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To give a summary of the legal environment of the eHealth Digital Service Infrastructure (eHDSI) for the Members of the eHealth Network and a non-lawyer audience.

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Acronyms and Abbreviations

Acronym	Description
Agreement	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
CBeHIS	Cross-Border eHealth Information Services
CSIRT	Computer Security Incident Response Team
DPIA	Data Protection Impact Assessment
eHAction	eHealth Action – 3rd Joint Action supporting the eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
eHMSEG	eHealth Member States Experts Group
EHRxF	Electronic Health Record exchange format
eID	Electronic Identification
eIDAS Regulation	Electronic Identification, Authentication and Trust Services Regulation
eP/eD	ePrescription/eDispensation
EU	European Union
GDPR	General Data Protection Regulation
HCP	Healthcare Providers
Implementing Decision of the eHN	Commission Implementing Decision providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU
JA	Joint Action
LWG	Legal Work Group of eHMSEG
MWP	Multi-Annual Work Programme of the eHealth Network for the years 2018-2021
NCPeH	National Contact Point for eHealth - acting as organisational and technical gateway for the provision of CBeHIS
NIS Directive	Network and Information Security Directive
PS	Patient Summary
PIN	Patient Information Notice
WP29	Article 29 Working Party (Directive 95/46/EC)

Executive Summary

The document in hand, eHDSI Legal Report, intends to give a summary of the legal environment of the eHealth Digital Service Infrastructure (eHDSI) for the Members of the eHealth Network (eHN) and a non-lawyer audience.

The focus of the eHDSI Legal Report is on the legal applicability and impact of EU legislation, already in place or upcoming, on the eHDSI and its services – Patient Summary and ePrescription/eDispensation. It additionally outlines currently known open legal points, agreed or single legal interpretations in that context and tries to give guidance to the responsible governance bodies and working groups for next steps.

Nowadays activities and initiatives are still lacking available legal resources with adequate capacity to keep up with arising matters and proceed with the already identified tasks. For further continuation of work, a permanent work structure dealing with legal matters on eHDSI and beyond needs to be foreseen and established. This would secure not only the transfer of knowledge generated in past activities but also to encourage more Member States to participate permanently and, backed by their legal expertise, in an orchestrated manner towards concrete aims and outcomes on European level.

A draft version of the document at hand was tabled in the eHealth Network Meeting in June 2019 and is being tabled in its final version for information in their November 2019 meeting.

Introduction

D6.2 - eHDSI Legal Report intends to give a summary of the legal environment of the eHealth Digital Service Infrastructure (eHDSI) for the Members of the eHealth Network (eHN) and a non-lawyer audience. Its aim is to provide an increased legal awareness and legal certainty for eHDSI among Countries; and between Countries and the European Commission in order to address Priority C.3 (Legal Challenges) of the eHN's Multi-Annual Work Programme (MWP) for the years 2018 to 2021. Additionally, it identifies open legal topics in the context of eHDSI and gives, where possible, advice on how to overcome these.

The final version in hand briefly describes a non-exhaustive selection of relevant legal topics for the eHDSI implementation in Countries and gives guidance on future work approaches on legal matters.

Legal Environment of the eHealth Digital Service Infrastructure

The cross-border exchange of data supports cross-border healthcare and in so doing supports the continuity of care and the right of Europeans citizens to choose their healthcare provider and pharmacist in another Member State under certain conditions. In recent years efforts have been made to define and pilot services that enable paperless and secure data exchange. The Cross-Border eHealth Information Services (CBeHIS) are being prepared to go live in three annual waves by 2020. A fourth and subsequent wave is in preparation.

Finland and Estonia have already made a start in wave 1 with ePrescriptions: since 21st January 2019, Finnish patients are able to go to a pharmacy in Estonia and retrieve medicine prescribed electronically by their doctor in Finland[1]. Among other countries, Finland and Estonia signed 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" (Agreement) and provided legal bases in their national laws for exchanging ePrescriptions. The service is already in usage by a number of Finnish patients in Estonia; an average number of 600 dispensations were performed successfully per month and this number is still rising.[2]

Today there are 5 services in operation: Finnish patients are able to go to a pharmacy in both Estonia and Croatia and retrieve medicine prescribed electronically by their doctor in Finland. Additionally, Luxembourger health professionals can view the patient summary of Czech patients visiting Luxembourg. The routine operations just started in June 2019 and numbers of service usage are not yet available.

The following section provides a non-exhaustive description of the legal environment on a European level for eHDSI and CBeHIS. It is a given that all Directives must be implemented through national law, and even the General Data Protection Regulation (GDPR) as a hybrid instrument between Regulation and Directive should, at least in some points, be transposed into national law. Therefore, the focus of the document in hand is on the legal applicability and impact of EU legislation, already in place or upcoming, on the eHealth Digital Service Infrastructure and its services. It additionally outlines currently known open legal points, agreed or single legal interpretations in that context and tries to give guidance to the responsible governance bodies and working groups for next steps.

Cross-border Healthcare Directive[3]

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 (cross-border healthcare Directive) is the fundamental basis for cross-border healthcare provision within the EU. The eHealth Network laid

[1] http://europa.eu/rapid/press-release_IP-18-6808_en.htm

[2] The exact numbers of successful dispensations were 451 in February, 509 in March, 528 in April, 566 in May, 572 in June and 831 in July 2019.

[3] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32011L0024

down in Article 14 of the cross-border healthcare Directive is in charge of diverse eHealth objectives including the cross-border sharing of patient data. Details on the functioning and tasks of the eHealth Network can be found in the Commission Implementing Decision 2011/890/EU.[4]

Amendment of Implementing Decision of the eHealth Network

The Commission Implementing Decision providing the rules for the establishment, management and functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU (Implementing Decision of the eHN) has not been published in its final version at the time of writing.[5] In their meeting on 23rd September 2019 the Committee on Cross-border Healthcare voted in favour of the presented draft Implementing Decision except for Estonia, Cyprus and Ireland who abstained. Next steps are the translation of the text into all EU official languages, the adoption of the Implementing Decision by the European Commission, the publication of the Implementing Decision in the EU Official Journal and the entry into force of the Implementing Decision.

Before, during and after finalisation of the amended Implementing Decision of the eHN, a detailed analysis of the impact on eHDSI should be undertaken in order to identify possible implications and actions for the preparation of the upcoming go-live waves.

Commission Recommendation on a European Electronic Health Record exchange format

The Commission Recommendation EU/2019/243 on a European Electronic Health Record exchange format was published on 6th February 2019[6]. The Commission Recommendation is addressed to the Member States and is not legally binding. The Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union. The framework includes:

> (a) a set of principles that should govern access to and exchange of electronic health records across borders in the Union;
>
> (b) a set of common technical specifications for the cross-border exchange of data in certain health information domains, which should constitute the baseline for a European electronic health record exchange format;
>
> (c) a process to take forward the further elaboration of a European electronic health record exchange format.

It also encourages Member States to ensure secure access to electronic health record systems at national level.

The legal interpretations by the European Commission included in the document seem to require additional analysis, especially as it contains a legal interpretation on eIDAS Regulation, GDPR and NIS Directive in the context of a European Electronic Health Record exchange format which will

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011D0890

[5] https://ec.europa.eu/info/law/better-regulation/initiatives/Ares-2019-116373

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019H0243

somehow take advantage of the eHDSI at least in terms of its existing CBeHIS, namely Patient Summary and ePrescription. The laid-down legal interpretation on eIDAS eID (cf. recital 14) seems to be more restrictive than, for example, corresponding articles in the Agreement.

The Agreement, its Annex and referenced documents

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" (Agreement) was adopted by the eHealth Network in May 2017 and lays down legal boundaries for CBeHIS provision on the grounds of several applicable laws, such as GDPR and eIDAS Regulation. As at the time of writing, the Agreement had been signed by the organisation responsible for the NCPeH of Croatia, Czech Republic, Estonia, Finland, Ireland, Luxembourg, Malta and Portugal. Preparations by other Member States to sign the Agreement can be expected.

The eHMSEG has since endorsed an amendment to the Agreement in clause II.1.1.1 following the Opinion of the Art. 29 WP in alignment with Chapter III on Governance for the Agreement and its Annex. Further amendment requests from Member States to the clauses of the Agreement are not known and seem not needed yet.

However, clear addition of a mechanism and agreed operational responsibilities supervised by the eHealth Network should be agreed and established for the referenced non-legal documents included in the Annex of the Agreement. These source materials in the Annex seem to be technical in nature and because of that, at a certain point in time are to be considered outdated. According to the Agreement, however, the Annex is proclaimed to be legally binding despite its technical nature. The set-up of a routine check of the referenced documents in the Annex of the Agreement, for the sake of their technical correctness and legal clarity, is highly recommended and should be undertaken by the eHMSEG LWG.

General Data Protection Regulation

The Regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)[7], became applicable on 25th May 2018. The General Data Protection Regulation made it explicitly clear that personal data concerning health and health care services as referred to in the cross-border healthcare Directive were taken into consideration (cf. recital 35).

According to Article 35, a Data Protection Impact Assessment (DPIA) has to be undertaken by the data controller in diverse situations specified in the Regulation. A DPIA seems among others deemed to be required for the Go-Live in eHDSI and the sharing of cross-border eHealth data. A DPIA for eHDSI is made by each Member State alone and, due to highly confidential content of the DPIA, sharing of the original DPIA documents between Member States is not envisaged. However, it could be beneficial to document the DPIA process in Member States and share common risks and solutions for future reference (e.g. lessons learnt, repository of common methodologies, document structures, etc.).

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679

Article 9 of the Regulation provides the legal basis for processing special categories of personal data including health/patient data which needs to be further analysed for the cross-border exchange of data and may have significant impact on consent management and conditions for secondary use of data. The more general conditions on processing of data in Article 6 and Article 7 are not as specific as the conditions of Article 9.

As set forth in Article 12, 13 and 14, Member States should provide information to the patients about the exchange of their personal data in a cross-border setting, in a concise, transparent, intelligible and self-explanatory manner. An eHDSI Patient Information Notice (PIN) Repository, a solution meant for the uploading and presentation of the PINs from all Member States providing cross-border services, based on business requirements defined by the eHMSEG PIN Implementation Task Force[8], is now operational[9].

Electronic Identification, Authentication and Trust Services Regulation

Regulation EU/910/2014 on electronic identification and trust services for electronic transactions in the internal market, and repealing Directive 1999/93/EC became effective on 1st July 2016.

Member States are obliged to recognise notified eID Schemes after September 2018 for online services with a transition period up to then where recognition is on voluntary basis. There is no obligation for Member States to notify eID Schemes neither now nor in the future. A continuously updated list on notified and pre-notified eID schemes of Member States can be found on the eID User Community site of the European Commission[10]. It also provides hints whether the notified eID scheme is intended to be used for eHealth purposes, however, it is not a guarantee for CBeHIS usage. In cross-border cases, authentication assurance levels of eIDs pursuant to Article 8 shall be harmonised.

Electronic signatures are regulated under eIDAS (Chapter on Trust Services) which repealed the eSignature Directive 1999/93/EC and are to be implemented for the PS and eP/eD use cases of CEF eHealth. The eIDAS Regulation differs substantially from Directive 1999/93/EC and has already forced a preliminary update of the specifications governing the processing of digital certificates and electronic signatures of eHDSI. This update is, however, only capable of providing a temporary foundation for the first waves of the eHDSI. Therefore, the eIDAS trust services and its impact still needs to be analysed more thoroughly and further actions for implementation need to be initiated and undertaken by eHMSEG LWG in close cooperation with the eHDSI Solution Provider.

For eHealth, the different components of the eIDAS Regulation might provide a holistic framework and a toolbox for establishing trust in CBeHIS. Once fully implemented, the eIDAS Regulation will create enabling conditions for secure transfer of health data across borders in the EU, e.g. by overcoming the specific challenge that the involved human and organisational actors are usually only recognised within one of the participating countries while being active participants in flows in other countries. The eIDAS Regulation can foster the establishment of regulation-backed cross-border trust relationships between Member States and provide both the identification and

[8] The work of the eHMSEG PIN Implementation Task Force was carried out between September 2018 and March 2019.

[9] https://ec.europa.eu/cefdigital/wiki/x/XplqB

[10] https://ec.europa.eu/cefdigital/wiki/display/EIDCOMMUNITY/Overview+of+pre-notified+and+notified+eID+schemes+under+eIDAS

authentication of health professionals and patients as well as assure the integrity and confidentiality of the sensitive health data shared cross-border for eHDSI.

Network and Information Security Directive

The Directive on security of network and information systems (NIS Directive) became applicable in August 2016. It provides legal measures to boost the overall level of cybersecurity in the EU by ensuring:

- Member States' preparedness by requiring them to be appropriately equipped, e.g. via a Computer Security Incident Response Team (CSIRT) and a competent national NIS authority;
- cooperation among all the Member States, by setting up a cooperation group, in order to support and facilitate strategic cooperation and the exchange of information among Member States. They will also need to set a CSIRT Network, in order to promote swift and effective operational cooperation on specific cybersecurity incidents and sharing of information about risks;
- a culture of security across sectors which are vital for our economy and society and moreover rely heavily on ICTs, such as energy, transport, water, banking, financial market infrastructures, healthcare and digital infrastructure. Businesses in these sectors that are identified by the Member States as operators of essential services will have to take appropriate security measures and to notify serious incidents to the relevant national authority.

Operators of essential services in Member States have to comply with the requirements of the NIS Directive. It has to be analysed whether this is also the case for cross-border eHealth infrastructure and - if applicable - how this has to be implemented then for the eHDSI. Additionally, it has to be examined whether the freshly adopted EU Cybersecurity Act has any legal implications on cross-border data exchange.[11]

[11] http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2019-0151

Concluding Notes

The eHDSI legal environment is currently changing, due to further preparation of sustainable and long-term cross-border sharing of patient health data in the European Union; however, the current legal bases, enriched by national laws, are sufficient for the first cross-border data exchanges between Member States.

Despite the activities already completed and ongoing, some legal points in the eHDSI context are still not fully understood or solved (eIDAS Regulation, GDPR and NIS Directive), new ones arise with to-be-expected changes of eHealth governance (Amendment of Implementing Decision of the eHealth Network) and new objectives for cross-border eHealth are now visible on the horizon (Commission Recommendation on European Electronic Health Record exchange format). Additionally, some operational lessons learnt from implementing eHDSI in Member States bring aspects to the table which, at least partly, have legal relevance (e.g. Maintenance of the Annex of the Agreement with its non-technical referenced documents, Data Protection Impact Assessment). After a first look at the Commission Recommendation on European Electronic Health Record exchange format, one can also come to the conclusion that on certain points the legal interpretation differs between European Commission and Member States (e.g. eIDAS eID in eHealth[12]).

Further elaboration on the already identified open legal points needs to be done in order to give guidance on appropriate solutions. This was initiated by the eHealth Action Task 6.2 in close collaboration with the eHMSEG Legal Work Group.

Nowadays activities and initiatives are still lacking available legal resources with adequate capacity to keep up with arising matters and proceed with the already identified tasks. For further continuation of work, a permanent work structure dealing with legal matters on eHDSI and beyond needs to be foreseen and established. This would secure not only the transfer of knowledge generated in past activities but also would encourage more Member States to participate permanently and, backed by their legal expertise, in an orchestrated manner towards concrete aims and outcomes on European level.

[12] For more details see JAseHN Deliverable D5.2.1 Recommendation Paper on Policies regarding eIDAS eID and JAseHN Deliverable D5.2.3 Report on notified eIDAS eID Schemes