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Joint Action to Support the eHealth Network

GUIDELINE

on

the Interoperability of Electronic Professional Registries

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
CBeHIS	Cross Border eHealth Information Services
CEF	Connecting Europe Facility
DSI	Digital Service Infrastructure
EC	European Commission
eHDSI	eHealth Digital Services Infrastructure
eHN	eHealth Network
eHN-LSG	eHealth Network Legal Subgroup
EIF	European Interoperability Framework
eP	electronic Prescription
EU	European Union
IOP	Interoperability
HP	Health Professional
JAseHN	Joint Action for support the eHN
LOST	Legal, Organisational, Semantic, Technical
MLA/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 former Multilateral Legal Agreement (MLA)
MS	Member States (of EU)
NCP	National Contact Point for cross border
NCPeH	National Contact Point for eHealth
NI	National Infrastructure
OFW	Organisational Framework
OFW-NCPeH	Organisational Framework for eHealth National Contact Point
PARENT JA	Patient Registries Joint Action
PoC	Point of Care
PS	Patient Summary
ReEIF	Refined eHealth European Interoperability Framework

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1. Introduction

One of the main challenges in supporting the eHN (eHealth Network) ambitions for sustainability policies regarding assets in the field of eHealth cross-border interoperability is the bond between policies and service provision by Member States (MS).

In order to establish the bond and allow it to grow and endure a set of simple but well-aligned instruments need to be prepared. One of the crucial instruments is an Organisational Framework which describes, in a commonly understandable language, the principles and requirements for National Contact Points for eHealth (NCPeH). Another important instrument is the Guideline on the Interoperability of Electronic Professional Registries, which will discuss and recommend the minimum interoperability requirements for Electronic Professional Registries for electronic cross-border services under the Cross Border eHealth Information Services (CBeHIS). CBeHIS stands for the infrastructure and the operations used to exchange real patient related data, in particular health data, between its Members.

1.1 Purpose of the document

The purpose of this document is to propose a Guideline on the Interoperability of Electronic Professional Registries to support the alignment of interoperable Electronic Professional Registries in MSs for the provision of Cross-Border eHealth Information Services (CBeHIS). This document serves as a draft version of the future Guideline on the Interoperability of Electronic Professional Registries.

The draft Guideline on the Interoperability of Electronic Professional Registries was prepared based on accomplished activities and in close alignment with still ongoing activities, namely (but non-exhaustively):

- Organisational Framework for eHealth National Contact Points (OWA-NCPeH) adopted by eHealth Network
- 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) to be adopted by eHealth Network and to be signed by the competent national authorities.
- eID specific framework for eHealth Release 1 to be adopted by eHealth Network.
- Final results of the work of PARENT for patient registries "Methodological guidelines and recommendations for efficient and rational governance of patient registries".[1]
- Policy work done by organizations like CPME[2] for specific roles in eHealth "Ensuring the secure use of telemedicine and e-health applications in an integrated Europe – Towards a Common Policy Agreement on Electronic ID Systems for Physicians"

1.2 Scope

The Guideline on the Interoperability of Electronic Professional Registries lays down requirements supporting the interoperability of Electronic Professional Registries in MSs - considering the legal basis for CBeHIS provision in Europe. It does not aim to alter already existing national Electronic Professional Registries, but to provide Member States with viable aspects for future enhancements and strategic orientation towards cross-border interoperability.

1 see http://patientregistries.eu/ and http://parent-wiki.nijz.si/

2 see http://www.cpme.eu/cpme-policy-ensuring-the-secure-use-of-telemedicine-and-e-health-applications-in-an-integrated-europe-towards-a-common-policy-agreement-on-electronic-id-systems-for-physicians/

The Guideline on the Interoperability of Electronic Professional Registries will help MSs to overcome the common interoperability challenges regarding Electronic Professional Registries by providing which activities by, towards and between health professionals are required and where a minimum set of information is required to enable the following activities:

- situations in which registry reference and/or query is required
- minimum attributes to sufficiently satisfy a use case
- minimum requirements towards the quality, reliability and actuality of registries

The Guideline on the Interoperability of Electronic Professional Registries will only consider and thus apply to the Patient Summary (PS) and ePrescription/eDispensation (eP/eD) use case. However, specific adaptions of the guideline for additional use cases may be necessary at a later time.

1.3 Objectives

The Guideline on the Interoperability of Electronic Professional Registries will be provided in a draft and a final version:

Draft Guideline (Document at hand)
Provide a draft Guideline, which

- lays down structure and future content of the Guideline as synthesis of the analysis of identified already existing Electronic Professional Registries in MSs and other documented sources and
- builds a common understanding of Electronic Professional Registries and what is needed for their interoperability for CBeHIS.

Final Guideline (in November 2017)
Provide a final Guideline, which

- adds concrete requirements concerning required roles, minimum data set and specific use case needs for the interoperability of Electronic Professional Registry and
- adds common denominators which allows cross-border data exchange without interfering with the kind, complexity and actual implementation of existing health professional registers
- sets up sustainable principles and requirements for the alignment of interoperable Electronic Professional Registries in MSs for CBeHIS.

1.4 Initial Considerations

The overall structure presented in the Guideline on an Organizational Framework for eHealth National Contact Point (OFW-NCPeH) foresees several instruments to support CBeHIS in its preparation, deployment and operation phase. Each Member State aiming to participate in the eHDSI shall undergo all three phases. For every phase JAseHN provides supportive documents. The Guideline on the Interoperability of Electronic Professional Registries is one of these documents which address the Preparation and Deployment Phase.

Interoperability of professional health registries is required to enable, control and regulate access to health related information across and between jurisdictions, domains and concepts. It is not possible and also not required that the concepts, owners, granularities etc. of registries are made the same across jurisdictions as long as sufficient common ground can be found. This common ground has to be large enough to support identified use cases for cross border health care. While the common ground may be quite small it is imperative that it is encompassing all four domains of the refined eHealth European Interoperability Framework (ReEIF), i.e. legal, organisational, semantic and technical aspects.

The draft Guideline discusses and recommends the minimum interoperability requirements with a view to supporting the use cases Patient Summary and ePrescription foreseen for CBeHIS as starting points. At the point of time this document has been written JAseHN had not concluded its assessment of the impact of electronic identification (eID) und the eIDAS regulation. However, it is assumed that notification of health professional identification is not required. Although notification would not change the considerations of this document in principle there may still be significant impacts on registries in the Member States.

It is taken for granted that an electronic health professionals register is required for cross-border data exchange to identify if a person is entitled to access particular sets of data.

The draft Guideline on the Interoperability of Electronic Professional Registries was designed with reference to the refined eHealth European Interoperability Framework (reEIF).

2. Electronic Professional Registries (ePRs)

For the purpose of this guideline, an *electronic professional registry* is defined as an organized electronic system that provides the data and information for each individual belonging to a group of people defined by a particular *professional role*, and that serves predetermined scientific, clinical or/and public health (policy) purposes. In the context of CBeHIS the predetermined purposes are limited to the use cases Patient Summary and ePrescription.

A (health care) *professional* means

- a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist 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.

For the purpose of this guideline, the role of professionals and with that their entitlements to access data are of special interest.

There are various purposes for electronic Professional Registries. According to *ISO 21091:2013 Health Informatics – Directory services for healthcare providers, subjects of care and other entities* sixteen different healthcare scenarios for electronic Professional Registries were identified. They contain a wide range of administrative as well as treatment related scenarios including *patient care in another country* (see scenario A.4.12). Each healthcare scenario is shortly described and the services needed for a suitable electronic Professional Registry (there called healthcare directory) are named. The Guideline will take into account the requirements of scenario *patient care in another country* and include relevant aspects for PS and eP/eD in CBeHIS.

As the intended purpose of the electronic Professional Registry plays a significant role for their design the national legal basis needs to be considered carefully for each MS. If national jurisdiction limits the scope of the electronic Professional Registry to national or specific scenarios only, the usage of that Registry would probably not cover the cross-border scenarios PS and eP/eD of CBeHIS.

ePRs in Member States

This section gives a short overview on some already existing ePRs in Member States. It is a non-exhaustive list, which will be filled with more Member States ePRs.

Switzerland has a couple of different registers. The national register for qualified health staff (Nationales Register für Gesundheitsfachpersonen, NAREG) does e.g. exclude doctors, veterinaries, chiropractors, dentists and pharmacists who are listed in the Medizinalberuferegister, MedReg. Health professionals with psychological qualifications will be registered in a third system.

In **Luxemburg** a national healthcare provider directory is in place, which contains information about authorized health professionals and institutions from the Ministry of Health. This directory is used to determine online the profession and specialty of a health professional. Based on the profession a health professional may be authorized, due to the mapping of the professions to profiles/roles, to access the electronic health record of a patient (or even parts of it).

The **Swedish Professional Health Registry (HOSP)** is an updated register of licensed health care professionals in Sweden, which contains all national certifed professionals and is governed and managed by *The National Board of Health and Welfare*. A unique id (förskrivarkod) is used to identify the licensed health care professional.

Depending on the purpose health care professional in Sweden has a license (e.g. to practise medicine) or a temporary license (e.g. being a foreign doctor or a doctor in training). For licenses general rules are provided by the Patient Safety Law. Each eligible individual must apply to the *The National Board of Health and Welfare* and gets registered in the *Swedish Electronic Professional Registry*. For temporary licenses rules are provided by regulation of the *The National Board of Health and Welfare*.

The right to prescribe is differentiated in Sweden: Licensed doctors can prescribe drugs for the treatment of humans. Dentists, dental hygienists, midwives and some nurses and optician can prescribe a limited selection of medicines. A non-licensed physician must prescribe only within the framework of the mandate. Doctors' right to prescribe is not completely unlimited, special rules apply for some drugs. These Rules are governed and managed by *Medical Products Agency* and *The National Board of Health and Welfare*.

The following issues for the Swedish Professional Health Registry were identified in Sweden:

- Public vs private health care provider access to the registry
- Citizens possibility to check doctors via the registry
- Not all temporary licenses are registered in a formal national registry

The Austrian **e-Health-Verzeichnisdienst** (eHVD; www.eHVD.at) is an electronic professional registry which is based on national legislation (*Gesundheitstelematikgesetz*) and provides data on health care professionals and its roles.

The eHVD's primary objective is to confirm the identity and role of health care professionals for electronic communication of health data and by doing this to enhance data security. eHVD enables role based qualified data access for the future health portal. Additionally eHVD serves as the basis for secure, cross-border data exchange in European and international collaboration.

Every access to eHVD has to be done in conformance with the eGoverment's requirements via the eCard for Austrian Citizens. This means that every heath care professional needs a certified environment for the eCard to be registered in the eHVD.

Being a national and cross-institutional body the Austrian MoH is currently the provider of the eHVD. It is foreseen to technically and/or organizationally link the eHVD with already existing directories and data bases of viable institutions. These existing directories and data bases will not be replaced.

3. Interoperability of Electronic Professional Registries

The following sections lay down concerns, challenges and known possibilities or recommendations regarding Interoperability of Electronic Professional Registries. They are structured following the LOST approach according to refined eHealth EIF complemented by additional sections where needed.

3.1 General Considerations, Responsibilities and Duties

In order to provide sustainable interoperability between Electronic Professional Registries in MS towards CBeHIS provision it is necessary to take a look at the following general considerations especially towards responsibilities and duties of relevant actors.

- It is the obligation of the NCPeH of the MS to establish the communication with the national electronic Professional Registry. In case there is more than one electronic Professional Registry in a MS this still applies.
- The national electronic Professional Registry supports the sufficient and documented identification and authentication of (healthcare) professionals in this MS according to its national jurisdiction.
- A professional may have one or more roles and may be affiliated with multiple organisations.
- EU Alert Mechanism – Providing Safty and Mobility: From 18th January 2016 on, EU countries are required to warn each other through the IMI about professionals working in the fields of health or education of minors who have been prohibited or restricted from practice in one EU country, or who have used falsified diplomas in support of their application for the recognition of their qualification. The alert mechanism[3] will provide strong data protection safeguards for the professionals, and safeguard people who use the professional services.
- The regulated professions database based on directive 2005/36/EU[4] and set up by DG GROW[5] has harmonized minimal levels for these professions: Doctors, Dentists, Nurses, Pharmasist and Midwifes for Europe. It has to be analysed if and how this database may be helpful for providing the final Guideline on Interoperability of Electronic Professional Registries.

MS need to consider all above to provide access to their Electronic Professional Registry(ies) either directly or to assess the rightfulness of a communication request via the NCPeH and the national eHealth infrastructure.

3.2 Legal Environment

This section provides a non-exhaustive description of the legal environment on European level for electronic Professional Registries.

The main foundation of the Guidelines on the interoperability of electronic Professional Registries is the eIDAS Regulation and the General Data Protection Regulation, which applies to several domains, not specifically to eHealth. The eIDAS Regulation and General Data Protection Regulation shall be followed by all Member States and shall be transferred into national legislation regardless of whether they participate in CBeHIS or not.

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3 http://ec.europa.eu/internal_market/imi-net/library/question_sets_forms/index_en.htm
http://ec.europa.eu/internal_market/imi-net/statistics/index_en.htm#maincontentSec4

4 2005/36/EU directive on the recognition of professional qualifications:
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32005L0036

5 http://ec.europa.eu/growth/tools-databases/regprof/

The recitals 10 and 12 of eIDAS explicitly state that the domain eHealth has been taken into consideration. The eIDAS regulation applies for cross-border patient data exchange with online-services such as Patient Summary and/or ePrescription services even though it is intended to serve needs beyond domain boundaries. The eIDAS set-up allows for optional agreed extensions based on the individual domain's needs and upon the domain's request.

On the 27th of April 2016 the EC published a 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). The General Data Protection Regulation makes it explicitly clear that personal data concerning health and health care services as referred to in the cross-border directive 2011/24/EU were taken into consideration, see recital 35.

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) is currently prepared by JAseHN task T6.2 and lays down legal boundaries for the CBeHIS provision on the grounds of eIDAS regulation and several other applicable laws. The Agreement is to be adopted by the eHealth Network in May 2017 and to be signed by the competent national authorities. Among several other clauses the Agreement refers to the identification and authentication of patients, health professionals and healthcare providers as well as to the authorization of a health professional.

The legal foundation of the Guideline on the interoperability of Professional Registries comprises of the eIDAS regulation, the GDP Regulation and the Agreement. However, national legislation for setting up and operating existing or future national Professional Registries may vary significantly between MS for example in their content, scope, use case and level of detail.

3.3 Organisational and Policy Requirements

A professional enquiring health data from another country is only entitled to request and receive information for which he is allowed to deal with according to his own jurisdiction. In epSOS terminology this means that the data source in country A (the place of residence or insurance of a patient) has to judge whether the requestor is entitled to receive the requested information. This judgement complements the requirements that only professionals entitled to see specific data request such information. From a country A perspective this cannot be technically achieved because the data source for Country B professionals is outside its jurisdiction but only by providing a legal foundation (e.g. with 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 data source in country A can either be an automated system (e.g. central health database) or a doctor holding the requested data. To judge whether it or he may provide the data contains three fundamental considerations given that the patient provided consent for data retrieval:

- is the ***type of requester*** (e.g. a general practitioner or a midwife) entitled to receive the data according to country B - the requester's country - legislations and rules. The question of entitlement or authorization for data retrieval may in some cases have two aspects:
    - formal authorization
    - situational authorization (e.g. emergency situations)
- is the ***actual requester instance*** matching the above profile requirements and how recent is this information

- sufficient and documented ***authentication*** of the actual requester instance has to be undertaken in country B. Country A must be enabled to trust requests providing patient data.

In epSOS each participating Member State prepared a mapping table in which professions were assigned to roles, with a role being defined as the set of principal actors entitled to perform a specific task, such as requesting and reading a patient summary. As an example in a country doctors, hospital nurses and midwives might be entitled to request and read patient summaries. This concept enables a transparent view on what principals actors are entitled to which cross-border functions for communicating countries. However, the judgement whether the requestor is entitled to receive the requested data is still to be undertaken within Country B according to its jurisdiction and before any request is sent to Country A. It is to be analysed if this mapping table is still needed if the adoption and signature of the Agreement introduces a legal basis for CBeHIS. This depends especially on clause II.4.1 Security Principles of the Agreement concerning trust between Member States.

A further consideration regards functional units in the outpatient and inpatient sector of healthcare. It has to be considered if e.g. a hospital meeting certain requirements shall be entitled by patients for hospital-wide use of their data by defined qualified staff. The same applies to doctor's offices, medical centres and other bodies of the outpatient sector.

In case a country's NCPeH does fan out into various other NCPeHs or in case there is not one but many professional health registries in a country then it is the obligation of the national NCPeH of that country to be the only addressed gateway irrespective of the Member State internal fragmentation.

1) Each MS participating in CBeHIS shall take care that in case of more than one Electronic Professional Registry needed for CBeHIS the national NCPeH encapsulates the communication as a single point of contact for other MS.

The above requirements have to be complemented by sufficient and documented identification of patients and their consent to data retrieval, but this subject is not the remit of these guidelines, see JAseHN Deliverable D5.2.1 eID specific framework for eHealth Release 1 and Release 2.

2) The eHealth Network shall adopt the Guidelines on Interoperability of electronic Professional Registries and the eID specific framework Release 1 and Release 2.

3) The eHealth Network shall adopt the Guidelines on Interoperability of electronic Professional Registries.

3.4 Semantic Requirements

At the time of the release of this document detailed semantic requirements were not known. A professional medical translation most likely only into English may be needed, as the English *speech therapist*, the French *orthophoniste* and the German *Logopäde* probably mean the same profession but do to not have much in common linguistically. This depends on whether this is useful to provide a mapping on professional roles and their entitlements to arrive transparency.

3.5 Technical Specifications

From a technical viewpoint the following controls have to be fulfilled by each MS participating in CBeHIS before a request from patient data is sent from Country B to Country A:

1) Check if patient has given a **consent**.
2) **Authenticate** the *(health care)* professional, i.e. make sure (electronically) the identity of the *(health care)* professional.
3) Check the **formal qualifications** (authorization) of the *(health care)* professional to use the CBeHIS.

4) Check the **situational qualifications** (also authorization) of the access. For example, does the *(health care)* professional have valid health care relation.

If all these requirements are fulfilled in Country B the requester is entitled to get data about the patient at the point of care. Country A will be able to trust the requester of Country B.

Taken into account the ISO 21091:2013 scenario A.4.12 'Patient care in another country' a technical scenario of using electronic Professional Registries to support communication of authorization credentials across jurisdictions for access control decisions will look like the following:

The patient (subject of care from country A) falls ill while visiting another country (country B). The patient contacts a local (health care) professional in country B (country of treatment) and provides according to country A's specifications his consent. That (health care) professional authenticates to the local medical institution using local certificate credentials verified against the local directory services (ePR of country B) and revocation checked against the Certificate Revocation List (all done in country B). Also the formal qualification of the (health care) professional to use CBeHIS has to be appropriately provided.

After all this was done successfully, the (health care) professional requests information e.g. patient summary or ePrescription/eDispensation from the primary (health care) professional in country A (the patient's country of origin) through an encrypted message, providing certificate credentials to the foreign directory (ePR of country A). The credentials and Certificate Revocation List (CRL) are checked against the source directory (ePR of country B).

This scenario used directory services for personal contact information, retrieval of public keys for encipherment and signature verification, organisation lookup, and CRL checking as described in detail in ISO 21091:2013. It remains to be validated if this proposed scenario provides a sufficient basis for technical requirements.

4. Electronic Professional Registries Data Set

This section provides some MS examples for ePR data sets and proposes a minimum ePR data set for interoperability for CBeHIS:

4.1 Example ePR Data Set from MSs

It is a non-exhaustive list of ePR Data Sets from MSs, which will be filled with more examples.

The Swedish ePR (HOSP) includes the following data:

1. Name, social security number or other similar identifiers and sex
2. Registered residence
3. Profession
4. Base profession, educational institution, country and date of issue of graduation
5. Specialist skills
6. Issue date of license and proof of specialist skills
7. Date when a time constrained license according to 6 expires
8. Decision on the partial admittance
9. Decision on probation and revocation of license
10. Identity code (förskrivarkod) and scope of the right to prescribe
11. Technical and administrative information necessary to register the objects to be met.

The Austrian ePR (eHVD) includes the following data according to GTelG2012 §10. (1): *Daten des eHealth-Verzeichnisdienstes*:

§10. (1) In den eHVD sind folgende Daten aufzunehmen:

1. Name sowie akademische Grade oder Bezeichnung des Gesundheitsdiensteanbieters,
2. die Bezeichnung des Rechtsträgers, wenn der Gesundheitsdiensteanbieter keine natürliche Person ist,
3. Identifikatoren des Gesundheitsdiensteanbieters einschließlich der eindeutigen elektronischen Kennzeichen gemäß §8 E-GovG,
4. Angaben zur beruflichen, postalischen und elektronischen Erreichbarkeit des Gesundheitsdiensteanbieters,
5. die Rolle(n) sowie besondere Befugnisse oder Eigenschaften des Gesundheitsdiensteanbieters,
6. die eindeutige Kennung (OID) und den symbolischen Bezeichner,
7. die Staatsangehörigkeit des Gesundheitsdiensteanbieters,
8. die zur Verschlüsselung von Gesundheitsdaten erforderlichen Angaben oder die elektronische Adresse, an der diese Angaben aufgefunden werden können,
9. die Angabe, ob es sich um einen ELGA-Gesundheitsdiensteanbieter handelt,
10. Angaben zur geografischen Lokalisierung des Gesundheitsdiensteanbieters,
11. Angaben über das Leistungsangebot des Gesundheitsdiensteanbieters,
12. die Bezeichnung jener Registrierungsstelle gemäß §2 Z4, von der die Daten in den eHVD eingebracht wurden, und gegebenenfalls die Bezeichnung der Herkunftsquelle der Daten sowie
13. das Datum der Aufnahme der Daten in den eHVD sowie das Datum der letzten Berichtigung.

4.2 Minimum ePR Data Set

Taken from the JAseHN Guidelines[6] it can be expected that registries contain at least the following data elements which may be sufficient for interoperability purposes:

- the name and profession,
- a personal identification number, including the ISO 3166 country code,
- the current address of the health care provider organisation with which the health professional is affiliated or the address of his or her private practice,
- the date of issue of the healthcare professional's licence to practice,
- the specialty may be recorded in line with national practice as the prescribing of some medicinal products may be restricted

5. Closing Remarks

The present document outlines the draft of the Guidelines on the interoperability of electronic Professional Registries and

- lays down structure and future content of the Guideline as synthesis of the analysis of identified already existing Electronic Professional Registries in MSs and other documented sources and
- builds a common understanding of Electronic Professional Registries and what is needed for their interoperability for CBeHIS.

The draft Guideline on the interoperability of electronic Professional Registries will be revised and enhanced to provide a final version in November 2017, which

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- adds concrete requirements concerning required roles, minimum data set and specific use case needs for the interoperability of Electronic Professional Registry and
- adds common denominators which allows cross-border data exchange without interfering with the kind, complexity and actual implementation of existing health professional registries
- sets up sustainable principles and requirements for the alignment of interoperable Electronic Professional Registries in MSs for CBeHIS.

Any necessary future updates of the final Guideline on the interoperability of electronic Professional Registries will take into consideration the lessons learnt and experience gained from the emergence of CBeHIS.

6. References

6.1 Legal references

- 2011/24/EU directive on the application of patients' rights in cross-border healthcare (cross-border directive)
- 2014/910/EU regulation on the electronic identification and trust services for electronic transactions in the internal market (eIDAS regulation) and delegated acts
- 2015/296/EU Commission implementing decision establishing procedural arrangements for cooperation between Member States on electronic identification pursuant to Article 12(7) of eIDAS regulation
- 2015/1501/EU Commission implementing regulation on the interoperability framework pursuant to Article 12(8) of eIDAS regulation
- 2015/1502/EU Commission implementing regulation on setting out minimum technical specifications and procedures for assurance levels for electronic identification means pursuant to Article 8(3) of eIDAS regulation
- 95/46/EU directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- 2016/679/EU regulation on the protection of natural persons with regard to the processing of personal data and the free movement of such data (General Data Protection Regulation)
- 2005/36/EU directive on the recognition of professional qualifications

6.2 Standards

- Health Informatics – Directory services for healthcare providers, subjects of care and other entities (ISO 21091:2013)

6.3 Content-related references

- eHealth Network documents
  - Organisational Framework for eHealth National Contact Points (OWA-NCPeH)
  - General Guidelines on electronic exchange of health data under cross-border Directive 2011/24/EU (Release 2)
  - Guideline on Patient Summary for unscheduled care (Release 2)
  - Guideline on ePrescription and eDispensation (Release 2)
  - 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)
  - eID for eHealth: towards EU governance

- eID for eHealth: towards coherence with the proposal of the Commission for eID regulation
- e-SENS document
  - WP4 Implication of eIDAS Regulation for eHealth (final draft available)
- PARENT document
  - "Methodological guidelines and recommendations for efficient and rational governance of patient registries"[7]
- CPME document
  - "Ensuring the secure use of telemedicine and e-health applications in an integrated Europe – Towards a Common Policy Agreement on Electronic ID Systems for Physicians" [8]

7. Appendices

7.1 Definitions

CONCEPT	DEFINITION
CBeHIS	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 (CBeHIS).
CEF eHealth DSI	is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription.
Communication Gateway	MS system that manages CBeHIS transactions with other MS and which connects to the NI. It is an entry/exit point from the MS, acting on behalf of a HP and citizen (at a Point of Care) that assures the exchange of patient's medical data in a controlled environment.
Compliance Establishment Process	A well-defined set of activities and evidences used to ensure that NCPeH compliance can be established, maintained and reinforced
Country A	The country of affiliation. This is the country that holds information about a patient, where the patient can be univocally identified and his data may be accessed.
Country B	The country of treatment i.e. where cross-border health care is provided when the patient is seeking care abroad.
Framework	Is a real or conceptual structure intended to serve as a support or guide for the building of something that expands the structure into something useful.
Guideline	A suggested way of compliance when doing something. It is visible to those using

7 see http://patientregistries.eu/ and http://parent-wiki.nijz.si/

8 see http://www.cpme.eu/cpme-policy-ensuring-the-secure-use-of-telemedicine-and-e-health-applications-in-an-integrated-europe-towards-a-common-policy-agreement-on-electronic-id-systems-for-physicians/

	or supporting the use of a particular service but there are no sanctions if not followed.
Guideline for Adoption	Intended to present to the eHealth Network's members a clear guideline with the intention for it to be adopted and optionally implemented by the EU MS at national level in the next step.
National Infrastructure	The healthcare IT infrastructure, which manages patient and HP/HCP[9] identification and health care records in MS
NCP	National Contact Point as referred in Article 6 of the 2011/24/EU Directive
NCPeH	National Contact Point for eHealth, that may act as an organization and technical gateway for the provision of eHealth Cross-Border Information Services
NCPeH Deployment	Set of activities aiming to evidence the NCPeH compliance with the full range of requirements (LOST) established towards CBeHIS provision
NCPeH Implementation	Process of Prepare, Deploy and Operate a NCPeH
NCPeH Operation	Set of activities performed by the MS while providing the service to the citizens and health professionals
NCPeH Preparation	Set of activities aiming to set up an NCPeH
Organisational Framework	Define core characteristics, duties and responsibilities of a NCPeH
PoC	Is a location where an EU citizen may seek healthcare services. It can be a hospital, a pharmacy or any other point of the healthcare system of Country B.
Requirement	Definition of relevant needs (business, functional, non-functional, technical and technological) for system specification and implementation

[9] see Article 3 (f) and (g) of Directive 2011/24/EU