit

to be elaborated with group WP X during 2016?

Annex

1. **Requirements on MS for the set-up of NCPeH**
2. **Requirements on MS for identification of patients**
3. **Requirements on MS for authorization of**
4. **Requirements on MS for authentication of**
5. **Requirements on MS for security policy**
6. **Requirements on MS for audit**