

**11TH EHEALTH NETWORK, 9 MAY 2017, SAINT JULIAN'S, MALTA
EXPLANATORY NOTE BY JASEHN TASK 6.2 DRAFTING TEAM**

Topic 3: Agreement for the exchange of health data (agenda point 9)

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*” sets out the relevant legal framework comprised of EU law and Member States’ national law while aiming at non-interference with one or the other, and refers to all organisational, semantic and technical criteria as agreed by the eHealth Network and to be adhered to by the Contracting Parties in order to enable the safe and secure exchange of information in the relevant use cases of Cross-Border eHealth Information Services, namely Patient Summary and e-Prescription as well as possible further services as they will be agreed by the eHealth Network in the future. Joining the Agreement is voluntary, though its signature is a prerequisite for participation in the Cross-Border eHealth Information Services.

The enclosed final draft version of the Agreement and supporting documents consider the discussions of Member States’ representatives that took place at legal level on 16 March 2017 and at strategical level on 11 April 2017.

The purpose of this Explanatory Note is to raise all remaining open issues concerning the Agreement that could not be solved by JAsEHN Task 6.2 and, based on these, propose the next steps to be taken by the eHealth Network in order to achieve a sustainable legal framework.

I.) JAsEHN Task 6.2 has identified the following open legal and political issues concerning the Agreement:

Lacking clarity about the application of the General Data Protection Regulation (GDPR, Regulation 2016/679/EU) and involvement of the Article 29 Data Protection Working Party (Art.29WP)

The GDPR will replace the current Data Protection-Directive (95/46/EC) as from 25 May 2018, whereas the exchange of Cross-Border eHealth Information Services will already start before this date. Therefore, the final draft version of the Agreement refers (in the text) to the GDPR and additionally (in footnotes) to “Directive 95/46/EC until 24 May 2018”.

The final agreement on the GDPR was full of compromises detrimental to the text of the GDPR, leaving a broad scope for its interpretation by the Member States. Therefore, many legal issues remain unclear as shown in the current discussion of the “Commission expert group on the application of Regulation 2016/679/EU” led by the Commission (DG JUST), which consequently had negative repercussions for drafting the Agreement. In this regard, it is also unclear if the GDPR requires more detailed criteria in the Agreement (as requested by some Member States, seeing the Agreement rather as a Framework and basis for further agreements to be made), or if there is no need at all for such an Agreement since the legal basis for the processing does already exist in EU law and Member States’ national law (as promoted by the Commission, even assuming a free flow of personal data concerning health under the GDPR).

Within Task 6.2, the Commission (DG SANTE and JUST) was given the task to consider when and how to involve the Art.29WP. Since this task was not fulfilled, it was too late for receiving an Opinion of the Art.29WP which was declared as a showstopper by some designated Contracting Parties for their adoption and/or signature of the Agreement.

The lacking signature of the Agreement by the Commission regarding the “Core Services”

The eHealth Digital Service Infrastructure is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility. The eHealth Digital Service Infrastructure sets up and starts deploying the core and generic services, as defined in the Connecting Europe Facility, for Patient Summary and ePrescription. The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of Cross Border eHealth Information Services.

Based on the “Commitment of the European Commission to deliver the Core Services for eHealth Digital Service Infrastructure” that was sent on 16 February 2017 by the Commission (DG SANTE) to the Chair of the eHealth Member States Expert Group, the Task 6.2 drafting team came up with a proposal by excluding the Contracting Parties’ liability for Core Services under the Agreement. However, for at least one designated Contracting Party the above approach is still insufficient (and the signature of the Agreement by the Commission thus required) since Core Services cannot be separated from Generic Services but only the seamless flow of both together form the eHealth Digital Service Infrastructure, thus enabling the provision of Cross-Border eHealth Information Services.

Lacking clarity about the implementation of a technical suspension from the Cross-Border eHealth Information Services

Pursuant to the final draft version of the Agreement, an immediate interim technical suspension from the Cross-Border eHealth Information Services of a Contracting Party at its own discretion or by the Governing body may be executed in case the Contracting Party or the Governing Body identifies a security “risk” or an “incident” as defined under Directive 2016/1148/EU of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (NIS-Directive). The definitions in the NIS-Directive of the terms “risk” (meaning any reasonably identifiable circumstance or event having a potential adverse effect on the security of network and information systems) and “incident” (meaning any event having an actual adverse effect on the security of network and information systems) are referred to in the Agreement as definitional elements for an immediate interim technical suspension of a Contracting Party.

Within Task 6.2 it was found that this immediate interim technical suspension is legally required for the period *after* the admission of Contracting Parties by the eHealth Network to participate in Cross-Border eHealth Information Services, given that the “Policy Paper on assessment and decision procedures under CEF funding” (as adopted by the eHealth Network at its 10th meeting on 21 November 2016) foresees an initial audit before a Contracting Party is admitted by the eHealth Network to participate in Cross-Border eHealth Information Services but no periodic audit *after* a Contracting Party has been admitted.

However, the NIS-Directive obliges Member States to apply the measures necessary to comply with it only from 10 May 2018 (and to identify the operators of essential services with an establishment on their territory for each sector including health only by 09 November 2018), whereas the exchange of Cross-Border eHealth Information Services will already start before these dates. Therefore, it is yet unclear how the Contracting Parties will (legally) implement the terms “incident” and “risk” as definitional elements triggering an immediate interim technical suspension. Moreover, the Clause in the Agreement on immediate interim technical suspension does not contain any details on exact grounds or specific procedures for technical suspension since those must be added into the technical documents referred to in the Annex of the Agreement, though there is no clarity yet about the (technical) implementation of this legal requirement.

Different Contracting Parties for different Cross-Border eHealth Information Services within one Member State?

In at least one Member State, the different Cross-Border eHealth Information Services lie under the responsibility of different National Organisations (i.e. one agency for Patient Summary and another agency for ePrescription). Even though it seems that this issue needs to be solved at the

respective national level since each *National* Contact Point for eHealth must act as one (single) communication gateway, it was however requested by some Member States to raise this issue for consideration at political level.

II.) Seeking for a compromise between the foreseen adoption of the Agreement (which raises some designated Contracting Parties' concern due to the open issues with special regard to those on data protection) and its non-adoption (as a special issue for those designated Contracting Parties participating in the 1st wave under the Connecting Europe Facility), Member States' representatives have agreed to propose the following 4-steps-approach to the eHealth Network:

1. Adoption of the final draft version of the Agreement including supporting documents (as described below under point III.) by the eHealth Network at its 11th meeting on 9 May 2017.
2. Start of the process for signing the Agreement (according to the RECOMMENDATION for the Governance and Implementation of the Agreement; see below point III.) and parallel involvement of the Art.29WP as well as national Data Protection Authorities (according to the RECOMMENDATION for a Request of the eHealth Network to the Art.29WP; see below point III.).
3. Receive Opinion(s) of the Art.29WP as well as national Data Protection Authorities.
4. Amendment of the Agreement, if there is a need depending on the outcome of above step 3., within 12 months by the eHealth Network either at its 12th meeting in November 2017 or at its 13th meeting in May 2018 (according to Clause I.4 of the Agreement; see below point III.).

III.) Based on this proposed 4-steps-approach, the following documents are submitted to the eHealth Network for adoption:

- Final draft version 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
 - The Agreement includes the following Clause I.4:
“The eHN shall amend the Agreement according to Clause III.1.1.3 within 12 months from the adoption of the Agreement on 9 May 2017, depending on the need for such an amendment based on the evaluations and conclusions reached until then.”
- RECOMMENDATION for a Request of the eHealth Network to the Article 29 Data Protection Working Party
 - This document seeks to take account of some designated Contracting Parties' request for an Opinion of the Art.29WP; the template contained in the document may also be used accordingly for parallel requests to Data Protection Authorities at national level.
- RECOMMENDATION for the Governance and Implementation of the Agreement
 - This document applies once and as soon as the Agreement has been adopted by the eHealth Network. Since JAseHN Task 6.2 has ended with the submission of the above documents, the eHealth Network is recommended to set up a new legal group in order to ensure the upkeep of the legal work, including the consultation of the Art. 29 WP and following possible amendment of the Agreement according to its Clause I.4.