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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE LUXEMBOURG

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European Commission
Directorate General Information Society

Brussels

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1.1 Applicable Documents

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

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[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
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[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
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[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/

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

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 infections, 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.
- **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
HiT	Health in Transition

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OCSP ..... Online Certificate Status Protocol

PKI..... Public Key Infrastructure

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NRN..... National Register Number

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SIS..... Social (security) Information System

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SSCD ..... Secure Signature Creation Device

SSIN..... Social Security Identification Number

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TTP ..... Trusted Third Party

3 Introduction

3.1 General overview of the Luxembourg healthcare system

A comprehensive but not very recent (1999) overview of the Luxembourg healthcare system can be found in the HiT country report published by the European Observatory on Health Systems and Policies (written by Elizabeth Kerr):
http://www.euro.who.int/document/e67498.pdf (76 p.).

From this report , we reproduce the following important observations:
"The fundamental principles of the Luxembourg health system are 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. Services eligible for reimbursement are registered on lists adopted jointly by the Ministers of Health and Social Security. Hospital budgets are negotiated annually between each individual hospital and the Union of Sickness Funds. All such negotiations must be endorsed by the Minister of Social Security."
"Health professionals in Luxembourg are represented by two different types of professional groups:

- Groups which are the official interlocutors with the government on any changes to the law which may affect their members. It is a legal requirement for the government to consult these groups on any draft legislation. These groups basically consist of the Medical College which represents doctors, dentists and pharmacists; and the Superior Council of Certain Health Professions which represents all other health professionals.
- Individual professional associations, of which one has developed for every specialism – there is no legal requirement for the government to consult these groups individually on legal changes, but in practice it usually does."

"The supply of primary care in Luxembourg is dictated by demand, since patients have free choice of primary care provider and there is no legal means to limit the volume of medical activity. For that reason, it is hard for the state to plan. Nor (since European Union legislation introduced the mutual recognition of medical qualifications) is there any legal means to curb the flow of medical personnel into Luxembourg. To practice in Luxembourg, physicians

simply need approval of their (foreign) diploma by the Ministry of Health (if delivered in an EU member state) or by the Ministry of Education (if delivered in other countries) and an authorization from the Ministry of Health. Luxembourg's remuneration and licensing system is attractive, as a license to practice in Luxembourg means automatic access to remuneration by the compulsory health insurance system."

"The hospital sector in Luxembourg is regulated by the law on hospitals of 28 August 1998. Numbers of hospitals and minimum standards for hospital services are planned via regulations (the so-called National Hospital Plans) enacted under this law. Hospitals are administered by boards of administrators, who are responsible for the general policy of the hospital. Hospitals are independent of the state although there may be representatives of the state on some boards (if so, state representatives are usually in the minority). The financing of hospitals is drawn from two sources:

1. Each hospital negotiates its operating budget with the Union of Sickness Funds, without the direct interference of the state.
2. Major investment costs for construction and equipment are financed by the state at a rate of 80%. Significant new equipment has to be authorized by the Minister of Health."

"Doctors are paid on a fee-for-service basis (with the exception of a few doctors working in the neuro-psychiatric hospital, and the unique salary system of the Centre Hospitalier de Luxembourg). Doctors have to accept the fixed statutory fee levels; there is no distinction between doctors on the basis of whether they work from within hospitals or not. Having paid for ambulatory care, the insured patient is reimbursed most of the fee at the rate set by law, minus a proportion which is forfeited as a co-payment."

"All services given by health professionals are defined by the Ministers of Social Security and Health on the basis of detailed proposals from a board of experts (the Nomenclature Committee). They are set out in the two volumes of fee schedules or "nomenclatures" which are published each year; one volume covers the services given by doctors and dentists, and the second the services given by other health professionals. The "nomenclatures" set out the value of each service, and the fee level for that service is calculated by multiplying the value by a factor (the "standard fee") which is negotiated each year between the Union of Sickness Funds and the organizations representing health professionals. The state maintains a comprehensive list of drugs approved for use in Luxembourg and the cost of most drugs on the list is 80% reimbursed by the sickness funds. However, drugs used for the treatment of specified long-term or serious illnesses are 100% reimbursed, drugs classed as for "comfort purposes" are reimbursed at 40%, and others are not reimbursed. Drugs administered during hospital treatment do not fall within the above system, but are charged to hospital budgets."

"As a proportion of total benefits reimbursed, voluntary health insurance has always been limited as the compulsory public system reimburses so many services. The main Luxembourg-based voluntary health insurance scheme is the Caisse Médico-Chirurgicale Mutualiste ("Mutual Medico-Surgical Fund") or "CMCM".

"The Directorate of Health maintains a comprehensive list of drugs approved for use in Luxembourg. The list displays the retail price of each drug, and the percentage of its price

which will be reimbursed by the sickness funds (as long as the drug is medically prescribed). Patients present their medical prescription and their insurance card and pay the non-reimbursable percentage of the drug cost (i.e. in most cases 20% of retail price) at a pharmacy in order to obtain their medicines. The pharmacy takes the prescription as proof of advance medical authorization, and also uses it as documentation when claiming back the rest of the drug cost from the Union of Sickness Funds. Drugs administered during a visit to a doctor or during hospital treatment do not fall within the above system; they are respectively claimed back by doctors or charged to hospital budgets. Hospitals base their drug budgets on the retail prices quoted by the state list."
"Generally, the main internal challenge facing the Luxembourg health system in future is the need to take on board the modern tools of evaluation and cost containment and tailor them to complement the principal characteristics of the current system."
"However, other challenges have resulted from external factors, and these will also need to be addressed. In particular, the "Decker and Kohll " judgments of the European Court of Justice have special significance for Luxembourg. In Luxembourg, people are already used to seeking goods and services in different member states which may only be half an hour's drive away. The Decker and Kohll judgments encourage them to treat health care no differently from other goods and services. Yet the impact for the sickness funds will probably be manageable as long as the judgments apply only to ambulatory health care services, not to inpatient care. If (as is thought likely) the principle of the judgments is extended via a further court case to cover inpatient care, the implications for the system will be more significant."

3.2 Use of ICT in the Luxembourg healthcare sector

There are no recent and reliable data on the use of ICT by Luxembourg specialists, hospitals or pharmacies. A recent (2007) status of the use of ICT by *general practitioners* in Luxembourg 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
From the Luxembourg country brief, we take over the following key findings:
"In comparison to the other EU Member States, Luxembourg represents one of the weaker average performers.. This concerns especially the use of ICT for different eHealth-related purposes."
"In terms of infrastructure, Luxembourg displays a slightly unusual picture: while use rates for computer and Internet stay at a comparatively low level (80% and 64% respectively, both figures being situated below EU27 averages), broadband connections are quite common."
"When it comes to the use of eHealth solutions, Luxembourg displays its best results in the areas of administrative and medical data storage as well as with relation to the use of a computer for consultation purposes: 70% of the GP practices store administrative patient data, 65% store at least one type of medical patient data and 59% use a computer for consultation purposes. For all three of these indicators Luxembourg however still stays behind the EU averages."

"The electronic transfer of individual patient data has not yet arrived on the agenda of GPs in Luxembourg. Not a single Luxembourgish GP practice exchanges electronic administrative data via networked connections; neither with other carers nor with reimbursers. The exchange of medical data via networked connections is equally little prevalent: no GP practice uses networks in order to exchange electronic medical data with other care providers. However, already one out of four of the GP practices participating in the survey receives laboratory results via network connections."

3.3 National eHealth strategy

An overview of the eHealth policy in Luxembourg can be found in the March 2007 ERA Fact Sheet: http://www.ehealth-era.org/database/documents/factsheets/Luxembourg.pdf

The Fact Sheet mentions e.g. what follows:
In July 2005,the Ministry of Health set up a national eHealth Working Group. Their work concluded with a proposed eHealth action plan report in July 2006.Three months later, the Government Council approved the eHealth proposal and published the key policy intentions and strategic targets for the eHealth. domain:

The objectives of this plan were defined as follows:

- Ensure a better accessibility to data regarding the health of the citizens;
- Avoid superfluous examinations and redundant analyses via a better exchange of data between health professionals;
- Promote transparency of the costs of health services and the available alternative treatments;;
- Ensure the interoperability of the Luxembourg healthcare system with those of other countries.

To implement these objectives the action plan proposes to take the following measures:

- Create an online platform for healthcare professionals;
- Provide secure exchange of health data;
- Introduce electronic prescription in order to increase the security of prescriptions; i
- Manage the access to health data by means of a health card for patients and a card for professionals;
- Create an electronic record containing the essential health data of the citizen;
- Making use of ICT for the follow-up of the health status of children and youth;
- Establish a health portal in order to inform and guide the citizens in the health sector, with the aim to gradually evolve towards an interactive access to certain health services provided via the Internet; see further details at: http://www.eluxembourg.public.lu/eLuxembourg/projets/portail_sante/index.html
- Introduce electronic invoicing in the health sector.

One of the first initiatives has been the consolidation of the already existing secure eHealth platform, called "Healthnet": http://www.healthnet.lu/. This project has already been started in 1995. Its objective is to develop a technical infrastructure allowing HealthCare professionals to safely communicate, to offer basic services like professional electronic mail, medical databases, secure access to Internet,... and to help the professionals working in

HealthCare to integrate or to develop specialized applications in the areas of teleradiology, laboratory results exchange, telepathology, ...

The network basically sets up on leased lines, ISDN or DSL connections (via VPN), according to the required bandwidth and the needs of the participants. Today all the hospitals of the Grand Duchy, some laboratories and around 200 physicians are connected to HealthNet, as well as the health insurance, the Entente des Hôpitaux (the organization representing all the hospitals) and the Ministry of Health. The complete list is published at: http://www.healthnet.lu/institutions

Besides the basic communications services (secure Internet access, e-mail (SMTP + Lotus Notes) and some e-government services (on-line social security affiliation control, transfer of accounting data to the social security administration), the list of value-added applications available via Healthnet is growing. It currently comprises e.g.:

- Exchange of laboratory data (Labo): An XML solution has been implemented which defines the data structure we use to exchange the data. All communications are encrypted and signed with the Internet Standard S/MIME. Therefore a Certification Authority (CA) has been established. The laboratories communicate with the central server via FTP. The central server stores these results until the doctors fetch the data via FTP.

  The solution has been implemented by a series of partners into their software products : Clinique Sainte Thérèse (CST), Hôpital du Kirchberg (HKB), Laboratoires Ketter-Thill, Laboratoires Kutter-Lieners-Hastert, Micromed SA, SIMS Solutions. Micromed S.A. has also developped free software which allows the doctors to retrieve their results from the central server. Additionally, the CRP Henri Tudor has developed a free JAVA based viewer which works on Linux, Macintosh and Windows systems. Every doctor can download this software freely from the Internet, submit a registration form to the GIE Healthnet administration and start to work with Labo.

- Carnet Radiologique: a radiological record in electronic form which contains the history of the radiological examinations of each patient. As a precursor of the electronic medical record, this radiological record will be accessible by the physicians who prescriber a radiological examination. The doctors will able to view, in his office and via Healthnet, the patient's history and his examination's results (report, radiological images) to order a new radiological examination. The record contains all the examinations using ionizing radiations (x-ray, nuclear medicine) and non-ionizing (ultrasounds, nuclear magnetic resonance).

- Oncology Patient Management and Administration System (OCPAS): this project will produce a virtual cancer centre for all oncology departments in Luxembourg. The project has been initiated by the FLCC - Fondation Luxembourgeoise Contre le

Cancer. SANTEC (http://santec.tudor.lu/) has taken over the technical implementation in the HealthNet Luxembourg network infrastructure and the integration of the different hospital information systems.Several hospitals are participating in the project, such as: the Clinique Ste Thérèse (CST), the Centre Hospitalier de Luxembourg (CHL), the Hôpital de la Ville d'Esch-sur-Alzette (HVEA), the Clinique St Louis (CSL), the Centre National de Radiothérapie François Baclesse (CFB) and the Laboratoire National de la Santé (LNS). Some of the objectives of the project are: the creation of an electronic national oncology patient record, usage of the system for the medical prescription, calculation of chemotherapy protocols, exchange of medical patient data, documentation of the chemotherapeutic protocols, production of national statistics regarding the treatment and support for research in this field

3.4 Regulatory framework for patients' summaries

Luxembourg doesn't have legal provisions in the area of patients' summaries. Patients have the possibility to conclude an "adhesion contract" designating a physician or a specialist to keep his or her general medical file.

3.5 Regulatory framework for telemedicine

There are no specific provisions in Luxembourg with regard to telemedicine. On the other hand, there doesn't seem to be major legal obstacles to practice telemedicine in Luxembourg. The scarce legal literature about telemedicine in Luxembourg refers mainly to the application of personal data protection law and to the absence of any reference to telemedicine in the "Nomenclature" of medical acts recognized for social security reimbursement. .

3.6 Regulatory framework for electronic prescriptions

No specific legal framework exists for electronic prescriptions. 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.

4 Regulatory framework for the healthcare profession

The main legal texts constituting the regulatory framework for the healthcare profession in Luxembourg are:

- The Grand-Ducal Regulation of 10 June 1997 fixing the procedure to follow in order to obtain the authorisation to exercise the profession of physician and dentist http://www.legilux.public.lu/leg/a/archives/1997/0463006/0463006.pdf?SID=d87fb1c11a903e7a4aeda7ee2cdccff7#page=13

- Consolidated text of 10 October 1995 of the law of 29 April 1983 concerning the exercise the professions of physician, dentist and veterinary http://www.legilux.public.lu/leg/a/archives/1995/0720609/0720609.pdf?SID=369a2aed577693ab47ce6edcbe83a31a#page=2

- Law of 28 August 1998 on hospitals http://www.legilux.public.lu/leg/a/archives/1998/0781809/0781809.pdf?SID=d5c926fb3cb98addd8806c2a4593d2cc#page=2

- Grand-Ducal Regulation of 13 February 2004 amending the Regulation of 10 June 1997 fixing the list of medical specialties recognized in Luxembourg and establishing the conditions for recognition of these titles. http://www.legilux.public.lu/leg/a/archives/2004/0232702/0232702.pdf?SID=a8743189c24e7588c338987661f8c902#page=5

- Grand-Ducal Regulation of 22 June 2001 fixing the homologation criteria of titles and degrees in medicine. http://www.legilux.public.lu/leg/a/archives/2001/0831807/0831807.pdf?SID=0d83faf3b93b1a9a1b19fc5a9d4e2ba3#page=2

- Law of 31 July 1991 determining the conditions for authorization to exercise the profession of pharmacist. http://www.legilux.public.lu/leg/a/archives/1991/0602908/0602908.pdf?SID=86cb4a554b7abdd994b6496fdff9cdda#page=2

- Grand-Ducal Regulation of 10 August 1992 fixing the procedure to follow in order to obtain authorization to exercise the profession of pharmacist. http://www.legilux.public.lu/leg/a/archives/1992/0611408/0611408.pdf?SID=772bce4975c50635e733f0ba533116f4#page=10

- Law of 4 July 1973 concerning the regulation of the pharmacy

  http://www.legilux.public.lu/leg/a/archives/1973/0432807/0432807.pdf?SID=6c5eb2b25114a6ee71d55973e70711e1#page=4

4.1 Legal conditions for the practice of healthcare

For the practice of medicine or dentistry in Luxembourg one needs an authorization of the Minister of Health. The authorization is granted if the following conditions are fulfilled: a) being a citizen of Luxembourg or from another EU Member State; b) having obtained the diploma required by the laws of Luxembourg or by the European directives and c) submitting certificates of morality and honorability and of good physical and psychological health. The Minister can also grant an authorization to citizens of countries outside the EU but these citizens will have to fulfill additional requirements such as knowledge of at least two of the official national languages. Applications for authorization have to be submitted first to the Medical College for advice.

A citizen of a Member State of the EU established in a Member State of the EU and exercising legally the medical profession in that Member State under the social security regime of that Member State is allowed to provide medical services on the territory of Luxembourg without authorization of the Minister of Health (art. 4 of the law of 31 July 1995).

The law of 1995 further regulates the authorized titles under which medicine can be practiced in Luxembourg. Under certain conditions a foreign practitioner can exercise his profession in Luxembourg under the title acquired abroad but this is subject to an authorization of the Minister of Health granted after advice of the Medical College.

Medical practitioners further need to guarantee the continuity of care for their patients. They need to have the necessary linguistic skills to practice in Luxembourg and acquire sufficient knowledge of the relevant health legislation and the code of medical deontology.

4.2 Control over the practice of medicine

The practice of medicine in Luxembourg is supervised by the Medical College (http://www.collegemedical.lu/Default.htm). The Medical College is in charge of the application of the Code of Medical Deontology. Contrary to many other EU Member States this Code is integrated in a Ministerial Order (of 7 July 2005) and therefore legally binding. It contains rules concerning the general duties of physicians, the relation between physicians and patients, relations between physicians and between physicians and other health professionals, replacements, provisions on experiments with human beings, medical controls, etc.

4.3 Professional liability

Professional liability of a physician is, with the exception of disciplinary liability, currently not governed by special laws in Luxembourg. 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. Non-contractual or tortuous 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.

4.4 Professional secrecy

One of the most important legal obligations owed by a physician to a patient is the protection of confidences revealed by the patient to the physician. Article 458 of the 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.
The obligation of non-disclosure applies not only to information acquired directly from the patient, but also to information concerning the patient which the doctor learns from other sources.
The duty of medical secrecy is not limited to physicians who are providing healthcare to the patient. A physician who medically investigates a person at the request of an employer or an insurance company, is also bound by the duty, although he may inform in such a case the employer or the insurer within the limits of his mission.
Article 458 of the Criminal Code has a large field of application and not only applies to physicians alone but to everyone who, in the course of his professional practice, is being informed of confidential information. Therefore it is generally accepted that not only physicians but also nursing and paramedical personnel are bound to a duty of secrecy.
Because all the members of a medical team are obliged to respect the confidentiality of the patient's information, one accepts that this information may circulate within the team (so-called "shared medical secret").

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

The Law of 2 August 2002 on the Protection of Persons with regard to the Processing of Personal Data has been modified by Laws of 31 July 2006, 22 December 2006 and 27 July 2007.

Generally speaking there is almost literal parallelism between this law and the European Directive with regard to:

- the definitions of the essential concepts: personal data, processing, controller, processor, third party, recipient and consent (art. 2 of the Directive); the Luxembourg legislator has added definitions of e.g. "health data" ("any information about the data subject's physical or mental state, including genetic information"), "medical authority" ("any health practitioner and any person subject to the same professional secrecy obligation as well as any hospital covered by the Law of 28 August 1998 on hospitals, carrying out the data processing necessary for the purpose of preventative medicine, medical diagnosis, provision of care or treatment, or health service management"),
- the rules regarding data quality (art. 6 of the Directive);
- the criteria for making personal data processing legitimate (art. 7 of the Directive);
- the information to be given by the controller to the data subject (art. 10-11 of the Directive);
- the data subject's rights (art. 12, 14 and 15 of the Directive) although the Luxembourg legislation added a specific provision on access to health data (see further);
- the provisions with regard to confidentiality and security of processing (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive); art. 12 of the Luxembourg law contains conditional exemptions on the obligation to notify for physicians, hospitals, pharmacists and other health professionals;
- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: more details about the Luxembourg National Commission for Data Protection (Commission nationale pour la protection des données) can be read at http://www.cnpd.lu .
- liability for damages as a result of unlawful processing (art. 23 of the Directive);
- transfer of personal data to third countries, outside the EU (art. 25-26 of the Directive).

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

Art. 6 of the Luxembourg law regulates the processing of special categories of data and is formulated as follows:

"(1) Processing operations that reveal racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, and the processing of data concerning health or sex life, including the processing of genetic data, are forbidden.

(2) Paragraph (1) will not apply where:

(a) the data subject gave his "express" consent to such processing, subject to the inalienability of the human body and unless forbidden by law, or where

(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 authorised by law, 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 with the consent of the data subject by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade union aim in the course of its legitimate activities and on condition that the processing relates to the necessary data solely of members of that body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed to third parties without the consent of the data subjects; or if

(e) the processing relates to data that have been clearly made public by the data subject, or

(f) the processing (…) is necessary to acknowledge, exercise or defend a right at law (…), or if

(g) the processing is necessary in the public interest for historical, statistical or scientific reasons without prejudice to Article 7 hereafter (…), or if

(h) the processing is implemented via a Luxembourg regulation as stated in Article 17, or if"

(i) the processing is implemented in the context of the processing of legal data within the meaning of Article 8."

(…)

(3) Nevertheless, (…) genetic data may be processed only:

(a) to verify the existence of a genetic link for the purpose of legal proof, for compensation of the data subject, or the prevention or punishment of a specific criminal offence in the cases covered by paragraph (2) letters (f), (h) and (i) of this Article, or

(b) in the case covered by paragraph (2) letter (c) of this Article if the processing is necessary to protect the vital interests, or

(c) in the case covered by paragraph (2) letter (g) of this Article if the processing is necessary in the public interest for historical, statistical or scientific reasons, or

(d) in the case covered by Article 7, paragraph (2) of this Law if the data subject has given his consent and if the processing is carried out only in the area of healthcare or scientific research subject to the inalienability of the human body and except where the law provides that the prohibition stated in paragraph (1) cannot not lifted by the data subject's consent.
In cases where the law allows the prohibition to be lifted by the data subject's consent but for practical reasons it proves to be impossible to obtain consent or disproportionate to the objective sought and without prejudice to the right of opposition on the part of the data subject, the requirement to obtain prior consent may be overridden, subject to conditions to be laid down in a Luxembourg regulation, or

(e) in the case covered by Article 7, paragraph (1) of this Law if the processing of genetic data is necessary for the purpose of preventive medicine, medical diagnosis or the provision of care or treatment. In this case the processing of this data may only be carried out by the medical authorities."

(4) Any party who carries out a processing operation or notifies a third party in violation of the provisions of the aforementioned paragraph (1) is liable to a prison sentence of between eight days and one year and a fine of between 251 and 125,000 euros or just one of these penalties. The court hearing the case may order the discontinuance of processing or communication that are contrary to the provisions of paragraph 1 of this Article, subject to a financial penalty the maximum amount of which will be set by the said court.

Article 7 of the Law adds the following provisions on the processing of specific categories of data by the health services:

"Without prejudice to application of Article 6, paragraph (3) concerning the processing of genetic data:

(1) The processing of data on health and sex life necessary for the purpose of preventative medicine, medical diagnosis or the provision of care or treatment may be carried out by the medical authorities.

(2) The processing of data on health and sex life necessary for the purpose of healthcare or scientific research may be carried out by the medical authorities, or by the research bodies or the natural or legal persons whose research project has been approved under the legislation applicable to biomedical research. If the controller is a legal entity, it shall indicate a delegated controller, who shall be subject to professional secrecy.

(3) The processing of data on health and sex life necessary for the management of healthcare services may be carried out by the medical authorities or, if the controller is subject to professional secrecy, by social security bodies and authorities that manage the said data in performance of their legal and regulatory tasks, by insurance companies, pension fund management companies, the *Caisse Médico-Chirurgicale Mutualiste* and by those natural or legal persons authorised to do so for socio-medical or therapeutic reasons under the Law of 8 September 1998 governing relations between the State and the bodies working in the areas of social security, family and therapeutic matters where their activity falls with the areas to be listed in a Luxembourg regulation.

(4) The processing may be sub-contracted subject to the conditions laid down in Article 21.

Provided their processing is in itself lawful as stated in Articles 6 and 7, the data covered therein may be notified to third parties or used for research purposes in accordance with terms and subject to conditions to be determined by Luxembourg regulations.

The providers of care and suppliers may communicate the data concerning their services to the general practitioner and to a social security body or to the *Caisse Médico-Chirurgicale Mutualiste* for the purpose of repayment of the corresponding expenditure.

(5) Any party who carries out processing or operates a communication to a third party in violation of the provisions of this Article will be liable to a prison sentence of between eight days and one year and a fine of between 251 and 125,000 euros or just one of these penalties. The court hearing the case may order the discontinuance of processing or notification that is contrary to the provisions of this Article, subject to a financial penalty the maximum amount of which will be set by the said court

The following comments can be made with regard to these articles of the Luxembourg law:

- The definition of “health data” in the Luxembourg law includes genetic data but the law contains specific provisions for this latter subset of health data;
- There is no general provision imposing that processing of health data necessarily implies the intervention of a health professional. Such intervention is, for example, not necessary if there health data are processed on the basis of express consent;

- There is no legal obligation to collect the health data directly from the person concerned; this principle (from the Council of Europe recommendation) has not been included in the data protection law of Luxembourg;

5.3 Information and access rights of data subjects

Art. 28 of the Luxembourg data protection law adds a specific provision on the right of the data subject to access personal data concerning his health.

"(3) Patients have the right of access to data on them. The right of access will be exercised by the patient himself or through a doctor he appoints. In the event of the patient's death, his non legally separated spouse and his children as well as any other person who at the time of the death has lived with him in his household, or in the case of minors, his father and mother, may exercise the right of access as stated in the previous paragraph through a doctor they have appointed.

The patient's right of access may still be exercised during the lifetime of a person under guardianship or trusteeship as set forth under the Law of 11 August 1982 though a doctor appointed by his guardian or trustee."

Article 29 adds:

"(2) In the event that there is obviously no risk of breaching the privacy of a data subject, the controller may limit the right of access when the data are being processed solely for the purposes of scientific research, or are stored in data form for a period not exceeding that necessary for the sole purpose of establishing statistics, and the said data cannot be used for the purpose of taking a measure or a decision relating to specific persons."

6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the Law on hospitals of 28 August 1998 and in the Code of medical deontology (Code de déontologie médicale). In Luxembourg the code of medical deontology is integrated in a Ministerial Order of 7 July 2005 and consequently legally binding

6.1 Scope

The Code of medical deontology is applicable to physicians and dentists providing services on the territory of the Grand-Duchy of Luxembourg and included in the official register of the profession. It is also applicable to foreign professionals who provide services in Luxembourg. Independent as well as salaried professionals are within the scope of the Code.

6.2 General duties of physicians and dentists

The Code contains provisions with regard to e.g. the following general duties:

- Professional secrecy: prohibition to share medical information with third persons; obligation to ensure respect of professional secrecy by all persons assisting the physician or dentist; certificates have to be delivered to the patient (and not directly to a third person or a public authority); the Code explicitly mentions the notion of "shared medical secret" between professionals working together in a medical team (art. 76 of the Code);
- Professional independence: duty to exercise the profession in an independent manner; the Code regulates more in detail the categories of remuneration which are permitted or prohibited to be received by physicians or dentists;
- Free choice: physicians and dentists should respect and facilitate the freedom of the patient to choose his/her health service provider;
- Non-discrimination between patients according to their condition: prohibition to discriminate between patients taking into account their race, religion, ideology, nationality, income, sexual orientation, etc.
- Freedom of prescription: physicians and dentists are free to prescribe but should limit their prescriptions to what is necessary for the quality, the security and the effectiveness of the treatment;
- Non-commercial nature of medical practice: physicians and dentists should avoid to exercise their profession as a commerce; all forms of advertising are prohibited; the Code describes how professionals should behave if they are contacted by the media or participating in an action of an event for the promotion of public health;
- Accepted professional information towards patients: the Code contains a list of items permitted to mention on the entrance signboard, the letterhead, a press communication announcing the opening of a new practice, etc.

- Professional information via Internet websites: the Code enumerates the items permitted to be published on the website of a medical practice; all forms of advertisement are prohibited; interactive procedures, such as making an appointment, a medical consultation or request a prescription are only allowed under the condition that the connection has been adequately secured;
- Organization of the medical practice: physicians should provide their services in a fixed and adequately equipment location; it is forbidden to establish a medical practice in a commercial location (e.g. a shopping mall); it is prohibited for a physician to install, even on a temporary basis, a colleague in his/her practice, except in the context of a group practice (based on a written contract) or in the context of a regular replacement;
- Prohibition to collude with peers: it is prohibited to conclude agreements between physicians in particular about sharing fees; fee sharing between physicians working together in group practices are only allowed if based on written contracts; to collude between physicians and other healthcare providers is forbidden, in particular between physicians and pharmacists.
- Restrictions to associate: associations between professionals of the same specialty are allowed; it is forbidden to associate with colleagues having another specialty; draft association contracts have to be submitted first to the Medical College; the Code contains a list of items to be included in association contracts.

6.3 Rights related to information

A patient has the right to receive from the health professional all relevant information necessary to assess his state of health and his prognosis. The Law on hospitals contains also a provision about the duty to inform the patient about the identity of the professionals with whom he/she is in contact during the treatment (art. 45). 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").

6.4 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, except when the health professional, after having adequately informed the patient, can reasonably infer consent from the patient's behavior; 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.

6.5 Rights related to the patient's medical file

As far as the obligation to keep a medical file for every patient is concerned, the Code of medical deontology refers to article 36 of the Law of 28 August1998 on hospitals. This article lists in general terms the type of information which should be included in the medical file.
The format of the medical file can be established in a model fixed in a Grand-Ducal Order.
The file should be stored during 10 years by the physician or the hospital.
The medical file should contain the information in chronological order. Information shouldn't be deleted or amended.
Every patient has a right to access his/her medical file. A patient has the right to receive a copy of his/her medical file or to consult the medical file at the premises of the hospital or the physician's practice.

6.6 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. 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 (art. 38 of the Law on hospitals)

6.7 Right to representation in case of incompetence

The Code 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

A co-ordinated identity management system for the healthcare sector including the identities of patients, healthcare professionals and other stakeholders is not yet available in Luxembourg. A dedicated identity management system exists however in the framework of Healthnet (www.healthnet.lu).
In the future the identity management for the health sector will probably make use of the general solution under development for e-Government services. The information in this chapter is based on our IDABC-report referenced under [RD9].

7.1 Overview

Luxembourg has a centralised identity infrastructure in the form of a general directory (repertoire general) containing identity information for all natural and legal persons registered in Luxembourg, along with a system of unique identifiers for these entities. In addition to this, Luxembourg has had a system of mandatory ID cards for citizens over the age of 15 since 1939. However, there is no central e-ID infrastructure in Luxembourg yet, nor are there specific plans for the establishment of a national electronic ID card in the near future.
From a policy perspective, the creation of LuxTrust S.A. as a public-private partnership involving i.a. the Luxembourg government and the Luxembourg Chambers of Commerce has been a major step. LuxTrust has been created in 2003 to manage the development of a common Public Key Infrastructure (PKI) in order to secure eCommerce and eGovernment in Luxembourg. LuxTrust has presented in July 2006 the consortium which was awarded the contract concerning the setting up of a PKI.
LuxTrust smartcards hold two certificates together with their respective private keys. One is exclusively used for authentication and the second, exclusively for signature. These smartcards are used along with a smartcard reader, which requires PIN input before the user can access his private keys. The principle of two certificates guarantees that the user does not carry out an electronic signature with legal validity by mistake. LuxTrust smartcards will be integrated in Luxembourg eGovernment projects in the future, and are expected to become a de facto standard for on-line eGovernment applications.
LuxTrust offers also signing server certificates. Within this solution, the user's certificate is stored on a secured server and both the certificate and its private key can only be accessed by him. The user can access this server and its relative certificate in two different ways; he can either choose the LuxTrust token solution, which generates new access codes every thirty seconds and, used in combination with his personal password, enables him to access his private key on that server. As long as the user keeps this device with him and does not reveal his personal password to any other person, he will be the only one with access to his private key. The user can also opt for the SMS solution whereby an SMS is automatically generated and sent to his mobile phone each time he wishes to login to an application. This SMS combined with his personal password enables him to access his private key on the server.

At the time of writing, it is not envisaged that LuxTrust provides qualified certificates in the short term.
However, all procedures that have been put in place as well as policies (Certificate Policy and Certification Practices Statement) have been developed to allow for an easy but costly adaptation to the level required by Qualified Certificates if needed.

Luxembourg has actually created a legal framework for the identification of natural and legal persons
by using unique identifiers as early as 1979, through the Act of 30 March 1979 organizing the unique identification of natural and legal persons[6]. This resulted in the aforementioned system of
the *repertoire general* and the unique identification numbers for natural and legal persons.
In practice however, these numbers are not (yet) systematically used for electronic identification in e-Government applications.

Natural persons of the Luxembourg nationality over the age of 15 receive a mandatory identity card, issued by the communes since the entry into force of the Grand-Ducal Decree of 30 August 19395; or in the case of non-nationals mandated to reside in Luxembourg for more than three months, a foreigner's card. These cards include a basic set of identification information, including the identification number, a card number, the issuing commune number, a check digit, the name, first name, nationality, gender, date and place of birth of the bearer, and the issuing commune. This information must be filled out by the mayor or his representative, who signs the document and provides it with the commune seal. Married women may elect to include their husband's name. The card is in principle valid for 10 years, unless it must be revoked for other reasons (including e.g. change of domicile).

7.2 Health Insurance Card

Since 1 July 2004 Luxembourg has started the distribution of the European Health Insurance Card. The card has a national side (front) and a European side (back). The European is compliant with the model defined at the EU level. See further: http://ec.europa.eu/employment_social/healthcard/index_en.htm and (for Luxembourg in particular): http://www.secu.lu/carte_europenne/explications.htm

7.3 Patient identifier

As noted above, identification of the citizen is primarily based on his national registry number. Use of this number is regulated. In accordance with the Act of 1979 on the numerical identification of natural and legal persons, all natural and legal persons mandated to reside in Luxembourg (natural persons), established there (legal persons), or registered in any administration get a unique identity number. These persons are all registered in a general directory (repertoire general), kept by the CIE as noted above. The identity number (and the

other information in the directory) is issued by CIE, is protected by law, and may only be communicated to the person involved, and to public services, civil servants and issuers of real estate documents or social security organisations on the grounds of a specific legal provision. This information is kept up to date by the communes, which are required to notify relevant changes to CIE. In effect, this makes the general directory a form of authentic source.
The identity number is semantic. In the case of natural persons, it contains the date of birth, a sequence number indicating the order of birth of that day and the gender (odd number for men, even number for women), and a check digit. For legal persons the number indicates the year of establishment or first registration for non-national legal persons, legal form, sequence number and check digit.
For natural persons, the general directory includes name, first name, gender, date and place of birth, civil status, date of death, official address, nationality, information regarding spouse, and identification numbers of the parents insofar as such numbers have been granted. In addition to this directory, civil servants at the commune level keep a number of separate civil status registers (such as registers of births, deaths and marriages), the information of which must be passed on to the general directory.

7.4 Authentication of healthcare professionals

Physicians and dentists are registered at the Ministry of Health and at the Medical College. They receive a matriculation number, which has to be used, e.g. on medical prescriptions.
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8 Electronic prescription

Prescriptions are regulated in Chapter 8 of the “Statuts de l”UCM” (the internal rules of the union of the health insurance funds), adopted by the general assembly and approved by Ministerial Order of 3 December 2008: see for the text (in French): http://www.secu.lu/legis/Statucm/statactuel/stat_c.html#c8. The provisions have been drafted taking only paper-based prescriptions into account but don’t, on the other hand, contain major obstacles for the introduction of electronic prescriptions.

9 General assessment

The regulatory framework is not yet entirely ready for a full implementation of eHealth projects such as the exchange of patient's summaries, telemedicine or electronic prescriptions. Patient's summaries, as such, don't exist in Luxembourg. There is not yet a co-ordinated identity management system for patients and for healthcare professionals. Electronic prescriptions are not yet used.

For the development of cross-border eHealth services, the legal landscape contains no specific peculiarities. The transposition of the European data protection directive into Luxembourg law follows quite closely the terminology of the Directive and no major additional requirements, compared to the EU Directive, have been added for the processing of personal data concerning health.

From the perspective of cross-border interoperability, the connection of the health sector to the identity management system used for public government services, will logically lead to the adoption of similar solutions in that area as well. The solution which will ultimately be chosen to make public government services interoperable on a EU level, will automatically also be valid in the domain of eHealth.

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