

# **SMART 2007/0059**

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Study on the Legal Framework for  
Interoperable eHealth in Europe

## **FINAL REPORT**

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European Commission  
Directorate General Information Society

Brussels

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Study on the Legal Framework for Interoperable eHealth in Europe

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SUMMARY:

The objective of the study is to identify and analyse the legal and regulatory framework for electronic health services in the EU Member States and for cross-border services when provided via eHealth applications, in particular in the areas of electronic health records, telemedicine and e-prescription. This report contains the analysis and assessment of the information collected in the Member States and draws some conclusions and recommendations.

KEYWORDS: eHealth, telemedicine, electronic health record, ePrescription, legal interoperability

National country profiles: [http://ec.europa.eu/information\\_society/activities/health/studies/published/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/studies/published/index_en.htm)

## Table of Contents

<b>1. DOCUMENTS</b>	<b>6</b>
1.1 APPLICABLE DOCUMENTS	6
1.2 REFERENCE DOCUMENTS	6
<b>2. GLOSSARY</b>	<b>8</b>
2.1 DEFINITIONS	8
2.2 ACRONYMS	9
<b>3. INTRODUCTION</b>	<b>10</b>
3.1 BACKGROUND AND OBJECTIVES OF THE STUDY	10
3.2 OVERVIEW OF EUROPEAN HEALTH LAW	11
3.3 STRUCTURE OF THE REPORT	16

## PART I: THE LEGAL CONTEXT FOR EHEALTH IN EUROPE. OVERVIEW OF RELEVANT ASPECTS OF HEALTH LAW IN THE MEMBER STATES

<b>4. MEMBER STATES' HEALTHCARE SYSTEMS</b>	<b>21</b>
4.1 (DE)CENTRALIZATION	21
4.2 PUBLIC AND PRIVATE HEALTHCARE	24
4.3 FINANCING	27
4.4 ICT MATURITY LEVEL	30
<b>5. REGULATORY FRAMEWORK FOR THE HEALTHCARE PROFESSION</b>	<b>32</b>
5.1 PRACTICE OF MEDICINE AND MONOPOLY OF PHYSICIANS	33
5.2 LICENSING/AUTHORIZATION FOR MEDICAL PRACTICE	35
5.3 CONTROL OVER THE PRACTICE OF MEDICINE	37
5.4 PROFESSIONAL LIABILITY	41
5.5 PROFESSIONAL SECRECY	44

Study on the Legal Framework for Interoperable eHealth in Europe

<b>6.</b>	<b>PROCESSING OF PERSONAL HEALTH DATA</b>	<b>48</b>
6.1	IMPLEMENTATION OF THE EUROPEAN LEGAL FRAMEWORK	48
6.2	TRANSPOSITION OF ARTICLE 8 OF DIRECTIVE 95/46/EC	52
6.3	INFORMATION AND ACCESS RIGHTS OF DATA SUBJECTS	55
6.4	OTHER RELEVANT RULES REGARDING PERSONAL DATA PROTECTION	59
<b>7.</b>	<b>PATIENTS' RIGHTS</b>	<b>ERROR! BOOKMARK NOT DEFINED.</b>
7.1	INTRODUCTORY OBSERVATIONS	61
7.2	EUROPEAN CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE	62
7.3	REGULATORY FRAMEWORK IN THE MEMBER STATES	63
7.4	SCOPE OF PATIENTS' RIGHTS	66
7.5	RIGHT TO FREE CHOICE	67
7.6	INFORMED CONSENT	68
7.7	OTHER PATIENTS' RIGHTS	70
7.8	CONCLUSION	71

**PART II : THE REGULATORY FRAMEWORK FOR EHEALTH IN THE MEMBER STATES**

<b>8.</b>	<b>REGULATORY FRAMEWORK FOR ELECTRONIC HEALTH RECORDS</b>	<b>75</b>
8.1	TRADITIONAL LEGAL RULES RELATING TO HEALTH RECORDS	75
8.2	NEW LEGAL RULES RELATING TO SHARED ELECTRONIC HEALTH RECORDS	78
8.2.1	DECENTRALIZED ELECTRONIC HEALTH RECORDS SHARED VIA NATIONAL PLATFORM	79
8.2.2	CENTRAL ELECTRONIC HEALTH REGISTERS	84
8.2.3	THE FRENCH "DOSSIER MEDICAL PERSONNEL"	87
8.3	LEGAL RULES CONCERNING PATIENTS' SUMMARIES	89
<b>9.</b>	<b>REGULATORY FRAMEWORK FOR TELEMEDICINE</b>	<b>93</b>
9.1	TELEMEDICINE USE CASES	93
9.1.1	TELEMEDICINE IN THE HEALTHCARE PROFESSIONAL – PATIENT RELATIONSHIP	93
9.1.2	TELEMEDICINE IN HEALTHCARE PROVIDER TO PROVIDER RELATIONSHIPS	95
9.2	TELEMEDICINE: THE PROBLEM OF A LEGAL DEFINITION	96

Study on the Legal Framework for Interoperable eHealth in Europe

---

9.3	ABSENCE OF SPECIFIC LEGAL PROVISIONS ON TELEMEDICINE	97
9.4	RELUCTANCE TO PROVIDE CARE TO PATIENTS AT A DISTANCE	100
9.5	EMERGING RULES ON TELEMEDICINE IN THE HEALTHCARE PROVIDER - PATIENT RELATIONSHIP	102
9.6	SOME CONCLUDING REMARKS	104
<b>10.</b>	<b>REGULATORY FRAMEWORK FOR ELECTRONIC PRESCRIPTIONS</b>	<b>106</b>
<hr/>		
10.1	INTRODUCTORY OBSERVATIONS	106
10.2	PRESCRIBING PHARMACEUTICALS: THE LARGER CONTEXT	107
10.3	LEGAL OBSTACLES FOR ELECTRONIC PRESCRIPTIONS	109
10.4	LEGAL PROVISIONS CONCERNING ELECTRONIC PRESCRIBING	110
10.5	OPERATIONAL EPRESCRIBING IN SCANDINAVIA	115
10.6	SOME CONCLUDING REMARKS	118
<b>11.</b>	<b>CONCLUSIONS AND RECOMMENDATIONS</b>	<b>120</b>
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## 1. Documents

### 1.1 Applicable Documents

[AD1]	Services Contract 30-CE-0162056/00-04

### 1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 <a href="http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf">http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf</a>
[RD2]	eHealth Action Plan, Progress Report <a href="http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf">http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf</a>
[RD3]	Recommendation of the Commission on eHealth interoperability, <a href="http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf">http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf</a>
[RD4]	Database of European eHealth priorities and strategies (Empirica), <a href="http://www.ehealth-era.org/database/database.html">http://www.ehealth-era.org/database/database.html</a> (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, <a href="http://www.euro.who.int/observatory/Hits/TopPage">http://www.euro.who.int/observatory/Hits/TopPage</a>
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, <a href="http://www.euro.who.int/observatory/Publications/20060522_4">http://www.euro.who.int/observatory/Publications/20060522_4</a>
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patients' summaries, <a href="http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf">http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf</a>
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: <a href="http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_sur">http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_sur</a>

Study on the Legal Framework for Interoperable eHealth in Europe

	<p><a href="#">vey_final_report.pdf</a>, Country profiles: <a href="http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm">http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm</a></p>
[RD9]	<p>Communication from the European Commission, “A Community framework on the application of patients’ rights in cross-border healthcare”, 2 July, 2008, <a href="http://ec.europa.eu/health-eu/doc/com2008415_en.pdf">http://ec.europa.eu/health-eu/doc/com2008415_en.pdf</a></p>
[RD10]	<p>Proposal for a Directive of the European Parliament and of the Council on the application of patients’ rights in cross-border healthcare, <a href="http://ec.europa.eu/health-eu/doc/com2008414_en.pdf">http://ec.europa.eu/health-eu/doc/com2008414_en.pdf</a></p>
[RD11]	<p>European Commission, IDABC, eID interoperability for public government services (with country profiles): <a href="http://ec.europa.eu/idabc/en/document/6484/5938">http://ec.europa.eu/idabc/en/document/6484/5938</a></p>
[RD12]	<p>European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): <a href="http://ec.europa.eu/idabc/en/chapter/6000">http://ec.europa.eu/idabc/en/chapter/6000</a></p>
[RD13]	<p>Legally eHealth, Study on Legal and Regulatory Aspects of eHealth, <a href="http://www.ehma.org/projects/default.asp?NCID=140">http://www.ehma.org/projects/default.asp?NCID=140</a></p>
[RD14]	<p>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, <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML</a></p>
[RD15]	<p>Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, <a href="http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf">http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf</a></p>
[RD16]	<p>International Encyclopedia of Medical Law (editor: Herman Nys), <a href="http://www.ielaws.com/medical.htm">http://www.ielaws.com/medical.htm</a>, (with country monographs)</p>

## 2. Glossary

### 2.1 Definitions

In the course of this Study, a number of key notions are frequently referred to. To avoid any ambiguity, the following definitions apply to these notions and should also be used by the correspondents.

- **Authorization:** refers to:
  - the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
  - or: the process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
- **Data authentication:** information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
- **Doctor:** refers to a medical doctor and is in particular to a title attributed to a physician.
- **eHealth:** all aspects relating to the transformation of the health sector as a consequence of introducing digital information and communication technologies.
- **Electronic health record:** a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;
- **Electronic signature:** data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
- **ePrescription:** a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC<sup>47</sup>, issued by a healthcare professional and transmitted electronically.
- **Healthcare:** the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions. Healthcare embraces all the goods and services designed for people's health, including preventive, curative and palliative interventions, whether directed to individuals or to populations.
- **Health professional:** a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications 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.
- **Identification:** using claimed or observed attributes of an entity (e.g. a person) to distinguish the entity in a given context from other entities it interacts with (= entity authentication).
- **Identifier:** attribute or set of attributes of an entity (e.g. a person) which uniquely identifies the entity in a given context.



Study on the Legal Framework for Interoperable eHealth in Europe

- **Identity management:** a broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
- **Patient:** any natural person who receives or wishes to receive healthcare in a Member State;
- **Physician:** healthcare professional to authorised to perform medical acts;
- **Patient summary:** subset of an electronic health record that contains information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;.
- **Registration:** process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
- **Telemedicine:** the provision of healthcare services, through use of ICT, in situations where the health professional and the patient, or two health professionals, are not in the same location

2.2 Acronyms

EHR.....	Electronic Health Record
eID .....	Electronic Identity
eIDM .....	Electronic Identity Management
GP.....	General Practitioner
HiT.....	Health in Transition
HSE.....	Health Service Executive
NHS.....	National Health Service
NHIF.....	National Health Insurance Fund
PKI.....	Public Key Infrastructure
SSCD.....	Secure Signature Creation Device
SHI.....	Statutory Health Insurance
VHI.....	Voluntary Health Insurance
TTP.....	Trusted Third Party

### 3. Introduction

#### 3.1 Background and objectives of the study

The term “eHealth” covers a very wide area of products, services, procedures and techniques. Basically it designates all aspects relating to the progressive transformation of the health sector due to the introduction of ICT. Similar to every other sector this transformation doesn’t consist merely in replacing paper-based information processing by ICT-based techniques. On the contrary, it affects the core of the whole activity sector and leads to a complete business re-engineering at all levels.

eHealth plays an important role in the European Union’s i2010 strategy, and became one of the lead initiatives to create an Innovative Europe in a dynamic, knowledge-based economy - the vision set out by the Lisbon European Council in March 2000.<sup>1</sup> A core strategic policy document is the European eHealth Action Plan<sup>2</sup> which contains a series of activities during the period 2005-2010, supported by the Commission services. A key point of this Action Plan directly relates to the underlying study, and covers the time period 2008-2009. It deals with what is termed – in the Action Plan – “Addressing common challenges: legal and regulatory aspects of eHealth”.

A first preparatory study “Legally eHealth”<sup>3</sup>, started in 2006, looked at how EU legislation on data protection, product and services liability, and trade and competition law applies to this field. In considering the protection of privacy, the report examined the European Directives on Data Protection Directive, Privacy in Electronic Communications, as well as the European Convention of Human Rights against the backdrop of a number of scenarios exploring data transfer for the purposes of better care provision both across European and international borders, as well as for commercial purposes. The report also addressed the issue of liability with regard to the provision of eHealth goods and services, covering both health services transacted over websites, as well as much more complex issues such as multiple and split liability for services provided through a series of co-operating providers. Finally, noting that eHealth is a significant, emerging European industry, the Legally eHealth report questioned the extent to which European trade and competition law might apply to eHealth.

Building further on the “Legally eHealth” study, this report examines *the legal situation in the 27 EU Member States*. The aim is to identify the principal legal and administrative barriers in providing eHealth services both within the territory of one Member State and while crossing borders of the Member State. The study underpins the activities initiated by the Competitiveness and Innovation Programme in the area of eHealth i.e. the implementation of the Large Scale Pilot European patient Smart Open Services (EPSOS) project “.<sup>4</sup> It also contributes to the implementation and uptake of the eHealth Action Plan, particularly in the legal and regulatory field, as anticipated by the end of 2009, by facilitating insight in the national legal frameworks of the EU Member States in the area of eHealth.

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<sup>1</sup> European Council (2000), *Presidency Conclusions*. Lisbon European Council. 23-24 March, 2000.

<sup>2</sup> Communication from the Commission (2004) 356, “e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area” ([http://www.europa.eu.int/information\\_society/eeurope/ehealth/index\\_en.htm](http://www.europa.eu.int/information_society/eeurope/ehealth/index_en.htm));

<sup>3</sup> “Legally eHealth. Putting eHealth in its European legal context”, Study report, March 2008, ([http://ec.europa.eu/information\\_society/activities/health/docs/studies/legally-ehealth-report.pdf](http://ec.europa.eu/information_society/activities/health/docs/studies/legally-ehealth-report.pdf))

<sup>4</sup> [http://ec.europa.eu/information\\_society/activities/health/docs/cip/200810epsos-factsheet.pdf](http://ec.europa.eu/information_society/activities/health/docs/cip/200810epsos-factsheet.pdf)

## Study on the Legal Framework for Interoperable eHealth in Europe

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To conduct the study the author relied on a network of national legal experts in the 27 Member States.<sup>5</sup> The correspondents are recognized legal experts in the field of this Study themselves but they also contacted the key stakeholders in their country in order to collect all recent information to draft a reliable country profile on the legal status, plans and trends in the field of eHealth of the Member State. Between May and August 2008 these national experts wrote their national country profile on the basis of a common template. All country profiles were subsequently submitted for review and comments to the national representatives of the i2010 subgroup on eHealth.<sup>6</sup> The country reports are available on the European Commission's eHealth portal website.<sup>7</sup>

The underlying final study report contains an analysis and assessment of the information provided in the national reports. Starting from the information collected in the Member States, the main objective is to contribute to a better insight into the legal framework for eHealth in Europe.

### 3.2 Overview of European Health Law

As a first preliminary step, it is necessary to briefly sketch the relevant legal context on the European level. Healthcare is a domain which largely remains under the competence of the Member States but this doesn't mean that European legal instruments in this field are completely missing.

The Community did not have legal authority in the field of public health until 1999, when the public health article was amended and renumbered by the Treaty of Amsterdam as the current Article 152. Treaty Article 152 presently defines the role of the EU as complementing national policies, sets out procedures by which the EU institutions may act in the health field, and delineates the types of measures that may be enacted. At the same time it explicitly bars the use of harmonization.<sup>8</sup> The current text of Article 152, worthwhile to quote here integrally, is as follows:

*"1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.*

*Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.*

*The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.*

*2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.*

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<sup>5</sup> For the UK, separate country profiles have been drafted for England and Scotland. The study didn't include Wales and Northern Ireland.

<sup>6</sup> The i2010 subgroup on eHealth was born in 2005, as the eHealth working group. It took on its current form after the launch of the i2010 initiative in 2006. Its mandate is to provide expert eHealth-related advice to the overarching i2010 High-Level Group.  
[http://ec.europa.eu/information\\_society/activities/health/policy/i2010subgroup/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/i2010subgroup/index_en.htm)

<sup>7</sup> [http://ec.europa.eu/information\\_society/activities/health/](http://ec.europa.eu/information_society/activities/health/), under "Studies"

<sup>8</sup> Julia Lear and Elias Mossialos, EU law and health policy in Europe, Euro Observer 2008, Vol.10, Nr. 3, [http://www.euro.who.int/Document/OBS/EuroObserver\\_Autumn2008.pdf](http://www.euro.who.int/Document/OBS/EuroObserver_Autumn2008.pdf)

Study on the Legal Framework for Interoperable eHealth in Europe

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*Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.*

*3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.*

*4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:*

- (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;*
- (b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;*
- (c) incentive measures designed to protect and improve human health, excluding any harmonization of the laws and regulations of the Member States.*

*The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.*

*5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.”*

Article 152 emphasizes that the role of the Community in this domain has a supportive, coordinating and complementary character. It can use a series of “soft law” instruments (e.g. recommendations) in order to coordinate and promote but harmonisation measures are explicitly excluded in 4 c). Also important is the obligation to “fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care”. Therefore the legal doctrine in the area of European institutional law mostly concludes that public health has to be considered as a “parallel complementary competence”.<sup>9</sup>

The Treaty of Lisbon will presumably put an end to the legal discussion about the nature of the EU competences in the sphere of public health. Article 4.2 k) of the (Consolidated Version of the) Treaty on the Functioning of the European Union<sup>10</sup> classifies “common safety concerns in public health matters, for the aspects defined in this Treaty” as a shared competence between the Member States and the Union. Additionally the Union has a parallel complementary competence for the “protection and improvement of human health” on the basis of Art. 6. This distinction is further explicated in Art. 168 which will succeed the current Art. 152. Art. 168, 4 stipulates that the Union, on the basis of its shared concurrent competence can take measures related to the common safety concerns in the area of public health with regard to three topics (organs and substances of human origin, blood and blood derivatives; veterinary and phytosanitary field; medicinal products and devices for medical use). On these three topics the Union can take harmonization measures. Art. 168, 5 continues further with by

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<sup>9</sup> E.g. R. Schutze, Co-operative federalism constitutionalised: the emergence of complementary competences in the EC legal order, *European Law Review* 2006, p. 179. A minority of legal authors categorise public health as a “shared concurrent competence” (mainly based on the competences attributed to the Community in Art. 152, 4 a) and b).

<sup>10</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0047:0199:EN:PDF>

## Study on the Legal Framework for Interoperable eHealth in Europe

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listing the measures which can be taken by the Union under its “parallel complementary competence” in order to “protect and improve human health”.

Although the EU has no formal legal powers to enact Community healthcare legislation, several other policy domains influence health policy, including principally: internal market, social affairs, enterprise and economic policy. One example is the European regulatory framework for medical devices.<sup>11</sup> Medical devices have become an increasingly important healthcare area in relation to their impact on health and healthcare expenditure. The sector covers some 8000 types of products, ranging from simple bandages and spectacles, through life maintaining implantable devices, equipment to screen and diagnose disease and health conditions, to the most sophisticated diagnostic imaging and minimal invasive surgery equipment. The Community's involvement concerns mainly market access, international trade relations and regulatory convergence, and the competitiveness of industry.

Particularly relevant, for example for the domain of “e-Prescription”, is the European directive on the transparency of measures related to the pricing and the reimbursement of medicinal products. The objective of this Directive is to obtain an overall view of national pricing arrangements, including the manner in which they operate in individual cases and all the criteria on which they are based, and to provide public access to them for all those involved in the market in medicinal products in the Member States<sup>12</sup>

Another example is provided by the European rules on working times.<sup>13</sup> While the Directive has the laudable aim of improving the health and safety of workers, it has created staffing problems for 24-hour healthcare facilities, especially in smaller communities. The directive defines minimum periods of daily and weekly rest, annual leave, and the maximum weekly working time. Although still not fully implemented in the health sector, two ECJ cases have concluded that both ‘on-call time’ and ‘stand-by time’ are both considered working time for the calculation of maximum working times.<sup>14</sup> Such regulatory aspects are evidently particularly relevant in an eHealth environment, for example, in a context of remotely monitoring of patients’ health status.

Frequently mentioned in relation to eHealth, is Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 “on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market” (the directive on electronic commerce).<sup>15</sup> The directive contributes to the functioning of the internal market by ensuring the free movement of information society services, including e-Health services, between the Member States. It stipulates information requirements on the information society services providers, rules on commercial communications, rules regarding contracts concluded by electronic means and liability of intermediary services providers.

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<sup>11</sup> [http://ec.europa.eu/enterprise/medical\\_devices/index\\_en.htm](http://ec.europa.eu/enterprise/medical_devices/index_en.htm)

<sup>12</sup> Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance system (OJ N°40 of 11.2.1989, p. 8),

<sup>13</sup> Council Directive 93/104/EC of 23 November 1993 concerning certain aspects of the organization of working time, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0104:EN:HTML>

<sup>14</sup> Case C-303/98 *Simap* [2000] ECR I-7963, and Case C-151/02 *Jaeger* [2003] ECR I-8389.

<sup>15</sup> [http://ec.europa.eu/internal\\_market/e-commerce/directive\\_en.htm](http://ec.europa.eu/internal_market/e-commerce/directive_en.htm) ; for the application of the directive to eHealth, read S. CALLENS, Telemedicine and the e-Commerce Directive, in: Callens (ed.), eHealth and the Law, The Hague, Kluwer Law International, 2003, Ch. 2.

## Study on the Legal Framework for Interoperable eHealth in Europe

One field where the EU does have explicit Treaty authority to legislate – within the borders of Article 152, 4 and 5 - is in the area of safety. Within the public health sphere the EU has enacted legislation to ensure the quality and safety of blood, blood products and human tissues<sup>16</sup>, and is considering legislative action to address the challenges of organ transplantation.<sup>17</sup> The Community has also enacted legislation and launched public health campaigns to reduce the negative health impacts of hazardous products such as tobacco, alcohol, and illicit drugs.<sup>18</sup>

Another important area of EU public health policy is the establishment of regulatory agencies to provide expert opinions and advice, collect and disseminate information, and generally support Community Institutions. Health related agencies range from the Monitoring Centre for Drugs and Drug Addiction<sup>19</sup> to the European Agency for Safety and Health at Work.<sup>20</sup> Two of the most important agencies are the European Medicines Agency<sup>21</sup> and the European Food Safety Agency<sup>22</sup> which play integral roles in the Community's legislative authority to regulate the market authorization of pharmaceuticals, medical devices, and food to ensure that the products meet high levels of quality and safety for human consumption. The Community has also engaged in several strategies to detect and control communicable diseases. The European Centre for Disease Control (ECDC) manages European disease surveillance and response systems, identifies emerging health threats, provides scientific opinions, publishes epidemiological research and trains scientists and researchers from all over Europe.<sup>23</sup>

The establishment of the Single European Market also enshrined the fundamental freedom of movement of persons, capital, services and goods throughout the Community. EU legislation on the free movement of professionals, including health professionals, has evolved through a series of directives leading to the current Directive on the recognition of professional qualifications.<sup>24</sup> The aims of the directive are to ensure that Member States enact uniform, transparent, and non-discriminatory rules recognizing professional qualifications and experience to allow professionals to work temporarily or permanently throughout the Union.

Increasingly, doctors and patients are making use of this freedom. In the United Kingdom, for example, the General Medical Council reported that 2205 Polish general practitioners have registered in the UK since 2000, while the number of German physicians has shot up to more than 8000 from

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<sup>16</sup> E.g. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC; For an overview of the EU policy in this domain, see [http://ec.europa.eu/health/ph\\_threats/human\\_substance/blood\\_tissues\\_organs\\_en.htm](http://ec.europa.eu/health/ph_threats/human_substance/blood_tissues_organs_en.htm)

<sup>17</sup> On 8 December 2008 the Commission adopted a proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation: [http://ec.europa.eu/health/ph\\_threats/human\\_substance/oc\\_organs/docs/organs\\_directive\\_en.pdf](http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/organs_directive_en.pdf)

<sup>18</sup> E.g. Directive 2003/33/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:152:0016:0019:EN:PDF>;

<sup>19</sup> <http://www.emcdda.europa.eu/html.cfm/index190EN.html>

<sup>20</sup> <http://osha.europa.eu/en>

<sup>21</sup> <http://www.emea.europa.eu/>

<sup>22</sup> <http://www.efsa.europa.eu>

<sup>23</sup> <http://ecdc.europa.eu/>

<sup>24</sup> Directive 2005/36/EC of the European Parliament and the Council on the recognition of professional qualifications, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:255:0022:0142:EN:PDF>

Study on the Legal Framework for Interoperable eHealth in Europe

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383 in 2003.<sup>25</sup> Given that the Council registered 11 630 new doctors in 2007, that means about 15% of all new registrants in the UK since 2003 came from Germany.<sup>26</sup> Germany, in turn, has had to pick up more physicians from elsewhere, which it has done by filling posts with doctors from Greece, Austria, Poland and other European nations. In fact, the Bundesärztekammer, Germany's medical association, noted that in 2007, 10 069 of the country's 314 912 active doctors came from other European Union countries, 8.7% more than in the preceding year. Ireland or Malta, for example, report that in 2005 they lost, respectively, 47.5% (10 065) and 23.1% (376) of the physicians they had trained. In short, although the numbers vary from member state to member state, physicians crossing borders has become commonplace within the European Union.

Also particularly relevant for the domain of eHealth is of course the European regulatory framework for personal data protection<sup>27</sup> and for the protection of privacy in electronic communications.<sup>28</sup> This framework and its application to eHealth has been explored in the "Legally eHealth" study, already mentioned before. The same study has also pointed to other European legislation, not directly connected to the health sector, such as the European product liability directives, the directive on the sale of consumer goods and associated guarantees and the directive on the protection of consumers in respect of distance contracts.

Finally, an area that has seen the most recent major developments is the free movement of patients.<sup>29</sup> In June 2008 the Commission published a proposal for a directive on patients' rights in cross-border healthcare.<sup>30</sup> Up to now most of the Community law in the area of patients' mobility came from the European Court of Justice. In 1998, the famous *Kohll* and *Decker* cases<sup>31</sup> gave the Court its first opportunity to apply the free movement of persons provisions to the health sector. The Court found that Community nationals had the right to obtain medical treatment in any Member State without prior authorization and also to be reimbursed consistent with the tariffs of the state in which they are insured. Subsequent decisions clarified that a distinction must be made between hospital care and non-hospital care.<sup>32</sup> Member States could adopt a system of prior authorization for planned hospital medical services obtained abroad, so long as the system is not arbitrary or discriminatory, is

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<sup>25</sup> Ira Allen, Doctors crossing borders: Europe's new reality, CMAJ January 20, 2009; 180 (2).  
<http://www.cmaj.ca/cgi/content/full/180/2/158>

<sup>26</sup> In the UK, 74.031 foreign doctors were registered to practice in 2007, or 30.94% of the overall physician pool, with about 20.863 coming from other European Union member states.

<sup>27</sup> 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:  
[http://ec.europa.eu/justice\\_home/fsj/privacy/law/index\\_en.htm](http://ec.europa.eu/justice_home/fsj/privacy/law/index_en.htm)

<sup>28</sup> Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

<sup>29</sup> M. Rosenmöller, M. McKee and R. Baeten, Patient Mobility in the European Union, WHO Regional Office for Europe, <http://www.crossborder.ie/pubs/e4p.pdf>, distinguish five categories of mobile patients; see also M. WISMAR et al., Cross-Border Healthcare. Mapping and Analysing Health Systems Diversity, European Observatory on Health Systems and Policies, 2007.

<sup>30</sup> European Commission, Proposal for a Directive of the European Parliament and the Council on the application of patients' rights in cross-border healthcare, COM(2008)414 final,  
[http://ec.europa.eu/health/ph\\_overview/co\\_operation/healthcare/docs/COM\\_en.pdf](http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf)

<sup>31</sup> Kohll Case C-158/96 [1998] ECR I-1931: <http://tinyurl.com/crpf5h>; Decker Case C-120/95 [1998] ECR I-1831:  
<http://tinyurl.com/c6zywww>

<sup>32</sup> Smits and Peerbooms judgement, Case C-157/99 of 12.07.01, ECR 2001 p. I-05473. <http://tinyurl.com/cyehyo>, and Case C-368/98 Vanbraekel [2001] ECR I-5363, <http://tinyurl.com/cp5uwt>

## Study on the Legal Framework for Interoperable eHealth in Europe

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necessary and proportional, and its removal would not undermine the planning of hospital services. However, non-hospital care does not require prior authorization.<sup>33</sup> The proposed directive goes further to define patients' rights to information and redress in the event of harm, as well as Member States' responsibilities:

- to recognize prescriptions issued by an authorized person in another Member State (Article 15);
- to collect and transmit data on cross-border health services (Article 17);
- to facilitate the development and functioning of National Contact Points that will maintain information on everything from quality and safety, to the process for seeking redress and international out-of-court settlements (Article 12); and
- to cooperate with EU institutions and other Member States in the implementation of the directive (Article 13).

Article 16 of the proposed directive specifically relates to eHealth and is worded as follows: "*The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data in accordance with the applicable law. They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.*"

Worth mentioning also is the proposed Article 14, requesting the Commission to adopt "*measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions*".<sup>34</sup>

### 3.3 Structure of the report

After this introduction the final report is divided into two parts:

- Part I (Chapters 4 – 7) deals with regulatory aspects related to healthcare in general, insofar as these aspects are relevant for eHealth.
- Part II (Chapters 8 – 10) deals with regulatory aspects which are directly related to eHealth as such.

**Part I** starts with a short overview of some *characteristics relating to the healthcare systems of the Member States* and to be taken into account in the context of eHealth. In some countries, healthcare

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<sup>33</sup> Case C-385/99 Muller-Faure and VanRiet [2003] ECR I-4503, <http://tinyurl.com/d8j3dd>

<sup>34</sup> This provision has already been criticized by the UK Government. See: Department of Health, The European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare – UK Government's response to consultation, April 2009, [http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH\\_098389](http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098389). Read in particular § 61: "On issues such as an EU-wide prescription template and e-prescription interoperability, it is hard to see the justification for introducing binding measures across all countries and all systems for what is a very small proportion of prescriptions."



**Study on the Legal Framework for Interoperable eHealth in Europe**

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is to a large extent decentralized. The role of the involved stakeholders such as healthcare professional organisations, health insurance funds or public authorities varies between the Member States. There are also remarkable differences in the division of roles between the private and the public sector. In some countries, new rules affecting the domain of eHealth are embedded in the larger national e-government policy. Also evident is that rules on financing and reimbursement will play a crucial role in the roll-out of an eHealth strategy. Last but not least previous studies contracted by the European Commission have shown that the level of ICT-penetration differs considerably from one Member State to another. The objective of this chapter is not to give a complete overview of the healthcare sector in every Member State but to demonstrate the large variety and its possible impact on the development of interoperable eHealth in Europe.

A second topic presented in Part I relates to the *regulatory framework for the healthcare profession*. Most healthcare professions are regulated professions<sup>35</sup> and can only be exercised under strict legal conditions. It is evident that these conditions can considerably diverge from one Member State to another. For example, with regard to the rules applicable to physicians, Member States have various interpretations of what constitutes the “practice of medicine” and which activities should be reserved to qualified physicians. Every Member State has also its own licensing system and, in most cases, a physician who wishes to exercise his/her profession in a Member State needs to apply for a license in that Member State. In a context of cross-border eHealth service provision this can lead to a need for registration in all the Member States where the service is accessible. A particular difficulty relates to supervision. Every Member State has its own supervisory bodies for the various healthcare professions and there is little or no exchange of information between these bodies. A healthcare professional banned from exercising medical practice by a disciplinary sanction in one Member State, will not necessarily be prevented from re-starting his activities in another Member State. Last but not least, there is also a noteworthy divergence between Member States in the application of the duty of confidentiality owed by healthcare professionals towards their patients.

Part I further contains a third chapter on the application of *personal data protection* rules to the healthcare sector. Our study confirms that the divergences in the implementation of the European data protection directive, discovered in the course of the 2003 review undertaken by the Commission, continue to exist. Some new divergences have been added in more recent years. With regard to the processing of personal data concerning health a majority of Member States have copied the exceptions mentioned under Art. 8.2 a) to e) of the Directive. Specifically with regard to health-related data most of the national legislators transposed Art. 8.3 more or less literally. Member States further, making use of the authorization offered by Art. 8.4, usually have completed the list of exceptions for processing data concerning health with a list of additional exceptions. Restrictions to the access right of the data subject in case of processing health-related personal data vary. Additionally these rights have to be combined with specific access rights to health records, attributed by national legal provisions on patients' rights. Finally the solution provided by the directive for determining the applicable Member State's data protection law, is not very patient-friendly in cross-border situations. Unlike the solution generally accepted in consumer protection law, data subjects cannot always benefit from the protection of the binding rules of the data protection law of the Member State where they are domiciled. If their rights are infringed in another Member State, they will often be forced to exercise their rights in that (foreign) Member State (and thus to overcome all possible barriers related to e.g. language, legal assistance, etc.).

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<sup>35</sup> Art. 2 (g) of the e-Commerce Directive 2000/31/EC defines “regulated profession” as follows: “any profession within the meaning of either Article 1(d) of Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three-years or of Article 1(f) of Council Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC”.

## Study on the Legal Framework for Interoperable eHealth in Europe

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The fourth and last chapter of Part I is dedicated to the domain of *patients' rights*. The way in which patients' rights are defined and implemented is largely determined by national law and differs from country to country. Moreover there exists no validated definition of patients' rights. The views on which rights have to be included in the definition of patients' rights vary from very narrow (patient's right to autonomy in different respects) to very broad (such as the right to respect for the patient's time and the right to benefit from innovation). Not all EU Member States have enacted specific comprehensive laws dealing with patients' rights as such. In some of the Member States patients' rights are contained in various legal texts regulating other topics as well. Sometimes not only legal provisions are relevant for patients' rights in a particular country but also ethical codes have to be taken into account. In some countries these ethical codes are legally binding. Other authors have already stated that "*even if the differing ways and levels of protection of individual patients' rights do not impede patient in receiving treatment in another Member State, they may contribute to the level of uncertainty that surrounds cross-border care. Patients tend to export their expectations and understanding of patients' rights*".<sup>36</sup>

**Part II** of this report deals with specific legal issues related to eHealth as such and in particular the legal aspects with regard to electronic health records, telemedicine and electronic prescriptions.

The first chapter of Part II attempts to give an overview of the regulatory framework in the Member States with regard to *electronic health records*. Legal provisions with regard to health records (paper-based files and electronic records) have traditionally been laid down in the Member States' healthcare laws and in the legislation on patients' rights. These provisions usually contain rules relating to the obligation for healthcare providers and institutions to keep a health record, the content of such records, archiving rules, access rights for patients, etc. They sometimes also take into account that individual health data, under certain conditions, needs to be shared among health professionals. More recent laws include specific conditions for accessing and sharing *electronic* health records. In many cases however, these rules don't suffice as a comprehensive legal framework for the introduction of electronic health records on a national scale. Therefore countries such as Austria, Belgium, Estonia, Finland, France, the Netherlands, Slovenia and others have created a new legal framework for sharing electronic health records by way of government-initiated eHealth services, platforms or registers. Generally speaking these new legal frameworks don't provide rules or solutions for cross-border situations and are exclusively focusing on the relationships between healthcare providers, public authorities, health insurers and patients within one national territory.

The second chapter of Part II is dedicated to legal issues related to *telemedicine*. Telemedicine can be defined as the provision of healthcare services at a distance by making use of electronic communications. A distinction can be made between two types of telemedicine services: 1) healthcare services provided by one or more healthcare providers to a patient on a distant location, 2) health-related services provided by one or more healthcare professionals to one or more other healthcare professionals on a distant location. Examples of the first category are services as, for example, teleconsultation or telemonitoring. The second category includes services like teleradiology, teledermatology, etc. Even within these two broad categories, the range of services that can be considered as "telemedicine" is extremely wide and diverse. It is therefore very difficult to formulate general rules applicable to all forms of telemedicine and perhaps also one of the reasons why legal rules dealing specifically with this field are practically inexistent. The rare exceptions mostly deal with one particular category of telemedicine (the healthcare professional – patient relationship).

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<sup>36</sup> NYS and GOFFIN, "Mapping National Practices and Strategies on Patients' rightsPatients' rightsPatients' rights", in M. VISMAR, et al. (eds.), *Cross-border healthcare: mapping and analyzing health systems diversity*, Brussels, European Observatory on Health Systems and Policies, 2008, Chapter 4, p. 120

**Study on the Legal Framework for Interoperable eHealth in Europe**

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Specialised health law doctrine or opinions and recommendations of medical supervisory authorities frequently express reluctance towards providing care to a patient at a distance but don't necessarily take into account the wide diversity of telemedicine services and applications. All this together creates uncertainty, in particular in a cross-border context.

The last chapter of Part II deals with the regulatory framework for *ePrescription* in the Member States. Electronic prescribing generally refers to a prescriber's ability to electronically send a prescription for a medicinal product directly to a pharmacy from the point-of-care. In practice however, prescribing pharmaceuticals to a patient is only one step in a larger administrative process. The details of this process are directly dependent on the organisational structure of the healthcare sector and in particular on the reimbursement procedures. In many Member States this larger process is still paper-based and therefore the legal framework for prescriptions has not yet been adapted in order to enable ePrescribing. A second category of countries have adapted their legal rules in order to enable ePrescription even if electronic prescribing is not yet operational at this stage. Large-scale operational ePrescription systems are operational only in the Scandinavian countries. Other Member States, such as Austria, Belgium, Germany or the Netherlands are currently running ePrescription pilots in the framework of their recently created national eHealth platforms. The draft Article 14 of the proposed European directive on the application of patients' rights in cross-border healthcare states that the Commission will bring forward measures to facilitate recognition of prescriptions, including an EU-wide prescription template, and supporting interoperability of e-prescriptions. One of the challenges for the future will consist in further specifying the type of measures to be taken to this effect.

Finally in a last chapter (Chapter 11) we will attempt to draw some conclusions and formulate a few recommendations for further Community action in this area.

## **Part I : The Legal Context for eHealth in Europe**

### **Overview of Relevant Aspects of Health Law in the Member States**

## 4. Member States' healthcare systems

It is impossible to understand the legal framework for eHealth in Europe without having a regard on the healthcare systems of the Member States.<sup>37</sup> Each national healthcare system is rooted in the Member State's political, social and economical environment. Comparisons and typologies are therefore risky and don't necessarily take into account all relevant factors. Nevertheless we will try to put forward some general characteristics in order to guide us through this heterogeneous landscape. In the following pages the diversity of the ways healthcare is organized and managed in the Member States will be illustrated by pointing at 1) the centralized or decentralized structure of the healthcare system, 2) the division of roles between the public and the private sector, 3) the diversity of financing models and 4) the unequal level of maturity in the penetration of information and communication technology in the healthcare sector in the EU Member States.<sup>38</sup>

### 4.1 (De)centralization

In many European Member States the responsibility for important areas of the healthcare system has been delegated to the regional level. The decentralization has been implemented, however, in diverse forms and to various extents.

According to the **Austrian** Federal Constitution, for example, almost all areas of the healthcare system are primarily the regulatory responsibility of the federal government but an important exception is the hospital sector. In this area, the federal government is only responsible for enacting basic law. Legislation on implementation and enforcement is the responsibility of the nine *Länder*.

In **Germany**, the federal Ministry of Health is responsible for matters such as international aspects, health policy planning, pharmaceuticals, statutory health insurance or long-term care prevention<sup>39</sup>, but the *Länder's* Ministries are responsible for public health services, hospital planning, supervision of health professions and their professional institutions, etc.

On the same line the **Belgian** health system is also organized on two levels, i.e. federal and regional. The federal government is responsible for the regulating and financing of the compulsory health insurance; determining accreditation criteria; financing hospitals and so-called heavy medical care units; legislation covering different professional qualifications; and registration of pharmaceuticals and their price control. The regional governments are responsible for health promotion; maternity and child health services; different aspects of elderly care; the implementation of hospital accreditation standards; and the financing of hospital investment.

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<sup>37</sup> The national reports produced in the context of this study contain a general description of the healthcare system. For most the Member States this description has been based on the HiT-reports of the WHO-Euro Observatory. European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, <http://www.euro.who.int/observatory/Hits/TopPage>

<sup>38</sup> In order to keep the text of this report easily readable the four parameters will not be developed for each of the 27 Member States but illustrated by way of examples. For more complete information about every Member State the reader is referred to the HiT-reports of the WHO-Euro Observatory. European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, <http://www.euro.who.int/observatory/Hits/TopPage>

<sup>39</sup> BUSSE R., RIESBERG A., Healthcare systems in transition: Germany, Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, p. 29.

## Study on the Legal Framework for Interoperable eHealth in Europe

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The organisation of the **French** healthcare system relies on a sharing of competences between the State, the Health Insurance (Assurance Maladie) and the local authorities. The State bases its health policy on objectives set up for 5 years in a law voted by the Parliament. The National Institute for health prevention and education (*Institut national de prévention et d'éducation pour la santé* – INPS) is in charge of implementing the health programmes managed by the State. Regional Health Conferences (*Conférences régionales de Santé*) bring together regional stakeholders, institutions, healthcare providers and patients. They analyse the local health needs and establish public health priorities at their level. Local authorities mainly intervene in three domains: prevention measures for the youth (preschool, elementary education), care of the elderly and formation of non-medical healthcare providers.<sup>40</sup>

Health policy-making power in **Spain** lies at regional level, with health authorities and regional health governments playing a central, key role. All autonomous communities have drawn up a “health map” stipulating territorial subdivisions (health areas and zones). Each health area, responsible for the management of facilities, benefits and health service programmes within its geographical limits, should cover a population of no fewer than 200 000 and no more than 250 000 inhabitants. Basic health zones are the smallest units of the organizational structure of healthcare. They are usually organized around a single Primary Care Team (Equipo de Atención Primaria, EAP).

**Italian** regional governments, through their departments of health, are responsible for pursuing the leading national objectives set by the National Health Plan at the regional level. Regional health departments are required to guarantee the benefit package to be delivered to the population through a network of local health units and public and private accredited hospitals. They are responsible for legislative and administrative functions, for planning healthcare activities, for organizing supply in relation to population needs and for monitoring the quality, appropriateness and efficiency of the services provided. The regional level has legislative functions, executive functions as well as technical support and evaluation functions.

The **Swedish** healthcare system is organized on three levels: national, regional and local. The regional level, through the county councils, together with central government, forms the basis of the healthcare system. The county councils plan the development and organization of healthcare according to the needs of their residents. Their planning responsibility also includes health services supplied by other providers, such as private practitioners and physicians in occupational medicine.<sup>41</sup>

The **Danish** health system is governed by a combination of national state institutions, regions and municipalities. All three levels have democratically elected assemblies and there is a tradition of decentralization of management and planning to the regions and municipalities. The state level is responsible for the overall legal framework for healthcare and for coordinating and supervising the regional and municipal delivery of services. Five regions are responsible for delivering both primary and secondary health services. Most hospitals are owned and operated by the regions, and hospital doctors are salaried employees of the regions. Practising doctors are private rather than state practitioners, but receive almost all of their income from services paid by the regions.<sup>42</sup>

Municipalities have, by law, the main responsibility for arranging basic social and health services in **Finland**. In 2008 Finland counts 415 municipalities. Primary healthcare is provided by health centres established by a single municipality or jointly by neighbouring municipalities. Municipalities may buy services from other municipalities or from the private sector. Health centre services include medical

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<sup>40</sup> L'organisation du système de santé publique, *Santé publique* 2004/4, N° 44, p. 645-654; and Ritter P., Rapport sur la création des agences régionales de santé présenté au Ministre de la Santé, de la Jeunesse et des Sports, Janvier 2008.

<sup>41</sup> [http://en.wikipedia.org/wiki/Health\\_care\\_in\\_Sweden](http://en.wikipedia.org/wiki/Health_care_in_Sweden);

<sup>42</sup> [http://www.im.dk/publikationer/healthcare\\_in\\_dk/healthcare.pdf](http://www.im.dk/publikationer/healthcare_in_dk/healthcare.pdf)

## Study on the Legal Framework for Interoperable eHealth in Europe

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consultations and provision of dental care, preventive care and environmental healthcare. Health centres run maternity and child health clinics, and arrange school and occupational health services. The country is further divided into 20 hospital districts, each providing specialist consultation and care for its population. Local municipal authorities are responsible for funding specialist treatment provided to inhabitants of their areas. Each hospital district has a central hospital with departments for most specialties. Finland has five university hospitals. These provide the most advanced medical care, including highly specialized surgery and treatment for rare diseases.<sup>43</sup>

The NHS in **England** is the responsibility of the Department of Health which operates under the direction of the Secretary of State for Health in England.<sup>44</sup> NHS Connecting for Health is an integral agency of the Department of Health that is responsible for delivering the National Programme for IT for the NHS in England. The Department of Health is also part of the UK Government, and is responsible for representing the UK internationally in health matters, liaising with the other “home countries” (Scotland, Wales and Northern Ireland) as appropriate. Health services are divided into primary and secondary services. Secondary care includes services provided by hospitals, mental health provision and ambulance services. Primary care covers general practice, dentistry and ophthalmic services and is delivered by Primary Care Trusts. Following a reorganisation in October 2006 there are now 152 Primary Care Trusts. Although overall strategy and policy is directed by the Department of Health, a fundamental element of the Government’s strategy for the NHS is to encourage decentralisation of public services and the creation of a patient-led NHS. An example of local control and ownership of health delivery is the channelling of funding for healthcare services through Primary Care Trusts as the main commissioning body for their area.

In **Ireland** the Health Service Executive (HSE)<sup>45</sup> replaced the existing regional service provision, which had take place through regional Health Boards, with a central organisation. The HSE is responsible for the provision of services in hospitals and at community level. In this respect, the HSE is divided into three service delivery units. These are: 1) Population Health, which has the function of protecting the health of the entire population; 2) Primary, Community and Continuing Care (PCCC) which has the function of delivering health and social services in the community and other settings; 3) National Hospitals Office (NHO) which has the function of providing acute hospital and ambulance services. Delivery of all three sets of services is organised through four administrative areas.

The **Hungarian** 1990 Local Government Act assigned responsibility for local health services to local governments, implying that they should plan health services for the local needs. Responsibility for primary care rests with municipalities, responsibility for secondary care rests with counties, but they are allowed to contract out service delivery to private providers. There is a large proportion of primary care contracted out to private physicians acting as entrepreneurs (under the scheme of the so-called functional privatization), and a smaller segment of secondary care contracted out mainly to a few church-owned hospitals.

In **Lithuania** municipalities are responsible for local primary healthcare. Municipalities are engaged in running small and medium sized hospitals within their localities. Primary healthcare is provided by diverse categories of medical professionals in health centres, GP cabinets, dispensaries and polyclinics. County administrations are responsible for secondary healthcare (physicians – specialists). The patient commonly is directed to the hospital by the GP or the secondary level doctor (referral system, except in case of emergency). Specialized outpatient services are provided in polyclinics and dispensaries of hospitals. In-patient care is exercised in general and specialized

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<sup>43</sup> <http://www.laakariliitto.fi/e/healthcare/> ; <http://pre20090115.stm.fi/aa1106916032942/passthru.pdf>

<sup>44</sup> <http://www.nhs.uk>

<sup>45</sup> <http://www.hse.ie/eng/>

## Study on the Legal Framework for Interoperable eHealth in Europe

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hospitals. The Ministry of Health of the Republic of Lithuania administers tertiary healthcare, which is comprised of high specialization university clinics in Vilnius city and Kaunas city. The number of private healthcare services provided in national hospitals is increasing and this evolution is intensively debated in the country.

### 4.2 Public and private healthcare

The above overview of examples of Member States' centralized or decentralized structures already demonstrates that, in most of the surveyed countries, the healthcare sector is very much based on a division of roles between the public and the private sector. Again, however, the situation from this perspective varies considerably depending on the Member State.

In **Belgium**, for example, compulsory health insurance is combined with a private system of healthcare delivery, based on independent medical practice, free choice of service provider and predominantly fee-for-service payment. All individuals entitled to health insurance must join or register with a sickness fund. The public sector is primarily in charge of overall policy development and implementation of, of course, of financial support. Typical for the Belgian situation is the freedom for patients to address themselves directly to any GP, specialist or hospital of their choice.<sup>46</sup>

In the **Netherlands** the healthcare system is also very much of a private character albeit provided under conditions imposed by the public authority. The government, for instance, has stipulated that everyone in the Netherlands is obliged to take out insurance; anyone who fails to do so, will be fined. Health insurers are obliged to accept everyone, irrespective of age, gender, state of health. The government no longer arranges everything. Parties in the market have greater freedom and responsibilities to compete for the business of the insured. Care providers will have to pay greater attention to their performance and can supply more tailor-made care for their customers. The patient/client occupies a central role, with more opportunities but also more responsibility. It is up to the patient/client to bring about improvements to the quality. A well-informed patient can single out the provider that offers the best care for his condition. This will spur healthcare providers (doctors, hospital boards, etc.) to raise their performance. Medical insurers will bear more responsibility for matching the demands of the consumer with the offerings of the providers. The government remains responsible for the accessibility, affordability and quality of healthcare.<sup>47</sup>

The fundamental principles of the **Luxembourg** health system are, along the same line, free choice of the provider by the patient, compulsory health insurance, and compulsory provider compliance with the fixed fees-for-service set for the insurance system. The system is split between prevention and treatment, in terms of both provision and financing. For the most part, preventive services are the responsibility of the Ministry of Health; interventions are provided by a few public services and by private practitioners and non-profit associations paid from the Ministry budget. Curative treatment is a shared responsibility of the Ministry of Health and the Ministry of Social Security. The former supervises the organization of health services and subsidizes the hospital sector, while the latter is responsible for the sickness insurance system. Insurance is compulsory, and is managed and provided by the Union of Sickness Funds in conjunction with nine individual agencies to which people are allocated on the basis of their professional occupation.

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<sup>46</sup> This feature of Belgian healthcare policy is currently under pressure. Read e.g. the Itinera Institute Memo, "Breaking the deadlock of budgetary autism: what paradigms for future healthcare organisation in Belgium?", 2009/08, 14 p.

<sup>47</sup> <http://www.justlanded.com/english/Netherlands/Netherlands-Guide/Health/Healthcare>



## Study on the Legal Framework for Interoperable eHealth in Europe

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The **Greek** healthcare system is characterised by the coexistence of the National Health Service (NHS) and private healthcare providers. The NHS provides universal coverage to the population through approximately 210 health centres, 1400 health posts and 110 hospitals and operates on the principles of equity, equal access to health services for all and social solidarity. Suppliers of healthcare services are the broader public sector (hospitals in the National Health System or hospitals with some other public character, health centres and regional surgeries, insurance fund and municipal surgeries, etc.) and the pure private sector (private hospitals and clinics, diagnostic centres, doctor's and dentist's clinics, etc.). Furthermore, healthcare is also provided by the Greek Social Security Organisation (IKA), which operates approximately 300 primary healthcare units in various regions of Greece and 5 main hospitals (4 of which can be found in Athens and one in Thessaloniki).

The **Portuguese** healthcare system is characterized by three coexisting, overlapping systems: the NHS, special public and private insurance schemes for certain professions (health subsystems) and private voluntary health insurance funds (VHI). The health system in Portugal is a network of public and private healthcare providers, each of them connected to the Ministry of Health and to the patients in its own way.<sup>48</sup>

In **Sweden** primary care is mainly provided by public care centres. The majority of healthcare providers are publicly owned, and therefore physicians, dentists, pharmacists and other professional groups are mainly salaried employees. Private healthcare is however increasing.<sup>49</sup>

Private healthcare in **Finland** is mainly a supplement to the care provided by municipalities and the state. Particularly in cities, many doctors, dentists, and physiotherapists offer private care. There are also a few small private hospitals. More than 10% of Finnish doctors earn their living solely as private practitioners. About one third of doctors run a private practice in addition to working in a hospital or health centre.<sup>50</sup>

In addition to the public healthcare system, an extensive private healthcare system operates in **Ireland**. A high proportion of Irish people have healthcare insurance which traditionally was provided by a state-backed, not-for-profit insurer, the Voluntary Health Insurance Board (VHI). Although there are some private hospitals, much of the private care provided has taken place through public hospitals: medical consultants were permitted to treat private patients in public hospitals. Recently, a number of changes have occurred. Competition has been introduced in the market through a number of new health insurance providers. In addition, moves are in progress to introduce new contracts for consultants which will restrict the amount of private practice which a consultant may engage in.

The National Health Service (**Scotland**) Act of 1947 marked the beginnings of the National Health Service (NHS) in Scotland<sup>51</sup>. The Scottish NHS has many component parts but essentially a distinction exists between non-acute medical care which is the prime responsibility of general practitioners (GPs) and more specialised care which traditionally has been undertaken within a hospital context. Technically, GPs are not employees of the NHS but are independent contractors who provide services to the NHS under a contract. All individuals qualifying for treatment under the NHS require to be registered with a general practitioner. Whilst hospitals are required to deal with any

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<sup>48</sup> <http://www.euro.who.int/document/e82937.pdf>

<sup>49</sup> C. Mason, Public-private health care delivery becoming the norm in Sweden, CMAJ • July 15, 2008; 179 (2), <http://www.cmaj.ca/cgi/content/full/179/2/129>

<sup>50</sup> Healthcare in Finland, Brochures of the Ministry of Social Affairs and Health 2004: <http://pre20090115.stm.fi/aa1106916032942/passthru.pdf>

<sup>51</sup> Although a private medical sector exists in Scotland, this is relatively minor in scale and the present report will deal exclusively with issues relating to the National Health Service.

## Study on the Legal Framework for Interoperable eHealth in Europe

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cases which are presented to them on an acute basis generally an individual can obtain a consultation with a specialist only following a referral from a general practitioner.

In **England** a not insignificant private medical sector exists alongside the NHS and indeed one of the key elements behind many recent NHS reforms in England has been the desire to forge closer links between the NHS and private medical sectors in order to ensure speedier treatment for patients.<sup>52</sup>

Since the early 1990s almost all primary care physicians, pharmacies, spas and pharmaceutical industries in the **Slovak Republic** have been privatized. From 1995, multiple insurance companies were introduced to compete for insured persons while pooling financial risks. In practice, competition was limited. Until January 2002, the Ministry of Health owned and operated almost all inpatient healthcare facilities. Since then, most secondary care hospitals and adjacent polyclinics have been transformed into non-profit public benefit entities or devolved to self-governmental municipalities or higher territorial units at regional level. Some outpatient clinics have been sold to private providers. Tertiary care hospitals continued to be owned by central government. The 2004 reform provides for a gradual privatization of state-owned hospitals and other healthcare facilities into for-profit joint stock companies supervised by the Office of Healthcare Supervision.

In **Bulgaria** private healthcare practice was legalized in 1991 and has since expanded significantly. The services offered by the Government are primarily secondary and tertiary health services, although there is an extensive network of rural hospitals, rural health centres, sub-centres and dispensaries providing primary care. The private health sector is dominated by the solo-practicing physician and dentist offering all types of outpatient services. There are also 100 small private clinics some of which are highly specialized, all concentrated in the urban areas. These are supported by all types of the other diagnostic and treatment services such as laboratories, pharmacies, x-ray etc. The private sector has recently established not-for-profit/ voluntary services mostly offering palliative support and rehabilitation in some of the important chronic disorders, such as diabetes, cancer, cardiovascular conditions etc. The private sector offers a more limited scope of services, however recently through amalgamation, private clinics have established some highly specialized facilities for kidney transplantation and open-heart surgery.

Also the **Romanian** healthcare system has gone through a transition from a situation in which it was almost entirely state-owned and coordinated by the Ministry of Public Health ("MPH") through 41 district health directorates and the Bucharest Health Directorate, towards a situation in which the relationships are more complex and diversified.

In the **Czech Republic** the Ministry of Health still directly manages and controls certain healthcare establishments and bodies, but also large hospitals with regional or supra-regional spheres of influence. In certain cases, communities are the owners and operators of small hospitals. Several dozen small hospitals have been privatized in the form of commercial companies, but continue to be financed from statutory health insurance. The network of outpatient services and pharmacy services has been nearly entirely privatized. The owners of those facilities are doctors, pharmacists, and other operators. Privatization of small hospitals is continuing and about two thirds of all hospitals were privatized in 2007.

The **Lithuanian** National Health System (LNHS) mainly covers general management of health affairs in the Republic of Lithuania, ensures social justice in health activities, integrates all health activities resources into the unified system according to the national priorities of health activities, integrates individual healthcare and public healthcare into a general system, ensures the implementation of the Health Programme of the Republic of Lithuania as well as of the state and municipal health

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<sup>52</sup> [http://en.wikipedia.org/wiki/Healthcare\\_in\\_England](http://en.wikipedia.org/wiki/Healthcare_in_England)

## Study on the Legal Framework for Interoperable eHealth in Europe

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programmes, ensures the interdepartmental co-ordination of health activities and ensures the participation of the public in the shaping of health policy.

The **Latvian** healthcare system has undergone a remarkable transformation in the years since independence, and is now in the process of consolidating its new structures and institutional arrangements. Having abolished the highly centralized system that prevailed during the Soviet period, it has focused on decentralization of healthcare delivery, administration and financing; full or partial privatization of some kinds of provider institutions; and the establishment of independent primary care practices, which have led to a wide variety of legal forms of healthcare providers and institutions. It has experimented extensively with a variety of social insurance structures ranging from highly decentralized to partially recentralized arrangements, as well as with organizational forms of healthcare delivery in parallel with reforms of the state administrative system. The wide-ranging reforms and continuous and ongoing process of change are prompted by the perceived need to increase the efficiency of healthcare financing and provision and to improve the quality of care.”

The **Estonian** government plays a planning and regulatory role in approving the development plan for the hospital network, setting healthcare prices and approving regulatory acts involving wider public health issues. The main role of the Estonian Health Insurance Fund is acting as a purchasing agency, and its responsibilities include: contracting healthcare providers; paying for health services; reimbursing pharmaceutical expenditure; paying for some sick leave and maternity benefits. Most hospitals are either limited liability companies owned by municipal governments, or foundations established by the state, municipalities and other public agencies. In this sense they are owned and managed by public institutions, either on a commercial (limited liability company) or non-profit (foundation) basis. Most ambulatory providers are privately owned. All family doctors are private entrepreneurs or salaried employees of private companies; these companies are restricted to providing only primary care services. The only areas of direct state control include county governors deciding on family doctor service areas within their region and the Ministry of Social Affairs deciding on the number of ambulance units to be financed by the state budget. The state’s influence on specialized care and independent nursing care is limited standard-setting and public financing.

### 4.3 Financing

A further item that is relevant in the legal discussion about eHealth in Europe is the way how healthcare is financed.

For example, in **Austria** the social health insurance system is the most important source of financing. Mandatory insurance is based on membership of an occupational group or place of residence; thus there is no competition between health insurance funds. Those covered by health insurance can freely choose between service providers in the outpatient sector, of whom the majority work in individual practices. In addition, outpatient clinics and hospital outpatient departments offer outpatient care.

In **Germany** autonomous sickness funds, statutory health insurance bodies, which are organized on a regional and/or federal basis, pay for the healthcare. These statutory health insurance bodies, their associations and associations of SHI-affiliated physicians have assumed the status of quasi-public corporations. These corporatist bodies constitute the self regulating structures that operate the financing and delivery of benefits covered by statutory health insurance within the legal framework. Furthermore on corporatist level professional ‘chambers’ (Ärzttekammern) exist for physicians, dentists, pharmacists, veterinarians, and psychologists providing psychotherapy. The membership for healthcare professionals in their respective chambers is obligatory.

## Study on the Legal Framework for Interoperable eHealth in Europe

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The **Belgian** health system is primarily funded through social security contributions and taxation. Public sector funding as a percentage of total expenditure on healthcare fluctuates around 70%. The system is based on the principles of equal access and freedom of choice, with a Bismarckian-type of compulsory national health insurance, which covers the whole population and has a very broad benefits package.

The **Irish** healthcare system is funded through taxation. All persons resident in Ireland are entitled to receive healthcare. Child health, maternity provision and emergency care is provided free of cost to all. In respect of other services, a Medical Card is available to specified categories of people. This card entitles holders to free hospital care, GP visits, dental services, optical services, aural services, prescription drugs and medical appliances. People who do not have a Medical Card are required to pay a fee for these healthcare services. A Medical Card is available to people in receipt of welfare payments, people on low incomes, all people aged 70 or over regardless of means and people with some long-term or severe illnesses.

In **Malta** there is no obligatory health insurance, as there is a national health service (free at the point of delivery) covering the whole resident population. All workers and employers pay national Insurance contributions on a weekly basis, but this money goes to finance welfare services in general (e.g. pensions) and not health services in particular. It is the exception for an employer in Malta to offer health insurance as an employment benefit. A number of residents purchase private health insurance on a voluntary basis; the proportion of the population availing itself of this option is growing. Many people also choose to make use of the services of private general practitioners and specialists on a direct fee-for-service basis. The private sector acts as a complementary mechanism for healthcare coverage and is financed through private health insurance and out of pocket payment. The two systems of general practice function independently from one another. It has been estimated that the private sector accounts for about two thirds of the workload in primary healthcare.

The **Swedish** healthcare system is primarily funded through taxation. Both county councils and municipalities have the right to levy proportional income taxes on their respective populations. The county councils and the municipalities also generate income through state grants and user charges. The mechanisms for paying providers vary among the county councils, but payments based on global budgets or a mix of global budgets and per-capita payments are the most commonly used systems. The social insurance system, managed by the Swedish Social Insurance Agency, provides financial security in case of sickness and disability. It is up to each county council to decide how to serve its population with primary care.

Similar to Sweden, **Denmark** is also characterized by a strong welfare state tradition, with universal coverage of health services mainly financed via taxation. Since 2007, financing has been obtained through earmarked proportional taxation at the national level. Most of this revenue (80 %) is redistributed to the regions via block grants, based on objective criteria (social and demographic indicators) and 20 % is redistributed to the new municipalities which will use these funds to co-finance regional hospital services for their respective populations. Access to the health system, including diagnostic and treatment services, is free for all citizens except for certain services such as dental care, physiotherapy and pharmaceuticals requiring patient co-payment. Doctors' fees are negotiated with the public authorities on a regular basis and activity profiles are monitored regularly. GP gatekeeping has been a significant feature of the Danish system for many years, along with the general principle of treating patients at the lowest effective care levels opposed to providing free access to more specialized units.

**Latvia** is in the unique position of possessing a tax-funded "social insurance" system with a purchaser-provider split. The central Government is responsible for financing the statutory healthcare

## Study on the Legal Framework for Interoperable eHealth in Europe

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system through tax revenue. In addition, financing for health services comes directly from household payments as well as voluntary health insurance. Tax revenue allocated for healthcare by the Ministry of Finance is transferred (via the Treasury) to the Health Compulsory Insurance State Agency (HCISA), a state-run organization under the jurisdiction of the Ministry of Health, which signs contracts with all statutory healthcare providers. What differentiates the Latvian financing system from most general tax-based systems is that the funds from the central government budget are transferred to the HCISA, which – together with its five regional branches – acts as purchaser of health services on behalf of the entire population.

The **Polish** Law on Universal Health Insurance, dated 6 February 1997, with later amendments, came into force on 1 January 1999 and radically changed the system of public healthcare, in terms of the structure and sources of finance. The establishment of mandatory health insurance broke with the centralized system of a national health service financed from the state budget. The former system was based on the right of every citizen to health services, which was administered by state authorities (Ministry of Health and voivodas). Health services were provided by public healthcare institutions with the status of budgetary entities. Sixteen regional sickness funds and one sickness fund for the uniformed forces were set up under the new system. They became holders of public healthcare funds that were raised primarily through health insurance contributions. The right to health services was linked to registration with a mandatory health insurance and payment of contributions. Public healthcare institutions changed their status to independent healthcare institutions obliged to cover their expenditures with their revenues from health services delivery. In April 2003, the sickness funds were replaced by a single National Health Fund, partly because of rising discontent with the new system among the insured population and partly for political reasons. The 1997 reform together with its numerous modifications introduced two major public sources of healthcare financing: universal health insurance contributions and budgetary expenditures from the state budget and budgets of voivodship, county and commune authorities. Owing to its dual nature, the system is defined as an insurance-budgetary system.

In 1992 **Slovenia** introduced a new system of health insurance combining compulsory and voluntary health insurance. Compulsory health insurance is mandatory for all the citizens of the Republic of Slovenia having their residence on the territory of Slovenia. Contributions, calculated either as a percentage of the specified bases or as flat sum charges, are paid by the employer. The compulsory health insurance contributions depend on the salary or other income earned by the insured person. This somewhat ensures solidarity within the system. For some groups of insured persons (the unemployed, the recipients of the social security allowances and similar), the health insurance contributions are paid by national or local community budgets. However the compulsory health insurance provides insurance only for a very limited scope of services (which are the same notwithstanding the individual contribution) and consequently an additional voluntary health insurance is necessary and subscribed by almost every individual. Voluntary health insurance is liberalised and provided by health insurance companies (to date there are four providers registered but one provider is dominant).

The **Slovakian** healthcare system is primarily funded through social security contributions (social health insurance) and taxation. All permanent residents and economically active immigrants have to contribute mandatorily a social health insurance which is partially contributed by employees (4% of gross earnings) and partially by employers (10% of gross earnings). The 2004 reform package in the Slovak Republic determines that the range of services reimbursed fully by mandatory health insurance will be restricted to priority diseases (“solidarity package”), defined by a ministry of health task force. Several other conditions may also be fully reimbursed on the basis of a decision of the Ministry of Health Categorization Committee, which will categorize “non-priority conditions” and specify the level of required co-payments.

## Study on the Legal Framework for Interoperable eHealth in Europe

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Healthcare in the **Czech Republic** is provided primarily on the basis of statutory health insurance, which is currently provided by nine health insurance funds

By the end of the 1980`s **Hungary** witnessed the beginning of a large scale healthcare reform. The so-called state-socialist, Semashko system was characterized by the overwhelming dominance of the state in both the financing and the delivery of services. The uniform model of the highly centralized, integrated health services was abolished. Replacing the tax based financing of the state-socialist system, as one of the first countries in the Central and Eastern European region, Hungary reverted the earlier Bismarckian model of compulsory social insurance in 1990, established the Health Insurance Fund (HIF) in 1992 and its national administration in 1993. In reality the model is a Bismarck-Beveridge mix, because less than 40 % of the population pay fees.

In **Bulgaria** the main sources of health system financing are compulsory health insurance, state and municipality budgets, voluntary health insurance (VHI), household expenditure allocated to the system as co-payments, fee for service or out-of-pocket expenses, and external resources allocated from donor organizations and national and international nongovernmental organizations (NGOs). Inpatient care is financed from three sources: government budgets, municipal budgets and health insurance. The NHIF pays only to contracted hospitals per case or clinical pathway consisting of a number of diagnoses, with fixed prices. Hospitals which have not contracted with the NHIF continue to be paid by the municipalities or by the State. Hospitals also receive additional revenue from compulsory co-payments and fees for those services that are not covered by the basic benefits package of health insurance. Physicians working in the inpatient sector are salaried. Providers of outpatient care are contracted with the NHIF and are paid by fee-for-service. Physicians in primary care are reimbursed per capita and reimbursement depends on the number of patients on the physician list. Reimbursement to general practitioners is based on per-capita monthly payments per insured person on the patient list. Specialized outpatient care and laboratories are reimbursed by means of a fixed fee for services provided to patients. Dental care is mostly paid out of pocket, based on fee-for-service, although a limited number of dental services are included in the basic benefits package.

Until 1997, the main source of funding for the centralized health system in **Romania** was general revenues, mainly through the state budget. In the 1997, the Health Insurance Law transformed the Romanian healthcare system from a Semashko state financed model to an insurance based system. The law made insurance membership mandatory and linked it to employment; contributions depend on income and are paid in even shares by the insured and the employer. The Health Reform Law no. 95 of 2006 which provides the legal framework for the insurance system took over and continued the reform initiated by the 1997 Health Insurance Law, thus payroll contributions are the main sources of health sector funding. The state and local budgets are mainly sustaining health programmes and investments in buildings, equipment, endowment, while the health insurance covers mainly the healthcare services, and the pharmaceutical products reimbursement.

Patients are recommended to have a family physician and to notify him/her about changes in their health status. The citizens can freely choose their family physician but should stay with him/her at least six months before making the change. In order to have the hospital expenses reimbursed, the patient has to go to the hospital recommended by the family physician.

### 4.4 ICT maturity level

The development of eHealth in the Member States is partly dependent of the penetration and the level of maturity of ICT-use among healthcare professionals. Although a lot of statistical work in this field remains to be done, a first indication on this issue is provided by the "Pilot on eHealth Indicators" study, carried out by *Empirica* in association with IPSOS on behalf of the European Commission,

**Study on the Legal Framework for Interoperable eHealth in Europe**

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Information Society and Media Directorate-General.<sup>53</sup> The data used for that report were collected by means of a survey of primary care physicians and their use of ICT for eHealth purposes. The survey was carried out in all 27 Member States of the European Union and in Norway and Iceland in 2007.

The study learned that, in 2007, almost all general practitioners (GP) practices (87%) in the European Union used a computer, with a tendency towards larger practices being better equipped — 93% using computers — than smaller ones — 84%. At the moment of the study 13% of practices were still without any computers. In some countries, the share of practices using a computer was as low as 65% (Malta, Romania) or 57% (Latvia).

69% of the EU27 GP practices had an Internet connection but in some Member States Internet use had reached saturation level — such as in Estonia, Finland, Denmark, Sweden — while there were also several Member States where less than 50% use the Internet (Bulgaria, Hungary, Romania and Slovakia). Broadband connections were used by nearly half of the EU27 GP practices (48%) with, again, considerable differences between the countries, the broadband penetration ranging from 93% in Finland to 5% in Romania.

From the data collected for the benchmarking study, Denmark, the Netherlands, Finland, Sweden and the UK emerged as the European frontrunners in eHealth use by general practitioners. On the other side there was a group of countries where either the use of eHealth at large or the use of advanced applications still left considerable room for improvement. At the time the study was performed, this group consisted of Greece, Latvia, Lithuania, Poland and Romania. In between there was the large group of average performers, consisting of the remaining 15 Member States.

Administrative patient data were stored electronically in 80% of the EU27 GP practices. In some countries, usage rates were at and below the 50% level, going down as far as 26%. Practice size played a certain role in this regard, with an average difference of 11 percentage points between the smallest and the largest size class. The highest use rates were found in Denmark (97%), Estonia (98%), Hungary (100%), the Netherlands (97%), Finland (100%), Sweden (96%) and the United Kingdom (95%). Storage of administrative patient data was practised least frequently in Greece (49%), Latvia (26%), Lithuania (39%) and Romania (47%).

A computer in the consultation room was found in 78% of the European GP practices. It was (nearly) ubiquitous in practices in Finland (100%), Denmark, Norway (98% each), Estonia, the Netherlands, the UK and Iceland (97% each). It was available in less than half of the consultation rooms of practices in Malta (48%), Poland (41%) and Lithuania (29%).

While the transmission of analytic results from a laboratory to the GP occurred with a comparatively high frequency (40%), other types of data were transferred electronically less often: administrative data were transferred to insurance institutions by 15% and to other care providers by 10%. Medical data were transmitted to care providers or other professionals by 10%.

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<sup>53</sup> [http://ec.europa.eu/information\\_society/eeurope/i2010/docs/benchmarking/gp\\_survey\\_final\\_report.pdf](http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_report.pdf)

## 5. Regulatory framework for the healthcare profession

One of the legal obstacles for interoperable eHealth in Europe is the diversity of the regulation of the healthcare profession in the Member States. There is, for example, not one European definition of what constitutes “practice of medicine”. Activities which belong to the exclusive monopoly of physicians in one Member State are not necessarily reserved for physicians in other Member States. This has evidently an impact on cross-border collaboration between healthcare providers, in particular in an eHealth environment. Individual healthcare providers who are entitled to exercise certain medical acts in the Member State where they are established, will sometimes not be authorized to exercise those same activities in another Member State, for example in a context of cross-border telemedicine.

The Community promotes and supports the mobility of physicians through mutual recognition of professional qualifications. Addressing the freedom of establishment Directive 2005/36/EC of 7 September 2007 on the recognition of professional qualifications (as amended) refers to three systems for the recognition of qualifications: the general system; the system of automatic recognition of qualifications attested by professional experience in certain industrial, craft and commercial activities; and the system of automatic recognition of qualifications for the professions of doctor, nurse, dentist, veterinary surgeon, midwife, pharmacist and architect. Hence the Directive provides for automatic recognition of qualifications for certain professions, including doctors.<sup>54</sup> It is inter alia based on the understanding that the full application of the rules on establishment cannot be required for the cross-border provision of services on a temporary or occasional basis. It, thus, provides for simpler conditions for the cross-border provision of services compared with those applicable to the freedom of establishment.<sup>55</sup>

This European regulatory framework allows, for example, individuals who have received medical education in one Member State, to exercise their profession in another Member State. However they will have to follow the rules and procedures in force in this latter Member State. For practically all Member States this means in the first place the necessity to apply for a license. A doctor licensed in one Member State is in most cases not authorised to use this license in order to practise medicine in another Member State.<sup>56</sup> A physician who provides healthcare services in two Member States, for example in the context of telemedicine, needs to be licensed in those two Member States. His activities will also be supervised by the respective competent disciplinary bodies in these Member States. Member States may also require physicians to have the language skills required to exercise their profession in the host member state. It should be noted that any assessment of language skills is done separately from the procedure for recognition of professional qualifications, and indeed after recognition, at the time of actual acceptance of professional ability in a hospital or surgery.

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<sup>54</sup> Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications (as amended). Directive 2005/36/EC on the mutual recognition of professional qualifications, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:255:0022:01:EN:HTML>; For an overview of the consequences of this Directive on the medical profession: Miek Peeters, Free Movement of Medical Doctors: The new Directive 2005/36/EC on the Recognition of Professional Qualifications, European Journal of Health Law, Volume 12, Number 4, 2005, pp. 373-396(24)

<sup>55</sup> For a very clear and concise presentation of the Directive 2005/36/EC see: [http://europa.eu/legislation\\_summaries/education\\_training\\_youth/vocational\\_training/qualifications\\_recognition/c11065\\_en.htm](http://europa.eu/legislation_summaries/education_training_youth/vocational_training/qualifications_recognition/c11065_en.htm)

<sup>56</sup> For the national transposition measures regarding Directive 2005/36/EC see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:72005L0036:EN:NOT>



## Study on the Legal Framework for Interoperable eHealth in Europe

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Specific problems also arise in the area of professional responsibility. Most of the Member States apply their general liability regime in case of medical errors or negligence in providing healthcare. A few Member States however have introduced specific liability rules increasing protection for patients. In other Member States the law provides insurance for patients in case of damages due to medical errors. It is not always clear how these divergent solutions have to be combined in case of cross-border eHealth services.

In the following paragraphs of this chapter, we will explain these issues in further detail by looking at some case examples from selected Member States. For a complete description of the situation in every single Member State, we refer to the national country profiles.

### 5.1 Practice of medicine and monopoly of physicians

In **Denmark** practice of medicine is not an exclusive monopoly of physicians or other healthcare professionals. However, a number of treatments and practices are reserved for healthcare professionals who have obtained a legal diploma authorizing him or her to practice a particular profession. In addition, persons without a legal diploma can be sanctioned if they treat people who are ill and thereby expose them to discernible danger. Furthermore, only healthcare professionals with a legal diploma are allowed to entitle themselves as “physician”, “nurse” etc.

The practice of medicine is regulated by the Act on Authorization of Healthcare Professionals and of Provision of Healthcare 2006.<sup>57</sup> The practice of pharmacists is regulated by Consolidating Act of Pharmacies 2007.<sup>58</sup> The legal diploma confers both rights and duties to the professionals. The duties include a general obligation to practice good care and a number of more specific obligations e.g. to report information to the National Board of Health and to various medical and administrative databases. The rights relate to the use of title and to the monopoly provided for the healthcare professionals.

The monopoly conferred to physicians with a legal diploma is both positively and negatively delimited in law. Section 74 of the Act on Authorization of Healthcare Professionals and of Provision of Healthcare stipulates that only physicians with a legal diploma are entitled to treat infectious diseases, to perform surgery and obstetrics, use anaesthetics and use pharmaceuticals which must be prescribed. Some exceptions are made in regards to dentists and midwives, and the physician may use assistants and authorize them to perform some of the medical practices which are under their monopoly. In addition the monopoly can be delimited negatively according to section 73 which stipulates that persons without a legal diploma are – within the limit of section 74 – free to provide treatment and care to persons who are ill, provided that they do not expose the patient to any discernible danger.

The Act on Authorization of Healthcare Professionals and of Provision of Healthcare does not clarify precisely which acts belong to the field of medicine and there have been discussions about the legal monopoly in connection with e.g. acupuncture, piercing and cosmetic services. Section 74 of the Act on Authorization of Healthcare Professionals and of Provision of Healthcare now clearly stipulates that acupuncture – which is defined as “surgery” – is outside the legal monopoly of physicians.

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<sup>57</sup> lov nr. 451 af 22 maj 2006 om autorisation af sundhedspersoner og om sundhedsfaglig virksomhed: <http://www.sundhedsjura.dk/lovsamling/AUTORISATIONSLOVEN.pdf>

<sup>58</sup> lovbekendtgørelse nr. 657 af 28 juli 2007 om apoteksvirksomhed

**Study on the Legal Framework for Interoperable eHealth in Europe**

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In the **Netherlands** a prohibition of the practice of medicine by others than medical doctors has been replaced by a system of “reserved actions” (medical acts which may only be performed by medical doctors or other groups of designated persons). This list of reserved actions is supposed to describe the most hazardous actions which must be certain to be performed by competent people. The reserved actions currently listed in Article 36 are:<sup>59</sup>

1. surgical treatment;
2. obstetric assistance;
3. endoscopy;
4. catheterization;
5. injections;
6. punctures;
7. anaesthetizing a patient;
8. the use of ionizing radiation
9. the employment of elective cardioversion;
10. applying defibrillation;
11. the employment of electro-convulsive therapy;
12. the use lithotripter for medical purposes;
13. actions with human reproductive cells and embryos, not aimed at accomplishing a natural pregnancy.

Doctors are the only medical professionals qualified to perform all reserved actions mentioned, as far as they may reasonably assume themselves to be competent. Besides doctors, dentists and midwives are qualified to perform a (certain) number of reserved actions, again as far as they may be deemed competent.

In **Belgium** or in **Slovakia** no person may practice medicine unless he holds a legal diploma of physician. This monopoly is exclusive, which means that with the exclusion of all others, physicians are competent to practice medicine. It is also all-embracing, which means that it covers every activity that has to be considered as belonging to medicine. An exception has been made for dentistry: generally speaking physicians are not allowed to practice dentistry. The term “medicine” is not explicitly defined by law but interpreted on a case-by-case basis.

In **France** physicians can perform acts of care, i.e. related to diagnostic and treatment, but also investigations and preventive acts. The scope of competence of physicians has been substantially enlarged but at the same time other healthcare professionals have been granted similar competences. The monopoly of prescription of physicians has moreover tended to be reduced. They now often share this prerogative with other healthcare professionals such as midwives, dental surgeons or nurses. This can be source of conflicts and confusion, especially given the fact that professions of the health sector keep multiplying. Furthermore, the legislator not only enlarged the scope of acts reserved to healthcare professionals but also the main concept of healthcare professionals. By way of example, the Law of 9 of August 2004 has broadened the competences of midwives who can perform examinations after “normal” pregnancy and deliveries.<sup>60</sup>

Finally, in **Germany** exclusively physicians are authorized to offer medical care services under the title “Arzt” (physician). The medical profession under the title “Arzt” is left to licensed, (“approbierte”) or temporary licensed persons. But unlike the French, Austrian or Swiss law, non-licensed persons may offer therapeutic services too, but they are not allowed to practice as “doctors” or “physicians” (“Arzt”).

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<sup>59</sup> Wet op de beroepen in de individuele gezondheidszorg, art. 36: <http://wetboek.net/lexicon/arts.html>

<sup>60</sup> Laude A. et al, Droit de la santé, coll. Thémis droit, ed. PUF, 2007,p.388

## Study on the Legal Framework for Interoperable eHealth in Europe

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They may, for instance, practise as “Heilpraktiker” (non-medical practitioners) and they also need a licence according to art. 2 par. 1 lit. i of the First Executive Decree on non-medical practice acts.<sup>61</sup>

These examples demonstrate that the delimitation of medical practice and the list of actions reserved for particular healthcare professionals is not necessarily identical in all Member States. When providing cross-border healthcare services, for example in the context of an eHealth environment, these divergences need to be taken into account.

### 5.2 Licensing/authorization for medical practice

Responsibility for licensing/authorization for independent medical practice in the Member States generally lies with the Ministry of Health. In only a few countries the full licensing responsibilities lie with an independent professional body. **Rowe and Garcia-Barbero** have summarised the situation in Europe as follows:<sup>62</sup>

“In some countries, while the license is issued under the Minister’s signature, membership or registration with an independent professional Chamber, Order, College or Council is an additional precondition for practice as a doctor, and obligatory membership/registration with these bodies is imposed by law as a condition of practice. The relevant professional body then maintains a Register of licensed physicians. These bodies are autonomous, but have delegated responsibilities provided for in primary or secondary legislation, notably to maintain a Register and to carry out Regulation of licensed medical practitioners.

Some Chambers are responsible for all licensing/authorization to practice, and of the others, most are responsible for registering specialist recognition. The Register of Licensed Physicians is not in every Member State considered as a public document.

In one or two countries, evidence of membership (or application for membership) of the professional Chamber is required when a physician is submitting an application to the Minister for a license/authorization. Either way, where such membership is obligatory, the Chamber/Order etc. clearly has a role in the verification and recognition of qualifications of the purpose of membership and registration.

In some countries, (Austria, France, Ireland, Slovakia and United Kingdom), licensing/authorization is directly the responsibility of totally independent Chamber established as such under separate legislation.

While licensing is in most countries carried out at national level, authorization for practice (mostly linked to registration) can sometimes take place at regional level. Locally it can be with the Chamber/Order/Council etc. or with the relevant Health Official, and may involve other appropriate government officials at provincial or local level. Specialist training recognition is commonly in the hands of the Chambers/Orders where these exist, and they generally have some role in determining the content of training either directly or indirectly.

In some countries, before practising a further license is required relating to the adequacy and appropriateness of the premises in which the physician proposes to provide services.”

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<sup>61</sup> Erste Durchführungsverordnung zum Gesetz über die berufsmäßige Ausübung der Heilkunde ohne Bestallung, as last amended BGBl. I 2002, p. 4456, 4458: [http://bundesrecht.juris.de/bundesrecht/heilprgdv\\_1/gesamt.pdf](http://bundesrecht.juris.de/bundesrecht/heilprgdv_1/gesamt.pdf)

<sup>62</sup> Alan Rowe and Mila García-Barbero, Regulation and licensing of physicians in the WHO European Region, WHO Regional Office for Europe, 2005, 161 p: <http://www.euro.who.int/document/e87789.pdf>

## Study on the Legal Framework for Interoperable eHealth in Europe

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The license may be granted on the basis of the following evidence:

- evidence of medical diploma and satisfactory completion of obligatory period of intern/practical training;
- evidence of medical diploma, completion of practical/intern period and certificate of completion of specialist training (including GP/FM specialist or GP training);
- completion of specific GP training, where the GP/FM specialist qualification is not a condition for obtaining a license for practice as a general practitioner.

Amongst other requirements the following may be demanded

- evidence of being a national of the country (many countries);
- evidence of being in good standing (no criminal convictions or professional disciplinary sanction);
- evidence of satisfactory physical and mental health (relatively common);
- evidence of membership of the professional Chamber (e.g. in **Slovenia**).

Most licenses are issued for an indefinite period. In some countries however, some form of re-licensing/re-accreditation is required every 3- 7, after some years without working (5 years for Poland and Romania) and in a few countries after 65-75 years of age. In a few countries the license ceases at the retirement age of 70 years. Re-licensing/re-accreditation is mostly associated with requirements to fulfil obligations concerning continuing medical education. .

In nearly all licensing legislation, there are special dispositions for dealing with applications for licensing from non-nationals holding foreign qualifications.

In the context of this report it is evidently not possible to go into the details of the licensing systems of all the Member States. We will only describe some typical cases by way of examples and refer the reader to the national country profiles for the situation in every single EU Member State. For this report the most important conclusion is that, in order to provide healthcare services in a Member State, it is almost always necessary to obtain a licence in that Member State. The conditions to fulfil vary from one Member State to another. Sufficient mastering of the national language(s) is generally one of the essential requirements.

In **Germany** the Federal Medical Practitioners' Act<sup>63</sup> rules the admission to the profession of physicians. Physicians need to be licensed to practise as doctors. It is also possible to practise on the basis of a temporary licence or a licence that is restricted to specific activities. In order to implement Council Directive 2005/36/EC, exemptions from the need of a licence are made for nationals of European Member States or nationals of a Signatory State which has granted a reciprocal treaty right to Germany and the European Community or to Germany and the European Union *but only for those who offer their medical service temporarily and occasionally*. Another exception is made for physicians in areas close to the borders, if special intergovernmental contracts have been concluded in this area.

The licence is granted if the demands in art. 3 are fulfilled. These are: German nationality according to art. 116 of the Basic Law or an equivalent (especially EU-Member state nationality), certificate of good standing, fitness to practise medicine, medical examination after 6 years of university studies of medicine including eight to ten months of practical training (or equivalent, e.g. medical training completed in EU-Member-States of equal value), and knowledge of German as deep as necessary to practice medicine.

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<sup>63</sup> Bundesärzteordnung, *abbrev.* BÄO, available at [http://bundesrecht.juris.de/b\\_o/BJNR018570961.html](http://bundesrecht.juris.de/b_o/BJNR018570961.html)

## Study on the Legal Framework for Interoperable eHealth in Europe

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According to art. 3 par. 6 of the Act, in order to get the licence to practise medicine, the applicant has to submit: a certificate to proof nationality, an officially certified copy of competence or education, official documents presenting information about non blameworthy behaviour, certificate concerning the applicants health, an official document confirming the accordance of the certificate of competence with the regulations of the BÄO, and – if relevant – information or official documents on the contents of education outside Germany.

In **France** the exercise of medicine is subject to the registration into the list of a provincial council of the competent Order. All professionals are subject to this obligation, included the healthcare professionals of the public sector. Only professionals from the army and civil servants are exempted. The registration is an administrative decision subject to the compliance with conditions of morality, independence, check of moral and physical capacity and a sufficient knowledge of French language.<sup>64</sup> Nationals of other EU Member States who are established as physicians in a Member State are entitled to provide medical services in France without being registered on the list of the Order of Physicians (but need to notify their activities to the National Council of the Order of Physicians and to demonstrate also a sufficient knowledge of French language.

The **Cyprus** Medical Council (CMC) is the Competent Authority in Cyprus for the recognition of professional qualifications and the registration of doctors. In order to work in the public sector in Cyprus individuals must either be a Cypriot citizen, a 'first degree' relation of a Cypriot citizen who usually resides in Cyprus, or a citizen of an EEA member state. Individuals are also required to have, as a minimum, a good knowledge of the Greek language, if one has excellent English. The Public Service Commission has a list of diplomas which are recognised as proof of competence in Greek and in English. This list is available upon request either from the Public Service Commission, or from the Medical and Public Health Services. To determine one's proficiency in the Greek language, written examinations are conducted twice a year by the Public Service Commission. The Public Service Commission also organises examinations for the determination of proficiency in the English language. Applications for vacancies in the sector must be made to the Public Service Commission. The Public Service Commission then distributes the applications as appropriate for assessment.

The Ministries in turn decide if the applicants for permanent posts should be invited for a written and/or an oral examination. After evaluation, the top scorers are short-listed and the list is passed to the Public Service Commission for final selection. In relation to locum posts, a waiting list of candidates is made according to skills and competencies; the list is used as a guide for employment in cases where shortages in the relevant services need to be addressed immediately. All public sector doctors are salaried employees of the Ministry of Health and belong to a centralised civil service staffing system that allocates them to posts based on specified needs.

### 5.3 Control over the practice of medicine

The provision of healthcare services, in particular the practice of medicine, is generally supervised by professional bodies. There is very little co-ordination or exchange of information between these national supervisory instances of the Member States. A disciplinary sanction in one Member State doesn't necessarily prevent a physician to register in another Member State.

Yet, Directive 2005/36/EC provides for exchange of information and cooperation between the competent authorities of the Member States. Articles 8 and 56 of this Directive refer to the exchange of information between the host and the home Member States' competent authorities regarding

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<sup>64</sup> For more details and for the requirements concerning other healthcare professions, see <http://www.conseil-national.medecin.fr/?url=instal/article.php&offset=0> .

Study on the Legal Framework for Interoperable eHealth in Europe

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disciplinary action or criminal sanctions taken or any other serious, specific circumstances which are likely to have consequences for the pursuit of the activities under the 2005/36/EC Directive.

Some efforts to promote coordination and exchange of information have been made in the context of the "Health Professionals Crossing Borders" (HPCB) initiative.<sup>65</sup> Early 2008 a "General Memorandum of Understanding Covering the Proactive and Case-by-Case Exchange of Disciplinary Information between Competent Authorities and Similar Bodies" has been approved.<sup>66</sup> At the time of closing this report, only 13 competent authorities had signed this MoU since its publication. The MoU was created to describe an agreed minimum level of information-sharing between regulators in disciplinary cases, and the processes for undertaking that exchange of information. Its purpose is to protect patients and the public from healthcare professionals whose practice might put patients at risk and to contribute to high-quality healthcare across Europe.<sup>67</sup> In a shared address to the Healthcare Professionals Crossing Borders initiative, Catherine Lien Jensen and Lars Swanstrøm, both of the Norwegian Registration Authority, noted that "proactive information sharing between regulators could be fairly uncomplicated in theory, but it seems that differences in systems and culture make the process more complicated and difficult than many have expected."<sup>68</sup>

Again we will illustrate the various ways in which the supervision is organised, by giving some examples from selected Member States. For the situation in every single Member State we refer to the national country profiles.

In **Austria** medical practice is supervised by the Chamber of Physicians. Physicians who want to practice medicine have to inscribe on a list of the Chamber, which automatically leads to a membership in the Chamber. The Chamber consists of 9 provincial chambers and the Austrian Chamber of Physicians. The latter organisation is responsible for supervision and also for disciplinary sanctions. The organisational structure of the Chamber and the disciplinary code (*Disziplinarrecht*) are regulated in the Physician Act of 1998.

All members of the Chamber of Physicians are subject to the disciplinary code, regardless whether they are employed or self-employed. A disciplinary offense is committed by a physician, if (section 136 Physician Act):

- the reputation of the medical profession is discredited (defamations);
- the physician is involved in malpractice;
- medical practice is exercised despite a temporary ban on profession due to a disciplinary sanction;
- sentenced to a minimum of 6 months custodial sentence due to a deliberate offence or a minimum fine of EUR 36 340.

In **Germany** the practice of the physicians, dentists, veterinary surgeons, and psychological psychotherapists is supervised by the medical associations. Each medical branch has its own medical association, and generally, each one of them exists in all German *Länder*<sup>69</sup>. According to the Medical

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<sup>65</sup> <http://www.hpcb.eu/hpcb/index.asp>

<sup>66</sup> [http://www.hpcb.eu/hpcb/activities/documents/MOU\\_Master\\_March\\_2009.pdf](http://www.hpcb.eu/hpcb/activities/documents/MOU_Master_March_2009.pdf)

<sup>67</sup> The list of signatories is available on the HPCB website at [www.hpcb.eu/hpcb/activities/information\\_sharing.asp](http://www.hpcb.eu/hpcb/activities/information_sharing.asp)

<sup>68</sup> Quoted by Roger Collier, Doctors crossing borders. Europe's new reality, CMAJ. 2009 January 20; 180(2): 158–161: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2621290>

<sup>69</sup> In North-Rhine/Westphalia, there are two associations for one branch; some associations have only one for all the 5 eastern New Länder, e.g. the Psychotherapeutenkammer Ostdeutschland.

## Study on the Legal Framework for Interoperable eHealth in Europe

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Associations Acts<sup>70</sup>, each physician etc. has to be member of the medical association in his area and branch. Nationals of other EU Member States who are established as physicians in a Member State are entitled to provide medical services in Germany. They also have to be members of the Medical Association if they are not only practising temporarily in Germany. If German physicians practise in Germany and start practising in another EU Member State at the same time, they have to announce that to their German Medical Association.

As its member, the physician is subject to the Medical Association's professional code of conduct. Furthermore, the members have to obey the Medical Associations Acts. These acts are ruling how to handle professional offences. Therefore, each member carrying out his profession has to notify this to the Medical Association in order to enable the Association to supervise the compliance with the professional code of conduct. Offences against the code of conduct may cause the following consequences: The Medical Association can rebuke physicians for a non-serious offence against the code of conduct (see e.g. art. 64 of the Medical Associations Act of Lower Saxony)<sup>71</sup>. In case of serious offences, the infringement comes before the Professional Court of Conduct (see e.g. art. 63 of the Medical Associations Act of Lower Saxony). In most of the German *Länder*, these Courts are part of the state courts for administrative or ordinary jurisdiction. Only three *Länder* have introduced specific courts of conduct.<sup>72</sup> The trial starts before the Professional Court of Conduct. Afterwards, the court of appeal, the *Landesberufsgesicht*, makes the final decision. There is no third instance on federal level, which could ensure uniform jurisdiction all over the country. This results in jurisdiction that differs from *Land* to *Land*.<sup>73</sup>

The Professional Code of Conduct contains the rules concerning the further vocational training, quality assurance, duty to inform the patient, medical secrecy and handing over of medical data to colleagues, duty to document diagnosis and therapy, conduct within physician-patient relationship, application of new measurements of therapy, dealing with ethical questions concerning abortion and medical research and death, shared praxis and corporation with other branches of healthcare providers, physicians as salaried employees, stand-by duty, advertising.

The practice of medicine in **England** is supervised by the General Medical Council (GMC). In order to practice as a doctor, a person is required to apply for registration with the GMC.<sup>74</sup> The GMC lays down standards of care expected from doctors and has the power to impose sanctions up to and including removal from the register on a temporary or permanent basis. Extensive guidance is published concerning professional standards with the main document being 'Good Medical Practice'.<sup>75</sup>

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<sup>70</sup> Kammergesetz für die Heilberufe (HKG) in German. This is federal state law, which results again in 16 of these Acts, one for each German Land.

<sup>71</sup> Act of Dec. 8, 2000, Official Journal of Lower Saxony (Nds. GVBl.) 2000, p. 301, last updated by act from May 18, 2006, Nds. GVBl. 2006, p. 209, *available at* [http://www.aekn.de/web\\_aekn/bibliothek.nsf/WebDocumentView/F44B714D87E6B941C1257180002FF124/\\$FILE/kammergesetz.pdf](http://www.aekn.de/web_aekn/bibliothek.nsf/WebDocumentView/F44B714D87E6B941C1257180002FF124/$FILE/kammergesetz.pdf)

<sup>72</sup> So did e.g. Lower Saxony by founding the Gerichtshof für die Heilberufe – Court of justice for the healthcare professions.

<sup>73</sup> Hoppe/Schirmer, in: Wenzel, Handbuch des Fachanwaltes Medizinrecht, 2007, ch. 9, recital 35, p. 824.

<sup>74</sup> The Medical Register contains details of all registered doctors and can be consulted on line <http://www.gmc-uk.org/register/index.asp>

<sup>75</sup> This can be accessed on line at [http://www.gmc-uk.org/guidance/good\\_medical\\_practice/index.asp](http://www.gmc-uk.org/guidance/good_medical_practice/index.asp) Extensive guidance is provided also on ethical issues and can be accessed at [http://www.gmc-uk.org/guidance/a\\_z\\_guidance/index.asp](http://www.gmc-uk.org/guidance/a_z_guidance/index.asp)

## Study on the Legal Framework for Interoperable eHealth in Europe

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The practice of medicine in **France** is supervised by the Order of Physicians. The Order includes all physicians who are permanently residing in France and who are inscribed on the list of the provincial orders. As already mentioned earlier in this report, nationals of other EU Member States who are established as physicians in a Member State are entitled to provide medical services in France without being registered on the list of the Order of Physicians but need to notify their activities to the National Council of the Order of Physicians and to demonstrate a sufficient knowledge of French language. Such a physician will nevertheless be subjected to the jurisdiction of the Order for his activities on the French territory.

The most important function of the provincial councils of the French Order of Physicians is to ensure observance of the rules of professional ethics for physicians and the upholding of the reputation, standards of discretion, probity and dignity of the members of the Order. The Code of medical ethics, established by the Order of Physicians, contains the rules concerning the general obligations of physicians (e.g., respect of individual dignity, professional secrecy, independence, morality, probity and, free choice of the physician, freedom in prescription of medicine), its obligations towards patients, towards other physicians and other healthcare professionals.<sup>76</sup> The code is approved by decree adopted by the State Council and as such has been integrated to the Public Health Code, in the regulatory part. The order of Physicians can impose a disciplinary sanction to the physician who has infringed a rule of the Code. It is the only authority to state on disciplinary sanctions, being however possible to appeal to the State Council [*Conseil d'Etat*]. It is moreover worth noticing that since the mid-nineties, civil and administrative jurisdictions make increasingly use of the code of medical ethics in civil or criminal liability cases.

In **Poland**, pursuant to the Act on the profession of physician and dentist, medical practices are supervised by the regional medical council. The supervising body is entitled to undertake necessary inspections and to issue recommendations. The National Medical Council has the same authority over the whole country. Controlling bodies may share inspection information with relevant authorities, on their request.

The examples mentioned before only deal with the supervision of *medical* practice in the Member States. Additionally most of the Member States have also supervisory schemes for healthcare *institutions*. This supervision relates to quality criteria but often also includes financial and management aspects.

By way of example, the National Public Health and Medical Officers' Service (NPHMOS) in **Hungary** practises vocational supervision on the healthcare providers and services. Regular monitoring of providers includes checking personnel and material, minimum standards and the quality of provided services. The system consists of supervisory chief medical doctors at the municipal level for primary care, and at the county and in some cases regional level for various medical specialties. The county and municipal chief medical officers appoint supervisor chief medical doctors, in collaboration with the professional colleges and national institutes of health. Quality assurance is supervised mainly by two authorities. OSZMK (National Centre for Healthcare Audit and Inspection) is responsible for monitoring on site with close cooperation with providers, while Health Insurance Supervisory Authority acts as health consumer protector and also disseminates quality indicators.

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<sup>76</sup> Conseil National de l'Ordre des Médecins, Introduction aux commentaires du Code, available online (in French) at: <http://www.conseil-national.medecin.fr/?url=deonto/rubrique.php&open=0#0>



## Study on the Legal Framework for Interoperable eHealth in Europe

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### 5.4 Professional liability

A further legal aspect to be examined in the framework of interoperable eHealth in Europe is professional liability. Most of the Member States apply their general liability regime in case of medical errors or negligence in providing healthcare. A few Member States however have introduced specific liability rules increasing protection for patients. Again this aspect is important to keep in mind when providing cross-border healthcare services in Europe. A patient taking cross-border eHealth services provided from another Member State will not necessarily remain under the scope of the legal protection against medical errors offered by his own legal system.

In **Germany** professional liability of physicians is not regulated within special legislation. Consequently, the professional liability of a physician, with the exception of disciplinary liability, derives from general laws of compensation of damage laid down in the German Civil Code. In addition to these general rules on compensation of damage, the courts have developed special rules on medical professional liability. Liability of contract and liability of torts do coexist. Non-contractual or tortious liability is especially relevant when services are rendered to a patient who is not in a position to give consent to treatment, e.g. because of his medical problem or his minority. Nevertheless, in these cases, the parents or other representatives may have completed a contract for the benefit of a third party which builds up the foundation for contractual liability. In the case of damage to a third party, contractual liability is applicable if a contract with protective consequences for third parties has been made. One example is the protection of the unborn child on the basis of the contract on the delivery with the pregnant woman.

Characteristic of medicine in all its forms is that a patient is confronted with more than one physician working as a medical team. This often complicates the determination of responsibilities when an accident happens. Matters are still more complicated because the physician may employ assisting staff (then liability of torts of the employed staff is applicable). Also the physician him- or herself may act under differing statutes: as an employee (then liability according to art. 823 and employer's liability according to art. 831), a civil servant (physicians liability: art. 823, liability of the employing body), or as a private service provider on his own account (only physician's liability according to art. 823). The difference between these situations is directly relevant for the nature and the parties to the contract with the patient and consequently also for the discussion about liability for damages.

Civil liability of a physician arises when an obligation is not fulfilled. Obligations originate either from a contract or from tort. The contract for medical services exists between a physician and his patient or between the employer of a physician (a hospital) and a patient. If the physician has referred the patient to another physician, e. g. a specialist, a second contractual relationship is build up between the latter physician and the patient. Both civil liability and criminal liability of the physician for damage or injury caused by improper performance are possible. There are two sources of improper performance: medical malpractice on the one hand and a lack of patient information and education on the other hand.

In **Poland** civil liability of a physician can originate from tort or contract. Different liability patterns may occur in practice. Contractual liability occurs when a physician or a healthcare institution signs a service provision contract directly with the patient. When, however, the service is remunerated from the health insurance scheme, and no separate contract is signed with the patient, the liability is based on tort. The same holds for liability of a physician employed by a healthcare institution, if he/she does not sign a separate contract with the patient. Liabilities of the healthcare institution (contractual or based on tort) and of the physician (based on tort) concur in such a situation.

No specific provisions exist concerning the extent of the liability of doctors within **England**. Because of the nature of the NHS, no contractual relationship exists between doctors and patients (although this may be the case with private medical treatment). Medical staff will be potentially liable on a non-contractual basis under the law of negligence and recent years have seen a considerable increase in

## Study on the Legal Framework for Interoperable eHealth in Europe

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the number of claims brought against doctors. In the case of claims brought against general practitioners, the individual doctor (though his insurance provider) will be the defender. In the case of hospital based doctors, the principle of vicarious liability whereby an employer is held liable for wrongs committed by employees in the course of their duties will mean that in most cases the relevant NHS trust will be the defender.

In terms of the standard of care expected of a doctor, English law requires that they comply with the standard which would be '*accepted as proper by a responsible body of medical men skilled in that particular art*'<sup>77</sup> Thus a higher standard would be expected of a senior than a junior doctor. Matters may become more complex when, as is normally the case in a hospital environment, care is provided by a team of health professionals. Whilst accepting that a component of a senior team member's duty of care is to check on the work carried out by others the courts have refused to impose overall liability in cases where there was limited possibility of intervention. In addition to civil liability there may in extreme cases of negligence be the prospect of criminal prosecution being brought. No specific test has been laid down for determining whether negligence is at such a gross level as to justify criminal prosecution. In the case of *R v. Adomoko*<sup>78</sup> the House of Lords held that this issue was one which should be left to the jury in a criminal prosecution.

In **Belgium** a law of 15 May 2007 on the compensation of damage as a consequence of healthcare introduced the concept of faultless liability in the health sector.<sup>79</sup> The basic principle of this law is that victims of damage as a consequence of healthcare do no longer have to prove the existence of a fault committed by the health professional. Normally the law had to enter into effect on the 1<sup>st</sup> of January 2008, but this date has been postponed. Consequently, the professional liability of a physician is, with the exception of disciplinary liability, currently not governed by special laws in Belgium. This means that both the civil liability and the criminal liability of the physician for damage or injury caused by improper performance of the duties entailed in the discharge of his professional functions, are governed by the general rules of civil and criminal law.

Civil liability of a physician arises when an obligation is not fulfilled. Obligations originate either from a contract or from tort. The Belgian courts have acknowledged the possibility of a contract for medical services existing between a physician and his patient or between the employer of a physician ( a hospital) and a patient. Non-contractual or tortious liability is only relevant in the case of damage to a third party or when services are rendered to a patient when the latter is not in a position to give consent to treatment. It is not surprising that hospital physicians are more involved in malpractice actions than general practitioners, and, in general, physicians who practice outside the premises of a hospital. Many malpractice cases before courts relate to medical apparatus: actions based on the use of defective equipment, inexperienced use of available apparatus and/or lack of supervision on the technicians using the apparatus. Especially anesthesiologists have been confronted with this sort of claims. A third category of malpractice suits relating to medical apparatus is based on the fact that no use was made of a piece of equipment, although it was available and in good shape at the time.

Characteristic of hospital medicine is that a patient is not confronted with one physician but with a medical team. This often complicates the determination of responsibilities when an accident happens. Matters are still complicated because a surgeon may employ his own nursing personnel while anesthesiologists can make use of personnel employed by the hospital. Also the physician may act

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<sup>77</sup> *Bolam v Friern HMC* [1957] 2 AllER 118 at 121.

<sup>78</sup> [1994] 2 All ER 79.

<sup>79</sup> *Moniteur belge*, 6 July 2007

## Study on the Legal Framework for Interoperable eHealth in Europe

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under different statutes: as an employee, a civil servant or as a private service provider on his own account. The difference between these situations is directly relevant for the nature of the contractual relationship with the patient and consequently also for the discussion about liability for damages.

In **France**, since an important ruling of the French Supreme Court of 20 May 1936, the so-called “Mercier judgment”<sup>80</sup>, the relationship of the physician and the patient is qualified as contractual relationship and thus subject to general civil liability rules. This ruling has also defined the nature of the obligation of the physician who does not have the obligation to cure the patient (obligation of result) but to provide him/her careful and adequate care (obligation of means). It further recognizes that medical acts are by nature unpredictable given that their results depend on a series of uncontrollable factors, e.g. the suffering of the patient to the treatment, the apparition of secondary effects, the nature of the sickness itself. The commission of a fault by the physician should thus be proved to engage his liability. In the public sector, the patient is considered as user of a public service and as such subject to the general State’s liability rules as defined by administrative law.

A French law of 4<sup>th</sup> May 2002, following the jurisprudence, has introduced two cases of faultless liability: for damages caused by contagion in a health establishment and by defective health products. The victim has only to demonstrate that the damage has been caused by the physician during the performance of the medical act. Contagions in a health establishment are however automatically repaired by the National Office of medical accident reparation (*Office national d’indemnisation des accidents médicaux*) whenever they have provoked an incapacity superior to 25% or the death. In these specific cases, the health establishment remains liable if a fault is at the origin of the damage. With regard to defective products, the jurisprudence had recognized an obligation of “security-result” of producing a device without default, on the basis of the law on defective products transposing the European Directive. This covered any device used by the physician when performing a medical act. However, some scholars wonders whether this specific obligation would survive to the new wording of the Law of 4 March 2002 which subjects the application of article L.1142-1 I to the conditions of liability as defined by the Law of 19 May 1998 on defective products.<sup>81</sup>

It is worth mentioning that since 1992, the administrative liability regime has been relaxed and a simple fault is sufficient to engage the liability of the public hospitals<sup>82</sup>. With regard to private hospitals, the jurisprudence has established that these establishments are liable for their staff.<sup>83</sup> A hospitalization contract is concluded between patient and the clinic, being the latter contractually liable for third parties’ acts towards the patient. This regime does not however apply to private hospitals or when a serious fault can be distinguished from the service. Civil judges would then be competent to determine the liability of the physician.

A doctor who is practising medicine in **Sweden** is requested to exercise his profession in *accordance with the scientific development and reliable experience* (Chapter 2 Section 1 of the Professional Activities in the Health and Medical Care Field Act). As there is no legal definition of this concept an explanation of “scientific development and reliable experience” has to be derived from administrative

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<sup>80</sup> Supreme Court, Civil Chamber (Cass. Civ.), 20 mai 1936, DP, 1936, I, 88, concl. Matter.

<sup>81</sup> Dorsnet-Dolivet A., La responsabilité du médecin, coll. Pratique du droit, ed. Economica, 2006, p. 212-213.

<sup>82</sup> State Council (CE), Assembly, 10 April 1992, *Epoux V.*

<sup>83</sup> See for instance, Civ. 1e, 9 novembre 2004, (01-17.168 for midwives and 01-17-908 for surgeons) ; D. 2004, inf. rap. p. 3039; JCP 2004, IV, 3452 et 3453 ; Gaz. Pal. 14 November 2004, p.34 ; Revue Lamy Droit Civil, December 2004, p. 21.

## Study on the Legal Framework for Interoperable eHealth in Europe

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provisions governing the professional duties as well as individual decisions of the Medical Responsibility Board (*Hälso- och sjukvårdens ansvarsnämnd*).<sup>84</sup> If the doctor fails in his professional duty, intentionally or negligently, and the fault is more than trivial, the Medical Responsibility Board may impose disciplinary sanctions (a reminder or a warning) after notification from the National Board of Health and Welfare or the patient concerned. In serious cases the licence to practise may be revoked and the doctor removed from the medical register.

All patients, in public as well as in private care, are covered by an insurance ("Patient Insurance") paid by the county councils and other care providers. The insurance gives the patient economic compensation for injuries that occur in connection with medical examination, treatment and care. It operates on a no-fault principle, i.e. the patient does not have to prove that the injury is due to negligence on the part of the physician or other personnel.

The examples described above illustrate how complex and diverse the liability rules of the Member States with regard to the provision of healthcare can be. Therefore it will be crucial to determine which national law applies in case of providing cross-border eHealth services. To a certain extent - e.g. between healthcare professionals involved in a teleradiology scenario – the question can be solved by a contractual choice-of-law clause. In other situations legal questions will arise about the validity of a contractual choice-of-law and the applicability of the protective rules for consumers in Art. 5 of the Rome Convention.<sup>85</sup> Still more complex could it be to determine the applicable law for torts and delicts arising from non-contractual obligations.<sup>86</sup> Finally the scope of the applicable insurance contract or of the insurance regime with regard to cross-border situations will come into play. The uncertainty with regard to the outcome of these complicated legal questions is without any doubt an important obstacle for interoperable eHealth in Europe.

### 5.5 Professional secrecy

A last item related to the regulatory framework with regard to the healthcare profession, which can be relevant for interoperable eHealth in Europe, is the professional secrecy duty of healthcare professionals. This is again a topic on which the rules in the Member States show considerable divergence. In some countries the secrecy obligation is very strict and patients are not able to relieve the healthcare professional from his duty to keep secret medical information. In other countries the obligation is less strict and professionals can transmit confidential medical information under certain conditions. The obligation of professional secrecy is, in most of the Member States, included in the criminal code but there are exceptions (e.g. **Spain**).

In **Austria** the medical secrecy of physicians is regulated in section 54 of the Physician Act 1998. This act stipulates that a physician and his assistants are obliged not to disclose confidential information acquired in the course of their professional practice concerning patients.

Medical secrecy is however not applicable if:

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<sup>84</sup> <http://www.hsan.se/>

<sup>85</sup> Convention on the law applicable to contractual obligations opened for signature in Rome on 19 June 1980 (80/934/EEC), Official Journal L 266, 09/10/1980 p. 0001 – 0019, [http://www.rome-convention.org/instruments/i\\_conv\\_orig\\_en.htm](http://www.rome-convention.org/instruments/i_conv_orig_en.htm)

<sup>86</sup> Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II), [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l\\_199/l\\_19920070731en00400049.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_199/l_19920070731en00400049.pdf)

Study on the Legal Framework for Interoperable eHealth in Europe

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- the physician is legally requested to give information about the state of health of a person;
  - the social security agency receives information by the physician, needed for the fulfilment of tasks;
  - the patient releases the physician from his obligation of confidentiality;
  - the disclosure is justified by reasons of public health or judicature.

In **Greece**, physicians are obliged to protect the confidence entrusted by their patients. According to article 13§1 of the Code of Medical Ethics the physician has the obligation to keep medical information confidential. This obligation is absolute. Paragraph 2 of the same article stipulates that “in order to strictly and effectively respect medical secrecy, the physician has to observe the necessary discretion regarding his collaborators, assistants or third parties which take part in one or another way or support the medical service”. He shall also take every necessary measure to safeguard confidentiality even after the termination of his medical practice. The duty to respect medical secrecy may be waived by the consent of the person concerned, except when this consent is not valid as in case of error, deceit, deception, physical or psychological violence or when it violates human dignity (14§3 Code of Medical Ethics).

In **France**, the breach of professional secrecy could imply a penal (Art. 226-13 Penal Code) but also a disciplinary sanction<sup>87</sup> sometimes combined with administrative or civil liability. Article 226-13 of the Penal Code states that “the disclosure of secret information by a person entrusted with such a secret, either because of his position or profession, or because of a temporary function or mission, is punished by one year's imprisonment and a fine of €15,000”. This article thus implies in first place that the person entrusted is depositary of a secret. In that sense, article 4 of the Medical Ethics Code compels physicians to secrecy about any information they would have access to during the practice of their profession, i.e. “not only the information (s)he has been told but also anything (s)he would have seen or understood (Public Health Code, article R.4127-4)”. In order to comply with this obligation they must ensure that their assistants are made aware of their professional secrecy obligation and comply with it. More recently, the Act n°2002-303 of 4 March 2002 has extended the professional secrecy to healthcare professionals and professionals participating in the health system (new article L.1110-4 of the Public Health Code). It covers any information accessed to during their activities. It also defines this obligation as a right of the patient and an obligation for the healthcare professional.

Secondly, article 226-13 of the Penal Code implies a information being ‘secret’. The source of the information, the content of the secret and its limits should thus be defined. Jurisprudence has recognized medical secrecy as general and absolute<sup>88</sup>. It follows that professional secrecy covers any disclosure of information in oral or written form<sup>89</sup>, made to another professional also subject to professional secrecy<sup>90</sup>, harmful or not<sup>91</sup>. In that sense and as mentioned above, the secrecy of article

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<sup>87</sup> State Council (CE), 29 December 2000, G.: Juris-Data n°2000-149274; Rec. CE 2000, p.676.

<sup>88</sup> Supreme Court, Criminal chamber (Cass.Crim.), 19 déc. 1885, Watelet et Crim., 8 mai 1947, Decraene.

<sup>89</sup> Supreme Court, Criminal Chamber (Cass. Crim.), 19 December 1885, W.:S 1886, 1, p.86, about letters: State Council (CE) 1<sup>st</sup> June 1994, n°150870, CHS Le Valmont: Juris-Data n°1994-048882 about information provided by a nurse from the psychiatric sector to a moviemaker which has allowed him to contact the patient.

<sup>90</sup> Supreme Court, 1<sup>st</sup> Civil Chamber (Cass. 1<sup>ere</sup> civ.) 12 January 1999: Bull. Civ. 1999, I, n°18, about a letter relative to a patient sent by his physician to an Insurance company.

## Study on the Legal Framework for Interoperable eHealth in Europe

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4 of the Medical Ethics Code includes not only the information (s)he has been told but also anything (s)he would have seen or understood. The new article L.1110-4 of the Public Health Code specifies that the secret covers all information related to the person that the healthcare professional gets to know. The obligation of secret is limited to the relation healthcare professional-patient and to the information gathered during this relationship. But it is irrelevant whether the information was already publicly known or not.

Contrary to the rule in Austria or Greece, patients in France are not entitled to relieve their physician from his professional secrecy.<sup>92</sup> This means that even if the patient consents to disclose the information protected by the secret, the physician is not allowed to do so and would be sanctioned if he would. The obligation thus does not disappear with the death of the patient.<sup>93</sup> Physicians are entitled not to testify when it concerns facts protected by professional secrecy, despite the prior consent of the patient.

Finally, the disclosure of the secret should have been intentional, i.e. the physician should be aware that he is disclosing a secret. Misfeasance or negligence does not allow for penal prosecution.

Article 226-14 of the Penal Code relieves the healthcare professional from professional secrecy in cases where the law authorizes or imposes the disclosure of secrecy. For instance, the Law of 4 March 2002 explicitly acknowledges the “shared secrecy” between two or more healthcare professionals or a medical team in a hospital or clinic. When the patient is followed-up by a medical team, the medical information is presumed to be provided by the patient to the whole team. However, in any other cases, strict conditions subject the sharing of medical information: the patient, duly informed, should not have opposed to such sharing; the sharing can only pursue the aim of ensuring the continuity of the care or to defining the best care to be provided.

Article 226-14 of the Penal Code moreover allows derogation to professional secrecy to inform certain public authorities for needs or prosecution or specific offences and crimes. Family and relatives of the patient can also be informed of relevant information (and not of all the information contained in the medical records)<sup>94</sup> in specific cases, e.g. in case of “serious diagnostic or prognostic” provided that the patient did not oppose to it.

In **Ireland** the duty of confidentiality of healthcare professionals vis-à-vis their patients is subject to four exceptions; these are: when order by a Judge in a Court of Law or by a Tribunal; when necessary to protect the interests of the patient; when necessary to protect the welfare of society; when necessary to safeguard the welfare of another individual or patient.

The legal basis for professional secrecy in Ireland derives from the right of privacy recognised in the Irish Constitution and under Article 8 of the European Convention on Human Rights. In addition, the duty derives from the common law protection afforded to confidentiality. Regardless of its legal basis, the duty of confidentiality is not absolute.

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<sup>91</sup> Supreme Court, 1<sup>st</sup> Civil Chamber (Cass. 1ere civ.), 14 December 1999, n°97-15756: Bull. Civ. 1999, I, n°345 about the revelations made by Doctor Gubler after the death of President Mitterrand.

<sup>92</sup> State Council (CE), 28 May 1999, n°189057, T.: Juris-data n°1999-050370; Rec. CE 1999, p.159, about a physician that authorises, with the prior consent of the patient, the dissemination in the press of her picture within an investigation about hypnosis

<sup>93</sup> Supreme Court, 1<sup>st</sup> Civil Chamber (Cass. 1ere civ.), 6 January 1998: Bull. Civ. 1998, I, n°3

<sup>94</sup> State Council (CE), 26 September 2005, n°270234, Conseil nat. Ordre médecins : Juris-Data n°2005-068951; Rev. gén. Dr. méd. 2006, p.379, chron. J. Saison)

**Study on the Legal Framework for Interoperable eHealth in Europe**

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Divergent rules with regard to professional secrecy can lead to complex legal questions in cross-border provision of (e)healthcare services. Is the healthcare professional bound by the legal rules applicable in the Member State where he is established? To which extent does he have to take into account the rules applicable in the Member States where his patient resides and receives eHealth services? The answers to such legal questions are not readily available. This creates uncertainty and can possibly constitute an important obstacle for interoperable eHealth in Europe.

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## 6. Processing of personal health data

### 6.1 Implementation of the European legal framework

Processing of personal data related to health is governed by the European directives on personal data protection<sup>95</sup> and on the protection of privacy in electronic communications.<sup>96</sup> For a general overview of the conceptual framework and of the provisions of these directives we refer to the numerous legal books and articles about this subject.<sup>97</sup>

The directives have been transposed into national/regional law in all the Member States.<sup>98</sup> A comparative study on the implementation of the data protection directive 95/46/EC has been carried out for the European Commission in 2003.<sup>99</sup> In that year the Commission also performed its first review of this directive. The report recognizes *“that the divergences that still mark the data protection legislation of the Member States are too great. (...) The Commission recalls that the ambition of a Directive is approximation and not complete uniformity and that, in order to respect the subsidiarity principle, the process of approximation should not go further than is necessary. Nevertheless, it thinks that stakeholders are right to demand more convergence in legislation and in the way it is applied by the Member States and the national supervisory authorities in particular. Some contributors to the review proposed the amendment of the Directive to add more detail or specification to achieve this convergence. The Commission prefers to proceed at least initially by other means.”*<sup>100</sup>

Our study confirms that the divergences in the implementation of the European data protection directive, discovered in the course of the 2003 review, continue to exist. Some new divergences have even been added in more recent years.

An example of such new divergence has been introduced by the 2006 amendments to the **Swedish** personal data act. The revised act exempts from now on certain processing of personal data from the strict rules of the personal data act and places it under the principle of misuse.<sup>101</sup>

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<sup>95</sup> 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: [http://ec.europa.eu/justice\\_home/fsj/privacy/law/index\\_en.htm](http://ec.europa.eu/justice_home/fsj/privacy/law/index_en.htm)

<sup>96</sup> Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), [http://ec.europa.eu/justice\\_home/fsj/privacy/law/index\\_en.htm](http://ec.europa.eu/justice_home/fsj/privacy/law/index_en.htm)

<sup>97</sup> E.g. C. Kuner, European Data Protection Law, Oxford University Press, 2<sup>nd</sup> edition, 2007, 460 p. : <http://www.oup.com/uk/booksites/content/9780199283859/>

<sup>98</sup> An overview of the status of implementation of the Directive 95/46/EC (unfortunately not up-to-date) is available from the European Commission's website: [http://ec.europa.eu/justice\\_home/fsj/privacy/law/implementation\\_en.htm](http://ec.europa.eu/justice_home/fsj/privacy/law/implementation_en.htm)

<sup>99</sup> D. Korff, Study on the implementation of the data protection directive. Comparative summary of national laws. (Study Contract ETD/2001/B5-3001/A/49), [http://ec.europa.eu/justice\\_home/fsj/privacy/docs/lawreport/consultation/univessex-comparativestudy\\_en.pdf](http://ec.europa.eu/justice_home/fsj/privacy/docs/lawreport/consultation/univessex-comparativestudy_en.pdf)

<sup>100</sup> European Commission, First report on the implementation of the Data Protection Directive (95/46/EC), COM(2003)265final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52003DC0265:EN:NOT>

<sup>101</sup> <http://www.notisum.se/rnp/SLS/lag/19980204.HTM> (text of the new law in Swedish); A short summary of the governmental proposal is available in English at <http://www.sweden.gov.se/content/1/c6/01/55/42/24980a18.pdf>



## Study on the Legal Framework for Interoperable eHealth in Europe

The new provisions allow processing of personal data that does not form part of and is not intended to form part of a set of personal data that has been structured in order to significantly facilitate searches for or compilations of personal data (the new Section 5a of the Personal Data Act), i.e. in practice personal data registers and personal data-related databases. In other words, the handling regulations of the Swedish Personal Data Act would not be applicable, inter alia, to everyday processing like the production of linear text in word processing software, the publication of linear text on the Internet, the use of sound and image recordings and email correspondence provided that the material is not intended for inclusion in a database with a personal data-related structure such as an electronic system for the management of a business. The amendment was deemed to be within the framework of the Directive.

In contrast to the general rules of the Personal Data Act, the new regulation penalises the misuse of personal data, i.e. the processing is allowed unless it involves an improper intrusion on somebody's personal integrity. An intrusion might exist if the data was processed for improper purposes, such as persecuting or disgracing an individual; if a large amount of information about one individual was collected without acceptable reasons; in case of slander or a violation of secrecy. In case of misuse, the registered person has the right to receive compensation for damages.

In addition, as has been the case, a registered person still has the right to subject access, i.e. to obtain on request a "data extract" including the personal data processed. The general exception being that it proves impossible to provide a data extract or it would require disproportionate effort to do so because, it is, for instance, difficult to find information about a particular person in text and in sound and image recordings.

Generally speaking the provisions of the data protection laws of the Member States are very similar to the ones of the European directive. For many provisions this results almost in a literal parallelism. The national legislators mainly used some possibilities to specify or to further detail the provisions of the Directive. Nevertheless there are important exceptions.

One example is the definition of "personal data". This definition determines the scope of the data protection rules. Art. 2(a) of the Directive reads as follows: "*personal data' shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.*"

Most of the Member States have correctly transposed the definition of personal data but sometimes there are small but important differences. The **French** law, for instance, defines "personal data" as follows (our translation): "*any information relating to a natural person who is identified or can be identified, directly or indirectly, by reference to an identification number or to one or more factors specific to this person. To determine whether a person is identifiable, account should be taken of all the means aiming at making possible the identification of the said person, and which are at the disposal of or accessible to the controller or to any other person.*"<sup>102</sup>

<sup>102</sup> Loi n°78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés, amended by the law of 6 August 2004, <http://tinyurl.com/p9svap> (« Constitue une donnée à caractère personnel toute information relative à une personne physique identifiée ou qui peut être identifiée, directement ou indirectement, par référence à un numéro d'identification ou à un ou plusieurs éléments qui lui sont propres. Pour déterminer si une personne est identifiable, il convient de considérer l'ensemble des moyens en vue de permettre son identification dont dispose ou auxquels peut avoir accès le responsable du traitement ou toute autre personne »).

## Study on the Legal Framework for Interoperable eHealth in Europe

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Not wishing to go too far into detail, by way of example it is interesting to take a closer look at the French definition. Where does it deviate from the text of the European directive?

- The words “in particular” are missing before “by reference to an identification number or ...”.
- The words “specific to this person” (“*qui lui sont propres*”) are used instead of “specific to his physical, physiological, mental, economic, cultural or social identity.”
- The definition of “identifiable” is more precise: all means “at the disposal of or accessible to the controller or to any other person” have to be taken into account. This precision is based on one of the Recitals of Directive 95/46/EC (Recital (26)), which states: “to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person”. The French text is however stricter than the text of the Recital (means “likely reasonably to be used” versus means “at the disposal of or accessible to”).

These nuances are particularly important in the health sector, for example, in case of transmitting pseudonymised medical data for secondary – non clinical – purposes (e.g. pharmaceutical research or health policy development). Each time data are transmitted after having substituted the identification (name, etc.) of a patient by a pseudonym, the person can no longer be identified without establishing the link between the identity and the pseudonym. Only the person who can establish this link is able to identify the patient. According to both the European and the French text, this person can be the controller or “any other person”. But it is far from certain that, in a practical situation, the ability of the controller or the other person to establish the link between the pseudonym and the identity, will be judged in the same manner. “Likely reasonably to be used” (as termed in the European Directive) doesn’t necessarily bear the same meaning as “at the disposal of or accessible to” (according to the French law).

If we compare the definition of the European and French text to the one used in the **UK** Data Protection Act, the divergence is even more important. Following the UK Act the term ‘*personal data*’ means “*data which relate to a living individual who can be identified (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual*”.<sup>103</sup>

The law in **Ireland** uses a similar definition: “*personal data means data relating to a living individual who is or can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller*”.<sup>104</sup>

Following the definitions of “personal data” in the UK and Irish data protection laws a person is only identifiable if identification is possible from the data in conjunction with other information that is “in the possession, or is likely to come into the possession of the data controller”. If identification is only possible via information in the possession of other persons - not of the data controller - the data will not be considered as “personal data”. The scope of the UK and Irish data protection laws is therefore narrower than the one of the European Directive.

Already in his 2003 survey study for the European Commission, Douwe Korff wrote: “The laws or formal clarifications or interpretations of the laws in Austria, Germany, Greece, the Netherlands and

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<sup>103</sup> Data Protection Act 1998, [http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980029\\_en\\_2#pt1-l1g1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_2#pt1-l1g1)

<sup>104</sup> Data Protection Acts 1988 and 2003 (informal consolidation prepared by the Office of the Irish Data Protection Commissioner): <http://www.dataprotection.ie/viewdoc.asp?DocID=796&ad=1#1>

## Study on the Legal Framework for Interoperable eHealth in Europe

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the UK make clear that, in those countries, encoded or pseudonymised data are to be regarded as “personal” with regard to a person who has access to both the data and the “key”, but not as such with regard to a person without access to the key”.<sup>105</sup> For this latter category **Austria** even introduced in its data protection law the specific (non-European) concept of “indirectly personal data”.<sup>106</sup> In a completely opposite direction, **Belgium** has considered this category explicitly as personal data and introduced specific legal rules applicable to it, in particular in case of transmitting personal data for research purposes.<sup>107</sup>

In order to counter such divergent implementations of the European Directive, the Article 29 Working Party in 2007 has made an attempt to establish a common understanding of the concept of personal data.<sup>108</sup> In its Opinion, one can read e.g. what follows: “Recital 26 of the Directive pays particular attention to the term “identifiable” when it reads that “whereas to determine whether a person is identifiable account should be taken of all the means likely reasonably to be used either by the controller *or by any other person* to identify the said person.” This means that a mere hypothetical possibility to single out the individual is not enough to consider the person as identifiable”.

In the same Opinion, the Article 29 Working Party also provides two examples relating to the health sector:

“Example No. 12: Publication of X-ray plates together with the patient's first name

A lady's X-ray plate had been published in a scientific journal, together with the lady's first name, which was a very unusual one. The first name of the person, combined by the knowledge by their relatives or acquaintances that she suffered a certain ailment rendered the person identifiable to a number of persons, and the X-ray plate would then be considered as personal data.”

“Example No. 13: pharmaceutical research data

Hospitals or individual physicians transfer data from medical records of their patients to a company for the purposes of medical research. No names of the patients are used but only serial numbers attributed randomly to each clinical case, in order to ensure coherence and to avoid confusion with information on different patients. The names of patients stay exclusively in possession of the respective doctors bound by medical secrecy. The data do not contain any additional information which makes identification of the patients possible by combining it. In addition, all other measures have been taken to prevent the data subjects from being identified or becoming identifiable, be it legal, technical or organizational. Under these circumstances, a Data Protection Authority may consider that

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<sup>105</sup> D. Korff, Study on the implementation of the data protection directive. Comparative summary of national laws. (Study Contract ETD/2001/B5-3001/A/49), p. 15:

[http://ec.europa.eu/justice\\_home/fsj/privacy/docs/lawreport/consultation/univessex-comparativestudy\\_en.pdf](http://ec.europa.eu/justice_home/fsj/privacy/docs/lawreport/consultation/univessex-comparativestudy_en.pdf)

<sup>106</sup> Unofficial English translation of the Austrian Federal Act Concerning the Protection of Personal Data (Datenschutzgesetz 2000 - DSGVO 2000), Art. 2,1: “Data are “only *indirectly personal*” for a controller, a processor or recipient of a transmission when the Data relate to the subject in such a manner that the controller, processor or recipient of a transmission cannot establish the identity of the data subject by legal means“:

<http://www.dsk.gv.at/site/6230/default.aspx>

<sup>107</sup> Royal Decree of 13 February 2001 implementing the Law of 8 December 1992 on the protection of privacy in relation to the processing of personal data; an unofficial translation of this Royal Decree is available from:

<http://www.privacycommission.be/en/static/pdf/wetgeving/uitvoeringsbesluit-2001-en-input-website-220109.pdf>

<sup>108</sup> Article 29 Data Protection Working Party, WP 136, Opinion 4/2007 on the concept of personal data

[http://ec.europa.eu/justice\\_home/fsj/privacy/docs/wpdocs/2007/wp136\\_en.pdf](http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp136_en.pdf)

Study on the Legal Framework for Interoperable eHealth in Europe

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no means are present in the processing performed by the pharmaceutical company, which make it likely reasonably to be used to identify the data subjects.”<sup>109</sup>

## 6.2 Transposition of Article 8 of Directive 95/46/EC

Article 8 of the European Data Protection Directive relates to the processing of special categories of data. Paragraphs 1 to 4 are relevant for the processing of health-related personal data and are worded as follows:

*“ 1. Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.*

*2. Paragraph 1 shall not apply where:*

*(a) the data subject has given his explicit consent to the processing of those data, except where the laws of the Member State provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject's giving his consent; or*

*(b) processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law in so far as it is authorized by national law providing for adequate safeguards; or*

*(c) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent; or*

*(d) processing is carried out in the course of its legitimate activities with appropriate guarantees by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects; or*

*(e) the processing relates to data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims.*

*3. Paragraph 1 shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.*

*4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.*

*(...) “*

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<sup>109</sup> Article 29 Data Protection Working Party, WP 136, Opinion 4/2007 on the concept of personal data, p. 16 [http://ec.europa.eu/justice\\_home/fsi/privacy/docs/wpdocs/2007/wp136\\_en.pdf](http://ec.europa.eu/justice_home/fsi/privacy/docs/wpdocs/2007/wp136_en.pdf)

## Study on the Legal Framework for Interoperable eHealth in Europe

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Most of the Member States, following the logic of the Directive, have included the personal data concerning health into the broader category of “special” or “sensitive” data. A few Member States, e.g. **Belgium**, did regulate the processing of data concerning health as a separate category. This doesn’t however necessarily result in practical consequences.

A majority of the Member States have copied the exceptions mentioned under Art. 8.2 a) to e) of the Directive and, specifically with regard to health-related data, transposed Art. 8.3 more or less literally. In some Member States, e.g. **Belgium**, the “written” consent of the patient is required instead of the “explicit” consent as mentioned in the Directive.<sup>110</sup> Such divergences can complicate cross-border provision of eHealth services. The applicable national data protection law in cross-border situations within Europe is usually the law of the Member State where the provider is established. In practice however patients will expect to be protected as a data subject by the data protection rules of their own country. Moreover the divergences can lead to discriminatory situations and unfair competition. For example, a Dutch healthcare provider could process health-related personal data of Belgian patients, whereas this would be considered unlawful if done by a Belgian provider.

Member States further usually, making use of the authorization offered by Art. 8.4, have completed the list of exceptions for processing data concerning health with a list of additional exceptions.

By way of example, the **Austrian** data protection law contains the following list of exemptions under which processing of sensitive data is permitted (*exemptions not mentioned in the European Directive are in italics*)

1. the data subject has obviously made public the data himself or
2. *the data are used only in indirectly personal form or*
3. the obligation or authorization to use the data is stipulated by laws, insofar as these serve an important public interest, or
4. *the use is made by a controller of the public sector in fulfilment of his obligation to give inter-authority assistance or*
5. *data are used that concern solely the exercise of a public office by the data subject or*
6. the data subject has unambiguously given his consent, which can be revoked at any time, the revocation making any further use of the data illegal, or
7. the processing or transmission is in the vital interest of the data subject and his consent cannot be obtained in time or
8. the use is in the vital interest of a third party or

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<sup>110</sup> The requirement of a “written” consent (instead of an “explicit” consent as required in Art. 8.2 a) of the European Directive) is probably not compliant with the Directive. In its judgment of 6 November 2003 in Case C-101/01 (Lindqvist), the European Court of Justice, on the question “Can a Member State provide more extensive protection for personal data or give it a wider scope than the directive”, decided “*that measures taken by the Member States to ensure the protection of personal data must be consistent both with the provisions of Directive 95/46 and with its objective of maintaining a balance between freedom of movement of personal data and the protection of private life. However, nothing prevents a Member State from extending the scope of the national legislation implementing the provisions of Directive 95/46 to areas not included in the scope thereof provided that no other provision of Community law precludes it*”.

Study on the Legal Framework for Interoperable eHealth in Europe

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9. the use is necessary for establishment, exercise or defence of legal claims of the controller before a public authority and the data were collected legitimately or
  10. data are used for private purposes pursuant to sect. 45 or for scientific research or statistics pursuant to sect. 46 or to inform and question the data subject pursuant to sect. 47 or
  11. the use is required according to the rights and duties of the controller in the field of employment law and civil service regulations and, and is legitimate according to specific legal provisions, or
  12. the data are required for the purposes of preventive medicine, medical diagnosis, the provision of healthcare or treatment or the management of health-care services, and the use of data is performed by medical personnel or other persons subject to an equivalent duty of secrecy, or
  13. non-profit-organisations with a political, philosophical, religious or trade-union aim process data revealing the political opinion or philosophical beliefs of natural persons in the course of their legitimate activities, as long as these are data of members, sponsors or other persons who display an interest in the aim of the organisation on a regular basis; these data shall not be disclosed to a third party without the consent of the data subjects unless otherwise provided for by law.”

In the **Netherlands**, according to article 21, paragraph 1 of the Data Protection Law the prohibition on processing personal data concerning a person's health does not apply where the processing is carried out by:

- a. medical professionals, healthcare institutions or facilities or social services, provided that this is necessary for the proper treatment and care of the data subject, or for the administration of the institution or professional practice concerned;
- b. *insurance companies* as referred to in the Insurance Supervision Act), insurance companies as referred to in the Funeral Insurance Supervision Act and intermediaries and sub-agents as referred to in the Insurance Mediation Act, provided that this is necessary for:
  - 1<sup>o</sup> assessing the risk to be insured by the insurance company and the data subject has not indicated any objection thereto, or
  - 2<sup>o</sup> the performance of the insurance agreement;
- c. *schools*, provided that this is necessary with a view to providing special support for pupils or making special arrangements in connection with their state of health;
- d. *institutions for probation, child protection or guardianship*, provided that this is necessary for the performance of their legal duties;
- e. the Minister of Justice, provided that this is necessary in connection with the implementation of prison sentences or detention measures, or
- f. *administrative bodies, pension funds, employers or institutions working for them*, provided that this is necessary for:
  - 1<sup>o</sup> the proper implementation of the provisions of laws, pension regulations or collective agreements which create rights dependent on the state of health of the data subject, or
  - 2<sup>o</sup> the reintegration of or support for workers or persons entitled to benefit in connection with sickness or work incapacity.

Article 21 paragraph 2 of the Dutch Data Protection Law states that in the cases referred to under paragraph 1, the data may only be processed by persons subject to an obligation of confidentiality by virtue of office, profession or legal provision, or under an agreement. Where responsible parties

## Study on the Legal Framework for Interoperable eHealth in Europe

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personally process data and are not already subject to an obligation of confidentiality by virtue of office, profession or legal provision, they are required to treat the data as confidential, except where they are required by law or in connection with their duties to communicate such data to other parties who are authorized to process such data in accordance with paragraph 1.

In **Finland** the exceptions for processing health-related personal data apply to:

1. a healthcare unit or a healthcare professional from processing data collected in the course of their operations and relating to the state of health, illness or handicap of the data subject or the treatment or other measures directed at the data subject, or other data which are indispensable in the treatment of the data subject;
2. an insurer from processing data collected in the course of its insurance activity and relating to the state of health, illness or handicap of the policyholder/claimant or the treatment or other measures directed at the policyholder/claimant, or data on the criminal act, punishment or other sanction of the policyholder/claimant or the person causing the damage, where necessary for the determination of the liability of the insurer;
3. a social welfare authority or another authority, institution or private producer of social services granting social welfare benefits from processing data collected in the course of their operations and relating to the social welfare needs of the data subject or the benefits, support or other social welfare assistance received by the person or otherwise indispensable for the welfare of the data subject;

The **Finnish** law moreover specifies that sensitive data should be erased from the data file immediately when there no longer is a reason for its processing. The reason and the need for processing needs to be re-evaluated at five-year intervals at the longest, unless otherwise provided in an Act or stated in a permission of the Data Protection Board. A personal identity number may be processed in activities relating to healthcare, in social welfare activities or other social services and in matters relating to the civil service.

In **Denmark** the legislator has adopted the exemption of Art. 8.3 of the Directive but this provision is – in practice – substituted by special provisions in the Health Act (see Part II). This is also a trend in other Member States. The processing of health-related personal data is more and more regulated by specific provisions in the framework of new legislation related to the introduction of electronic patient records. Such evolution is not necessarily in contradiction with the European Data Protection Directive. Recital 22 of this Directive states: “*Whereas Member States shall more precisely define in the laws they enact or when bringing into force the measures taken under this Directive the general circumstances in which processing is lawful; whereas in particular Article 5, in conjunction with Articles 7 and 8, allows Member States, independently of general rules, to provide for special processing conditions for specific sectors and for the various categories of data covered by Article 8.*”

### 6.3 Information and access rights of data subjects

Article 12 of the Directive relates to the access right of data subjects and is formulated as follows:

*“Member States shall guarantee every data subject the right to obtain from the controller:*

*(a) without constraint at reasonable intervals and without excessive delay or expense:*

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## Study on the Legal Framework for Interoperable eHealth in Europe

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- confirmation as to whether or not data relating to him are being processed and information at least as to the purposes of the processing, the categories of data concerned, and the recipients or categories of recipients to whom the data are disclosed,
  - communication to him in an intelligible form of the data undergoing processing and of any available information as to their source,
  - knowledge of the logic involved in any automatic processing of data concerning him at least in the case of the automated decisions referred to in Article 15 (1);
- (b) as appropriate the rectification, erasure or blocking of data the processing of which does not comply with the provisions of this Directive, in particular because of the incomplete or inaccurate nature of the data;
- (c) notification to third parties to whom the data have been disclosed of any rectification, erasure or blocking carried out in compliance with (b), unless this proves impossible or involves a disproportionate effort."

Also relevant is Article 13.2 of the Directive: "Subject to adequate legal safeguards, in particular that the data are not used for taking measures or decisions regarding any particular individual, Member States may, where there is clearly no risk of breaching the privacy of the data subject, restrict by a legislative measure the rights provided for in Article 12 when data are processed solely for purposes of scientific research or are kept in personal form for a period which does not exceed the period necessary for the sole purpose of creating statistics."

Restrictions to the access right of the data subject in case of processing health-related personal data vary between the Member States. Additionally these rights have to be combined with specific access rights to health records, attributed by national legal provisions on patients' rights.

In **Italy** data subjects can be communicated their health-related data only through a physician selected either by the data subjects themselves or by the processor.

A similar provision exists in **Portugal**: the right of access to information relating to health data, including genetic data, can only be exercised via the doctor chosen by the data subject.

In **Sweden**, despite the general access rights of the Personal Data Act (Section 23-27), the Swedish Patient Data Act (SFS 2008:355, *patientdatalagen*) regulates access rights specifically with regards to health data. Chapter 8 of the Patient Data Act deals with the rights of the individual. According to Section 2 the patient's journal should as soon as possible be released to the patient or a near related person unless otherwise stipulated in Chapter 2 Section 8 or Section 9 of the Professional Activities in the Health and Medical Care Field Act (SFS 1998:531, *lagen om yrkesverksamhet på hälso- och sjukvårdens område*). Chapter 8 Section 5 of the Patient Data Act stipulates that the care provider shall inform the patient about all access to the patient's data. Section 6 regulates more in detail which information needs to be given to the individual, e.g. purpose with processing, which categories of data are processed, possible secrecy, and also refers to Sections 26 and 29 of the Personal Data Act.

In **Finland** the controller should without undue delay reserve the data subject an opportunity to inspect the data or, upon request, provide a hard copy of the data. The data shall be given in an intelligible form. If the controller refuses to provide access to the data, a written certificate to this effect needs to be issued. The certificate should mention the reasons for the refusal. A failure by the controller to give a written response to the data subject within three months of the request is deemed equivalent to a refusal to provide access to the data. In this event, the data subject may bring the matter to the attention of the Data Protection Ombudsman.



Study on the Legal Framework for Interoperable eHealth in Europe

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According to section 31 of the **Danish** Act on Processing of Personal Data, data subjects are entitled to have access to personal information which has been processed. The provision also covers access to health information. However, the Act on Health has separate rules regarding access to health information which substitute section 31 of the Act on Processing of Personal Data. Section 37-38 of the Health Act stipulates (unofficial translation):

*“§ 37. Where a patient submits a request to that effect, the patient shall be informed whether or not data relating to his or her health in patients records etc are being processed. Where such data are being processed, communication on the patient’s request shall take place in an intelligible form about;*

- 1. the data that are being processed;*
- 2. the purpose of processing;*
- 3. the categories of recipients; and*
- 4. any available information as to the source of such data*

*(2) The right to access according to sub-section 1 may be delimited in so far as the patient’s interest in obtaining this information is found to be overridden by essential considerations for the patient himself or for other private interests.*

**§ 38.** *Decisions regarding the right of access must be taken by the public authority, institution or healthcare professional who posses the patient record etc.*

*(2) The public authority, institution or healthcare professional shall reply to a request without a delay and decide about whether access should be provided in form of a copy or by having an opportunity to inspect the patient record etc*

*(3) If the request has not been replied to within 10 days from the receipt of the request, the public authority, institution or healthcare professional shall inform the patient on the grounds for this and of the time at which the decision can be expected to be available.*

*(4) In situations where according to sub-section 1-3 a healthcare professional is entitled to make a decision regarding the patients right of access, the overall legal responsibility is on the operationally responsible authority”*

The rules regarding access to medical records in the Health Act only covers health information which has been collected in connection with the provision of care. If health information has been collected for other purposes – e.g. for scientific purposes – the rules in the Act on Processing of Personal Data are applicable. In general, the data subject does not have right to access information which has been collected for scientific purposes, see section 32, sub-section 4 of the Act on Processing of Personal Data.

In **France** a minor can oppose his data to be communicated to his legal representatives by the physician. The physician should then indicate such opposition in written in the file. In case the legal representative formulates a request of access, the physician should try to obtain the consent of the minor but if the minor maintains his opposition, the request should be refused.

The successors can access to information relative to the dead person insofar these data are necessary to understand the causes of the death, to defend the memory of the dead person or to

Study on the Legal Framework for Interoperable eHealth in Europe

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defend his rights, except if the dead person has previously opposed to it. The successor should indicate the motive of his request. Any refusal to the request should be motivated.

When the data subject is hospitalized ex officio or upon the request of a third party, the controller can decide that the disclosure should take place via a physician. In this case, he informs the data subject. If the data subject refuses to designate a physician, the controller or the data subject can appeal to the provincial commission of psychiatric hospitalizations whose decision is binding.

In case access would be denied, the patient could file a complaint to the CNIL or a judicial complaint in case it concerns self-employed health professionals, or to the Commission for accessing administrative documents (*Commission d'accès aux documents administratifs - CADA*), before going to administrative courts. It is worth noticing that the CADA has extended the access to the personal notes of the health professional insofar these notes participate to the establishment of a diagnostic.<sup>111</sup> This extensive interpretation has been followed by the Administrative Appeal Court of Paris.<sup>112</sup>

Art. 10, § 2 of the **Belgian** data protection law adds a specific provision on the right of the data subject to access personal data concerning his health.

*" Any person shall have the right to get knowledge of the personal data that are processed relating to his health, either directly or with the assistance of a health professional.*

*Upon request of the controller or of the data subject, communication may be done through mediation of a health professional chosen by the data subject.*

*If there is apparently no risk of offending against the privacy of the data subject and if the data are not used for taking measures and decisions with regard to an individual data subject, communication may be postponed if the health-related data are processed for purposes of medical scientific research, yet only to the extent that communication would interfere seriously with the research and no later than the moment on which the research is terminated.*

*In that case the data subject must have given in advance his explicit consent to the controller that the personal data relating to him may be processed for purposes of medical scientific research and that communication of the personal data relating to him may be postponed for that reason."*

This short overview of national legal rules regarding access rights of data subjects to personal data concerning health demonstrates the diversity in this domain. This can again constitute an obstacle for providing cross-border eHealth services. Article 4.1 a) of the European data protection directive states that each Member State should apply the national provisions it adopts pursuant to the directive to the processing of personal data where the processing is carried out in the context of the activities of an establishment of the controller on the territory of the Member State". As a consequence a Belgian patient receiving eHealth services from a provider established in Italy or Portugal needs a doctor to access the personal data related to his health but can access such data directly if they are processed by a healthcare professional established in Belgium.

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<sup>111</sup> CADA, Council of 15 april 2004, n°20041645

<sup>112</sup> Administrative Appeal Court of Paris, 30 September 2004, n°03PA01769, Ulla G.

## Study on the Legal Framework for Interoperable eHealth in Europe

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Generally speaking the solution provided by the directive for determining the applicable Member State's data protection law, is not very patient-friendly in cross-border situations. Unlike the solution generally accepted in consumer protection law, data subjects cannot always benefit from the protection of the binding rules of the data protection law of the Member State where they are domiciled. If their rights are infringed in another Member State, they will often be forced to exercise their rights in that (foreign) Member State (and thus to overcome all possible barriers related to e.g. language, legal assistance, etc.).

### 6.4 Other relevant rules regarding personal data protection

The divergent national implementations of the European data protection directive are also apparent with regard to other provisions and, similar to the experience in other sectors, this evidently hinders the roll-out of cross-border eHealth services in Europe.

One of these other provisions relates to the duty to notify the processing of personal data to the data protection supervisory authority. In many countries healthcare professionals are exempted from this duty but this is not the case in all Member States.

In **Cyprus**, for example, section 7(6) of the data protection law provides that the data controller is discharged from the duty to notify where the processing is carried out by doctors or other persons offering health services and concerns medical data, as long as the data controller is bound by medical confidentiality or any other duty of confidentiality set out in any law or code of ethics and as long as the data are not transmitted or disclosed to third parties.

Persons offering health services such as clinics, hospitals, rehabilitation centres, insurance funds and insurance companies, as well as data controllers of personal data are not discharged from the obligation to notify when the processing is carried out in the context of telemedicine programs or the provision of medical services through a network.

By contrast healthcare providers are not exempted to notify in **Belgium** and theoretically this means that every GP and every hospital needs to notify the processing of personal data to the Privacy Commission. Non-compliance can lead to serious penal sanctions but in practice the legislation on this point is rarely enforced.

More important is the observation that processing health-related data is, in many Member States, not only or even mainly regulated by the general data protection law but by specific legal rules dedicated to the health sector.

In **Germany**, for example, data protection in hospitals, at least if a *Land* or a religious organisation is responsible for running the hospital, is ruled by the Hospital Laws of the *Länder*. Those laws slightly differ from each other. Nevertheless, the following guidelines can be pointed out: All data that are necessary to conduct and to bill the medical care may be collected, stored, modified and used. Furthermore, storing, modifying and using are allowed for purposes of quality assurance, avoidance of and struggle against infections in hospitals, supervision and professional training. Data transfer to doctors and institutions of rehabilitative care, domestic or nursing care for purposes of follow-up treatment is admitted. The patient has to give his/her consent in data transfer to the relatives and to domestic or nursing care institutions. Hospitals may outsource their data processing after if this is notified to the data protection agency.

## Study on the Legal Framework for Interoperable eHealth in Europe

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In **Austria**, exchange of health data is regulated by the eHealth Telematics Act that contains special provisions for confidentiality and security of health data (see further in Part II of this report).

**Danish** legislation is quite liberal in regards to disclosure of health data for administrative purposes. Healthcare professionals are under a legal obligation to report various data to centralized data bases, and in regards to other public authorities it is normal administrative routine that public authorities should give each other a helping hand. In general, the data controller has the authority to assess whether disclosure of information is justified according to either the Act on Processing of Personal Data or the Health Act.

Another area of concern is the patient's right to have information in health records corrected or deleted. In **Sweden** and Denmark, for example, patients do not have a right to have incorrect information deleted from their records. If health information is incorrect, it must be noted in the patient's record, and the correct information must be stored, but it is forbidden to delete incorrect information.

In **Ireland**, the FOI Act permits the head of a public body to refuse to grant an access request where, in the opinion of the head, "disclosure of the information concerned to the requester might be prejudicial to his or her physical or mental health". Provision is made for the release of records to which access has been denied, to "such health professional having expertise in relation to the subject matter of the record as the requester may specify". The implication of such release is that the health professional will then be able to indirectly release the information to the requester. As in the case of the Data Protection Acts, provision is made in the FOI Act for the granting of access to an edited version of the health information requested.

The most important conclusion of this chapter is that the divergent implementations of the European data protection directive constitute an important obstacle to the cross-border flow of personal data concerning health in Europe. The diversity will considerably increase with the introduction of national regulatory frameworks for electronic health records, as we will examine in Part II of this report. This leads to a fragmented legal landscape, thus creating uncertainty and consequently hindering the provision of cross-border eHealth services.

## 7. Patients' rights

The introduction of eHealth, whether within the borders of one Member State or in a cross-border context, will further be affected by the regulatory framework relating to *patients' rights*. The way in which patients' rights are defined and implemented is largely determined by national law and differs from country to country. More details on this topic are reported in the national country profiles produced in the framework of this study and some relevant examples will be highlighted further in this chapter.

### 7.1 Introductory observations

*Nys and Goffin* confirm that there exists no validated definition of patients' rights. "The views on which rights have to be included in the definition of patients' rights vary from very narrow (patient's right to autonomy in different respects) to very broad (such as the right to respect for the patient's time and the right to benefit from innovation)".<sup>113</sup>

The European Charter of Patients' rights, established by a group of European citizens' organizations in 2002, includes the following 14 rights: the right to preventive measures, access, information, consent, free choice, privacy and confidentiality, respect of patients' time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain, personalised treatment, and the right to complain and receive compensation.<sup>114</sup>

Comprehensive comparative research on this topic has been undertaken in the context of the EU funded Network of Excellence "EuroGentest", by the K.U.Leuven Centre for Biomedical Ethics and Law.<sup>115</sup> Additionally the research team of this Centre has published a series of other comparative studies, e.g. funded by the Dutch Healthcare Inspection.<sup>116</sup> Still interesting, although somewhat outdated, is the comparative study of Leenen, Gevers et al., funded by the Regional Office for Europe of the World Health Organisation in 1993.<sup>117</sup>

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<sup>113</sup> H.NYS and T.GOFFIN, "Mapping National Practices and Strategies on Patients' rightsPatients' rightsPatients' rights", in M. VISMAR, et al. (eds.), *Cross-border healthcare: mapping and analyzing health systems diversity*, Brussels, European Observatory on Health Systems and Policies, 2008, Chapter 4, p. 131

<sup>114</sup> Active Citizens' Network, European Charter of Patients' rightsPatients' rightsPatients' rights, Rome, 15 November 2002, [http://www.patienttalk.info/european\\_charter.pdf](http://www.patienttalk.info/european_charter.pdf)

<sup>115</sup> [http://www.eurogentest.org/professionals/ethical\\_and\\_legal/](http://www.eurogentest.org/professionals/ethical_and_legal/) ; In the context of the EuroGentest NoE 12 national studies on patients' rightsin EU Member States have been produced between 2006 and 2008 (Czech Republic, Denmark, Estonia, Greece, Bulgaria, Cyprus, Hungary, Lithuania, Portugal, Slovakia, Spain and Slovenia). They are available from <http://www.kuleuven.be/cbmer> under "European Ethical-Legal Papers".

<sup>116</sup> H. NYS & L. STULTIENS, Report on Patients' rightsin Belgium, Denmark, Germany, France, Luxembourg, Spain and the UK, [http://www.igz.nl/15451/106463/SGZ\\_2006\\_Achtergrondstudie\\_3.pdf](http://www.igz.nl/15451/106463/SGZ_2006_Achtergrondstudie_3.pdf) (only in Dutch)

<sup>117</sup> H. LEENEN, S. GEVERS & G. PINET, *The rights of patients in Europe*, Kluwer Law and Taxation Publishers, Deventer/Boston, 1993

## Study on the Legal Framework for Interoperable eHealth in Europe

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Rules on patients' rights rarely refer to eHealth in an explicit manner.<sup>118</sup> Nevertheless their impact on the deployment of eHealth should not be underestimated. One example is the right of the patient relating to the medical record. In a recent publication on the effect of patients' rights on cross-border patient mobility in the EU,<sup>119</sup> *Nys and Goffin* report on the different forms that this right can take:

- The right to access the medical file directly;
- The right to access the medical file indirectly;
- The right to access personal notes of the doctor directly/ indirectly/ not at all;
- Right to access without any time limitation or only at regular intervals (e.g. once a year or another period);
- Limits to access in the interest of the patient (therapeutic exception);
- The right to obtain a copy may be absolute (no restrictions);
- The right to obtain a copy may be limited to protect the patient against pressures of third parties;
- The right to obtain a copy may be free of any costs;
- The right to obtain a copy may be against payment;
- The obligation to keep a record may vary (between 5 to 30 years);
- Rights to erasure, to correct, to modify, to block may differ.

The variety of possible patients' rights with regard to medical records is consequently very large and it can therefore be expected that this variety is also reflected in the relevant legal provisions enacted in the Member States.

## 7.2 European Convention on Human Rights and Biomedicine

Convention n° 164 on Human Rights and Biomedicine<sup>120</sup> was adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and opened for signature in Oviedo (Spain) on 4 April 1997. After the fifth ratification, that of Spain, the Convention entered into force on 1 December 1999 in the countries Party to the Convention and having ratified it. Almost all EU Member States have signed and a large majority have ratified the Convention.<sup>121</sup>

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<sup>118</sup> One notable exception is the "Patients' Charter for eHealth" developed by the patients' group of EHTEL: [http://www.ehtel.org/publications/patient-and-citizen-group-empowering-patients-citizens/Patient\\_Charter\\_2008-11-04%20public.pdf/view](http://www.ehtel.org/publications/patient-and-citizen-group-empowering-patients-citizens/Patient_Charter_2008-11-04%20public.pdf/view)

<sup>119</sup> H.NYS and T.GOFFIN, "Mapping National Practices and Strategies on Patients' rightsPatients' rightsPatients' rights", in M. VISMAR, et al. (eds.), *Cross-border healthcare: mapping and analyzing health systems diversity*, Brussels, European Observatory on Health Systems and Policies, 2008, Chapter 4, p. 129

<sup>120</sup> <http://conventions.coe.int/treaty/EN/Treaties/Html/164.htm>

<sup>121</sup> For different reasons the Convention has not been signed by Austria, Belgium, Germany, Ireland, Malta and the UK. Signed but didn't ratify: Finland, France, Italy, Latvia, Luxembourg, the Netherlands, Poland and Sweden. For the reasons for non-ratification: T. GOFFIN, P. BORRY, K. DIERICKX, H. NYS, Why eight EU Member States signed, but not yet ratified the Convention for Human Rights and Biomedicine, *Health Policy*, Volume 86, Issue 2,

## Study on the Legal Framework for Interoperable eHealth in Europe

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The title of the Convention may be misleading as to its objectives. Certainly, the Convention contains dispositions regarding the human genome, scientific research, and organ and tissue removal. In this respect, the concern of the Convention is that the individual has to be “shielded from any threat resulting from the improper use of scientific developments”. However, this is not the Convention’s only concern. It is further intended that the Convention as a whole “will provide a common framework for the protection of human rights and dignity in both longstanding and developing areas concerning the application of biology and medicine”. In this respect the Convention may be considered as offering ‘protection’ of the rights of the patient in ordinary healthcare wherever it formally applies.

The Convention claims to cover “all medical and biological applications concerning human beings, including preventive, diagnostic, and therapeutic and research applications”. For that reason the Convention is really a “patients’ rights treaty”. Most widely accepted general patients’ rights are incorporated in the Convention, such as the right to equitable access to healthcare, the right to freely give or refuse consent to any medical intervention, the protection of persons not able to consent, the protection of private life, the right to be adequately informed, etc.

### 7.3 Regulatory framework in the Member States

Not all EU Member States have enacted specific comprehensive laws dealing with patients’ rights as such. In some of the Member States patients’ rights are contained in various legal texts regulating other topics as well. Sometimes not only legal provisions are relevant for patients’ rights in a particular country but also ethical codes have to be taken into account. In some countries these ethical codes are legally binding. In the context of this report we will restrict ourselves to some examples and refer for a more comprehensive overview to the studies mentioned in the beginning of this chapter.

**Finland** was, in 1993, the first country in Europe to enact legislation relating to the status and rights of patients. The Finnish legislation covering the rights of patients is contained in the Act on Status and Rights of the Patients 1992/785 and it applies to every part of the general healthcare system and to healthcare services provided in social welfare institutions.

The Act rules that:

- treatment requires the consent of the patient;
- the patient's agreement must also be obtained as to the forms of treatment;
- patients must, if they so request, be given information on their state of health, the extent of the proposed treatment, any risk factors, and possible alternative forms of treatment;
- patients are entitled to see and correct the information entered in their own patient histories;
- those on a waiting list for treatment must be told the reason for the delay and its estimated duration;
- patients dissatisfied with their treatment are entitled to lodge a complaint with the establishment concerned;

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- establishments providing medical treatment must have a patient ombudsman, whose duty is to inform patients of their rights and assist them, if necessary, in submitting a complaint, appeal or claim for indemnity;
  - the opinion of young patients must be taken into account if they have reached a stage of development at which they are able to express an opinion. A doctor or other professional person assesses the stage of development;
  - a child's parent or guardian is not entitled to refuse treatment that would avert a health risk or save the life of an underage person.

The **Swedish** Professional Activities in Health and Medical Care Field Act deals with the obligations of healthcare employees (Chapter 2), the requirements for the practice of medicine in Sweden (Chapter 3), professional liability (Chapter 4 and 5), and supervision by the National Board of Health and Welfare (*Socialstyrelsen*) as well as by the Medical Responsibility Board (*Hälso- och sjukvårdens ansvars nämnd*) (Chapter 6 and 7).

The Health and Medical Services Act regulates the general conditions for health care and the competences of both county councils and municipalities. The Act defines health and medical services as medical measures to prevent, investigate and treat diseases and injuries. This also includes medical transport as well as taking care of diseased. Dental care is regulated in another law. Abortion, inseminations, transplantations and autopsies are also considered health and medical services, but are regulated in specific laws.

In **Belgium** the rights and duties of healthcare providers and patients are regulated in the law on the rights of patients of 22 August 2002.

Along the same line, the rights and duties of healthcare providers and patients in **France** are regulated in the law on the rights of patients and of the quality of the healthcare system of 4 March 2002. This Law introduces two new chapters in the Public Health Code, respectively dedicated to "the rights of persons" and "the participation of users in the health system". The provisions of this law have been defined by jurisprudence and completed by other legislative provisions such as the Law of 9 August 2004 about health policy, the healthcare insurance Act of August 2004 and the Law of 22 June 2005 about rights of patients at the end of their life.

In **Cyprus** rights and duties of healthcare providers and patients are regulated by the Law on the Protection of the Rights of Patients and Related Issues of 2005. The Law forms a comprehensive regulation of patients' rights. It safeguards among others the good quality and continuous care of health; the choice of physicians and institutions; and treatment that does not violate the integrity of the person. It is in conformity with the Convention on Human Rights and Biomedicine of 1997 and also with the Declaration of Amsterdam of 1994. The Law among others safeguards:

- (a) good quality and continuous care of health;
- (b) free choice of doctors and healthcare institutions;
- (c) treatment that does not violate the integrity of the person.

It also provides for mechanisms monitoring the protection and respect of patients' rights. These mechanisms include:



Study on the Legal Framework for Interoperable eHealth in Europe

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- (a) the establishment in every state hospital of an independent official who would be in charge of receiving complaints by patients and their families and of providing advice to patients concerning their rights; and
  - (b) the establishment of a Patients' Complaint Committee which will look at patients' complaints after a referral by the official for the protection of patients' rights. The Patients Complaint Committee will also deal with complaints on appellate level.

In **England** the duties and powers of NHS bodies and primary care providers are set out in the National Health Service Act 2006 and legislation made under that Act. The legislation does in effect confer certain rights on patients. Also relevant are the National Health Service Reform and Health Care Professions Act 2002, and the National Health Service (Complaints) Regulations 2004<sup>122</sup> as amended which prescribe the procedures which NHS bodies must follow in dealing with complaints regarding the provision of treatment. In the event a complainant is not satisfied with the outcome of the internal complaints procedure, a reference may be made to the Healthcare Commission.

At the other end of the spectrum, we find **Germany** where no specific law ruling on the entire relationship between healthcare providers and patients has ever been enacted.

A similar situation exists in **Austria**. A "Patient Charta" (*Patientencharta*) has been agreed in so-called Article 15a Agreements between the Federal Government (*Bund*) and the nine *Länder*.<sup>123</sup> This Patient Charta compiles rights and duties of patients and healthcare providers. The Federal Government and the nine *Länder* have to implement this treaty by transposing it into relevant laws. So far, none of them has taken action. As a result, the content of the Patient Charta is not legally binding yet. Specific legal provisions exist in the Physician Act 1998 and the Hospital Act. Overall, however, rights and duties of patients and healthcare providers are mostly regulated by contract, in particular in the medical treatment contract (*Behandlungsvertrag*), a so-called services contract (*freier Dienstvertrag*). This contract requests the physician to treat the patient with due diligence (fault liability).

In the **Netherlands** the Medical Treatment Contracts Act (WGBO) is the end result of years of efforts to strengthen the patient's position. The legislators have chosen a solution under private law, in the form of a special contract between the care provider and the patient. Given the fact that the WGBO comes under private law, it has been included in volume 7 of the Dutch Civil Code. The new regulation is to be seen as the more general legal regulation of the rights and obligations of patients, in addition to which criminal law will have a further role, whereas the standardisation that the regulation contains will also be important for the application of disciplinary stipulations.

The scope of the WGBO is not restricted to the parties to the agreement. By including an extension stipulation (article 464 of the WGBO), the regulations in principle also cover non-contractual but nevertheless similar relationships. Examples of these are treatments that are medical in nature in the context of legal regulations covering working conditions, social security and social facilities.

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<sup>122</sup> SI 2004 No 1768

<sup>123</sup> i.e. the Art. 15a Agreement between the Federal Government and the *land* of Vienna, Federal Law Gazette I 42/2006.

## Study on the Legal Framework for Interoperable eHealth in Europe

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A similar solution has been adopted in **Estonia**. The rights and duties of healthcare providers and patients are regulated in chapter 41 (the healthcare service provision agreement) of the Law of Obligations Act. The relationship between the healthcare provider and the patient is subjected to a contract, which is to some extent regulated by imperative clauses of the law. Additionally the healthcare provider can be held responsible for non-contractual obligations. This chapter focuses on the rights and obligations arising from the healthcare service provision agreement.

An agreement for the provision of healthcare services under the Law of Obligations Act is an agreement, whereby one person (healthcare provider) obliges, in the professional activities thereof, to provide healthcare services to another person (the patient), particularly by examining the patient in the interests of his health and in accordance with the rules of medicine, by consulting and treating the patient or offering obstetrical care to the patient, and by informing the patient of his state of health and of the progress and results of his treatment. Patient care within the framework of the provision of healthcare services and other activities directly related to the provision of healthcare services are considered to constitute provision of healthcare services.

Qualified doctors, and nurses or midwives providing healthcare services independently, and dentists who participate in the provision of healthcare services and operate on the basis of an employment contract or other similar contract with a healthcare provider are held jointly and severally liable with the healthcare provider for the performance of the healthcare service provision agreement.

Within the scope of the Law of Obligations Act healthcare service providers are legal persons providing healthcare services. The party to the agreement for the provision of healthcare services is always the healthcare provider as a legal person (e.g. hospital) and not the healthcare professional.

Healthcare services must at the very least conform to the general level of medical science at the time the services are provided and the services must be provided with the care which can normally be expected of healthcare providers. If necessary, a healthcare provider must refer a patient to a specialist or involve a specialist in the treatment of the patient.

Any agreements which derogate from the provisions of chapter 41 (the healthcare service provision agreement) of the Law of Obligations Act to the detriment of the patient are void.

### 7.4 Scope of patients' rights

The scope of the legal provisions establishing patients' rights is not necessarily identical in all Member States. The definition of "a patient" will probably not vary very much but not every Member State uses the same definition of "a health professional" bound by the various laws establishing patients' rights.

Just by way of example, in **Belgium** "patient" means "the natural person to whom healthcare services are provided, whether at his request or not". Healthcare means "the services that a health professional provides in order to promote, determine, preserve, restore or improve a patient's state of health or in order to support a dying patient." Following this definition, acts such as removing an organ from a donor, terminating a pregnancy, etc. do not constitute healthcare. Moreover medical experiments involving persons are not covered by the law's domain of application. Health professionals in the current state of the legislation are: physicians, dentists, midwives, pharmacists, physiotherapists, nurses, paramedics and nurse assistants. Practitioners of non-conventional medicine (regulated by the Law of 29 April 1999) are also considered as health professionals.

On the other hand the definition of a "patient" in **Danish** law is equivalent to the definition used by WHO: "user(s) of healthcare services, whether healthy or sick", (WHO, "A Declaration on the Promotion of Patients' rights in Europe", 1994). According to section 5 of the Danish Health Act the term "patient treatment" encompasses examination, diagnostics, treatment and care, midwifery,

## Study on the Legal Framework for Interoperable eHealth in Europe

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rehabilitation, prevention and health promoting measures. Removal of an organ and termination of pregnancies without medical justification is not covered by this definition. However, the Health Act has special rules regarding both organ donation and abortion. The Act does not cover medical experimentation and assisted procreation where special acts apply. Health professionals in the current state of the legislation are defined as authorized health professionals, in particular those with a legal diploma, and assisting personnel operating under the responsibility of an authorized healthcare professional. Pharmacists are covered by special legislation which is also the case in regards to psychologists. Practitioners of non-conventional medicine are not considered as health professionals except in cases where they have a legal diploma or perform their activities under the responsibility of an authorized healthcare professional.

### 7.5 Right to free choice

With regard to the provision of eHealth services, one of the most relevant patients' rights is the right of a patient to freely choose a healthcare provider. This right is not implemented identically in every Member State.

In **Austria**, for example, the patient may, in principle, choose a physician or a hospital at his own discretion. Costs of treatment are paid directly by the social security agency to the physician in case of a "contract physician" (physicians who have a contract with the social security agency). Otherwise, patients must pay the treatment and get refund of about 80% of these costs.

The patient's right to free choice in **Bulgaria** is restricted with respect to choosing general practitioners who have contracts with the NHIF. He may choose only one general practitioner and can change his choice only twice for one year. The access of the patient to specialist in different area of the medicine is also restricted in the system of the compulsory health insurance since it is necessary to have a referral from a GP.

In **Denmark**, as part of the right to receive information, patients must be informed about the available options in regards to treatment and care, and is entitled to choose among these options. If the hospital does not offer a specific kind of treatment, the patient must be informed about the possibility to receive treatment at other hospitals. Patients are entitled to seek treatment at any public hospital in Denmark and not only in the county of residence. Furthermore, patients have an extended right to free choice in situations where the regional hospital is not able to provide treatment within 1 month. In this situation the patient is entitled to seek treatment at certain private clinics and hospitals in Denmark or abroad. Patients also have the right to freely choose his or her GP.

General Practitioners in **England** provide primary medical services under the terms of a contract agreed with Government.<sup>124</sup> This contract provides that patients will continue to be free to register with any local practice that is open and practices will continue to have discretion over new patient registrations. However, it is expected that in exercising this discretion, practices will have reasonable and fair grounds for doing so. Under the National Programme's Choose and Book procedures, patients will be offered a choice of hospital referrals when this is considered appropriate by their GP. It is open to the hospitals concerned to choose whether to accept referrals to a pool of specialists or to allow a referral to be made to named specialists<sup>125</sup>. Patients have no right to refer themselves to NHS hospitals (other than in cases of accident and emergency).

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<sup>124</sup> [http://www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/GMS/DH\\_4125637](http://www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/GMS/DH_4125637)

<sup>125</sup> <http://www.chooseandbook.nhs.uk/staff/commsmaterials/factsheet>

## Study on the Legal Framework for Interoperable eHealth in Europe

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In **Estonia** the patient has full freedom of choice whether to conclude the agreement at all and with which healthcare provider. The patient can also terminate the agreement without any limitations (this does not mean that financial obligations do not have to be performed by the patient), while the options for the healthcare provider to terminate the agreement are quite limited – the healthcare provider must have good reason to terminate the agreement. Even if the healthcare provider terminates the agreement, it must in case of necessity carry on the provision of healthcare services to the patient until the patient finds another healthcare provider.

Article L.1110-8 of the **French** Public Health Code recognizes the right of patients to freely choose their health professional and establishment as a fundamental principle of health-related legislation. In that sense, a ruling of the French Supreme Court [*Cour de cassation*] of 7 November 2000<sup>126</sup> has affirmed the right of a physician to sell his “clientele” provided that patients’ free will would be preserved. Limitations to the freedom of choice are admitted on the basis of the technical capacities of the establishments, their rate base or the criteria governing the reimbursement of care. Furthermore, this right cannot ground the opposition to a medical act on the basis of religious motives. In that sense, the obligation to designate an attending physician whose consultation is mandatory before any other consultation of other physicians, sanctioned by worse reimbursement rates, could limit the practical application of the principle of free choice.

The **Finnish** legislation does not provide any right for the patient to freely choose his health professional or to change that choice. The Law on Public Health and the Law on Specialised Healthcare both provide the option for the patient to choose a private or European (EU/EEA) healthcare provider in case the time to receive treatment exceeds 3 months. The patient can of course choose any healthcare service provider at his or her own expenses.

In **Sweden**, the obligation to provide care does not mean that the patient can decide in which form care should be given, rather this is decided by the healthcare provider with regards to the need for care of the patient and other fact such as access to available places and priorities with regards to the need of other patients. According to the Health and Medical Services Act a patient does not have to right to treatment outside the county (Section 3 a) or municipality (Section 18 a) he is living in if the county/municipality can offer the treatment he requires.

### 7.6 Informed consent

Another right that may come into play in the context of eHealth services is the right of a patient to decide whether or not he gives consent to a treatment. Again this right is implemented in the Member States in various ways.

In **Germany**, if the physician wants to avoid liability, he must ensure that the patient has given his consent to the treatment. This consent has to be an *informed consent*, which means, that the patient has to be informed on all the facts concerning his state of health, risks and chances of therapy. This demand of consent derives from art. 1 and 2 of the Basic Law.<sup>127</sup> A physician (not necessarily the one who is treating the patient himself) must inform the patient. If solely the nurse or administrative staff has informed the patient, the consent is invalid. The information does not have to be and should not be upheld in a written manner. Paper based information can support and complement the session of information and can be used as proof for the information and the patient’s consent. But a solely paper-based information is invalid. If forms are used, courts can check them on observing the rules on

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<sup>126</sup> Supreme Court, 1<sup>st</sup> Civil Chamber (Cass. Civ. 1ere), 7 nov. 2000, JCP G 2001, II, 10452, note F. Violla.

<sup>127</sup> See Deutsch/Spickhoff, *Medizinrecht*, 6<sup>th</sup> ed., 2008, recitals 306 ff.

**Study on the Legal Framework for Interoperable eHealth in Europe**

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general terms of business according to art. 305 ff. of the Civil Code. The information must contain the physician's explanations, and should be a conversational dialogue of the physician's explanations, the patient's questions and the physician's answers. The information has to be adjusted to each patient and his psychical situation. In exceptional cases the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient (so-called "therapeutic exemption").

In **Belgium** the patient has the right to consent well informed, freely and in advance to any service provided by a health professional. The consent is only valid for the medical intervention consented to. Consent must be given expressly, except when the health professional, after having adequately informed the patient, can reasonably infer consent from the patient's behaviour; The consent has to be recorded and added to the medical record at the patient's or the professional's request and with the health professional's or patient's approval. The information to be given to the patient prior to the consent is specified in the law. Patients have the right to refuse or withdraw consent for any service.

In **Cyprus** consent is only valid when it is retrieved after the necessary information was given to the patient. Without a valid consent, no medical treatment may be started. It may be given in writing or orally, but orally given consent has to be put in writing as soon as possible. This is also the case in emergency situations. When the patient is in a position where he/she is not able to express his/her will, due to his/her mental or physical state, and immediate medical care is urgently necessary, the consent of the patient may be presumed, unless it is obvious, from previously expressed wishes that he/she would have refused.

A patient in **Finland** has the right to receive from the health professional all relevant information necessary to assess his or her state of health and prognosis. Information must be given about the necessity of treatments, the different treatment options, possible effects and side-effects of treatments, and all other information that can be relevant to the patient in order to decide upon a treatment or cure. Communication with the patient must take place in clear language, adapted to the individual needs and in accordance with the language legislation, providing both Finnish and Swedish speaking patients to be informed in their preferred language. Also interpretation services have to be used if the patient and physician do not share any common language or idiom. The patient may request that the information be confirmed in writing and the patient is entitled to see what information is recorded on him or her.

**France** introduced the principle of prior consent to the performance of medical acts or treatments in its legislation as well. The healthcare professional who would perform the act or treatment without the prior consent of the patient would engage his liability. This right is absolute and is based on the principle of autonomy of the person implying that only the individual can decide upon the attempts to his body and on the principles of individual freedom and human dignity. Specificities arise with regard to minors or protected majors. The consent of minors is required for acts relevant to their strict intimacy such as birth control or abortion. The Code moreover gives the right to the minor to keep secret his health condition and provides that his consent should systematically be sought whenever he is able to express himself and to participate to the decision. These two last cumulative conditions should be assessed against his capacity of judgment. The minor could however object to the consultation of his parents. The healthcare professional should in this case try to convince the minor, but if he maintains his opposition, has to perform the medical act. In any other case, the healthcare professional should obtain the consent of the minors' legal representatives.

Consent should be free and informed. When the refusal of the patient puts his life at risk, everything should be done to convince him to accept the necessary care. When the performance of the medical act seeks to protect life and health, the jurisprudence has recognized the right of the healthcare professional to perform the medical act despite the refusal of the patient (e.g. Jehovah witnesses).

## Study on the Legal Framework for Interoperable eHealth in Europe

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The Law of 22 April 2005 moreover recognizes the right for patients at the end of their life to decide to cease the treatment. The healthcare professional must respect this decision.

The consent of the patient can be kept in “anticipated directives” [*directives anticipées*] to be used by healthcare professionals for situations in which patients are not able to express their will. In case the patient did not draft “anticipated directives”, the person appointed by the patient as “trustworthy” can take the decision in place of the patient. The trustworthy person cannot make a decision that would trigger serious consequences for the health of the minor or protected major.

This short overview could easily lead to the conclusion that rights, such as the right to give or not to give informed consent, are more or less identical in all Member States. The devil is however in the details. *Nys and Goffin* who have carried more comprehensive legal research in this field, have made the following interesting overview of “modalities” of informed consent:

- Written informed consent
- Oral informed consent
- Tacit/implied/ non-verbal consent
- Standard of information prior to consent: the average physician
- Standard of information prior to consent: the average patient
- Standard of information prior to consent: what is relevant for the particular patient.
- Burden of proof on the doctor
- Burden of proof on the patient
- Burden of proof on either doctor or patient according to circumstances
- Similar differences regarding refusal and withdrawal of informed consent.<sup>128</sup>

It is evident that this diversity of modalities is reflected in the Member States’ legislation in this domain. In a cross-border situation it is therefore necessary to study the details of the legal rules in every Member State involved.

### 7.7 Other patients’ rights

Although we will not deal with all other patients’ rights granted by Member State’s laws in the context of this report, most of them can be relevant for the provision of eHealth services as well.

In **France** for example, like in many other countries, the law contains the right of every person to receive care and therapy appropriate to his health condition and with recognized efficiency and to receive emergency treatment whenever required. This article is the legal basis for the definition of the “reference practices” and ensures that medical practices correspond to processes regarded as optimal. The provision is also the legal basis for the obligation for healthcare professionals to ensure their continuous formation and their evaluation. It moreover provides for an efficient organization of the healthcare system and its structures. Finally this right implies that the healthcare professional does not

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<sup>128</sup> H.NYS and T.GOFFIN, “Mapping National Practices and Strategies on Patients’ rightsPatients’ rightsPatients’ rights”, in M. VISMAR, et al. (eds.), *Cross-border healthcare: mapping and analyzing health systems diversity*, Brussels, European Observatory on Health Systems and Policies, 2008, Chapter 4, p. 118

## Study on the Legal Framework for Interoperable eHealth in Europe

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put patients under excessive risks with regard to the expected benefit on the basis of the medical state of the art.

In **Austria** the patient has a right to privacy and discretion. As a matter of principle, other persons may be informed only with patient's agreement. For this purpose the patient can appoint a confidant that has a comprehensive right to information. The information of the patient must be sufficiently and as sympathetically and carefully as possible. The information must be given by a physician. The patient must be informed about diagnosis, possibilities and risks of treatment. He has the right to refuse being informed by the physician. The patient has also some duties. He should give the physician the necessary information to enable a correct diagnosis, if the physician cannot make a diagnosis by investigation. Generally speaking the patient has to take part in the efforts of the physician to provide adequate care.

In **Belgium** a patient has the right to receive from the health professional all relevant information necessary to assess his state of health and his prognosis. Communication with the patient must take place in clear language, adapted to the individual needs. The patient may request that the information be confirmed in writing. The obligation to inform the patient cannot be delegated by a physician to nursing or paramedical personnel. This doesn't mean that these latter categories of health professionals don't have a duty to inform the patient about the activities that they may legally perform. Information is not provided to the patient if the latter explicitly requests not to know. The explicit request not to know can be given in writing or orally, in which case it has to be noted in the medical record. It is accepted that a patient has a right to relinquish his right to information, but this relinquishing must be voluntary and certain. In this case the healthcare professional is no longer required to inform. In exceptional cases the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient and on condition that the health professional has sought the opinion of another health professional (so-called "therapeutic exception").

One has to conclude that, if similar patients' rights exist in most of the Member States, the way in which they are implemented may differ. Whereas, for instance, a patient in Germany needs to be informed about every possible serious risk – even if it occurs only very rarely – in Belgium and other countries this obligation to inform is limited to the so-called normal and foreseeable risks. Whereas in some Member States patients need to consent explicitly to the treatment they will receive, in others that consent can be assumed.

### 7.8 Conclusion

Regardless of general rights that are also applicable in healthcare and that may be derived from more general sectors of law such as the civil code (right to privacy; right to redress and compensation) and the penal code (right to physical integrity; medical secrecy) in all 27 EU Member States one or another scheme for establishing individual patients' rights exists. They may however differ in considerable ways according to their enforceable character.<sup>129</sup>

"a) Patients' rights may be **legal rights**. These are well defined rights actionable against specified parties that should be respected with no limitations as to the providers' resources. The patient has a

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<sup>129</sup> Fallberg L. Patients' rights in Europe: where do we stand and where do we go? *European Journal of Health Law*. 2000, 1-3, as quoted by Nys and Goffin, "Mapping National Practices and Strategies on Patients' rights Patients' rights Patients' rights", in M. VISMAR, et al. (eds.), *Cross-border healthcare: mapping and analyzing health systems diversity*, Brussels, European Observatory on Health Systems and Policies, 2008, Chapter 4, p. 120

Study on the Legal Framework for Interoperable eHealth in Europe

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right of appeal to a Court or similar authority if they are not respected. If violation occurs, compensation and/or sanction can be imposed. One good model here is the Dutch law on medical treatment that has served as an example for other EU Member States (see below). This is sometimes also called the ‘civil law’ approach or ‘horizontal’ approach of protecting patients’ rights.

b) Patients’ rights may be **quasi legal rights**. These are mainly obligations imposed on physicians and other healthcare providers often formulated as rights of patients, for instance in a legally binding code of medical deontology. In Nordic countries patients’ rights belong to this category. This is also called the ‘public law’ approach or ‘vertical’ approach because the patient has no avenue for direct action against the healthcare provider.

c) Patients’ rights may be embedded in non-legally binding documents such as **patient charters** and non-binding codes of medical deontology. These “rights” are mainly moral in character.”

Nys and Goffin conclude that *“even if the differing ways and levels of protection of individual patients’ rights do not impede patient in receiving treatment in another Member State, they may contribute to the level of uncertainty that surrounds cross-border care. Patients tend to export their expectations and understanding of patients’ rights”*.<sup>130</sup>

Researchers from the Leuven Centre for Biomedical Ethics and Law have attempted to map the countries according to enforceable character and type of legislation. This includes the distinction between special and split patient right laws<sup>131</sup>, between legal and quasi-legal rights and between the horizontal (‘civil law’) and the vertical (‘public law’) approach of protecting patients’ rights. As a further classification, nominate and *innominate* contracts are distinguished. Nominated contracts are contracts which have a particular name to distinguish them from other contracts, whereas *innominate* contracts have no particular name. This attempt has resulted in the following table.<sup>132</sup>

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<sup>130</sup> NYS and GOFFIN, “Mapping National Practices and Strategies on Patients’ rightsPatients’ rightsPatients’ rights”, in M. VISMAR, et al. (eds.), *Cross-border healthcare: mapping and analyzing health systems diversity*, Brussels, European Observatory on Health Systems and Policies, 2008, Chapter 4, p. 120

<sup>131</sup> A ‘special’ law contains all (or at least the most commonly accepted) general patients’ rightswhereas in case of ‘split’ legislation the general patients’ rightsare embedded in different pieces of law. See further: Hart D. Patients’ rightsand patient’s participation. Individual and collective involvement: partnership and participation in health law. *European Journal of Health Law*. 2004:17-28.

<sup>132</sup> For more details see [http://europatientrights.eu/general\\_overview\\_patient\\_rights\\_legislation.html?LAN=E](http://europatientrights.eu/general_overview_patient_rights_legislation.html?LAN=E)



Study on the Legal Framework for Interoperable eHealth in Europe

		<i>Special</i> <small>(Single Patient Rights Law)</small>		<i>Split</i> <small>(Rights embedded in different laws)</small>
<i>Contractual - Horizontal</i> <small>(Civil Law)</small>	<b>Legal</b> <small>(Well defined actionable rights)</small>	<b>Nominate</b> <small>(Treatment contract as specific contract for services)</small>	the Netherlands Estonia Lithuania Slovakia	Bulgaria Czech Republic Germany Italy Luxembourg Poland Portugal Slovenia
	<b>Quasi Legal</b> <small>(Obligations imposed on healthcare providers)</small>	<b>Innominate</b> <small>(No specific, nominate contract of services for Treatment contract)</small>	Hungary Belgium Spain	
<i>Public - Vertical (incl. Charters)</i> <small>(Public Law)</small>		Finland Denmark		Ireland Malta Sweden United Kingdom

## **Part II : The Regulatory Framework for eHealth in the Member States**

## 8. The regulatory framework for electronic health records

Legal provisions with regard to health records (paper-based files and electronic records) have traditionally been laid down in the Member States' healthcare laws and in the legislation on patients' rights. These provisions usually contain rules relating to the obligation for healthcare providers and institutions to keep a health record, the content of such records, archiving rules, access rights for patients, etc. In this chapter we will take a closer look at some typical legal provisions in this regard.

The legal provisions related to patient records, which can be found in the national healthcare laws or in the laws on patients' rights, need to be applied in combination with the general legal rules on personal data protection. This combination can sometimes lead to contradictions. For example, it is not unusual that Member States regulate access rights for patients to their own health-related data both in the general data protection legislation and, in a different way, in the legislation on patients' rights. Both are necessary because the scope is also different. The national data protection laws are in principle not applicable to patient records if they are kept in the form of paper files. The reason is that the European directive 95/46/EC, of which these national data protection laws are a transposition, only applies to files that are structured in order to permit systematic consultation of the data stored in those files.

More recent legislation adds a new layer to this regulatory framework. This legislation focuses on the processing of electronic patient records in the framework of national eHealth initiatives. It foresees, for example, under which conditions healthcare providers and institutions are entitled to connect to a national eHealth platform in order to access patient information processed by other healthcare providers and institutions. It is primarily this type of legislation that is envisaged by the Article 29 WP in its 2007 working paper on electronic health records. The working paper makes a distinction between the health record kept by individual healthcare providers and the new concept of an electronic health record in which information is combined from different sources. *“Traditionally, documentation on medical treatment episodes was available with different healthcare professionals but would not be combined in a single record. In contrast, the concept of “EHR” aims at compiling existing documentation on medical treatments relating to an individual from different sources and from different periods of time.”*<sup>133</sup>

### 8.1 Traditional legal rules relating to health records

Over the last decades Member States have enacted legal rules dealing with health records as part of a general healthcare law, laws regulating healthcare institutions or in specific laws on patients' rights.

For example, in the **Czech Republic** a patient has the right to a medical record, carefully updated and safely stored by the health professional. Every health professional should keep a “medical documentation” about every patient to whom he provides healthcare services. Every medical establishment is obliged to keep medical documentation as well. These rights and duties are laid down in the Public Healthcare Act. The act contains basic rules for the processing of patients' health records. It is possible to use paper or an electronic format for the medical documentation. The law defines specific requirements for those who wish to keep their medical documentation in electronic

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<sup>133</sup> Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP131, adopted on 15 February 2007, p. 4

## Study on the Legal Framework for Interoperable eHealth in Europe

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form. There is also an obligation for a physician to pass the documentation on to another physician if the patient asks for it.

A “Decree on Medical Documentation” contains more precise requirements on the content of the medical documentation and requirements on how to delete specific content. There are defined periods for archiving specific parts of the medical documentation. These periods vary between 5 years up to 150 years (!) depending on type of record.

Patients have the right to access their own medical documentation and to obtain a copy at cost price, as soon as possible and not later than 30 days following the request. Every access must be recorded in the medical documentation.

Similar legal provisions as these of the Czech Public Healthcare Act have been enacted in many other Member States as well. In most of the cases these laws don’t explicitly distinguish between health records in the form of paper files and electronic health records. The objectives of the legal provision are primarily to ensure a minimum quality of service and to protect the interests of the patients.

Some Member States’ laws make a distinction between various types of health records. In **Belgium**, for example, a decree of 3 May 1999 contains precise rules about the content of the “General Medical Record”. There should be one GMR per patient, kept by the usual general practitioner. A patient can freely choose by which general practitioner his medical record should be kept and can modify this choice at any moment. He communicates his choice to his health insurance fund, which forwards the number of patients per general practitioner to the Ministry of Health. A medical record (not only the GMR) can be kept in paper or in electronic format. According to the code of professional ethics of the Order of Physicians it should be archived during 30 years.

A second decree of 3 May 1999 regulates the medical records to be kept by hospitals. This decree explicitly states that the medical record can be kept in electronic format. It needs to be kept for at least 30 years in the hospital. The decree also contains precise rules with regard to the content of the record. Some of the documents in the medical record need to be signed by the physician(s) who provided care to the patient. Hospitals should archive the records of all patients who left the service, preferably in a central database or at least per service and in electronic format with a unique number per patient. The archive should be accessible to physicians who are involved in the provision of care to the patient.

Under Belgian federal law, hospitals also need to keep a “nursing record”. A Royal decree of 28 December 2006 provides the minimum requirements for this type of record. It should, for instance, contain the medical and paramedical information needed for providing nursing care to the patient, structured observation notes, the nursing plan, etc. The law doesn’t specify a minimum archiving term for these records. In the terminology of the Belgian legislation, together with the nursing record, the medical record constitutes the “patient’s record”.

Further there is also a Royal decree of 21 September 2004 regulating the patient’s record to be held by homes for elderly care, rest homes or centres for daycare. And because of the regionalization of healthcare in Belgium, there is finally also regional legislation which needs to be taken into account. One example is the decision of the Flemish government on the minimum requirement for patients’ records in the context of homecare.<sup>134</sup>

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<sup>134</sup> Art. 1, § 3 of the Decision of the Flemish government of 21 December 1990 holding co-ordination and support of homecare.

## Study on the Legal Framework for Interoperable eHealth in Europe

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Sometimes the legal provisions on health records include specific rules for health records in electronic format. These rules can be quite strict in some Member States. For example, in the **Slovak Republic** Article 20 of Healthcare Act allows the keeping of the medical records in written form or in electronic form but in this latter case the record needs to be secured by means of a qualified electronic signature (*zaručený elektronický podpis*). Medical records in electronic form and secured by means of a qualified electronic signature can moreover only be kept if:

- backup copies of data files are made at least once per day,
- accurate recordings are maintained on backup copies of data files which are stored in a place available only to persons authorized to make backup copies,
- a copy is made from the archived data and these are removed from an old medium before expiry of a writing on archive medium,
- archive copies are made at least once a year and the procedure of making the archive copies disables additional intervention taken later.

In a few cases Member States have amended the current legislation on health records because this legislation didn't sufficiently take into account the existence of *electronic* health records. These amendments progressively start to take into account the concept of a shared electronic health record.

Such amendments have, for example, been enacted in **Denmark** in 2007. The Danish Health Act distinguishes between disclosure of health information to other healthcare professionals in connection with treatment and care (section 41-42), collection of electronic medical data in connection with treatment and care (section 42a, 42b and 42c) and disclosure of health information for other purposes (section 43-45). There are special rules concerning disclosure of health information for scientific and statistical purposes (section 46-48) and disclosure to third countries (section 49). Furthermore, there are special rules concerning the "Personal Medicine Profile" in section 157.

The provisions regarding professional secrecy and disclosure of information in the Danish Health Act originate from the Act on Patients' rights which came into force in 1998. At that time there was no widespread use of electronic medical records in the hospital sector, and the provisions regarding medical files in the Act on Patients' rights were designed to function in a non-electronic information environment. Later it came into view that the wording of the provisions was not suitable in an electronic information environment where healthcare professionals are provided with direct access to electronic medical records and databases. As a reaction, the Health Act was amended in 2007 with section 42a-c. These provisions are explicitly dealing with the collection of electronic medical data.

The following comment can be made in regards to section 42a of the Danish Act on Health:

- Compared to section 41, section 42a provides physicians and hospital dentists with more extensive access to patient information. Sub-section 42a stipulates that if necessary physicians and hospital dentists are entitled to access electronic medical files to obtain information regarding the patient's health and other purely private and confidential matters. It is required that the accessed information is "necessary" in connection with "current care" and the physician may consequently access a medical record with extensive information about the patient to select the information which is relevant in connection with the provision of care.
- Other healthcare professionals have more limited access to electronic information. Access for this group is restricted to electronic systems which only contain information about patients

## Study on the Legal Framework for Interoperable eHealth in Europe

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who are receiving treatment at the particular unit where the healthcare professional is working, and they are only allowed to access information regarding the current treatment which is necessary to provide proper treatment and care (section 42a, sub-section 2-3).

- As is the case in regards to section 41, this section 42a is based on the patient's presumed consent, and patients are entitled to oppose access to his or her electronic medical information (section 42a, sub-section 7). However, if sufficiently substantial interest speaks in favour of allowing access it is possible to overrule the patient's objection (section 42a, sub-section 5).

In **Sweden** the new Patient Data Act of 29 May 2008 contains detailed rules on the processing of personal data within the health sector in general. It stipulates on one hand the rules for the legitimate processing of personal health data and on the other hand the legal requirements concerning patients' journals. This Law repeals, inter alia, the Patient Case Record Law (No. 562) of 13 June 1985. The table of contents of the law illustrates its comprehensive character: 1. Scope of the Law, etc.; 2. Basic provisions on the processing of personal data; 3. Duty to keep a patient case record; 4. Basic provisions on internal secrecy and electronic access within the context of a care provider's activities; 5. Basic provisions on the disclosure of information and documents and the duty to communicate certain information; 6. Joint keeping of case records by care providers; 7. National and regional quality registers; 8. Rights of the individual; 9. Care of and return of patient case records; and 10. Compensation for damages and appeals.

One of the new items of the Patient Data Act is the introduction of a coherent *patient journal*. This means, inter alia, that care providers can access each other's information if they fulfil the requirements of the Act. One of the requirements is that only those who need the information in their healthcare are allowed to access the patient's data (internal secrecy). The Act also sets up rules for different levels of access rights as well as control of access. The patient has the right to lock his data both within a certain database as well as towards other care providers. Finally, the Act also allows patients to access their own health data via the Internet. The Act is complemented with the Patient Data Ordinance. The Ordinance authorizes the National Board of Health and Welfare, after consultation with the Data Inspectorate, to issue regulations on: the allocation of authority to access such data, as well as the allocation of authority in the case of joint record-keeping by more than one care provider; documentation and the control of electronic access and documentation and control of direct access in the case of joint record-keeping; the requirements governing security measures in the case of direct access; and the information to be communicated to the patient. The Board may also issue the necessary regulations for the implementation of the Law with respect to wholly or partially automatic processing of personal data.

### 8.2 New legal rules relating to shared electronic health records

The existing legal rules relating to health records, as they have been progressively introduced in the Member States by integrating them in a general healthcare act or in a law on patients' rights, certainly take already into account that individual health data, under certain conditions, can be shared among health professionals. More recent laws also include specific conditions for accessing and sharing electronic health records. In many cases however, these rules don't suffice as a comprehensive legal framework for the introduction of electronic health records on a national scale. Therefore countries such as Austria, Belgium, Estonia, Finland, France, the Netherlands, Slovenia and others have created a new legal framework for sharing electronic health records by way of government-initiated eHealth services, platforms or registers.

## Study on the Legal Framework for Interoperable eHealth in Europe

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Every national approach in this field has its own peculiarities and it is not easy to group them into clusters. In its working paper on electronic health records, the Article 29 Working Party mentions the following categories:

- EHR as a system furnishing access to medical records kept by the healthcare professional, who has the obligation to keep records on the treatment of his patients – this is often called “decentralized storage”, or
- EHR as a uniform system of storage, to which medical professionals have to transfer their documentation; this is often called “centralized storage”;
- a third alternative could be to enable the data subject to be “master” of his own medical records by offering him storage of patients’ medical data as a special eservice under the patient’s control, possibly even including the power to decide what goes into an EHR.<sup>135</sup>

In the following pages we will use these categories in order to cluster the examples of recent legislative initiatives taken by the Member States in this respect.

### 8.2.1 Decentralized electronic health records shared via national platform

A first approach to introducing shared electronic health records at a national or regional level is to leave the individual health record on the IT systems of every (connected) healthcare provider and healthcare institution. Following this scenario a physician continues to work with the health record system which he used before but the system will be connected to a national switch point. Via this switch point the healthcare providers can access each other’s health records, more or less on a peer-to-peer basis.

The switch point usually provides a series of elementary services such as secure authentication and encrypted communication. Also essential is some form of directory service in order to allow a health care professional to retrieve the data of a particular patient in the local system of his colleague where these are stored. The decentralized approach is further not possible without a unique identifier for every patient in the network.

Given the complexity of such a system, especially due to the number of different parties involved, Member States adopting this decentralized approach have also created a specific legal framework which precedes or accompanies the introduction of the system.

In **Austria** these legal provisions have been introduced by the Health Telematics Act. The Act creates a platform for secure electronic exchange of health information about patients, provided care and the results of the provided care, and for the exchange of electronic care prescriptions between all relevant actors.

Electronic exchange of health-related data between healthcare providers is only allowed if the identity and the role of the recipient are properly established (Chapter 2 of the Health Telematics Act). Several options for proof of identity exist: qualified certificate, registration in the electronic directory of the health service providers or server certificates. Identity is proven by an electronic certificate that

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<sup>135</sup> P. 17 of Working Paper nr. 131. With regard to the third alternative, the Art. 29 Working Party refers to the French system.

## Study on the Legal Framework for Interoperable eHealth in Europe

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confirms the identity of the healthcare provider in accordance with Sections 3 to 6 of the E-Government Act. Such proof is not required if the healthcare provider is registered in the electronic directory of the health service providers and the identity is checked with reference to this register. In case of automated applications, this proof can be replaced by server certificates. In case of direct access to data applications the proof of identity is not required for each single transaction if technically or economically not feasible. Identity has to be established at the start of the access authorization and is further checked in regular intervals.

Healthcare providers offering access to third parties have to encrypt health data in order to prevent unauthorized access. Encryption has to comply with technical standards (Section 6 of the Health Telematics Act). The integrity of the transmitted health data must be assured using electronic signatures complying with the minimum requirements of Section 7 para. 5 of the Health Telematics Act. Use of electronic signatures is not mandatory if exchange of health data is done automatically or via direct access to a distant data service.

In an agreement according to Federal Constitution Article 15a concerning organization and financing of the health sector 2005 (Federal Law Gazette I 73/2005), the federal government and the regions (the "Länder") agreed on the priority of conceiving and introducing an electronic health record (ELGA) and a system for ePrescriptions. After a feasibility study, the pilot implementation phase has started in 2007. The project is managed by the working group ELGA (ARGE ELGA) that consists of representatives of the social security institutions, the federal government and the nine regions.<sup>136</sup>

As far as electronic health records are concerned, no centralized storage of individual-related health data is envisaged. ELGA consists of a directory providing links to the locally stored data of healthcare providers.

ELGA will basically contain the following information:

- A health service provider index: identification of healthcare providers is a central prerequisite of ELGA. The index should contain uniformly structured and complex data of all healthcare providers with their access structures, roles and rights. For this purpose, the existing eHVD (e-Health Verzeichnisdienst) should be built up and enlarged.
- A patient identification and index: this Austrian master index of patients should also form the interface to region-specific and local patient indices.
- A document registry: The registry should contain metadata about important medical documents. The reference directory thus doesn't contain the medical information itself (only references). At present, the following documents for entry in the registry are envisaged: prescriptions, radiology reports, laboratory results, discharge letters.
- A document repository: The storage of the documents shall be realised in a decentralised system under the responsibility of the healthcare provider.

Access to health data is organised with a roles and responsibilities concept. The patient can get an overview of accesses, write and read rights to his health record at any time.

The legal framework for the ELGA platform is not yet entirely complete. The registry could be based either under a – not yet existing – specific legal basis for an ELGA registry or the consent of the patient. The required circumstance-aware coercion-free consent for access and transfer of data is

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<sup>136</sup> <http://www.arge-elga.at/>



## Study on the Legal Framework for Interoperable eHealth in Europe

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currently considered as not really practicable. A legal basis for ELGA must comply with the basic right for data protection, e.g. requiring a sophisticated regime for access, write and read rights.

In **Belgium** a law on the establishment and the organisation of the *eHealth-platform* has been enacted on 21 August 2008.

The eHealth Platform is a government institution, managed by representatives of the stakeholders in the healthcare sector. It manages a cooperation platform for secure electronic exchange of information about patients, provided care and the results of the provided care, and for the exchange of electronic care prescriptions between all relevant actors in the health care sector. Besides providing a network and basic services, it also coordinates the development of functional and technical interoperability standards.

The eHealth Platform does not change the current division of tasks between the actors in the health care sector. It doesn't store information in a central way or doesn't monopolize electronic service delivery to the end users. It essentially provides basic services which can be used by providers of value added services. The platform makes use of the existing network infrastructure (internet, social security extranet, federal government network) with end-to-end encryption of the information (concept of virtual private network. The providers of value added services are also able to use validated authentic data sources via the eHealth Platform but the administrators of these databases remain responsible for the availability and (the organization of) the quality of the information made available.

Obvious basic services provided by the eHealth Platform include:

- integrated user and access management;
- orchestration of electronic processes;
- portal environment including a content management system and a search engine (<https://www.behealth.be>);
- personal electronic mailbox for each health care provider;
- logging.

These services are completed by additional basic services that are currently being developed, in particular time stamping, coding and anonymising and the provision of a reference directory. The *reference directory* indicates, on demand of the patient, which type of information with regard to the patient, the provided care and the results of the provided care is available at what places. It will, on the one hand, provide a table with fixed care relations between health care providers and their patients, the nature of the relation, the starting date and final date of the relation, and, on the other hand, a table indicating the places where, without a fixed care relation, electronic information is available about patients. It further has a multi-stage and decentralised character: a general reference directory referring further to specific reference directories for each group of health care providers or each health care institution. The main functions of the reference directory are:

- preventive control on the legitimacy of the access to the information regarding a patient;
- routing of information requests to the places where the information about the patient is available;
- possibility of pushing automatically particular information to certain health care providers.

## Study on the Legal Framework for Interoperable eHealth in Europe

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Patient information can be retrieved by means of the National(Citizen) Number, that is used also for other e-government services. Therefore the use of this National Number is mandatory for every exchange of data via the eHealth-Platform. Belgium has chosen not to introduce a separate unique identifier for the health sector.

Authentication of the users of the eHealth-Platform is differentiated according to the security level required and includes the three traditional levels used in Belgian e-government services: the electronic identity card, a combination of user number, password and citizen token, or authentication by simple user number and password. Authentication includes verification of characteristics and mandates, necessary for accessing validated authentic sources and authorization to use an added value service managed by a service supplier. These authorizations are attributed on the basis of a generic policy enforcement model.

The Belgian eHealth-Platform further makes use of currently existing validated authentic sources, such as the register of health care providers, held by the Ministry of Health and containing information about the diploma and the specialization of a health care provider identified through his social security identification number (SSIN). Other validated authentic sources are the database with recognitions of the National Institute for Sickness and Invalidity Insurance – which contains information about the social security recognition of health care providers identified through their SSIN -, and the database with the identities of the persons authorized to act on behalf of a health care institution, containing information about which persons, identified through their SSIN, are authorized to use which applications on behalf of a health care institution.

All types of data exchanges via the eHealth-Platform need to be authorized by an independent sector committee for the protection of personal data. Health care providers and institutions who wish to exchange data health data via the eHealth-Platform need the informed consent - in writing - of the patient.

In the **Netherlands** the new – at the time of writing not yet enacted - legal provisions on the electronic health record are integrated in the Dutch law on the “Citizen Service Number” (the unique personal number used by citizens in their contacts with government agencies). The law provides a legal framework for the national infrastructure for healthcare (called AORTA). This infrastructure consists of several components such as (i) a national registration system for identification and authentication of patients, healthcare providers, insurers and other care agencies, and (ii) a National Switch Point (LSP) which provides a reference index for routing, identification, authentication, authorization and logging. This LSP has been compared to a traffic-control tower which regulates the exchange of patient data between the healthcare providers. Similar to Austria and Belgium the electronic health record is a virtual record. The health information remains, decentralized, in the information systems of the health care providers and institutions providing care to the patient and health data are exchanged amongst the health care providers and institutions in a peer-to-peer network.

In the Dutch context digital exchange between healthcare providers takes place via AORTA, an architecture consisting of different components, including the Citizen Service Number (BSN), the Unique Healthcare Provider Identification (UZI), the National Switch Point (LSP) and the information systems used by the healthcare providers. Together these components form the ‘chain of trust’ in which medical data can be safely shared. The information systems used by physicians, hospitals and other healthcare providers need to be certified before they can connect to the National Switch Point. They need to comply with a set of requirements related to the application, implementation and usage

## Study on the Legal Framework for Interoperable eHealth in Europe

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of the system. These requirements (GBZ) for a safe and adequate (a well-managed<sup>137</sup>) healthcare information system have been developed by NICTIZ.

The requirements mainly deal with connectivity (connection with the national switch point, use of IP addresses, etc.), security, availability, response times, capacity, robustness, update frequency, and technical support. Following these requirements, in order to be allowed to connect, an information system used by a physician needs to be available on a 24 hours/ 7 days a week basis for the processing of messages coming from the national switch point. The only exception is planned maintenance but such maintenance should occur maximum 12 times a year and take no longer than one hour. A system can be exceptionally disconnected due to minor disturbances but this should not happen more than once a month and the connection should be restored within 15 minutes. Major disturbances should occur maximum twice a year and be solved within one day. The system needs to be protected against power breakdown and fire.

Once a system has been certified for connection to the national switch point, the healthcare provider has to sign a contract. According to this contract, NICTIZ has a right to perform audits on the healthcare provider's system in order to control that the GBZ requirements are correctly applied.

For the purposes of identification and authentications the Dutch government introduced the Citizen Service Number (BSN) for patients and the Unique Healthcare Provider Identification (UZI) for healthcare providers. The structure of the BSN is the same as the one used for the current social security number (so-called *sofi* number).

Healthcare providers can look up and check out the BSN via the care sector message service (SBV-Z). They need an "UZI-pass" and a UZI server certificate. The UZI is a register that is used for the unique healthcare provider identification.

Various types of UZI-passes have been developed. Besides the pass for healthcare providers (which permits e.g. to store encrypted data, to send encrypted data and to create electronic signatures) there are also passes for collaborators (for example paramedical personnel). They can be nominative, in which case the pass gives access to more or less identical functions as the pass for healthcare providers, or not nominative. In the latter case the UZI pass has of course a more limited functionality. Besides these passes the healthcare provider also receives a server certificate to secure the information system and to guarantee a secure connection with the central switch point.

The government has opted to deploy the EHR gradually and started by the launch of an Electronic Medication Record (EMD) and a Patient Summary Record (WDH), a record for the general practitioner who is in service evenings and in the weekend. Many other applications, chapters of the EHR, are in the pipeline.

The application "Patient access to the EHR" will give a patient the possibility to view his own medical data. Through the patient access the patient gets more control over his own care and health. In the future, the patient will have the possibility to add, change or delete data in his personal health record. For connecting to the national infrastructure and starting to exchange health data, the healthcare providers and institutions don't need the explicit consent of the patient. The patient has however a right to opt-out if he doesn't want his data to be included in the national EHR.

In **Germany** article 10 of the medical professional code rules the doctor's duties concerning the documentation of diagnosis and provided care. Doctors have to produce "necessary" documentation. There are several possibilities: paper based documentation and digital documentation. If the data is

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<sup>137</sup> Nictiz is the Dutch national knowledge centre for ICT and innovation in healthcare. <http://www.nictiz.nl/>

Study on the Legal Framework for Interoperable eHealth in Europe

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stored on electronic processing units within the institution that collects the data, e. g. the doctor in his surgery or the hospital, special rules in art. 10 par. 5 of the medical professional code and recommendations of the German medical assembly have to be observed.

Pursuant to general data storage rulings in article 9 of the Federal Data Protection Act<sup>138</sup> and article 10 par. 5 of the medical professional code the digital external storage of data requires actions to protect the data against unauthorised modification, destruction or utilization. The German Medical Assembly has published recommendations concerning digital data storing operations<sup>139</sup> and suggests use of digital signatures, vpn-clients and qualified digital time stamps.

Beside this documentation under direct supervision of doctors and other healthcare service providers, it will be possible to file data concerning treatment, diagnoses, etc. by means of the electronic health card and the Health Professional Card. Relevant data protection is ruled in art. 291a SGB V. The data within the electronic patient file are in charge of the patients in so far as they decide by themselves, if data are stored at all, which data to be stored and whom to grant access. The access to these data is restricted by a two-key-principle: In general, access is only possible, if the reader uses an electronic health professional card or an equivalent and the patient admits access by entering his PIN. An exemption from this is made for the so called *Patientenfach*, the patient's storage area: art. 291a SGB V guarantees that the patients get access to this storage area. They will for instance be able to store their blood sugar levels or keep a diary on their dizzy spells in this storage area.<sup>140</sup> Up to now, there are plans that the patients will be able to store the data on the eGK or by means of their eGK by themselves via the so called *eKiosk*, *EKiosks* are special card reading and internet connected terminals which enable the patients to access their data out of a physician's control.

This fact sets ePA's apart from so called personal eGA's (persönliche elektronische Gesundheitsakte, personal electronic health records), a service offered by a third party, (private) service providers. Those data are in charge of the patients, too. Those records are not ruled by the strict provisions in art. 291a SGB V, but only by article 68 of SGB V – regulating the financial support of electronic storage of patients' data in general – and the statutes of the health insurance companies. The insurance health companies may grant the insured party financial support, when patients use third party services to store and transmit their health related data. Each insurance company decides by itself in its statutes if such contributions towards the costs for the third party services are granted. Up to now, not many statutory health insurance companies have introduced such services.<sup>141</sup> The health insurance companies have developed different models: some companies make contracts with particular third party service providers. Only if the patients and insured parties use services of these third party service providers, they can claim the contributions.<sup>142</sup> Others refrain from service contracts,

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<sup>138</sup> Bundesdatenschutzgesetz, BDSG, renewed Jan. 14, 2003, BGBl. I 2003, p. 66, as last amended by Act from Aug. 22, 2006, BGBl. I 2006, p. 1970

<sup>139</sup> Empfehlungen zur ärztlichen Schweigepflicht, Datenschutz und Datenverarbeitung in der Arztpraxis, published in 105 Deutsches Ärzteblatt (DtÄBl.) 19, p. A1026 of May, 9<sup>th</sup> 2008, available at [http://www.bundesaerztekammer.de/downloads/Empfehlung\\_Schweigepflicht\\_Datenschutz.pdf](http://www.bundesaerztekammer.de/downloads/Empfehlung_Schweigepflicht_Datenschutz.pdf) and technical attachment Technische Anlage, available at <http://www.aerzteblatt.de/v4/plus/down.asp?typ=PDF&id=2316>

<sup>140</sup> <http://www.heise.de/newsticker/Elektronische-Gesundheitskarte-Befreites-Dokument-wirft-Fragen-auf-meldung/81575>

<sup>141</sup> See for some examples BKK Bertelsmann, statutes art. 12, n° 13, available at , <http://default.kunden.ogvit.de/tmp/pdftohtml549626305.html> ; KKH, statutes article 29i, available at <http://www.kkh.de/filesserver/kkh2006/BROCHURES/Broschuere584.pdf>

<sup>142</sup> So does BKK Bertelsmann.

## Study on the Legal Framework for Interoperable eHealth in Europe

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but limit the contributions to a certain percentage and amount, e.g. 80 % or 150 EUR, and demand the use of the stored data by the patient's physicians to a great extent.<sup>143</sup>

### 8.2.2 Central electronic health registers

A second model for organising electronic health records is the creation of a central register. This model is typical for some Scandinavian countries and has also been adopted in Estonia.

The **Finnish** Act on Electronic Handling and Archiving of Electronic Healthcare Records (so called Client Data Act 2007/159) mandated the Social Insurance Institution KELA to provide for all the so-called KANTA services for handling electronic patient information. KANTA services cover archive services, encryption and certification services, and the patient's access to the data. The Act mandates the National Authority for Medico-legal Affairs TEO to act as Certificate Authority for all medical professionals and healthcare institutions; and the National Research Centre for Welfare and Health STAKES to maintain the code server of core data and other electronic patient record structures and ISO-OID codes of healthcare organisations.

The law makes mandatory the incorporation of all public healthcare units into the electronic archiving system, as well as private healthcare units that do not use paper-based archives.

A roadmap document foresees that patient information will be available in real time whenever the treatment relationship and patient consent allow it, and this will improve the continuity, quality and patient safety of services. Structurally uniform entry, storage and transfer of data make data easier to be retrieved and easier to reuse. Structured information will also enable the introduction of smart support systems for decision-making directly in medical care situations. The supra-organizational availability of data will enable the introduction of new procedures and agreements on cooperation and division of duties between organizations in the healthcare system. The centralized archive system will enable patients to view data and usage logs pertaining to them. This will increase the potential for citizens to participate in their medical treatment and, consequently, increase confidence in the system. Centralized services make planning, monitoring (including real-time statistics) and management much easier and also open up new opportunities for research. International cooperation is easier to organize when national systems are uniform. Uniformity also means that the IT infrastructure can be built more cost-effectively while ensuring a high level of data security.

The eHealth strategy of the **Estonian** government foresees a comprehensive central register of the health information for all 1.35 million Estonians from birth to death. The register is intended to facilitate the exchange of all types of health data between healthcare providers. Responsibility for implementation has been entrusted to the private non-profit Estonian eHealth Foundation (Eesti E-Tervise Sihtasutus). It was set up by the hospitals and professional associations in October 2005 following an initiative of MoSA. The main goals of this foundation are the development and governance of nationwide eHealth projects, and the coordination of the unification of Estonian healthcare provider information systems.<sup>144</sup>

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<sup>143</sup> So does KKH.

<sup>144</sup> More information about the eHealth Foundation can be found at: <http://www.e-tervis.ee>

## Study on the Legal Framework for Interoperable eHealth in Europe

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The “heart” of the eHealth information system is a centrally managed electronic health record that is a central database of the most important medical information and provides the necessary information to various partners.

MoSA fulfils the coordinating and directing role in developing the national Health Information System. Currently four eHealth projects are under development: Electronic Health Record (EHR), Digital Images, Digital Registration and Digital Prescription. The implementation of these four projects will create a unified national Health Information System that will be linked with other public information systems and registers and will in its IT solution use the existing public information technology solutions.

The EHR database will include the most important personal data, medical records, visits and other health-related information of the patient. With the help of EHR, medical doctors will be able to exchange documents that are produced in the course of the treatment and allow doctors to make enquiries of time-critical and general information about the patient. The information system stores the medical history of the patient and enables the doctors who are treating the patient access to this specific information.

Data provided in the EHR can be used only for the treatment of patients and for checking the patient’s medical condition, assessment of medical quality and for national statistics. The partners in the information system are medical establishments or other legal persons who have entered into the accession contract with the eHealth Foundation and have the right to use EHR data and exchange of medical information through the EHR system. EHR will offer the partners authorized access to the persons’ health data and create the opportunity for digital forwarding of medical documents between healthcare establishments.

Persons can access their health data by using their electronic ID cards at all times and from all computers with Internet access through the patient’s portal.” Bank eID and Mobile-ID solutions can also be used to gain access to health data.

To implement the eHealth projects, changes in the legal system had to be made. A draft Health Information System Act was drawn up in 2006 and it had to be implemented as a separate legal act, however it was never presented to the Parliament. Instead the current Health Services Organisation Act (Tervishoiuteenuste korraldamise seadus) was amended and expanded to facilitate the required legal framework needed for the implementation of the eHealth projects. The said amendments were adopted by the Parliament on 20.12.2007 and entered into force on 01.09.2008.

The norms stipulate 01.01.2013 as the final date when the Health Information System must be fully in use. Further, the Minister of Social Affairs must issue a detailed timeline for the implementation of the Health Information System.

It will be mandatory for the healthcare providers to input data to the Health Information System. In the broadest sense it will be necessary to provide data:

- required for the administration of waiting lists;
- required to make available the medical image;
- about the healthcare services provided to the patient (including data concerning state of health).

The Minister of Social Affairs has the obligation to specify the categories of the said data as well as the conditions and regulations concerning the retention of such data. It is mandatory to use the classifications and address details of the national information system in order to ensure the quality of data.

Of great importance are the norms that regulate access to the Health Information System. The patients have full access to their personal data in the Health Information System, with a single

## Study on the Legal Framework for Interoperable eHealth in Europe

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exception that a healthcare provider may deny access to the patient for a period of up to six months for the purpose of protecting the life and health of the patient. The argumentation behind making such an exception is to preclude the patient of learning about data entered into the Health Information System before the healthcare provider has had an opportunity to explain the meaning of such data to the patient. This provision was added as a consequence of broad discussions with professional and patient associations.

The healthcare providers have access to the personal data in the Health Information System for the conclusion and performance of the healthcare provision agreement.

The patients have the right to deny healthcare providers access to their personal data in the Health Information System, and they also have the right to ask the healthcare provider to immediately apply access restrictions to the personal data.

Forensic experts of the national forensic institution have access rights to the Health Information System for the purposes of determining the nature of a person's injuries under the Code of Criminal Procedure and for the performance of a forensic autopsy.

Other persons have access rights to personal data in the Health Information System if such a right is stipulated in law.

The new regulatory framework also foresees the creation of a special ethics committee that assesses the necessity and justification of extracting personal data from the Health Information System for the purposes of scientific research and statistics. The special ethics committee also has the obligation to draw up guidelines of good practice. The decisions of the ethics committee are not binding, the Estonian Data Protection Inspectorate has the final say, however it has an obligation hear out the position of the ethics committee.

### 8.2.3 The French “Dossier Medical Personnel”

A third approach is more patient-centred and leaves the electronic health record under control of the patient. Essentially the patient has to choose a service provider who will host the record and ask his healthcare provider to enter the data into this record. This model has been adopted in **France**. The legal rules concerning electronic health records, the so-called “Dossier Médical Personnel” (DMP, Personal Medical Records) have been integrated in the Health Insurance Act.<sup>145</sup>

Article L. 161-36-1 of the Social Security Code specifies that the DMP contains the personal data collected or obtained during preventive, diagnostic or care activities, and more generally any information that allows the follow-up of the provision of care, included prevention. Medical files created by health institutions should already contain the identification of the patient; each written act, dated and identifying the healthcare professional who performed it; each prescription, time stamped and signed by the health professional who issued it, duly identified.

Each healthcare professional must report the diagnosis or therapeutic elements to the DMP after performing a medical act or consultation. The law moreover subjects the application of conventions between health professionals and the Social Security to the consultation and update of the DMP. The healthcare professional should moreover specify on the reimbursement form that (s)he has been able to access the DMP. Healthcare professionals employed by a health establishment should report a summary of the stay of the patient. This creates an obligation for health professionals to create and update a DMP for each patient. This record is likely to be converted in the new mandatory tool to

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<sup>145</sup> <http://www.d-m-p.org/index.php>

## Study on the Legal Framework for Interoperable eHealth in Europe

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report information related to the patient. Several points are however still pending of definition: the exact list (and nature) of health data to be included or the persons compelled to its follow-up and update.

Patients have the obligation to present their DMP to the healthcare professional. They however keep the right to refuse the healthcare professional to access the DMP but then would obtain lower reimbursement's rates. This economical sanction puts at stake the principle of prior consent pointed out by the CNIL as a core principle of the system.<sup>146</sup> Moreover, healthcare professionals are entitled to access the DMP without the prior consent of the patient in case of emergency, except if the patient has previously opposed to such access. Access to the DMP by other healthcare professionals, e.g. of a medical team, are subject to the prior consent of the patient. In accordance with the guidelines given by the Minister of Health, advocating for the relief of the patient from this obligation, the report GAGNEUX recommends that the DMP should be presented by patients to healthcare professionals on a voluntary basis.<sup>147</sup>

The possibility granted to the patient to refuse the access to the DMP does not mean that the healthcare professional cannot include this information into his own medical records. Moreover, some elements of the medical records remain restricted from the right to information of the patient: the personal notes of the healthcare professional (with exceptions acknowledged by CADA and administrative jurisprudence); the information collected towards third parties which do not intervene in the therapeutic follow-up; the information not formalized and that cannot be included in the records.

Moreover, healthcare professionals are granted with a limited access to the DMP according to their field of competences and the act they are to perform. To that effect, a decree adopted in State Council [*Conseil d'Etat*] after opinion of the CNIL and the national councils of health professional orders, should define the conditions of access to the categories of information contained into the DMP, the conditions under which certain information can be masked by patients or their legal representatives and how the healthcare professional obtains knowledge from the existence of masked information.

Finally, the DMP cannot be consulted by third parties for other purposes than the ones defined to Article L. 161-36-2 even with the prior consent of the data subject. More specifically, the access is prohibited for the conclusion of any contract requiring the evaluation of the health condition of the user. It cannot be consulted by the occupational physician either. Commercialization of health data is moreover sanctioned by the Penal Code (Article 226-21).

The DMP is created by a certified host. Article L.1111-8 of the Public Health Code compels healthcare professionals to "deposit the personal data, gathered or produced during prevention, diagnostic or care acts into [the systems] of accredited physical and legal persons." The deposit should be governed by a contract with the host provider. Medical data host providers and their staff are subject to the same professional secrecy as protected by article 226-13 of the Penal Code.

The deposit is subject to the prior and express consent of the patient. Derogation is foreseen to allow healthcare professionals to use their own information system to store the medical records provided that the access is restricted to the sole healthcare professional or institute and to the patient. Article L.1111-8 of the Public health Code explicitly specifies that such processing is subject to the provisions of the Data Protection Act. They are moreover subject to the specific provisions on professional secrecy and to conditions of interoperability of systems as defined by the Ministry of Health.

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<sup>146</sup> <http://www.cnil.fr/index.php?id=2212>

<sup>147</sup> [http://www.sante-jeunesse-sports.gouv.fr/IMG/pdf/Rapport\\_DMP\\_mission\\_Gagneux.pdf](http://www.sante-jeunesse-sports.gouv.fr/IMG/pdf/Rapport_DMP_mission_Gagneux.pdf)



## Study on the Legal Framework for Interoperable eHealth in Europe

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Host providers must process the data with the sole purpose of the maintenance of the DMP, they cannot transfer the data to other healthcare professionals or institutes and must transfer the data to the healthcare professional or institute or data subject counterpart of the contract initially signed.

Article R. 1111-9 defines the conditions for the certification of host providers. They should in particular prove their professional competence, define their confidentiality and security policy, identify their representative established in France, separate the activity of medical data hosting from other activities of hosting, define the information process due to person who has originally deposit the data and finally identify the person in charge of the hosting, in particular the physician part of the team. The certification is delivered for a period of 3 years by the Ministry of Health after prior opinion of the CNIL and the certification committee. The core mentions of the host contract and of the confidentiality and security policy are defined by articles R.1111-13 and R.1111-14.

Every individual born in the French territory or who becomes a beneficiary of the French Social Security is attributed a registration number (NIR - *numéro national d'inscription au répertoire des personnes physiques*). The NIR is a meaningful identifier. It is based on a chain of character that allows determining the gender, date and place of birth of the individual (Art. 4). It is highly reliable insofar it is certified by the INSEE on the basis of the civil status information sent by the municipalities.

Because of these characteristics, the NIR is a convenient identifier to link databases. The Data Protection Act however restrains the use of the NIR and of data matching processing to a previous authorisation given either by the CNIL (Art. 25.6°), by legal provisions, or by regulatory provisions taken after the (non-binding but public) opinion of the CNIL (Art. 27.1°) and under the control of the State Council (*Conseil d'Etat*)<sup>148</sup>. The infringement of these provisions is punished by five years of imprisonment and a fine of 300,000 euros (Art. 226-16-1 of the Penal Code). The RNIPP is currently and mainly used, apart from Social Security agencies, by Fiscal Agencies, the National Bank, and by the INSEE for the administration of the companies' directory (SIREN) and of the electoral file.

The use of the NIR as "health identifier" for health medical records such as the DMP and the Pharmaceutical Records has triggered public debate. Article 25 of the Act n°2007-127 of 30 of January 2007 provides for the creation of a specific identifier for health medical records without specifying how this identifier should be formed. The CNIL has opposed to such use due to the sensitivity of the medical data which call for reinforced safeguards, incompatible with the risks of using an identifiers largely known by several stakeholders. It would require not only the implementation of specific measures of protection but would also risk altering the trust between healthcare professionals and patients. The CNIL has proposed a more balanced approach based on the creation of a specific and meaningless identifier for health data, generated from the NIR but according to certified procedures of anonymisation.<sup>149</sup> According to the CNIL the creation of a new identifier would allow to take benefit from the advantages offered by the NIR at the time it would maintain a high level of protection.<sup>150</sup>

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<sup>148</sup> The State Council is the highest administrative jurisdiction in France. It ensures the legal validity of administrative acts.

<sup>149</sup> CNIL, Conclusions on the use of the NIR as health identifier [*Conclusions sur l'utilisation du NIR comme identifiant de santé*], 20 February 2007, available at: [http://www.cnil.fr/index.php?id=2197&news\[uid\]=434&cHash=dd6d3df873](http://www.cnil.fr/index.php?id=2197&news[uid]=434&cHash=dd6d3df873)

<sup>150</sup> <http://www.d-m-p.org/index.php>

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### 8.3 Legal rules concerning patients' summaries

The Commission Recommendation on cross-border interoperability of electronic health record systems<sup>151</sup> defines its scope as "electronic health record systems, including *patients' summaries*, *emergency data sets*, and medication records facilitating ePrescription solutions". "Patient summary, emergency data set, medication record" are defined as subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription".

In a general sense, a patient summary is an electronic clinical document with relevant data about a patient, perhaps stored in repositories with a cumulative indexing system (registry) and secure access by authorised people. However, there was no attempt so far to agree on a definition of "patient summary" across Member States. As a matter of fact, several kinds of documents may be considered (or not) under the same concept of "patient summary".

Efforts are being undertaken to develop standards for patients' summaries. The European Commission has issued in 2007 a mandate to the European Standardization Organizations (ESOs), CEN, CENELEC, and ETSI, to develop a coordinated work programme for standardization in health informatics (Mandate M/403).<sup>152</sup> In **Belgium** a standardized "Summarized Electronic Health Record" (SUMEHR) has been developed.<sup>153</sup> Similar efforts have also been undertaken in other Member States.

In **Scotland**, as an initial step in the development of comprehensive electronic patient records, an emergency care summary (ECS) has been produced for all patients except for those who have exercised a right to opt out of the system. The summary contains details of the patient's name, CHI number, date of birth, registered general practitioner, details of medicines prescribed by the GP within the previous seven weeks and information as to any instances reported of adverse reactions to particular medications. The ECS is prepared by the patient's GP and is then uploaded to a central server. The ECS may be seen by NHS staff treating a patient (including staff at NHS 24 which provides a telephone based service for patients seeking non-emergency medical advice and assistance when their GP surgery is closed). Patient consent must be obtained where possible for each occasion when the summary is consulted and a record is kept of all consultations. The ECS system was launched in 2006 and to date ECS's have been accessed on more than one million occasions.

In common with many aspects of NHS operations in **England** no legislative reforms have been necessary to introduce electronic patients' summaries. Legally, patient records have always been regarded as the property of the NHS rather than of the patient. The key legal requirement is that the records should comply with the requirements of the Data Protection Act 1998. Some issues have arisen concerning the extent to which patient consent might be obtained. In evidence before the House of Commons Health Committee in 2007, the Department of Health stated that: "At first, the Summary Care Record will contain only basic information such as known allergies, known adverse reactions to medications and other substances (e.g., peanuts) acute prescriptions in the past 6 months and repeat prescriptions that are not more than six months beyond their review date...In due course more information will be added about current health conditions and treatment."<sup>154</sup>

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<sup>151</sup> [http://ec.europa.eu/information\\_society/activities/health/docs/policy/20080702-interop\\_recom.pdf](http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf)

<sup>152</sup> For more details: <http://www.ehealth-interop.nen.nl/publicaties/2860>

<sup>153</sup> [https://portal.health.fgov.be/portal/page?\\_pageid=56,4280424&\\_dad=portal&\\_schema=PORTAL](https://portal.health.fgov.be/portal/page?_pageid=56,4280424&_dad=portal&_schema=PORTAL)

<sup>154</sup> The Electronic Patient Record. Sixth Report of Session 2006-7 at page 24.

## Study on the Legal Framework for Interoperable eHealth in Europe

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**Finland** is one of the only Member States having enacted legal provisions in the area of patients' summaries in the form of the Act on Electronic Handling and Archiving of Electronic Healthcare Records (so called Client Data Act 2007/159). In the §6 of the Client Data Act 2007/159, the Summarized Electronic health Record is defined as a structured data system, which enables the electronic Use, Releasing, Storing and Safeguarding of patient data within the framework of the national Electronic Healthcare Record and Archive service defined in §14 of that Act. The §14 sets the responsibilities for creating and managing the national Electronic Healthcare Record and Archive service KANTA, with KELA being in charge of the complete system. Roles of the National Authority for Medico-legal Affairs TEO and the National Research and Development Centre for Welfare and Health STAKES are also defined.

**France** doesn't have legal provisions in the area of patients' summaries. As mentioned already before in this chapter, the drafted decree on the content of the DMP includes patients' summaries. The content of the summary is however still under discussion. Provisions are foreseen for the creation of an electronic health record for the follow-up of children's health condition (*carte de santé*). Children's health records contain the results of the mandatory preventive examinations that base the issuance of a health certificate. Regulation is pending in order to define the articulation between the DMP and children's health records. On the other hand, private initiatives have tended to develop electronic health records. "Monpass.santé" is a smart card with a secured chip (clearys TM), PKI based and a PIN code that has been developed by Orange Business Services together with the Mutuelle Générale (a private healthcare insurer). The card can be read with physicians' Vital Card readers. It contains a vaccination's history of the patient. The patient can access a personal area on the website of the healthcare insurance, consult his vaccination agenda and the ones of his beneficiary and receives alerts related to vaccination obligations.<sup>155</sup>

In **Germany** electronic patients' summaries are planned to be established through the electronic health card. In so far, the eGK is to be used for access to two different kinds of data collections: data that are necessary and useful in case of emergency according to art. 291a paragraph 3 sentence 1 n° 1 Social Code Book V (SGB V)<sup>156</sup> and data within an electronic patient record (*or file*, elektronische Patientenakte, EPA) according to article 291a par. 3 sentence 1 n° 4 SGB V. At the end of the test phase, the electronic health card-system must provide these applications. Nevertheless, at the moment, only the emergency data storage is tested.<sup>157</sup> Medical data to be used in cases of emergency must be accessible without using networks, meaning that key medical data will be stored directly on the electronic health card (art. 291a n° 1 SGB V). It is up to the patient's decision to get his doctor store the relevant data or store those data himself, but nobody is forced to do so and the consent is revocable, art. 291a par. 3 sentence 3, 4 SGB V. Medical data, that are not that important for medical assistance in emergency cases, can also be stored, e. g. in central or in non-central electronic data processing units or also directly on the electronic health cards (n° 4). Those data make up the electronic patient file<sup>158</sup> shall inform about the facts, that and when which diagnostics, lab results have

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<sup>155</sup> Press release, Monpass.santé: premier carnet de santé électronique, available online at: <http://www.imedicale.fr/document/1593>

<sup>156</sup> Sozialgesetzbuch V in German, *abbrev.* SGB V, Act on Statutory Health Insurance, Act from Dec. 20, 1988, Federal Law Gazette (Bundesgesetzblatt) BGBl. I 1988, p. 2477, as last amended by Act from May 28, 2008, BGBl. I 2008, p. 874..

<sup>157</sup> [http://www.gesundheitskarte-wolfsburg.de/index.php?option=com\\_content&task=blogcategory&id=19&Itemid=79](http://www.gesundheitskarte-wolfsburg.de/index.php?option=com_content&task=blogcategory&id=19&Itemid=79); <http://www.gesundheitskarte-rlp.de/>

<sup>158</sup> Elektronische Patientenakte in German, *abbrev.* ePA.

## Study on the Legal Framework for Interoperable eHealth in Europe

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been made and which therapy is administered. The patient has to consent in the electronic-health-card-based data storage, regardless whether the data is stored central or non-central on external servers or directly on the card, article 291a par. 5, sentence 1 SGB V.

In **Denmark** one of the focal points in the latest eHealth strategy is the development of a National Patient Index which is intended to be a single, comprehensive electronic patient record for each individual citizen. According to the plan of action it is planned to make an analysis regarding the possibility of producing a patient summary on the basis of the patient's personal patient index.<sup>159</sup>

Patients' summaries have been a matter of intense discussion in **Estonia**. The draft acts contained a clause for time critical health related personal data that could be accessed in emergency situations. However, the legal framework that was adopted leaves the supreme authority to the patient to determine what kind of personal data can be accessed and what cannot be accessed by healthcare providers and no exceptions are made for emergency situations. If a patient asks the healthcare provider to close access to the personal data already in the Health Information System or to data that is generated during a visit, the healthcare provider has an obligation to explain the possible consequences of closing access to such data.

Last but not least there is no specific legislation in **Sweden** dealing with electronic patients' summaries. The project National Patient Overview (NPO) is, however, aiming at a national patients' summaries database.<sup>160</sup> Until recently, the legal obstacles concerning electronic patients' summaries and exchange of data between different care providers were unclear. The new Patient Data Act (*patientdatalag*), in force since 1 July 2008, aims at removing these obstacles. There are also several specific acts dealing with different databases containing health data held by public authorities, e.g. the (until recently in force) Care Registers Act (*lag (1998:544) om vårdregister*), and the Act on Databases held by the Social Services

It can be expected that legal rules concerning patients' summaries will progressively be introduced in the Member States in the context of the legal framework with regard to electronic health records and ePrescription. From a European perspective a structured, standardized and language-independent format for patients' summaries is probably one of the core objectives. Cross-border exchange of patients' summaries will depend on the interoperability of the electronic health record systems of the Member States.

The Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems<sup>161</sup> foresees *"the adoption by Member States of a comprehensive legal framework for interoperable electronic health record systems. Such a legal framework should recognise and address the sensitive nature of personal data concerning health and provide for specific and suitable safeguards so as to protect the fundamental right to protection of personal data of the individual concerned"*. It also invites Member States *"to implement interoperability of electronic health record systems as an integral part of regional and national eHealth strategies"*. The Recommendation invited the Member States *"to report, on a yearly basis, to the Commission on the measures they have taken in relation to the implementation of cross-border interoperability of electronic health record systems."*

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<sup>159</sup> <http://www.sdsd.dk/~media/Files/handlingsplannotat.ashx> (only in Danish).

<sup>160</sup> More information at <http://www.npö.nu/>

<sup>161</sup> [http://ec.europa.eu/information\\_society/activities/health/docs/policy/20080702-interop\\_recom.pdf](http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf)

**Study on the Legal Framework for Interoperable eHealth in Europe**

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The first report should be presented by Member States one year following the day of publication of this Recommendation.

## 9. Regulatory framework for telemedicine

Telemedicine can be defined as the provision of healthcare services at a distance by making use of electronic communications.<sup>162</sup> A distinction can be made between two types of telemedicine services: 1) healthcare services provided by one or more healthcare providers to a patient on a distant location, 2) health-related services provided by one or more healthcare professionals to one or more other healthcare professionals on a distant location. Examples of the first category are services as, for example, *teleconsultation* or *telemonitoring*. The second category includes services like *teleradiology* or *teledermatology*.

### 9.1 Telemedicine use cases

To make this more concrete, we will first look at some examples. These examples demonstrate the wide range of services encompassed by the term “telemedicine”.

#### 9.1.1 Telemedicine in the healthcare professional – patient relationship

First we mention some examples of the first category: healthcare professionals provide health-related services to patients on a distant location by means of electronic communications.

**NHS Direct**<sup>163</sup> (UK) is known worldwide for its telephone health line – 0845 4647. Additionally it has an informational website and a digital TV service. NHS Direct also offers commissioned services to other parts of the NHS to help them meet their patients’ needs.

The services include:

- out of hours support for GPs and dental services,
- telephone support for patients with long-term conditions,
- pre and post operative support for patients,
- 24 hour response to health scares, and remote clinics via telephone.

With regard to the telephone health line, the NHS Direct website mentions:

*“Whatever your health concern or query, we’re here for you 24 hours a day, 365 days a year. Just call 0845 4647. When you call NHS Direct, we’ll ask you to provide some basic information, including details of any medication you may be taking. If you’re calling on behalf of someone else, you’ll need to provide this information on their behalf.”*

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<sup>162</sup> B. Stanberry, Legal and ethical aspects of telemedicine, Journal of Telemedicine and Telecare, 2006, Vol.12, nr. 4, p. 166

<sup>163</sup> <http://www.nhsdirect.nhs.uk/> ; For recent research results about the usage of NHS Direct telephone service: Andrew J. Lerner, NHS Direct Telephone Helpline: Frequency of Use over Time and by Age and Gender in an Outpatient Population, Telemedicine and e-Health. March 2009, 15(2): 199-201.

## Study on the Legal Framework for Interoperable eHealth in Europe

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*We'll assess your problem and advise you on the best course of action. If you're feeling unwell at the time of your call, you may be told how you can look after yourself at home, or we may recommend seeing a pharmacist (chemist). If it's something more serious, you may be advised to see another health professional, such as your doctor. If the problem is very serious, we can help you to access the ambulance service. "*

The **University Eye Hospital of Greifswald** (Germany) developed a digital patient record that allows close monitoring of glaucoma, diabetes and hypertension.<sup>164</sup> The record stores contemporary, long-term profiles containing intraday variation and interaction of intraocular pressure, blood pressure and serum glucose levels even at night. All patients are equipped with a home monitoring system. They subsequently transmit self-measurements via the "telemedical interface" to the server. Physicians use a web front-end to access electronic patient records.

The County of **Funen Alcohol Rehabilitation Centre** (ABC)<sup>165</sup> in Denmark has successfully started using videoconferencing equipment for alcohol abuse therapy for patients on the islands of Aeroe and Langeland. ABC is the public institution responsible for providing alcohol abuse therapy to the inhabitants of the county. The therapy offered at ABC is conducted as individual out-patient sessions on a weekly basis involving only the patient and the therapist. The ABC units are located on the main island of Funen, and noticeably few people from the remote islands of the County of Funen (compared to the number of inhabitants) were seeking treatment for alcohol abuse. The putative reason for that is that it is rather inconvenient for alcohol abusers to have to travel to the main island of Funen in order to receive treatment. Furthermore, the patients may experience it as stigmatising to enter the ABC. Patients from Aeroe and Langeland now choose for themselves whether they want to travel for a therapy session in Svendborg or prefer a videoconference session in the Prevention Centre in Rudkoebing or the Hospital in Aeroeskoebing.

The **European Vascular Center**<sup>166</sup> is mainly dedicated to cross-border research cooperation but there is also an application whereby vascular surgery is done at the premises of one of the hospitals while a neurophysiologist monitors the patient's health status remotely from the other hospital.

Mobile telephone operator Orange, together with the Medic4all foundation launched a health service via mobile phone, called **Medic4you**. This service makes people know their health condition via mobile phone.<sup>167</sup> Medical services are provided by qualified physicians trained by health service organizations, who have also received instruction regarding telemedicine services from the Medic4all group. Clients can set up the service for an existing Orange phone number or through an Orange service plan. Monthly charges vary according to the minimum service agreement period. An option with the service is the "Wrist Clinic", a light-weight monitoring device in the form of a wrist band which transmits health parameters such as blood pressure, pulse, temperature, etc. via Bluetooth to the mobile phone. A one-year service plan costs about 1000 EUR (but only 20 EUR without the monitoring device). The service plan includes two calls per month, of up to one hour each. Unused calls are rolled over to the next month. The offer is available in any Orange shop. Customers can set up the service plan by registering via SMS and signing a Medic4you service agreement. The service can be accessed online with username and password.

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<sup>164</sup> <http://www.teleaugendienst.de/>

<sup>165</sup> <http://www.medcom.dk/dwn1177>, p. 11

<sup>166</sup> <http://www.european-hospital.com/topics/index.html>

<sup>167</sup> <http://www.orange.ro/services/medic4you.html>

## Study on the Legal Framework for Interoperable eHealth in Europe

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### 9.1.2 Telemedicine in healthcare provider to provider relationships

A second type of telemedicine consists of health-related services provided by one or more healthcare professionals to one or more other healthcare professionals on a distant location. Again we can illustrate this category by looking at some typical examples.

The **Barcelona Telemedicine Clinic (TMC)**<sup>168</sup> is a sub-specialist radiology centre that provides day and night reporting services and support to more than 100 public service hospitals and local health authorities in Europe. The clinic has over 70 accredited sub-specialist radiologists who focus on specific diagnostic areas that include Neuro, Body, Musculoskeletal, PET-CT, Mammography Screening and Nuclear Medicine. Remote reporting (teleradiology) forms part of the integrated radiology service offered to client hospitals in Sweden, Spain, the UK and other European countries. It often steps in when additional capacity is needed at these client hospitals, providing short and long-term back-up reporting services for highly complex as well as routine “bulk” examinations. TMC guarantees turnaround times specified for each client and type of examinations. Reporting times range from less than an hour to 48 hours depending on cases and client. TMC has set up a centre in Sydney (Australia) that provides On-Call reporting services i.e. night-time and emergency coverage to European hospitals. Recently radiologists from the Sydney centre began to read night-time and emergency cases for Kristianstad Hospital in Sweden.

The **KSYOS TeleDermatology System**<sup>169</sup> is a secure, web based platform in the Netherlands on which over 4000 general practitioners ask the advice of 160 connected dermatologists. Instead of physically referring the patient to a dermatologist, the general practitioner is in more than 60 percent of the cases, able to take care of his patient independently, with the distant support of a dermatologist in the background. The service makes use of the Unique Health professional Identification pass (UZI-pass) that has been implemented by the Dutch Ministry of Health in order to secure safe communication. It connects with the national IT health infrastructure as set up by the Ministry of Health. The teledermatology consultation is reimbursed by most of the Dutch health insurance funds. Efforts are undertaken to expand the service to Belgium.

**iPath**<sup>170</sup> is a collaborative platform for exchange of medical knowledge, distance consultations, group discussions and distance teaching in medicine. Any medical professional who is interested in participating is welcome and you can register yourself a user account. This server is operated by the iPath association in collaboration with the University of Basel. About 4000 professionals exchange opinions in 265 different groups (histopathology, hematology, pediatric pathology, various cancers, ...).

**NomHad Hospital**<sup>171</sup> is a platform management system for home care units. While moving to the patients' homes the clinicians remain connected with the most current clinical information at the point of care. The solution is a product of *TSB Soluciones* (Valencia) and it is currently implemented by three Spanish hospitals. The technological infrastructure of our solution is composed of a central server, one or more fixed stations at the hospital and mobile stations (in the form of a tablet PC) taken by the home care unit on the road. The devices communicate with the central server, sending and receiving patient information, using mobile communications technology.

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<sup>168</sup> <http://www.telemedicineclinic.com/>

<sup>169</sup> <http://www.ksyos.org/>

<sup>170</sup> <http://telemet.ipath.ch/lithuania/group/listall>

<sup>171</sup> <http://www.tsbtecnologias.es/solutions/NOMHADhospital>



## Study on the Legal Framework for Interoperable eHealth in Europe

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**9.2 Telemedicine: the problem of a legal definition**

Several regulatory and other official texts include a definition of “telemedicine”. The Communication of the European Commission on telemedicine<sup>172</sup>, for example, uses the following definition:

*“Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient, or two health professionals, are not in the same location.” The Commission refers to services like teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology, but it includes also call centres, online information centres for patients, remote consultation/e-visits or videoconferences between health professionals in the definition of telemedicine. Excluded from the definition are e.g. health information portals, electronic health record systems and electronic transmission of prescriptions or referrals (e-prescription, e-referrals).*

Following this definition the term “telemedicine” is restricted to situations wherein electronic communications are used to provide services to an individual patient. An online videoconference briefing medical teams about the current status of the swine flu would therefore not be considered as “telemedicine” because no patients are involved. On the other hand, according to the definition, a physician who, after a first face-to-face consultation, communicates with a patient via e-mail in order to follow up the results of a treatment, delivers a telemedicine service. In the examples mentioned above under the second category, the iPath discussion forums could possibly be used to exchange peer opinions about a specific medical case but often the exchanges in such forum will deal with issues which are not related to an individual patient. It is thereby not relevant whether patient is identified or not because very often a second opinion will be collected without transmitting the identity of the patient. Along the same line, personalized medical advice to a patient by means of e-mail or telephone should be considered as telemedicine, but general health information provided on a website would not.

The distinction operated in the definition of the Communication, according to which the actors can either be two healthcare professionals (e.g. teleradiology, telesurgery) or a healthcare professional and a patient (e.g. telemonitoring of chronically ill such as those with diabetes and heart conditions, telepsychiatry, etc), is apparently crucial. Many legal definitions used in the Member States focus only on the latter type of telemedicine or sometimes even only on a subset of this type.

By way of example, in a draft law proposed by the Belgian federal Minister for Public Health<sup>173</sup> the term “telemedicine” was defined as “transmission of personal health data between a patient and a healthcare professional , aiming at a total or partial provision of a diagnosis, a treatment or intervention with regard to the patient’s health”. The draft law also aimed at introducing two other concepts:

- Teleconsultation: “consultation of one or more healthcare professionals by one healthcare professional who is locally present, about the case of a patient, the diagnosis and the treatment, by means of telecommunications”;
- Telemonitoring: “registering, transmitting, receiving and processing parameters concerning a patient, with or without the patient’s intervention, in order to permit one or more healthcare

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<sup>172</sup> Communication on telemedicine for the benefit of patients, healthcare systems and society of 4 November 2008, [http://ec.europa.eu/information\\_society/activities/health/policy/telemedicine/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm)

<sup>173</sup> Projet de loi relative au traitement et à l’informatisation des données de santé ainsi qu’aux applications de télémédecine (10-10-2005) : this draft law has never been discussed and adopted by the Belgian Parliament and became finally obsolete.

## Study on the Legal Framework for Interoperable eHealth in Europe

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professionals on a distant location to follow up and evaluate the health status of the patient and to decide about a treatment within the boundaries of the transmitted parameters”.

One of the rare examples of adopted legal provisions concerning telemedicine is Article 32 of the French Health Insurance Act. It defines telemedicine as *“including amongst others the practice of medical acts on a distance, under the control and responsibility of a physician, in direct contact with the patient, through communication means appropriate to the performance of the act.”*<sup>174</sup> Two uncertainties arise from this definition, namely what should be understood by the expression “in direct contact with the patient” and whether this article refers to a clinical and physical relation between the physician and the patient or a virtual relation with no clinical examination.<sup>175</sup>

The conclusion is that any legal discussion about telemedicine needs to start by determining which definition of this concept will be used.<sup>176</sup> Moreover, even in case of consensus about this definition, it will often also include a range of situations that are considered too trivial to form an issue for regulatory measures (e.g. physicians discussing about individual cases via phone, instant messaging or e-mail).

### 9.3 Absence of specific legal provisions on telemedicine

Legal provisions dealing specifically with telemedicine are extremely rare. It is moreover questionable whether such provisions are necessary or even useful.

There are no specific legal provisions in **Belgium** with regard to telemedicine. On the other hand, there doesn't seem to be major legal obstacles to practice telemedicine in Belgium. The scarce legal literature about telemedicine in Belgium refers mainly to the application of personal data protection law and shared medical secret and to the regulatory framework for information society services (transposition of the e-commerce directive). In order to have a treatment reimbursed by the health insurance funds the physical presence of the physician seems to be required (Royal decree of 14 September 1984, art. 1 § 4bis on the nomenclature for medical treatments) but it is evident that this doesn't prevent physicians, after a face-to-face consultation to send, for instance, laboratory results to patients by e-mail and/or discuss these results by phone.

There is some jurisprudence in Belgium with regard to the liability of physicians who provided medical advice to patients by telephone but the rules applied are in line with the traditional liability for negligence (e.g. if a physician didn't have all relevant information about the patient's health because he was not physically present). Application of product liability rules may be relevant but the use of sophisticated technical devices is not necessarily more frequent in a telemedicine care setting than in the traditional hospital environment.

In an Opinion of 2000 the Council of the Order of Physicians stated that an American physician who, on a non-occasional basis, wishes to be employed on board on a ship under Belgian flag, has to fulfil the conditions for exercising medicine in Belgium, e.g. the condition to be registered on the list of the Order of Physicians. It also emphasized that, generally speaking, the provision, on a regular basis, of

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<sup>174</sup> “La télémédecine permet, entre autres, d'effectuer des actes médicaux dans le strict respect des règles de déontologie mais à distance, sous le contrôle et la responsabilité d'un médecin en contact avec le patient par des moyens de communication appropriés à la réalisation de l'acte médical. »

<sup>175</sup> Dr. Deau X., Télémédecine, Report adopted by the National Council of the Order of Physicians during its session of July 2005, available at: <http://www.coinseil-national.medecin.fr/?url=rappport/article.php&id=70>

<sup>176</sup> Berger, S. & Cepelewicz, B., Medical-legal issues in teleradiology. *AJR Am J Roentgenol* 1996, Nr. 166, p. 505-510; Laske C. Legal aspects of digital image management and communication. *Med Inf* 1994;19:189-196; Granade PF., Malpractice issues in the practice of telemedicine, *Telemedicine Journal* 1995, nr.1, p. 87-89; Schiffer M. Legal aspects of telepathology, *Zentralbl Pathol* 1992;138:393-394

**Study on the Legal Framework for Interoperable eHealth in Europe**

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medical advice to a patient has to be considered as a form of exercising medicine if it 1) relates to a particular therapy, 2) aims at treating or preventing a particular disease, 3) is addressed to a particular individual or identifiable group of individuals, and 4) specifies the way the therapy has to be applied. If a particular form of providing advice by a foreign physician fulfils these conditions and the advice is provided by a physician who has his medical residence in Belgium, the physician needs to comply with the conditions for exercising medicine in Belgium. Unfortunately this opinion doesn't provide an answer to the question about the rules to apply if the physician is established abroad.

There has been a specific group working on telemedicine under the Telematics Commission<sup>177</sup> which has produced a pre-recommendation.<sup>178</sup> The recommendations deal in particular with issues such as informed consent, data privacy, information security, etc.

A similar situation has been found in **Bulgaria** with regard to telemedicine. The provisions of the health insurance legislation are currently not adapted to the needs of the telemedicine and the compulsory health insurance does not cover telemedicine services. However, pursuant to the Bulgarian Health Insurance Act the provision of health services or products that are not covered by the compulsory health insurance may be covered by the voluntary health insurance. No jurisprudence with regard to the provision of medical advice to patients by telephone has been found in Bulgaria.

The same situation has been detected in the **Czech Republic**. There are applications of telemedicine operational in the Czech Republic and there haven't been practical problems with the regulatory framework in case of telemedicine applications until now.

There are no specific provisions with regard to telemedicine in **Greece**. The draft law for the establishment and operation of primary healthcare includes telemedicine in the primary healthcare. More specifically it describes the provision of medical consultancy and services from a distance and via the use of advanced technologies and infrastructures, especially via a special telemedicine system and an open communication line. However this provision has already been heavily criticised by medical doctors because it is not defined whether the offering of the services will be done by all medical doctors of the system or there will be a specific entity for this purpose, equipped with the necessary technical facilities.

The situation is similar in **Hungary**. There are no specific provisions but on the other hand, if the rigorous data protection rules are not violated there doesn't seem to be major legal obstacles to practice telemedicine in Hungary.

Neither are there specific legal provisions in place in **Ireland** with regard to telemedicine. On the other hand, there don't seem to be any major legal obstacles to the practice of telemedicine in Ireland and indeed a number of initiatives have been undertaken in that regard.<sup>179</sup> The National Health Information Strategy (2004) recommended that HIQA develop a multi-annual information and ICT action plan which would set out national ICT priorities for inter alia "Telehealth solutions". The Discussion paper of June 2008 acknowledges the potential contribution of proper use of quality based information systems and modern communications technology (ICT) to extending the scope of healthcare beyond its current boundaries in areas such as "telemedicine which has particular relevance for rural and island

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<sup>177</sup> This commission has been created in 1999 and is aimed at providing advice to the Minister of Public Health on all matters related to eHealth.

<sup>178</sup> <https://portal.health.fgov.be/pls/portal/docs/1/9902009.PDF> (in Dutch) or <https://portal.health.fgov.be/pls/portal/docs/1/9902008.PDF> (in French)

<sup>179</sup> MacFarlane, A., Murphy, A. and Clerkin, P., "Telemedicine services in the Republic of Ireland: An evolving policy context" Vol.76, Issue 3, May 2006, 245.

## Study on the Legal Framework for Interoperable eHealth in Europe

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communities". However it does not specifically invite submissions on the issue of the regulation of telemedicine.

In **Italy** telemedicine is not currently regulated through specific legislation, so general rules on data protection and medical liability and ethics apply. The Decree no. 196/2003 puts a special emphasis on the privacy notice to be given to the data subject in the case of telemedicine, requiring such notice to detail the specific risks of processing health-related data in telemedicine. It should be added that any processing of health-related data needs to be notified to the Italian Authority for data protection, before starting, when such processing is performed via an electronic communication for the purpose of putting in place medical services concerning databases or the provision of goods.

There are no specific legal provisions in **Lithuania** regarding telemedicine. In 2004 the Minister of Health of the Republic of Lithuania issued a decision on Telephone Consultation by Healthcare Providers (No. V-230, 14 April 2004). It regulates the procedure and payment for telephone consultation services provided by physicians. Before this decision, telephone consultations were not regulated, although, it was a common practice to make a call directly to a physician. It must be pointed out that telephone consultations (Phone number 8 655 65 555) under the regulation adopted in 2004 are not so popular because the patients are charged for them and the State Patients' Fund does not cover these expenses.

There is no specific legislation in the **Netherlands** with regard to telemedicine. However, the Royal Dutch Medical Association (KNMG) introduces a guideline for doctor-patient contact in 2005 (see further infra)

In **England** telemedicine as a specific concept does not feature prominently in NHS reforms but is implicit in many developments such as the NHS Direct service<sup>180</sup>. This provides patients with access to a library of medical advice and also to a telephone assistance service. Staffed largely by nurses this answers calls from patients on a 24 hour service and in cases deemed urgent will either make arrangements for a patient to receive out of hours care at a hospital, emergency GP centre or on the basis of a home visit by a GP.

Although not specifically related to telemedicine the issue has been raised in other contexts whether a doctor is obliged to physically attend a patient. There does not appear to be any general legal principle requiring this. NHS Direct makes heavy use of the telephone and nurse advisers for consulting and advising patients. In legal terms, however, the fact that advice was dispensed by telephone rather than in face to face consultation would not per se give rise to potential liability unless in all the circumstances of that particular case, the giving of telephone advice alone was unreasonable and not supported by a reasonable body of medical opinion.

There are no specific provisions in **Scotland** with regard to telemedicine. Although not specifically related to telemedicine the issue has been raised in other contexts whether a doctor is obliged to physically attend a patient. There does not appear to be any general legal principle requiring this and in the case of the Centre for Telehealth it would appear that the rationale is to provide a superior level of service to that which might be provided using more traditional methods. In other instances, perhaps most notably the system "NHS 24" which was introduced when responsibility for out of office hours care for patients was removed from GPs under the terms of a revised contract, and which makes heavy use of the telephone and nurse advisers for consulting and advising patients, that a reluctance

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<sup>180</sup> <http://www.nhsdirect.nhs.uk/>

## Study on the Legal Framework for Interoperable eHealth in Europe

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to send doctors to make house visits has contributed to loss of life. In one case in May 2008<sup>181</sup>, the Health Services Ombudsman criticized the service in respect of an incident when a patient who had telephoned with symptoms consistent with his having suffered a stroke (which was indeed the case) was wrongly diagnosed as suffering a less serious condition and instructed to drive himself to a local emergency care centre rather than ensuring that an ambulance was summoned. In legal terms, however, the fact that advice was dispensed by telephone rather than in face to face consultation would not per se impact upon the existence or extent of potential liability

There are no specific provisions in **Slovakia** with regard to telemedicine. On the other hand, there doesn't seem to be major legal obstacles to practice telemedicine in Slovakia. There may appear only practical problems to exercise telemedicine in its purest form, whereby patients are really receiving treatment from a distance. The scarce legal literature about telemedicine in Slovakia refers mainly to the application of personal data protection law and shared medical secret and to the regulatory framework for information society services (transposition of the e-commerce directive). In order to have a treatment reimbursed by the health insurance funds the physical presence of the physician seems to be required. Until the introduction of an electronic identity management system in the eHealth sector which will allow to identify the patient (mostly for the purposes of reimbursement of the costs by the health insurance), there is a doubt about possibilities to implement real telemedicine in Slovakia (providing reimbursable treatment from a distance by electronic communications).

### 9.4 Reluctance to provide care to patients at a distance

Most of the Member States have introduced their general legal provisions on the provision of healthcare before the concept of "telemedicine" was known. Therefore they sometimes contain requirements that doesn't seem adapted to a situation of providing care to patients remotely, by means of electronic communications.

The example most often cited is **Austria**. The Health Telematics Act contains only provisions on exchange of health data, data security provisions and publication of health information on the Internet. Obstacles to practise telemedicine in Austria are found in the general provisions on practising healthcare. According to section 49 of the Physician Act 1998 a physician must carry out his profession personally and directly ("*persönlich und unmittelbar*"). Treatment can be given, if required, in cooperation with other physicians. The physician must not assign the treatment to another physician without the consent of the patient. Thus, in general, the physical presence of the physician is necessary and, as a consequence, telemedicine is prohibited. A "Guideline Physician and Public" (*Richtlinie Arzt und Öffentlichkeit*) of the Austrian Chamber of Physicians further clarifies this provision. Telemedicine is therefore only allowed in case of emergency.

Due to this quite strict legal provision, an alternative interpretation is discussed in Austrian legal literature on telemedicine. Some legal writers have argued that certain types of telemedicine fulfil the requirement of personal and direct treatment; others have taken the position that telemedicine is possible if personal and direct treatment is not required. Leading writers broadly define the requirement of personal and direct treatment allowing some adjustments according to existing practice. As the question remains contested and due to this legal uncertainty, a revision and clarification of section 49 Physician Act 1998 has already been proposed.

Telemedicine is not explicitly mentioned in the list of compensations covered by the Austrian Social Security. Therefore, general rules apply accordingly. For coverage by health insurance, treatments

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<sup>181</sup> Available from <http://www.spsso.org.uk/reports/report.php?id=874>

## Study on the Legal Framework for Interoperable eHealth in Europe

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have to be necessary, adequate and appropriate. Accident insurance includes more benefits: All appropriate measures must be taken to improve the consequences of accidents or to prevent deterioration of a patient's health condition.

As far as **Romania** is concerned the Health Reform Law refers to *telemedical systems* which are used for the transfer of data in emergency situations, without defining the concepts of telemedicine, telemedical systems and communications. According the Professional Ethics Code of the Physicians (the "Ethics Code"), the physician may not treat a patient without personally examining him/her first. Only in exceptional cases, of emergency or force majeure (falling ill on sailing ships, flying planes, inaccessible places), treatment directions shall be given by telecommunications means. Generally speaking however there does not seem to be major legal obstacles to practice telemedicine in Romania.

A similar situation exists in **Poland**. The Act of 5 December 1996 on the Professions of Physician and Dentist<sup>182</sup> provides explicitly that the doctor should announce the state of health of a given person after examining him/her *personally*, unless separate legislation provides otherwise. No such a provision regarding telemedicine exists, which excludes setting diagnosis remotely, implicitly assuming that proper assessment requires physical contact with the patient, in order to receive the information which otherwise might be missing. Except for this only aspect of setting the diagnosis, there is no other regulatory framework allowing or precluding telemedicine. It is assumed, explicit legal provisions missing in this matter, that the profession of a physician needs to be exercised with due diligence, using appropriate means, current medical knowledge and professional ethics. If, therefore, a given telemedicine practice complies with the standards, it fits into both the obligations of medical professionals and rights of patients. On the other hand, as long as more old-fashioned treatment is still the only one available to the doctor, and complies with the medical knowledge requirement at the same time, the physician cannot be blamed for not using telemedicine.

Last but not least mention has also to be made of **Germany**: One major legal obstacle to practice (a certain type of) telemedicine in that country derives from the professional code of conduct. The code requires that physicians do not diagnose and start therapy if they have not examined the patients personally. A physician who practises offending the code of conduct does not practise in line with the professional standard. Therefore, liability for damages may arise.

Art. 7 par. 3 of the Medical Association's professional model code of conduct further prescribes that physicians must not treat concrete and individual illnesses of their patients on basis of information they solely got via letter, telephone or telemedia or other people's report. That means that physicians may diagnose and advise their patients how to go on with their aches and pains when they gained an impression of the patient's state of health personally. Exceptions may be made in cases of emergency, when the physician gives advice what to do until the ambulance arrives. Another exception is made for advices in isolated cases given to a patient normally receiving the physician's medical treatment.<sup>183</sup> General advices on questions of medical care are not covered by the ban on tele-treatment, even if those general remarks are answers on questions on individual health problems.<sup>184</sup>

The Medical Association's professional model code of conduct is implemented into the codes of conduct of all 16 German *Länder*. They are part of the professional law. A violation of these codes of

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<sup>182</sup> *Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentystry*, Journal of Laws Year 2005, No. 226, item 1943, with further amendments.

<sup>183</sup> Kroha, *Ärztliche Online-Beratung*, 2007, p. 26.

<sup>184</sup> Kroha, *Ärztliche Online-Beratung*, 2007, p. 26.

## Study on the Legal Framework for Interoperable eHealth in Europe

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conduct can result in a law suit before the court of professional conduct. At the same time tele-treatment service infringes the Unfair Competition Act if the service is provided free of charge.

Furthermore, tele-treatment can result in liability for damages, if the patient has not been treated *lege artis*. It is easy for the physician to make mistakes concerning the diagnosis. The physician acts negligent if he does not examine the patient to the necessary extent and does not assess the results according to physicians' standards.

Another obstacle is the observance of personal data protection law. The general provisions within the Federal and the state data protection acts have to be observed. Furthermore, specific provisions for the data protection within the Social Code Books are applicable. Those rules expressly refer to access and process of health related data as they are supposed to be accessible by means of the electronic health card. The problems of data protection law are closely connected to the health personnel's observance of medical secrecy. This issue is supposed to be solved by issuing the Health Professional Cards. Only the patient himself has access to his data, without needing a second person or card. All other persons who want to have access must be authorized by the patient (either in general – if technically registered within the IT-system, e.g. by means of an electronically recorded ticket which documents permissions for access – or case by case by using his PIN) and must authenticate themselves by their Health Professional Cards.

### 9.5 Emerging rules on telemedicine in the healthcare provider - patient relationship

Uncertainty about how to deal with new applications in the area of telemedicine and reluctance about examining a patient at a distance doesn't prevent the progressive emergence of certain rules in this domain.

A – at the time of writing not yet official - opinion of the Order of Physicians in **Portugal**, after having stated that there are no legal or deontological rules with regard to telemedicine and that professionals therefore should better wait for clear deontological rules before starting experiments in this domain, contains nevertheless some guidelines to be followed, such as: (i) observe the guidelines of the Permanent Committee of European Physicians; (ii) patients must be preferably be personally assisted and telemedicine should be limited to the situations where the physicians is not able to be on site; (iii) when a patient opts for telemedicine, the assistance must be made by its usual doctor; (iv) secrecy and other registration data must be observed; (v) the practice of telemedicine is only allowed by registered physicians.

In **Denmark** the National Board of Health has issued legal guidelines regarding liability and other legal matters in connection with physicians' use of telemedicine.<sup>185</sup> The guidelines refer to rules and principles in the existing legislation and apply them on the use of telemedicine. The conclusion is that the use of telemedicine does not affect the usual legal liability and other legal obligations of physicians.

The Executive Board of the Medical Association in **Finland** has approved ethical guidelines on telemedicine in 1997. The guidelines define the following domains: medical competence, patient - doctor relationship, physician's responsible, quality, security and safety in telemedicine, handling of patient documents, and rules and practices for medical ethics, patient consent and confidentiality.

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<sup>185</sup> Vejledning nr. 9719 af 9. November 2005 om ansvarsforholdene m.v. ved lægers brug af telemedicine" <https://www.retsinformation.dk/Forms/R0710.aspx?id=10132> (only in Danish)

## Study on the Legal Framework for Interoperable eHealth in Europe

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There are no limitations related to physical presence of the physician as long as professional accreditation, authorisations and patient consent can be obtained as required by the law. This remains a substantial challenge for telemedicine service providers, as well as users.

There is no jurisprudence in Finland with regard to the liability of physicians who provided medical advice to patients by telephone but the rules applied are in line with the traditional liability for negligence (e.g. if a physician didn't have all relevant information about the patient's health because he was not physically present). Most jurisprudence related to telemedicine concerns liability for negligence for not providing healthcare service in due delay. Long delays coincide with long distances thus the use of telephony and distance monitoring services for out-patients and homecare is growing and generally seen as a positive solution rather than a risk. Telemedicine services are usually used when geographical distances become a real risk for patient safety and telemedicine is often seen as the only solution to tackle the requirements of medical service accessibility and availability, and large geographical distances.

In **France** the Healthcare Insurance Act provides a legal basis for the practice of telemedicine. Article 32 subjects the practice of telemedicine to strict compliance with professional ethics rules. The National Council of the Order of Physicians has analyzed the ethics rules applying to telemedicine and has defined six criteria to guide its practice:

- Only the health condition of the patient could justify the use of telemedicine in specific circumstances (emergency, insufficient number of physicians in a defined area, etc.).
- The technical and communication means, the competence and qualification of "tele-experts" should meet quality requirements, independently of the problems that could stem from health economics.
- The patient should freely consent to the use of telemedicine. The information should be simple, concise and accurate. Consent should be obtained in written. By the same token, inadequate telemedicine tools cannot be imposed to the physician. It goes without saying that these requirements should be relaxed in emergency situations.
- Professional secrecy. The anonymity of the patient, the confidentiality of the personal medical records and the related communication, the staff's professional secrecy, the tracking of the medical acts performed should be ensured. The means to ensure professional secrecy should be clearly described in the contract governing the provision of telemedicine tools.
- Liability. Patients are responsible for the information provided. The physician is fully liable for the use he makes of this information. The telemedicine contract should identify clearly the identity of the patient, the "tele-experts" and the physician in contact with the patient.
- The physician practicing telemedicine on a usual basis should be bound by a contract compliant with the aforementioned criteria. The contract should include the usual functioning mode of telemedicine, the material used, modalities of information to the patient; and identity the physician consulted, the physician carrying out the act, as well as the means implemented to ensure professional secrecy. The contract should moreover be submitted to the Provincial Council of the Order of Physicians for opinion.

Article 33 of this Act compels regional health organizations plans to integrate telemedicine and to define operational modes to meet the requirements relative to public health and access to care.



## Study on the Legal Framework for Interoperable eHealth in Europe

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A last example of emerging rulemaking in the area of telemedicine comes from the **Netherlands**. A guideline issued by the Royal Dutch Medical Association<sup>186</sup> concerning *online doctor-patient contact* addresses the question of the conditions under which doctors may treat patients via the Internet.<sup>187</sup> It is partly based on a similar guideline issued in 2001 by the Standing Committee of European Doctors.<sup>188</sup> The guideline is applicable to all contact between doctor and patient that take place over the Internet and in which an agreement for treatment is initiated or continued. The guideline is however restricted to three types of contact and not applicable in other cases:

- contact in which the doctor gives a patient advice for a specific situation
- contacts in which the doctor commences pharmacotherapy
- contacts in which the doctor gives repeat prescriptions

The basic principle is that care is required when the Internet is used, in the interests of the quality and continuity of the care provided for the patient. Medication may only be prescribed online if there is a pre-existing doctor-patient relationship, i.e. if the doctor knows the patient, has seen him and has the medication history available. Additionally, the doctor must have a reliable medical file before he prescribes medication online.

There must also be a pre-existing relationship involving treatment if a doctor is to provide a patient with advice over the Internet about medical matters. This can only be otherwise if the risks associated with the online advice are minimised. Whether or not that is the case will depend on the type of contact and the type of treatment and will have to be assessed by the doctor.

In addition to these general principles, the guideline contains a number of requirements for taking care during online contact. The guideline also discusses the responsibilities of the patient.

### 9.6 Some concluding remarks

Telemedicine is probably not an adequate legal concept because it covers a much too heterogeneous field. Legal issues can better be tackled by approaching the various situations covered by this concept from another point of view. By way of example, it appears to be much more useful to issue specific guidelines for e-mail communication between physicians and patients than general guidelines attempting to cover every possible “telemedicine” use case.

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<sup>186</sup> The Royal Dutch Medical Association (KNMG) is the professional organization for physicians of The Netherlands. Since January 1st 1999 the KNMG has become a federation of medical practitioners' professional associations. The federation exists of the National Association of salaried Doctors (LAD), the National Association of General Practitioners (LHV), the Dutch Association for occupational Health (NVAB), the Dutch Association for Nursing Home Physicians (NVVA), the Dutch Association of Insurance Medicine (NVVG), the Dutch Order of Medical Specialists (Orde van Medisch Specialisten) and a group of individual KNMG members and students. <http://knmg.artsennet.nl/Over-KNMG/about-knmg.htm>

<sup>187</sup> In 2007 this guideline has been revised and in January 2008 the revised guideline came into force. The key change with respect to the old guideline is that prescribing medication over the Internet for patients who you do not know is no longer allowed, as a result of a change in the new Pharmaceuticals Act. <http://knmg.artsennet.nl/web/file?uuid=9f20288a-48d8-43f6-a004-dfb4273147a7&owner=fee3a874-12d9-4756-b7e1-55b6ae79a364>

<sup>188</sup> Lignes directrices du CP pour la correspondance par e-mail entre un médecin et un patient / CP Guidelines for e-mail correspondence between a doctor and a patient. Auteur: dr Makinen. CP: Comité Permanent des Médecins Européens / Standing Committee of European Doctors. Adopted by the Board on 17 November 2001. <http://cpme.dyn dns.org:591/adopted/CP%202001-112%20Final%20EN.pdf>

## Study on the Legal Framework for Interoperable eHealth in Europe

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For the same reason it doesn't seem very wise to consider "telemedicine" as such as a category of healthcare adapted for reimbursement. The discussion about telemedicine from an insurance viewpoint will gain efficiency by tackling it at a more precise level (e.g. at the level of particular telemonitoring applications).

Many types of telemedicine applications are directly linked to the introduction of the shared electronic health record. Healthcare professionals will, in most of the situations, combine the provision of a telemedicine service – either to another professional or to a patient – with accessing the patient's record. An illustrating example is Ksyos, the teledermatology service mentioned in the first subparagraph of this chapter. The platform provided by Ksyos will be connected to the national switchpoint (LSP) and the participating professionals will make use of the authentication tools provided by the Dutch eHealth platform. Along the same line, telemedicine is considered as a "value-added service" in Belgium for which the providers and users can rely on the "basic services" provided by the national eHealth platform.

Multiple legal obstacles hinder the provision of cross-border telemedicine services in Europe. These obstacles can be divided in two categories. A first category of obstacles is related to the national character of the regulatory framework governing healthcare in the Member States. The Barcelona Telemedicine Clinic, for instance, works with "national" radiologists. A radiologist working for Scandinavian countries must be fully registered with the Swedish medical board or with another Scandinavian country." For the UK candidates must be fully registered with the GMC, or eligible for inclusion on the GMC specialist register. It is evident that such requirements prevent flexibility in the service provision and can lead to almost unsolvable complexity in case of European-wide roll-out of telemedicine services.

As a consequence of the divergences between the national legal frameworks for healthcare it is crucial to determine which national law applies in case of a cross-border telemedicine relationship. If a physician established in France provides a telemedicine service to a patient in Belgium, does he have to comply with French or Belgian law? The answer to this question requires a detailed analysis of the particular case and requires specialised legal expertise. What is the scope of the provisions of the e-Commerce Directive with regard to telemedicine? In which cases can it be considered as an "information society service"<sup>189</sup> and in which cases will the country-of origin principle apply?<sup>190</sup> Unfortunately most of these questions can only be answered on a case-by-case basis and the answer will very much depend on which countries are involved in the cross-border situation.

A second category of legal obstacles relates to the fact that eHealth, as it is currently conceived in the Member States, is based on the creation of a national online community including exclusively the stakeholders of the national healthcare sector: healthcare professionals, healthcare institutions, patients, health insurers, public health administrations. The rules that are created to govern this community are primarily – in most cases even exclusively – designed for being applied by and to the members of this community. This results in numerous practical difficulties in case of cross-border provision or use of online healthcare services. By way of example NHS Direct telephone service uses a UK 0800 (freephone) number. Such numbers can't be called from abroad (except by subscribers of UK mobile phone operators when they are travelling outside the UK).

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<sup>189</sup> An information society service is any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

<sup>190</sup> There are exceptions to the country of origin principle and notably Member States have the right to derogate from this principle i.e. if it is necessary for the protection of public health.

## 10. Regulatory framework for electronic prescriptions

Electronic prescribing generally refers to a prescriber's ability to electronically send a prescription for a medicinal product directly to a pharmacy from the point-of-care. According to the European eHealth Action Plan the majority of European health organisations and health regions (communities, counties, and districts) should be able to provide online services such as ePrescription in the near future.<sup>191</sup> The draft Article 14 of the proposed European directive on the application of patients' rights in cross-border healthcare states that the Commission will bring forward measures to facilitate recognition of prescriptions, including an EU-wide prescription template, and supporting interoperability of ePrescriptions.<sup>192</sup>

### 10.1 Introductory observations

With regard to the situation of ePrescription in the USA the magazine InformationWeek recently reported that more and more doctors have traded in their paper prescription pads for e-prescribing over the last two years.<sup>193</sup> However, the bulk of e-prescriptions are still being generated by doctors using standalone e-prescribing software and not more comprehensive, integrated e-medical record systems including network communications. Just two years ago, in 2006, only about 19,000 U.S. doctors and other clinicians were prescribing drugs for patients electronically. That number has soared to 103,000 in 2008, according to a new report from *Surescripts*, the largest e-prescribing network in the US. E-prescribing message volume doubled between 2007 and 2008 to over 240 million.<sup>194</sup>

A report by Frost and Sullivan<sup>195</sup> describes a typical ePrescription scenario as follows:

"Initiation of the e-prescription process requires that the hospitals or clinics have a computer, laptop or a personal digital assistant (PDA) with an internet connection. The physician is provided with a user ID and password using which he logs in. After having chosen the patient, he enters other relevant patient information. The physician next prescribes medication from the displayed list of drugs. He can also check for the drug being covered under patient's health plan. The dosage, frequency and strength of the medication are to be specified next. The physician may assign a pharmacy for the patient from the available database before clicking on to send option. Once the prescription reaches the designated pharmacy, it is also archived with patient history records before being dispensed."

It is clear that this described scenario applies to the e-prescribing practice in the USA. In Europe a number of additional factors have to be taken into account. In most of the Member States the

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<sup>191</sup> Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004, p. 27  
[http://ec.europa.eu/information\\_society/doc/qualif/health/COM\\_2004\\_0356\\_F\\_EN\\_ACTE.pdf](http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf)

<sup>192</sup> European Commission, Proposal for a Directive of the European Parliament and the Council on the application of patients' rights in cross-border healthcare, COM(2008)414 final,  
[http://ec.europa.eu/health/ph\\_overview/co\\_operation/healthcare/docs/COM\\_en.pdf](http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf)

<sup>193</sup> E-Prescription Adoption Picking Up,  
<http://www.informationweek.com/news/showArticle.jhtml?articleID=2170002>

<sup>194</sup> <http://www.surescripts.net/downloads/NPR/national-progress-report.pdf>

<sup>195</sup> Frost and Sullivan, e-Prescription in Europe: First Things Fast, 2007, <http://tinyurl.com/obl9gf>

## Study on the Legal Framework for Interoperable eHealth in Europe

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pharmacy is chosen by the patient, freely and independently from the prescriber. Moreover the prescription will not be sent to the pharmacy by e-mail but immediately entered into an online database. The prescription should be accessible not only to the prescriber and the pharmacy but also to the patient, the health insurance fund and, under certain conditions, to public authorities in charge of healthcare policy implementation (e.g. to monitor the prescription behaviour of physicians).

ePrescription has some evident advantages in comparison to handwritten paper-based prescriptions. As the patient gets his medication immediately upon reaching the pharmacy, the long waiting time is avoided. Also as the prescription reaches the pharmacy in the form of an e-mail, fewer phone calls from pharmacies to physicians are required for clarifying various doubts on the otherwise manual prescription. Besides this, according to the German Ministry of Health about 300 million Euros could be saved annually by eliminating need for re-scanning of the paper document in pharmacies for accounting purposes.<sup>196</sup>

On the other hand ePrescribing is not without any risks. “Doctors might pick the wrong patient on a selection menu. Using computerized entry they might also slip on menus for selecting a diagnosis or medication regimen, particularly if drug names are similar. Forcing doctors through a series of menu choices can increase the time it takes to write the prescriptions. If a system uses the same codes for both diagnosis and billing, clinically important distinctions might not be recorded. In addition, systems might limit the choice of drugs with formulary lists. Finally the implementation of e-prescription must not at any time interfere with professional autonomy of physicians that is the ultimate safeguard of patient’s interests and patient’s safety.”<sup>197</sup>

From a terminological viewpoint ePrescription as a concept traditionally refers to prescribing medicinal products in the outpatient care. It doesn’t, for example, refer to the distribution of pharmaceuticals to patients in the context of a hospital. Nor does the term include prescriptions for products and services, other than pharmaceuticals. This narrow interpretation of ePrescription has be kept in mind for the legal discussion. In Belgium, for instance, the regulation about prescriptions makes a distinction between seven categories of prescriptions:

- kinesiology, nursing, bandages, orthopaedics, opticians, etc.
- medical imaging;
- clinical biology;
- pharmaceuticals;
- prostheses;
- dietetics;
- speech therapy.

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<sup>196</sup> <http://eprescription.us/>

<sup>197</sup> M. BITENC, Perspectives for ePrescribing: Enhancing Patient Safety and Reducing Medical Errors, Presentation, presentation at the EHTEL conference on ePrescribing, Ljubljana, 2006  
<http://www.ehtel.org/references-files/2006-06-ljubljana-eprescribing>

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## 10.2 Prescribing pharmaceuticals: the larger context

Prescribing pharmaceuticals to a patient is only one step in a larger administrative process. The details of this process are directly dependent on the organisational structure of the healthcare sector and in particular on the reimbursement procedures.

In **Belgium** only physicians and (to the extent that their profession requires) dentists and midwives can prescribe pharmaceuticals. About 2500 pharmaceutical products are on a positive list and therefore are partly or fully reimbursable. The reimbursable percentage of the cost varies depending on the therapeutic importance of the pharmaceutical. The patient only pays the non-reimbursable percentage as a co-payment to the pharmacy. The sickness funds reimburse the reimbursable percentage directly to the pharmacies through the third party payment system. An important characteristic of this system is that pharmaceuticals are reimbursable only to patients covered by compulsory health insurance.

By means of the Sickness Funds Act, sickness funds are entrusted with a central position in compulsory health insurance. They have to control the conformity of healthcare expenditure with the legal regulations. Some services are only reimbursed if there has been an a priori approval by the so-called advisory physicians of the sickness funds. These advisory physicians can question the prescription of expensive pharmaceuticals.

In 1996 an online information system "*Pharmanet*" was created to inform physicians about their prescription behaviour and to allow them to compare their own prescription habits with those of their colleagues. With *Pharmanet* data are collected per prescribing physician and related to the supply of reimbursed pharmaceuticals that are delivered by public pharmacies. The collection of the data is carried out via pharmacies, the pharmacists' "tarification" services and the sickness funds. The latter transfer the data to the RIZIV-INAMI, assisted by the Committee on the Evaluation of Medical Practice concerning pharmaceuticals. One of this Committee's tasks is to organize regularly, at least two times per year, consensus meetings that are meant to evaluate the medical practice concerning pharmaceuticals in a certain sector and to formulate recommendations for all prescribing physicians. Physicians can be requested to explain and substantiate their deviating prescription behaviour. Procedures are in place to penalize physicians whose profile is not in accordance with the parameters, or to reclaim unjustified amounts from physicians in case of obvious over-prescription.<sup>198</sup>

In **Latvia** the HCISA regional branches are responsible for paying pharmacies for prescriptions made by GPs and specialists. Patients pay the full price for a significant share of prescribed pharmaceuticals and the full price of all non-prescription drugs (in the outpatient sector). Due to scarce financing resources for reimbursement, a set of cost-containment measures has been introduced. These include, for example, budgets for doctors; prescribing of certain products only under special conditions according to approved treatment guidelines; recommendations for prescribing issued by the Medicines Pricing and Reimbursement Agency; and generic substitution. Compliance with specific requirements and recommendations for prescribing is monitored by the HCISA and supervised by the Medicines Pricing and Reimbursement Agency (one of the agencies of the Ministry for Health). There is a database of all reimbursed prescriptions, providing monitoring and supervision possibilities of the system.

In **Portugal** prescribed drugs are subject to variable patient co-insurance based on effectiveness criteria, with full payment required for those pharmaceuticals deemed to have little or no clinical value. Pharmacists in retail pharmacies obtain their income from two main sources: partly payment directly

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<sup>198</sup>For further details: Global analytical report on the content of Pharmanet – Singular Pathway, 2007: [http://www.riziv.fgov.be/drug/nl/statistics-scientific-information/pharmanet/introduction/pdf/analyticalreport\\_eng.pdf](http://www.riziv.fgov.be/drug/nl/statistics-scientific-information/pharmanet/introduction/pdf/analyticalreport_eng.pdf)

## Study on the Legal Framework for Interoperable eHealth in Europe

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from patients and the remainder from the NHS (via the RHA) or the relevant insurance fund. The remuneration is set as a maximum fixed margin over the wholesale price. Pharmaceuticals used by some highly vulnerable groups of patients are fully paid for by the NHS. If the prescription is from a health centre the payments due from the NHS are centralized through the RHA. Members of the National Association of Pharmacies invoice the RHA, which reimburses them immediately; it then bills the RHA in bulk on behalf of its members. One of the perverse incentives of the payment system for pharmacists is that they benefit from dispensing more expensive drugs; therefore they do not stock the cheapest drugs.

Pharmaceuticals that require prescription can only be sold in a pharmacy. In addition to this, the location of pharmacies is still highly regulated. There are a maximum number of pharmacists permitted in each community. The Ministry of Health decides whether there is a need for a new pharmacy in an expanding residential area. Thus, established pharmacists have a considerable degree of monopoly over the prescription drug market.

### 10.3 Legal obstacles for electronic prescriptions

In some of the Member States the legal framework for prescriptions has not yet been adapted in order to enable ePrescribing at least from a legal point of view.

In **Romania** the medical prescriptions are regulated by the Health Reform Law and by orders issued by the MPH and the President of the NHHI. Order no. 832/302/2008 of the Ministry of Public Health and the President of NHHI regulates the authorization of the model of the medical prescription application. According to the Methodological Norms regarding the Use and Methods of the Filling In of Medical Prescription Applications with Special Regime with Regard to Medicines (hereinafter "the Norms") which implement the above-mentioned Order, every prescription shall be signed and dated by the physician, and shall be stamped with the stamp which will include the physician code. In an annex to the Norms, a model of the prescription document is provided. Further on, the Norms provide that the medical prescriptions shall be printed on auto copy paper in 3 colours. The 3rd page (green) shall remain with the notebook of the physician who prescribed the medicines, while the 1st page (white), and the 2nd page (pink) shall be submitted to the insurance holder, who will submit them to the medicine supplier. The medicine supplier shall keep the pink page, while the white one (the original) shall be filed with the NHHI together with the invoice and the centralization registers.

In **Lithuania** the physician has to indicate the name, surname of the patient, date of birth, address, number of the patient's record, date of dispense and physician's phone number. The prescription has to be clearly written in Lithuanian, signed and confirmed with the personal seal of the physician. It is forbidden to correct and to make amendments in the prescriptions. There should never be any mentions, marks and other graphical signs on the other side of the prescription form. The rules, although they don't explicitly forbid to use electronic forms, are not adapted to the digital environment.

In **Hungary** the paper form of a prescription is strictly regulated by the Act CLIV of 1997 (form, signature, stamp etc). For most of the prescriptions, in particular for prescribing pharmaceuticals to the ambulatory patient, it is not possible to use electronic means to transmit a prescription due to a lack of the necessary infrastructure.

No specific legal framework for electronic prescriptions exists in the **Slovak Republic**. For most of the prescriptions, in particular for prescribing pharmaceuticals to the ambulatory patient, it is not possible to use electronic means to transmit a prescription.

## Study on the Legal Framework for Interoperable eHealth in Europe

In **Poland** the Ordinance of the Minister of Health of 17 May 2007 on medical prescriptions,<sup>199</sup> issued pursuant to Art. 45 Act on Professions of Physician and Dentist makes it clear that the Polish law does not allow for digital prescriptions. First, issuing a prescription requires affixing a handwritten signature (§ 2.1). Second, any alteration must be endorsed with “inserting” a stamp (§ 2.2), which may occur only when the prescription is recorder on a physical carrier. Third, the term “prescription” is used throughout the Ordinance only in the context of a printout (e.g. § 2.4) and an annex to the Ordinance (No. 6) defines both the content and size of each of the prescription pages (§ 9.1). Finally, confirmation that the prescription has been realized requires that the pharmacist puts a handwritten signature on it (§ 14.2.2).

In **Austria**, electronic prescription of medicine is in principle allowed in Austria (section 3 para. 1 letter Prescription Act, Federal Law Gazette 413/1972 latest amendment Federal Law Gazette I 59/2008). The physician has to use a qualified electronic signature in line with the Signature Act (Federal Law Gazette I 190/1999, latest amendment Federal Law Gazette I 59/2008). However, refund for prescriptions by the Austrian Social Security still requires a paper form. As mentioned before the situation in Austria will drastically change in the near future since ePrescription is one of the first applications to become operational in the context of the ELGA platform.<sup>200</sup>

### 10.4 Legal provisions concerning electronic prescribing

A second category of countries have adapted their legal rules in order to enable ePrescription even if electronic prescribing is not yet operational at this stage.

There exists, for example, legislation for electronic prescriptions in the **Czech Republic**. The Act on Pharmaceuticals no. 378/2008 establishes an “Electronic Prescription Central Repository”. Section 82 of this act makes it legally possible to use electronic prescription. This act is new (issued 6 December 2007) and the central repository had to be in operation on 6 December 2008. There is also a decree No. 54/2008 Coll. on the Pharmaceuticals Prescribing Procedure, Data Indicated on Prescription and on Rules for Prescription Usage where a procedure for electronic prescription is described. While this system is still under development, it is not yet possible to currently prescribe in electronic form in the Czech Republic. There must be at least a paper form together with an electronic form of the prescription and therefore electronic prescription is almost never used.

Similar to other countries, prescriptions in **England** traditionally have been issued on approved forms with the details of the medication hand written by the prescribing doctor and signed by that person<sup>201</sup>. Regulations have been required to be made to allow the requirements of writing and signature to be

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<sup>199</sup> *Rozporządzenie Ministra Zdrowia z dnia 17 maja 2007 r. w sprawie recept lekarskich*, Journal of Laws, Year 2007, No. 97, item 646, with further amendments.

<sup>200</sup> See the recent presentation of Dr. Schanner: [http://www.ihe-austria.at/fileadmin/user\\_upload/CAT2009/documents/CAT\\_Schanner\\_20090422\\_1.pdf](http://www.ihe-austria.at/fileadmin/user_upload/CAT2009/documents/CAT_Schanner_20090422_1.pdf)

<sup>201</sup> Before the introduction of electronic prescriptions there were already other options (for most medicines) apart from writing out the prescription by hand which had been available for some time e.g while the signature had to be signed in ink, other parts of the prescription did not have to be handwritten in ink – for instance they could be typed or written on carbon paper or computer generated. Therefore it was not the case of jumping from handwritten prescriptions to electronic prescribing. Also, over the last 10 years or so a number of other independent prescribers apart from doctors and dentists have been given the power to write prescriptions e.g nurse independent prescribers.

Study on the Legal Framework for Interoperable eHealth in Europe

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complied with electronically. The National Health Service Pharmaceutical Services Regulations 2005<sup>202</sup> provide that

71. - (1) A Primary Care Trust shall prepare, maintain and publish a list (to be called the ETP list) of all chemists in its area who participate in the ETP service.

(2) The list referred to in paragraph (1) shall include -

(a) the name of the chemist; and

(b) the address of the premises at which the ETP service is provided.

The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2005<sup>203</sup> inserted the following provision into the NHS (General Medical Services Contracts) Regulations 2004 (SI 2004/291):

39A. (1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if -

(a) the contractor holds a contract with a Primary Care Trust which is specified in directions issued by the Secretary of State under section 17 of the (National Health Service) Act 1977 as being a Primary Care Trust which can authorise its contractors to use the ETP service[16];

(b) the patient to whom the prescription relates has -

(i) nominated one or more dispensers in his NHS Care Record,

(ii) confirmed that he intends to use that dispenser (or one of them) for the purposes of obtaining the drugs, medicines or appliances ordered on the electronic prescription in question, and

(iii) consents to the use of an electronic prescription on the particular occasion;<sup>204</sup>

Effectively, the regulations envisage a phased introduction of the system of electronic prescriptions as different areas and medical practices install the necessary hardware and software. The regulations provide further for advanced electronic signatures.<sup>205</sup>

Around 8 million prescriptions are issued in **Estonia** every year that now will be digitalized as a result of the digital prescription project. In the course of the project, a central system will be developed that will store the incoming prescriptions (messages) and issue, on the basis of a request, the prescriptions of the specific patient to the information system of pharmacies. The Digital Prescription Centre (Retseptikeskus) will be established as an official database. It enables the issuing and processing of digital prescriptions for medicines and digital cards for medical devices. It also serves the purpose of generating medicinal statistics. The benefits for medicinal products and benefits for medical devices payable under the Health Insurance Act are also processed through this database.

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<sup>202</sup> SI 2005 No 641

<sup>203</sup> SI2005 No 893.

<sup>204</sup> Reg 39A: Those regulations also inserted into the NHS (Personal Medical Services Agreements) Regulations 2004 (SI 2004/627), regulation 38A, in similar terms to regulation 39A.

<sup>205</sup> Regulation 2, amending Regulation 2 of the GMS Contracts Regulations 2004. SI 2004 No 291



## Study on the Legal Framework for Interoperable eHealth in Europe

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The Digital Prescription Centre is a separate database from the Health Information System, however it also makes use of the technical possibilities of X-Road.

Under the new norms all healthcare providers are obliged to issue prescriptions digitally, except when not possible for objective reasons (e.g. house calls). Persons who have the right to issue prescriptions have access to the Digital Prescription Centre. A proprietor of an activity licence for provision of pharmacy services has the obligation to immediately notify the Health Care Board of the conclusion or termination of an employment contract with a dispensing chemist or pharmacist. This is necessary for prevention of unauthorized access to the data in the Digital Prescription Centre.

A person whose data is being processed in the Digital Prescription Centre has the right to deny access to such data for the healthcare provider. The person has access to the personal data that is processed in the Digital Prescription Centre.

Article 34 of the Healthcare Insurance Act in **France** allows the prescription of care by email provided that the issuer can be identified and the integrity and confidentiality of the prescription is guaranteed. It is however required that a prior clinical examination of the patient has been carried out. Derogation is foreseen for emergency cases. The creation of pharmaceutical records (Dossier pharmaceutique- DP) was planned by law in early 2007 (new article L.161-36-4-2 of the Social Security Code) in connection with the DMP. Article L.4231-2 of the Public Health Code entrusts its implementation to the Order of Pharmacists. These records should allow pharmacists to share personal data related to the delivery of medicines in order to prevent dangerous medicine interactions. Their use and creation are facultative and subject to the prior consent of the patient who will be able to withdraw at any moment. The patient will be granted with a right of access that (s)he will be able to exercise via any pharmacists and with a right to object to the processing of some information. In the future, these records will be incorporate to the DMP. An experimental project has been authorized by the CNIL on the 15 May 2007 which has allowed 400 pharmacies to create about 168000 records. The development of the software is financed by the Order of Pharmacists which plans to equip all pharmacies in a period of two years.<sup>206</sup> The government estimates that more than one million of DPs were created since the beginning of 2008.

Up to now, in **Germany** the electronic prescription, called *eRezept*, is only realised in the model regions for the electronic health card. In this regard, the following rules are applicable<sup>207</sup>:

The necessary information for a prescription are stored by the practitioner on or with the help of the patient's electronic health card (at the moment, only the first option is tested as the online-applications have not already been realized). As a supplement and bare for the patient's information, the practitioner can print an informal sheet of paper with the relevant information about which drugs and how much of each to take when. This sheet of paper is not a valid prescription.

The general data protecting rules call for either the patients consent or a legislative permit to store the patient's personal data. In so far, the storage of prescription-relevant data is permitted by article 291a par. 2 n° 1 SGB V. The patient's consent is not required and the patient cannot revoke the storage of his data. Nevertheless, remains the patient's own decision to hand in the prescription or not. Thus the patient keeps the authority over his data. If the patient decides to hand in the prescription, he/she is free to take it to the healthcare provider of his/her own choice.

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<sup>206</sup> Le Monde, Press release, Le Dossier pharmaceutique bientôt étendu à tout le territoire, 21 March 2008, available online at: [www.lemonde.fr/web/recherche\\_breve/1,13-0,37-1029365,0.html](http://www.lemonde.fr/web/recherche_breve/1,13-0,37-1029365,0.html)

<sup>207</sup> [http://www.bmg.bund.de/cln\\_117/nn\\_1168300/SharedDocs/Publikationen/DE/Gesundheit/g-07016,templateld=raw,property=publicationFile.pdf/g-07016.pdf](http://www.bmg.bund.de/cln_117/nn_1168300/SharedDocs/Publikationen/DE/Gesundheit/g-07016,templateld=raw,property=publicationFile.pdf/g-07016.pdf)

Study on the Legal Framework for Interoperable eHealth in Europe

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The rules on the running of pharmacies<sup>208</sup> already consider the electronic prescriptions. If chemists hand out drugs, they have to add the information in the electronic prescription and complete this information with their qualified electronic signature. Specific electronic transmission rules shall be developed in order to enable the mail-ordering of drugs by using electronic prescriptions. If SHI-associated physicians (148.000) want to use software to write electronic prescriptions, the software used has to fulfil certain standards and has to be certified by the National Association of Statutory Health Insurance Physicians.<sup>209</sup> A core requirement is that the software guarantees that the prescriptions cannot be manipulated. A special catalogue summarizing technical demands to the software has been developed.<sup>210</sup>

Within the amendments to the Bundesmantelvertrag the parties have agreed on special forms for prescriptions. Up to now, they are used as binding model for the paper based prescriptions. The ePrescription (the set of data accessible for the purpose to hand out medicine resp.) will at least contain those information that are now also part of the paper based model: name and health insurance company, date of birth and of expiration of the card, patient's and insurance company number, the prescribed drug including how and when to take it, codes on the amount the patient has to pay. Finally, the hand-written signature of the practitioner who prescribes the medicine will be replaced by generating a qualified electronic signature by using his electronic health professional card.

Article 291a SGB V determines that the electronic health card system shall be able to support electronic prescriptions. Nevertheless, electronic prescriptions could also be realized by means of other techniques, the technique using eGK is not obligatory, Several acts previously only ruling paper based prescriptions have already been adapted to the new possibilities to use electronic prescriptions.

In **Belgium** a pilot project on ePrescribing in the ambulatory sector (eMed-eCare) is currently (2009) starting in the framework of the national eHealth-platform. Uses cases and a basic architecture have been determined and a consortium of relevant stakeholders in charge of this pilot project has been established.

In The **Netherlands** ePrescription is currently being set up in the framework of the National Patient Record.<sup>211</sup> Pharmacies will progressively be connected to the National Switch Point (LSP) on a voluntary basis, at least in a first stage. Operational characteristics and details about the regulatory framework are not yet adopted at the moment of closing this report.

No specific legal framework for electronic prescriptions exists in **Greece**. A project on the "Designing and pilot application of an operating system of electronic prescription" has been proclaimed by the Civil Servants' Sickness Insurance Fund (OPAD). This project deals with the designing and the operation of an electronic prescription system that will offer an interoperable environment between OPAD (and the insured patient to it) and the entities of the primary healthcare (insured citizens, doctors, diagnostic centres, pharmacists). Given that it is a pilot project it does not aim at the direct and at national level operation of the system, but rather the definition of the architecture of the system, the recording of the procedures, the defining of the technologies and the spotting of potential problems. Therefore the pilot project is planned to be realised in the city of Livadia and will include: 2.500 insured citizens, 24 pharmacies, 65 doctors, 3 of which bio-practitioners and 2 radiologists, 1 diagnostic centre and the General Prefectural Hospital. Main goals of the project are to electronically

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<sup>208</sup> Verordnung über den Betrieb von Apotheken (Apothekenbetriebsordnung - ApBetrO), last changed July, 20<sup>th</sup> 2007, BGBl. I 2007, p. 1574, available at [http://www.gesetze-im-internet.de/apobetro\\_1987/index.html](http://www.gesetze-im-internet.de/apobetro_1987/index.html)

<sup>209</sup> Kassenärztliche Bundesvereinigung in German.

<sup>210</sup> See Anforderungskatalog AVWG, available at <http://www.kbv.de/rechtsquellen/2310.htm> |

<sup>211</sup> [http://www.infobsnzorg.nl/informatiepunt\\_com/informatiepunt\\_com\\_homepage.php](http://www.infobsnzorg.nl/informatiepunt_com/informatiepunt_com_homepage.php)

## Study on the Legal Framework for Interoperable eHealth in Europe

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interconnect OPAD with its suppliers on the one hand, and the electronic support of the control and clearance procedures, which OPAD has to perform according to the current legal framework, on the other.

In **Latvia** there is a special section for electronic prescriptions on the web site of the Ministry of Health. Among other documents, the document “Electronic prescription IS development concept” is available under this section. According to the concept currently the circulation of prescriptions is determined by the Cabinet Regulations No.175 as of 8 March 2005 on Manufacture and Storage of Prescription Forms, as well as Writing out and Storage of Prescriptions. On 26 June 2007 amendments to these Regulations were adopted, allowing the use of electronic prescriptions along with the paper prescriptions. According to point 55.1 of these Regulations, the content of electronic prescription complies with the requirements of the Regulations and it is made in accordance with laws governing electronic documents. However, the more detailed provisions on the procedure of use are not provided.

Largely because of the sometimes complex nature of the financial implications arising from prescriptions, it has been necessary to make specific regulatory provision for these in **Scotland**. The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) (Amendment) Regulations 2007<sup>212</sup> and the National Health Service (Pharmaceutical Services) (Scotland) (Amendment) Regulations 2007<sup>213</sup>, provide the principal legal basis for the use of electronic prescriptions. Effectively the legislation replaces previous references to paper based prescriptions with terms applicable to electronic ones. In one significant respect, e-prescriptions are more favourably treated. Where a patient claims exemption from payment on the ground of age (either above or below statutory limits), the Pharmacist is required to ask for supporting evidence in the case of paper based prescriptions but can accept an electronic prescription as definitive when the patient’s date of birth is printed by computer

Under the traditional system prescriptions for medicines have been hand written by GPs and taken by the patient to a NHS registered pharmacy for dispensing. In some cases the patient will pay the Pharmacist a fee but in the majority of cases, no payment is required from the patient. The Pharmacist will subsequently be reimbursed by the NHS for any costs incurred.

The move towards electronic prescriptions has attraction both on the grounds of efficiency and also as a means to reduce incidents, frequently caused by unclear hand writing, where the wrong medicine has been dispensed to the patient.

The move towards electronic prescriptions is taking place in a number of stages involving investment in IT systems for both GPs and Pharmacists. In both cases a number of suppliers offer systems designed to be compatible with NHS requirements.

Under the system, GPs will continue to provide their patients with a paper prescription. The details of the prescription would be uploaded to a secure central server and a bar code containing a unique identifier printed on the prescription form. This could then be read by the Pharmacist’s equipment which would connect with the central server for dispensing purposes and would also have the capability to process automatically a claim for reimbursement. It is estimated that the definitive system will be widely used from early 2009.

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<sup>212</sup> SI 2007 No 205.

<sup>213</sup> SI 2007 No.208.

## Study on the Legal Framework for Interoperable eHealth in Europe

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Finally in **Spain** the *Law 29/2006 of Guaranteed and Rational Use of Medicines and Sanitary Products*<sup>214</sup> (hereinafter, Law 29/2006 on Use of Medicines) regulates electronic prescriptions and states that the Government will set up the general framework of minimum requirements to be accomplished by the medical prescriptions issued or edited in a computer device, so that they can be used by all citizens with the right to NHS pharmaceutical prescriptions. In Spain, a “medical prescription” is considered as the document that guarantees the establishment of a treatment with medicines under the instruction of a doctor or a dentist. In the future the information on the electronic prescription will flow through the NHS Communications Network. The information will be transmitted through this network in a manner that will permit its exchange and its becoming immediate knowledge of all administrations and organs integrated in the NHS.

### 10.5 Operational ePrescribing in Scandinavia

The development of e-prescriptions in **Sweden** has increased rapidly since a new strategy was decided at the end of the 1990s. This strategy was the result of a decisive strategic action within the National Corporation of Swedish Pharmacies (Apoteket AB) in co-operation with the different regional healthcare bodies and national players. Carelink, a co-operating network for healthcare in Sweden, was instrumental in the deployment of the technical platform for secure communication, the Sjunet. A national project organisation co-ordinated and supported activities in regional teams.

A national mailbox for e-prescriptions allows the patient to have access to valid prescriptions at any pharmacy with the presentation of valid identification. Patients may also store their prescriptions in a national online repository, with no need for paper prescriptions and with the introduction of new services, like mail order prescription drugs. Less than two years after the launch, more than two million of Sweden's nine million inhabitants have agreed to store their prescriptions in the online repository.

Another milestone for e-prescribing in Sweden was the implementation of the National Pharmacy Register in July 2005, in which all dispensed drugs are stored for the duration of 15 months. With the patients' consent, doctors and pharmacists may retrieve information from the database for reasons of optimising their patients' medical therapy. The patient has, with a secure digital signature, full access to the register on the internet..

The Medicinal Products Act (SFS 1992:859) and the Medicinal Products Ordinance (SFS 1992:1752) regulate the prescription of medicine in general. The Medical Products Agency (*Läkemedelsverket*)<sup>215</sup>, which is the national authority responsible for the control and supervision regarding medicinal products, cosmetic and hygiene products and medical technical products, issues furthermore specific regulations when it comes to medicine. A system for electronic prescriptions has been in use though for quite some time.<sup>216</sup>

E-prescriptions (electronically transmitted prescriptions) have been increasingly used in Sweden. The prescription is issued in the doctor's electronic prescribing system and then transmitted through a secure network (Sjunet) to the national e-prescription mailbox at Apoteket AB. Only the prescribing

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<sup>214</sup> [http://www.060.es/te\\_ayudamos\\_a/legislacion/disposiciones/35257\\_LEG-ides-idweb.html](http://www.060.es/te_ayudamos_a/legislacion/disposiciones/35257_LEG-ides-idweb.html)

<sup>215</sup> [http://www.lakemedelsverket.se/Tpl/StartPage\\_395.aspx](http://www.lakemedelsverket.se/Tpl/StartPage_395.aspx)

<sup>216</sup> For a summary see eHealth IMPACT - Descriptive report on site study results: Apoteket and Stockholm County Council, Sweden – eReceipt, an ePrescribing application, February 2006: [http://www.ehealth-impact.org/case\\_tool/data/binary/d9448cc8ce8d4b44ab01f211908dd02f.pdf](http://www.ehealth-impact.org/case_tool/data/binary/d9448cc8ce8d4b44ab01f211908dd02f.pdf)

## Study on the Legal Framework for Interoperable eHealth in Europe

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physicians and Apoteket AB's pharmacy personnel have access to the prescription. The patients can then get their medication dispensed at any pharmacy in Sweden.<sup>217</sup>

The Prescription Register Act (SFS 1996:1156, *lag om receptregister*) stipulates the conditions for Apoteket AB to keep a register and the accepted purposes for the processing of personal data. The Act corresponds to the general principles of data protection.

The Regulation on prescription and delivery of medicine (*Läkemedelsverkets föreskrifter om förordnande och utlämnande av läkemedel m.m. (receptföreskrifter); 1997:10*)<sup>218</sup> stipulates the requirements for prescriptions, both paper-based as well as electronic prescriptions. It includes specific rules concerning electronic prescriptions as well as telephone prescriptions. According to Section 35 an electronic prescription is only possible if the care provider and the pharmacy have concluded a written agreement. The agreement has to contain rules on a secure and accurate transfer of data between the care provider and the pharmacy.

Electronic prescriptions are also widely used in **Denmark**. In the European Pilot Study on eHealth indicators "Benchmarking ICT use among General Practitioners in Europe" (Empirica) it is reported that 97 % of Danish GP's are using ePrescriptions.<sup>219</sup>

Prescribing medicinal products is regulated in Administrative Order No. 155 of 20 February 2007. According to section 1 of the Order prescription of medicinal products may take place in the form of a written prescription which can be handed over to the patient or communicated to the pharmacist electronically or by telefax. A prescription may also be communicated by telephone. Section 5 of the Order stipulates that any prescription needs to be signed and dated by the physician or by the dentist. Electronic prescriptions do, however, not need to be signed (see section 20 of the Order). The Order stipulates detailed rules regarding the content of the prescription.

In 2003 Denmark adopted a law creating the "Personal Medicine Profile". This is a register which provides an electronic overview of the purchases of prescribed pharmaceuticals for every patient. All purchases are registered automatically on the citizens' individual personal profile. *Registration is mandatory*. The following comments can be made to this provision:

- According to section 157, physicians are entitled to have access to the Personal Medicine Profile of patients who are currently receiving treatment, provided it is necessary to the actual treatment and care. A physician may also access the Personal Medicine Profile to investigate if his or her patients are being treated inappropriately with pharmaceuticals. The patient does not have a right to object in regards to access to the Personal Medicine Profile.
- Nurses and social assistants are under certain circumstances also entitled to access a patient's Personal Medicine Profile, provided the patient has given an oral or written consent.
- Pharmacists may access the Personal Medicine Profile with the patient's oral or written consent or if it is necessary for the deliverance of pharmaceuticals to the patient.

Since February 2007 the Personal Medicine Profile<sup>220</sup> has been supplemented by a Prescription Server. All electronic prescriptions are transferred to the Prescription Server which is connected to the Personal Medicine Profile. The pharmacies have access to the Prescription Server, and can deliver

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<sup>217</sup> [http://www.e-receptstockholm.se/imcms/servlet/GetDoc?meta\\_id=1008](http://www.e-receptstockholm.se/imcms/servlet/GetDoc?meta_id=1008)

<sup>218</sup> Available in Swedish at [http://www.lakemedelsverket.se/upload/lvfs/konsoliderade/LVFS1997\\_10%20omtryck.pdf](http://www.lakemedelsverket.se/upload/lvfs/konsoliderade/LVFS1997_10%20omtryck.pdf)

<sup>219</sup> [http://ec.europa.eu/information\\_society/eeurope/i2010/benchmarking/index\\_en.htm](http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm)

<sup>220</sup> [https://www.sundhed.dk/Fil.ashx?id=79&ext=pdf&navn=The\\_Danish\\_eHealth\\_experience.pdf](https://www.sundhed.dk/Fil.ashx?id=79&ext=pdf&navn=The_Danish_eHealth_experience.pdf)

## Study on the Legal Framework for Interoperable eHealth in Europe

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pharmaceuticals to patients on the basis of the prescription. The patient can obtain the medicine at any pharmacy and does not need to decide in advance which pharmacy to use. The prescriptions is stored in the server which means that the patient does not need him or herself to keep the prescription in situations where the prescriptions covers several dispenses of medicine.

There are no special regulations regarding the use of electronic prescriptions. The general rules in the Act on Processing of Personal Data together with those of the Health Act apply for processing of health information and use of prescriptions.

**Finland** has adopted legislation for electronic prescriptions in 2007 (Act on Electronic Prescription 2007/61). A national ePrescription pilot was already launched in Finland in 2002.<sup>221</sup> The piloting of the system took place in 2004-2006 and with the Act on Electronic Prescriptions 2007/61, permanent ePrescription legislation is now in effect.<sup>222</sup> The legislation was drafted based on the experiences of the pilot project.

The Finnish ePrescription system is based on a national database hosted by KELA, strong authentication and a smart ID-card for professionals with advanced electronic signature implementation and SSL-secured messages from health care providers and pharmacies to the database. The Finnish e-Prescribing is aimed to be fully integrated with the different EPR systems and a centralised receipt data file, to cover all pharmacies, and to contain continuously updated knowledge about all prescribed drugs of the patients, by using highly secured networks. The application to be built offers a usable platform for decision support for the drug safety.

The Act on Electronic Prescriptions §7 determines that the electronic prescription needs to be signed using an advanced electronic signature issued by The National Authority for Medico-legal Affairs. The healthcare service unit has to ensure that the physician is authorised to prescribe the medicine before allowing application of the signature. Several electronic prescriptions written to a single patient during one session can be signed once, and multiple electronic prescriptions can be signed as a batch. An amendment to the current Act has been introduced in June 2008. The act was given out in July 2008 and is in effect now. Some of the changes occur in the definition of the signatory role and authorisation, which was very challenging to implement under the provisions of the former legislation. In the current legislation, a physician or a dentist has a “personal” right to sign electronic prescriptions, but the healthcare unit has a legal obligation to control to whom and in which circumstances the physician can and cannot effectively sign prescriptions.

The electronic prescription’s information content includes:

- Patient name and SSIN, or date of birth for non-Finnish
- Information about the medicine with pharmacological database reference and composition description
- Information necessary for delivery and taking of the medicine

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<sup>221</sup> For a description of the situation at that time: Suomi, R. and Salmivalli, L., Electronic Prescriptions – Developments in Finland, in: Monteiro, Swatman, Tavares (editors). Towards the knowledge society – eCommerce, eBusiness and eGovernment, Proceedings of the second IFIP conference on E-commerce, E-business, E-government (I3E 2002), October 7-9, Lisbon, Portugal, 481-495.  
<http://www.tucs.fi/publications/attachment.php?fname=pSuSa02b.pdf>

<sup>222</sup> Bertelmanns Stiftung, Health Policy Monitor, Country Surveys. Finland  
[http://www.hpm.org/en/Surveys/THL/09/Electronic\\_prescriptions\\_and\\_patient\\_records.html](http://www.hpm.org/en/Surveys/THL/09/Electronic_prescriptions_and_patient_records.html)

## Study on the Legal Framework for Interoperable eHealth in Europe

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- Information necessary for identifying the physician or dentist giving out the prescription and the healthcare service unit in question
  - All necessary information needed by insurance institutions
  - Identifier for the electronic identifier

A patient's consent is not required for writing an electronic prescription, but a patient can deny the use of an electronic prescription. The patient has to be informed about the electronic prescription and the national database service in order for the patient to be aware of the new data exchange and archiving services and to be able to understand what are the privacy and safety issues involved. Informing the patient is recorded in the patient record and this event frees the healthcare service providers to repeatedly query consent information.

The electronic prescription is secret and it has to be encrypted using certificates. The patient can allow decrypting but this service will become available only once the transition period of electronic prescription transition is over (end 2011). The electronic prescription can be modified, revoked and renewed if patient consent is acquired, by the prescribing physician or a pharmacist, after due consultation. All modifications have to be signed by the healthcare professional applying the modification, as well as all renewals also. Any pharmacy in the country has access to the electronic prescription database and access is granted by the user or his or her assigned proxy. The patient has to identify herself and a proxy must have a signed assignment. The pharmacy will use information discovery services in order to retrieve patient care specific data from the database, such as use of proxy, insurance details etc. A paper information sheet is always delivered together with the medicines, unless the patient explicitly denies reception.

Limitations to secrecy are defined in §15 of the Act and they cover the following cases: information related supervision of healthcare professionals, medical safety guidance development, study and research. When not necessary, patient identifiers are automatically omitted from the data and all organisations requesting information on electronic prescriptions, have to justify their request according to the Act on the Openness of Government Activities 1999/621 §28.

The patient has right to view and audit his or her personal data stored in the electronic prescription database. The patient has right to request viewing of the data and access log data from any of the parties involved in the process: KELA, the pharmacy or the healthcare unit. The access log data has to contain all information related to the access, use, transfer or other handling of the electronic prescription data.

Electronic prescriptions are first stored in an active electronic prescription centre, where they are readily available for up to 30 month. After this period, the electronic prescriptions are automatically transferred to a long term electronic archive, where they are stored for 10 more years, after which the data is destroyed.

The Act on Electronic Prescriptions also defines the technical implementation of the electronic prescription system. The technical definition requires that users are strongly authenticated and access is only granted based on authorisation, prescription data matches with medical data, only legally compliant electronic prescriptions are introduced to the prescription centre, electronic prescriptions are signed and encrypted, the prescription centre service is resilient and operations gather relevant log information for audit purposes, finally that all equipment used in the process are compliant with relevant standards.

**Study on the Legal Framework for Interoperable eHealth in Europe**

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Finally, the use electronic prescriptions will become mandatory for all medical service providers in mainland Finland (an exception has been made for the Åland islands) by the end of 2011.

**10.6 Some concluding remarks**

In a paper published in 2003 researchers from the Public Health Department of the University of Turku (Finland)<sup>223</sup> found that electronic prescriptions were in everyday use in only a few EU member countries, while many others were running or considering pilot projects. Apparently the situation hasn't drastically changed since then. Large-scale operational ePrescription systems are operational only in the Scandinavian countries. Other Member States, such as Austria, Belgium, Germany or the Netherlands are currently running ePrescription pilots in the framework of their recently created national eHealth platforms.

In the coming years e-Prescribing will be introduced in many more European countries, and paper prescriptions will progressively become the exception rather than rule. Where there has been early implementation, the attitude to regulation has been pragmatic. Where e-prescribing has seen later implementation, there has been greater emphasis on legislation and safety issues before introduction. In both cases, e-prescribing provides an opportunity for achieving systematic improvements in healthcare safety. However, new technology could also introduce new errors, so systematic evaluation of the prescribing and dispensing process is vital. To increase safety and quality, as well as developing efficiency and cost-effectiveness, electronically transferred prescription technology should become a two-way communication process between the prescriber and the pharmacist, with automated checks on missing, inaccurate or ambiguous information.<sup>224</sup>

Traditionally legal rules in the Member States have been adopted for regulating the physician-patient-pharmacist triangular relationship. They have been introduced, however, for a situation whereby a patient receives a prescription from a physician and this patient goes subsequently to the pharmacist of his choice. On the basis of this scenario countries have at the same time set up their social security reimbursement procedures and possibly also the collection of prescription data for the development of their national health policies and for statistical and scientific purposes. The introduction of *e-prescription* systems changes basically every component in these relationships. Therefore fundamental legal and deontological questions arise in all Member States about how to apply the current rules to the new environment but also about how far the ICT-based re-engineering can go before entering into conflict with fundamental legal principles no one wishes to give up.

From a regulatory point of view two models, making personal health records available, have been presented; the opt-in and the opt-out model, where individuals have the choice to participate voluntarily or to reject to contribute to the collection of their personal information. Another approach to solve this dilemma, in the national dispensing databases in Scandinavian countries, has been to

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<sup>223</sup> M. MÄKINEN, J. FORSTRÖM, M. MARKKU ÄÄRIMAA and P. RAUTAVA,, European Survey on the Possibilities and Obstacles of Electronic Prescriptions in Cross-Border Healthcare, Telemedicine and e-Health, Volume 12, Number 4, 2006, <http://www.liebertonline.com/doi/abs/10.1089/tmj.2006.12.484>

<sup>224</sup> Bengt Åstrand, Prescriptions minus the paper, Public Service Review: European Union - Issue 16, (<http://www.publicservice.co.uk>) <http://tinyurl.com/om92nc>. See also the PhD Dissertation of Bengt Åstrand, ePrescribing. Studies in Pharmaco-informatics, University of Kalmar, 2007, 87 p. <http://hik.diva-portal.org/smash/record.jsf?pid=diva2:1874>



**Study on the Legal Framework for Interoperable eHealth in Europe**

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mandatorily allow the collection and registration of the information in the national databases and give the patient the right to restrict the accessibility of the information to certain individual healthcare professionals and also to permit the patient full transparency to whom has accessed the information.

In 2003 the Turku researchers also found that electronic prescribing across national borders was impeded by many obstacles, related to other systems or to lack of standardization. Nevertheless their conclusion was that “information technology is likely to gradually spread to prescribing in Europe. Before more countries will integrate electronic prescribing into national healthcare, it would be important to ensure interoperability and common standards between national systems. Only then can electronic prescribing offer its full potential, and cross-border electronic prescribing can be realized at the EU level”.

## 11. Conclusions and recommendations

In its call for a study on the legal framework for interoperable eHealth in Europe, the Commission explained the objective of this study as follows:

*“The eHealth Action plan (COM(2004) 356, p25) - according to which the implementation and deployment activities of eHealth throughout Europe is taking place - specifies that one of the important elements of the implementation of eHealth in Europe is its legal aspects, particularly in relation to product and services liability. However, many complex questions exist over the legal and regulatory implications for eHealth area, especially as relates to health services that can cross borders of one Member State.*

*Therefore, the Commission is launching a study in view to analyse legal orders of the 27 EU Member States to identify the principal legal and administrative barriers in providing the eHealth services both within the territory of one Member State and while crossing borders of the Member State. The principal message of the study is to contribute to eliminate/reduce fragmentation of eHealth market in Europe and of the interpretation of Community legislation that is unequally applicable in all Member States. The study will address a detailed description of the current situation in the national frameworks of 27 EU Member States, i.e. the existence of national laws, regulations and administrative provisions in the most relevant legal areas of eHealth sector (e. g. regulation impeding access to eHealth services in general and in particular towards e-prescription, e-referrals, e-booking, telemedicine, etc., professional qualification of eHealth providers, accreditation, personal data protection, liability legislation)”.*

Our study has resulted in 28 country profiles and in the underlying final analysis and assessment report. The analysis doesn't go into the details of national health law in the Member States. This field of law is far from stabilised. Only since a few decennia conflicts between patients and healthcare professionals are being submitted to legal courts and in most of the Member States jurisprudence on how to apply traditional legal concepts and categories to the healthcare domain is still scarce. Legal uncertainty is therefore inherent to the healthcare sector. In most of the Member States discussions, for instance, about the legal qualification of the doctor-patient relationship, are just starting and a consensus among legal experts about crucial legal problems related to healthcare is still missing. One example is the application of consumer protection law to the healthcare sector. Some authors prefer to use the term “healthcare consumer” instead of “patient”. There is an undeniable trend to “commercialisation” and “consumerism” in the health sector but many legal experts are intensively contesting such trends.

We have started our study with a short overview of some characteristics relating to the healthcare systems of the Member States in order to emphasize the diversity in this field. In some countries, healthcare is to a large extent decentralized. The role of the involved stakeholders such as healthcare professional organisations, health insurance funds or public authorities varies among the Member States. There are remarkable differences in the division of roles between the private and the public sector. The legal qualification of the relationship between a healthcare provider and a patient diverges. Rules on financing and reimbursement are different. The level of ICT-maturity of the healthcare sector differs considerably from one Member State to another. The conclusion is therefore that the health sector in Europe necessarily needs to be seen as a very fragmented landscape and that this fragmentation will not be eliminated in the near future. A European regulatory framework for eHealth should therefore not only take this diversity into account but it should fundamentally be based on it.

## Study on the Legal Framework for Interoperable eHealth in Europe

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It is important in this context to point at the limits of the Community competences in this field. Article 152 of the Treaty emphasizes that the role of the Community in the health sector has a supportive, coordinating and complementary character. It can only use a series of “soft law” instruments (e.g. recommendations) in order to coordinate and promote but harmonisation measures are explicitly excluded. Also important is the obligation to “fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care”. Public health, by definition, has to be considered as a “parallel complementary competence”. Nevertheless, although the EU has no formal legal powers to enact Community healthcare legislation, several other policy domains have a considerable impact on the health sector.

Article 16 of the proposed directive on patients’ rights in cross-border healthcare specifically relates to eHealth and aims to give the Commission specific empowerment to “*adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data in accordance with the applicable law. They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services*”

From a legal perspective the Commission can play a supportive, coordinative and complementary role in order to stimulate eHealth not only within the borders of separate Member States but also on a Community level as a whole. One of the main challenges consists in promoting legal interoperability without harmonisation.

One of the first challenges in this perspective is to overcome the regulatory barriers for healthcare professionals to provide, on a regular basis, services in other Member States than the one where they are established and officially registered. This is important, for example, in situations where telemedicine services – see the example of the Barcelona Telemedicine Clinic described in Chapter 9 of this report – are provided to hospitals in different Member States.

Most healthcare professions are regulated professions and can only be exercised under strict legal conditions particular to every Member State. For example, with regard to the rules applicable to physicians, Member States have various interpretations of what constitutes the “practice of medicine” and which activities should be reserved to qualified physicians. Every Member State has also its own licensing system and, in most cases, a physician who wishes to exercise his/her profession in a Member State needs to apply for a license in that Member State. In a context of cross-border eHealth service provision this can lead to a need for registration in all the Member States where the service is accessible. One can refer again to the example of the Barcelona Telemedicine Clinic: radiologists established in Barcelona or Sydney and providing services to Swedish hospitals need to be fully registered as a medical professional in Sweden. If providing services to Danish hospitals they need to register in Denmark, etc.

Every Member State has further its own supervisory bodies for the various healthcare professions and there is – in practice - little or no exchange of information between these bodies. A healthcare professional banned from exercising medical practice by a disciplinary sanction in one Member State, will not necessarily be prevented from re-starting activities in another Member State. As a consequence of the absence of information exchange and cross-border transparency, professionals established and registered in other Member States are not automatically trusted. A business model based on the provision of medical services via a mobile telephone operator – see the example of Medic4You described in Chapter 9 of this report – unavoidably bumps against such distrust because

## Study on the Legal Framework for Interoperable eHealth in Europe

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potential subscribers have no means to control the status of e.g. a healthcare provider established and registered in Romania.

A further obstacle for the delivery of cross-border eHealth services is the divergence in the liability regimes. A general harmonization of liability for services has been considered in the past but encountered so much resistance that the Commission was forced to withdraw the proposal. Without such harmonization cross-border liability cases can mostly be solved, at least from a theoretical point of view, but in practice it will frequently result in extreme legal complexity. In our overview of the liability regimes in the Member States we have seen that the majority of the Member States apply common liability rules to the healthcare sector. A few Member States did however introduce systems of faultless liability. The Swedish patient insurance, for example, gives the patient economic compensation for injuries that occur in connection with medical examination, treatment and care, and it operates on a no-fault basis, i.e. the patient does not have to prove that the injury is due to negligence on the part of the physician or other personnel. Hence, it is not entirely clear whether a Swedish patient will keep this privilege if he/she takes cross-border healthcare services from a professional established outside Sweden.

Last but not least, there is also a noteworthy divergence between Member States in the application of the duty of confidentiality owed by healthcare professionals towards their patients. Again this problem isn't insurmountable in individual cases, at least from a theoretical point of view. In practice, however, the healthcare professional, wishing to provide cross-border eHealth services in several Member States, will be confronted with a complex landscape of rules, e.g. stipulating in detail the conditions for sharing medical secrets with other colleagues. Since, moreover, infringements to these rules are often enforced by criminal sanctions professionals automatically become reluctant to engage themselves in cross-border adventures as long as they haven't got sufficient legal security.

The regulatory framework for the exercise of healthcare professions is a domain where the Commission can take some action. Cross-border delivery of eHealth services can be facilitated if providers don't necessarily have to register or apply for a license in every Member State separately. The current system could ideally progressively evolve towards a system of mutual recognition, as it exists already to a certain extent in the Scandinavian countries. The Commission can also promote the exchange of information between national supervisory bodies. Initiatives could further be taken in the domain of liability, not by harmonising liability regimes, but by stimulating better protection for patients via insurance schemes. Last but not least efforts can be undertaken to provide practical legal support to professionals wishing to deploy cross-border eHealth activities.

The application of *personal data protection* rules to the healthcare sector remains a second important legal issue. Our study confirms that the well-known divergences in the implementation of the European data protection directive continue to exist. Some new divergences have been added in more recent years. Member States, making use of the authorization offered by the Directive, usually have completed the list of exceptions for processing data concerning health with a list of additional exceptions.

Restrictions to the access right of the data subject in case of processing health-related personal data vary. Additionally these rights have to be combined with specific access rights to health records, attributed by national legal provisions on patients' rights. Finally the solution provided by the directive for determining the applicable Member State's data protection law, is not very patient-friendly in cross-border situations. Unlike the solution generally accepted in consumer protection law, data subjects cannot always benefit from the protection of the binding rules of the data protection law of the Member State where they are domiciled. If their rights are infringed in another Member State, they will often be

**Study on the Legal Framework for Interoperable eHealth in Europe**

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forced to exercise their rights in that (foreign) Member State (and thus to overcome all possible barriers related to e.g. language, legal assistance, etc.).

The Commission can take action in order to have a better protection for patients who wish to exercise their data protection rights in a cross-border context. This is possible without amending Directive 95/46/EC, for instance, by stimulating the national data protection commissioners to take up an interfacing role. As a result a patient could exercise his rights always via the data protection commissioner of his/her own Member State, even the infringement of rights is under the scope of another Member State's legislation.

A third series of legal obstacles relates to the application of patients' rights. If a patient wishes to make use of cross-border eHealth services delivered by a provider established in another Member State, she/he will immediately be confronted with uncertainty about the applicable rights as a patient. The way in which patients' rights are defined and implemented is largely determined by national law and differs from country to country. Moreover there exists no validated definition of patients' rights. The views on which rights have to be included in the definition of patients' rights vary from very narrow (patient's right to autonomy in different respects) to very broad (such as the right to respect for the patient's time and the right to benefit from innovation). Not all EU Member States have enacted specific comprehensive laws dealing with patients' rights as such. In some of the Member States patients' rights are contained in various legal texts regulating other topics as well. Sometimes not only legal provisions are relevant for patients' rights in a particular country but also ethical codes have to be taken into account. In some countries these ethical codes are legally binding. Harmonization of patients' rights on a European level is probably not a realistic option on a short term. Nevertheless there are other possibilities to put some steps forward.

The Commission can take action to stimulate the Member States to ratify the European Convention on Human Rights and Biomedicine of the Council of Europe. It could further promote, building further on a series of already existing initiatives in this domain, such as the development of a European charter of patients' rights with regard to the use of cross-border online health services. Most important is however the need for more transparency in this area. Today providers who are taking the risk to provide cross-border eHealth services are forced to invest a lot in highly specialized legal support in order to overcome the current complexity. Therefore they should to a maximum extent be provided with ready-to-use legal guidance, for example, in order to enable them to inform correctly their potential customers about the applicable rules with regard to patients' rights and other relevant legal items.

All legal issues mentioned above - regulation of the healthcare profession, personal data protection, patients' rights – are not specifically and exclusively linked to the provision of (cross-border) eHealth services. Legal obstacles due to the diversity of the Member States' legal frameworks in these areas will also arise in other situations, for example when patients are seeking healthcare services in other Member States. A patient who receives medical treatment in a hospital during her/his holidays abroad will, for instance, not be able to "export" the patients' rights he/she is used to at home. The patient insurance offered in Sweden to compensate potential damages due to medical errors will probably not cover accidents caused by professionals in the hospital in Spain.

Nevertheless the legal problems related to patient mobility are essentially different in comparison to the ones regarding cross-border eHealth. Studies carried out, e.g. in the framework of the proposed directive patients' rights on the application of patients' rights in cross-border healthcare, distinguish *five categories of mobile patients*.

**Study on the Legal Framework for Interoperable eHealth in Europe**

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The first category includes those citizens who, while on holiday, need to use health care services in the country they are visiting. In these cases there are arrangements throughout the European Union to facilitate the process, based on the European Health Insurance Card (EHIC), conferring the right to treatment during a temporary visit. The second category includes those citizens who retire to a different country (for example to Spain) and wish to use the health care system of the country where they are moving to. The third category consists of people sharing close cultural or linguistic links with the region – which happens to be on the other side of the border, where care is provided. This patient group also includes migrants returning to their country of origin to receive care. The fourth category includes those patients who cross a border to receive health care or to buy health goods. Examples include patients going abroad to avoid long waiting lists in their home country and patients seeking treatments that are cheaper (for example seeking dental treatment in Hungary). The fifth, and numerically the least significant category concerns those patients who are sent abroad by their own health system to overcome capacity restrictions at home. Health care provided in this category is, in general, actively managed by public authorities, seeking to ensure continuity of care, coverage of extra expenses and appropriate selection of providers abroad. Patients in this situation sometimes cross borders within the framework of cooperative agreements in order to share facilities, especially in relation to capital-intensive or highly-specialized services.

For most of these categories major legal obstacles do not appear in the field of such issues as licensing, personal data protection or patients' rights but are mainly related to reimbursement. In the last category, where healthcare abroad is provided in the framework of cooperative agreements, legal issues related to e.g. liability, quality of care standards or professional insurance are tackled via contractual clauses. In their study on patient mobility in the European Union *Rosenmöller et al.* report that these contracts are often based on an interpretation of European Court of Justice rulings stating that care provided abroad should be under the same terms and conditions as that provided domestically. Thus, a Czech provider contracting with a German sickness fund is expected to apply German quality standards.

On the other hand healthcare providers treating foreign patients and providers of cross-border eHealth services also face similar barriers. For example both categories are interested in a ready access to patient's medical history. This is one of the reasons why the proposed directive on patient mobility also refers to issues such as interoperable electronic health records and interoperability of national ePrescription systems.

Legal provisions with regard to health records (paper-based files and electronic records) have traditionally been laid down in the Member States' healthcare laws and in the legislation on patients' rights. These provisions usually contain rules relating to the obligation for healthcare providers and institutions to keep a health record, the content of such records, archiving rules, access rights for patients, etc. They sometimes also take into account that individual health data, under certain conditions, needs to be shared among health professionals. More recent laws include specific conditions for accessing and sharing *electronic* health records. In many cases however, these rules don't suffice as a comprehensive legal framework for the introduction of electronic health records on a national scale. Some Member States have created or are planning to create a new legal framework for sharing electronic health records by way of government-initiated eHealth services, platforms or registers. Generally speaking these new legal frameworks don't provide rules or solutions for cross-border situations and are exclusively focusing on the relationships between healthcare providers, public authorities, health insurers and patients within one national territory.

The Commission already closely monitors these developments in other areas related to e-government e.g. in the framework of the IDABC program. Interoperability between the solutions adopted by Member States in the domain of electronic patient records is also one of the priorities of the European Patients Smart Open Services – epSOS large scale pilot project. The main current challenge in this

## Study on the Legal Framework for Interoperable eHealth in Europe

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field is without any doubt the adoption of a workable solution for cross-border user and access management. How will we organise the authentication of a Spanish pharmacist to the Belgian eHealth-platform in order to give him access to the medical history of a Belgian tourist? But also – referring to the case of the Ksyos platform described in Chapter 9 - : how will a Belgian dermatologist be authenticated by the Dutch National Switch Point in order to obtain access to the electronic patient record stored on the IT infrastructure of the referring Dutch physician.

The example above brings us to a further series of legal issues related in particular to “telemedicine”. The range of services that can be considered as “telemedicine” is extremely wide and diverse. It is therefore very difficult to formulate general rules applicable to all forms of telemedicine and perhaps also one of the reasons why legal rules dealing specifically with this field are practically inexistent. The rare exceptions mostly deal with one particular category of telemedicine (the healthcare professional – patient relationship). Specialised health law doctrine or opinions and recommendations of medical supervisory authorities frequently express reluctance towards providing care to a patient at a distance but don’t necessarily take into account the wide diversity of telemedicine services and applications. All this together creates uncertainty, in particular in a cross-border context.

Telemedicine is probably not an adequate legal concept because it covers a much too heterogeneous field. Legal issues can better be tackled by approaching the various situations covered by this concept from another point of view. By way of example, it appears to be much more useful to issue specific guidelines for e-mail communication between physicians and patients than general guidelines attempting to cover every possible “telemedicine” use case. For the same reason it doesn’t seem very wise to consider “telemedicine” as such as a category of healthcare adapted for reimbursement. The discussion about telemedicine from an insurance viewpoint will gain efficiency by tackling it at a more precise level (e.g. at the level of particular telemonitoring applications).

Many types of telemedicine applications are directly linked to the introduction of shared electronic health records. Healthcare professionals will, in most of the situations, combine the provision of a telemedicine service – either to another professional or to a patient – with accessing the patient’s record.

Multiple legal obstacles hinder the provision of cross-border telemedicine services in Europe. These obstacles can be divided in two categories. A first category of obstacles is related to the national character of the regulatory framework governing healthcare in the Member States. The requirement to comply with the rules of every Member State separately prevents flexibility in cross-border service provision and can lead to almost unsolvable complexity in case of European-wide roll-out of telemedicine services. As a consequence of the divergences between the national legal frameworks for healthcare it is crucial to determine which national law applies in case of a cross-border telemedicine relationship. Unfortunately most of these questions can only be answered on a case-by-case basis and the answer will very much depend on which countries are involved in the cross-border situation.

A second category of legal obstacles relates to the fact that eHealth, as it is currently conceived in the Member States, is based on the creation of a national online community including exclusively the stakeholders of the national healthcare sector: healthcare professionals, healthcare institutions, patients, health insurers, public health administrations. The rules that are created to govern this community are primarily – in most cases even exclusively – designed for being applied by and to the members of this community.

From a legal point of view “telemedicine” is not an adequate concept. The legal issues can better be tackled on a more specific level. A better insight in the practical legal obstacles for cross-border service delivery in this field can be acquired by investing in in-depth use case studies. In Chapter 9 of this report a series of “telemedicine cases” have been briefly described in order to illustrate the

**Study on the Legal Framework for Interoperable eHealth in Europe**

diversity in this field. Unfortunately most of these cases don't include the provision of cross-border eHealth services. Where this is the case, the legal problems are avoided via contractual solutions or – as in the case of the Barcelona Telemedicine Clinic – by requesting professionals to be fully registered in each Member States to which services are provided. It would however be extremely useful to study further on these (and possibly other) telemedicine cases, not from a “as is” point of view but rather from the hypothetical perspective that the services would be provided crossing national borders. Such a study would most probably give a deeper practical insight in the legal barriers faced by potential providers of cross-border eHealth services and hopefully lead to concrete and workable legal guidelines and recommendations in this field.

Finally the last issue tackled by this report related to ePrescription. Electronic prescribing generally refers to a prescriber's ability to electronically send a prescription for a medicinal product directly to a pharmacy from the point-of-care. In practice however, prescribing pharmaceuticals to a patient is only one step in a larger administrative process. The details of this process are directly dependent on the organisational structure of the healthcare sector and in particular on the reimbursement procedures. In many Member States this larger process is still paper-based and therefore the legal framework for prescriptions has not yet been adapted in order to enable ePrescribing. A second category of countries have adapted their legal rules in order to enable ePrescription even if electronic prescribing is not yet operational at this stage. Large-scale operational ePrescription systems are operational only in the Scandinavian countries. Other Member States, such as Austria, Belgium, Germany or the Netherlands are currently running ePrescription pilots in the framework of their recently created national eHealth platforms.

The draft Article 14 of the proposed European directive on the application of patients' rights in cross-border healthcare states that the Commission will bring forward measures to facilitate recognition of prescriptions, including an EU-wide prescription template, and supporting interoperability of e-prescriptions. Further study is needed in order to determine the type of measures to be taken to this effect. Meanwhile action should be taken to promote sharing of best practices among the Member States.

**A final conclusion of this study is that it is absolutely necessary to invest in further legal study in this field. More in-depth legal analysis is, for instance, urgently needed with regard to the upcoming national legislation with regard to electronic health records. Better insight in the current legal discussions on this topic in the Member States should feed the discussion on a European scale and prevent additional fragmentation. The same effort is without any doubt also needed in the areas of telemedicine and ePrescription. Our study has mainly provided a better insight in the relevant legal framework of the Member States and emphasized the complexity of the issues. Our understanding is that this complexity can, in the current stage, best be tackled by more specific case studies, e.g. starting from currently provided eHealth services – even if they are only provided within the borders of one Member State – in order to examine the specific legal issues that would arise if those services were provided crossing national borders. Rather than dealing with all possible legal issues related to cross-border eHealth services at one, this approach can possibly provide – if not for all, certainly for a few representative situations – more practical and workable legal guidelines and recommendations.**

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