



## RECOMMENDATION

for the Governance and Implementation of the  
**Agreement between National Authorities or National  
Organisations responsible for National Contact Points for eHealth  
on the Criteria required for the participation in Cross Border  
eHealth Information Services**

### Document Information:

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## TABLE OF CHANGE HISTORY

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**LIST OF ABBREVIATIONS**

<b>ACRONYM</b>	<b>DEFINITION</b>
CBeHIS	CROSS-BORDER eHEALTH INFORMATION SYSTEMS
CEF	CONNECTING EUROPE FACILITY
eHDSI	eHEALTH DIGITAL SERVICE INFRASTRUCTURE
eHMSEG	eHEALTH MEMBER STATES EXPERT GROUP
eHN	eHEALTH NETWORK
MS	MEMBER STATES
NCPeH	NATIONAL CONTACT POINT FOR eHEALTH
SP	eHDSI SOLUTION PROVIDER

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## 1. Introduction

Since November 2015 JAseHN WP6 (Monitoring and Assessment of Implementation) T6.2 (Development of legal interoperability in a cross-border context) continued the work done by the legal sub-group established by the eHealth Network (eHN) in November 2014. Main objective of this task is to create a stable and secure legal environment for cross-border data exchange. The activities of T6.2 mainly focusing on drafting a multi-lateral agreement that shall serve as a sustainable legal basis for cross-border exchange.

According to the projects timeline, T6.2 will present its deliverable, the *Agreement between National Authorities or Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross Border eHealth Information Services (later on referred to as Agreement)* on the 11<sup>th</sup> eHN in May 2017. In addition there will be an *Explanatory Note* on open legal questions and a *Recommendation for a Request to the Article 29 Data Protection Working Party (Art. 29 WP)*. Because the work of T6.2 is finished after the eHN in May, in order to safeguard the continuity of the legal work done so far by the eHN's legal sub-group and by the T6.2, and to fulfill the legal tasks that will emerge after the intermediate adoption of the Agreement, the upkeep of the work on legal interoperability must be secured, primarily the further implementation of the Agreement.

## 2. Purpose of the document

This document intends to give a broader overview and explanation to the content of the *Agreement between National Authorities or Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross Border eHealth Information Services* regarding

- the governance structure for the Agreement;
- the implementation process for the Agreement after its adoption by the 11<sup>th</sup> eHN on 9 May 2017.

In order to keep the Agreement as stable as possible while having the Annexes more flexible when it comes to updating, more generic terms are used when describing methodology and naming of governance structures (which might change in time).

For the sake of stability of the Agreement (meaning also the avoiding of potential amendments of the Agreement), the Agreement defines “Governing Body” merely as “eHN or another body agreed by the eHN” whereas the Governance is described in this separate document.

### 2.1 Governance structure of the Agreement

In order to implement the Agreement a governance structure must be in place. The request towards T6.2 by the European Commission and also from Member States was to use the existing governance schemes that are already in place enhancing the cooperation of Member States in the field of cross-border eHealth services and not to create parallel structures with same or similar tasks and responsibilities.

The method of the T6.2 drafting team was to identify all tasks that must be carried out by a Governing Body under this Agreement for the purpose of supporting the implementation of the Agreement and then to analyze the existing governance structures, the competences and responsibilities of the relevant bodies and based on this analysis the identified tasks were assigned to the most suitable bodies already operating in the existing structures (see Table 1. below).

Reference Clause	Identified tasks relevant for the implementation & governance of the Agreement	Assigned body
	adoption of the final version of the Agreement	eHN
I.4	consultation of the Article 29 Data Protection Working Party and following possible amendment of the Agreement	eHMSEG
III.1.1.1(2)	receiving and collecting the signed versions of the Agreement/written approvals from the Ministry responsible for eHealth	eHN Secretariat
III.1.1.1(2)	the Governing Body shall keep one signed version of the Agreement of all the Contracting Parties. The Governing Body keeps an updated list of all the Contracting Parties.	eHN Secretariat
III.1.1.3	amendment of the Agreement	eHN
III.1.2.1	decision on admission of a Contracting Party to participate in the CBeHIS	eHN
III.1.2.2(1)	receiving the written declaration of the Contracting Party on its withdrawal	eHN Secretariat
III.1.2.2(3)-(4)	decision on exclusion of a Contracting Party	eHN
III.1.2.2(4)	sending written notification to the Contracting Party of the decision on exclusion of the Contracting Party	eHN Secretariat
III.1.2.2(5)	executing an immediate interim technical suspension of a Contracting Party from the CBeHIS	eHMSEG
III.1.2.2(5)	sending immediate information to all Contracting Parties on the execution of an immediate interim technical suspension	eHMSEG
III.1.2.2(5)	decision on ending the technical suspension	eHMSEG

1. Table: Identified tasks and assigned bodies of the Agreement

According to the content of the table, tasks of the Governance Body under this Agreement are to be carried out by these bodies:

1. eHN
2. eHN Secretariat
3. eHMSEG.

Ad 1. Article 14 of the Directive 2011/24/EU assigned the European Union to support and facilitate cooperation and the 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) is currently the high-level decision making body on eHealth politics. Therefore, the major tasks that have political relevance were assigned to the eHN.

Ad 2. According to the Article 4 of the Rules of Procedures of the eHN, the European Commission shall provide secretarial support for the Network and any sub-groups created by the Network. All administrative functions that support the implementation of the Agreement were assigned to the eHN Secretariat.

Ad 3. eHMSEG is a body that is part of the governance model for the eHealth Digital Service Infrastructure during the CEF funding. eHMSEG is a group representing the participating Member States, which is responsible to provide assistance on the management of risks and opportunities, including existing or emerging service management issues, that affect the DSI and also to ensure that the national implementation solutions

- a. comply with legal agreements and provisions in force;
- b. comply with agreed technical solutions and specifications, in line with the guidelines adopted by the eHealth Network.

Beyond 2020, a new, permanent governance structure is needed for operation and maintenance of CBeHIS, meaning that the current governance model for the eHealth Digital Service Infrastructure during the CEF funding will most probably be replaced by the permanent structure. In order to prevent the possible amendment of the Agreement (without prejudice to its Clause I.4), referring to eHMSEG must be avoided in the text. That is why the Agreement only refers to eHMSEG and possible other bodies as “*another body agreed by the eHN*”. This method also gives the eHN the opportunity to alter the competent bodies at a later stage by the eHN.

## 2.2 The process of the adoption of the Agreement and the implementation process of the Agreement after its adoption by the eHN

The following process was identified taking into account the *Policy Paper on How to Assess MS Overall Readiness to Go Live* and the *Policy Paper on Assessment and Decision Procedures under the CEF Funding* but concentrating on the process that is relevant for adopting and implementing the Agreement.

1. **Adoption of the Agreement by the eHN** is foreseen at its 11<sup>th</sup> meeting on 9 May 2017. A final text will be then available for Member States.
2. In order to allow EU Member States and EFTA States to assess the final, adopted text and appoint the signing body/person, certain time must be provided for this signature process.

Member States of the EU and EFTA may sign the Agreement at any time but at the latest point before the Go Live decision of the eHN.

Signing the Agreement is only one requirement in the admission process. The whole admission process is described in details in *the Policy Paper on How to Assess MS Overall Readiness to Go Live* (to be adopted on the 11<sup>th</sup> eHN) and in the *Policy Paper on Assessment and Decision Procedures under the CEF Funding* (adopted by the 10<sup>th</sup> eHN, November 2016).

3. After signing the Agreement, **eHN will decide upon the admission** of Contracting Parties, according to the defined processes in *the Policy Paper on How to Assess MS Overall Readiness to Go Live* and in the *Policy Paper on Assessment and Decision Procedures under the CEF Funding*.
4. After signing the Agreement,
  - Contracting Parties and eHN members have the right to propose amendments to the Agreement according to Clause III.1.1.3(1) that is managed by the eHN Secretariat and decided upon by the eHN; Upon receiving such a proposal, the eHN Secretariat shall forward the proposal to the

other Contracting Parties; if the Contracting Party is not the eHN member and if that is necessary under the respective national law, the eHN member shall consult the Contracting Party before decision making in the eHN

This is without prejudice, that there can be proposals for amendments to the Agreement by eHN members before any Contracting Party has signed the Agreement.

- eHMSEG can execute immediate interim technical suspension;
- Contracting Parties can withdraw from the Agreement;
- eHN can exclude Contracting Parties from the Agreement;
- the Agreement can be terminated.

### **2.3 T6.2 proposal on the upkeep of the work on legal interoperability**

According to the projects timeline the T6.2 will present its deliverable, *the Agreement between National Authorities or Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross Border eHealth Information Services (Agreement)* on the 11 eHN in May 2017, thus the work of the T6.2 is finished. In order to safeguard the continuity of the legal work done so far by the eHN's legal sub-group and by the T6.2 and to fulfill the legal tasks that will emerge after the adoption of the final draft version of the Agreement, which includes the consultation of Art. 29 WP and possible amendment procedure after receiving the Opinion of Art. 29 WP, the upkeep of the work on legal interoperability must be secured.

T6.2 drafting team proposes therefore to:

1. Create a legal taskforce under eHMSEG for the immediate legal support (notably the consultation of the Art. 29 WP and following possible amendment of the Agreement according to its Clause I.4) and a legal subgroup under eHN for long-term legal sustainability for implementation and governance of the Agreement.
2. Plan for a legal task in the new Joint Action by introducing the topic to the new Multiannual Work Programme.

## **3. Recommendations**

The eHN members are asked to agree with the below listed recommendations:

Recommendation 1

- **The eHN agrees with the proposed tasks and bodies as described in *Table 1. Identified tasks and assigned bodies of the Agreement.***

Recommendation 2

- **The eHN agrees to set up a legal taskforce under eHMSEG for the immediate legal support and a legal subgroup under eHN for long-term legal sustainability for the implementation and governance of the Agreement and also plan for a legal task in the new Joint Action by introducing the topic to the new Multiannual Work Programme.**