

# SMART 2007/0059

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Study on Legal Framework of  
Interoperable eHealth in Europe

## **NATIONAL PROFILE SLOVENIA**

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European Commission  
Directorate General Information Society

Brussels

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## Table of Contents

<b>TABLE OF CONTENTS</b>	<b>2</b>
<b>1 DOCUMENTS</b>	<b>5</b>
<b>1.1 APPLICABLE DOCUMENTS</b>	<b>5</b>
<b>1.2 REFERENCE DOCUMENTS</b>	<b>5</b>
<b>2 GLOSSARY</b>	<b>8</b>
<b>2.1 DEFINITIONS</b>	<b>8</b>
<b>2.2 ACRONYMS</b>	<b>9</b>
<b>3 INTRODUCTION</b>	<b>11</b>
<b>3.1 GENERAL OVERVIEW OF THE SLOVENIAN HEALTHCARE SYSTEM</b>	<b>11</b>
<b>3.2 USE OF ICT IN THE SLOVENIAN HEALTHCARE SECTOR</b>	<b>13</b>
<b>3.3 NATIONAL EHEALTH STRATEGY</b>	<b>14</b>
<b>3.4 REGULATORY FRAMEWORK FOR PATIENTS' SUMMARIES</b>	<b>15</b>
<b>3.5 REGULATORY FRAMEWORK FOR TELEMEDICINE</b>	<b>16</b>
<b>3.6 REGULATORY FRAMEWORK FOR ELECTRONIC PRESCRIPTIONS</b>	<b>16</b>
<b>3.7 OVERVIEW OF RELEVANT LEGISLATION</b>	<b>16</b>
<b>4 REGULATORY FRAMEWORK FOR THE HEALTHCARE PROFESSION</b>	<b>19</b>
<b>4.1 LEGAL CONDITIONS FOR THE PRACTICE OF HEALTHCARE</b>	<b>19</b>
<b>4.2 CONTROL OVER THE PRACTICE OF MEDICINE</b>	<b>22</b>
<b>4.3 PROFESSIONAL LIABILITY</b>	<b>22</b>
<b>4.4 PROFESSIONAL SECRECY</b>	<b>23</b>
<b>5 PROCESSING OF PERSONAL HEALTH DATA</b>	<b>24</b>

**Study on Legal Framework of Interoperable eHealth in Europe**

---

<b>5.1</b>	<b>SHORT OVERVIEW OF PERSONAL DATA PROTECTION LEGAL FRAMEWORK</b>	<b>24</b>
<b>5.2</b>	<b>TRANSPOSITION OF ARTICLE 8 OF DIRECTIVE 95/46/EC</b>	<b>25</b>
<b>5.3</b>	<b>INFORMATION AND ACCESS RIGHTS OF DATA SUBJECTS</b>	<b>26</b>
<b>5.4</b>	<b>OTHER RELEVANT RULES REGARDING PERSONAL DATA PROTECTION</b>	<b>27</b>
<b>6</b>	<b>RIGHTS AND DUTIES OF HEALTHCARE PROVIDERS AND PATIENTS</b>	<b>29</b>
<b>6.1</b>	<b>SCOPE OF THE LAW</b>	<b>29</b>
<b>6.2</b>	<b>DUTY OF THE PATIENT TO CO-OPERATE</b>	<b>30</b>
<b>6.3</b>	<b>RIGHT TO QUALITY CARE – NON-DISCRIMINATION</b>	<b>30</b>
<b>6.4</b>	<b>RIGHT TO FREE CHOICE</b>	<b>31</b>
<b>6.5</b>	<b>RIGHTS RELATED TO INFORMATION ABOUT THE STATE OF HEALTH</b>	<b>31</b>
<b>6.6</b>	<b>RIGHT TO GIVE CONSENT</b>	<b>31</b>
<b>6.7</b>	<b>RIGHTS RELATED TO THE PATIENT’S MEDICAL RECORD</b>	<b>32</b>
<b>6.8</b>	<b>RIGHT TO PROTECTION OF PRIVACY AND INTIMACY</b>	<b>32</b>
<b>6.9</b>	<b>RIGHT TO REPRESENTATION IN CASE OF INCOMPETENCE</b>	<b>32</b>
<b>7</b>	<b>IDENTITY MANAGEMENT IN THE HEALTH SECTOR</b>	<b>33</b>
<b>7.1</b>	<b>OVERVIEW</b>	<b>33</b>
<b>7.2</b>	<b>THE HI CARD</b>	<b>34</b>
<b>7.3</b>	<b>CENTRE FOR DATA INTERCHANGE</b>	<b>35</b>
<b>7.4</b>	<b>PATIENT IDENTIFIER</b>	<b>36</b>
<b>7.5</b>	<b>AUTHENTICATION OF HEALTHCARE PROFESSIONALS</b>	<b>36</b>
<b>7.6</b>	<b>EXCHANGE OF HEALTH-RELATED DATA</b>	<b>36</b>
<b>8</b>	<b>ELECTRONIC PRESCRIPTION</b>	<b>38</b>
<b>9</b>	<b>GENERAL ASSESSMENT</b>	<b>41</b>

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**Study on Legal Framework of Interoperable eHealth in Europe**

---

<b>ANNEX: CONTACT DETAILS OF NATIONAL CORRESPONDENTS</b>	<b>42</b>
<b>9.1 PRIMARY CONTACT</b>	<b>42</b>
<b>9.2 ALTERNATIVE CONTACT</b>	<b>42</b>

**Study on Legal Framework of Interoperable eHealth in Europe**

**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/200807_02-interop_recom.pdf">http://ec.europa.eu/information_society/activities/health/docs/policy/200807_02-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: Patient 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:

Study on Legal Framework of Interoperable eHealth in Europe

	<p><a href="http://ec.europa.eu/information_society/europe/i2010/docs/benchmarking_gp_survey_final_report.pdf">http://ec.europa.eu/information_society/europe/i2010/docs/benchmarking_gp_survey_final_report.pdf</a>, Country profiles: <a href="http://ec.europa.eu/information_society/europe/i2010/benchmarking/index_en.htm">http://ec.europa.eu/information_society/europe/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>

**Study on Legal Framework of Interoperable eHealth in Europe**

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## 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.
- **eHealth:** a very broad term that encompasses many different activities related to the use of the information and communication technology (ICT) for healthcare. Many of these activities focus on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care.
- **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/EC47, issued 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. Health care 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

**Study on Legal Framework of Interoperable eHealth in Europe**

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.
- **Identity management:** Identity management (ID management) is 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 health care in a Member State;
- **Patient summary:** 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;.
- **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:** exchange of medical information from one site to another via electronic communications with the purpose to improve patients' health status.

**2.2 Acronyms**

CBSS.....	Crossroads Bank for Social Security
....	
EHR.....	Electronic Health Record
....	
eID .....	Electronic Identity
eIDM	Electronic Identity Management
.....	
GP.....	General Practitioner
...	

**Study on Legal Framework of Interoperable eHealth in Europe**

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<b>HiT</b> .....	Health in Transition
.....	
<b>OCSP</b> .....	Online Certificate Status Protocol
<b>PKI</b> .....	Public Key Infrastructure
....	
<b>NRN</b> .....	National Register Number
..	
<b>SIS</b> .....	Social (security) Information System
.	
<b>SSCD</b> .....	Secure Signature Creation Device
<b>SSIN</b> .....	Social Security Identification Number
....	
<b>TTP</b> .....	Trusted Third Party

### 3 Introduction

#### 3.1 General overview of the Slovenian healthcare system

Slovenia has a centralised healthcare system with the following major stakeholders:

1. Ministry of health (<http://www.mz.gov.si/>);
2. Healthcare providers (including physicians);
3. Health insurance institute (HII) (<http://www.zzs.si/>);
4. Health insurance companies (major <http://www.vzajemna.si/>);
5. Individuals (insurance holders)
6. Others (e.g. Institute for health protection <http://www.ivz.si/>, Medical Chamber <http://www.zzs-mcs.si/>).

The Ministry is the major policy maker with regard to all aspects of the healthcare system. It lays down the regulatory framework for healthcare providers, physicians, is the policy maker for insurance schemes and it also sets out the major guidelines for eHealth development. In this respect at ministerial level two expert bodies (comprising different experts from all the major stakeholders as well as civil society and other experts) are established:

1. Council for informatics in healthcare and
2. Committee for healthcare information standards

[http://www.mz.gov.si/si/svet\\_za\\_informatiko\\_siz\\_in\\_ozis/svet\\_za\\_informatiko\\_siz/](http://www.mz.gov.si/si/svet_za_informatiko_siz_in_ozis/svet_za_informatiko_siz/)  
[http://www.mz.gov.si/si/svet\\_za\\_informatiko\\_siz\\_in\\_ozis/ozis\\_odbora\\_za\\_zdravstveno\\_informacijske\\_standarde/](http://www.mz.gov.si/si/svet_za_informatiko_siz_in_ozis/ozis_odbora_za_zdravstveno_informacijske_standarde/)

Healthcare providers can be divided into two major groups:

1. Public healthcare institutes and
2. Individual practitioners

Both are incorporated into the network on equal terms on the basis of concessions and having a contract with the HII. A list of service providers (in specific regions) is available on: <http://www.zzs.si/Izvjalci>. At the end of 2007, the national public network was constituted of 224 public institutions and 1.514 private practice doctors and other health care practitioners. As a rule the majority of healthcare services is provided by the public institutes employing physicians of different profiles. The percent of individual practitioners is in general still rather small, it can be however observed that there are differences between fields of healthcare (e.g. dentists usually work as individual practitioners). As a matter of public policy, communities have certain obligations in view of ensuring public healthcare, which can be done by establishing their own healthcare Institutes or giving concessions for the provision of services to individual practitioners.

**Study on Legal Framework of Interoperable eHealth in Europe**

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In addition to private practitioners, participating in the public healthcare network healthcare services are also provided by the so called "purely private practitioners". All the services by such practitioners, with the exception of emergency medical aid, are to be paid directly by the patients.

Just in 1992, Slovenia introduced a new system of health insurance, which comprises compulsory and voluntary health insurance (Article 12 Health Care and Health Insurance Act). 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 payed by the employer to the HII. 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.

The amount of paid contributions in 2007 amounted to 2 billion EUR and has increased by 7,9 % compared to 2006. The rates of contributions under compulsory health insurance are specified by the Law on Contributions for Social Security. The Resolution on the Flat Sum Contributions for the Compulsory Health Insurance determines periodically the new fixed amounts in effect every year. The amount of the flat sum charges is set by the HII itself.

However the CHI provides insurance only for a very limited scope of services (which are the same notwithstanding the individuals 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), however as the new (divided) system was derived from a unified health insurance system, the voluntary insurance holders were practically taken over by one major mutual insurance company, which is still the major player in the voluntary insurance market.

Individuals (insurance holders) identify themselves to the healthcare provider with the health insurance (HI) card. As it will be explained further in this report the HI card gives mainly information on the individual insurance status. As a general rule an individual included in a voluntary health insurance scheme (noting that CHI is mandatory) is insured almost for every service of the healthcare provider, whereas an individual having only CHI will be charged extra for most of the services.

As far as pharmaceuticals are concerned some of them are covered by the voluntary insurance schemes, whereas others have to be payed for extra if prescribed. To this end the HII has also contracts with pharmacies.

**Study on Legal Framework of Interoperable eHealth in Europe**

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**3.2 Use of ICT in the Slovenian healthcare sector**

There are only fragmented data on the use of ICT by Slovenian specialists, hospitals or pharmacies. A recent (2007) status of the use of ICT by general practitioners in Slovenia has been drafted in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe' (Empirica):

[http://ec.europa.eu/information\\_society/eeurope/i2010/benchmarking/index\\_en.htm](http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm)

From the Slovenian country brief, we take over the following key findings:

"In terms of infrastructure, 97% of the Slovenian GP practices use a computer. 82% of practices dispose of an Internet connection. In Slovenia, broadband connections are quite common; they represent the usual form of Internet access in 54% of the GP practices. When compared to the other European countries, Slovenia scores at or above average for all three types of ICT infrastructure that represent the baseline for a successful uptake of eHealth solutions.

When it comes to the use of eHealth applications, Slovenia shows a very particular pattern. 86% of Slovenian GP practices store electronic administrative patient data. In comparison to the other EU Member States this share translates to an upper mid-field position. 83% of Slovenian GP practices store at least one type of medical patient data as well. Of those 80% GP practices in Slovenia that do store electronic patient data, 89% store diagnosis information. Otherwise only medicamentations (43%) Symptoms (33%) and basic medical parameters (31%) are stored in more than one-third of those Slovenian GP practices that do store electronic medical patient data. All other data types are stored to a much lesser degree. Medical history, examination results, viral sign measurements and treatment outcomes are integrated in less than 20% of local EHRs, radiological images are even stored in only 8% of the local EHR.

In Slovenia, computers are used in consultation with the patients only to a very limited extent (18% of the GP practices).

The electronic transfer of individual patient data via Internet or other network connections has as yet not very much arrived on the agenda of Slovenian GPs. Only 10% receive laboratory results and not a single GP practice exchanges medical patient data with other carers. Neither is the exchange of administrative data via networked connections more common: only 3% of the GP practices participating in the survey reported having exchanged administrative data with other care providers while 14% exchanged administrative data with reimburses.

ePrescribing is still not a reality in most European Member States. This holds true for Slovenia as well where none of GPs having participated in the survey reported using

## Study on Legal Framework of Interoperable eHealth in Europe

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ePrescribing. The rather low level of eHealth use can be attributed to the fact that this policy field is relatively new in Slovenia."

Notwithstanding the remarks above, it should be noted that certain relations in healthcare are very well using ICT: e.g. the insurance rights system together with prescribed medication is almost completely using ICT solutions via the HI card and its functionalities. Furthermore there are obviously some fragmented (pilot) projects implementing ICT other solutions in healthcare (e.g. use of teleradiology, introduction of electronic document management etc.), however it can be observed that no general strategic approach can be identified.

[http://www.mz.gov.si/si/splosno/cns/novica/browse/36/article/698/5395/?tx\\_ttnews%5Byear%5D=2008&tx\\_ttnews%5Bmonth%5D=08&cHash=7534fc52e9](http://www.mz.gov.si/si/splosno/cns/novica/browse/36/article/698/5395/?tx_ttnews%5Byear%5D=2008&tx_ttnews%5Bmonth%5D=08&cHash=7534fc52e9)

As it is explained in this report broader usage of ICT can be expected through the renovation of the HI card, including electronic prescriptions and consultational use (including diagnostics) of ICT.

### 3.3 National eHealth strategy

A national eHealth strategy for the period 2006-2010 was adopted in december 2005: see further

[http://www.mz.gov.si/fileadmin/mz.gov.si/pageuploads/Svet\\_za\\_informatiko\\_SIZ\\_in\\_OZIS/SIZ\\_Temeljna\\_listina.doc](http://www.mz.gov.si/fileadmin/mz.gov.si/pageuploads/Svet_za_informatiko_SIZ_in_OZIS/SIZ_Temeljna_listina.doc)

Whilst for the general part identifying the current status of ICT in healthcare, the Strategy points out the following strategic objectives for the 2006-2010 period:

1. setting up of core information infrastructure and definition of key datasets enabling the establishment of the individual electronic record, including identification, authentication and authorisation of the entities (end of 2007)
2. integration of existing information systems on a national level, through standardisation and interoperability (end of 2010)
3. promotion of e-commerce use in healthcare as a common means of communication (end of 2010)

In order to achieve the objectives above following actions were foreseen by the Strategy:

1. Identification of the current status
2. Establishment of expert groups/bodies
3. Drafting of an action plan for eHealth

## Study on Legal Framework of Interoperable eHealth in Europe

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4. Ongoing upgrading of existing information infrastructure
5. Introduction and use of PKI infrastructure
6. Development of applications
7. Other regulatory, financial and promotion issues

Up to date points 1. and 2. can be regarded as achieved, referring to the renewal of the HI card, partly also an action plan (objective 3) is visible, whereas there is no information available on the progress with regard to the other objectives.

The Strategy is somewhat fuzzy with respect to ICT, not drawing a clear line between information infrastructure and information services projects. It would be favourable that the strategy clearly points out certain projects such as e-prescription, individual electronic record and some other mostly "back office" applications, already defining certain standards (ISO/CEN 13606 in ISO/CEN 21549, HL7 v.3, OpenEhr) or principles (PKI, XHMTL) to be respected

Summarising all together it can be observed that the current policy focuses firstly on the upgrading of information infrastructure and secondly on the integration of existing data. Both should provide the basis for new services, which will be accessible to the individual with his new HI card. Tho this end it can be observed that, although the HI is not specifically mentioned a as strategic objective of the national eHealth strategy, it can nevertheless be regarded a a key factor in the process as it represents the main communication channel between the individual and other stakeholders and shall be applicable in almost every relation. This will contain merely the electronic signature of the individual, thus providing authentication to the system, when using a certain healthcare service. Other stakeholders shall have limited access to the data of the individual, depending of the nature of the service provided.

### 3.4 Regulatory framework for patients' summaries

The Healthcare Databases Act provides a general and unified legal basis for personal data processing valid for all public stakeholders in healthcare. In terms of patients' summaries the Healthcare Databases Act provides the legal basis for the inclusion of summaries on the HI card (Annex of the Healthcare Databases Act, database no. 2).

Together with the basic personal data and insurance status it provides a general legal basis for the inclusion of all relevant basic health data, diagnostics, vaccine treatment, cronical diseases, allergies, injuries, disabilities, addiction, operative treatment, work restrictions, issued medicine and protetics.

## Study on Legal Framework of Interoperable eHealth in Europe

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Thus it can be observed that a valid regulatory framework in this respect is already in place, with the HI card being the focal point. However as it is explained later in the report, the HI card used does not support all functionalities, which are theoretically and/or legally possible.

### 3.5 Regulatory framework for telemedicine

There are no specific provisions in Slovenia with regard to telemedicine. However the recently adopted Act on patients rights (<http://www.uradni-list.si/1/objava.jsp?urlid=200815&stevilka=455>) could represent a major obstacle for performing telemedicine at all. Namely its Article 20, para. 2 explicitly states that a patient has the right to be informed on every aspect of his health status (diagnose, treatment, risks, alternative treatment etc.) directly in person by the responsible physician, who has a respective obligation.

Furthermore the physician can be liable for a misdemeanor if he act contrary to this obligation. Although there are no information nor jurisprudence available on the interpretation of this article and it is rather unlikely, that any physician will give any information, relating to the health status of any patient as he would most likely contravene his obligations of direct personal contact with the patient.

There is no information available on physicians exercising telemedicine in Slovenia in practice.

### 3.6 Regulatory framework for electronic prescriptions

No specific legal framework exists for electronic prescriptions. However electronic prescriptions are referred to as one of the key new functionalities of the revised HI card referred to in chapter 7.2, whereas general rules on prescriptions are explained in chapter 8.

### 3.7 Overview of relevant legislation

An overview of the regulatory framework for the medical profession and/or healthcare in general is available at:

- [http://zakonodaja.gov.si/rpsi/kazala\\_podrocje/kazalo\\_10\\_4\\_0\\_0.html](http://zakonodaja.gov.si/rpsi/kazala_podrocje/kazalo_10_4_0_0.html)
- [http://zakonodaja.gov.si/rpsi/kazala\\_podrocje/kazalo\\_10\\_0\\_0\\_0.html](http://zakonodaja.gov.si/rpsi/kazala_podrocje/kazalo_10_0_0_0.html)
- [http://www.mz.gov.si/si/zakonodaja\\_in\\_dokumenti/](http://www.mz.gov.si/si/zakonodaja_in_dokumenti/)
- [http://zakonodaja.gov.si/rpsi/r04/predpis\\_ZAKO214.html](http://zakonodaja.gov.si/rpsi/r04/predpis_ZAKO214.html)

Relevant legislation in the field of health insurance:

- [http://zakonodaja.gov.si/rpsi/r03/predpis\\_ZAKO213.html](http://zakonodaja.gov.si/rpsi/r03/predpis_ZAKO213.html)
- [http://zakonodaja.gov.si/rpsi/kazala\\_podrocje/kazalo\\_6\\_7\\_0\\_0.html](http://zakonodaja.gov.si/rpsi/kazala_podrocje/kazalo_6_7_0_0.html)

Other relevant legislation (e-signature, data protection, electronic communications)

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- [http://zakonodaja.gov.si/rpsi/kazala\\_podrocje/kazalo\\_3\\_1\\_0\\_0.html](http://zakonodaja.gov.si/rpsi/kazala_podrocje/kazalo_3_1_0_0.html)
- [http://zakonodaja.gov.si/rpsi/r03/predpis\\_ZAKO1973.html](http://zakonodaja.gov.si/rpsi/r03/predpis_ZAKO1973.html)
- [http://zakonodaja.gov.si/rpsi/kazala\\_podrocje/kazalo\\_8\\_0\\_0\\_0.html](http://zakonodaja.gov.si/rpsi/kazala_podrocje/kazalo_8_0_0_0.html)

In terms of eHealth and personal data protection a very interesting document worth noting is the Healthcare Databases Act:

- [http://zakonodaja.gov.si/rpsi/r09/predpis\\_ZAKO1419.html](http://zakonodaja.gov.si/rpsi/r09/predpis_ZAKO1419.html)

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#### 4 Regulatory framework for the healthcare profession

For a physician (doctor / dentist) to be an independent medical services practitioner it is compulsory to comply with the terms imposed by labour law and other regulations:

- [http://zakonodaja.gov.si/rpsi/kazala\\_podrocje/kazalo\\_10\\_1\\_0\\_0.html](http://zakonodaja.gov.si/rpsi/kazala_podrocje/kazalo_10_1_0_0.html),

as well as comply with specific requirements provided by the General Practitioners Services Act:

- ([http://zakonodaja.gov.si/rpsi/kazala\\_podrocje/kazalo\\_10\\_0\\_0\\_0.html](http://zakonodaja.gov.si/rpsi/kazala_podrocje/kazalo_10_0_0_0.html))

To summarise the regulatory framework is provided by the:

- General Practitioners Services Act
- Health Services Act
- Rules on the Register of Physicians
- Regulation on medical licences
- Rules on the types and curriculum of specialization of doctors
- Rules on the curriculum of secondment
- Preparatory training programme required for the profession of a physician
- Internship and professional examination curricula for the profession of a dentist

The core institution in respect of exercising the medical profession is the Medical chamber of Slovenia.

##### 4.1 Legal conditions for the practice of healthcare

A physician is first of all required to have **adequate professional qualifications and training**, needing a degree from the Medical faculty of a Slovenian University or an evidence on the official recognition of a foreign university degree, provided that he has also completed:

1. Dentist: to complete internship,
2. Specialist doctor: to complete medical specialisation,
3. Dental specialist: dental specialisation,

**For the recognition of a specialist title**, acquired abroad in another country of the the European Economic Area in principle mutual recognition applies. If this is not the case the candidate has to comply with the following conditions for the recognition of a specialist title:

1. completed studies at a medical faculty in the Republic of Slovenia or at a foreign medical faculty,
2. having passed specialist exam abroad,
3. having passed the professional exam in the Republic of Slovenia,
4. having completed the supplementary conditions or having acquired a favourable written opinion of an expert.
5. the candidate, to whom a decision on the recognition of qualification to practice the regulated profession of doctor or dentist was issued within the procedure of recognition under a special act, shall not need to pass the professional exam in the

**Study on Legal Framework of Interoperable eHealth in Europe**

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Republic of Slovenia.

Should there be no appropriate specialisation programme in Slovenia to make the comparison, the specialisation programme that is the most similar in contents to the one completed abroad will be used for these purposes. The comparison will be made by an expert. Should the expert estimate that the programme of specialisation completed abroad as well as possible work experience and additional knowledge do not meet the appropriate programme requirements, he/she can recommend that the candidate satisfies at least one of the following requirements:

1. emergency medicine exam or the exam on emergency states in stomatology,
2. a training of no less than three and no more than twelve months at an authorized institution,
3. aptitude test.
4. the chamber issues a decision on recognition of foreign specialist title to the candidate:

If noted that that the programme of specialisation completed abroad as well as possible work experience and additional knowledge in total meet the requirements of the appropriate specialisation programme that was used for comparison, or that the candidate's qualifications suffice for recognition of a foreign specialist title, when the candidate submits evidence on completing additional requirements to the Chamber.

Compulsory enclosures with the application are as follows:

1. request for recognition of foreign specialist title on the prescribed form,
2. evidence on completed studies at a medical faculty in the Republic of Slovenia or evidence on completed studies at a medical faculty within the former Yugoslav republics before 25 June 1991, or official recognition of a foreign medical university degree or a decision on equivalence of foreign title with the Slovenian professional title of doctor of medicine or doctor of dental medicine obtained within the procedure of recognition under a special act,
3. evidence that professional exam has been passed in the Republic of Slovenia,
4. translation of evidence for of specialisation completed abroad,
5. translation of the programme of specialisation completed abroad,
6. translation of curriculum vitae with a description of work experience and bibliography, validated by the employer.

Futher every practitioner must be fully registered with the Medical Chamber of Slovenia and have a valid licence of the Medical Chamber of Slovenia.

**Entry in the register** is made upon the request of a doctor, complying with the terms provided by the General Practitioners Services Act and the Rules on the Register of Physicians. The Chamber issues a decision for any register entry or removal within administrative procedures. A complaint about the register entry or removal can be lodged

**Study on Legal Framework of Interoperable eHealth in Europe**

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within 15 days of receipt of a written copy of the decision. The complaint, lodged with the Chamber, shall be adjudicated by the Ministry of Health.

To enter the register a doctor / dentist must submit a completed application to the Chamber. The doctor must attach the required documentation to prove his eligibility to enter the register, to be removed from the register a doctor / dentist must lodge a request for removal with explanation. Registration of an honorary member is executed on the basis of the decision to appoint the doctor.

All doctors who wish to provide medical services independently in The Republic of Slovenia must further **obtain the licence** according to the specifically prescribed procedure. The procedure of granting, extending and withdrawal of the licence is regulated by the Regulation on medical licences.

A national of a Member State of the European Economic Area or Switzerland, providing medical services within the area of a Member State of the European Economic Area or Switzerland and wishing to provide medical services in the Republic of Slovenia occasionally, may do so without obtaining the licence in compliance with the act regulating periodical and irregular providing of medical services. In this case the doctor has to be temporarily recorded in the Chamber's register after a prior notification to the Ministry of health, which can be filed electronically (Article 24a. Health Services Act).

A specialist doctor or specialist dentist, national of a Member State of the European Economic Area or Switzerland, shall gain qualification for independent practice if a decision on the recognition of qualification to practice the regulated profession of a specialist doctor or specialist dentist has been delivered in accordance with the regulations on the qualifications recognition procedure for nationals of Member States of the European Union for practicing regulated professions or regulated professional activities within the Republic of Slovenia.

Compulsory enclosures with the application are:

1. a signed membership application for the Medical Chamber of Slovenia,
2. the decision on the recognition of qualification to practice the regulated profession of a specialist doctor or specialist dentist, with enclosures, based on which the decision was issued; provide the original for inspection (the issue of the decision is under the authority of Ministry of Labour, Family and Social Affairs, Ljubljana, Kotnikova 5),
3. a certified translation of the evidence on clear criminal history record, not older than 3 months from the date of issue (issued by the ministry of justice in the country of residence or the competent court in the country of residence),
4. a certified translation of the evidence on good character and good repute, not older than 3 months from the date of issue (issued by the competent medical chamber or other competent authority),
5. curriculum vitae with an account of professional work and bibliography in Slovene.

## Study on Legal Framework of Interoperable eHealth in Europe

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Applications (<http://www.zzs-mcs.si/library/includes/file.asp?FileId=427>) must be submitted to the Medical Chamber of Slovenia, Department for legal and general procedures Dalmatinova 10 p. p. 1630 SI-1001 Ljubljana.

Another condition for the practice doctor is required to **use the Slovenian language** while practicing medical services and if working in a mixed bilingual area of Italian or Hungarian national minority, he /she also has to use the Italian or Hungarian language. Language knowledge is proven by a secondary school certificate or an educational institution certificate.

For third country nationals different rules apply, which are however not discussed in detail in this report.

### 4.2 Control over the practice of medicine

The practice of medicine in Slovenia is supervised by the Medical chamber, the Ministry of Health, HII. According to the Health Services Act also internal supervision is provided.

Consequently there are four different levels of control:

1. Internal control which is provided by the Institute where the practitioner is employed
2. Professional control of the Medical chamber
3. Administrative control provided by the Ministry of health and
4. contractual HII control in respect of insurances.

As far employment and use of language is concerned, control is exercising also by the Labour Inspectorate and Culture and Media Inspectorate.

The main supervision is on the Ministry of health and on the Medical chamber. The Ministry of health exercises control on compliance with the provisions of the General practitioners Services Act. Fines are provided for practicing without licence and/or registration. Professional control is exercised by the Medical Chamber on a public mandate provided by law. To this end it can be noted that the Medical Chamber adopts internal Acts which are mandatory to the practitioners and also exercises control over their compliance. In this process different sanctions are available, there are however no reliable data available on their enforcement.

### 4.3 Professional liability

Professional liability of a physician in Slovenia is not governed by special laws or regulations. Thus 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.

**Study on Legal Framework of Interoperable eHealth in Europe**

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Civil liability of a physicians originates either from a contract or from tort. It is widely accepted that a contractual relationship between the patient and the organisation exists, which would imply also contractual liability. However practically even in this case to impose liability (malpractice or failure to provide explanation or others) at least forms of negligence (or purpose) had to be substantiated, making it very similar to tort liability. Further it must be observed that liability of a practitioner will be assessed according to professional standards and duties of care.

As practitioners are mostly employees of Institutes (referring to the general overview of healthcare) a potential claim will be as a rule directed against the Institute and not directly against the practitioner. In this respect it should be noted that there are mandatory insurance requirements for practitioners who must insure their professional liability; thus in most cases the claim will be directed against insurance companies. Of course a direct claim against the practitioner is also possible in case of grave negligence or purpose (in this case also the Institute and/or insurance can claim for refundation if such a claim is granted).

**4.4 Professional secrecy**

Protection of confidences revealed by the patient to the physician is subjected to civil and criminal liability. Accordingly a breach of secrecy obligation can have civil, (in form of tort liability and/or termination of employment contract), administrative (license revocation - disabling the practitioner to perform services, fines as result of non-compliance with data protection requirements) but also criminal consequences. As far as the latter are concerned, Article 153 (Unlawful disclosure of professional secrecy) of the Slovenian Criminal code lays upon a physician a legal obligation not to disclose confidential information concerning a patient which he learns in the course of his professional practice. An additional remedy in case of breach of professional secrecy is provided by the recently adopted Patient's rights Act, referenced below. It is however rather doubtful that it will be deployed in a larger extent. Criminal liability is in this respect imposed only on physicians, whereas other forms of liability stated above can be imposed also on other healthcare workers providing services to the patient.

## 5 Processing of personal health data

### 5.1 Short overview of personal data protection legal framework

Personal data protection is in Slovenia governed mainly by the Personal Data Protection Act, governing the protection of personal data, together with general substantive provisions on processing of personal data. Another important document is the Information Commissioner Act transferring the competences of the supervisory authority to the Information commissioner. From 2004 the mentioned regulatory framework transposes the provisions of the European Directive 95/46/EC. It can be observed that the transposition is very literal in almost every definition and concept provided by the directive, however also some slovene specifics, deriving from its constitutional provision are also implemented.

Accordingly the Personal Data Protection Act regulates all following concepts of the Directive:

1. principles of data protection
2. criteria of legitimate data processing
3. special categories of data
4. access and information rights of data subjects
5. confidentiality and security
6. supervisory authority
7. duty of notification and supervision
8. transfer of data to third countries
9. codes of conduct

An interesting notion in respect of (also) health data processing is the exemption, provided by Article 12: According to that provision, if processing of personal data is necessarily required to protect the life or body of an individual, his personal data may be processed irrespective of the fact that there are no other statutory legal grounds for the processing of such data. Especially in cases of urgency this provision grants justification of on in itself illegal processing.

In respect of transfer of data to third countries rules on acquiring required information for the decision-making on the transfer of personal data to third countries must be observed ([http://zakonodaja.gov.si/rpsi/r08/predpis\\_PRAV6178.html](http://zakonodaja.gov.si/rpsi/r08/predpis_PRAV6178.html)).

In terms of healthcare related data the concepts of sensitive personal data, biometrics must be observed more closely as it is very likely that those, that they will have to be respected in every e-health project. Furthermore it shall be noted that in the public sector (to whom almost all of the major stakeholders belong) more strict rules on data processing apply (Article 9):

## 5.2 Transposition of article 8 of Directive 95/46/EC

Transposition of Article 8 of Directive 95/46/EC follows the following regulatory framework:

1. **Definition of sensitive personal data** - (Article 6, Personal data protection Act) are data on racial, national or ethnic origin, political, religious or philosophical beliefs, trade-union membership, health status, sexual life, the entry in or removal from criminal record or records of minor offences that are kept on the basis of a statute that regulates minor offences (hereinafter: minor offence records); biometric characteristics are also sensitive personal data if their use makes it possible to identify an individual in connection with any of the aforementioned circumstances.
2. **Processing of sensitive personal data** - (Article 6, Personal data protection Act) sensitive personal data may only be processed in the following cases:
  - a) if the individual has given explicit personal consent for this, such consent as a rule being in writing, and in the public sector provided by statute;
  - b) if the processing is necessary in order to fulfil the obligations and special rights of a data controller in the area of employment in accordance with statute, which also provides appropriate guarantees for the rights of the individual;
  - c) if the processing is necessarily required to protect the life or body of an individual to whom the personal data relate, or of another person, where the individual to whom the personal data relate is physically or contractually incapable of giving his consent
  - d) if they are processed for the purposes of lawful activities by institutions, societies, associations, religious communities, trade unions or other non-profit organisations with political, philosophical, religious or trade-union aim, but only if the processing concerns their members or individuals in regular contact with them in connection with such aims, and if they do not supply such data to other individuals or persons of public or private sector without the written consent of the individual to whom they relate;
  - e) if the individual to whom the sensitive personal data relate publicly announces them without any evident or explicit purpose of restricting their use;
  - f) **if they are processed by health-care workers and health-care staff in compliance with the law and for the purposes of protecting the health of the public and of individuals and the management or operation of health services;**
  - g) if this is necessary in order to assert or oppose a legal claim
  - h) if so provided by another statute in order to implement the public interest.

Notwithstanding technically a somewhat different legal approach (no general prohibition, however explicit legal requirements) the transposition of the Directive can be regarded as very literal. Exemptions such as a special framework for criminal records are provided by sector specific legislation.

Further exemptions are possible, however must be provided by law: to this end it should be noted that according to constitutional provisions but also practice of the Constitutional court a

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**Study on Legal Framework of Interoperable eHealth in Europe**

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law providing an exemption will have to substantiate a constitutionally valid reason for personal data protection, which is also a noteworthy observation in view of the understanding of the Slovene implementation.

**5.3 Information and access rights of data subjects**

Information and access rights are Constitutional rights. According to Para. 3 of Article 38 of the Slovene Constitution everyone has the right of access to the collected personal data that relate to him and the right to judicial protection in the event of abuse of such data.

Operational the rights are governed by Articles 30-33 of the Personal data protection Act. Accordingly the Data controller shall on request of the individual be obliged to the following:

1. to enable consultation of the filing system catalogue;
2. to certify whether data relating to him are being processed or not, and to enable him to consult personal data contained in filing system that relate to him, and to transcribe or copy them;
3. to supply him an extract of personal data contained in filing system that relate to him;
4. to provide a list of data recipients to whom personal data were supplied, when, on what basis and for what purpose;
5. to provide information on the sources on which records contained about the individual in a filing system are based, and on the method of processing.
6. to provide information on the purpose of processing and the type of personal data being processed, and all necessary explanations in this connection;
7. to explain technical and logical-technical procedures of decision-making, if the controller is performing automated decision-making through the processing of personal data of an individual.

The extract of personal data is subjected to a special lodging procedure with the data controller. Accordingly such request may be lodged once every three months, and in respect of personal data on video surveillance once a month. In specific cases (e.g. constant updating) also a shorter re-lodging period is possible.

The data controller must enable the individual to consult, transcribe, copy and obtain a certificate on personal data controlled in 15 days from the date of receipt of the request, or within the same interval to inform the individual in writing of the reasons why he will not enable consultation, transcription, copying or the issuing of a certificate. The data controller is obliged to supply the extract, list, explanation and/or information within 30 days from the date he received the request.

In principle costs are to be bared by the data controller, however in certain cases (certificate on related data, extract of data contained, list of recipients, information on sources, processing

**Study on Legal Framework of Interoperable eHealth in Europe**

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and procedures) also the data subject is obliged to pay the material costs of document production (thus only for information which is given in document) according to the Rules on the charging of expenses concerning the execution of the individual's right to acquaint himself with his own personal data.

**5.4 Other relevant rules regarding personal data protection**

In case of other relevant rules regarding personal data protection in healthcare the decisions and opinions of the Information Commissioner have to be noted. (<http://www.ip-rs.si/nc/varstvo-osebni-podatkov/iskalnik-po-odlocbah-in-mnenjih/odlocbe-in-mnenja-varstvo-osebni-podatkov/>). For now, there are 131 decisions and opinions published, dealing with very different and detailed issues of personal data protection in healthcare.

Notwithstanding that mostly the published documents are non-binding opinions on certain specific issues, they are very helpful and it is very likely that they will be consulted and followed in the process of healthcare projects. The overall scope of the decisions is broader than the aims of this report, however certain topics, which almost every eHealth project will have to resolve have to be underlined:

- access of parents to health data of their children
- access rights of relatives
- access of employers to health data of their employees
- access of insurance companies to health data of the insured
- collection, communication and storage of health data
- interchange of healthcare data between the stakeholders

Another interesting point in respect of other rules regarding personal data protection is that Public healthcare institutions are under part of the public sector and according to Article 9 of Personal data protection Act authorised to process personal data only if the processing of personal data and the personal data being processed are provided by statute. Statute may provide that certain personal data may only be processed on the basis of personal consent of the individual.

(It can be noted, that in one of the opinions the Information Commissioner explicitly stated that HII as a public body will have to provide statutory basis for the introduction of new functionalities on the HI card, referred to in chapter 7).

A somewhat less stricter approach can be observed in case of private practitioners: these are authorised to process personal data if the processing of personal data and the personal data being processed are provided by statute or if the individual whom the personal data relate to has given consent for specific purpose of processing.

**Study on Legal Framework of Interoperable eHealth in Europe**

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The distinction is legally of less importance, however and interesting point is that in the first place it is the duty of the controllers of personal data (Healthcare institutions or Private practitioners) and not of individual doctors to ensure that there is a legal basis or in case of Private practitioners potentially individual's consent for the collection and processing of personal data of all the patients being treated in specific institutions; according to a non binding opinion from the Information commissioner (<http://www.ip-rs.si/index.php?id=383>). Two interesting observations can be made in this respect: firstly it is in principle not the obligation of the very doctor providing medical treatment to ensure data protection rules are being followed, provided he is not a private practitioner at the same time and secondly individual doctors do not have authority to use freely the data of their patients (if their not their controllers as private practitioners).

A key document in respect of healthcare data processing and management is the Healthcare Databases Act (HDA), referenced below as it provides a general legal basis for the interconnection of various public registers in respect of collection and generation of health data of the individual. However only a limited scope of possibilities was put into practice.

## 6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the Act on Patients Rights of January 29, 2008.

### 6.1 Scope of the law

The law defines the basic rights of patients, their relatives and the respective duties of healthcare service providers. Further also new institutions are established and the procedures for the enforcement of rights are regulated. For better understanding the following definitions are to be noted:

- Patient means »a natural person who is ill or to whom healthcare services are provided, whether at his request or not«.
- Healthcare services are »services, provided to patients by healthcare service providers through its professionals«.
- Healthcare means »medical and other services in order to promote, determine, preserve, restore or improve, diagnose a patient's state by healthcare service providers«.
- An interesting point is that the law distinguishes between close relatives (persons with a familiar relations) and close persons (other persons, not related to the patient, who can claim a close relationship to the patient).

In respect of institutions the law establishes a special ombudsman for patients rights; according to the law the ombudsman is institutionally part of the »general« ombudsman, being one of his deputies, appointed by the ombudsman.

Further every healthcare service provider has to designate a person for resolving patients claims under the law.

On state level in this respect a special Commission for patients rights is established, including a president and 75 (!) members. The president has to fulfill conditions for a judge on an appellate court and is designated by the government, whereas members can be named by the minister for health from experts with a medical, legal and economic background, having at least 5 years of practice.

The enforcement procedure is as follows:

1. in case of unsatisfactory services a first claim has to be filed to the responsible person of the provider in 15 days from the alleged unsatisfactory service;
2. a complete claim (to this end the law is very formalistic) is examined in an oral examination
3. if after the oral examination an agreement on the dispute is achieved the case is closed; possible forms of dispute resolution include damages up to max. 300 EUR,

## Study on Legal Framework of Interoperable eHealth in Europe

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external expert control, acquisition of a second opinion, written apology, however also other forms are possible

4. if no agreement can be negotiated the case can be presented to the Commission for patients rights, which however basically has the same possibilities in resolving claims, it has however some additional competences in ordering external, financial and disciplinary control over the service providers. The procedure before the Commission is even more formalistic.

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 (Law of 29 April 1999) are also considered as health professionals.

### 6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is specified in Article 54 of the law. It defines the basic principles of cooperation of the patient by providing all relevant health information timely to the person exercising healthcare. There are no administrative sanctions to that (logical), however failure to provide those information would most likely exculpate the providers in a potential damages claim. A likely observation is that as the duty to co-operate is defined very broadly it could represent an argument for the provider in almost every dispute: the provider could always argue that the patient failed to provide relevant information in time.

### 6.3 Right to quality care – non-discrimination

High quality care, entails care in accordance with the prevailing standards as determined by the current state of science, secure care preserving deterioration of the patients status, but also includes fair and friendly treatment by the providers, together with religious support (Articles 11-13)

Every patient has the right to equal and non-discriminatory care. Children and groups with the need to special protection have to be treated with special care (Articles 7 and 8).

Perhaps this right is somewhat Slovenian-specific as queues in healthcare are regarded as a major practical (lack of practitioners and/or infrastructure) but also political problem (forms of corruption are often suggested as urgency is determined by the practitioner himself, leading to faster treatment). Consequently the law defines special rights of information in this respect. The main aim is to make the waiting queues more transparent (even a national waiting list is regulated).

#### **6.4 Right to free choice**

According to article 9 of the law, the patient has the right to freely choose his health professional and to change that choice, except for some restrictions in determined cases (e.g. urgency).

Every patient on the secondary or tertiary level has the right to obtain a second opinion to his medical status by another provider, however only once in respect of one service (illness).

#### **6.5 Rights related to information about the state of health**

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 has the right to cooperate and take part in the healing process. An exception to the duty to provide information is given if the physician assesses that information provision could lead to a deterioration of the patients' status or in case if the patient refuses to receive information. The obligation to inform is on the physician performing the service and cannot be delegated by a physician to nursing or paramedical personnel. Additionally the patient has the right to be informed specially on his status when he is released from treatment. The patient has also a special right to be informed about the costs of his treatment.

#### **6.6 Right to give consent**

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, on a prescribed form, prescribed by the minister for health. Exemptions are cases of urgency or cases where a person is incapable of expressing consent, provided that such service is not operative.

Patients have also the right to refuse or withdraw consent for any service. Revocation must be made on the prescribed form.

Every patient has the right to express his consent or refusal in case he will be incapable to express his will after the treatment. To this end every patient has also the right to nominate and/or exclude individuals having the right to decide on his further treatment.

The law contains rules to protect the rights of patients who are legally or factually not capable of exercising their rights as a patient. In the case of minor patients, the patient rights are exercised by the parents asserting authority over the minor or by the patient's guardians. The minor patient will be involved in exercising his rights, bearing in mind his age and level of maturity. Minor patients who are deemed capable of reasonably grasping their situation may exercise their rights on their own behalf.

**Study on Legal Framework of Interoperable eHealth in Europe**

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**6.7 Rights related to the patient's medical record**

The patient has the right to a medical record, carefully updated and safely stored by the health professional. Every health professional should keep a medical record about every patient to whom he provides healthcare services.

In respect of access to the medical record basically the same observations can be made as in case of general access to personal data, however the patient has some additional right in respect of inclusion of his comments, proposals and the information provided to him orally in his medical record.

The law also provides legal basis for an on-line access of the medical record via the HI card, if technically possible.

Rights of relatives and closers in respect of access are also regulated.

**6.8 Right to protection of privacy and intimacy**

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health; which is a more detailed definition of the general principles of the Personal data protection Act.

They have also a right to the protection of their intimacy. Not other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, without the patient's consent.

The law further defines also some key aspects of professional secrecy, does however not provide for additional remedies in this respect (e.g. administrative in form of fines).

**6.9 Right to representation in case of incompetence**

The law contains rules to protect the rights of patients who are legally or factually not capable of exercising their rights as a patient. In the case of minor patients, the patient rights are exercised by the parents asserting authority over the minor or by the patient's guardians. The minor patient will be involved in exercising his rights, bearing in mind his age and level of maturity. Minor patients who are deemed capable of reasonably grasping their situation may exercise their rights on their own behalf.

## **7 Identity management in the health sector**

As already referred to above key documents in respect of identity management are the Healthcare Databases Act (HDA) and the Health Care and Health Insurance Act (HCHIA). The HDA provides a general legal basis for almost any health data processing (comprising collection, communication, interchange, etc.) of the stakeholders, whereas the HCHIA further clarifies some key aspects of data collection, interchange and control. In terms of registers the HCHIA refers to the HDA. To this end it can be observed that the main aim of the HCHIA was the provision of legal basis for data processing by the HII, as the HDA only provided clear and explicit legal basis for the IHC, which is a separate legal entity, established mostly for research reasons.

### **7.1 Overview**

Though the HDA was implemented already in the year 2000 it is obviously a very technology neutral and modern law as it survived until now without any amendments. The HDA defines 75 different databases according pre-defined attributes with the IHP being their key processor. Two very interesting notions in this respect can be made: firstly the HDA provides legal basis for the interconnection of healthcare databases with the Central register of population (CRP - the interchange of data is in real time) and secondly the healthcare data processors (all the main stakeholders) have the right to deploy the HI card as a unified identifier in terms of data collection, processing and communication. Thus the HI card functions are twofold: on one side it defines the insurance status of the individual, whereas on the other side it functions as a medical data medium. According to the law both functions have to be strictly separated. It can be observed that the HI card is the key instrument of identity management in the health sector.

Just recently a project was introduced by the government, aiming at merging the HI card with the personal identity card. However the idea was met with great scepticism by the Information Commissioner as the Government failed to prove any risks analysis in terms of personal data protection was being made, but also failed to produce any relevant reasoning for the merge of such sensitive datasets and the consequent level of availability of such data to different controllers in the public but also private sector. Basically the main consideration of the Information Commissioner was, that an overview at least on the scope of accessible and on compliance with valid standards should be elaborated prior to a merge. Finally the project was set a bit aside.

The HDA provides the legal basis for the setup of the healthcare data interchange center, which is established as a part of the IHP. According to the law the interchange center in

## Study on Legal Framework of Interoperable eHealth in Europe

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principle could function as a crossroads bank for almost all health related data, however this was never put into practice.

The HDA further defines the main methodological principles of healthcare databases.

### 7.2 The HI Card

The health insurance (HI) card system was developed in 1996 and finally implemented in mid 2000. The HI card is a smart card with a bank card format without a photo of the bearer. The issuer of the HI card is HII. It is issued, free of charge, to every person upon the first regulation of the compulsory health insurance status in Slovenia. The card data are updated by the card holder autonomously, through the self-service terminals installed throughout the national territory.

As already referred to above, the HI card functions are twofold: it is an insurance rights holder on one and a media of healthcare data of the individual on the other side. As the latter the HI card can be regarded by the provisions HDA as the focal carrier of almost any healthcare data of the individual. It should be noted the both mentioned functions are technically and logically separated.

The data in the card chip, are protected against unauthorised access by being accessible only to the holders of health professional cards. A key observation of the system is, that relevant data are currently physically stored on the HI card, thus the card itself is the media of the holders rights.

The following information is printed visibly on the card: the national register number, name, date of birth and HI card number. The card number has no expiry date, it must be however reaffirmed by the holder in every three months.

The HI card interconnects to a certain level of services all users of the system: insurance holders, healthcare providers and health insurance companies. The HI card is not mandatory, however without the HI card all health services will be directly charged by the healthcare provider.

Today it can be observed that the HI card is often the second most important personal document, used and needed nearly as often as the personal ID.

Firstly its functionalities were limited almost only to the identification of the insurance status of the individual, thus identifying the scope of its rights deriving from compulsory and voluntary health insurance schemes. Afterwards gradually new functionalities were introduced with the inclusion of new datasets enabling identification of the chosen personal

## Study on Legal Framework of Interoperable eHealth in Europe

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physician and dentist and the on-line (and self service terminal) ordering of the European health insurance card and providing data on issued medication. Both functionalities somewhat improved the number of applications and ease of use.

Nevertheless it can be observed that the smart card approach to the HI card could include more services and/or datasets, which was also identified by all the major stakeholders. Thus a renovation of the HI card is in preparation with the main objective being to introduce a new card platform to allow upgrading and further development in addition to offering current functionalities, simplified procedures (including on-line services) and greater security, whilst ensuring a fluent transition.

As all required data is gradually made available on-line, the new health insurance card combined with the new health professional card will allow secure communication within the network and will gradually begin to serve merely as an access key to the data rather than a data storage medium. The new health insurance card will give the cardholder access to his or her own data stored on the servers while giving health professionals access to insurance and personal medical data (pursuant to the authorization agreed upon between the users of the system), through a PKI.

According to the available information of the HII the following functionalities of the HI card will be gradually introduced in subsequent stages of establishing on-line access:

1. electronic prescription,
2. insurance holder's access to his own health and insurance-related data,
3. access to analytical data for health insurance purposes,
4. other electronic health insurance documents.

### 7.3 Centre for Data Interchange

As already observed above the HI functions as the main identifier enabling access to different rights and/or data of the HI holder. At least in terms of social security (insurance information) it can be observed that interchange of data is provided through the reaffirmation of the HI card. In this respect the HI functions as a reference directory interconnecting mandatory and voluntary insurance information with basic personal information and thus (by automating information transfers between decentralised service providers: HII, Insurances Ministry of the interior as the controller of CRP) reaffirming data for a limited time period. However, a legal basis is provided only for the interconnection with the CRP, whereas in case of voluntary insurance information interchange is contractually based.

As it is explained above, the legal possibilities of the HI card go somewhat beyond its practical applicability, however certain data (chosen physician) are obviously also transferred

## Study on Legal Framework of Interoperable eHealth in Europe

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on the card from other service providers, presumably on contractual basis with the institutes and/or individual practitioners.

Though the HDA provides legal basis for the establishment of a "Center for data interchange", according to the law, as a separate entity of the IHP, comprising and interchanging almost all health related data (thus functioning as a crossroads bank) this was never put into practice. Consequently it can be noted that there is no crossroads bank in the main sense of a separate entity or directory automating information transfers.

### 7.4 Patient identifier

The HI card functions as the main patient identifier, as it is explained above. Due to the real time interconnection with the CRP, the patient basic personal data are always updated.

### 7.5 Authentication of healthcare professionals

Authentication of healthcare professionals is provided by the healthcare professional card (HPC). The HPC is a smart card with a 8kb microchip and bank card format without a photo. The holder identifies himself on a special card reader with a provided personal PIN. There are three types of reader used: integrated, non-integrated and portable; together there are 6733 readers used. A HPC is submitted to every healthcare worker interacting with patients and to certain insurance referents.

HPC is used in order to be able to read a personal HI card. The HI card can be accessed only if both cards are used at the same time through a special software.

As this is the case in the HI card, also the HPC card is in the process of renovation. Accordingly the new HPC will be used for identification and authentication of the health professional, ensuring secure communication and e-signing. The new health professional card fully retains the functionality of the current health professional card, while the certificates stored on it allow the additional functionality of on-line access to data stored in central databases and secure e-signing (e.g. issuing electronic prescriptions).

### 7.6 Exchange of health-related data

As already explained above (7.4.) exchange of health related data on a systematic level is automated only to a very limited extent. Mostly exchange of health related data in

**Study on Legal Framework of Interoperable eHealth in Europe**

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contractually based, with the HII, as the controller of the HI card being the central point of data collection and control.

## 8 Electronic prescription

As already explained above, there is no specific legal framework for electronic prescriptions existant. However general rules on prescriptions are governed mainly by the Rules on the classification, prescribing and dispensing of medicinal products for human use (<http://www.uradni-list.si/1/objava.jsp?urlid=200886&stevilka=3730>), explicitly state the possibility of electronic prescriptions in Article 22/3. Accordingly in respect of issuance of electronic prescriptions regulations on electronic commerce and rules on prescription must be respected. The rules do not contain any futher regulations or clarifications.

The prescription is defined as a public document prescribed by an authorised expert on behalf of which medicinal products can be issued to the individual. A prescription can be revolving (allowing more than one issuance of medicine - e.g. until revocation) or non-revolving (allowing only one issue). Futher there are four different types of prescription, depending on the medicine issued.

Accordingly a prescription covered (mainly or wholly) by mandatory insurance must be issued on a predefined formular provided by the HI, whereas a prescription not covered by mandatory insurance is issued on a predefined formular provided by the IHP.

In terms of form a prescription is comprised of the administrative part (containing information on the medicine, usre and physician) and the expert part containing a mandate to the issuer which medicine to issue and the instructions for use. At least the following informations are mandatory:

1. physicians name
2. pharmaceutical form and strenght of medicine
3. quantity experssed in form of original packages and units
4. use instructions
5. physicians signature and official stamp
6. physicians telephone number
7. stamp of the natural or legal person prescribing medicine in the process of healthcare service provision
8. date of prescriptions
9. name, year of birth, sex and adress of the patient
10. other data if so provided by law

Electronic commerce in general is regulated in Slovenia by the Electronic Commerce and Electronic Signature Act (referred to above). To this end it could be noted that the Slovene legislation doesn't have a special definition of the term **electronic document**, however the Electronic Commerce and Electronic Signature Act provides the definition of data in electronic form (Article 2, indent 1). According to the relevant provision data in electronic form are data designed, stored, sent, received or exchangeable electronically. This definition

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**Study on Legal Framework of Interoperable eHealth in Europe**

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clearly applies also to electronic documents, which could be described as a subgroup of data in electronic form, having some additional attributes in design. This is however only an doctrinal interpretation of the relevant provision, which is on the other side vast enough and also technology neutral. Up to date there is no knowledge of any specific jurisprudence in this respect.

As far as the **validity of electronic documents** in general is concerned Article 4 of the Electronic Commerce and Electronic Signature Act explicitly provides that data in electronic form may not be declared invalid or lacking in evidential value solely because they are in electronic form (principle of non-discrimination). Another provision in respect of validity is provided by paragraph 1 of Article 13 stating that where the law or other regulation requires a written form in order for a document to be legally valid, an electronic form shall be considered equivalent to the written form if the data in electronic form are accessible and appropriate for later use. There is no additional formal requirement to accessibility and appropriation for later use as far as the document type is concerned.

**Restrictions** to the acceptability of electronic documents are provided by Article 13/2. Accordingly certain contracts do not benefit from the above mentioned presumption of equivalence of the electronic form. Thus those types of contracts are de facto excluded from valid formation in electronic form. This restriction encircles contracts on legal transactions transferring ownership rights to real estate or establishing other material rights to real estate, testamentary transactions, contracts arranging property relations between spouses, contracts disposing of the assets of persons declared legally incapacitated, contracts on the handover and distribution of assets for life, endowment contracts and agreements on renunciation of inheritance, promises of gifts and gift contracts in the event of death, other legal transactions which the law stipulates must be concluded in the form of a notarised record. All of the above mentioned contracts require according to the law at least the written form in most cases however also an additional formal intervention of a public body (e.g. notary).

Further as far as electronic signatures are concerned Article 15 of the Electronic Commerce and Electronic Signature Act states that secure electronic signatures certified by a qualified certificate shall with regard to data in electronic form be equivalent to an autographic signature, and shall have the same validity and evidential value. Thus all types of contracts and/or documents for which the law requires being in writing, can be concluded also by electronic means, provided that they do not fall into one of the exclusions presented above.

According to the observations made above, it can be concluded, that no legal barriers to the introduction of electronic prescriptions can be identified. Clearly it is completely possible to issue an electronic prescription as it does not fall under the restrictions of the electronic form. To this end five guidelines must be followed:

1. the HI and/or the IHP must issue an according electronic formular
2. the formular must include all mandatory information and allow electronic signing

**Study on Legal Framework of Interoperable eHealth in Europe**

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3. the physician must have an electronic signature
4. the healthcare institute must have an own electronic signature (however it can be noted tha in pracitce one signature will be sufficient)
5. the issuer must be able to access the electronic prescription through the PKI.

## **9 General assessment**

As already explained throughout the report it can be observed that there are in fact very little legal barriers to the introduction of almost any electronic healthcare service in Slovenia as a very comprehensive legal framework in this respect is already functional. From a solely legal perspective introduction of new electronic healthcare services is to the major part "connecting the dots" of already known legal concepts.

However the practical implementation is lacking behind as only a limited scope of legal possibilities is put into practice. Nevertheless the strategic approach can be argued as a little confused and not perfectly defined it doubtlessly addresses all the major issues and thus is aimed in the right direction. A fact explaining a somewhat sluggish progress is perhaps the fact, that many different stakeholders from the public and private sector as well as the individual users are and must be involved and more importantly actively take part in the process of introducing new electronic services.

Klemen Tičar  
31. August 2008

## Annex: Contact details of National Correspondents

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