



Remote Accessibility to Diabetes Management and Therapy in  
Operational healthcare Networks.

REACTION (FP7 248590)

## **D9-2 Regulatory framework and data protection including patient rights**

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## Table of Contents

<b>1. Executive summary .....</b>	<b>6</b>
<b>2. Introduction .....</b>	<b>10</b>
2.1 Purpose, context and scope of this deliverable .....	10
2.1.1 Background.....	10
<b>3. Data Protection Framework in Reaction.....</b>	<b>11</b>
3.1 Introduction .....	11
3.2 Legal sources of data protection .....	11
3.3 Principles, rights and obligations in data protection .....	12
3.3.1 Principles: Data minimisation .....	13
3.3.2 Legitimate basis.....	14
3.3.3 Rights.....	15
3.3.3.1 User control .....	15
3.3.3.2 The right to be forgotten.....	16
3.3.3.3 The right to data portability.....	16
3.3.3.4 The right to not be subject of decisions based on profiling .....	16
3.3.4 Obligations.....	17
3.3.4.1 Data protection by default .....	18
3.3.4.2 Data breach notification duty.....	18
3.3.4.3 Data protection impact assessment.....	110
3.3.4.4 Codes of conduct and certification .....	110
3.4 Processing of medical data .....	20
3.4.1 Explicit consent.....	20
3.4.2 Vital interest of the data subject .....	23
3.4.3 Processing of (medical) data by health professionals .....	23
3.4.4 Substantial public interest.....	24
<b>4. Human Rights Framework .....</b>	<b>28</b>
4.1 The right to health as a human right.....	28
4.2 The right to privacy .....	30
4.3 The right to access information .....	31
4.4 The principle of non-discrimination.....	32
4.5 Specific human rights for diabetes patients?.....	33
<b>5. Corporate Social Responsibility.....</b>	<b>34</b>
5.1 Legislation.....	34
5.2 The Ruggie Framework .....	35
5.3 REACTION and CSR .....	35
5.4 Sustainability.....	35
5.5 System responsibility and accountability.....	36
5.6 Evaluation.....	36
5.7 Remarks .....	36
<b>6. Internal Market product regulation .....</b>	<b>38</b>
6.1 New approach directives .....	38
6.1.1 The Product Liability Directive .....	38
6.1.2 The Low Voltage Directive.....	40
6.1.3 The EMC Directive.....	40
6.2 The Medical Device Framework.....	41
6.2.1 The definition of a 'Medical device'.....	43
6.2.2 Software as a Medical Device .....	43
6.2.3 The role of standards within the MDD Framework .....	44
6.2.4 Device categorization .....	45
6.2.5 Future revisions of the MDD Framework.....	46
<b>7. Reimbursement.....</b>	<b>47</b>
7.1 The limited explicit competences of the EU on matters of health .....	47
7.2 Provisions related to the Single Market.....	48

7.2.1	The Right to the Free Movement of Persons.....	48
7.2.2	The Freedom to Provide Services .....	50
7.2.3	Further impact of the Patient Rights Directive on REACTION .....	52
7.2.3.1	Reimbursement issues associated with eHealth/telemedicine.....	52
7.2.3.2	Remote access to patient record.....	53
7.3	Examples of Reimbursement in different EU Member States.....	56
7.3.1	The UK.....	56
7.3.2	Germany .....	57
7.3.3	Italy .....	58
<b>8.</b>	<b>Liability and eHealth .....</b>	<b>59</b>
8.1	Jurisdictional issues: a difference between conventional medicine and eHealth based medicine .....	59
8.2	Jurisdiction in terms of procedural and substantive law .....	60
8.3	European legislation relating to substantive law in eHealth .....	61
8.4	The E-Commerce Directive .....	61
8.4.1	Implications for Member States .....	62
8.4.2	Requirements on those offering eHealth services using Information Society Services .....	63
8.4.3	The Directive on Electronic Signatures .....	64
<b>9.</b>	<b>Radio spectrum policy and eHealth.....</b>	<b>65</b>
9.1	The importance of spectrum regulation .....	65
9.2	The importance of radio spectrum policy to REACTION – the example of mBANs .....	65
9.2.1	Decision No 76/2002/EC .....	65
9.2.2	The possible harmonization of the use of spectrum in mBAN application .....	66
 ANNEX		
<b>1.</b>	<b>Member State legislation and patient rights .....</b>	<b>68</b>
1.1	Austria .....	68
1.2	Belgium .....	69
1.3	Bulgaria .....	70
1.4	Cyprus .....	71
1.5	Czech Republic .....	72
1.6	Denmark .....	73
1.7	Estonia .....	74
1.8	Finland .....	75
1.9	France .....	76
1.10	Germany .....	78
1.11	Greece .....	710
1.12	Hungary .....	80
1.13	Ireland .....	81
1.14	Italy .....	82
1.15	Latvia .....	83
1.16	Lithuania .....	84
1.17	Luxembourg .....	85
1.18	Malta .....	86
1.19	The Netherlands .....	87
1.20	Poland .....	810
1.21	Portugal .....	100
1.22	Romania .....	101
1.23	Slovakia.....	102
1.24	Slovenia .....	103
1.25	Spain .....	104
1.26	Sweden .....	105
1.27	United Kingdom .....	106

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## 1. Executive summary

Diabetes is one of the most prevalent chronic conditions in contemporary society. REACTION, as a treatment platform that is designed to address this condition, demands specific attention not only with regard to clinical and cost effectiveness, but also regarding its use in the prevailing legal and societal context. In the context of the REACTION service platform there will be a focus on human rights which include a right to health, a right to development and particularly the user's sovereignty over their private life including *inter alia*, issues of data protection, privacy and accountability. Furthermore, patients' rights in a European context will be highlighted. The freedom of movement and to provide services have allowed increased mobility for patients and an increased possibility for treatment platforms to offer services such as REACTION on a cross border basis. EU rules concerning the single market will both offer opportunities and restrict the possible shape of REACTION, not only with regard to reimbursement, but also in relation to product liability and legislation concerning consumer products. This chapter will give an overview of the regulatory and socio-economic aspects which need to be considered in order to make REACTION successful.

### 1.1 Data protection framework

The Data Protection Framework aims to protect individuals with regard to the processing of their personal data, and at the same time allow the free movement of such data. REACTION actors that process personal data concerning health, by means of health grids, electronic records, and information systems used for diabetes treatment, need to comply with the principles of data protection. The fundamental principle of data protection is the data minimization principle, which is an expression coined by legal doctrine to refer to two key data protection principles, namely, purpose limitation and data quality. These key principles have been codified at constitutional level (for the EU) by article 8 of the EU Charter, which states that personal data *'must be processed fairly for specific purposes.'* The expression *'fair processing and specific purpose'* in Article 8 replicates precise provisions of the Data Protection Directive. Article 6 of Directive 95/46/EC foresees that personal data may only be *'collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes'*, and that they should be *'adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed and 'accurate and, where necessary, kept up to date.'*

For sensitive categories of data and health or medical data, which are used in the REACTION project, strict rules apply with regard to processing. Article 8 of Directive 95/46 states that the processing of personal data concerning health is, in principle, prohibited. However, Article 8 recognizes that there may be important private and public interests in the sharing and processing of personal information related to health. Accordingly, certain derogations exist which permit processing of personal medical data. These derogations must abide by the principles of data protection, notably data minimization. In addition, as each of these are derogations from the general rule of prohibition, they must be construed in a narrow fashion and applied taking into account the concrete and real (genuine) basis on which the processing is based. Those derogations are explicit and informed consent, the vital interest of the data subject, processing of (medical) data by health professionals and a substantial public interest. Strict conditions exist for the use of each of these exceptions. These must be taken into account in REACTION.

The Data Protection Directive also recognizes a number of subjective *rights* for data subjects. These rights are intended to empower the user by giving him or her control over personal information. They are: the right to receive some information whenever data is collected, to access the data, to have data corrected, the right to have data deleted, and to object to certain types of processing.

A major revision of the European Data Protection Framework is planned as the European Commission presented its proposals for a General Data Protection Regulation in January 2012. Major innovations introduced in the area of data subjects' rights by the Proposed Regulation are the 'right to be forgotten', the right to data portability, and the right to object profiling, or better, not to be subject to decisions based on profiling. It would be advisable for REACTION to take this issues into account as such proposals are likely to become binding law in the future.

### 1.2 Human rights framework

Next to the right of data protection there are several other human rights which are essential in the context of the REACTION service platform. Health is often regarded as most precious value. Personally, characterized as important commodity it is also essential as an element contributing to a productive workforce which is a condition for a successful economy. Furthermore, the 'right of health' has been described as a human right. The interrelatedness of the right to health with other human rights, often indicated as 'underlying determinants of health', illustrates the complexity of this right. The

realization of a right to health depends on a variety of conditions and cannot merely be fulfilled by the provision of good health care. The recognition and realization of other human rights is crucial.

Furthermore, in close relation to the right to data protection, the right to privacy needs to be emphasized. In the context of new eHealth technologies such as REACTION, complex dynamics between the individual and the community are brought into the focus. Privacy, as a function of the relationships that, at a given time and place, exist between the individual and the community, is an important human right which frames the discussion on the use of new technologies in medicine. A more extensive description of this right can be found in Deliverable 9-1.

The development of new applications in the context of the REACTON platform requires access to information and communication networks. The right to access information is related to the policy of inclusion in the information society and is part of the Digital Agenda for Europe, discussed above. The body area network which is used for the transmission of data of REACTION applications sends data to medical knowledge systems and health care professionals. The use of the application therefore relies on communication and processing of patient data. The latter relates to the right to data protection and access to these data is therefore limited to authorized persons mainly health care professionals. However, in eHealth projects in general and in the REACTION project in particular patients themselves also have a right to access this information.

An interesting development during the last years is the issuing of specific human rights charters for people with diabetes. These charters highlight the human rights which are important in the area of diabetes and introduce, in the tradition of non-Western human rights documents, duties and responsibilities of diabetes patients. Those documents highlight the debate concerning the need for specific protection.

### **1.3 Corporate Social Responsibility**

Business and human rights have become a popular topic during the last years. There is an increasing perception that business can contribute to society and shape the political, public and academic debate. Theories but also practices focusing on how business manages the relationship with society are described by the umbrella term corporate social responsibility (CSR). With enterprises increasingly crossing borders, the demand for creating accountability, not only for economic but also for ethical misconduct, inside and outside their home countries grew.

The question is no longer seen as being whether there is an obligation for business at all to adhere to principles of human rights and to accept their CSR. CSR is often seen as a chance for and by business to positively contribute to society. Many companies already apply principles of CSR. Still the reality with regard to the conduct of enterprises differs from their promises. Thus, the debate should rather focus on the way in which the responsibilities of companies should be framed and whether there should be a stronger legal enforcement.

Furthermore, end-users like doctors and patients might not have considered CSR. After discussing the responsibility of business a broader discussion might extend to single citizens. System responsibility will play an essential role in the future of CSR. The capability of end-users to make right decisions and their responsibility and accountability will be subject to further discussion. In the area of health the dependency of end-users might limit the ability to make free choices and the accountability of users. Any large commercial organisations that are to play a role in the delivery of a REACTION platform will likely want to take such principles into account.

### **1.4 Internal market product regulation**

The regulations relating products in the internal market relate to the requirements products must comply with to be allowed free circulation in the European Single Market (ESM) and sometimes the consequences if such products are the cause of harm to consumers. There are a variety of legislative instruments that are potentially applicable to components of medical systems. These directives, according to their applicability given the products in question, pose greatly differing level of difficulty in terms of being a regulatory barrier for those involved in bringing health related products to market. At one end, these range from all-encompassing-directives on product safety that apply to all products (including electrical products) placed on the European market which impose lesser, though still important requirements. At the other end of this spectrum are the directives that form the Medical Device Framework; these impose tougher regulatory hurdles on products that meet the definition of 'medical devices'. Given that a REACTION platform is likely to employ medical devices, the existence of the Medical Device Framework is of paramount importance for projects that are attempting to innovate new medical devices. The Medical Device Framework is extremely complex and, given its flexibility, is of an ever-evolving application. It can represent a significant regulatory barrier to those wishing to innovate in the area of medical devices.

All manufacturers of medical devices will be subject to at least some part of this regulatory spectrum. The result of the correct application of the relevant regulatory requirements is usually that the CE mark can be placed upon the product in question. This indicates that the product in question is in compliance with the relevant European regulations and that it is to be allowed free-circulation within the EU. It is thus imperative upon manufactures of medical products to be aware of this framework in order to meet the required legal requirements.

### 1.5 Reimbursement

Reimbursement is an issue of pivotal importance for the success or failure of innovations in the healthcare sector. The decisions of the various social security institutions of various states to reimburse (or not to do so) certain categories of medical treatment can have an important effect on the decision of product manufacturers to attempt to innovate with a new product. Additionally, reimbursement decisions by national bodies can play a definitive role in the acceptance and uptake of recent innovations in medical technologies. This will bear true also for REACTION. Reimbursement has however in recent times moved from being an issue of national importance to one which has pan-European relevance. In theory, the European Single Market should allow medical services to be offered by an organization all over Europe. This would offer significant possibilities for the deployment of eHealth platforms such as REACTION. However, in reality, there are many issues that make this difficult. Reimbursement is one such issue. The following pages will explore the manner in which the EU has been able to impact upon reimbursement rules and therefore have an effect on the innovation on new technologies. Cross-border reimbursement will likely become ever more important. This development opens up the possibility of REACTION services being offered cross border. Such a development could allow one or a few large organizations to offer such a service throughout Europe. It could be argued that this would allow efficiencies in terms of cost and organization to be achieved, with new economies of scale being achievable. There are however significant problems that exist with regards to reimbursement for cross border services. Most fundamentally, the service sought must be recognized as a reimbursable act by the individual's state of residence. Given that some EU member states still do not recognize eHealth services as reimbursable acts, significant problems still exist for services such as REACTION that may wish to offer themselves on a pan-European basis. Other problems exist with regards to services connecting to assisted living and the possibility of Member States to refuse prior authorization for hospital based services that it can itself offer in good time.

### 1.6 Liability and REACTION

eHealth is seen as a partial solution to the growing demographic crisis which many Member States are facing. It is hoped that the correct deployment of telemedicine would allow resources to be deployed more optimally, thus reducing the strain on healthcare budgets. At present however, despite the existence of the European Single Market, laws relating to liability are largely a matter of Member State competence. Thus, if problems occur in the use of medical technology and the provision of medical services, both the *location* and the *outcome* of any legal proceedings will depend upon where exactly the treatment occurred. This may create legal problems for service providers such as REACTION that envisage the possibility of offering their service to individuals in different jurisdictions than their own. With such services it is often difficult to decide where exactly such services are actually being carried out. In 2009 the Commission set out a number of priorities with regards to telemedicine. One of these was described as being to address 'issues of liability with respect to telemedicine services'. Unfortunately however, the Patient's Rights Directive had little impact on eHealth and its associated issues of liability. This means that there is still a marked inconsistency regarding matters of liability for eHealth when compared to conventional medical services. This involves a system of liability for failures in eHealth that runs counter to the logic that exists in the directive for more conventional forms of medical treatment. This issue which will be important to those operating in the ever expanding market that e-Health represents. The result of this divergence in laws relating to liability is that operators of platforms such as REACTION that wish to offer services in different Member States of the EU will have to have an in-depth legal knowledge of each state in order to protect themselves from necessary liability. This will entail increased expense for prospective projects such as REACTION.

### 1.7 Radio spectrum policy and REACTION

The EM Spectrum is of immense importance for modern digital innovation. Wireless services, the economic recovery, long term growth, high-quality jobs and long-term EU competitiveness all depend on its efficient utilization. The innovation of novel medical systems such as that proposed in REACTION represents one aspect of this. Policy initiatives related to the radio spectrum have been an important part of the EU's Digital Agenda for Europe and to the Europe 2020 strategy for smart,



sustainable and inclusive growth. Innovations in matters of telemedicine are increasingly being realized by the use of devices or sub-components that often operate at a distance from the principal system hardware. This is often achieved through wireless methods that utilize the EM spectrum. Efficient regulation of spectrum use will therefore be important in insuring that innovations have access to the requisite areas of the EM spectrum and that such use is not interfered with in an unacceptable manner. Future innovations in the regulatory framework in this area may therefore be important to platforms such as REACTION that may utilize such possibilities.

mBANS (Mobile Body Area Networks) are a good example of a potential problem area for eHealth projects in relation to radio spectrum issues. mBANS are small networks of medical components and communications devices located on or around the physical bodies of individuals. mBANS will play an important role in enabling ubiquitous and non-invasive telemetry and healthcare systems in the future. Depending on the components they contain they can be used to conduct a variety of functions including observing various body functions, administering medications or other types of treatment and communicating data to a hub or a central data processing location. One of REACTION's visions is that patients can enjoy enhanced freedom and quality of life through avoidance or reduction of hospital stays. An impending proposal on the harmonization of the rules concerning access to the EM spectrum for mBANS will likely have a beneficial effect on future harmonization.

## 2. Introduction

### 2.1 Purpose, context and scope of this deliverable

This document will be delivered at the end of M24 of the REACTION project. At this stage the direction of the project is becoming more apparent, this has permitted research into the various legal regimes that will be applicable to REACTION. The aim of this deliverable will be to provide a clear picture of these legal regimes and how they are capable of impacting upon the deployment of a REACTION system in the future. Projects such as REACTION may be subject to both national and international legal systems. The national regimes constitute the laws of the state or states that such systems are operating in. Such laws are largely the responsibility of each state concerned. The international regimes may include European Union law or international human rights law such as the European Convention on Human Rights. This second category may be applicable in a particular State in question because it is obliged to apply such a regime (e.g. the Member States of the European Union) or because platforms REACTION may be operating across the frontiers of several states (e.g. being based in one state and offering services to individuals in another). This document will be mainly focused on the second category of laws. Such laws provide a useful focus as they are applicable in many States and often act to harmonise the laws of those states in specific areas. The individual laws of the Member States in other areas however are each different and complex in their own idiosyncratic manner. An exploration of all of the various systems present in Europe and which therefore could be of application to REACITON would be a monumental and voluminous task that would be beyond the scope of this document. The focus of this document is therefore on the international or European systems of law applicable to the project. These include *inter alia* areas of fundamental rights, laws relating to the protection of personal data, rules relating the cross border re-imburement of medical costs, EU laws relating to product regulation (including Medical Devices), EU rules on electronic commerce and also electronic signatures. In presenting this these issues the aim of this document is to provide a clear description of how such rules may be applicable to REACTION and the impact they may have upon its deployment.

#### 2.1.1 Background

REACTION will likely make intensive use of sensitive personal data as described by the European Union's Directive of data protection. It will be important for REACTION to be designed so as to ensure that personal data is utilised in a legal manner. This will involve taking into account the existing Data Protection Framework and also its imminent revision. Other areas of European Union law will also likely have an impact on the REACITON project. The most important of these is the Medical Device Framework. This can represent a significant barrier to placing medical devices on the European Single Market. Meeting the requirements of this framework is important as it will allow the free circulation of the medical device in question throughout the European Union. Other EU rules related to the placing of products upon the European market will also likely be capable of having an impact upon REACTION. These include rules related to electronic devices in general, rules relating to products that emit and detect electromagnetic radiation and also a general regime relating to product liability. Furthermore it is important to analyse EU rules regarding electronic commerce and electronic signatures in order to discern their possible impact upon REACTION. In addition to specific requirements this document will also explore some of the ways in which individual fundamental rights will apply to the REACTION project. These rights have been developed by international organisations on the global level and also by the European Court of Human Rights for states that are members of the Council of Europe.

### 3. Data protection framework in REACTION

#### 3.1 Introduction

Task 9-1 'Ethical analysis of the overall REACTION vision and special analysis of privacy, autonomy and theoretical aspects of inclusion' studied and discussed, *inter alia*, the privacy issues relevant for the REACTION service platform. It was underlined how REACTION should consider and promote, rather than restrict, two aspects or notions inherent in the idea of privacy: on the one hand, the notion of *informational self-determination*, as the ability to determine for one's self whether to dispense one's personal information. On the other hand, REACTION should respect individual privacy in a 'wider sense'. This wider concept recognizes the individual's right to determine their own path in life, free from the steering of others. For eHealth platforms such as REACTION this means allowing individuals the possibility to retain more conventional methods of diabetes treatment and not providing undue pressure on individuals to participate.

The present deliverable deals with a crucial aspect of privacy as informational self-determination in both its narrow and broader dimensions, namely, the data protection legal framework or law. The Data Protection Framework aims to protect individuals with regard to the processing of their personal data wholly or partly by automatic means, and at the same time allows the free movement of such data. REACTION actors that process personal data concerning health, by means of health grids, electronic records, and information systems used for diabetes treatment need to comply with the principles of data protection.

A general discussion on the Data Protection Directive as well as on legal and socio-economic issues was developed in Deliverables 7-2 and 9-1, respectively. The aim of this Deliverable is to describe in greater detail specific provisions of data protection that are relevant for REACTION. In order to do this, the Deliverable will, first, outline the main legal sources, including the newly introduced Proposed Regulation on data protection. This is designed to reform the EU data protection regime. It is likely to apply in future. In the second part, the legal provisions of data protection which are relevant for REACTION will be outlined in the following order: principles, rights, obligations, and processing of medical data.

#### 3.2 Legal sources of data protection

At the European level, data protection is recognized and protected as a fundamental right. The explicit recognition of the fundamental right to data protection can be attributed to an explosion in international, European and national legislation promulgated since the late 1970s.<sup>1</sup> Such a vast body of law is codified at constitutional level in Article 8 of the European Charter of Fundamental Rights and Freedoms (EU Charter) and detailed in numerous pieces of secondary legislation. Article 8 of the EU Charter states that the processing of personal data should be surrounded with constitutional safeguards: data must be processed fairly for specified purposes, on the basis of the consent of the person concerned or some other legitimate basis laid down by law. In addition, everyone has the right of access to data which has been collected concerning him or her, and everyone has the right to have it rectified, or deleted. Article 8 also provides that compliance with these rules shall be subject to control by an independent authority.<sup>2</sup>

The most important, but not the sole piece of secondary legislation in data protection is Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive.<sup>3</sup> Besides the Data Protection Directive, three other relevant EU instruments compose the European data protection framework. Two of them are not directly relevant for REACTION, namely, the 'Framework Decision on the Protection of Personal Data Processed in the Framework of Police and Judicial Cooperation in Criminal Matters of 27 November 2008'<sup>4</sup> and 'Regulation EC No. 45/2001 on the Protection of

<sup>1</sup> De Hert, P. & Gutwirth, S. (2009). 'Data protection in the case law of Strasbourg and Luxembourg : Constitutionalisation in action', in *Reinventing data protection?* (Springer).

<sup>2</sup> Charter of Fundamental Rights of the European Union (2000). *Official Journal of the European Communities*, C 364, 1-22.

<sup>3</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC 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. *Official Journal of the European Communities* L281.

<sup>4</sup> Council of the European Union (2008). Council Framework Decision 2008/877/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters. *Official Journal of the European Communities* L350, 60. This Framework Decision aimed to fill the gap left by the restricted scope of the Data Protection Directive, by providing a regulatory framework for the protection of personal data in the area of police and judicial cooperation, or what was called the 'third pillar' before the entry into force of the Lisbon Treaty.

Individuals with Regard to the Processing of Personal Data by the Community Institutions and Bodies and on the Free Movement of Such Data.<sup>5</sup> Of direct relevance is, by contrast, Directive 2002/58/EC (the so-called E-Privacy Directive) as revised in November 2009 in Directive 2009/136/EC, which actualized the data protection principles to face some of the new challenges raised by the continuing developments in the electronic communications sector<sup>6</sup> and introduced some important concepts such as the data breach notification duty. The legal data protection framework is completed by the interpretations and opinions of the Article 29 Working Party and of European Courts, namely, national courts as well as the European Court of Justice (ECJ) and the European Court of Human Rights. Formed of a representative from each Member State's national data protection authority, the European Data Protection Supervisor and the European Commission, the Article 29 Working Party gives expert advice regarding data protection, and promotes the common application of the Data Protection Directive. Amongst European courts, a prominent place is accorded to the case law of the Strasbourg based European Court of Human Rights on Article 8 of the European Convention of Human Rights (ECHR), the right to private and family life. The Court of Strasbourg has ruled that Article 8 ECHR can cover a wide range of issues such as integrity, access to information and public documents, secrecy of correspondence and communication, protection of the home, and also protection of personal data.<sup>7</sup>

On 25 January 2012, the European Commission released a proposal for a General Data Protection Regulation.<sup>8</sup> The 'Proposed Regulation' is the outcome of a broad review of the current legal framework on data protection, launched in 2009. The draft Regulation draws on the EU Charter and includes new rights for data subjects, such as the right to be forgotten and the right to object to profiling, obligations upon data processors such as Data Breach Notification and data protection assessment, increased powers for data protection agencies, new remedies and sanctions. The Proposed Regulation is at this time facing discussion by Parliament and Council. It is unlikely to come into effect before 2014 after the conclusion of the REACTION project. It is therefore appropriate that, given the potential impact that some of its provisions will arguably have on REACTION, the present deliverable makes reference to the Proposed Regulation while discussing the actual and existing data protection legal framework as enshrined in Directive 95/46/EC.

### 3.3 Principles, rights and obligations in data protection

The objective of the data protection is stated in Directive 95/46/EC, Article 1, as the protection of *'the fundamental rights and freedoms of natural persons, and in particular their right of privacy with respect to the processing of personal data.'*<sup>9</sup> *'Personal data'*, explains Article 2(a) shall be *'any information relating to an identified or identifiable natural person ('data subject') [...] directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.'*<sup>10</sup> In the case *Lindqvist*, the ECJ argued

<sup>5</sup> European Parliament and the Council (2001). Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. *Official Journal of the European Communities* L8, 1. This Regulation is particularly important because, inter alia, it created the European Data Protection Supervisor, an autonomous EU institution with the powers of supervision, consultation and co-operation (Article 41).

<sup>6</sup> Recital 4 mentions that the aim of the directive is to translate 'the principles set out in Directive 95/46/EC into specific rules for the telecommunications sector'. European Parliament and the Council (2002). Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications). *Official Journal of the European Communities* L 201, 37 as revised by Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009.

<sup>7</sup> European Court of Human Rights (2000). *Amann v. Switzerland* judgment of 16 February 2000: *'The Court reiterates that the storing of data relating to the "private life" of an individual falls within the application of Article 8 § 1 [...]. It points out in this connection that the term "private life" must not be interpreted restrictively.'* (§ 65-67)

<sup>8</sup> European Commission (2012). Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), COM(2012) 11/4 draft (including explanatory memorandum).

The Proposed Regulation is part of a package of measures which include a Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions based on Article 29(2) of the Council Framework Decision of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters (including annex), COM(2012) 12 final, an Impact assessment (including annexes) accompanying the Proposed Regulation and the Proposed Directive, SEC(2012) 72 final and an Executive summary of the impact assessment, SEC(2012) 73 final. All the documents are available at [http://ec.europa.eu/justice/newsroom/dataprotection/news/120125\\_en.htm](http://ec.europa.eu/justice/newsroom/dataprotection/news/120125_en.htm)

<sup>9</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities* L281.

See Recital 1, which indicates that the fundamental rights to be protected are those *'in the constitution and laws of the Member States and in the European Convention for the Protection of Human Rights and Fundamental Freedoms.'*

<sup>10</sup> European Parliament and the Council (1995). Directive 95/46/EC. *Official Journal of the European Communities* L281.

that the fact that it was mentioned in an Internet web site that an individual had injured her foot and was on half time leave on medical grounds constituted personal medical data.<sup>11</sup> Given the porous boundaries of the definition of personal data found in Article 2, the question arises as to what is to be considered medical data, whether it even be as wide so as to cover can be data about lifestyle or eating habits. According to the Article 29 Working Party<sup>12</sup>, given the potential breadth of this class of data it is probably wise to consider all data contained in medical documentation, in electronic health records and in Electronic Health Record (EHR) systems, including administrative data, social security number, date of admission to treatment or to hospital, as 'sensitive personal data.' Processing of personal data enjoys a wide definition too as it '*shall mean any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.*'<sup>13</sup>

In principle, the processing of personal data in the name of legitimate interests is by default acceptable. However, it is also accepted that the free flow of personal data can be balanced against other interests and/or risks. Accordingly, the data protection framework is based on a series of *fair processing principles*, the most important of which are data minimisation, having a legitimate basis for conducting processing, *respecting the rights of data subjects*, and *upholding the obligations* of the actors involved. Importantly for the purpose of REACTION, data protection foresees that some categories of data, including data relating to the health status of a person, shall be subject to special, yet more stringent rules of communication and processing.

### 3.3.1 Principles: data minimization

The fundamental principle of data protection is the data minimization principle, which is an expression coined by legal doctrine to refer to two key data protection principles, namely, the purpose limitation and the data quality principles.<sup>14</sup> The purpose or use limitation, or purpose binding principle<sup>15</sup> prohibits further processing which is incompatible with the original purpose(s) of the collection. The data quality principle implies that data must be accurate, up to date, relevant and not excessive for the purposes for which they were collected. Irrelevant data must not be collected and if it has been collected it must be discarded.<sup>16</sup> These key principles have been codified at constitutional level by Article 8 of the EU Charter, which states that personal data '*must be processed fairly for specific purposes*'. Article 8's expression '*fair processing and specific purpose*' replicates precise provisions of the Data Protection Directive.<sup>17</sup> Article 6 of Directive 95/46/EC foresees that personal data may only be '*collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes*', and that such data should be '*adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed and accurate and, where necessary, kept up to date*'.

The principle of data minimization is the veritable linchpin of data protection. This has been confirmed also in the Proposed Regulation: "*Personal data*", it is stated in the Proposed Regulation, must be '*adequate, relevant, and limited to the minimum necessary in relation to the purposes for which they are processed; they shall only be processed if, and as long as, the purposes could not be fulfilled by processing information that does not involve personal data.*'<sup>18</sup>

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In Opinion 4/2007 the Article 29 Working Party confirmed the definition provided in Directive 95/46/EC, Article 2, as any information relating to an identified or identifiable natural person, the data subject. An identifiable person is '*a person who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.*'

<sup>11</sup> Case C-101/01, *Lindqvist* (2003). ECR I=12971.

<sup>12</sup> Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007

<sup>13</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. Article 2.

<sup>14</sup> See Bygrave, L. (2002). *Data Protection Law. Approaching Its Rationale, Logic and Limits*. (Springer, The Hague – London - New York).

<sup>15</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. Article 6.1(b).

<sup>16</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. Article 6.1(c).

<sup>17</sup> As the travaux préparatoires indicate, Article 8 codifies and must be read in the light of the legislation of the Council of Europe and the European Union, in particular of Directive 95/46/EC.

<sup>18</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. Article 5.

Compliance with data minimization principle is often a difficult to ensure. It is for data controllers and data processors, which are subject to national legislation, to ensure that the fair processing principles are complied with.<sup>19</sup> The German Federal Data Protection Act provides that data processing systems must strive to collect and process as little personal data as possible; the Italian Personal Data Protection Code states that *'information systems and software shall be configured by minimizing the use of personal data and identification data [...].'*<sup>20</sup> National legislation allows some degree of discretion. Unless they are specifically challenged, data controllers can choose how much data they need; many businesses choose to retrieve and retain more data than they need and for longer than they need to for the reason that they hope they can gain higher profits.<sup>21</sup> It is still too early to say whether the Proposed Regulation will result in harmonization of more stringent implementation of the data minimization principle, for instance by enforcing the principle in the design of software and hardware, or by giving DPAs power to intervene and fine controllers and processors.

### 3.3.2 Legitimate basis

The data protection Directive foresees a number of other quintessential conditions for the processing of personal data, namely: the *'unambiguous consent of the data subject'* and/or the fact that the processing serves *'legitimate interests pursued by private parties'*<sup>22</sup>.

A distinction is drawn in the 1995 Directive, and reconfirmed in the Proposed Regulation, between the legitimate basis for the processing of personal data and those for the processing of sensitive personal data. As already mentioned, personal data concerning the health status are considered sensitive data. The distinction is justified by the different regime that both the 1995 Directive and the 2012 Proposed Regulation dedicate to sensitive health or medical data.<sup>23</sup> The rationale is that, in any processing activities, not only the legitimate interests of the parties come in play, but also the risks. The risk inherent in the violation of the privacy of patients is that the latter would refrain from seeing any physicians out of concern of information relating to them being leaked or disclosed to third parties.<sup>24</sup> This would put in jeopardy one of the core fundamental rights, also enshrined in the EU Charter, the right to a high level of human health care.<sup>25</sup> In addition, knowledge about a person's health status or prediction about a person's health status in the near future can lead to discrimination with regards to, e.g., access to jobs, education, housing etc., a situation that would be totally unacceptable for constitutional democratic states.

These risks, therefore, justify a regime for the circulation of health data based on general prohibition and strict conditionality. Accordingly, Article 8(1) of the Directive prohibits *'the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life'* and, in the other paragraphs, lists a series of grounds which allow derogation from the general prohibitive rule, which must be interpreted and applied in a restrictive fashion. The most important grounds that allow processing of medical data are: *'the data subject explicit consent'*<sup>26</sup>, *'or'*, *'vital interests of the data subject'*<sup>27</sup>, *'or'*, *'processing of (medical) data by health professionals for the purpose of preventive medicine, diagnosis, the provision of care or treatment or the management of health-care services'*,<sup>28</sup> *'or'*, *'reasons of substantial public interest.'*<sup>29</sup> These are the grounds on which the legitimacy of any private or public eHealth systems must rest, including a system such as REACTION. The Proposed

<sup>19</sup> See respectively Craig, P. & de Búrca, G. (2011). *EU Law: Text, Cases, and Materials*. 5<sup>th</sup> ed. (Oxford University Press, Oxford), 105-06 and Bullesbach, A., Pullet, Y. & Prins, C. (eds) (2010). *Concise European IT Law*. 2<sup>nd</sup> ed. (Kluwer Law International), 53-73.

<sup>20</sup> Federal Data Protection Act (BDSG). In the version promulgated on 14 January 2003 (Federal Law Gazette I, p. 66), last amended by Article 1 of the Act of 14 August 2009 (Federal Law Gazette I, p. 2814), in force from 1 September 2009. Section 3.

<sup>21</sup> Pedreschi, D. (2011). Big data mining, fairness and privacy. *Privacy Observatory*. Retrieved 07 February 2012 from: <http://www.kdnuggets.com/2011/10/big-data-mining-fairness-privacy.html>; see also Groenfeldt, T. (2012). Big Data -- Big Money Says It Is A Paradigm Buster. *Forbes*. Retrieved 07 February 2012 from: <http://www.forbes.com/sites/tomgroenfeldt/2012/01/06/big-data-big-money-says-it-is-a-paradigm-buster/>.

<sup>22</sup> European Parliament and the Council (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. Article 7.

<sup>23</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4. Recital 122.

<sup>24</sup> Herveg, J. (2008). 'What is the nature of the patient's consent in the processing of medical data in European law?' *Lex Medicinæ* 10, 15-38. Available at: [http://works.bepress.com/jean\\_herveg/12](http://works.bepress.com/jean_herveg/12)

<sup>25</sup> Charter of Fundamental Rights of the European Union (2000). *Official Journal of the European Communities*, C 364, Article 35.

<sup>26</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. Article 8(2), see also Recital 30. This derogation cannot be used however where the laws of the Member State provide that the general prohibition may not be lifted by the data subject's giving his consent" –

<sup>27</sup> *Ibid*, Article 8(3)

<sup>28</sup> *Ibid*.

<sup>29</sup> *Ibid*, Article 8(4). See also Recital 34. Compare Article 9 of the Proposed Regulation

Regulation, in Article 9, confirms the legal regime based on general prohibition for processing special categories of personal data and exceptions.<sup>30</sup>

Before describing these derogations/grounds in more detail below, it is important to stress the position these grounds have *vis-à-vis* the above mentioned principle of data minimization. The processing, says the Directive, must be based on legitimate basis, 'including', consent, 'or', medical confidentiality, 'or', public interest specified by law. On the top of these grounds reigns as linchpin and veritable lighthouse data minimization, which must be respected in each of the above mentioned instances in which data are processed or communicated. The incorporation of data minimization is the architecture of REACTION must therefore be seen as condition *sine qua* the system may violate data protection law.

### 3.3.3 Rights

The Data Protection Directive recognises a number of subjective *rights* of data subjects. These rights include the right to be informed whenever data is collected, to access the data, to have data corrected, the right to have data deleted, and to object to certain types of processing. The purpose of these rights is to empower the user by giving him or her control over personal information.<sup>31</sup>

#### 3.3.3.1 User control

As Article 12 indicates, the data subject has the right to access all data processed about him. The data subject even has the right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or not being processed in compliance with the data protection rules. In order for users to be in control of their personal data, they have to be aware that data is actually collected and in the conditions to understand what happens with it data are disclosed to the service provider. For this reason, articles 10 and 11 of Directive 95/46/EC ('information to be given to the data subject') requires to make information about relevant events, processes, stakeholders and attributes of the collection and use of personal data to be made available in a comprehensible form to users. In this connection, REACTION should consider that users have different needs and different backgrounds, which means that what counts as comprehensive information differs from one individual to the next.<sup>32</sup>

User control mandates that users can correct mistakes they, or the service providers, make with respect to their data. Users may also have the possibility to reset choices they have made. Especially novice users might make decisions about the sharing of their personal data, which they might regret later. Also experienced users may occasionally conclude that (third) parties abuse data disclosed to them. If users are not satisfied with the way their data is handled, they should be able to recall or change the access rights to their data. Levels of user control that can be distinguished are: to *rectify*) the power to change or update personal data that a party possesses; to *block*) the power to cancel or change the rights that parties have to use the personal data and; to *erase*) the power to delete the personal data that parties possess. These levels of control should be guaranteed in the context of REACTION. More problematic and still unclear is the relationship that links the right to have access and control data and the psychological and societal need for forgetfulness. Particularly amongst young native Internet users, there is awareness of the importance of being forgotten, which allows individuals a second chance, the opportunity for a fresh start in life.<sup>33</sup> The right to be forgotten, which is one of the innovations of the Proposed Regulation, could enable people to have data held about them deleted if there are no legitimate grounds for retaining it. As discussed below, the distinct character of the right to be forgotten, as opposed to the existing right to have data about oneself deleted, is unclear.

With the aim to increase the transparency of data processing, the 2012 Proposed Regulation foresees detailed procedures for allowing individuals to exercise their rights.<sup>34</sup> According to Article 12(6), the European Commission is empowered to adopt acts setting forth standard forms and procedures for

<sup>30</sup> Explanatory Memorandum to the Proposed Regulation, Chapter II – Principles, Paragraph 3.4.2. Article 9 of the Proposed Regulation replicates Article 8 of the Directive 95/46/EC.

<sup>31</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. Article 12.

<sup>32</sup> Milne, G. & Culnan, M. (2004). Strategies for reducing online privacy risks: Why consumers read (or don't read) online privacy notices. *Journal of Interactive Marketing*, 18(3), 15-29.

<sup>33</sup> Blanchette, J. & Johnson, D. (2002). Data Retention and the Panoptic Society: The Social Benefits of Forgetfulness. *The Information Society*, 18(1), 33-45.

<sup>34</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 12

individuals to exercise their rights, which should eliminate the need to follow separate procedures in individual member states.

Arguably, the major innovations introduced in this area of data subjects' rights by the Proposed Regulation are the above mentioned 'right to be forgotten', the right to data portability, and the right to object to profiling, *i.e.*, not to be subject to decisions based on profiling.

### 3.3.3.2 The right to be forgotten

Article 17, the right to be forgotten, presents itself as a development of the right to have data deleted enshrined in Article 12 of Directive 95/46/EC.<sup>35</sup> This right would place data controllers under the obligation to erase any data made public, e.g., through an internet link to or copy of the data. In fact, the formulation of Article 17 foresees only the obligation, rather than to erase data which have been put in the public, to inform third parties processing the data that the data subject has requested that they be erased.<sup>36</sup> Such an obligation, furthermore, is limited by what is possible and it must not require a disproportionate effort.<sup>37</sup> In addition, the liability rules of intermediary service providers contained in Articles 12–15 of the E-Commerce Directive<sup>38</sup> apply, limiting the liability of such providers with regard to the right to be forgotten. It is still unclear how Article 17 will be implemented in practice, also in the light of the need to balance this right with other rights such as free expression.<sup>39</sup> Equally unclear are the implications of Article 17, the right to be forgotten, for REACTION since its implementation would primarily affect users of the Internet. The applicability of this potential provision to areas such as medical records is at this time still uncertain.

### 3.3.3.3 The right to data portability

A new 'right to data portability' has also been introduced.<sup>40</sup> Such a right would allow individuals to change online services more easily by giving them the right to obtain a copy of their data from their service provider. If they are enforced when the Proposed Regulation become law, these new requirements are likely to affect the companies' privacy policies and practice of information exchange. For REACTION, the right to data portability would make it easier for users to change or terminate a contract with service providers and have their personal data follow them to the new service provider. This right is also at the source of the provisions in the Patient's Rights Directive<sup>41</sup> requiring that patients seeking treatment in a different Member State of the EU should be allowed to have access to a copy of their patient record in their home state (see section 7.2.3.3.2) This concept should facilitate the acceptance new patients by services such as REACITON. An important issue that will arguably be in need of clarification is whether the right to data portability implies an obligation to export data in a 'standard format', *i.e.*, non-proprietary format.

### 3.3.3.4 The right not to be subject of decisions based on profiling

Important implications may derive from the right to object profiling, or the right not to be subject of decisions based on profiling. Article 20.1 contains a definition of profiling as '*a measure which produces legal effects concerning this natural person or significantly affects this natural person, and which is based solely on automated processing intended to evaluate certain personal aspects relating to this natural person or to analyse or predict in particular the natural person's performance at work, economic situation, location, health, personal preferences, reliability or behaviour.*'<sup>42</sup> Prediction of health performance, if narrowly interpreted, is actually what technologies such as REACTION do; indeed, the formulation contained in Article 20.1 would seem to cover many routine data processing

<sup>35</sup> Rosen, J. (2012). The Right to be Forgotten. *Stanford Law Review* 64(88). Hustinx, P. (2011). European Data Protection Supervisor, Opening Session: "General context - where we are now and where we are heading - current and future dilemmas of privacy protection", Hungarian Presidency, Budapest.

<sup>36</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 17.2.

<sup>37</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 13.

<sup>38</sup> European Parliament and the Council of the European Union (2000). Directive (EC) 2000/31 of the European Parliament and the Council of 8 June 2000 on certain legal aspects of electronic commerce in the Internal Market. *Official Journal of the European Communities*, L178/1.

<sup>39</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 17.3.

<sup>40</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 18.

<sup>41</sup> European Parliament and the Council of the European Union (2011). Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. *Official Journal of the European Union* L88, 45.

<sup>42</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 20.1.



operations. Article 20.2 allows derogations detailing the way that profiling may be conducted, which refer to the balancing of interests that individuals may have in being subjected to profiling. Article 20.3 adds a safeguard against the risk that sensitive information about health be used for profiling beyond the strict medical context in which, profiling, as defined in Article 20, is performed: *'Automated processing of personal data intended to evaluate certain personal aspects relating to a natural person shall not be based solely on the special categories of personal data referred to in Article 9<sup>43</sup>, including data concerning health.* The provision on profiling responds to the increased use by private companies or state agencies of techniques involving the mining of large amount of data, so called big data, which are left behind almost naturally by individuals as they cross different spaces, e.g., use a credit card, enter a cinema, go to the supermarket etc...leave data behind. The right not be subject to decisions based on profiling is therefore more specific, because deals with a precise practice adopted in particular by private companies, and also more general, because it covers all data left behind by an individual, as compared to the prohibition of article 15.1 of Directive 95/46/EC. Article 15.1 states the right to every person *'not to be subject to a decision which produces legal effects concerning him or significantly affects him and which is based solely on automated processing of data intended to evaluate [our italics] certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc.'*

Article 21 of the Proposed Regulation states that a number of users' rights (including the rights of information, access, rectification, erasure, data portability, and the right to object, protections against profiling; and the communication of a data breach to individuals) may be limited to safeguard certain public interests.<sup>44</sup> This implies that the rights related to data access of actors and users of the REACTION platform could be restricted in a number of nominated circumstances (mainly related to public security, but also) including *'(d) the prevention, investigation, detection and prosecution of breaches of ethics for regulated professions;'* and *'(f) the protection of the data subject or the rights and freedoms of others.'*

### 3.3.4 Obligations

The rights of the data subject, to information, access, rectification, etc.<sup>45</sup> create obligations for the data controller and data processors.

The controller is a central actor in the provisions on notification and prior checking<sup>46</sup> and is held liable, in principle, for any damage resulting from unlawful processing.<sup>47</sup> In addition, and most importantly, Article 6 (2) of Directive 95/46/EC explicitly provides that *'it shall be for the controller to ensure that paragraph 1 is complied with.'* This is where the main principle of data minimization that *'personal data must be processed fairly and lawfully'*, discussed above, is found. Furthermore, Article 17.1. of the Directive states that the controller *'must implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing.'*<sup>48</sup> In sum, the definition of controller in the Directive contains three main building blocks. The data controller is i) *'the natural or legal person, public authority, agency or any other body'* ii) *'which alone or jointly with others'* iii) *'determines the purposes and means of the processing of personal data.'*<sup>49</sup> The existence of a *data processor* depends on a decision taken by the controller, who can decide either to process data within his organization, for example through staff authorized to process data under his direct authority, or to delegate all or part of the processing activities to an external organization. Therefore, two are the basic conditions for qualifying as processor: being a separate legal entity with respect to the controller and processing personal data on his behalf.

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<sup>43</sup> Ibid, Article 20.3.

<sup>44</sup> Ibid. See Recital 139, "Data protection is not an absolute right, but must be considered in relation to its function in society, and must be balanced with other fundamental rights" and the decision of the European Court of Justice in Joined Cases C-92/09 and C-93/09 Volker und Markus Schecke [2010] ECR I-0000, para. 48.

<sup>45</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Articles 10-12 and 14.

<sup>46</sup> Ibid, Articles 18-21.

<sup>47</sup> Ibid, Article 23.

<sup>48</sup> Ibid, Article 17 & Recital 46.

<sup>49</sup> Ibid. For an analysis see Article 29 Working Party, Opinion 1/2010 on the concepts of "controller" and "processor", 16 February 2010, WP 169.

### 3.3.4.1 Data protection by default

The concept of data controller and its interaction with the concept of data processor play a crucial role in the application of Directive 95/46/EC, since they determine who shall be responsible for compliance with data protection rules, how data subjects can exercise their rights, which is the applicable national law and how effective Data Protection Authorities can operate. According to the Article 29 Working Party, the obligation of data controllers and processors to *'implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss'* should convert *'into a broader and consistent principle of privacy by design.'*<sup>50</sup> Privacy by design principles should be binding both for technology designers and producers as well as for data controllers who have to decide on the acquisition and use of ICT systems.<sup>51</sup> In this connection, the Proposed Regulation tries to make a step forward and, in article 23, introduces the notions of data protection by design<sup>52</sup> and data protection by default.<sup>53</sup> Accordingly, data controllers are required to implement *'appropriate technical and organizational measures...'*<sup>54</sup> 'by default' so that the data minimization principle is respected (*'only those personal data are processed which are necessary for each specific purpose of the processing'*).<sup>55</sup> The implications of data protection by design are as of yet unclear. The principle will be subject to delegated acts of the Commission specifying criteria of data protection by design requirements applicable across sectors, products and services. The foregoing might have relevant implications for software and hardware developers including those involved in REACTION. These provisions may mean that privacy-friendly features of products and services may have to be activated automatically when they are used (e.g., the privacy settings in internet browser should be turned on high from the time the browser is first used).<sup>56</sup>

### 3.3.4.2 Data breach notification duty

In terms of data security, a general data breach notification requirement applicable horizontally to all types of data controllers is introduced. The data breach notification was first introduced by Directive 2002/58/EC on the protection of privacy in the electronic communications sector (Privacy and Electronic Communications Directive)<sup>57</sup> as a duty for providers of publicly available communication services, such as internet service providers and telecommunication operators. Under Article 4.2 national laws must require providers of publicly available electronic communications services to inform subscribers of any special risks of a breach of the security of the network. According to the amended Directive 2002/58/EC, Article 2(h), 'data breach' includes any breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed. Should a breach occur, article 4.3 requires providers to give 'without undue delay' a notice of the breach to the competent national authority.

Data Breach Notification requirements are not explicitly foreseen in the Data Protection Directive. However, a number of countries, such as Germany and Norway, have introduced a notification requirement for data breaches.<sup>58</sup> In addition, the Article 29 Working Party has argued that an extension of personal data breach notifications, beyond telecoms firms, to Information Society Services is necessary given the ever increasing role these services play in the daily lives of European citizens, and the increasing amounts of personal data processed by these services, including access to medical records.<sup>59</sup>

Accordingly, the Proposed Regulation foresees the duty of notification of a data breach. According to Article 31 of the Proposed Regulation, notification is to be given by a data controller to both its lead Data Protection Authority (DPA)<sup>60</sup> and the data subjects concerned.<sup>61</sup> Data processors are to notify the

<sup>50</sup> Article 29 Data Protection Working Party, *The Future of Privacy. Joint contribution to the Consultation of the European Commission on the legal framework for the fundamental right to protection of personal data*, Adopted on 01 December 2009, 02356/09/EN, WP 168. para. 46.

<sup>51</sup> Ibid.

<sup>52</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 23.1.

<sup>53</sup> Ibid, Article 23.2.

<sup>54</sup> Ibid, Article 23.3, "Data protection by design".

<sup>55</sup> Ibid, Article 23.2, "Data protection by default"

<sup>56</sup> Ibid. The details of what they mean in practice are to be set forth in delegated acts and technical standards issued by the Commission, Articles 23.3– 4.

<sup>57</sup> Directive 2009/136/EC entered into force on December 19, 2009. This directive amends and supplements the ePrivacy Directive, i.e., Directive 2002/58/EC Concerning the Processing of Personal Data and the Protection of Privacy in the Electronic Communications Sector.

<sup>58</sup> Kierkegaard, P. (2011). Electronic health record: Wiring Europe's healthcare. *Computer Law & Security Review* 2, 503-515.

<sup>59</sup> Article 29 Working Party, Opinion 1/2009 on the proposals amending Directive 2002/58/ EC on privacy and electronic communications (ePrivacy Directive).

<sup>60</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 31

controller 'immediately' after establishing that a breach has occurred.<sup>62</sup> Notification should be given by the controller to its lead DPA *'without undue delay and, where feasible, not later than 24 hours after having become aware of it.'*<sup>63</sup> Notification to the data subject is not required if the controller implemented 'appropriate technological protection measures' prior to the data breach<sup>64</sup>; this is expected to provide a powerful incentive for companies to improve their data security procedures and technologies. Neither Directive 2009/136/EC nor the Proposed Regulation set specific formal requirements for data breach notification. According to paragraph 4 of article 4 Directive 2009/136/EC, however, *'the competent national authorities may adopt guidelines and, where necessary, issue instructions concerning [...] the format of such notification and the manner in which the notification is to be made.'* According to a study performed by the European Network and Information Security Agency, ENISA, few regulatory authorities have formal procedural guidelines. Most data protection authorities considered sufficient a phone call and an email, the mean of notification being principally decided on a case-by-case basis.<sup>65</sup>

In any case, for the purposes of REACTION, there is no doubt that a Data Notification mechanism should be foreseen in the architecture of the system.

### 3.3.4.3 Data protection impact assessment

Another important provision that appears to be relevant for REACTION is encompassed in Article 33 of the Proposed Regulation and concerns the obligation of data controllers to carry out Data protection impact assessments. Data protection impact assessments are to be carried out only in certain circumstances, e.g., when data processing operations *'are likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes.'*<sup>66</sup> Recital 71 indicates that the requirement to conduct them should apply in particular *'to newly established large scale filing systems, which aim at processing a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects.'* The foregoing suggests that an institution operating a system such as REACTION, for instance a hospital or a national health service, should carry out an impact assessment. In addition, the Proposed Regulation introduces the profile of the 'Data protection officers' (DPOs). The Proposed Regulation would make DPOs mandatory for all public authorities, and for all companies with more than 250 permanent employees in Article 35(1).

### 3.3.4.4 Codes of conduct and certification

As Metzger suggested, assurance mechanisms like warranties and seal programs can return a sense of trust more than privacy policies, which are often not read by the user.<sup>67</sup> Vedder and Wachbroit add that the mark of reliability and robustness of a device in terms of data privacy protection is very important. However, while only experts can recognize certificates attesting the quality of the technology, non-experts mostly are more familiar and rely on well reputed organisms or authorities of control.<sup>68</sup> Users-patients need rely on markers like brand name, reputation and past performance. This is important in order to build trust between REACTION actors.<sup>69</sup>

Article 27 of the Data Protection Directive 95/46 encouraged the *'the drawing up of codes of conduct intended to contribute to the proper implementation of the national provisions adopted by the Member States pursuant to this Directive, taking account of the specific features of the various sectors.'* The Proposed Regulation tries to accelerate the adoption of codes of conduct. In Article 38 it foresees the drafting of codes of conduct covering various data protection sectors, and allows them to be submitted to Data Protection Authorities (DPAs), which may give an opinion as to whether they are *'in*

<sup>61</sup> Ibid, Article 32.1 *'when the personal data breach is likely to adversely affect the protection of the personal data or privacy of the data subject'*

<sup>62</sup> Ibid, Article 31.2

<sup>63</sup> Ibid, Article 31.1.

<sup>64</sup> Ibid, Article 32.3

<sup>65</sup> ENISA, *ENISA report: Data breach notification in the EU*, 13 January 2011.

<sup>66</sup> Ibid, Article 33.1

<sup>67</sup> Metzger, M. (2006). Effects of site, vendor and consumer characteristics on web site trust and disclosure. *Communication Research* 33(3), 155-179.

<sup>68</sup> Vedder, A. (2005). Expert knowledge for non-experts: Inherent and contextual risks of misinformation. *ICES, Journal of Information, Communication and Ethics in Society*, 113-119. Vedder, A. & Wachbroit, R. (2003). Reliability of information on the internet: Some distinctions. *Ethics and Information Technology* 5, 211-215.

<sup>69</sup> In literature, most definitions focus on trust in the contexts of interpersonal relationships and of relationships between persons or institutions on the one hand and (other) institutions on the other. Uslaner, E. (2002). *The moral foundations of trust*. (Cambridge University Press, Cambridge). Gambetta, D. (1988). *Trust: Making and breaking cooperative relations*. (Basil Blackwell, New York). O'Neill, O. (2002). *A question of trust*. (Cambridge University Press, Cambridge).

compliance with this Regulation<sup>70</sup>, and to the Commission, which may adopt implementing acts determining that codes 'have general validity.'<sup>71</sup> Article 39 encourages the establishment of 'data protection certification mechanisms and of data protection seals and marks'.<sup>72</sup> It is too early to say whether such determinations by a DPA or the Commission would mean that compliance with a code of conduct would also satisfy the legal requirements of the Proposed Regulation.

Eventually, the transfer of data cannot be outsourced to third countries without the country having an adequate level of data protection and applying a set of EU standards and specifications. This is not the case with REACTION, whereby data are processed by a server located in Sweden. However, should the processing of data collected via the REACTION service platform be sent to a third country, the transfer will have to comply with the provisions of Article 25 and 26 Directive 95/46/EC. In this connection, the Proposed Regulation has introduced new rules with significant innovations.<sup>73</sup>

### 3.4 Processing of medical data

It should be clear by now that data protection law, rather than being a set of rules written in stone, operate, in practice, many and manifold balancing acts that are necessary to ensure respect for fundamental rights and democracy in constitutional states and the different interests populating any processing of personal data, which are the life and blood of the information society. As discussed above in the introduction, these balancing acts also involve an assessment of the risks inherent in the processing of personal data and sensitive personal data, which include data concerning the health status of individuals. In both cases, as paragraph 3.3.2 has showed, a legal justification, a legitimate basis for conducting the processing must be identified. Data must not only be processed fairly, i.e. following the data minimization principle, but also "lawfully".

For sensitive categories of data and health or medical data, the grounds that can justify, making it legitimate, their use (processing) are confined to a series of grounds listed in article 8 of Directive 95/46/EC. Article 8 states that the processing of personal data concerning health is, in principle, prohibited.<sup>74</sup> However, data protection law recognizes that there may be important private and public interests in the sharing and processing of personal information related to health. Accordingly, certain derogations exist which permit processing of personal medical data. These derogations must abide by the principles of data protection, notably data minimization. In addition, as each of these are derogations from the general rule of prohibition, they must be construed in a narrow fashion and applied taking into account the concrete and real (genuine) basis on which the processing is based.<sup>75</sup>

#### 3.4.1 Explicit consent

The legal notion of (informed) consent incorporates a rather elementary ethical principle giving a person reasonable assurance that she or he has not been deceived or coerced when entering in negotiation or any other purposive personal relationships.<sup>76</sup> Over the last twenty years, consent has been increasingly bureaucratized in areas such as education, financial services, consumer protection, as well as in health care and in the area of information and communication. In the area of e-health, the basic uncontroversial non-legal notion of consent is twisted by the requirements of, on the one hand, consent to a medical act and, on the other, consent to the communication and processing of medical data, to which this part refers. Processing of personal medical data is allowed where *'the data subject has given his explicit consent to the processing of those data.'*<sup>77</sup> Consent is defined as *'any freely given and informed indication of his or her wishes by which a data subject signifies his or her agreement to data related to him or her being processed.'*<sup>78</sup> Consent can therefore constitute a

<sup>70</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 38.2.

<sup>71</sup> Ibid, Article 38.4.

<sup>72</sup> Ibid, Article 39.

<sup>73</sup> Kuner, C. (2012). The European Commission's Proposed Data Protection Regulation: A Copernican Revolution in European Data Protection Law. *Privacy & Security Law Report*, 11 PVLR 06.

<sup>74</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Article 8(1). A general prohibition is also required according to Article 6 of the Council of Europe Convention No108

<sup>75</sup> The Data Protection Directive provides for mandatory derogations laid down in Article 8(2) and (3) plus an optional exemption in Article 8(4).

<sup>76</sup> O'Neill, O. (2003). Some limits of Informed consent, *Journal of Medical Ethics* 29(4), 7.

<sup>77</sup> This derogation cannot be used however where the laws of the Member State provide that the general prohibition may not be lifted by the data subject's giving his consent. European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Article 8 (2)

<sup>78</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Article 7(a) and Common Position of the Council on the proposal for a Parliament and Council Directive on

justification for the processing of sensitive data, but, in order to be valid, consent must be '*freely given*' and contain '*specific and informed indication of the data subject's wishes*.'<sup>79</sup> In addition to that, the processing that a person gives consent to must respect the principles of data processing, notably data minimisation.

In order to be valid, consent must meet several conditions.<sup>80</sup> '*Free*' consent means that reliance on consent should be confined to cases where the individual data subject has a genuine free choice and is subsequently able to withdraw the consent without suffering from detrimental consequences. Consent must therefore express a voluntary decision taken by an individual in possession of all of his faculties, taken in the absence of coercion of any kind, be it social, financial, psychological or other. Any consent given under the threat of non-treatment or lower quality treatment in a medical situation cannot be considered as 'free'. The Article 29 Working Party has stated that where a health professional has to process personal data in an EHR system as a necessary and unavoidable consequence of the medical situation, it is misleading if he seeks to legitimize this processing through consent.<sup>81</sup> Reliance on consent should be confined to cases where the individual data subject has a genuine free choice and he or she is consequently able to withdraw consent without detriment. When this is not the case, the health professional should take responsibility.

The adjective '*specific*' indicates that consent must relate to a well-defined, concrete situation in which the processing of medical data is envisaged. Therefore a 'general agreement' of the data subject, e.g., to the collection of his medical data for an EHR and to subsequent transfers of these medical data of the past and of the future to health professionals involved in treatment, would not constitute 'specific' consent. The reason for this is that, over time, the conditions for giving consent may change. For instance, a patient may want to discontinue treatment with the original health professional.

'*Informed consent*' means that consent by the data subject is based upon an appreciation and understanding of the facts and implications of a given situation and of an action. The individual concerned must be given, in a clear and understandable manner, accurate and full information of all relevant issues, in particular those specified in Articles 10 and 11 of the Directive, such as the nature of the data processed, purposes of the processing, the recipients of possible transfers, and the rights of the data subject (see below on 'comprehension'). The data subject should be aware of the consequences of not consenting to the processing in question.<sup>82</sup>

Consent must be *explicit*.<sup>83</sup> The data subject must be aware that he or she is renouncing special protection. Explicitness relates, in particular, to the sensitivity of the data. Clearly, opt-out solutions are not acceptable, since this would allow 'implied consent' and thus frustrate the rational behind the general prohibition clause. The solution preferred is to first inform the user and to obtain unambiguous and explicit consent before any data collection. This is what is known as opt-in. The foregoing means that when health data are exchanged as a part of a medical act performed by electronic means, a patient must be made aware that he or she is sharing his medical information or that he or she is allowing others to "enter his or her house" to monitor his or her health parameters. There should be ways to ensure that, over time, e.g., when the treatment via electronic means becomes routine, patients remain aware of the transmission of their health data. Last, in some European countries explicit consent must be traceable, thus a proof must be kept, usually in written form.<sup>84</sup> That being said, the rule of consent applies only when the patient has a genuine choice. In a case heard in front of the Belgian Constitutional Court<sup>85</sup>, the Belgian court took the view that, when a healthcare professional decides to process or communicate data through an electronic health system as an unavoidable consequence of the medical situation, e.g., in order to decide the appropriate treatment or prescription, it is misleading to justify it on the basis of consent. When the data processing is part of

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the protection of individuals with regard to the processing of personal data and the free movement of such data, (00/287) COD, adopted on 15/03/95.

<sup>79</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Article 2(h).

<sup>80</sup> *Ibid.*

<sup>81</sup> Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007.

<sup>82</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*.

<sup>83</sup> *Ibid.*, Article 7(a). Unlike for plain personal data where consent can be also implicit.

<sup>84</sup> Article 29 Working Party, Opinion 15/2011 Consent, WP 187 (13.07.2011)

<sup>85</sup> Cour Constitutionnelle, Arrêt n° 15/2008 du 14 février 2008, Numéro du rôle : 4163, 2008/200551. (in Dutch, "gezondheidsinformatiesysteem"). The case involved an action for annulment of certain provisions of a decree by the Flemish government of 16 June 2006 establishing a *Système d'information Santé (SIS)*. The *Union des médecins belges* alleged that the way health data contained in the medical dossier are communicated violated the right to private life of Belgian patients.

the medical act, the patient has no genuine free choice, consent cannot be given or refused, and should therefore not be used as legal basis.<sup>86</sup> The health professional will take responsibility.

An important tenet of giving consent is its negative dimension, the withdrawal of consent, the right to live and stay healthy outside the information society. Withdrawal of consent relates to an important requirement of individual access and use of ICT, which is also relevant for REACTION services, choice. Driven by imperatives of saving costs, the development of services for e-health might engender the situation whereby choice is so imbalanced, that it can hardly be called fair.<sup>87</sup> Only when individuals are able to choose and control the information they disclose, they can manage the way they portray themselves to others.<sup>88</sup> If people are obliged to disclose information in order to receive an essential service, such as medical care, this cannot be considered as 'real choice'. Choice here relates to the background conditions under which consent is, in the first place, given. The choice should include also the possibility to stop using a service like REACTION and return to a traditional model of care.

Between the two extremes of engaging or disengaging completely from ICT, there should also be intermediate positions, in which different choices of involvement in the health world are permitted. Indeed, also privacy is valued differently by different persons, and expectations and experiences of privacy will differ from person to person. This means that people need to be able to choose by themselves which information they regard as privacy-sensitive. Granularity of choice, however, should not be exaggerated, as an overload of choices can be de-motivating or counter-productive.<sup>89</sup> In addition, there are clinical requirements that may limit the choice of which information a patient/user is willing to disclose.

In the Proposed Regulation, Article 7, the use of consent for legitimizing data processing is significantly restricted 'where there is a significant imbalance between the position of the data subject and the controller.'<sup>90</sup> This provision suggests the recognition by the European legislator that, under some environmental conditions or personal conditions, consent cannot be said to be genuinely free. While this provision seems to be addressed mainly to the context of employment, power imbalances between, for instance, patient and physician, or patient and e-health systems, cannot be ignored. As discussed by the Article 29 Working Party in two opinions on electronic health records<sup>91</sup> and informed consent<sup>92</sup>, and in a report on the 'future of privacy'<sup>93</sup>, the complexity of information systems, which are hard to understand and therefore control, the declining cognitive capacities amongst what is expected to become the largest segment of REACTION users, older persons; the distance between patient and physician relationship, which impede eye – to eye human to human check, weakens the reliance on consent as the legal basis on which eHealth services like REACTION could be provided. As discussed above, courts assess not only the absence of dourness and coercion but also whether any genuine possibility to give consent freely actually exists and is in place. In the ultimate instance, the snag may be that it is not always easy to discern the subjective perception of consent amongst different users and in different contexts.

At the same time, technology developers, clinicians and in general third party need to rely on the legal security that consent can yield. The foregoing suggests that consent should be used only when there is genuine choice. When this is not the case, then the legal basis and the responsibility for the data communication and processing should be found in another basis, described below, and place on someone else's shoulders. In the many instances, some of which mentioned above, when it is not clear whether consent is genuinely given, it may be sensible to conceive of supportive or ancillary measures. One option that the REACTION platform may consider is the adoption of cooling off periods and regular interviews to verify whether, over time, the user still wants to signify his or her agreement to participate in the platform and have data related to him or her being processed. Inspiration could be

<sup>86</sup> Compare Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), adopted on 15 February 2007, 00323/07/EN WP 131, mentioned above.

<sup>87</sup> Stalder, F. (2002). The failure of privacy enhancing technologies (pets) and the voiding of privacy. *Sociological Research Online* 7(2).

<sup>88</sup> Nissenbaum, H. (1998). Protecting privacy in an informatino age: The problem of privacy in public. *Law and Philosophy* 17, 559-596.

<sup>89</sup> Iyengar, S. & Lepper, M. (2000). When choice is demotivating: Can one desire too much of a good thing? *Journal of Personality and Social Psychology* 79, 995-1006.

<sup>90</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Article 7(4).

<sup>91</sup> Working Document on the processing of personal data relating to health in electronic health records (EHR), 15 February 2007, WP 131.

<sup>92</sup> Opinion 15/2011 Consent, 13 July 2011, WP 187.

<sup>93</sup> The Future of Privacy: Joint contribution to the Consultation of the European Commission on the legal framework for the fundamental right to protection of personal data, 1 December 2009, WP 168. There three documents were discussed in REACTION, Ethical issues milestone.

taken also from mediation services in public hospitals which assist users in understanding the consequences of giving or refusing consent, or afford the possibility to renegotiate the contract of service.

### 3.4.2 Vital interest of the data subject

It may occur that the data contained in a portable mobile device are necessary to doctors in a situation where the data subject cannot take a decision. This derogation can apply where processing of sensitive personal data 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. Such processing must relate to essential individual interests of the data subject or of another person in a medical context, viz., be necessary for a life-saving treatment in a situation where the data subject is not able to express his intentions. Accordingly, this exception could be applied only to a small number of cases of treatment e.g. emergency treatment upon admission to hospital.

### 3.4.3 Processing of (medical) data by health professionals

The third ground for the processing of personal medical data, enshrined in Article 8.3 of Directive 95/46/EC, is when personal health data are processed by health professionals. This derogation is likely to be the one that is most relevant for REACTION use cases.

The processing is legitimate when two basic conditions are met: the data processing is “required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services and, the data controller offers an adequate guarantee of confidentiality.”<sup>94</sup> The present ground for processing of medical data seems to be fitting with REACTION’s purposes. There are, however, important conditions that must be met and that could limit the use of this ground.

The expression ‘required’, explains the Article 29 Working Party, means that any processing must be *fully justified*, the mere ‘usefulness’ of, e.g., having personal data stored not being sufficient.<sup>95</sup> In addition, further processing which do not have a clear and immediate link cannot be justified, e.g., medical research, public health and social protection, reimbursement claims, processing aimed at measuring quality and cost-effectiveness of the procedures, settling claims, insurance etc.<sup>96</sup> In these cases, the consent of the person concerned must be sought. In addition, use of information relating to the health status of a person is allowed only within the limits of the treatment contract, and cannot be used or communicated to third parties, including other health care professionals, unless the patient has agreed to passing on his or her data to named physicians or unless the exchange is foreseen by the law.<sup>97</sup> This will be important in REACTION where there is no direct treatment-relationship between the patient and the party to which the data is sent. If no such pre-existing treatment-relationship exists, expressed consent will have to be sought. This will be very Important where data is been passed to experts in a different institution.

The second condition, which is cumulative with the first one, is that personal data are ‘*processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.*’<sup>98</sup> If it is non-medical personnel who receive information, as it often happens in e-health where a simple administrator usually collect the medical data relating to a patient, they are too subject to at least an equivalent level of confidentiality and data protection.<sup>99</sup>

<sup>94</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Article 8(3) allows the processing of data ‘for the specific purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy’.

<sup>95</sup> Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007

<sup>96</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*. These are mentioned in recital 34 of the Directive as examples for invoking Article 8(4).

<sup>97</sup> In WP 131, mentioned above, the Working Party pointed out that the special obligation of professional secrecy must be either established in the national law of the Member States, or by national competent professional bodies with the power to adopt binding rules on the profession. These national rules on professional secrecy must also provide for corresponding effective sanctions in case of breach.

<sup>98</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Article 8.3.

<sup>99</sup> Article 29 Working Party, WP 131, p. 11.

The duty of medical confidentiality is a fundamental tenet of traditional medicine, first set out in the 'Hippocratic Oath'.<sup>100</sup> In the aftermath of WWII, the principle of medical confidentiality was reaffirmed in the 1948 World Medical Association's Declaration of Geneva and in other codes of conduct.<sup>101</sup> This principle proscribes the divulgence of the information about a patient collected by a health care professional in the course of the treatment. Indeed, if patients realise they cannot control who sees their electronic health records, they will be far less likely to tell their doctors about drinking problems, feelings of depression, sexual problems, or exposure to sexually transmitted diseases. In the case *Z v. Finland*, the European Court of Human Rights explained that respecting the confidentiality of health data is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general.<sup>102</sup> On a similar line, a recent Eurobarometer survey showed that 74 % of Europeans across the 27 Member States regard their medical data as private information. There is trust in the medical professionals and in the hospitals that they will treat their information confidentially.<sup>103</sup>

As Article 8.3 is a derogation from the general prohibition to process sensitive data; it must be applied in a restrictive way. The question arises as whether Article 8.3 of Directive 95/46/EC could serve as the sole legal basis for the processing of personal data in systems that are based on the continuous processing of electronic health records. The Article 29 Working Party gives a strict interpretation of the letter of Article 8.3:<sup>104</sup> according to this view, the derogations contained therein could only pertain to the processing of medical data for the medical and health-care purposes mentioned above, insofar as the processing is specific and required, and granted it is performed by a health professional or by another person subject to an obligation of professional or equivalent secrecy. If the processing of EHRs is beyond these purposes and conditions, e.g., general public health policy goal or vaccination security reasons, Article 8.3 cannot be invoked as the legal basis for the legitimate processing of that personal data. It will be important to take these recommendations into account where REACTION is seeking to transfer data between one institution and another.

#### 3.4.4 Substantial public interest

Article 8.4 of Directive 95/46/EC makes room for the opportunity, should the necessity arise, to restrict the data subject's control over his or her life and personal information for '*reasons of substantial public interest*'.<sup>105</sup> More explicitly, Recital 34 of the Directive concedes that '*[w]hereas Member States must also be authorized, when justified by grounds of important public interest, to derogate from the prohibition on processing sensitive categories of data where important reasons of public interest so justify in areas such as public health and social protection [...]*'.<sup>106</sup> It is added that any measures adopted must be proportionate and there should not be other less infringing measures available; they should also be subject to procedural rules ensuring participation and scrutiny and use of this derogation must be notified to the Commission.<sup>107</sup> The provision in Article 8.4 reminds that the protection of private information is not an absolute value, but that it must be balanced, in a fair and proportionate manner, with the competing interest of the community.<sup>108</sup> However, in order for states to lift the general prohibition on the processing of medical data, the interest of the community must be

<sup>100</sup> Edelstein, L. (2000). The Hippocratic Oath: Text, translation and interpretation. Veatch, R. (Ed.). Cross-cultural perspectives in medical ethics. (2<sup>nd</sup> ed.) (Jones and Bartlett Publishers, Sudbury). '*What I may see or hear in the course of the treatment or even outside the treatment in regard to the life of men, which on no account one must spread abroad, I will keep for myself holding such things shameful to be spoken about.*'

<sup>101</sup> "I will respect the secrets which are confided in me, even after the patient has died", Declaration of Geneva, World Medical Association [1948, amended 1968, 1983].

<sup>102</sup> ECtHR, *Z v. Finland*, judgment of 25 February 1997.

<sup>103</sup> European Commission (2010). Special Eurobarometer 359. Attitudes on data protection and electronic identity in the European Union. Retrieved 09 February 2012 from: [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_359\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_359_en.pdf)

<sup>104</sup> Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007

<sup>105</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities L281*, Article 8(4) of the Directive allows the Member States to derogate further from the prohibition of processing sensitive categories of data: '*Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.*'

<sup>106</sup> *Ibid*, Recital 34, [ *especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system - scientific research and government statistics*]

<sup>107</sup> *Ibid*, Article 8.6.

<sup>108</sup> Compare ECtHR, *Hatton v. UK*, judgment of 2 October 2001, §96, where the Court held that "regard must be [have] to the fair balance that has to be struck between the competing interests of the individual and of the community as a whole." (A clear illustration of this tension is the case of compulsory vaccination, whereby respecting individual consent would frustrate the attainment of the public health objective)



‘important’. Recital 34 provides a non-exhaustive list of what such important or substantial interest may be, ‘*especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system - scientific research and government statistics.*’

Should a Member State intend to make use of this derogation, such a course of action should be provided for in national legislation. This means that the state must put in place procedural and substantive rules ensuring participation, scrutiny, and protection. In addition, any measures adopted under this derogation should be justified by substantial reasons of public interest,<sup>109</sup> be proportional and there should not be other less infringing measures available. Member States must also provide sufficient safeguards in order to protect the rights of individuals. Uses of this derogation must be notified to the Commission<sup>110</sup>.

From a legal point of view, data protection law cautions that any derogation from the general prohibition rule for a substantial public interests should be surrounded or be equipped with ‘*specific and suitable safeguards so as to protect the fundamental rights and the privacy of individuals.*’<sup>111</sup> This paragraph provides for a relevant recognition of fundamental rights and, in particular,<sup>112</sup> of the case law of the European Court of Human Rights on article 8, the right to private and family life. In the area of private life and health, the European Court’s assessment has been concerned both with states’ negative duty to refrain from excessive, unjustified interference, and with states’ positive obligation to put in place adequate measures to guarantee the respect of private life in the health care context. This case law provides important lessons for a system such as REACTION, which deals with a chronic disease – diabetes - that bears significant public health implications.

In the area of negative obligations, the Court has expressed its views in concrete cases involving the cogent disclosure of personal medical information and in instances involving a restriction of individual control over private information. In the judgment of *Z. v. Finland*, mentioned above, the Court of Strasbourg assessed the requirement of necessity in relation to the disclosure by a state court of information concerning Z’s health status, concluding that there were no cogent reasons supporting the publication of this information in the *dispositive* of the sentence.<sup>113</sup> In the case of *S. and Marper v. United Kingdom* of 8 December 2008, the Court of Strasbourg held that the unlimited storage of cellular samples, DNA profiles and fingerprints of un-convicted individuals, including minors, was not surrounded by adequate safeguards against possible abuses, therefore interfering excessively and without necessity in individuals’ private life.<sup>114</sup> As the Strasbourg judge repeatedly stated, as a matter of principle any law providing for interference in the private life sphere ‘*must indicate the scope of any such discretion conferred on the competent authorities and the manner of its exercise with sufficient clarity, having regard to the legitimate aim of the measure in question, to give the individual adequate protection against arbitrary interference.*’<sup>115</sup>

Much more extensive are the positive implications that the court derived from Article 8. In general, according to the Court, ‘respect’ for private and family life imposes on the State not merely the duty to

<sup>109</sup> These include the fields of public health and social security, to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system.

<sup>110</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities* L281, Article 8.6.

<sup>111</sup> *Ibid*, Recital 34.

<sup>112</sup> *Ibid*. Which says that the content of the fundamental right to privacy and data protection can be derived from the ECHR and related case law.

<sup>113</sup> The *Z. v. Finland* judgment of 25 February 1997 concerned the alleged violation of the right to private life of a woman with HIV, identified as Z, who was married to a man committing rapes on other women who was subsequently prosecuted for attempted manslaughter. Finland’s criminal justice system required evidence of when the criminal defendant had a reasonable knowledge that he was also HIV positive. The Finnish Court of Appeal released a judgment identifying convicted rapist (X) and his wife (Z), who had become a reluctant witness in the proceedings, disclosing her identity and medical condition. The Strasbourg Court examined whether there were sufficient reasons to justify the disclosure of Z’s identity and HIV infection in the text of the Court of Appeal’s judgment made available to the press, holding unanimously that such a disclosure by the Helsinki Court of Appeal constituted a breach of Article 8, as there were no cogent (“necessity”) reasons supporting the publication of the information concerning Z’s health status.

<sup>114</sup> In the case *S. and Marper v. United Kingdom* of 8 December 2008, the Court of Strasbourg found that the retention (storage) of cellular samples, DNA profiles and fingerprints of unconvicted individuals constituted interference with the right to respect for private life. In that case, the court attacked the blanket and indiscriminate nature of the power of retention; the lack of a time-limitation for retention, the absence of independent review mechanisms; the risk of stigmatization; and the insufficient attention to protect minors following acquittals of a criminal offence. According to the Court of Human Rights, the retention of DNA samples for public interest failed to strike a fair balance between competing public and private interests.

<sup>115</sup> *Al-Nashif v. Bulgaria*, Application No. 50963/99, Judgment of 20 June 2002, paragraphs 119, 123. National provisions in their compliance with Article 8 of the ECHR should be read in the light of the Strasbourg jurisprudence: it needs to be done “*in accordance with the law*” and be “*necessary in a democratic society*” for a public interest purpose.

abstain from inappropriate interference but also, in some cases, to adopt certain positive measures.<sup>116</sup> In the specific area of health and private life the Court placed on the defendant states, Finland and Lithuania, specific and far reaching obligations.

*I v. Finland* concerned a case of unauthorized access to personal health status of *I*, a nurse working at a Finnish public hospital and who regularly attended the same hospital's infectious diseases clinic, having previously been diagnosed with HIV.<sup>117</sup> In front of the ECtHR, the dispute was whether the measures taken by the domestic authorities to safeguard *I*'s right to respect for her private life had been sufficient. In the view of the Court, Finland had failed to take two positive obligations inherent in an effective respect for private or family life, under article 8 of the Convention. First, the judges held that there was an obligation by the state to put in place practical and effective protection to exclude any possibility of unauthorized access.<sup>118</sup> The court went on to detail that this obligation should involve technological and organizational measures, such as log in systems, which would have allowed *I* to collect and take sufficient evidence to the domestic court.<sup>119</sup> It concluded that, in any case, deficiencies in record keeping systems cannot result in higher burden of proof on the individual.<sup>120</sup> The ruling in this case establishes a nexus between the right to privacy under human rights law and the protection of personal information. From a human rights perspective, one of the immediate preoccupation of states should be to mitigate the risks inherent in data processing of sensitive health information by putting in place systems of ex post control and access to justice. Additional efforts are required when a state or an institution of public utility, such as hospitals, create electronic health records systems. These efforts should enable to inspect which personal data has been disclosed to whom, when, and under what conditions. Since many services require the involvement of multiple service providers, user control should not stop at the first party in the interaction chain. Users should be able to see what happens with their data along the entire service chain.

In *I v. Finland* the European Court of Human Rights held that it is a positive obligation of states to ensure that information systems used in a hospital are transparent and allow to identify responsibility in case of wrongdoings or mistakes. The positive obligations may not stop here, but include also the obligation to foresee and provide reasonable and substantial compensation in case of errors, as the second case poignantly illustrates.

In *Armonas v. Finland*<sup>121</sup>, the applicant turned to the European court complaining that that her right to private life had been violated because of the ridiculously low compensation that was granted to her as a consequence of the disclosure of information relating to the health status of Armonas' deceased husband, and despite the recognition by the Lithuanian court that a violation of privacy had occurred. The question that the court had to answer was whether the amount of compensation was proportionate to the harm and to what extent the legal provisions restricting the compensation to a fixed, (and low), sum were in line with Article 8. The European court does not take it on itself to require states to impose heavy sanctions, leaving this decision to states. However, in case of a manifest abuse, the court considered that the heavy legal restrictions on the compensation of victims, and the low amount that was accordingly paid to the victim, could not meet the expectations of just satisfaction that people must have in the area covered by private and family life. Therefore, the low compensation amounted to a violation of Article 8 and Lithuania was held accountable.<sup>122</sup> States have therefore a duty to protect the right to privacy and data protection in an alert and appropriate way. Yet, since mistakes are possible, reaction and safeguards, as discussed in *I v. Finland*, may not suffice. There should be also compensation that ought to be not symbolic or nominal but, as found in *Armonas*, reasonable and substantial.

In this connection, it is noteworthy to mention the new regime for penalties and administrative fines suggested by the 2012 Proposed Regulation. The considerable pecuniary penalties and fines elevate the significance of data protection on a par with corporate compliance with other topics such as

<sup>116</sup> *I v. Finland*, paragraph 36, *Airey v. UK judgment*, 1979, paragraph 32; *X and Y v the Netherlands*, 1985, paragraph 23; *Whiteside v UK*, 1994; *Botta v Italy*, 1998; *Marzari v. Italy*, 1999; *Hatton v. UK*, 2001; *MC V. Bulgaria*, 2001)

<sup>117</sup> *I v. Finland*, judgment of 17 July 2008. In this case *I* began to suspect that news of her disease had spread to fellow employees and decided to sue the District Health Authority for failing to keep her medical records confidential. At first instance the domestic court found that there was insufficient evidence that her medical records had been accessed unlawfully. An appeal and permission to appeal to the Finnish Supreme Court were rejected.

<sup>118</sup> *Ibid.*, paragraph 47: 'What is required in this connection is practical and effective protection to exclude any possibility of unauthorised access occurring in the first place.'

<sup>119</sup> *Ibid.* Paragraph 20.

<sup>120</sup> *Ibid.*, Paragraph 44. 'It is plain that had the hospital provided a greater control over access to health records by restricting access to health professionals directly involved in the applicant's treatment or by maintaining a log of all persons who had accessed the applicant's medical file, the applicant would have been placed in a less disadvantaged position before the domestic courts.'

<sup>121</sup> *Armonas v. Lithuania*, judgment of 25 November 2008.

<sup>122</sup> *Ibid.*, paragraph 47.

competition law, anti-corruption, and money laundering.<sup>123</sup> All controllers and processors involved in the data processing are jointly and severally (Article 77(2–3)). The sanctions must be imposed mandatorily for any intentional or negligent violation of certain provisions of the Proposed Regulation. Furthermore, under the Proposed Regulation, sanctions are to be imposed in a uniform way on companies operating in the EU area, rather than being left to the discretion of member states, - as was allowed under Directive 95/46, with the result that they varied widely.<sup>124</sup>

The foregoing indicates a series of precise requirements for the REACTION service platform or system. The first one is a 'log-in system' used to identify and authenticate a given person. And the second one is a 'log system' that records who did what and when in an audit log. Clearly, the first one can work without the second one, but not vice versa. This would contribute to realise those "technical and organizational measures" capable of ensuring the traceability of those who access the data of patients. Besides robust log-in and log systems showing who has accessed information and when, REACTION could consider the allocation of compensation or insurance schemes in case errors occur in the processing of medical data.

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<sup>123</sup> European Commission (2012). Proposal for a Regulation. COM(2012) 11/4, Articles 79.4 to 6. Sanctions are divided into three categories, ranging from up to 0.5 percent, 1 percent, or 2 percent of a company's worldwide revenues.

<sup>124</sup> European Parliament and the Council of the European Union (1995). Directive 95/46/EC. *Official Journal of the European Communities* L281, Article 24.

## 4. Human rights

With diabetes becoming an increasing challenge not only for the health system but having the opportunity to become a burden for whole populations and the economic systems, the focus often rather lies on finding a financially satisfying solution than on the human rights of patients. Diabetes associations however point out the specific needs and requirements of diabetes patients and attempt to strengthen the right of this group by for example publishing a specific 'Charter of Rights of People with Diabetes'.<sup>125</sup> Human rights are legal entitlements, both, collective and individual, which are granted to every human being.<sup>126</sup> Rights of the first generation cover civil and political rights, the so-called 'negative' rights.<sup>127</sup> Economic, social and cultural rights, often described as 'positive' rights, belong to the second generation.<sup>128</sup> The third generation comprises complex collective rights.<sup>129</sup> With the entry into force of the Lisbon Treaty the European Charter of Fundamental Rights and the entailed human rights became legally binding.<sup>130</sup>

### 4.1 The right to health as a human right

Health is often regarded as most precious value. Often characterized as important commodity it is also essential as an element contributing to a productive workforce which is a condition for a successful economy. Moreover, health is a human right. The interrelation of the right to health with other human rights, often indicated as 'underlying determinants of health'<sup>131</sup>, illustrates the complexity of this right. The realization of a right to health depends on a variety of conditions and cannot merely be fulfilled by the provision of good health care. The recognition and realization of other human rights is crucial.<sup>132</sup> New technologies offer new forms of treatments leading to an improved quality of life. At the same time, however, they pose significant challenges for governments and patients. The application of new technologies like in the REACTION project must not impair human rights but facilitate their realization. Such considerations must always be underpinned by the recognition of human rights and legal obligations, either positive or negative.

In the context of REACTION not only the right to health will be highlighted but other human rights like the right to privacy, access to information and data protection will be scrutinized.

One of the first questions which might arise if the right to health is discussed in the context of REACTION is how a right to health can be realized for patients suffering from a chronic condition. Therefore, it shall be emphasized that the right to health or health care does not equate a right to be healthy. The right to health is rather an obligation for states to strive for the realization of what is formulated in the WHO's definition of health as being '*a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.*'<sup>133</sup> Modern technologies are seen as a mean to achieve this goal. Hence, it is often argued that this right does not only cover basic health care services but extends to the use of modern technologies in the area of health care. Facilitating the live of patients with diabetes can therefore be a contribution to the realization of the right to health.

What was formulated more than 60 years ago, in 1946, in the preamble of the *Constitution of the World Health Organization* (hereinafter WHO)<sup>134</sup> is nowadays considered as the first international recognition of this right.<sup>135</sup> The *Universal Declaration of Human Rights* (hereinafter UDHR) recognised the right to a '*standard of living adequate for the health and well-being*' for every human being just two

<sup>125</sup> The Parliamentary Association for the Protection and the Promotion of the Right to Health & Associazione Diabete Italia (2009). Charter of Rights of People with Diabetes. Retrieved 14 February 2012 from: [http://www.novonordisk.it/media/download/manifesto\\_english.pdf](http://www.novonordisk.it/media/download/manifesto_english.pdf)

<sup>126</sup> Tomuschat, C. (2008). *Human Rights – Between Idealism and Realism*. (2<sup>nd</sup> ed.) (Oxford University Press, Oxford).

<sup>127</sup> *Ibid.* Chapter 3.

<sup>128</sup> *Ibid.*

<sup>129</sup> *Ibid.*

<sup>130</sup> Charter of Fundamental Rights of the European Union (2000). *Official Journal of the European Communities*, C 364, 1-22.

<sup>131</sup> UN Economic and Social Council (2000). The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4. § 4.

<sup>132</sup> *Ibid.* §3.

<sup>133</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

<sup>134</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. The definition has not been amended since 1948.

<sup>135</sup> Da Costa Leite Borges, D. (2011). Making Sense of Human Rights in the Context of European Union Health-Care Policy: Individualist and Communitarian Views. *International Journal of Law in Context*, 7(3), 335-356. P337.

years later.<sup>136</sup> The obligations of states to realize the right to health are enshrined in the *International Covenant on Economic, Social and Cultural Rights*.<sup>137</sup> Article 12 does not only recognize a 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'<sup>138</sup> but also indicates that states are under the obligation to take specific steps towards 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness.'<sup>139</sup> As illustrated in General Comment No. 14 of the Committee on Economic, Social and Cultural Rights, the right to health does not equate to a right to be healthy. Instead, it covers a series of several entitlements, one of them being access to health care.<sup>140</sup> This includes access to modern technologies and eHealth devices as those promoted in REACTION. The right to health is based on the fundamental interrelating principles of availability, accessibility, acceptability and the quality of service or care.<sup>141</sup>

With the entry into force of the Treaty of Lisbon in 2009 the European Charter on Fundamental Rights became legally binding and the position of human rights on European level was strengthened.<sup>142</sup> Article 6 of the Consolidated Version of the Treaty on European Union (hereinafter TEU) clarifies that the Charter has to be regarded as primary EU law.<sup>143</sup> Article 35 of the Charter states: 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.'<sup>144</sup> The Charter herewith specifically grants a right to health care. In addition, Article 35 states that 'A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.'<sup>145</sup> This provision is binding on the Union acts but not on Member States acts, unless they are implementing EU law.<sup>146</sup> The REACTION project must therefore consider both national and European law.

Another important reference for the EU legal framework on health is the 1950 *European Convention on Human Rights and Fundamental Freedoms* (hereinafter ECHR) of the Council of Europe. Although it does not contain an explicit right to health<sup>147</sup>, this instrument has an important function since it provides principles on important rights, such as the right to privacy (see below). The legal framework is completed by the 1961 *European Social Charter* promoting the right to the highest attainable standard of health, the protection of health and to medical assistance (which can also include modern eHealth technologies).<sup>148</sup>

With regard to diabetes the right to health should not merely be acknowledged as a right to access health care. Health has many determinants not all of them related to care. An important aspect, closely link to diabetes, is nutrition. Nutrition plays an important role in diabetes type II. Health education and health promotion are therefore at the moment tremendously used to promote life style changes and better eating habits.<sup>149</sup> Some scholars however do not regard diabetes type II as a

<sup>136</sup> UN General Assembly (1948). The Universal Declaration of Human Rights. Adopted and Proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948. Article 25.1.

<sup>137</sup> UN Treaty Collections (2011). Status International Covenant on Economic, Social and Cultural Rights. Retrieved 20 October 2011 from: [http://treaties.un.org/Pages/ViewDetails.aspx?chapter=4&lang=en&mtmsg\\_no=IV-3&src=TREATY](http://treaties.un.org/Pages/ViewDetails.aspx?chapter=4&lang=en&mtmsg_no=IV-3&src=TREATY)

<sup>138</sup> UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights. Adopted and Opened for Signature, Ratification and Accession by General Assembly Resolution 2200A (XXI) of 16 December 1966 *Entry into Force* 3 January 1976, in Accordance with Article 27.

<sup>139</sup> UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights. Article 12.

<sup>140</sup> UN Economic and Social Council (2000). The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4. §9.

<sup>141</sup> UN Economic and Social Council (2000). The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4.

<sup>142</sup> European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403.

<sup>143</sup> European Union (2010). Consolidated Version of the Treaty on European Union. *Official Journal of the European Union* 53(C83), 13 -46. Article 6.

<sup>144</sup> European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403. Article 35.

<sup>145</sup> Ibid.

<sup>146</sup> This competence flows from Article 6 of the Treaty on the Functioning of the European Union (hereinafter TFEU), the 'social clause' in Article 9, which enables the EU to focus on areas of social responsibility, such as the protection of human health, and Article 168 TFEU, which requires the promotion and protection of public health. The Charter addresses EU institutions and is only applicable for Member States when implementing EU law. The scope of this Charter therefore encompasses EU legislation and the implementation of it by Member States.

<sup>147</sup> Council of Europe, European Convention on Human Rights and Fundamental Freedoms (1950, 2010). Retrieved 15 January 2012 from: [http://book.coe.int/sysmodules/RBS\\_fichier/admin/download.php?fileid=3502](http://book.coe.int/sysmodules/RBS_fichier/admin/download.php?fileid=3502)

<sup>148</sup> Council of Europe (1961). European Social Charter . Part I (11), Article 11 and 13.4.

<sup>149</sup> Chaufan, C. (2008). What Does Justice Have to Do With It? A Bioethical and Sociological Perspective on the Diabetes Epidemic. *Bioethical Issues, Sociological Perspectives, Advances in Medical Sociology* 9, 269 – 300.

disease originating only from a wrong life style or genetic predisposition. Even though those influences are acknowledged, this type of diabetes is rather seen as a life-course disease. The causal relation between diabetes type II and poverty requires new measures in the light of a right to health. People growing up in poverty are exposed to an unhealthy life style throughout their life. Often even their ancestors have suffered from bad conditions. Poverty for example makes it often impossible to buy healthy food. Realizing a right to health with regard to diabetes type II would therefore mean focusing of principles of equality and enable disadvantaged people to change their environment. Even though health education is important it will not change the conditions and environments of poverty.<sup>150</sup> Being a life course disease, 'treatment' of diabetes has to start as early as the disease, before birth. Factors during pregnancy and the health status of ancestors and particularly the mother have been proven to be influential.<sup>151</sup> The so-called intergenerational non-genetic reproduction can only be stopped by changing the circumstances and lifting people out of poverty. Here the right to health interrelates with a right to development and a right to social justice.

At the moment, the possibilities of enforcement of the right to health in courts are limited. However, one should consider the possible use of this right to gain access to certain treatments, for example the services of REACTION.

#### 4.2 The right to privacy

In the context of new eHealth technologies complex dynamics between the individual and the community get into the focus. Privacy, as a function of the relationships that, at a given time and place, exist between the individual and the community,<sup>152</sup> is an important human right which frames the discussion on the use of new technologies in medicine. Access to those technologies needs to be granted on equal basis which led to the launch of many eHealth initiatives in the context of the European Digital Agenda. This will likely result in an increase in the amount of information exchanged between healthcare providers within and across different Member States.<sup>153</sup> Moreover, technological developments emphasize the significance of being an autonomous individual who can stand apart and develop his or her personality and personal relationships without undue external influence and control.<sup>154</sup> Data protection and notions of privacy are therefore essential in the debate of a regulatory framework. This section will shortly elaborate on the right to privacy. A more extensive description can be found in Deliverable 9-1 of the REACTION project.

The European Union Charter of Fundamental Rights includes the right to privacy in Article 7. By mentioning privacy and data protection in separate Articles (Article 7 and 8 respectively) a formal difference is indicated.<sup>155</sup> The right to privacy as a right 'to respect for his or her private and family life, home and communications' is established in Article 7 using almost the same terms of Article 8.1 of the European Convention of Human Rights (ECHR).<sup>156</sup>

Case law of the European Court of Human Rights illustrates the meaning and the importance of privacy on European level.<sup>157</sup> Accordingly, Article 8 ECHR can cover a wide range of issues such as for example integrity, access to information and public documents, secrecy of correspondence and

<sup>150</sup> Ibid.

<sup>151</sup> The influence of (mal)nutrition was proven in a study which focused on the effects of the Dutch famine. Participants exposed to those extreme conditions in a prenatal phase have been shown to have a stronger predisposition to insulin resistance. Ravelli, A. (1998). Glucose Tolerance in Adults after Prenatal Exposure to Famine. *The Lancet* 351, 173 – 177.

<sup>152</sup> See Westin, A. (1967). *Privacy and Freedom*. (Atheneum, New York). Habermas, J. (1992). *The Structural Transformation of the Public Sphere*. (Polity Press, Cambridge). Originally published as *Strukturwandel der Öffentlichkeit: Untersuchungen zu einer Kategorie der bürgerlichen Gesellschaft*. (1962) (Luchterhand, Neuwied, Berlin). Merton, R. (1968). *Social Theory and Social Structure*. (The Free Press, New York). Schoeman, F. (1992). *Privacy and Social Freedom*. (Cambridge University Press, Cambridge).

<sup>153</sup> Douwe, K. (2002). EC Study on implementation of data protection Directive. Retrieved 13 February 2012 from: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1287667](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1287667)

<sup>154</sup> See Mordini, E., Wright, D., de Hert, P., Mantovani, E., Wadhwa, K., Thestrup, J. and Van Steendam, G. (2009). Ethics, e-Inclusion and Ageing. *Studies in Ethics, Law, and Technology* 3(1), Article 5.

<sup>155</sup> European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403. See Friedewald, M., Schütz, P., Gutwirth, S., Gellert G, Bellanova, R., Wright, D., Mordini, E. & Venier, S. (2010). Privacy and emerging fields of science and technology: ethical, social and legal aspects - WP 1 – Current legal, socio-economic and ethical approaches to privacy and technology, *Discussion Paper*.

<sup>156</sup> Council of Europe, European Convention on Human Rights and Fundamental Freedoms (1950, 2010). The CFR mentions the more up-to-date term of "communications" instead of "correspondence" in the ECHR.

<sup>157</sup> European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403. In accordance with Article 52(3) of the EU Charter, the meaning and scope of this right are the same as those in the corresponding article of the ECHR. Consequently, the meaning is the same and the limitations which may legitimately be imposed on this right are the same as those allowed by Article 8 of the ECHR

communication, protection of the domicile or the protection of personal data.<sup>158</sup> Privacy is therefore a relational concept that goes well beyond a mere right to intimacy. Consequently, Article 8 may also protect visible and public features and conduct of individuals (public privacy).<sup>159</sup> The case law highlights that privacy is not to be understood as a concept merely protecting the individual from external interferences but that it also covers notions of self-determination and autonomy and facilitates personal decisions.<sup>160</sup> Similarly to other human rights, progressive realization has been postulated for the right to privacy during the last years. States are therefore under the obligation to not only respect the right to privacy but also to realize conditions enabling the enjoyment of a private life.<sup>161</sup>

Among these conditions, it is important that states put in place appropriate systems for the detection and compensation of data breach. As discussed above in the section on data protection, in *I. v. Finland* (2008), it was found that privacy in health care systems can be protected also by ensuring that the system is transparent and responsibility in case of wrongdoings or in case of mistakes can be demonstrated.<sup>162</sup> This case gives important clues to the REACTION project towards giving implementation to similar measures. As was mentioned above, in *Armonas v. Lithuania*, the need for a substantial and reasonable compensation was established. Access to justice and redress is essential. The REACTION project should take the lessons from this case into account. Accepting that errors can occur when technology is used means that there is a need for strict rules which have to be adopted regarding not only reaction to errors but also compensation.<sup>163</sup> If such a provision is not made individuals will likely be able to seek such remedies in court in the light of the cases above.

### 4.3 The right to access information

The development of new applications in the context of the REACTON platform requires access to information and communication networks. The right to access information is related to the policy of inclusion in the information society and is part of the Digital Agenda for Europe, discussed above.<sup>164</sup>

The body area network which is used for the transmission of data of REACTION applications sends data to medical knowledge systems and health care professionals. The use of the application therefore relies on communication and processing of patient data. The latter relates to the right to data protection and access to these data is therefore limited to authorized persons mainly health care professionals. However, in eHealth in general and in the REACTION project in particular patients themselves also have a right to access this information. This right is addressed in several human rights documents<sup>165</sup> and in European case law.<sup>166</sup>

A general ongoing debate at the moment concentrates on the right to access the Internet which does not constitute a separate human right as of yet.<sup>167</sup> Internet access is considered as human right by significant groups of individuals.<sup>168</sup> At the moment, the right to access the Internet is postulated by soft law only. Access to the Internet is therefore at the moment not generally enforceable in courts. The Charter of Human Rights and Principles for the Internet states in Article 1 that 'everyone has the right

<sup>158</sup> ECtHR. *Niemietz v Germany* of 16 December 1992, § 29 and *Pretty v U.K.*, of 29 April 2002, Judgment: 'The Court does not consider it possible or necessary to attempt an exhaustive definition of the notion of 'private life'. However, it would be too restrictive to limit the notion to an 'inner circle' in which the individual may live his own personal life as he chooses and to exclude there from entirely the outside world not encompassed within that circle. Respect for private life must also comprise to a certain degree the right to establish and develop relationships with other human beings.' *Bensaid v. the United Kingdom*, no. 44599/98, para. 47. *Koua Poirrez v. France*, Judgment of 30 September 2003, dissenting opinion of judge Mularoni

<sup>159</sup> ECtHR. *Rotaru v Romania* of 4 May 2000, § 43; *P.G. & J.H. v U.K.*, of 25 September 2001, § 57, *Peck v U.K.*, of 28 January 2003, § 58.

<sup>160</sup> MOVING LIFE, Consultation Workshop - mHealth in a Socio-economic Context', 18 January 2012, Brussels. Presentation by prof. P. De Hert, *The implications of article 8 ECHR*.

<sup>161</sup> ECtHR. *Botta v. Italy* (1998) 26 EHRR 241. ECtHR. *Kutzner v. Germany* (2002) EHRR 653. 1991) 14 EHRR 319

<sup>162</sup> The European Court of Human Rights (2008). Judgement in the *Case I. versus Finland*. Retrieved 26 January 2012 from: <http://www.cl.cam.ac.uk/~rja14/Papers/echr-finland.pdf>

<sup>163</sup> ECtHR (2008). Judgement in the Case *Armoniene versus Lithuania*. Retrieved 26 January 2012 from: [http://en.tm.lt/dok/Armoniene\\_v\\_Lithuania.pdf](http://en.tm.lt/dok/Armoniene_v_Lithuania.pdf)

<sup>164</sup> See also European Commission (2009). *Telemedicine for the Benefit of Patients, Healthcare Systems and Society*. Commission Staff Working Paper. SEC (2009) 943 final.

<sup>165</sup> UN General Assembly (1948). *The Universal Declaration of Human Rights*. Adopted and Proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948. Article 19. See also EU Charter, article 11.

<sup>166</sup> ECtHR (2008). Judgement in the *Case I. versus Finland*. Retrieved 26 January 2012 from: <http://www.cl.cam.ac.uk/~rja14/Papers/echr-finland.pdf>

<sup>167</sup> Hick, S., Hapin, E. & Hoskins E. (eds.) (2000). *Human Rights and the Internet*. (Palgrave Macmillan).

<sup>168</sup> La Rue, F., UN Human Rights Council (2011). *Report of the Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression*; Frank La Rue. (A/HRC/17/27).

to access to, and make use of, the Internet.' It continues in Article 17(a) that 'everyone shall have access to health-related and social services on the Internet.'<sup>169</sup> Access to the Internet has two dimensions: access to content and connectivity.<sup>170</sup> The latter is a central aspect for eHealth, as it covers aspects such as infrastructure such as cables or wifi, and the necessary software. The availability of this infrastructure is closely linked to the right to development. Constant connectivity is also of crucial importance for the REACTION applications. Content on the other hand relates to the freedom of expression, a political right which requires states to refrain from interference.<sup>171</sup> In order to ensure that mobile health technologies 'protect and fulfil' the attainment of the highest level of health, as demanded by Article 12 ICESCR, it is important to consider the implications of this 'right of technological access' in terms of accessibility, acceptability, availability, and the quality of service. A more detailed description of those dimensions of the right to access information can be found in REACTION Deliverable 9-1.

#### 4.4 The principle of non-discrimination

A basic principle not only in human rights law but also with regard to EU legislation is the principle of non-discrimination. Its value is emphasized internationally in for instance the International Covenant on Civil and Political Rights which establishes the principles of non-discrimination and equality in Articles 2 and 3.<sup>172</sup> Equality is characterized by the absence of direct and indirect discrimination. State parties to the Covenant might be required to take affirmative action including the elimination of conditions which are a cause of discrimination.<sup>173</sup> On European level the Treaty on European Union demands combating discrimination and highlights the importance of the principle of non-discrimination.<sup>174</sup>

It is therefore required that services are provided '*without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status*'.<sup>175</sup> The REACTION project should therefore avoid making those distinctions. Health care providers that provide health care services such as REACTION in a discriminatory fashion will be acting illegally. Special consideration should be given to the field of cross-border care in the EU. The provision of services does not end at a border and patients expect to receive good care in other Member States. Member States may not easily prevent citizens to go abroad to seek health care and patients even have a right to reimbursement. Discrimination because of nationality is not allowed. These rules equally apply to the provision of eHealth services. Issues of accessibility and inclusion have to be taken into account when using new technologies. REACTION should aim at the provision of care based on principles of equality and enable those to access it who might have experienced difficulties before. Marginalized groups, people with disabilities and the ageing society should get special attention.

A recent Belgian judgment clarifies that a chronic condition as diabetes does not serve as a reason for general exclusion. The applicant was rejected for a job based on internal guidelines prohibiting people with diabetes to work in this job. Since the employer and the medical service which was responsible for the test could not prove a risk related to the function originating from the chronic condition, the practice was regarded as discriminatory. The guidelines have to be dismissed and the applicant was awarded compensation.<sup>176</sup>

<sup>169</sup> Internet Rights and Principles Coalition (2010). Charter of Human Rights and Principles for the Internet.

<sup>170</sup> Connectivity refers to the physical and technical infrastructure that is necessary to guarantee access to the Internet.

<sup>171</sup> La Rue, F., UN Human Rights Council (2011). Report of the Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression; Frank La Rue. (A/HRC/17/27).

<sup>172</sup> UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights. Adopted and Opened for Signature, Ratification and Accession by General Assembly Resolution 2200A (XXI) of 16 December 1966 *Entry into Force* 3 January 1976, in Accordance with Article 27.

<sup>173</sup> UN Economic and Social Council (1989). General Comment No. 18: Non-Discrimination.

<sup>174</sup> European Union (2010). Consolidated Version of the Treaty on European Union. *Official Journal of the European Union* 53(C83), 13 -46. Article 2, 3.3.

<sup>175</sup> UN Economic and Social Council (1989). General Comment No. 18: Non-Discrimination.

<sup>176</sup> Arbeidshof te Antwerpen (2011). A.R. 2010/AA/334, E.D.B. v. VZW Medimar & Belgische Staat, FOD Werkgelegenheid, Arbeid en Sociaal Overleg.



#### 4.5 Specific human rights for diabetes patients?

Several organizations and parliamentary groups of Member States published charters comprising the rights and duties of people with diabetes.<sup>177</sup> The charters cannot be considered as hard law. They often rather have the status of a recommendation and therefore constitute soft law. Aiming at a social and working life equal to those living without diabetes, the charters were published to raise awareness for the specific needs of diabetes patients. They urge for support of diabetes patients and want to clarify that diabetes does not prevent patients from reaching goals in personal and working life.

Those charters postulate several rights, e.g. a right to care, a right to social justice and a right to education. The right to care comprises different dimensions reflecting aspects of the right to health. Issues of accessibility, affordability and availability are central. The principle of non-discrimination and the importance of respect and dignity are highlighted. In terms a right to information and education a patient-centered approach with the possibility of patient involvement is promoted. Access to medical records should be granted. Education does not only focus on health education of diabetes patients but includes the education of health care professionals.

In the tradition of African human rights charters not only rights but also duties and responsibilities are promoted. Those responsibilities include i.a. sharing information with healthcare providers, compliance with treatments and the adoption of a healthy life-style.<sup>178</sup>

The inclusion of the general public in health education to raise awareness and understanding is demanded. Even though the rights and duties of current patients are central the charters also lobby for an anticipatory approach. Prevention and research are topics that should be put on the political agendas. Furthermore, particular attention is paid to certain groups. An emphasis is put on groups with specific needs and characteristics like adolescents or the problem of diabetes and pregnancy.<sup>179</sup>

These charters are no human rights documents in a classical way and not binding on states or individuals. Nonetheless, they show that patients with diabetes have specific needs, many of them in the area of adequate education, information and promotion. Furthermore, their own responsibility in managing the disease is highlighted. Diabetes patients can and want to lead an independent life. Applications like those developed in the REACTION project enhance their mobility and independence and are therefore very much in line with the demands of the charters.

Although these are not binding on courts these instruments might have persuasive effect in case of such treatment platforms as REACTION.

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<sup>177</sup> Examples of these Charters are: The Parliamentary Association for the Protection and the Promotion of the Right to Health & Associazione Diabete Italia (2009). Charter of Rights of People with Diabetes. Retrieved 14 February 2012 from: [http://www.novonordisk.it/media/download/manifesto\\_english.pdf](http://www.novonordisk.it/media/download/manifesto_english.pdf) & International Diabetes Federation (n.d.). International Charter of Rights and Responsibilities of People with Diabetes. Retrieved 15 February 2012 from: <http://www.idf.org/sites/default/files/IDF%20International%20Charter%20of%20Rights%20and%20Responsibilities%20of%20People%20with%20Diabetes.pdf>

<sup>178</sup> International Diabetes Federation (n.d.). International Charter of Rights and Responsibilities of People with Diabetes.

<sup>179</sup> The Parliamentary Association for the Protection and the Promotion of the Right to Health & Associazione Diabete Italia (2009). Charter of Rights of People with Diabetes.

## 5. Corporate Social Responsibility

Business and human rights became a popular topic during the last years. There is an increasing perception that business can contribute to society and shape the political, public and academic debate. Theories but also practices focusing on how business manages the relationship with society are described by the umbrella term corporate social responsibility (CSR). With enterprises increasingly crossing borders, the demand for creating accountability, not only for economic but also for ethical misconduct, inside and outside their home countries grew.

Whereas, profit maximisation was for a long time seen as a main responsibility of business and governments where responsible to regulate by enacting sufficient legislation<sup>180</sup>, the idea changed during the last years and now the responsibility of enterprises is emphasized. It is often stated that CSR begins where the law ends.<sup>181</sup> CSR is characterized by a self-regulatory and voluntary nature. Rather than strict legislation, rules and regulations the focus lays on moral and ethical obligations that business is believed to have. Hence, the self-regulatory and voluntary nature of a contribution of market-based solution to societal change is often very much emphasized. CSR is therefore believed to go beyond mere legal compliance. Voluntary not obligatory actions are central.<sup>182</sup> Ethical responsibilities, environment and sustainability are central in CSR. It is believed that there is no need for a trade of between environment and business but there is the possibility of acting eco-efficient.<sup>183</sup>

In diabetes care the responsibility of companies might not be the first issue that comes to one's mind. The REACTION project however involves new technologies developed, produced and later marketed by companies which will have to take their responsibility towards society. Furthermore, the cross-border aspect is becoming more important for enterprises and patients cross. The field of diabetes care is getting more international. This process is perfectly illustrated by a project like REACTION bringing together organizations and enterprises from different countries.

CSR norms and guidelines are as mentioned above not legally binding. Still, most companies have incentives to use CSR policies. Maintaining the relationship with society is one incentive which is based on the assumption that challenges can be addressed without financial losses or even with making benefits. Sticking to CSR guidelines can therefore be a marketing strategy and create advantages compared to those companies that are known to violate these concepts. Furthermore, internal guidelines and values which influence the interaction with society due exist in many companies. This refers to accountability for societal outcomes.<sup>184</sup>

### 5.1 Legislation

In a globalising world enterprises increasingly cross borders and so do their responsibilities and obligations. Whilst their conduct and misconduct is often sufficiently regulated on national level, the international level lacks enforcement mechanisms. However, legal consequences for misconduct are totally lacking. Already in 1789 the USA adopted the Alien Torts Claim Act making it possible to hold companies accountable for their misconduct committed overseas.<sup>185</sup> In general the legal basis for misconduct abroad is rather weak. Extraterritorial application is not available for most legislation. The existing human rights framework does often not serve the needs of a globalised economic world. Accountability of particularly multinationals is often difficult to enforce.

Therefore, voluntary principles are applied. Next to the Ruggie Framework on business and human rights which is described below, the OECD Guidelines for Multinational Enterprises might be amongst the most important. The focus of these guidelines is broad and covers fields like human rights, environment, employment, taxation, information disclosure, consumer interests, bribery, science and technology, and competition. The responsibility for monitoring and control lies with national contact points which can start proceedings against companies<sup>186</sup> which violate the guidelines.<sup>187</sup> Still, these guidelines are voluntary and do not provide for effective remedies. They rather establish a system of naming and shaming than being able in effectively prosecute. The creation of publicity is central.

<sup>180</sup> Friedman, M. (1962). *Capitalism and Freedom*. (University of Chicago Press, Chicago).

<sup>181</sup> Davis, K. (1973). The case for and against business assumption of social responsibilities. *Academy of Management Review* 16, 312 – 322.

<sup>182</sup> Blowfield, M., Murray, A. (2011). *Corporate Responsibility*. (2<sup>nd</sup> ed.) (Oxford University Press, Oxford).

<sup>183</sup> Ibid.

<sup>184</sup> Ibid.

<sup>185</sup> Ibid.

<sup>186</sup> This was illustrated in the Afrimex case where a company was found to be in violation of the rules. *Global Witness vs Afrimex (UK) Ltd.* (2008).

<sup>187</sup> OECD (2011). *OECD Guidelines for Multinational Enterprises*. 2011 Edition.

## 5.2 The Ruggie Framework

In 2011 the final version of the Ruggie Framework 'Protect, Respect and Remedy' was published. Playing a crucial role in the current idea of CSR, the UN Guiding Principles on Business and Human Rights aim at creating accountability for human rights violations by business. Whilst, international human rights law very much focuses on the responsibility of states in human rights, highlights the positive duties to protect human rights and requires states to take action in case of violations, obligations for co-operations are still lacking. The control of the conduct of national companies not only on their own territory but also abroad is the responsibility of the state. Countries lacking a sufficient judicial system and have problems with enforcement often struggle with this control function. Because of this lack of accountability the UN aimed at the adoption of guidelines. The Ruggie framework is the result of a struggle taking nearly four decades. After initiatives aiming at strengthening weaker nations started, e.g. the UN Code of Conduct for Transnational Corporations, struggled for decades, the Ruggie framework was created.<sup>188</sup> It emphasizes the classical idea of the state duty to protect human rights but enlarges it by the demand for business to respect them. This means compliance with national laws and in absence of sufficient human rights legislation a policy of due diligence. Finally, the access to effective remedies must be guaranteed.<sup>189</sup>

## 5.3 REACTION and CSR

As stated above, enterprises can have different incentives to stick to CSR guidelines and codes of conduct. Most businesses are first and foremost focused on profit. Values of CSR will therefore be tested against financial outcomes. Due to a positive image, behaving according to the ideas of CSR can create a positive image and be beneficial for profit.

In the case of REACTION the application of CSR guidelines is of particular importance. REACTION explores areas where several human rights are at stake. As discussed above, the right to health, issues of privacy and data protection are some of the human rights which need to be regarded when implementing a project like reaction. A responsible conduct with regard to human rights and ethical obligations is therefore of particular importance for this project.

Particularly, if the involvement of private corporations in REACTION increases, the application of CSR will become more important. Private healthcare providers are operating on a commercial basis. Taking into account that they might be one of the main future users of the REACTION platform, REACTION should embody values which can be shared and applied by those target groups. Discussions about sponsorship of the REACTION project by private companies highlight the need for a consideration of CSR related values. The discussion on CSR is therefore an important prospect for the future.

## 5.4 Sustainability

CSR is often equated with sustainability. Even though, this definition is disputed, sustainability for certain plays a central role in CSR. With regard to REACTION and eHealth more in general, there are several aspects. Environmental responsibility with regard to the production of devices is central. The increasing use of mobile devices in health should pose the question of sustainable production. Modern technological equipment requires the use of scarce resources often not available in the EU. Instead, in countries in transition and developing countries the current practice is very much influenced by exploitation of both natural and human resources.<sup>190</sup> Products sold in the EU are often based on materials extracted in countries with instable political conditions. The example of the export of rare earths from the Democratic Republic of Congo illustrates the difficulties. Those earths are just a part of the mobile devices and therefore the conditions under which they are produced are often not in the focus. Furthermore, European legislation does not extend to third countries like the DR Congo. Just recently, there is a stronger focus on the societal and environmental exploitation related to these products.<sup>191</sup> Companies using these materials should accept their responsibility. This also applies of companies involved in eHealth. Eco-efficiency to effectively manage scarce resources, protect the environment and sustaining a high quality of life for future generations is crucial in this industry. Publicity here leads to higher compliance with societal standards.

<sup>188</sup> De Hert, P. (2011). From the Principle of Accountability to System Responsibility Key Concepts in Data Protection Law and Human Rights Law Discussion. International Data Protection Conference.

<sup>189</sup> UN General Assembly, Human Rights Council (2011). Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises – John Ruggie; Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework.

<sup>190</sup> Ragnarsdóttir, K. (2008). Rare metals getting rarer. *Nature Geoscience* 1, 720 -721.

<sup>191</sup> Pehlken, A., Rolbiecki, M., Decker, A., Thoben, K.-D. (2011). Methods for sustainable management of secondary resources in Brebbia, C. (ed.) *'The sustainable world'* (WIT Press, Ashurst).

This example also illustrates the societal responsibility which is included in a sustainable conduct. Both the political and societal impact of enterprises and their conduct are considerable. A possible struggle between weaker and stronger players operating from different countries and adhering to different standards is often discussed. Globalisation is believed to lead to a weaker position of national governments and a strengthening of the private sector. In a time where a global government which could fill this gap is lacking, CSR is an opportunity to address these challenges of globalisation.<sup>192</sup>

### 5.5 System responsibility and accountability

The human rights aspects of a project like REACTION provoke other questions in the area of CSR. The establishment of system responsibility extending to every producer and user of ICT is discussed. Accountability would then include producers, providers and users which could be made responsible for misconduct. Currently, there is however a lack of a clear scheme for accountability.<sup>193</sup>

System responsibility has been object of European case law. The case *I. v. Finland* illustrates the doctrine of positive obligations with regard to the use of personal data. A hospital which did not take appropriate measures to protect the personal data of an employee was found to be in violation with Article 8 of the European Convention of Human Rights was constituted.<sup>194</sup> The data controller therefore also bears considerable responsibility and can be held accountable. Enterprises with a focus on administration and data management have to be aware of their CSR.<sup>195</sup>

Accountability for damages includes next to effective remedies the possibility to claim damages. The European Court constituted that reimbursement must be reasonable and substantial.<sup>196</sup> Misconduct of enterprises can therefore lead to financial consequences.

### 5.6 Evaluation

In the context of CSR, reporting is a method to evaluate an enterprise's conduct and compliance with external and internal guidelines. This form of social accounting assesses the non-financial aspects of their company's performance. Often, as a part of the regular annual reporting process, a report on CSR is published. These reports addressing external stakeholders can influence the public opinion and are therefore often used to enhance transparency, show social responsibility and highlight positive actions in the area of CSR.<sup>197</sup> Social accounting is used in the area of eHealth by big telecommunication companies. They for example focus on their strategic mission in eHealth.<sup>198</sup> The values of CSR are influential in the area of eHealth. Companies take them into account. Whether this is done out of conviction of the need to adopt moral and ethical values and to take responsibility for society or rather out of financial and publicity considerations remains unclear.

### 5.7 Remarks

Nowadays, the question is not anymore whether there is an obligation for business at all to adhere to principles of human rights and to accept their CSR. The commitment of organizations like the OECD and the UN to the issues of CRS and the topic of business and human rights led to a relatively high acceptability of CSR in general. CSR is often seen as a chance for and by business to positively contribute to society. Many companies already apply principles of CSR. Still the reality with regard to the conduct of enterprises differs from their promises. Thus, the debate should rather focus on the way in which the responsibilities of companies should be framed and whether there should be a stronger legal enforcement.<sup>199</sup>

<sup>192</sup> Blowfield, M., Murray, A. (2011). *Corporate Responsibility*. (2<sup>nd</sup> ed.) (Oxford University Press, Oxford).

<sup>193</sup> De Hert, P. (2011). From the Principle of Accountability to System Responsibility Key Concepts in Data Protection Law and Human Rights Law Discussion. International Data Protection Conference.

<sup>194</sup> The European Court of Human Rights (2008). Judgement in the Case *I. versus Finland*. Retrieved 26 January 2012 from: <http://www.cl.cam.ac.uk/~rja14/Papers/echr-finland.pdf>

<sup>195</sup> Răman, J. (2008). European Court of Human Rights: Failure to take effective information security measures to protect sensitive personal data violates right to privacy – *I v. Finland*, no. 20511/03, 17 July 2008. *Computer Law & Security Report* 24(6), 562-564.

<sup>196</sup> ECtHR (2008). Judgement in the Case *Armoniene versus Lithuania*. Retrieved 26 January 2012 from: [http://en.tm.lt/dok/Armoniene\\_v\\_Lithuania.pdf](http://en.tm.lt/dok/Armoniene_v_Lithuania.pdf)

<sup>197</sup> Blowfield, M., & Murray, A. (2011). *Corporate Responsibility*. (2<sup>nd</sup> ed.) (Oxford University Press, Oxford).

<sup>198</sup> An example of a company including eHealth in the CSR report is the Deutsche Telekom. The report of 2010/2011 can be found here: <http://www.cr-report.telekom.com/site11/en/gesellschaft/vernetztes-leben/e-health/index.php?tcfs=e7dc8bd39ba99ccd5a47c0b87ef3b624?page=1> (Retrieved 26 January 2012).

<sup>199</sup> De Hert, P. (2011). From the Principle of Accountability to System Responsibility Key Concepts in Data Protection Law and Human Rights Law Discussion. International Data Protection Conference.

Moreover, end-users like doctors and patients might not have considered CSR. After discussing the responsibility of business a broader discussion might extend to single citizens. System responsibility will play an essential role in the future of CSR. The capability of end-users to make right decisions and their responsibility and accountability will be subject to further discussion.<sup>200</sup> In the area of health the dependency of end-users might limit the ability to make free choices and the accountability of users.

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<sup>200</sup> Ibid.

## 6. Internal market product regulation

The following section of this document will focus upon the various European legislative instruments related to the internal market that have the potential to impact upon products that could form part of a future REACTION platform. Unlike rules on the availability of reimbursement, which can apply often to services, these rules relate to the requirements products must comply with to be allowed free circulation in the European Single Market (ESM) and sometimes the consequences if such products are the cause of harm to consumers. As will become clearer in the following pages, there are a variety of legislative instruments that are potentially applicable to components of medical systems. These directives, according to their applicability; given the products in question, pose greatly differing level of difficulty in terms regulatory barrier for those involved in bringing health related products to market. At one end, these range from all-encompassing-directives on product safety that apply to all products (including electrical products) placed on the European market which impose lesser, though still important requirements. At the other end of this spectrum are the directives that form the Medical Device Framework; these impose tougher regulatory hurdles on products that meet the definition of 'medical devices'. All manufacturers of eHealth devices will be subject to at least some part of this regulatory spectrum. The result of the correct application of the relevant regulatory requirements is usually that the CE mark can be placed upon the product in question. This indicates that the product in question is in compliance with the relevant European regulations and that it is to be allowed free-circulation within the EU.<sup>201</sup> It is thus imperative upon manufactures to of medical products to be aware of this framework in order to meet the required legal requirements.

### 6.1 New approach directives

The EU has been using the so called 'new approach' form since the 1990s. New approach directives have been used to usher in further technical standardization across Europe<sup>202</sup>. In these directives the exact form of regulation is usually limited to some very general requirements that must be applied to a group of products. These requirements are often vague and are very undetailed and not specific to the almost unlimited potential range of products with which the directive in question may be applicable to. Rather than attempting to describe in detail the requirements of all possible products and activities the directives relate to, there will be a presumption that general requirements stated in the directives will be met by following certain standards that have been harmonized at the European level. The detail required is essentially contained within these standards. This provides a certain level of pan-European harmonization, boosting the cohesion of the single market. This approach also has the benefit of being adaptable to future innovations. A directive that attempted to spell out all possible regulations in the smallest detail would quickly become redundant in the light of new technological evolutions. Reference to standards bodies however allows these directives to remain applicable even in the face of unforeseen technological innovation. The system employed in the new approach requires that adequate standards bodies exist and that they remain vigilant and continue to produce guidelines in the event of new technological innovations in an expeditious manner. The usual goal of these directives is to allow the manufacturer in question to certify that the product meets the general requirements in question. This often allows the community CE mark to be affixed to the device question as a symbol of its compliance with the relevant regulations. The 'new approach' directives described below generally serve two primary purposes. First, they impose a minimum set of requirements that are to be seen as acceptable across the Union, thus improving safety and second, they provide a reassurance to manufactures that if they meet such requirements their products should, in theory, be allowed to circulate freely within the Union. The following pages will highlight the most prominent with regards to their possible impact upon REACTION. This will culminate with a focus on the Medical Device Directive which represents the most arduous of the new approach directives in terms of a regulatory barrier for those wishing to bring medical products to the market.

#### 6.1.1 The Product Liability Directive

Product liability arises through the idea that a consumer has a right to legal redress for damage that is caused by a defective product. Traditionally redress can be found through both contract and tort law. A

<sup>201</sup> See for example Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Article 4, Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC, Article 8 and and Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, Article 8

<sup>202</sup> Pelkmans, J. (1987). The New Approach to Technical Harmonisation and Standardisation. *The Journal of Common Market Studies* 25, 3.

solution in contract is often more difficult for a consumer that has been harmed to secure than is the case in tort. This is because for a consumer to have a valid action in contract for damage caused by a defective product, provision will have to exist in the contract allowing redress for such problems. Consumers are also often in a position of greater weakness than sellers in terms of understanding and availability of information.<sup>203</sup> Often product suppliers or manufactures seek to leave such provisions out of contracts in order to reduce their own risks, weakening the protection for the consumer to be found in such contracts. Another problem that occurs frequently in the healthcare industry is that the consumer (usually the patient) often does not sign a formal contract for the provision of healthcare products or services, meaning that such individuals are unlikely to be able to find a means of action in contract law for problems they have suffered. These problems associated with the law of contract often make it unappealing as a form of redress for harm caused by defective products.<sup>204</sup> Fortunately, many legal systems have developed protection in their various systems of tort law. Such protection often appears in the form of a right of action for consumers who have suffered damage at the hands of various defective products against the manufacturer of the product in question, even if there is no direct relationship between the consumer and the manufacturer (i.e. the product has passed through the hands of intermediates).<sup>205</sup> In this way tort allows a flexibility that is often not present in contract law due to the notion of privity of contract<sup>206</sup>.

The varying situation with regard to tort systems in each Member State provided a cause for concern for the Commission because the presence of often differing and even conflicting laws represented a barrier to the implementation of the single market. As a result the Product Liability Directive<sup>207</sup> was enacted<sup>208</sup>. This directive harmonized (to a very limited extent) Member State tort laws by introducing a basic and uniform protection for consumers against defective products. The main principle of the directive is that consumers can hold manufacturers liable for defects in their products that give rise to damage. The Commission wanted the directive to provide for a regime of strict liability, something that was new to some Member State legal systems<sup>209</sup>. Under such a system, manufactures would be responsible for all defects to their products even if they had not been at fault in their design or manufacture. In order to garner the consensus needed to produce a directive, the directive provided for a general system of no fault liability, but with certain exceptions. These exceptions provided certain conditions that, manufactures could abide by in order to exclude the possibility of liability for unforeseeable defects in their products. For manufacturers of health related products this compromise can provide an important reassurance that if they act properly and according to proper procedures they can avoid liability. For manufactures who might be involved in producing components for REACTION it will be important to be familiar with such principles and the application to their industry in order to avoid unnecessary exposure to liability. In order to do this manufactures are required to have documentary evidence that any damage that might arise was unforeseeable at the time of manufacture<sup>210</sup>. This will require REACTION manufacturers to show that they had an up-to-date knowledge of the literature relating to their type of product. It should be noted that many REACTION components are likely to meet the definition of a medical device (see below). Compliance with the requirements of the Medical Device Framework are likely to represent a sufficient enough standard for manufacturers who wish to show that they acted sufficiently to avoid all foreseeable risks and therefore escape compliance under the Product Liability Directive. The requirements of the Product Liability Directive will therefore be of more importance where the product in question does not meet the definition of a medical device. This could be the case for numerous minor components involved in a REACTION platform ranging from certain communication devices to products designed to carry and transport medical devices when they are not being used. In such cases, manufacturers will still have to be aware of the requirements of the Product Liability Directive, as they will not be required to meet the

<sup>203</sup> Stuart, C. (1981). Consumer Protection in Markets with Informationally. *Weak Buyers* 12(2), 562 - 573

<sup>204</sup> Stanberry, B. (2006). Legal and ethical aspects of telemedicine. *Journal of Telemedicine and Telecare*.

<sup>205</sup> *Donoghue v Stevenson* [1932] UKHL 100 is the well-known decision from the House of Lords which established tort of negligence in the UK. There the court found that the manufacturer of a brand of ginger beer was ultimately responsible to the consumer who had become ill after drinking a bottle that was infested with snails. This was despite the fact that there was no direct relationship between the two as the beer had passed through middlemen in the meantime.

<sup>206</sup> The notion privity of contract expresses the idea that an individual that is not bound to a contract i.e a signatory cannot be bound by its contents. See: Lilienthal, J. (1887). Privity of Contract. *Harvard Law Review* 1(5).

<sup>207</sup> The Council of the European Communities (1985). Directive 85/374/EEC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products. *Official Journal of the European Communities* L210, 29.

<sup>208</sup> An important motivator behind the directive, in addition to preventing competition distortions was the thalidomide disaster that occurred with children in the 1960s and 1970s. See: Stanberry, B. (2006). Legal and ethical aspects of telemedicine. *Journal of Telemedicine and Telecare* 12, 166-175, 174.

<sup>209</sup> The UK for example did not recognise a system of strict product liability before the directive was created.

<sup>210</sup> The Council of the European Communities(1985). Directive 85/374/EEC *Official Journal of the European Communities* L210, Article 7(e).

more onerous requirements of the Medical Device Framework. In addition it is important to remember that the Product Liability Directive represents only a very basic harmonized 'floor of protection' that will be applicable in each Member State. Each of these is free to have further requirements on liability which may entail further risks. An analysis of the various legal regimes applicable in each Member State is unfortunately beyond the scope of this deliverable.

### 6.1.2 The Low Voltage Directive

The Low Voltage Directive (LVD)<sup>211</sup> is intended to apply to a wide range of electrical equipment that utilizes voltage within a limited range.<sup>212</sup> This often corresponds to products that are intended for use by simple consumers or individuals that are not engineers. Importantly from the perspective of REACTION, the directive states that it is not applicable in the case of equipment destined for 'radiology and medical purposes'.<sup>213</sup> Unfortunately the directive does not provide a clear definition of what exactly this means. A sensible approach would seem to be to assume that this means that the LVD will not be applicable where devices can be classed as a 'medical device' in terms of the Medical Device Directive (see below). This would indeed seem logical because the Medical Device Directive imposes a greater regulatory burden on manufacturers including for issues of electrical safety.<sup>214</sup> As with the foregoing discussion on the Product Liability Directive above, it may still therefore be important to consider the LVD applicable to components related to REACTION that do not have a strict medical function (e.g. that do not meet the definition of a medical device) such as communication devices.<sup>215</sup> Manufacturers of such devices, even if they are not subject to the more strenuous requirements of the Medical Device Directive may still have to comply with the LVD (assuming the product in question is electrical).

The Low voltage Directive was one of the earliest 'new approach directives' and follows that approach. It sets out only some very general requirements. These include for example that the equipment in question 'can be used safely for the purpose that it was made', 'that risks to human and animal health will be minimized' and that the 'device will not be a danger under normal hazards and conditions'.<sup>216</sup> In line with the 'new approach' methodology a presumption once again exists that such requirements have been met by compliance with the relevant European or international standards.<sup>217</sup> As with the EMC directive (below) the manufacturer is required to perform a conformity assessment and keep it on Union territory for ten years after the product has been manufactured.<sup>218</sup> Once the manufacturer has completed the conformity assessment, it is required to issue a declaration of conformity, after which the CE stamp can be affixed to the product in question.<sup>219</sup>

### 6.1.3 The EMC Directive<sup>220</sup>

Numerous devices produce and detect electromagnetic radiation as part of their functioning. This involves not only products and devices used in the healthcare sector but also many other sectors, ranging from specialized industrial equipment to devices found in the average home. The problem that can occur with such an array of devices in existence is that they have the potential to interfere with each other's operation. This can have negative consequences, ranging from inconvenience with respect to simple household devices or more catastrophic consequences in devices that are safety critical such as those involved in transport and healthcare. As a consequence there is a need for regulation to control on the one hand, the emission of Electromagnetic Interference (EMI) from such

<sup>211</sup> The European Parliament and the Council of the European Union (2006). Directive 2006/95/EC of the European Parliament and the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use with certain voltage limits. *Official Journal of the European Union L374*, 10 – 19.

<sup>212</sup> *Ibid*, Article 1 states that the directive applies to electrical equipment that utilises a voltage between 50 and 1000V for alternating current and 75 and 1500 for devices that use direct current

<sup>213</sup> *Ibid*, Annex II

<sup>214</sup> Requirements on electrical safety are included in Medical Device Directive See: The Council of the European Communities (1993). Council Directive 93/42/EC of 14 June 1993 concerning medical devices. *Official Journal of the European Communities L169*, Annex I, Section 12.6

<sup>215</sup> A discussion about the medical device and the definition of a medical device can be found below. The main issue here appears to be the intended use of the product in question.

<sup>216</sup> European Parliament and the Council of the European Union (2006). Directive 2006/95/EC. *Official Journal of the European Union L374*, Annex 1.

<sup>217</sup> *Ibid*, Article 5.

<sup>218</sup> *Ibid*, Annex IV Point 3.

<sup>219</sup> *Ibid*, Article 10 and Annex II.

<sup>220</sup> European Parliament and the Council of Europe (2004). Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC. *Official Journal of the European Union L390*, 24.



devices and on the other, the resistance of devices to the EMI of other devices. Without such regulation there would be little to stop manufacturers from creating products that through their EM emissions would unnecessarily interfere with others. In addition, regulation is also needed to ensure that the manufactures of critical devices are capable of withstanding the 'background' emissions of other devices. In order to prevent Member States regulating such matters individually in a manner that would create conflicts and barriers within the internal market it was necessary for the EU to act in order to introduce a certain level of harmonization in order to allow for the correct functioning of the internal market.<sup>221</sup> This approach, like that of the other directives in the 'new approach' category, depends on the possibility of reference to a number of standards that are created at the European level. Compliance (which is optional) with the standards relevant to the product in question will invoke a presumption that the product in question is safe and therefore is to be allowed to circulate freely within the Union. This means that Member States are not permitted to erect barriers to the free circulation of such products.

The directive's essential requirements require that devices which are likely to be sensitive to EMI issues are required to be designed and manufactured having regard to the state of the art so as to ensure that the electromagnetic disturbance which it generates does not exceed the level above which radio and telecommunications equipment of other devices cannot operate. Additionally, devices must be designed to be able to operate in the presence of the expected level of electromagnetic interference in the environment in which it is expected to operate<sup>222</sup>. The manufacturer is expected to perform a conformity assessment of the product in order to ensure that it meets these essential criteria<sup>223</sup>. The manufacturer can demonstrate that it has met such criteria by reference to the relevant set of standards.<sup>224</sup> It is required to keep documentation related to this conformity study for at least ten years.<sup>225</sup> Upon completion of this process the manufacturer is to make a declaration of conformity that is open to the inspection of the relevant authorities if so requested.<sup>226</sup> Once this has been carried out the manufacturer can affix the CE stamp to the product in question.<sup>227</sup>

It should however once again be noted that the Medical Device Directive also contains requirements in relation to the emission and tolerance of EMI.<sup>228</sup> Given that the MDD contains more onerous requirements in terms of proving safety this will represent a greater hurdle in terms of a regulatory barrier than the EMC directive. What is once again crucial is for manufacturers of products, including those involved in REACTION, that have a potential eHealth application to be aware of is the definition of what constitutes a 'medical device' in the MDD as if their product is caught by such a definition it will be incumbent upon them to meet the more stringent requirements of that directive<sup>229</sup>. If a potential device is not classed as a 'medical device' then the lower regulatory obligations of the EMC Directive will be the primary focus for those involved in the manufacture of this type of device.

## 6.2 The Medical Device Framework<sup>230</sup>

If manufactures wish to place a new medical device on the European Market the design, manufacture and testing of the product in question will likely have to comply with the EU framework on medical devices. Given that a REACTION platform is likely to employ medical devices, the existence of the Medical Device Framework (MDF) is of importance. The Medical Device Framework is extremely complex and, given its flexibility, is of an ever evolving application. It can represent a significant regulatory barrier to those wishing to innovate in the area of medical devices.

As with other areas of its intervention into healthcare regulation the MDF acts primarily so as to protect the internal market i.e. the free movement of goods<sup>231</sup> within the Union.<sup>232</sup> Prior to the introduction of

<sup>221</sup> This is given as a justification for the Directive in recital 3.

<sup>222</sup> Directive 89/336/EEC, Article 1, Annex 1

<sup>223</sup> Ibid, Annex II Art 1.

<sup>224</sup> Ibid, Article 6.2.

<sup>225</sup> Ibid, Annex II Article 3.

<sup>226</sup> The manufacturer is also able to opt for a different procedure where the notified body carries out an inspection of the manufacturer's documentation. If this occurs the manufacturer can then add a certificate of such inspection to relevant documentation for the product see Directive 89/336/EEC, Article 7 and Annex III

<sup>227</sup> The Council of the European Communities (1989). Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility. *Official Journal of the European Communities* L139, Article 8.

<sup>228</sup> Requirements on resilience to electromagnetic interference are also included in Medical Device Directive See: Directive 93/42/EEC –Annex I, Section 12.6

<sup>229</sup> That the MDD imposes stricter requirements that the EMC directive is logical given that it has been shown that EMC interference with critical medical infrastructure can have potentially lethal effects. See: Calcagnin, G., Federica, C., & Bartolini, B. (2007). Electromagnetic immunity of medical devices: the European regulatory framework.

<sup>230</sup> The reader should also consult the deliverable D7-5 Safety Issues in REACTION applications for a description of some of the requirements of the Medical Device Framework.

<sup>231</sup> The main treaty provisions related to the freedom of movement for goods are Articles 34–36 TFEU

the EU framework on Medical Devices in the 1990s, the regulation of medical devices was subject to the differing regimes of each member state. This created barriers to the functioning of the single market and the free circulation of medical devices. As a consequence, the Commission decided to harmonize regulation in the area of medical devices so as to remove obstacles to the internal market. In addition the Medical Device Framework also aims to provide users in the European Single Market with a higher degree of protection than that which existed previously. This occurs by requiring that the same basic safety requirements are present throughout Europe. This was effectuated by the harmonization of essential requirements and certification and inspection procedures.<sup>233</sup> The three EU directives, which represent the Medical Device Framework lay down numerous different requirements and basic safety standards which a product must meet before it can receive approval to be placed upon the European market. The directives in question are <sup>234</sup>:

- The Medical Devices Directive (MDD) 93/42/EEC amended by Directive 2007/47/EC;
- The Active Implantable Medical Devices Directive (AIMD) 90/385/EEC<sup>235</sup>;
- The In Vitro Diagnostic Medical Devices Directive (IVDMD) 98/79/EEC.

The MDD is applicable to most medical devices, with the AIMD<sup>236</sup> and the IVDMD<sup>237</sup> applying in only more narrowly defined circumstances. The MDD will therefore likely apply to most medical devices in REACTION that are to be placed on the market in Europe. In order to be placed on the market, all products that fall within the scope of the directive and meet its requirements are required to bear an EC conformity mark to show compliance with the directive. The aim of this is to allow products that conform to the directive's requirements to be sold freely throughout the EEA without hindrance from national governments. The Medical Device Framework is important for the e-health sector especially with regard to medical software that is used in many applications.<sup>238</sup> The impact of the MDD framework on the medical software industry has become yet more pronounced with the event of Directive 2007/47/EC, which widens the definition of medical devices to include software (see below).<sup>239</sup> The MDD Framework represents only a limited harmonization of essential device requirements. This harmonization is restricted to adoption of certain essential safety criteria with which all products must conform to. The requirements are worded in a general manner so as to be adaptable to as wide as possible a range of situations. In order to ensure that the MDD Framework aids in creating a single market for medical devices where such essential requirements are not expressed within the directive a system of mutual recognition is employed. Under such a system devices recognized by the relevant body in one Member State as meeting its standards, must be recognized in others. The directive therefore uses a dual approach, one that utilizes both the concepts of mutual recognition and harmonization.

<sup>232</sup> The recitals of the Medical Devices Directive (MDD) 93/42/EEC begin by referring to the Single Market as a justification for action.

<sup>233</sup> Institute for Prospective Technological Studies Seville (2000). Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry.

<sup>234</sup> Note: The Medical Devices Directive (MDD) has been subsequently amended by four directives and one regulation. These are; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998; Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000; Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001; Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007.<sup>234</sup>

<sup>235</sup> The Active Implantable Medical Device Directive (90/385) regulates powered implants or partial implants that are placed in and left in the human body. The definition of active implantable devices is based on the definition of medical devices and is defined as follows; 'Active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity. 'Active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

<sup>236</sup> This Directive covers all powered medical devices implanted and left in the human body, such as pacemakers, implantable defibrillators, implantable infusion pumps, cochlear implants and implantable neuromuscular stimulators. The Directive also covers implanted passive parts of active devices such as pacemaker leads and adapters, and external parts that are an essential part of the systems, e.g. pacemaker programmers.

<sup>237</sup> This Directive covers any medical device, reagent, reagent product, kit, instrument, apparatus or system which is intended to be used for the in vitro examination of substances derived from the human body, such as blood grouping reagents, pregnancy testing and Hepatitis B test kits.

<sup>238</sup> Callens, S. The EU Legal Framework on E-health in Mossallos, E., Permanand, G., Baeten, R. & Hervey, T. *Health Systems Governance in Europe*. (Cambridge University Press, Cambridge).

<sup>239</sup> See The Guidelines on the Qualification and Classification of Stand Alone Software which have been published as MEDDEV 2.1/6 January 2012 for a description of how stand-alone software can be assessed as meeting the MDD's essential requirements. 2.1/6

### 6.2.1 The definition of a 'Medical Device'

In order to decide whether a device is subject to the rules of the directive it must be discerned whether it is a 'medical device' or not. The definition of what exactly a medical device is described as any *'instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application.'* Such a device should be intended by the manufacturer for one of a number of defined purposes, one of which is, *'diagnosis, prevention, monitoring, treatment or alleviation of disease.'*<sup>240</sup>

Devices not used for these purposes, including software, would therefore not be classed as a 'medical device' and therefore not be governed by the directive. However, software that does not perform one of the above functions itself will still be considered a medical device if it is used in combination with another medical device that does meet the above definition. Meeting the definition of a 'medical device' is therefore likely to entail the need to comply with a more onerous set of regulations<sup>241</sup> than might have otherwise been the case. This will entail a greater investment of money and time for those manufacturers concerned.<sup>242</sup>

### 6.2.2 Software as a Medical Device

Directive 2007/47/EC represented an important innovation to the MDD framework, not least because it introduced software as a technology category that could also be classified independently as a Medical Device. This applies not only to standard medical devices but also to active implantable medical devices. This innovation had become important because in the years since the original directives were enacted, the prominence of software as a medical device has increased dramatically. Indeed, in many cases, the software itself can now represent all or perhaps the most important and complicated part of the medical device in question. The range of functions that such software could perform is enormous, in some cases calculating the dose of a particular drug that should be administered to a patient but not actually being involved in such administration, whilst in other cases the software might be built into an implanted device that plays a role within the body itself. Indeed, the use of software has allowed an ever greater increase in the complexity of medical devices. With such an increase in complexity however comes an increase in dangers to those that are using such devices.<sup>243</sup> The wide range of possible roles software can play as a medical device made its explicit introduction by Directive 2007/47/EC necessary. Software programs are likely to play a central role in a REACTION platform that *inter alia* use sophisticated modeling systems to analyze blood sugar level.

The expansion in the definition of what exactly constitutes a medical device means that manufactures of software in/for medical devices will have to take care to insure that the device in question meets the requirements of the directive.<sup>244</sup> Additionally, if the software in question is not itself a medical device but is responsible for controlling another physical device that fits within the definition of a medical device, then such software itself will be classified as a medical device. Other types of software that will be caught by the device include software used in analyzing patient data generated by a medical device with a view towards diagnosis and monitoring. This could include software used to provide images from scans or even data analysis tools that interpret data provided from other devices. Software that meets such criteria must be approved under the MDD criteria and itself carry the CE mark of approval.

<sup>240</sup> The Council of the European Communities (1993). Council Directive 93/42/EC. *Official Journal of the European Communities* L169, Article 2(a).

<sup>241</sup> Other more general regulatory regimes will still however apply. One such directive that has a very general application to all products placed on the European market place is the Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC). Another very generalized directive that applies to low voltage equipment is Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits. Additionally equipment that utilizes portions of the electromagnetic spectrum must often meet the conditions of the EMC Directive, i.e. Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

<sup>242</sup> For example trial of medical devices must obtain the strict informed consent of all participants. This rules out all trials on individuals that are medically incapacitated for example. See: Singer, E. (2002). Implications of the EU directive on clinical trials for emergency medicine. *British Medical Journal* 324(7347), 1169–1170.

<sup>243</sup> Mc Caffery, F. & Coleman, G. (2007). Developing a configuration management capability model for the medical device industry. *International Journal of Information Systems and Change Management* 2, 139-154.

<sup>244</sup> Forsström, J. (1997). Why certification of medical software would be useful? *The International Journal of Medical Informatics*, 47(3), 143-151. *'The main argument to resist all attempts to regulate medical software has been that it is impossible to guarantee that software is error-free. This is true of all software. However, in medical software the correctness of medical knowledge is at least as important as the correctness of the code itself. The medical contents of the software could usually be evaluated but the end-users do not have the time or possibilities to do so.'*

Manufactures of software that can be categorized as medical devices face several important problems that do not occur as commonly for manufactures of other more conventional medical devices. One such example is software updates. Such updates are a common feature of many computer programs including those used in medical devices. Such updates may be installed regularly during maintenance or possibly even downloaded automatically from the Internet. Though easy to miss, it is important for manufacturers to follow correct procedures for such updates, making sure that the update in question complies with the MDD.<sup>245</sup> This may entail once again following all the rigorous regulatory testing requirements (and placing of the CE mark) that were required when the original program was developed.

#### *Software that falls outside of the Medical device directive*

Whether or not a potential innovation is likely to meet the definition of a medical device will be an important consideration for manufacturers, one which they are likely to give careful consideration to. Although the definition in the MDD Framework is extensive there will be numerous types of software which may have a pseudo medical function and that will not fit within the definition above of a medical device. Such program will escape the need for compliance with the MDD Framework. Such software could come in many forms. Examples could include educational software designed to train medical professionals or software designed to manage databases such a patient records.

### **6.2.3 The role of standards within the MDD Framework**

The MDD recognizes that medical device manufacturers can demonstrate adherence to the directives' essential requirement by following standards relevant to their area of expertise. Manufacturers can use standards to set out objective definitions of what the necessary requirements would be for a particular device. The European Standards bodies CEN and CENELEC have the role of ensuring that further technical guidelines are produced within harmonized European standards.<sup>246</sup> These bodies are tasked with producing European standards that, once formed, are binding on all bodies within the Member States. This reduces the possibility of conflicts between different standards, such as those that might have been produced by bodies in the Member States before the establishment of a single European set of standards. Despite the importance and the potential benefit of using standards, their use is voluntary. This voluntary nature of standards within the MDD framework is important. This is because standards are primarily based upon previous experience with medical devices. Given that novel, innovative products might be very different than those products that have preceded them, the need to meet pre-existing standards designed with different medical devices in mind might hamper further innovation. The voluntary nature of these standards means that manufacturers are able to use alternative methods to demonstrate the safety of their products.<sup>247</sup> Such flexibility will be important for innovations in m-Health that will often be in domains that do not have clear precedents. There are a number of software standards available that manufacturers can use to demonstrate compliance with the MDD's essential requirements. Despite this possible flexibility, it is, in order to facilitate a regulatory process more conducive to innovation, important that standards for m-Health are developed and regularly updated. This is because adherence to such standards is a certain method of ensuring compliance with the essential requirements of the MDD.<sup>248</sup> This makes the task of manufacturers easier as available standards mean the availability of clear roadmaps to follow. Where existing standards are not suitable, manufactures do not have to follow them if they are able to demonstrate using other methods that the medical device in question meets such standards. This freedom is

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<sup>245</sup> This means ensuring that changes are well documented, validated and approved. All significant changes must be reported to the relevant notified body. If the changes made alter the classification of the Medical device manufacturers will have to perform a new conformity assessment for the device in general. If a CE certificate was issued for previous versions of software i.e. where the software itself was considered a device the manufacturer must nonetheless contact the notified body informing it of the changes that have been carried out. Standard EN 60601-1-4 provides guidelines on how this can be done.

<sup>246</sup> Institute for Prospective Technological Studies Seville (2008). Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry.

<sup>247</sup> These include national and international standards that have not been given the status of harmonized, industry standards, internal manufacturer standard operating procedures developed by an individual manufacturer and not related to an international standard and also where possible current state of the art techniques related to performance, material, design, methods, processes or practices. See Institute for Prospective Technological Studies Seville (2008). Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry.

<sup>248</sup> The following standards have already been harmonised throughout the EU and are available for use by manufacturers in showing conformity with the MDD's essential requirements. These include EN 60601-1:2005 – relating to general requirements for basic safety and essential performance, EN60601-1-4 relating to programmable electrical medical systems, EN 60601-1-6 relating to useability and EN 62304 relating to standards for risk-management-driven life cycle requirements for medical device software.

important in allowing innovators the flexibility to bring new products to the market, though it can entail, in effect, a greater burden of proof for manufacturers.

#### 6.2.4 Device categorization

The MDD framework recognizes that different classes of medical devices exist, to which different levels of stringency should be applied.<sup>249</sup> This can have important and beneficial effects on innovation in the medical device sector, given the large variety in potential medical devices. Such variety means that it would not be conducive to innovation in general to apply the most stringent sets of standards to all products as some will by their very nature carry less risk than others. This means that manufacturers' products may face different regulatory hurdles depending upon the type of device in question. This will likely be true even amongst the various products used in a potential REACTION platform. The different procedures open to the medical device manufacturer for assessing conformity in different risk classes vary in the level of strenuousness according to the class the device has been categorized with. The following paragraphs represent a very brief outline of these classes together with some examples of what may be required for such devices.

**CLASS I** – In general all non-invasive devices are categorized as Class I devices. There are however certain exceptions to this.<sup>250</sup> For this class, the manufacturer is responsible for declaration of conformity with the provisions of the directive, including compliance of the product with all relevant Essential Requirements. This means that the manufacturer is legally obliged to meet those Essential Requirements. The manufacturer is required to retain technical documentation for inspection (if required by national authorities.<sup>251</sup> For certain products in this class e.g. sterile equipment) national bodies are required to intervene by checking certain specific characteristics such as claims to sterility for example.

**CLASS IIA** - Surgically invasive devices which are intended only for 'transient use' are generally categorized as Class IIA<sup>252</sup> devices. In addition all active therapeutic medical devices intended to administer or exchange energy are categorized as Class IIA unless they do so in a potentially hazardous way, in which case they are categorized as Class IIb. In addition to the requirements for Class I medical devices, for Class II devices, a Notified Body<sup>253</sup> must back up the declaration of conformity in all cases with a conformity assessment. The manufacturer has the choice between various types of assessment including an audit of the production quality assurance system<sup>254</sup>, an audit of final inspection and testing of the device in question or an examination and testing of sample products. Alternatively, the manufacturer may follow the full quality assurance route as for Class IIb devices (see below).

**CLASS IIb/III** - Active devices which are intended to administer/remove medicines which involve the administration of a potentially dangerous are classified as Class IIb. Again, as with Class IIb, Class III devices have the possibility of assessing conformity for design and production is the operation of a full quality assurance system that has been audited by a Notified Body. This involves the manufacturer

<sup>249</sup> The classification of medical device products follows criteria outlined in Annex IX of Directive 93/42 EEC. It contains definitions and 18 rules that are a set of broad statements relating to product properties, functions and intended purpose rather than a list of products. This has the advantage of being more flexible and better able to take new technological developments into consideration. A list of products on the other hand would only require constant updating.

<sup>250</sup> Ibid, Annex 9 Rules 2 – 4 These include devices intended for channelling or storing blood (Class IIA), devices intended to modify the biological or chemical composition of blood or other body liquids (ClassIIa), certain devices that come into contact with wounds (Class IIA or IIb) or injured skin (Class IIA or IIb) (unless they are merely acting as a mechanical barrier in which case they are still Class I)

<sup>251</sup> This documentation must be prepared prior to making the CE declaration of uniformity and must be available for manufacturer by notified bodies. See: Schnoll, L. (1997). *The CE Mark: Understanding the Medical Device Directive*. (Paton Pr).

<sup>252</sup> The Council of the European Communities (1993). Council Directive 93/42/EC. *Official Journal of the European Communities L 169*, Annex 9 Rule 5. Devices intended for transient duration are classified as type I, devices intended for long term duration are classified as type IIA and devices intended for long term use are classified as type IIb (except those to be used in the oral cavity as far as the pharynx, in the ear as far as the ear drum, in a nasal cavity and which are not liable to be absorbed by a mucosal membrane, such long-term devices are categorized as IIA). The exceptions to this are: a) devices used to control, diagnose or monitor a heart or central circulatory system defect through direct contact (Class III); b) reusable surgical instruments (Class I); c) instruments that are used in direct contact with the central nervous system (Class III); d) devices which supply ionizing radiation (Class IIb), devices intended to have a biological effect or to be wholly or mainly absorbed (Class IIb); and e) those intended to administer medicine in a potentially dangerous manner (Class IIb).

<sup>253</sup> Manufacturers are free to apply to any notified body in the EU and not only the one they are established in. As a medical device that has been one notified body can be marketed and sold anywhere in the EU this creates a wide field to which manufacturers can go to seek approval. In theory however such variation in the practice of Notified bodies should be limited as all are meant to perform the same practices when approving new medical devices.

<sup>254</sup> The role of a quality assurance assessment system is to ensure that the highest possible standards are used in design, manufacture and testing of the product in question. Software used in medical device directives is often deemed to safety critical land thus standards that apply to it when used in the context of medical devices must be even more exacting than normal. See: Cosgrif, P. (1994). Quality Assurance of Medical Software. *Journal of Medical Engineering & Technology*, 18(1), 1-10.

following quality assurance standards both during the design process and during the production and testing process. In addition, the notified body must carry out a surveillance of the manufacturer's adherence to the quality control process verifying the quality of the device's design and issuing an EC certificate of design examination. Alternatively, the manufacturer can use a similar but slightly different process whereby the manufacturer submits type and technical documentation to the Notified Body, which will then ascertain conformity. The manufacturer must also make use of one of the audit of production quality methods described in Class II a above.

CLASS III<sup>255</sup> - Devices incorporating medicinal products as an integral part and which are liable to act upon the human body with ancillary action to that of the Medical Device itself are categorized as Class III.<sup>256</sup> Being classified in this class entails the most onerous category of regulation for manufacturers. The procedure for Class, III devices is similar to those for Class IIb devices but also requires the manufacturer to submit the design dossier to the Notified Body for approval.

### 6.2.5 Future revisions of the MDD Framework

Recommendations for a re-framing of the MDD Frame have recently been provided.<sup>257</sup> It is hoped that future iterations of medical device legislation will place an even greater emphasis on software given its increasing importance in medical devices. In particular there will be a need for a further development in usable standards, especially concerning interoperability. This will be important for eHealth related aspects as increased networking ability and interoperability will be a central facet of future plans. It is likely that in the future, in order to realize economies in terms of health care budgets, medical devices will be called upon to not only diagnose, but also to prevent certain diseases in the first place. MDD regulation will have to adapt to the evolution of such devices. With an increase in the amount of software based medical devices and the increased use of 'off the shelf' software based applications that is likely to occur comes a consequent increase in the opportunity for bugs, viruses and other malware to cause problems. In order to ensure that the relevant dangers are assessed and, where possible avoided, it will be important to ensure that standards are rapidly created in order to meet such threats but also that manufactures are given the possibility to employ novel methods where the most recent standards are out of date. It will be important for future revisions of the medical device directive to take into account the issues described above. These include a need for the MDD to be reframed in a way that will allow it to correctly regulate mobile phone 'apps', a potential important source of future innovation in eHealth. In addition the process of standards creation will need to be revisited in order to ensure that the production of standards meets the needs of an industry that is attempting to innovate. It will also be important to take into account the opinions of Member State regulatory organizations. The following points below summarise some of the areas improvement that Mariana Madureira, from the Health Products Directorate of INFARMED,<sup>258</sup> felt could be made to the Medical Device framework.

1. Security in data transmission: At present there are gaps which present possible risks. Security is not covered by the directive but, this could be improved in future revisions.
2. Compatibility/interoperability of hardware and software: e.g. software modularity will be important in various working environments such as hospitals.
3. Training (Physicians/Patients): more involvement of clinicians and patients in mobile technologies. Alert messages, for instance, relate to risk situations. Industry if putting monitoring systems on the market should mitigate risks. Thus, training is very important, guidelines should be added to the device.
4. Classification rules: specific rules for standalone software.
5. Manufacturers rules: more guidelines
6. Maintenance: there is a need for harmonized standards, related to interoperability, at present compatibility definition is very generic<sup>259</sup>.

<sup>255</sup> Controls for this class are broadly equivalent to the controls applied under Directive 90/385 EEC for active implantable devices.

<sup>256</sup> The Council of the European Communities (1993). Council Directive 93/42/EC of 14 June 1993 concerning medical devices. *Official Journal of the European Communities L169*, Annex IX Rules 13-18.

<sup>257</sup> The Council of the European Union (2011). Council conclusions on innovation in the medical device sector (2011/C 202/03). *Official Journal of the European Union C202*.

<sup>258</sup> INFARMED – National Authority of Medicines and Health Products, IP is a Portuguese Government agency accountable to the Health Ministry. The objective is to monitor, assess and regulate all activities relating to human medicines and health products for the protection of Public Health. Presentation of Maria Madureira during the MovingLife Consultation Workshop on mHealth in a socio-economic context (2012).

MovongLife is a FP7 project.

<sup>259</sup> These points were made at the Consultation Workshop mHealth in a Socio-economic Context, 18 January 2012

## 7. Reimbursement

Reimbursement is an issue of pivotal importance for the success or failure of innovations in the healthcare sector.<sup>260</sup> The decisions of the various social security institutions of various states to reimburse (or not to do so) certain categories of medical treatment can have an important effect on the decision of product manufacturers to attempt to innovate with a new product. Additionally, reimbursement decisions by national bodies can play a definitive role in the acceptance and uptake of recent innovations in medical technologies. This will bear true also for REACTION. Reimbursement has however in recent times moved from being an issue of national importance to one which has pan-European relevance. In theory the European Single Market should allow medical services to be offered by an organization all over Europe. This would offer significant possibilities for the deployment of eHealth platforms such as REACTION. However in reality there are many issues that make this difficult. Reimbursement is one such issue. The following pages will explore the manner in which the EU has been able to impact upon reimbursement rules and therefore have an effect on the innovation on new technologies. Cross-border reimbursement will likely become ever more important. This development opens up the possibility of REACTION services being offered cross border. Such a development could allow one or a few large organizations to offer such a service throughout Europe. It could be argued that this would allow efficiencies in terms of cost and organization to be achieved, with new economies of scale being achievable.

Such possibilities might also be appealing to individuals that are part of an ethnic or lingual minority and wish to obtain or continue their health care in another Member State or even where for other reasons, individuals simply desire to pursue their treatment in another Member State. This paper will conduct a brief exploration of the competences the Union has been provided under the treaties and how this competence has been developed and exercised, culminating in the recent Directive on Patient Rights.<sup>261</sup> This section will conclude with a summary of the possibilities of cross-border reimbursement available to REACTION or a REACTION-like service. Unfortunately, an in-depth exploration of the various systems of reimbursement that exist throughout the EU is outside the scope of this paper. There will however be a brief overview of the systems used in Germany, Italy and the UK in order to highlight the diverse nature of the systems that exist at Member State level.

### 7.1 The limited explicit competence of the European Union on matters of health

Healthcare is a sensitive political issue for every one of the 27 Member States of the European Union. Elections are frequently won and lost on such issues. As a result of this, governments of Member States have been extremely reluctant to cede powers to the EU in this area.<sup>262</sup> Doing so would leave them with a reduced level of control over activities that might have a significant effect on their political existence. This lack of desire to give the EU direct powers over healthcare can be seen in the treaties of the European Union. Article 168 of the Treaty on the Functioning of the European Union (TFEU) states that the Union's role is limited to 'complementing national policies'. In doing this, the Union is able to 'encourage'<sup>263</sup> co-operation between member states on certain areas of public health.<sup>264</sup> In order to encourage such co-operation the European Parliament and the Council are able, acting in accordance with the normal legislative procedure, to release guidelines *recommending* measures that Member States should take in order to achieve such co-operation.<sup>265</sup> Though the Union has no power to enact measures on healthcare directly, it is required to ensure the protection of human health in all of its other policies and activities.<sup>266</sup> The Union must at all times respect the responsibilities of Member States to define their own health policy and to organise the delivery of health services and medical

<sup>260</sup> Schreyögg, J., Bäumlner, M. & Busse, R. (2009). Balancing adoption and affordability of medical devices in Europe. *Health Policy* 92, 218-224.

<sup>261</sup> European Parliament and the Council of Europe (2011). Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, commonly known as the Patient's Rights Directive. *Official Journal of the European Union* L88, 45.

<sup>262</sup> Greer, S. (2006). Uninvited Europeanization: neofunctionalism and the EU in health policy. *Journal of European Health Policy* 13(1), 134 - 152. P 134

<sup>263</sup> European Union (2010). Consolidated Version of the Treaty on the Functioning of the European Union. *Official Journal of the European Union* 53(C83), 47, Article 168.2.

<sup>264</sup> *Ibid*, Article 168.1. 'Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.'

<sup>265</sup> *Ibid*, Article 168.4.

<sup>266</sup> *Ibid*, Article 168.1.

care. Such responsibilities include the management of health services and the amount of resources to be allocated to them.<sup>267</sup> One can clearly see that the demarcation of the EU's responsibilities in the treaties is done so in a manner that would provide a minimal level of competence for the Union in terms of healthcare. Under such a distribution of competence a Member State is free to define the structure of its healthcare system, what services exist, what charges are levied on individuals and the level of reimbursement that patients receive for such charges.<sup>268</sup> The effective result of this limitation of competence at Union level is that there are in reality 27 different health systems across the Union, each unique in its own way regarding the services it provides and the way it pays for or reimburses citizens who avail themselves of such services. eHealth initiatives will therefore have to take such a variation into account when attempting to make decisions on possible directions for future innovation.

## 7.2 Provisions related to the Single Market

Despite the limited explicit Union competence on healthcare in the TFEU, the EU and its predecessors, the EEC and the EC, have been able to intervene in health matters where it appears to be required in order to support and maintain the ESM. The Union has intervened in matters of European healthcare in a manner that seems to show that it sees itself as primarily responsible for regulating market based issues of healthcare, whilst more lofty human rights based issues are left to other international organizations<sup>269</sup> such as the Council of Europe.<sup>270</sup> The EU promotes and protects the ESM by extolling four key freedoms that are contained within the treaties. Two of these, The Free Movement of Persons<sup>271</sup> and the Freedom to Provide Services<sup>272</sup> have allowed the European Institutions to act in ways that affect the provision of healthcare, despite healthcare not being itself a competence of the European Union as defined in the treaties. The justification for this has been recognized on numerous occasions by the European Court of Justice (ECJ), namely that whilst it is up to Member States to decide their own healthcare policy framework, they must do so within the bounds of Union law<sup>273</sup>. The following section will describe how the EU institutions, including the ECJ on one hand and the Commission, Parliament and Council of Ministers on the other, have made use of these freedoms in order to make laws that impact upon the provision of healthcare in Member States. An understanding of this pre-existing 'European constitutional context' is important if one is to grasp what in reality is novel about the recent Patient Rights Directive and what is not<sup>274</sup>.

### 7.2.1 The Right to Free Movement of Persons

The Right to Free Movement of Persons (freedom of movement) within the treaties provided the original impetus for the Community/Union rules on the provision of healthcare to citizens who seek healthcare outside their Member State of Residence. Whilst the provision of social security (including healthcare) is a matter of competence for the Member States, the Union has a role in ensuring that individuals that move between Member States are adequately protected and do not 'fall between the cracks' by not being protected by any framework as a result of their movement from one jurisdiction to

<sup>267</sup> Ibid, Article 168.7.

<sup>268</sup> Conclusions of 1-2 June 2006 on Common Values and Principles in European Union Health Systems. *Official Journal of the European Union* 146.

<sup>269</sup> Given this it can perhaps be argued that in addition to it not being permitted under Article 168 of the TFEU, there is also no need for the EU to legislate regarding general medical rights of Union citizens as the Council of Europe has already acted robustly on such issues. Union initiatives in this area could risk being superfluous as well as being legally and politically and legally suspect.

<sup>270</sup> See: Roscam Abbing, H. (2010). Patient's rights in a Technology and Market Driven Europe. *European Journal of Health Law* 17, 11-12. P 42 EU interventions capable of impacting upon European health provision, in addition to those on freedom of movement and freedom to provide services, include the Data Protection Directives and the Medical Device Directives (beginning with 93/42/EEC) concerning the use and testing of medical devices. With regards to human rights both the European Convention on Human Rights and Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (the Oviedo Convention) are intended to provide human rights protection in the practice of medicine. Roscam Abbing, H. (2010). Patient's rights in a Technology and Market Driven Europe. *European Journal of Health Law* (17), 11-12. P 43 – It must be admitted however that not all States have ratified the Oviedo Convention however.

<sup>271</sup> European Union (2010). Consolidated Version of the Treaty on European Union. *Official Journal of the European Union* 53(C83), Article 45.

<sup>272</sup> Ibid, Article 56, 5.

<sup>273</sup> See for example *Kohl Case C-158/96* para 17 – 19.

<sup>274</sup> This discussion is primarily concerned with EU policies affecting the provision of healthcare. This should not be confused with the wider area of EU health policy. This can include other aspects such as the health and safety of products marketed in the Union. See: Greer, S. (2006). Univited Europeanization: neofunctionalism and the EU in health policy. *Journal of European Health Policy* 13(1), 134 - 152



another. This has been termed the 'Coordination of Social Security Rights'.<sup>275</sup> The situation that gave rise for the need to co-ordinate social security rights is described in the paragraph below. The EU's response in terms of co-ordination of social security is described in the paragraphs that follow thereafter.

The 'Coordination of Social Security Rights' includes the coordination of a range of rights called 'benefits in kind' that are normally available to individuals resident in a Member State, who have qualified under domestic social security legislation to enjoy such rights. The provision of healthcare is one of such benefits in kind. It has been recognized that the non-availability of health care can act as an impediment to the freedom of movement.<sup>276</sup> Individuals would be less likely to travel to another Member State if it was not possible for them to access medical care should they fall ill. Whilst a literal right to freedom of movement alone (as in no frontier restrictions on movement) would in theory allow individuals to access healthcare in other Member States, individuals would be limited in reality by their ability to pay. Health care interventions are extremely expensive and are frequently outside the price range of most individuals. Most member states have therefore created various social security mechanisms that will subsidize or completely pay for such interventions. The problem in terms of the free movement of individuals is that such schemes are usually linked to the residency of the Member State in question. An individual that finds himself in need of medical assistance whilst on a temporary stay in another Member State (the Member State of Treatment) may not be covered by the social security protection (or the benefits in kind) offered by that Member State. This would mean that the individual would be forced to bear the full and unsubsidized cost of the medical treatment alone. The risk of such a situation arising would act as a disincentive to individuals to travel to other Member States as they could be liable for very large medical costs should they fall ill there. This disincentive would therefore provide an obstacle to the freedom of movement for individuals and therefore would, if left unchecked be contrary to the provisions in Union's primary law, the treaties which guarantee freedom of movement.

As a consequence, in 1971 the Commission released *Regulation 1408/71/EEC 'On the Application of Social Security Schemes to Employed Persons, to Self-Employed Persons and to Members of Their Families Moving Within the Community'*. This regulation allowed, *inter alia*, individuals to obtain the same treatment as that available to residents of the Member State of Treatment in which they find themselves, at the expense of the Member State of which they are resident if the need for such treatment arises during a temporary stay in that Member State<sup>277</sup>. This originally applied to workers and self-employed individuals but has subsequently expanded to apply to all nationals of one member state that are on a temporary stay in another Member State.<sup>278</sup> Additionally, protection was also extended to all legal residents of a Member State (assuming they are covered by that Member State's social security arrangements) in addition to Union citizens.<sup>279</sup> The result of this is that individuals, if they are covered by the social security system in their Member State of Residence, are entitled to treatment under the same conditions as residents of the Member State in which they find themselves. This will occur at the expense of the social security system of the Member State of Residence. Thus, individuals legally resident in one Member State should be able to have the peace of mind that if they fall ill during a temporary stay in another Member State they will be entitled to treatment on the same conditions (including price) as residents of that Member State. The result is (at least in theory) that

<sup>275</sup> The Council of the European Communities (1971). Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community. *Official Journal of the European Communities L149*, 2. The Preamble states 'the provisions for coordination of national social security legislations fall within the framework of freedom of movement for workers who are nationals of Member States and should contribute towards the improvement of their standard of living and conditions of employment.'

<sup>276</sup> The European Parliament and the Council of the European Union (2004). Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems. *Official Journal of the European Union L166*. See Recital 45, which states intention of the co-ordination of social security rights, is to secure freedom of movement.

<sup>277</sup> The Council of the European Communities (1971). Regulation (EEC) No 1408/71. *Official Journal of the European Communities L149*, Article 22.

<sup>278</sup> The Council of the European Union (1995). Council Regulation (EC) No. 3095/95 of 22 December 1995 amending Regulation (EEC) No. 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, Regulation (EEC) No. 574/72 fixing the procedure for implementing Regulation (EEC) No. 1408/71, Regulation (EEC) No. 1247/92 amending Regulation (EEC) No. 1408/71 and Regulation (EEC) No. 1945/93 amending Regulation (EEC) No. 1247/92. *Official Journal of the European Communities L335*, 1.

<sup>279</sup> The Council of the European Union (2004). Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality. *Official Journal of the European Union L124*, 1.

reimbursement fears regarding health care should no longer provide an obstacle in terms of freedom of movement for those considering a temporary stay in another Member State.<sup>280</sup>

### 7.2.2 The Freedom to Provide Services

Regulation 1408/71/EEC and its subsequent amendments provide important protection for European residents seeking emergency health care the need for which arises in another Member State based on the notion of the freedom of movement. These limited interventions however fall a long way short of creating anything like a European Single Market in healthcare. This is apparent if one looks at the limitations of (EEC) 1408/71 and its successor (EC) 883/2004.<sup>281</sup> Perhaps most important is that it only applies to health care that becomes necessary during a stay in another Member State. It does not provide a broad right to travel to another Member State to obtain treatment at the expense of the Member State of Affiliation. The regime started by (EEC) 1408/71 effectively provides only a form of emergency medical cover, valid during temporary stays in other Member States. It does not allow the right for individuals to opt to travel (and receive reimbursement) to another Member State for treatment for a pre-existing condition<sup>282</sup>. A totally free market in healthcare would allow patients to access healthcare in any member state of the European Union. The freedom to provide services, as provided in the treaties<sup>283</sup>, would seem to support such a notion, notably that healthcare providers should be able to offer medical services to individuals residing in Member States other than the one in which they are based. The definition of what constitutes a 'service' is very wide and includes medical services (see point 1. below). Whilst it might seem that if freedom of movement exists, one would be able to go to another state to obtain healthcare (a medical service), the reality of the situation is again somewhat more complex for the same cost-based reasons that apply to issues of freedom of movement discussed above i.e. lack of social security coverage. Importantly the ECJ, several decades ago highlighted in *Luisi and Carbone*<sup>284</sup> that the freedom to provide services does not just entail a freedom to provide services in another Member State, but also includes the right for recipients of services to go to another Member State in order to receive services there. This important judgment allowed the ECJ decades later to develop case law which protected the rights of patients to seek medical services in Member States other than which they are resident<sup>285</sup>. The ECJ has in the last decade produced several important judgments concerning restrictions on re-imburement for healthcare in another Member State. In particular it has ruled that such restrictions can, under certain conditions, constitute an illegal barrier to the free movement of services. The EU has, with the recent Patient Rights Directive (2011/24/EU) (PRD),<sup>286</sup> codified and clarified many of these points. This means that they will be written into national law through implementation measures, with providing for a higher level of visibility to national organizations than is at present the case. The paragraphs below summarize the most important principles of law raised by the ECJ and confirmed in Directive (2011/24/EU).

<sup>280</sup> Though in reality obstacles may still remain. An important one is the administrative hurdles individuals must go through in order to receive reimbursement. Other problems are associated with upfront payment. This could exist where for example, the Member State in which the individual finds himself or herself normally demands payment upfront and later offers reimbursement. This could require the upfront payment of a large amount of cash which the individual in question might not be in possession of. This will for example concern individuals that are resident in a Member State where no upfront payment is required and who find themselves needing treatment in a Member State where an upfront payment may be required. For a more detailed explanation see: Health and Consumer Protection Directorate - General, European Commission, Summary Report of the responses to the consultation regarding "Community action on health services" (SEC (2006) 1195/4 of 26 September 2006) 30

<sup>281</sup> The European Parliament and the Council of the European Union (2004). Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems. *Official Journal of the European Union* L166, 1.

<sup>282</sup> The Council of the European Communities (1971). Regulation (EEC) No 1408/71. *Official Journal of the European Communities* L149, Article 21.1(c) allowed individuals the right to travel to other member states to receive treatment if they were granted authorisation by their social security system. This authorisation is at the discretion of the social security system of the member state concerned. The one exception to this is where individuals are entitled to a certain type of healthcare in the Member State and which is not available within an acceptable timeframe. Under such circumstances an individual should be allowed to travel to another Member State to receive the equivalent treatment – See Article 22.2.

<sup>283</sup> European Union (2010). Consolidated Version of the Treaty on European Union. *Official Journal of the European Union* 53(C83), Articles 56 - 62

<sup>284</sup> Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377

<sup>285</sup> Cruz, J. (2011). The Case Law of the European Court on Justice on the Mobility of Patients: An Assessment in Van de Gronden, J., Syszczak, E., Neergaard, U. & Krajewski, M., *Health Care and EU Law, Legal Services of General Interest*. (Asser Press, The Hague).

<sup>286</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, commonly known as the Patient's Rights Directive. *Official Journal of the European Union*, L88.

1. Medical care can be categorized as a service. Despite their special nature, the ECJ confirmed in *Smits and Peerbooms*<sup>287</sup> that medical services can be classed as services for the purposes of the treaty<sup>288</sup>. Certain Member States had contended that medical services could not constitute services as understood under the treaty given their special nature<sup>289</sup>. The court stated that “It is settled case-law that medical activities fall within the scope of Article 60<sup>290</sup> of the Treaty, there being no need to distinguish in that regard between the care provided in a hospital environment and care provided outside such an environment.<sup>291</sup>” In *Watts*<sup>292</sup> the court confirmed that despite the fact that medical services are often provided on a not-for-profit basis, that they may be reimbursed or that the patient may not pay himself does not detract from the fact that the patient is being provided with a service<sup>293</sup>. Union rules on the provision of services therefore apply.
2. In *Kohf*<sup>294</sup> it was recognized that the requirement of prior authorization is a barrier to the freedom to provide medical services. (EEC )1408/71 and (EC) 883/2004 allowed individuals to obtain treatment in another Member State at the cost of their own security system, but only with the prior authorization of the Member State in which they were resident. Such a barrier is not acceptable in the case of non-hospital based treatment which does not call into question the same issues with regards to management of resources. Non-hospital costs are not likely to affect the balance of social security systems<sup>295</sup>. This is recognized in Article 2 of Directive 2011/24/EU which does not allow a system of prior authorization for normal non-hospital costs.
3. The requirement of prior authorization may however be acceptable with regards to hospital services. This is because according to the court, unlike non-hospital based services, hospital based services will require careful planning. The need for such planning may mean that prior authorization may be justified by overriding reasons of general interest. This is so as to ensure that “there is sufficient and permanent access to a balanced range of high-quality hospital treatment... to assist in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources<sup>296</sup>”. The ECJ considered that it was important to eliminate such wastage given the considerable costs and financial resources involved in healthcare, meaning that such resources are finite. The ECJ acknowledged however that the distinction between hospital and non-hospital care could be difficult to make in reality<sup>297</sup>. This can occur, when one considers for example the case of outpatients who though not ‘staying in a hospital’ may be undergoing complicated and expensive procedures. Directive 2011/24/EU has therefore clarified that certain non-hospital treatments that require the use of highly specialized equipment or procedures can be made the subject of a requirement for prior authorisation<sup>298</sup>.
4. Whilst authorization is acceptable under appropriate circumstances it must be done in an objective and transparent manner. In *Smits and Peerbooms* the court stated that in order for prior authorisation to be justified it must be based on ‘objective, non discriminatory criteria which are known in advance, in such a way so as to circumscribe the exercise of the national authorities’ discretion so that it is not used arbitrarily... Such a prior administrative authorisation scheme must likewise be ... dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in a judicial or quasi-judicial environment.<sup>299</sup> The court also stated that in this case, where the healthcare insurance provider had contracted with a national medical service provider to provide procedures authorization could

<sup>287</sup> *Smits and Peerbooms* Judgement Case C 157/99 of 12 July 2001.

<sup>288</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union*, L88, Article 3 (a).

<sup>289</sup> *Smits and Peerbooms* Paras 48 - 52

<sup>290</sup> It should be noted that the reference to Article 60 is an earlier version of the treaty, prior to the amendments contained in the Lisbon Treaty. The relevant article is now Article 57 of the Treaty on European Union.

<sup>291</sup> *Smits and Peerbooms* Para 53

<sup>292</sup> Case C-372/04 *Watts* [2006] ECR I-4325

<sup>293</sup> See also *Müller-Fauré/Van Riet* Case C-385/99 of 13 May 2003

<sup>294</sup> *Kohll v Union Des Caisses De Maladie* C-158/96

<sup>295</sup> *Müller-Fauré/Van Riet* Para 93

<sup>296</sup> *Smits and Peerbooms* Para 78, 79

<sup>297</sup> Explanatory note from the Commission Services on the provisions of the proposed Directive on services in the Internal Market relating to the assumption of health care costs incurred in another Member State with a particular emphasis on the relationship with the Regulation No 1408/71 11570/04 16 July 2004 Page 4 and see *Müller-Fauré/Van Riet* Para 93. This difficulty would serve to act a source of contention during negotiations for the PRD.

<sup>298</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union*, L88, Article 2(a)(ii).

<sup>299</sup> *Smits and Peerbooms* Para 90 Such requirements are now also contained in Article 9(1) of Directive 2011/24/EU.

be refused if the procedures were available in a justifiable timeframe in the Member State of Residence. Directive 2011/24/EU also states that such procedures should be easily accessible to individuals and should be based upon information and procedures that are publically accessible<sup>300</sup>. Procedures with regards to reimbursement should be properly reasoned and capable of being challenged via judicial routes<sup>301</sup>.

5. *In Vanbraekel*<sup>302</sup> the court confirmed that reimbursement for treatment carried out in another Member State must be at the same level as that which would occur if the treatment had been carried out in the Member State of Residence. This is the case even if the Member State of Treatment has a less generous level of reimbursement under its own system. The Member state of Residence does not however have to reimburse more than the cost of the treatment<sup>303</sup>.

The principles above provide an essential platform for providing truly mobile possibilities for healthcare in the future. This will involve not only the possibility of people physically moving to another Member State to obtain treatment there but also them being able to obtain treatment from other Member states using eHealth based technologies such as eHealth and telemedicine.

### 7.2.3 Further impact of the Patient Rights Directive on REACTION

The above judgments and their inclusion in Directive 2011/24/EU represent the primary and most salient aspects of the directive. There are however certain other issues that, under closer inspection of the directive appear to have the potential to impact upon eHealth services such as REACTION. Some of these are directly related to reimbursement of healthcare in another member state whilst others are related to certain practical arrangements that must be made in order to make the directive's main goals a reality.

#### 7.2.3.1 Reimbursement issues associated with eHealth/telemedicine

Importantly for matters of eHealth, the regime described in Directive 2011/24/EU also applies if the act sought outside the Member State of Affiliation is an act of telemedicine.<sup>304</sup> Telemedicine can be conceived of as a system of healthcare delivery that employs telecommunications and computer technology as a substitute for face-to-face contact between provider and client.<sup>305</sup> Additionally, the recitals<sup>306</sup> of the PDR make it clear that the Commission views the case law of the ECJ as being clear, that an act of eHealth should be categorized as a medical service for the purposes of reimbursement just like any other service. This confirms that the reasoning the ECJ adopted allowing reimbursement for cross border treatment will also apply to telemedicine based procedures. This should allow for an increased level of certainty and a better environment for innovation, uptake and acceptance of technologies that offer services that can be utilized in more than one Member State of the EU.

However, significant problems that reduce certainty for those wishing to innovate in eHealth remain to be resolved. The European Commission had, prior to its efforts in Directive 2011/24/EU, in consultation with key stakeholders (including patients and industry groups), identified several key problems hampering the growth of telemedicine and the e-health industry in Europe. Perhaps the biggest problem is that not all Member States even recognize an act of telemedicine as an act of medicine for the purposes of reimbursement. The healthcare systems of some Member States require health professionals and individuals to be present in the same place for act to be considered an act of medicine.<sup>307</sup> This can have negative effects for individuals seeking reimbursement for medical treatment that occurred both within their Member State of Residence and also for those seeking reimbursement for treatment that originated elsewhere. If the Member State of Affiliation's social security scheme recognizes an act of telemedicine as a medical act then it should reimburse the equivalent act that occurs in another Member state. This however does nothing for the residents of those Member States that do not recognize an act of telemedicine as a medical act. Such individuals

<sup>300</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union* L88, Article 9.2.

<sup>301</sup> Ibid Article 9.4.

<sup>302</sup> Case C-368/92 *Vanbraekel and others* [2001] ECR I-5363

<sup>303</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union*, L88. These requirements are contained in Article 7.4.

<sup>304</sup> Ibid, Article 7.7.

<sup>305</sup> Bashurb, R. (1995). On the Definition and Evaluation of Telemedicine, *Telemedicine Journal* 1(1), 19-30.P.19.

<sup>306</sup> See Directive 2011/24/EU Recital 26

<sup>307</sup> Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009 In addition many Member States do not have a specific legal framework covering aspects of telemedicine.

will effectively be barred from availing themselves of procedures both in their own and in other Member States of the European Union because their social security system will not be obliged to reimburse an individual for an act that would not be recognized on its own territory. The bizarre effect of this is that certain individuals may be allowed access to eHealth services throughout the Union whilst others, by virtue of the Member State they are resident in, may be prevented from accessing the same services anywhere in the Union. There is little in the PRD that deals with issues such as the legal recognition of acts by the Member States of eHealth. This has been left to the Member States themselves to formulate. This means that in order to discern the picture in each state it is essential to look to the regulations in place in that state in order to determine the 'reimburseability' of e-Health services such as REACTION.

As a result of this some states are more fertile than others in the possibilities they offer for the reimbursement of such services. France, for example has enacted a decree that (le décret telemedicine) is a good example of how reimbursement for services can be arranged<sup>308</sup>. This decree lists the types of services for which reimbursement can be expected and also the manner in which they will be reimbursed. Various funds have been set-up at the regional and national level to support this re-imbusement. In the Netherlands the relevant regulations allow e-Health services to become involved in the healthcare plans of chronically ill individuals. There instead of reimbursement per medical event, a fixed budget is allocated for the patient's treatment that requires reference to performance standards and criteria concerning the quality of output. The Ministry of Health has even taken the recent step of introducing a system of that allows for the reimbursement of costs associated with the integrated care of a number of conditions, including diabetes<sup>309</sup>. In some other states such as Slovenia, Greece and Italy however the picture is less favorable. These states have been known to use the issue of limited resources to justify a lack of intervention in this area.

The reticence to attempt to include rules regarding the recognition of acts of telemedicine in the PRD is understandable given that it would be of dubious legality given that competences in matters of healthcare lie with the Member States according to Article 168 TFEU. Given this clear delineation of competence it would be doubtful that, barring a treaty change, any provision that allowed the Commission to take measures to make the recognition of acts of telemedicine/eHealth uniform would be legal given that it is up to each Member State to decide the character of its health provision.

### 7.2.3.2 Remote access to patient record

The directive also requires Member States to ensure that individuals seeking healthcare in another Member State are entitled to receive at least a copy of their health records or to have remote access to them from the Member State of Affiliation.<sup>310</sup> The provision of such records must be in conformity with the national implementing measures of Union provisions on the protection of personal data.<sup>311</sup> This will of course (see below) involve a certain degree of reflection<sup>312</sup> on how access to patient records should be regulated according to data protections provisions, perhaps on the part of both national authorities and healthcare providers.<sup>313</sup> This represents an important step in the provision of a truly mobile system of healthcare. The right of access to one's personal record means that individuals should be able to obtain medical treatment in other Member States that can be precisely tailored to their needs given their specific medical history. This will be important for individuals who use mobile devices or methods of accessing healthcare as it will mean that they should in theory be able to depend upon such devices even if they cross Member State frontiers. It also means that individuals should be able to utilize the services of different medical professionals in different Member states in a coordinated manner if they wish. This would in theory allow a REACTION like service that was based in a different state than the one in which the patient was resident in to access his/her patient record for the purposes of treatment. This may be of utility in offering REACTION services to individuals who live in small member states where the deployment of such a service on a national basis may be less feasible. It should however be noted that many states will not, at the time of writing have transposed this directive into national law. This means that the legal requirements mandating the availability of a patient's record may not yet be in place. In addition, the presence of legal requirements do not

<sup>308</sup> See 'European countries on their Journey towards nationale Health infrastructures', eHealth Strategies Report, January 2011

<sup>309</sup> Ibid.

<sup>310</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union*, L88, Article 5(d).

<sup>311</sup> The Directive 2011/24/EU emphasises in particular Directives 95/46/EC and 2002/58/EC

<sup>312</sup> The Dutch government offered its own recently agreed system of national patient records as a suitable guide on how such principles should be applied. See *Nederlands regeringsstandpunt in reactie op de mededeling van de commissie in het kad van de raadpleging over communautaire maatregelen op het gebied van gezondheidsdiensten*, 10.

<sup>313</sup> See section 5.3.4 for a brief discussion on the data protection principles applicable to medical records.

guarantee, that the practical or technological requirements for the smooth transfer of such data will be in place. The picture will only become clear in the years following the deadline for the directive's imposition into national law.

*Requirements on the Mutual Recognition of Prescriptions (Article 11 of the Directive)*

The PRD also attempts to create a system of mutual recognition of prescriptions, whereby prescriptions made in one Member State are recognized in another. This is intended to apply to products that are authorized to be marketed in the latter according to Directive 2001/83/EC or Regulation (EC) No 726/2004. Member States must ensure that prescriptions issued for such products in another Member State for a named patient can be dispensed in their territory in compliance with the national legislation in force.<sup>314</sup> Such rules must however be compatible with Union law. Member States are not allowed to prohibit the recognition of prescriptions unless restrictions would be necessary and proportional to safeguard human health<sup>315</sup> or if restrictions are based on legitimate doubts about the authenticity, content or comprehensibility of an individual prescription.<sup>316</sup> In order to further these aims the Commission has been given the power to adopt measures enabling health professionals to verify the authenticity of the prescription and also the fact that it was issued by an authorized individual in another Member State who is a member of a regulated healthcare profession.<sup>317</sup> This shall be done by developing a 'non-exhaustive' list of elements to be included in prescriptions and which must be clearly identifiable in all prescription formats. These elements will facilitate, if needed, contact between the prescribing party and the dispensing party.<sup>318</sup> Guidelines will be produced by the Commission in order to support the Member States in developing the interoperability of ePrescriptions.<sup>319</sup> The Commission will also be able to adopt measures to identify the correct identification of products or devices described in the prescription. This will include measures required to address patient safety concerns including measures regarding substitution of medicines in cases of cross border health care.<sup>320</sup> The possibility of cross border prescriptions could also be useful for REACTION like services that were intended to have a cross-border reach. This option could possibly allow patients that live or are travelling temporarily through other member states to access pharmacy services that are often essential for those having chronic conditions such as diabetes. Individuals would for example be allowed to obtain a prescription from a preferred physician in another Member State, perhaps even through an eHealth medium and then be allowed to collect it where they live. This could be important for those who for one reason or another do not speak the prominent or legally recognized language in their own state. Even for those that do speak the language they may simply prefer to consult with a physician in their own mother tongue. Others may only be able to find a physician with a highly specific expertise in a different member state than the one in which they are living. A ready example (which is only one of many possible) of a group of people that could possibly benefit from such a provision would be the small German speaking population of Belgium. It is conceivable that individuals with diabetes amongst this group might well want to consult a physician in their mother tongue. Given that the German speaking population of Belgium is very small it might be more likely that a suitable expert is easy to find in Germany. Using telehealth the patient might be able to obtain a prescription from a physician in Germany and use it at a local pharmacy where they live.

*The Exclusion of Assisted Living Care from the PRD (Article 1(3)(a) of the Directive)*

In order to placate national concerns over budgetary control the Patient Rights Directive was written in a way so as to exclude assisted living. This exception means that the directive does not apply to services in the field of long-term care, which are intended to support people in carrying out routine everyday tasks.<sup>321</sup> This exception appears to be primarily aimed at individuals that find themselves in

<sup>314</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union L88*, Article 11.1. This presumably means that the dissemination of the prescription must be according to the law of the state where a patient is attempting to obtain the medication. This will presumably include rules governing quantities, the language of the instructions and other similar issues.

<sup>315</sup> Ibid, Article 11.1(a)

<sup>316</sup> Ibid, Article 11.1(b).

<sup>317</sup> Ibid, Article 11.2. In adopting the measures and guidelines the Commission must have regard to the proportionality of any costs in compliance with, as well as the likely benefits of the measures or guidelines- Article 11.4.

<sup>318</sup> Such measures must be adopted by the Commission by 25 October 2012

<sup>319</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union, L88*, Art 10.2.

<sup>320</sup> Directive 2011/24/EU Article 11(2)(c) - Substitution will still only be allowed however where the legislation of the dispensing Member State Allows such substitution.

<sup>321</sup> Ibid, Article 1.3(a) Although it is difficult to be sure, the explicit exclusion of this exception seems to have been included in order to reflect the judgment in *von Chamier-Glisczynski*<sup>321</sup>. That case concerned a German resident that had requested that that Member State funded the cost of her staying in a care home in Austria. The result of this exclusion is that individuals will not be entitled to reimbursement for forms of 'assisted living care' in another Member State. This could include for example individuals who through chronic conditions face a long-term disability and require assistance with day-to-day tasks. Likewise elderly

long-term care homes or using services deemed necessary in order to enable the person in need of care to live as 'full and self-determined a life as possible'. Long-term care facilities, homecare services, and residential or nursing homes seem therefore to fall outside the scope of the PRD. This means that individuals wishing to obtain such services on a cross border basis would appear to be excluded from the protection the PRD offers to other types of non-hospital based treatment.

Unfortunately it seems likely that the exclusion of assisted living from the normal rules on reimbursement could serve to hamper some eHealth based projects that could be of use in providing assisted living applications to individuals who have difficulties due to conditions related to disabilities or old age. One could envisage for example e-Health applications designed to provide mental stimulation to house-bound or even bed-bound individuals. Such modern technological solutions to the problem of loneliness and isolation have been shown to reap psychological and health benefits for individuals.<sup>322</sup> Passive eHealth based monitoring applications<sup>323</sup> have also been shown to improve the health of those living in assisted care and reduce further treatment related costs.<sup>324</sup> Unfortunately however, despite the fact that such services could feasibly provide tangible benefits they will not be classified as 'medical services' for the purpose of the PDR. This could have unfortunate implications for individuals that would be able to benefit most from open pan-European access to healthcare. These being once again individuals living in border areas or that find themselves in a Member State where they do not speak the legally recognized languages. In such instances e-Health based methods of communication might allow such services to be accessed in a language that is intelligible to the individual concerned. It is conceivable that such an exclusion might make it more difficult for certain aspects of prospective REACTION service to be funded. This would apply more specifically to aspects (if they were to be include in a potential REACTION platform) that are not specifically included for the purposes of treating diabetes but are instead included in order to manage conditions associated with the reduced capacity that comes with old age. This could, for example, include gait sensors of other sensors that could detect a fall. It is possible given the wording of the PDR that states would exclude such aspects from possible reimbursement schemes (if they were cross-border) that would support potential REACTION-like platforms.

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individuals who suffer from physical or cognitive difficulties and as a result require assistance in day-to-day living would seem to be excluded. In that case a significant part of the problem for the individual concerned was that in moving to another Member State to obtain assisted living care the individual concerned became resident there.

<sup>322</sup> Morán, L. & Meza-Kubo, V. (2009). Towards a Tele-assistance Service for the Cognitive Stimulation of Elders with Cognitive Decline. International Conference on eHealth, Telemedicine, and Social Medicine, 160-165.

<sup>323</sup> Such services would furthermore not seem to be caught by the 'catch 22' described above whereby a person wishing to access such services that were supplied in another Member State would likely become a resident of that state and lose the connection with his original Member State of Affiliation. See Fn xx above and the problems this presented in *von Chamier-Glisczynski*.

<sup>324</sup> Alwan, M., Brito-Sifferlin, E., Tuner, B., Kell, S., Brower, P., Mack, D., Dalal, S. & Felder, R. (2007). Impact of Passive Health Status Monitoring to Care Providers and Payers in Assisted Living. *Telemedicine and eHealth* 13(3), 279 – 285.

## 7.3 Examples of reimbursement in different EU Member States

### 7.3.1 The UK

The UK system is conceptually different than many of the Bismarckian<sup>325</sup> based healthcare systems found in Europe. In the UK, one government provider, the National Health Service (NHS) dominates healthcare provision. This organisation provides most medical services free at the point of use to individuals that are legally resident in the UK. The concept of reimbursement as understood in continental Europe does not therefore exist in the UK. The NHS is funded through a system of general taxation and not insurance. Individuals themselves are not required to pay for most medical services<sup>326</sup>, negating the need for reimbursement. It would however be incorrect to assume that all medical services can be obtained by UK residents through the NHS. As with all large public organisations, its resources are finite and as a consequence it must make a decision as to which services it will fund and which it will not. An important body responsible for deciding what service the NHS will offer is the National Institute for Clinical Excellence (NICE). NICE produces guidelines for the NHS that will often determine which technologies and practices are adopted by the service. In these guidelines NICE will convey the results of studies it has conducted into the cost-effectiveness of proposed treatments. Often such analysis will be based on concepts such as the Costs per Quality Adjusted Life Year Gained (QALY). This is because clinical effectiveness alone is not sufficient to judge the suitability of a treatment as the cost required to achieve that clinical effectiveness must also be taken into account. The QALY allows these two functions to be combined. The QALY will represent a figure that represents the cost for each year of quality-adjusted life that may be gained. Whilst NICE looks at every treatment on a case-by-case basis a QALY above a certain threshold will likely result in a negative recommendation, meaning that the treatment is unlikely to be adopted by the NHS<sup>327</sup>.

Whilst NICE can make decisions on individual projects, the UK has recently signalled its willingness to support more practices of telemedicine within the NHS. A recently produced NHS Operating Framework document has suggested that more use of telehealth should be made with the NHS. Such documents are intended to provide an overall vision and direction to the NHS and are not related to specific projects. The framework states, 'Clinical commissioning groups should spread the benefits of innovations such as telehealth and telecare as part of their on-going transformation of NHS services.'<sup>328</sup> They should also take full consideration of the use of telehealth and telecare as part of local reconfiguration plans. Evidence of this new enthusiasm can be seen by the recent conclusion of a UK project aimed at the demonstration of telemedicine. This trial, which has been described as the largest randomised controlled trial of telehealth and telecare globally, was conducted with more than 6000 patients. The aim of the trial was to test the capacities of new technologies to support the remote management and treatment of patients with chronic conditions. Preliminary results have shown that the use of remote healthcare technology may reduce the number of emergency admissions to hospital amongst patients with long term conditions. This will increase the likelihood of the NHS employing such services in the future. The NHS has also shown itself to be willing to use telehealth programmes in trials with diabetes. Once such an example occurred in Cornwall, which represents one of the more remote and poorer contexts of the UK. In legal terms UK residents who wish to access telehealth services from another Member State will have to first look to see if the service in question is available on the NHS. If it is, they will under the Patients' Rights Directive be in a position to demand that such a service received abroad be reimbursed by the UK at home.

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<sup>325</sup> A Bismarckian system was traditionally seen as basing social protection mainly on social insurance, or the 'conservative corporatist' type of welfare capitalism See Palier, B. & Martin, C. (2007). From 'a Frozen Landscape' to Structural Reforms: The Sequential Transformation of Bismarckian Welfare Systems. *Social Policy and Administration*, 41(6), 535-554.

<sup>326</sup> There are some exceptions. A co-payment system exists for prescriptions and dental services for example.

<sup>327</sup> Rawlins, D., and Culyer, A. (2004). National Institute for Clinical Excellence and its Value Judgements. *British Medical Journal* 329, 224.

<sup>328</sup> Wise, J. (2011). UK Government signals its support for telemedicine. *British Medical Journal* 343.



### 7.3.2 Germany

The German health insurance system which is based on the Bismarckian system has a long tradition and roots in the 19<sup>th</sup> century.<sup>329</sup> Due to the particular political structure of Germany as a federal state which shares many of its powers with the 16 states (Bundesländer) the list of those who determine and plan the German health policies is rather long. The main decision makers are the Federal Ministry for Health with the Institute for Health Technology Assessment and the Federal Institute for Drugs and Medical Devices which both are part of the Ministry. Moreover, organizations of the social and the health insurances and of doctors, dentists, hospitals and patients are influential and part of the official decision making process. All these groups determine or influence which services will be reimbursed. The final decision on reimbursement is taken by the Statutory Health Insurance and the Federal Joint Committee comprising representatives of patients, dentists, doctors, hospitals and the social insurances.<sup>330</sup>

Germans pay an income related contribution for statutory health funds. The contribution is nearly the same for all funds (there are about 150 at the moment). The services and drugs which are reimbursed are similar due to the federal decisions. Additional services might however vary. This has a particular impact in the area of new services and experimental medicine. The reimbursement of eHealth services can depend on the choice of the insurance. Furthermore, there is the opportunity to have a private insurance (only for higher income groups). Contributions and reimbursement vary in between the statutory and the private health insurance.<sup>331</sup>

The importance of eHealth for health care for recognized in the German eHealth Strategy of 2005. Because of the particular structure of the German systems with its many actors and decision makers involved, eHealth is considered as a chance for improved communication. The targets of the strategy are a reduction of cost, a better (patient-centered) care provision, an improvement of quality and service and a better health data collection. To achieve these aims the strategy is focusing on building a solid ICT infrastructure and the application of a private electronic patient record. The German strategy takes a European perspective into account and aims at enabling a cross-border use of eHealth. The key project of eHealth in Germany during the last years has been the introduction of the Electronic Health Card (Elektronische Gesundheitskarte). This proved to be a difficult process due to privacy and data protection concerns. The access to the data is however restricted and the patient is not only asked for explicit consent but also seen as the owner of the data with a right to delete them.<sup>332</sup> In comparison, the EU just started discussing a 'right to be forgotten' in the context of the revision of its data protection framework.<sup>333</sup>

Despite the national strategy, reimbursement for eHealth is often lacking. Whereas the government strongly supported the introduction of the Electronic Health Card and offered reimbursement for the acquisition of new machines by physicians, the reimbursement of other eHealth/telemedicine services is rather limited.<sup>334</sup> In the treatment of diabetes telemedicine became a popular option. The possibilities of reimbursement are still under review.

<sup>329</sup> For more information please consult REACTION Deliverable D9-4 'Healthcare Economics and Reimbursements'

<sup>330</sup> ISPOR (2009), Pharmaceutical HTA and Reimbursement Processes – Germany. Retrieved 15.02.2012 from: <http://www.ispor.org/htaroadmaps/germany.asp>

<sup>331</sup> Ibid.

<sup>332</sup> Bundesministerium für Gesundheit und Soziale Sicherung (2005), The German eHealth Strategy. Retrieved 15.02.2012 from: [http://www.ehealth-era.org/database/documents/German\\_eHealth\\_Strategy\\_July-2005.pdf](http://www.ehealth-era.org/database/documents/German_eHealth_Strategy_July-2005.pdf)

<sup>333</sup> A proposal of the new Regulation of the European Commission can be found here: [http://ec.europa.eu/justice/data-protection/document/review2012/com\\_2012\\_11\\_en.pdf](http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf)

<sup>334</sup> E-Health-Com News (2011), ZVEI: Elektrotechnik-Verband fordert Erstattung von Telemedizin. Retrieved 16.02.2012 from: <http://www.e-health-com.eu/details-news/zvei-elektrotechnik-verband-fordert-erstattung-von-telemedizin/>

### 7.3.3 Italy

The Italian National Healthcare System SSN (Servizio Sanitario Nazionale) is ranked amongst the best of the world<sup>335</sup> even though it is often perceived differently by the public.<sup>336</sup> Therefore, extensive reforms took place during the last years to decentralize the system and redistribute responsibilities to several levels.<sup>337</sup>

The system now is divided into three levels, the national, regional/semantic and local/territorial level. The government determines the general healthcare policies on national level. The implementation takes place on regional level with the resources of the region. Health care delivery is the responsibility of the local level. The Italian health system is mainly financed by indirect taxes. The budget from the national fund is distributed by government to the regions. Remaining costs have to be covered by the regions with the help of their own budget. General rules for reimbursement are established on national level. Their implementation takes place at regional level.<sup>338</sup>

The three levels in health care feature different program. In 2004 a eHealth Board was established in the territorial area. It shall facilitate communication of the different levels and enable implementation of new strategies. Pilots were launched in the areas of eBooking, eSignatures, telemedicine and telehealth. Due to the decentralization of the system the quality of services can vary between different regions.<sup>339</sup> At national and regional level new program focusing on the exchange of data (patient data and data on the quality and efficiency of services) were established. These new initiatives encourage the use of eHealth. However, the services are still not fully developed and regional disparities remain.<sup>340</sup>

With regard to diabetes eHealth is possibly applied as a tool of intervention in Italy.<sup>341</sup> Furthermore, telemonitoring services are applied for diabetes patients. Again regional differences exist. Specific treatment options related to eHealth and diabetes are rather pilot projects in model regions often supported and implemented in the context of EU projects.<sup>342</sup>

The three main initiatives for data exchange and the eHealth board were mainly financed by the state. Still funding is allocated to pilot projects in eHealth.<sup>343</sup> The reimbursement of specific eHealth services is still unclear. There are legal constraints with regard to data protection, privacy and responsibility. These issues need to be clarified before a scheme for reimbursement can be agreed on.<sup>344</sup>

<sup>335</sup> OECD Health Data 2011. How Does Italy Compare (2011). Retrieved 20 February 2012 from: <http://www.oecd.org/dataoecd/45/52/43216313.pdf>

<sup>336</sup> Maio, V. & Manzoli, L. (2002). The Italian Health Care System: W.H.O. Ranking Versus Public Perception. *Pharmacy and Therapeutics*, 27(6), 301 – 306.

<sup>337</sup> Mercusio, G., Rossi Mori, A., Agnello, P., Mangia, M. & Mazzeo, M. (2007). eHealth Strategy and Implementation Activities in Italy. eHealth ERA. Retrieved 20 February 2012 from: [http://www.ehealth-era.org/database/documents/ERA\\_Reports/Italy\\_eHealth-ERA\\_Country\\_Report\\_final\\_01-06-2007.pdf](http://www.ehealth-era.org/database/documents/ERA_Reports/Italy_eHealth-ERA_Country_Report_final_01-06-2007.pdf)

<sup>338</sup> REACTION Deliverable 9-4 Healthcare Economics and Reimbursement (2011). Retrieved 16 February 2012 from: [http://www.reactionproject.eu/downloads/deliverables/D9-4\\_Healthcare\\_economics\\_and\\_reimbursements.pdf](http://www.reactionproject.eu/downloads/deliverables/D9-4_Healthcare_economics_and_reimbursements.pdf)

<sup>339</sup> Mercusio, G., Rossi Mori, A., Agnello, P., Mangia, M. & Mazzeo, M. (2007). eHealth Strategy and Implementation Activities in Italy. eHealth ERA.

<sup>340</sup> Ibid.

<sup>341</sup> Ibid.

<sup>342</sup> Tamburini, E., Giest, S., Dumortier, J. & Artmann, J. (2010). eHealth Strategies. Country Brief: Italy. Retrieved 20 February 2012 from: [http://ehealth-strategies.eu/database/documents/Italy\\_CountryBrief\\_eHStrategies.pdf](http://ehealth-strategies.eu/database/documents/Italy_CountryBrief_eHStrategies.pdf)

<sup>343</sup> Mercusio, G., Rossi Mori, A., Agnello, P., Mangia, M. & Mazzeo, M. (2007). eHealth Strategy and Implementation Activities in Italy. eHealth ERA.

<sup>344</sup> Tamburini, E., Giest, S., Dumortier, J. & Artmann, J. (2010). eHealth Strategies. Country Brief: Italy. Retrieved 20 February 2012 from: [http://ehealth-strategies.eu/database/documents/Italy\\_CountryBrief\\_eHStrategies.pdf](http://ehealth-strategies.eu/database/documents/Italy_CountryBrief_eHStrategies.pdf)

## 8. Liability and eHealth

The following pages of this document will explore how eHealth practices such as REACTION can intersect with issues of liability. Europe is estimated to have one third of the total global eHealth market, the industry has been estimated as having a potential value of €20 billion.<sup>345</sup> Telemedicine and eHealth is seen as a partial solution to the growing demographic crisis which many Member States are facing. It is hoped that the correct deployment of telemedicine would allow resources to be deployed more optimally, thus reducing the strain on healthcare budgets. At present however, despite the existence of the European Single Market, laws relating to liability are largely a matter of Member State competence. Thus, if problems occur in the use of medical technology and the provision of medical services, both the *location* and the *outcome* of any legal proceedings will depend upon where exactly the treatment occurred. This may create legal problems for service providers such as REACTION that envisage the possibility of offering their service to individuals in different jurisdictions than their own. With such services it is often difficult to decide where exactly such services are actually being carried out. In 2009 the Commission set out a number of priorities with regards to telemedicine. One of these was described as being to address 'issues of liability with respect to telemedicine services'.<sup>346</sup> Unfortunately however, the Patient's Rights Directive had little impact on eHealth and its associated issues of liability. This means that there is still a marked inconsistency regarding matters of liability for eHealth when compared to conventional medical services. This involves a system of liability for failures in eHealth that runs counter to the logic that exists in the directive for more conventional forms of medical treatment. This issue which will be important to those operating in the ever expanding market that e-Health represents is outlined below. This work does not attempt to outline the various systems of law that relate to medical liability that exist in each Member State. To attempt to describe one in detail alone would in itself represent a voluminous task and would be beyond the scope of this work. The description below rather represents a description of how one can discern which law is applicable for in cases of dispute over eHealth practices such as reaction.

### 8.1 Jurisdictional issues: a difference between conventional medicine and eHealth based medicine

#### Conventional Medical Treatment (i.e not using distance based e-Health methods)

According to the prevailing system of division of liability which is re-iterated in the Patients' Rights Directive, conventional medical procedures are to be carried out according to the laws and regulations laid out in the Member State of Treatment. A conventional procedure can be considered one where the patient involved physically travels to the Member State where the treatment is occurring. For the purposes of this discussion non-conventional medical treatment would include areas such as eHealth and telemedicine including situations where the patient in question can remain in their Member State of residence and receive treatment there. With regards to conventional medicine it is expected, and confirmed in the Patient Rights Directive<sup>347</sup> that if a problem were to arise it would be dealt with according to the laws of that Member State of Treatment, i.e. where treatment was taking place. This means that conventional medical institutions that treat an individual resident in another Member State would not face being brought before a court in another Member State if they were at fault, rather disputes would be dealt with under the rules of the Member State where the service was provided.

#### eHealth and Telemedicine

With eHealth platforms such as REACTION and acts of telemedicine however the picture is somewhat more complicated. There are broadly two regimes for determining which Member State's rules would apply to disputes arising through the provision of telemedicine on a cross border basis. The first concerns 'professional-to-professional' uses, which in the telemedicine environment could for example include a consultation of one health professional with another specialist health professional (perhaps to discuss a patient's condition). In such a circumstance the 'country of origin' principle would apply whereby the services must comply with the rules of the Member State of Establishment. However, with 'professional-to-consumer' activities the opposite situation exists, with the rules of the Member State where the consumer resides applying. This means that the eHealth provider must, when providing services to consumers, comply with the rules of the Member State in which that individual resides. The

<sup>345</sup> Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009

<sup>346</sup> See Annex 2 of Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009 In addition many Member States do not have a specific legal framework covering aspects of telemedicine.

<sup>347</sup> The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU. *Official Journal of the European Union L88*, Article 1.

consequence is that the eHealth provider must be aware of, and comply with, the legal requirements of the various Member States in which it provides services to individuals. This places a burden on eHealth providers and acts as an inhibitor to the pan-European development of the industry. The Patients' Rights Directive, itself does nothing to alter this underlying position which places eHealth outside the usual regime for determining liability. It could however on the other hand be argued that such a state of affairs represents an important protection of the consumer, which in this case being a patient is an issue of paramount importance. Such a setup allows an individual to seek such services in another Member State secure in the legal protection that applies to him in his own Member State. This vision is the basic idea of the Brussels II regulation that regulates liability in terms of services and other matters for business-to-business and business-to-consumer matters.<sup>348</sup>

For REACTION this means that different legal scenarios may apply according to laws of various jurisdictions of the Member States may apply according to the nature of the dispute in question. One could envisage both uses of REACTION that would fall under the 'professional-to-professional' and 'professional-to-consumer' categories described above. Under the second category one could imagine situations where negligent advice was given to a patient through REACTION or where a patient's data was handled incorrectly in the course of his treatment under REACTION. In such a situation the dispute would be handed under the law of the Member State in which the patient resides. This would be the case whether the REACTION service provider was based in that Member State or not. This means that the service provider would require knowledge of the law in that Member State to avoid such liability and to contest any cases should they unfortunately arise. This places a significant legal burden on suppliers of such services in terms of preparedness and resources. The second scenario could conceivably exist in a REACTION platform where data is passed from one physician, nurse or even technician to another. This could be for example between a local hospital and a central processing site at another location. It is conceivable that an error by the latter party could lead to a problem occurring to the end user. Whilst this end user might decide to hold either his local hospital or the distant service provider liable for the problem occurred the local hospital might decide to hold the distant service provider liable for the costs that it has incurred (including for the liability it may have been exposed to through the damage caused to the patient). The first two of these situations would likely be governed by the law in the Member state of the patient whilst the last would likely be governed according to the law of the Member state of the distant service provider (assuming that this was a different Member State). This means that professional service providers acting as intermediate service providers in a REACTION-like platform may need to be aware of the law applicable in other Member States if other components of the service are offered by organizations based in different Member States.

## 8.2 Jurisdiction in terms of procedural and substantive law

The issues above are important in relation to jurisdictional disputes. Questions of jurisdiction are important because they decide both the procedural and the substantive law that will apply to a dispute. Procedural law can be important to parties in that it decides, amongst other things, the location and the timeframe against which the dispute in question is to be decided. For individuals this can be of critical importance, as they will often be lacking the financial resources or the know-how to bring about proceedings outside their favored jurisdiction (usually where they are resident). For service providers such issues will also be important because although they are usually endowed with more resources than individuals, having to fight proceedings brought about in other jurisdictions can be extremely costly. With respect to substantive law, the jurisdictional setting can be decisive in determining the outcome of a case as a set of given facts may be decided differently in different jurisdictions with different laws.<sup>349</sup> The variation in the substantive law of the legal systems of the EU's member states is substantial and it would be beyond the scope of this work to explore in depth. It can be argued that such a variation in substantive law relating to matters of medical liability can have a detrimental effect on the use of telemedicine. This, it is argued results from the uncertainty that having such a variation in laws creates.<sup>350</sup> Future harmonization of such laws could remedy such a problem and may be permissible under the EU's constituent treaties, as it would bring about an increase in the freedom of movement for individuals and the freedom to provide services for medical service providers.

<sup>348</sup> See: Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

<sup>349</sup> A good example of this the variation that exists in some Member States with respect to non-fault legislation and healthcare. Such laws exist in Belgium France but not in many other Member States. See Callens, S. (1996). *The EU Legal Framework on E-health in Mossailos, E., Permanand, G., Baeten, R. & Hervey, T. Health Systems Governance in Europe.* (Cambridge University Press), 586.

<sup>350</sup> *Ibid.*, 587.

### 8.3 European legislation relating to substantive law in eHealth

The following directives can all be considered as having a bearing in the development and deployment of potential health solutions. These directives have been written into Member State law and so are binding (although in slightly different forms throughout the EU). They are each capable of creating liabilities for the manufacturers and operators of e-Health systems. Some of these legislative initiatives have been tackled elsewhere and will not be examined in detail here<sup>351</sup>.

- Directive 85/374/EEC on liability for defective products.
- Directive 92/59/EEC concerning general product safety
- Directive 93/42/EEC on medical devices
- Directive 95/46/EC on the protection of individuals with regards to the processing of personal data
- Directive 96/9/EC concerning the legal protection of databases
- Directive 97/EC/66/EC on the processing of personal data and the protection of privacy in the telecommunications sector
- Directive 199/93/EC providing a community framework for electronic signatures
- Directive 2000/31/EC on certain legal aspects of information security services, in particular electronic commerce in the Internal Market (see below).

### 8.4 The E-Commerce Directive

The e-Commerce Directive<sup>352</sup> was intended to compliment pre-existing rules concerning online purchases and other types of online commerce. More specifically the directive is intended to apply to services normally provided for remuneration, at a distance, by electronic means.<sup>353</sup> This means that services that are not offered on a commercial basis will not have to meet the requirements of this directive. This will include a large amount of possible health services including public health information messages. It was hoped that the directive will create a legal framework to ensure the free movement of information society services between Member States.<sup>354</sup> Communications by phone (including mobile phones) and fax are also not included in the remit of the directive.<sup>355</sup> Importantly, consultations with medical professionals by means of phone or fax are explicitly excluded from the definition of information society services.<sup>356</sup> This means that the requirements of the e-Commerce directive (described below) will not apply to a range of e-Health services.<sup>357</sup> Whilst the most obvious area of application of the directive is to activities such as the sale of goods and services online, the directive also makes clear that it can be considered to be applicable to a wide range of activities that involve re-numeration, even if such remuneration is not provided by the direct recipient of the service. This has potentially important implications for health-based services such as REACTION as it means that e-Health providers may be subject to requirements of the directive even if they are not receiving payment directly from the patient. This may be the case where a state insurance organization (e.g. the 'mutualities' in Belgium and France) is ultimately responsible for the payment of the service that the patient himself has decided to purchase. This will inevitably catch a large range of potential e-Health services where individuals ultimately decide to purchase such services because they know they will not have to foot the bill themselves (i.e. the state will pay in their place).

It will be important for those wishing to offer eHealth services to be aware of this distinction in order to be certain which services will be subject to the requirements of the e-Commerce directive. However,

<sup>351</sup> These directives were outlined as having an important impact on information society services in a report submitted to the Belgian Presidency of the European Union entitled 'The influence of EU law on the social character of health care systems in the European Union', Brussels 19 November 2001, 105.

<sup>352</sup> The European Parliament and the Council of the European Union (2000). Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce in the Internal Market (Directive on electronic commerce). *Official Journal of the European Communities L178*, 1.

<sup>353</sup> Communications by phone fax or mobile phone are excluded from the remit of the e-Commerce Directive. This can be seen by Directive 2000/31/EC's reference in Article 2(a) to the definition of information society services in Directive 98/34/EC, Article 1(2) (which) refers to Annex V of that directive for a list of services that can not be considered as 'information society services'.

<sup>354</sup> The European Parliament and the Council of the European Union (2000). Directive 2000/31/EC. *Official Journal of the European Communities L178*, Recital 8.

<sup>355</sup> Ibid, Article 2(a) refers to the e-Commerce directive refers to Article 1(2) of Directive 98/34/EC for a definition of 'information society services'. Annex V (2) states that this definition does not include telephony or fax services.

<sup>356</sup> Ibid

<sup>357</sup> This means that those offering mHealth services through the medium of phone or fax will not have to comply with the requirements of the directive. Uncertainty remains with regard to SMS based services. For further See Bain, M. & Subirana, B. (2003). E-commerce oriented software agents: Some legal challenges of advertising as semi-autonomous contracting Agents. *Computer Law & Security Review*, 19(4), 282-288

this distinction between phone based and Internet based services described in the directive is not always clear cut in practice. One can for example consider that the use of SMS services might constitute services that will fall under the e-Commerce directive. Such services have proved useful in trials in developing countries<sup>358</sup>. In addition the e-Commerce directive does not generally apply to the behavior of the service provider throughout its relationship with the service user. It is instead more applicable to the attempts by the service provider to establish the initial commercial relationship or contract. It may thus be applicable to REACTION in instances where REACTION like services are trying to secure the participation of individuals using information society services. This could apply where individuals are approached over the internet or by email.

#### 8.4.1 Implications for Member States<sup>359</sup>

##### Exclusion Of prior authorization

The e-Commerce Directive does not allow Member States to have prior systems of authorization for Information Society services unless such authorization schemes are not targeted aimed at targeting such services specifically by reason of them being information society services. Prior authorization schemes will however be permitted if they incidentally cover a service that can also be offered by information society means. What this means for eHealth based services is that member states will not be able to demand extra requirements in terms of prior authorization if such requirements are not present when services are offered on a more conventional basis. This means that if a conventional service is already available without authorization or similar requirements then it can in principle be offered using information society services i.e. using the internet also. This might mean for example that if products are allowed to be sold on an unlicensed basis in a Member state then they should be allowed to be sold in a similar manner using the internet. The directive does however not mean that all services can be offered through the internet on a *laissez-faire* basis. The same rules that are applicable to medical enterprise using non-information society services will be applicable to enterprises using information society services. This may be true even if the regulations in question have the effect of in reality preventing the service in question from being offered using information society services (see the Doc Morris Case below for a good example regarding online pharmacies).

##### Exclusion of Liability for Intermediate Service Providers

An important aspect of the e-Commerce Directive is exclusion of liability for intermediaries that merely provide the service of conveying information for problems that arise as a result of the information itself.<sup>360</sup> The aim of such a provision was to prevent companies such as ISPs being held liable for the services provided by others through their medium. Such an exclusion is however only available if the intermediate service provider (i) has not initiated the transmission, (ii) has not selected the recipients of the transmission and (iii) has not modified the information content in any way.<sup>361</sup> This restriction of liability is also important for eHealth service providers such as REACTION. This is because it provides organizations such as ISP's with an assurance that they will not, in general, be held liable for the content of the services they allow to be transmitted through their infrastructure. If this were not the case there could be reticence on the part of ISP's to allow some potentially risky traffic (in terms of liability through their medium). This could prevent innovative eHealth services from gaining access to the very infrastructure that would be needed for their dissemination. ISPs will however have to remain wary of complying with the conditions described above in order to avoid the possibility of liability. From the point of view of REACTION this means that an ISP will not be held liable for problems in REACTION services that use ISP infrastructure, if the above conditions are met. These conditions however mean that ISP's and eHealth providers will only be able to work together in very limited ways if ISP's are to be able to guarantee an avoidance of liability. This will exclude potential collaborations whereby such organizations might help select or target potential recipients. Nothing however excludes organizations such as ISPs however from voluntarily stepping out from under this liability shield to play a more active role in eHealth. This will however only be likely to occur where such organizations judge as low risk the potential liabilities that they may be exposing themselves to. The consequence is that an ISP will be more likely to play an active role in the dissemination of low risk activities such as prevention based lifestyle campaigns (e.g. the selection of smokers for anti-smoking messages) than

<sup>358</sup> At the Consultation Workshop mHealth in a Socio-economic Context, 18 January 2012 an SMS based service that was used to give advice to diabetes patients in India was described.

<sup>359</sup> The European Parliament and the Council of the European Union (2000). Directive 2000/31/EC. *Official Journal of the European Communities L178*, Article 22 - Member States were required to have fully transposed the e-commerce directive into their respective legal systems by 17 January 2002.

<sup>360</sup> Ibid, Article 12

<sup>361</sup> Ibid, Article 12(a)-(c).

in radical new experimental treatments that could have tangible effects on matters of life and death.<sup>362</sup> In such instances services such as ISPs and telecommunications companies are not likely to play an active role.

#### 8.4.2 Requirements on those offering eHealth services using Information Society Services

The e-Commerce Directive impacts upon information society services in three principal ways;

a) Requirements on the provision of general information

The e-Commerce Directive supersedes the requirements of the Distance Selling Directive.<sup>363</sup>

The party attempting to sell products or provide services online must provide information such as its name and address, all prices and essential conditions, an email address for contact, information concerning its presence on trade registers and information regarding the professional body with which the organization may be registered with. Other such important information that may need to be communicated includes the organization's VAT number and any professional titles granted to the service providers or its members by the Member State concerned. Many of these provisions might not be applicable to REACTION, but that would depend on who was offering the service and upon what basis.

b) Matters of Commercial Communications

Service providers must identify clearly the commercial nature of any service conducted,<sup>364</sup> the person on whose behalf the communication is being made and if applicable, promotional offers that exist (for example discounts, premiums, gift competitions and games). eHealth providers must therefore clearly outline to potential customers that they are indeed offering a commercial service (if indeed they are doing so), especially if this might not be readily apparent from the consumer's perspective because of its purported medical nature. This would apply also where such services were the subject of re-imburement by national, regional or local reimbursement regimes. This will also include the presence of any sponsors that might have contributed financially REACTION for commercial motives<sup>365</sup>.

c) The Conclusion and Regulation of Contacts Made Online

The directive spells out important requirements that must be present in order to be able to consider a contract concluded. This entails in reality requirements for both Member States and those offering services. Member States are required to ensure that their respective legal systems allow contracts to be concluded by electronic means and that such contracts are recognized.<sup>366</sup> Those offering services are required to present information providing the different technical steps that must be taken in order to complete a contract and the terms and conditions of a contract must be both capable of being stored and accessed by the individual offered the contract. A service provider must also indicate before the conclusion of the contract whether the contract will be stored and if it will be accessible. Furthermore, there is a requirement that the service provider offering the contract must spell out clearly what alternative languages are available for the conclusion of the contact. Finally the service provider must provide a procedure for customers to highlight and amend errors. Once an individual agreement has been received by a service provider, it must notify the individual concerned as soon as possible that such agreement has been received<sup>367</sup>.

It should be noted that these requirements apply to organizations that are offering contracts for services that utilize information society services. This means that eHealth service providers that approach individuals using such means i.e. using the Internet or email must comply with the above requirements. This will only apply to providers attempting to arrange contracts for the provision of such services. This means that once such a contract has been agreed the eHealth service provider will not

<sup>362</sup> ISPs will of course have to remember their obligations under the data protection directive with regards to the personal information of their clients.

<sup>363</sup> The European Parliament and the Council of the European Union (1997). Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the Protection of Consumers in respect of distance contacts. *Official Journal of the European Communities L144*, 19.

<sup>364</sup> The European Parliament and the Council of the European Union (2000). Directive 2000/31/EC. *Official Journal of the European Communities L178*, Article 6.

<sup>365</sup> On its website the European Commission makes it clear that according to its interpretation, sponsorship schemes are covered by the directive see: [http://ec.europa.eu/internal\\_market/e-commerce/directive\\_en.htm](http://ec.europa.eu/internal_market/e-commerce/directive_en.htm)

<sup>366</sup> Ibid, Article 9.

<sup>367</sup> Ibid, Article 11.

be required to meet these requirements for each of its communications with individuals i.e. stating that its service is in reality a commercial service. Such requirements will apply though where new services are offered (on a commercial basis) to those who are already pre-existing customers of another e-Health based services. This could be the case where participants in a 'basic service' are offered the chance to participate in more complex services (that operate on a commercial basis). In such instances, it will be important for those offering the services to comply with the informational requirements described above.

### 8.4.3 The Directive on Electronic Signatures

In the information age contracts can be, or are perhaps even more likely to be concluded on an electronic basis. This will include contracts relating to healthcare in general and, especially medical services such as REACTION. In addition to being useful for the formation of contracts, signatures can provide an indispensable legal indication of a legal function such as consent. This will be important for eHealth services such as REACTION that attempt to secure the consent of individuals for various functions from a distance using electronic means. Common rules and regulations both on a national and a European level can therefore be important in insuring that a fertile environment is fostered in order to facilitate such an important aspect of most services. During the 1990s, Member States began to legislate relating to the information society, including areas related to electronic signatures. In order to avoid contradictory regulations that would harm the internal market it was necessary for the EU to act in order to set a common framework where possible. The EU's directive on Electronic Signatures<sup>368</sup> represented an initiative that aimed to address this goal. The aim of the directive is to create a technology neutral framework for the issuance of electronic signatures through certification services providers throughout the EU. It was expected that *inter alia* electronic signatures would be useful in the healthcare sector.<sup>369</sup>

The directive obliges Member States to treat 'qualified electronic signatures'<sup>370</sup> equally in legal terms as paper signatures. The directive does not however regulate the legal use and the requirements of the handwritten signature itself, this is instead left to Member States to regulate through national law. This means that matters that may be of extreme importance to sensitive areas such as eHealth are often governed by national law. This could include the situations governing where and when a signature is required and also the evidential weight that is given to a signature in legal proceedings.<sup>371</sup> Given this, the purpose of a qualified signature is merely to give organizations and individuals the confidence that an electronic signature has at least equivalent value in legal terms to its paper-based counterpart. It would thus not be correct to assume that an individual's agreement by a Qualified Electronic Signature in one part of Europe means precisely the same in legal terms as another as it is the national laws governing signatures in general that will determine this. In addition the directive does not seek to alter national rules on contract law, meaning that one must look to national rules on the formation of contract in legal disputes.<sup>372</sup> Some Member States have specific laws requiring some health related documents to be based on paper, including prescriptions, the Directive on Electronic Signatures does not alter this. This means that potential eHealth service providers such as REACTION once again will have to have a good understanding of the legal requirements of the countries in which they intend to operate. This may well require legal expertise not only in the Member State in which the eHealth organization is based in but also all the potential member states of its users.

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<sup>368</sup> The European Parliament and the Council of the European Union (1999). Directive 1999/93/EC of the European Parliament and the Council of May 13 December 1999 on a Community Framework for electronic signatures, *Official Journal of the European Communities L 13*, 12-20.

<sup>369</sup> *Ibid*, Article 19.

<sup>370</sup> No discrimination is allowed against an electronic signature if it is "advanced," based on a "qualified certificate," and created by a "secure signature creation device" – Directive 1999/93/EC, Article 5 An "advanced" e-signature is defined to require: a unique link to the signatory; capability of identification of the signatory; creation using means under the sole control of the signatory; and linkage to the data in a manner whereby the recipient is able to detect any alterations to the original document sent by the signatory – Directive 1999/93/EC, Article eal2(2) (a)-(d).

<sup>371</sup> For a good analysis of the directive and its interaction with national laws in the years proceeding its enactment see 'The Legal and Market Aspects of Electronic signatures – Legal and market aspects of the application of Directive 1999/EC and practical applications of electronic signatures in the Member States, the EEA, the Candidate and the Accession Countries' - A Study for the European Commission – DG Information Society (2003)

<sup>372</sup> The European Parliament and the Council of the European Union (1999). Directive 1999/93/EC. *Official Journal of the European Communities L 13*, Recital 17.



## 9. Radio spectrum policy and eHealth

### 9.1 The importance of spectrum regulation

The EM Spectrum is of immense importance for modern digital innovation. Wireless services, the economic recovery, long term growth, high-quality jobs and long-term EU competitiveness all depend on its efficient utilization. The innovation of novel medical systems such as that proposed in REACTION represents one aspect of this. Policy initiatives related to the radio spectrum have been an important part of the EU's Digital Agenda for Europe and to the Europe 2020 strategy for smart, sustainable and inclusive growth. Innovations in matters of telemedicine are increasingly being realized by the use of devices or sub-components that often operate at a distance from the principal system hardware. This is often achieved through wireless methods that utilize the EM spectrum.<sup>373</sup> Efficient regulation of spectrum use will therefore be important in insuring that innovations have access to the requisite areas of the EM spectrum and that such use is not interfered with in an unacceptable manner. Future innovations in the regulatory framework in this area may therefore be important to platforms such as REACTION that may utilize such possibilities.

### 9.2 The importance of radio spectrum policy to REACTION – the example of mBANS

mBANS (Mobile Body Area Networks) are a good example of a potential problem area for eHealth projects in relation to radio spectrum issues. mBANS are small networks of medical components and communications devices located on or around the physical bodies of individuals. mBANS will play an important role in enabling ubiquitous and non-invasive telemetry and healthcare systems in the future.<sup>374</sup> Depending on the components they contain they can be used to conduct a variety of functions including observing various body functions, administering medications or other types of treatment and communicating data to a hub or a central data processing location. One of REACTION's visions is that patients can enjoy enhanced freedom and quality of life through avoidance or reduction of hospital stays. This would also allow pressure on overstretched hospital services to be alleviated.<sup>375</sup> The devices used in an mBAN can use a variety of different spectrum frequencies depending upon their location and type of use, the criticality of the data they may transmit and also the distance that is required for transmission.<sup>376</sup> This may vary depending upon for example whether the individual is a patient in a hospital ward or is an out-patient in the community that may be given free reign around his entire home or even the community at large.

In all these circumstances it is of crucial importance that the equipment used within the mBAN is secure from a spectrum related issues perspective. This entails several important requirements including, that the device in question has access to the required spectrum range, that this spectrum range is not subject to an unsafe level of interferences from other related equipment that may be operating in the environment, and that the device in question is able to withstand the normal acceptable level of interference associated with the spectrum frequency in question. These requirements represent both technical requirements of the device in question and also requirements of the wider regulatory environments in question.

#### 9.2.1 Decision No 676/2002/EC

The aim of *Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision)* was to establish a policy and legal framework in the Community in order to ensure the co-ordination of policy approaches and, where appropriate harmonized conditions with regard to the availability and efficient use of the radio spectrum necessary for the establishment and functioning of the internal market.<sup>377</sup> The decision creates procedures that aim to facilitate policymaking and also harmonization in light of the relevant policy grounds including, 'economic, safety, health and also

<sup>373</sup> Tan, Wen, H. & Gyires, T. (2003). M-commerce security: the impact of wireless application protocol (WAP) security services on e-business and e-health solutions. *International Journal of Mobile Communications* 1(4), 409-424

<sup>374</sup> Fang, G., Dutiewicz, E., Huq, M., Vesilo, R. & Yihuai, Y. (2001). Medical Body Area Networks: Opportunities, challenges and practices. *Communications and Information Technologies (ISCIT)*.

<sup>375</sup> Jones, V., Halteren van, A., Widya, I., Dokovski, N., Koprinkov, G., Bults, R., Konstantas, D. & Herzog, R. (2006) Mobehealth: Mobile Health services based on Body Area Networks' in: 'M-Health: Emerging Mobile Health Systems. Springer, pp. 36-219.

<sup>376</sup> There may be a device located in the mBAN that is used to transmit data to a more distant location such as a mobile phone using device or the mBAN may need to communicate a short distance to a hub that is capable of transmitting data over longer ranges.

<sup>377</sup> The European Parliament and the Council of the European Union (2002). Decision No 676/2002/EC of the European Parliament and the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community. *Official Journal of the European Communities L108*, Article 1.

public interest'. In pursuing activities under this decision the Commission must take into account the work of existing international organizations related to radio spectrum management such as the International Telecommunications Union (ITU) and the European Conference of Postal and Telecommunications Administrations (CEPT).<sup>378</sup>

At present, regulation in the area of spectrum access is predominantly an area of Member State competence. The Commission has however been charged<sup>379</sup> with presenting a legislative proposal to the European Parliament and Council to establish a multiannual Radio Spectrum Policy Program (RSPP)<sup>380</sup> setting out policy orientations and objectives for the strategic planning and harmonization of the use of spectrum. This will take into account the opinion of the Radio Spectrum Policy Group (RSPG).<sup>381</sup> At present the electronic communications spectrum policy is covered by the Framework Directive 2002/21/EC and the Authorisation Directive 2002/20/EC as amended by Directive 2009/140/EC. These directives attempted to ensure efficient use of spectrum frequencies, remove rigidities in management of spectrum use and deliver easier access to the spectrum.

The RSPG has opined that a main objective of an EU spectrum approach shall be to facilitate the development and operation of the internal market and to permit improved access to spectrum for applications and uses where demand is growing.<sup>382</sup> Given that mobile applications are clearly an area of growing importance it is likely that this sector will receive attention in the future. In its report, it underlined that avoidance of harmful interference is of primary importance in spectrum management.<sup>383</sup> In order to achieve this, decisions and measures on spectrum use have to maintain a balanced approach. In employing such an approach the use of harmonized standards will be a key element in spectrum regulation, including sharing the conditions defined by regulators. In addition, the RSPG also stated that it will be important to use harmonized standards for electric and electronic equipment and networks as a method of preventing interference with spectrum use. Preventing such interference will be of paramount for devices used in eHealth applications that will often be involved in critical functions. This will be important in facilitating the innovation of eHealth that will in future utilize numerous possibilities of wireless communication.

The RSPG does not however call for a complete harmonization of spectrum policy, recognizing that member states still have an important role to play. Rather a strong need is perceived for enhanced cooperation between competent national authorities, the European Commission, European Conference on Postal and Telecommunications and European Telecommunications Standards Institute. At present such coherence between these actors is not sufficient and could be increased.<sup>384</sup> The RSPG opined that a main objective of an EU spectrum approach shall be to facilitate the development and operation of the internal market and to permit improved access to spectrum for applications and uses where demand is growing.<sup>385</sup>

## 9.2.2 The possible harmonization of the use of spectrum in mBAN application

The European Telecommunications Standards Institute (ETSI)<sup>386</sup> produces globally-applicable standards for Information and Communications Technologies (ICT), including fixed, mobile, radio, converged, broadcast and internet technologies. ETSI is officially recognized by the EU as a European Standards organization. A Memorandum of Understanding (MoU) has been agreed between ETSI and another European standards body, the CEPT Electronic Communications Committee (ECC), for co-operation. In the development of harmonized standards for radio equipment as well as in relevant ECC deliverables, the provisions of the ETSI-CEPT will be applied MoU are

<sup>378</sup> It should be noted that CEPT does not only contain EU members but also non EU States also.

<sup>379</sup> The European Parliament and the Council of the European Union (2002). Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services (as amended by Directive 2009/140/EC). *Official Journal of the European Communities L108*, Article 8(a)(3).

<sup>380</sup> The RSPP will determine until 2015 how spectrum use can contribute to EU objectives and optimize social, economic and environmental benefits.

<sup>381</sup> The RSPP is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), given the importance of the availability and efficient use of spectrum for the establishment of an internal market for electronic communications and for other EU policy areas.

<sup>382</sup> RSPG Opinion on the radio spectrum policy programme, RSPG10-330 Final, DG INFSO, Brussels, 9 June 2010, Para 9

<sup>383</sup> Ibid, Para 16

<sup>384</sup> Ibid, Para 20

<sup>385</sup> With regard wireless technology the spectrum itself has historically been considered as the limited resource and as a limiting factor that needed to be controlled carefully. See: Gruber., H and Verboven., F, (2001), "The diffusion of mobile telecommunications services in the European Union" *European Economic Review*, 45, 3, 577-588

<sup>386</sup> ETSI is a not-for-profit organization with more than 700 ETSI member organizations drawn from 62 countries across 5 continents world-wide. Please visit [www.etsi.org](http://www.etsi.org) for more information

applied. Under this guise the ECC has recently been presented a proposal<sup>387</sup> to designate frequencies in the range 2360-2500 MHz as a suitable designation for MBANs to be used in hospitals, at home or by ambulances.<sup>388</sup> This band was selected as it proposed that use of this frequency for MBANs, based on their known technical and operational characteristics would not prove to be a source of interference to the current limited users of this band. The ETSI document is intended to lay the foundation for industry to quickly implement systems within Europe while avoiding harmful interference with other services and systems whilst providing spectrum allocation similar to that provided elsewhere in the world. The hope was that this would allow Europe to become more competitive and allow its products in this area to compete in other markets.

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<sup>387</sup> ETSI Proposal – DTR/ERM-TG30-100

<sup>388</sup> A regulation in the USA from the FCC is also under development. – Information provided by Thomas Weber in his presentation on 18 January 2012.

## ANNEX

### 1. Member State legislation and Patient Rights

In striving for a Single European Market the EU has harmonized many areas of policy and legislation. In the area of health its competences are however limited by primary EU legislation i.e. the treaties. As a consequence there are many differences in the legislation of the 27 Member States and those differences will continue to exist. The following information is intended to provide a very brief and non-exhaustive overview of the various patient rights that may exist in each of the EU's Member States. The main focus will be on a few simple concepts that are commonly associated with patient rights. The aim is to show the reader the variety that exists in terms of the legal systems that provide patient rights in each Member State. Whilst certain concepts may be considered a patient right in some Member States but not in others, the following concepts are regarded as patient rights issues all across Europe. This is evidenced by their appearance in the European Patient Rights Charter.<sup>389</sup> Although this Charter was not originally binding many of the rights it contains have been given legal force at the European level through the European Charter of Fundamental Rights and Freedoms which in the light of the changes made in Lisbon Treaty, now has full legal recognition. The following information has largely been collected by the fastidious work of other individuals and projects and has been replicated here in a simple format in order to ensure compactness.<sup>390</sup> The different reimbursement schemes of the Member States can be found in REACTION D9.4.

#### 9.1 Austria

Austria is a federal state which implies that next to the federal power the influence of the nine Länder is important. Each has its own constitution and government. This federalist structure also applies to the healthcare system. Some responsibilities in this area are with the federal government whilst others are shared.<sup>391</sup>

##### 9.1.1 Patients' rights

Austrian patients' rights can be found in the Agreement on Guaranteeing the Rights of Patients (Patients' Charter), the Federal Act concerning the Protection of Personal Data, the Federal Hospitals Act and a Federal Physicians Law (1998).<sup>392</sup> Patients' rights are currently debated particularly because of new developments like the introduction of an electronic health record system. Privacy concerns are central and the possibility of an opt-out is discussed.<sup>393</sup>

###### 9.1.1.1 Consent

Article 17 of the Patients' Charter elaborates on consent. In general, consent is necessary. However, there are deviations in cases in which patients are for example incapable of giving consent.<sup>394</sup>

###### 9.1.1.2 Health information

Patients have a right to self-determination and information. The Patients' Charter states that *'Patients shall have the right to be informed from the start about possible diagnoses and kinds of treatment, and about the risks and consequences of same. They shall have the right to be informed about their state*

<sup>389</sup> The Charter was drafted in 2002 by Active Citizenship Network. This is a European network of about 100 civil organizations from 30 EU countries, promoted by the Italian NGO Cittadinanzattiva. In 2007, the European Economic and Social Committee passed her opinion to European Committee for an acknowledgement of the Charter. With this opinion there is a proposal to establish and celebrate 18 April as the European day of patients' rights. This Charter contributed to the promotion of directive for Cross Border Health Care

<sup>390</sup> The content and style of this annex are highly indebted to the Centre for Biomedical Ethics and Law of the Catholic University of Leuven, Belgium and its website on Patient Rights Legislation in all 27 EU Member States. This website proved to be an indispensable source of information for all of the EU's 27 Member States. It can be found at

[http://europatientrights.eu/about\\_us.html](http://europatientrights.eu/about_us.html) The research in preparation for this website was performed in the framework of the EuroGentest project. The content and style of this Annex should be attributed largely to this effort. The EuroGentest is a five-year European Commission funded program that aims to develop the necessary infrastructure, tools, resources, guidelines and procedures that will lead to the establishment of harmonized, qualitative genetic services in Europe. <http://www.eurogentest.org/>

<sup>391</sup> Pfeiffer, K., Giest, S., Dumortier, J. & Artmann, J. (2010). eHealth Strategies. Country Brief: Austria. Retrieved 04 March 2012 from: [http://ehealth-strategies.eu/database/documents/Austria\\_CountryBrief\\_eHStrategies.pdf](http://ehealth-strategies.eu/database/documents/Austria_CountryBrief_eHStrategies.pdf)

<sup>392</sup> European Patients' Forum (2009). Patients' Rights in the European Union. Retrieved 02 March 2012 from: [http://www.eu-patient.eu/Documents/Projects/Valueplus/Patients\\_Rights.pdf](http://www.eu-patient.eu/Documents/Projects/Valueplus/Patients_Rights.pdf)

<sup>393</sup> Pfeiffer, K., Giest, S., Dumortier, J. & Artmann, J. (2010). eHealth Strategies. Country Brief: Austria.

<sup>394</sup> Nationalrat (1999). Agreement on Guaranteeing the Rights of Patients (Patients' Charter). *Federal Law Gazette for the Republic of Austria*, Article 17.

of health and also about the cooperation required on their part during the therapy and about how to conduct their life in a way which supports the therapy.<sup>395</sup> There is also a right not to be informed.<sup>396</sup>

### 9.1.1.3 Medical records

Documentation of diagnosis, treatment and other measures is guaranteed. Wishes of the patients must be included in the medical record.<sup>397</sup> The Patients' Charter establishes that patients have the right to access their medical records.<sup>398</sup> Patients can copy their medical files.<sup>399</sup>

### 9.1.1.4 Complaints

Austria established independent patient representative bodies to represent the interest of patients in case of complaints. Their service is free of charge and they have to investigate each complaint.<sup>400</sup> Often an ombudsman is involved in the procedure.<sup>401</sup>

### 9.1.1.5 Privacy and data protection

The Austrian Law on Fundamental Rights (Staatsgrundgesetz über die allgemeinen Rechte der Staatsbürger für die im Reichsrat vertretenen Königreiche und Länder) entails a right to privacy. The privacy of communication is acknowledged.<sup>402</sup> Article 9 of the Patients' Charter states that '*the private sphere of the patients shall be safeguarded.*'<sup>403</sup>

### 9.1.1.6 Implementation of Directive 95/46/EC

The Federal Law on the Protection of Personal Data (Bundesgesetz über den Schutz personenbezogener Daten (Datenschutzgesetz 2000) came into force in 2000. It applies to all processing by automatic means. Furthermore, the nine Austrian Länder implemented data protection laws.<sup>404</sup>

## 9.2 Belgium

### 9.2.1 Patients' rights

Since 2002 the rights of the patient in Belgium are defined by one primary piece of law at the country's Federal level.<sup>405</sup> This is the "Law on the rights of patients" of August 22, 2002.<sup>406</sup>

#### 9.2.1.1 Consent

The right of informed consent is provided in the Law of the Rights of Patients. A patient must give informed consent before any procedure starts. This consent only lasts as long as the medical intervention. Neither the refusal nor withdrawal of consent ends the right to high-quality care.<sup>407</sup> Refusal by the patient to undergo an advised medical treatment does not terminate the legal relations between the patient and the physician.

#### 9.2.1.2 Health information

The patient has the right to receive all information concerning his/her state of health.<sup>408</sup> In exceptional cases, the health professional may withhold information about the patient's state of health if disclosure would cause great harm to the patient. This is called the therapeutic exception.

<sup>395</sup> Ibid, Article 16(1).

<sup>396</sup> Ibid, Article 16 (4).

<sup>397</sup> Ibid, Article 21.

<sup>398</sup> Ibid, Article 20.

<sup>399</sup> Ibid, Article 22.

<sup>400</sup> Ibid, Article 29 & 30.

<sup>401</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>402</sup> Staatsgrundgesetz vom 21. Dezember 1867 (R.G.Bl. 142/1867), über die allgemeinen Rechte der Staatsbürger für die im Reichsrat vertretenen Königreiche und Länder (1867/1988), Article 9 & 10. Retrieved 04 March 2012 from: <http://www.verfassungen.de/at/stgg67-2.htm>

<sup>403</sup> Nationalrat (1999). Agreement on Guaranteeing the Rights of Patients (Patients' Charter). *Federal Law Gazette for the Republic of Austria*, Article 9.

<sup>404</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#austria](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#austria)

<sup>405</sup> A useful source of information can be found at [http://www.belgium.be/fr/sante/soins\\_de\\_sante/droits\\_du\\_patient/](http://www.belgium.be/fr/sante/soins_de_sante/droits_du_patient/)

<sup>406</sup> Loi du 22 août 2002 relative aux droits du patient

<sup>407</sup> Article 8.4 of the Law on the Rights of Patients.

<sup>408</sup> Article 7 Law on the rights of patients" of August 22, 2002

### 9.2.1.3 Medical records

The patient has the right to a medical record.<sup>409</sup> The definition of what exactly constitutes a medical record is not however provided. Patients also have the right to be provided with a copy of their own record at the price of production.

### 9.2.1.4 Complaints

The patient can register a complaint with the competent ombudsperson's office.<sup>410</sup>

### 9.2.1.5 Privacy and data protection

Privacy is specifically provided for by the Belgian Constitution.<sup>411</sup> Importantly, a distinction is made between the right of privacy of the patient (privacy of data regarding health and protection) and the obligation of the physician to medical secrecy (protection of confidence regarding the information the patient shares with the physician). However, the Law on patients' rights does cover the subject regarding the protection of intimacy regarding the patient in Art. 10 (paragraph 1).

### 9.2.1.6 Implementation of Directive 95/46/EC

Belgium modified the consolidated text of the Belgian law of December 8, 1992 on Privacy Protection in relation to the Processing of Personal Data in 2002 to implement the Directive. This law was amended several times between 2005 and 2007.<sup>412</sup>

## 9.3 Bulgaria

Bulgaria is one of the newest Member States of the EU. After big political changes in 1989 most health care legislation was reformed.<sup>413</sup> The Bulgarian Constitution now guarantees a right to health insurance.<sup>414</sup>

### 9.3.1 Patients' rights

Patients' rights are laid down in the Act for professional associations of physicians and dentists, the Human Medicinal Drugs and Pharmacies Act, the Health Insurance Act, the Food Act and the Law of Health. Health insurance is guaranteed under the Health Insurance Act and the Constitution. The rights and obligations in the area of health are mainly regulated in the Health Act.<sup>415</sup>

#### 9.3.1.1 Consent

The Bulgarian Constitution excludes forced treatment and recognizes the right of informed consent.<sup>416</sup> Furthermore, the Law of Health reinforces this right. '*The medical activities shall be implemented after expressed informed consent by the patient.*'<sup>417</sup> It is important to note that the consent needs to be expressed. The same law also establishes a framework for informed consent which will be described below.

#### 9.3.1.2 Health information

Article 88 of the Law of Health describes the information which has to be provided to patients. Information has to be given about the disease, the treatment, the risks, adverse effects and alternatives.<sup>418</sup> Those requirements also apply to information given in general not focusing on consent explicitly.<sup>419</sup> The Law of Health includes a right not to know and provides for a therapeutic exception.<sup>420</sup>

<sup>409</sup> Article 9 of Law on the rights of patients" of August 22, 2002

<sup>410</sup> The responsibilities of the ombudsperson's office are established in Article 11, 2. Of the Law on the Rights of Patients.

<sup>411</sup> Constitution belge du 17 février 1994, Article 22.

<sup>412</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from: [http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#belgium](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#belgium)

<sup>413</sup> Goffin, T., Zinovieva, D., Borry, P., Dierickx, K. & Nys, H. (2007). Patient Rights in the EU – Bulgaria. European Ethical-Legal Papers, Leuven.

<sup>414</sup> National Assembly of the Republic of Bulgaria (1991/2007). Constitution of the Republic of Bulgaria, Article 52. Retrieved 07 March 2012 from: <http://www.parliament.bg/en/const>

<sup>415</sup> Goffin, T., Zinovieva, D., Borry, P., Dierickx, K. & Nys, H. (2007). Patient Rights in the EU – Bulgaria. European Ethical-Legal Papers, Leuven.

<sup>416</sup> National Assembly of the Republic of Bulgaria (1991/2007). Constitution of the Republic of Bulgaria, Article 52(4).

<sup>417</sup> Law of Health (2005), Article 87(1). Retrieved 07 March 2012 from: <http://www.lexadin.nl/wlg/legis/nofr/eur/lxwebul.htm>

<sup>418</sup> Ibid, Article 88.

<sup>419</sup> Ibid, Article 92.

<sup>420</sup> Ibid.

### 9.3.1.3 Medical records

Health care providers are required to collect and store health information.<sup>421</sup> This constitutes an indirect right to a medical record. Additionally, some rules are laid down in the Personal Data protection Act.<sup>422</sup>

### 9.3.1.4 Complaints

Whilst the Law on Health does not establish a right to complain or to retrieve compensation, other legal provisions can be used to file complaints. Particularly, Section III of the Act on the Obligations and Contracts is of importance.<sup>423</sup>

### 9.3.1.5 Privacy and data protection

Article 32 of the Bulgarian Constitution protects the right to privacy. 'The privacy of citizens shall be inviolable.'<sup>424</sup> This is extended by the protection of the privacy of communication.<sup>425</sup> With regard to health, privacy is protected under Article 28 of the Law of Health.<sup>426</sup> The medical secrecy is constituted in the Code of Professional Ethics.<sup>427</sup> Data protection is regulated by the Personal Data Protection Act. Personal data can be processed in specific situations. This exemption applies to health law.<sup>428</sup>

### 9.3.1.6 Implementation of Directive 95/46/EC

The Bulgarian Law for Protection of Personal Data came into force in 2002. It was amended several times between 2005 and 2007.<sup>429</sup>

## 9.4 Cyprus

### 9.4.1 Patients' rights

Cyprus created the 'Law on the protection of the rights of patients and related issues' in 2005.<sup>430</sup> The principal focus of this legislation is on the quality of health, the choice of doctors or institutions, and also the integrity of the patient.<sup>431</sup> The Act was designed to be compatible with the European Charter of Patient Rights.<sup>432</sup>

#### 9.4.1.1 Consent

Article 11(1) of the Patients' Rights Act of 2005 states that a patient's consent must be given before starting any medical treatment.

#### 9.4.1.2 Health information

According to Article 10, the patient shall have the right to complete medical information. This includes the diagnosis and the prognosis of the patient medical condition. The physician may use the therapeutic exception (Article 10(3)).

#### 9.4.1.3 Medical records

The healthcare service provider has a duty to keep medical records containing all relevant information of the patient (Article 17). The patient also has the right to access these records. The therapeutic exception also apply for medical records.

#### 9.4.1.4 Complaints

The right to complain is not directly regulated in the Patients Rights Act of 2005. A Patients' Rights Officer is available to handle complaints and can send such complaints to a Complaints Examinations

<sup>421</sup> Ibid, Article 27.

<sup>422</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>423</sup> Ibid.

<sup>424</sup> National Assembly of the Republic of Bulgaria (1991/2007). Constitution of the Republic of Bulgaria, Article 32(1).

<sup>425</sup> Ibid, Article 34.

<sup>426</sup> Law of Health (2005), Article 28.

<sup>427</sup> Goffin, T., Zinovieva, D., Borry, P., Dierickx, K. & Nys, H. (2007). Patient Rights in the EU – Bulgaria. European Ethical-Legal Papers, Leuven.

<sup>428</sup> Ibid.

<sup>429</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#bulgaria](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#bulgaria)

<sup>430</sup> Law N° 1(l)/2005 The Safeguarding and Protection of the Patients' Rights of 7 April 2005. From "Patients Rights in EU, Cyprus". Goffin, T. (2005).

<sup>431</sup> T.GOFFIN, et al., "Patient Rights in the EU - Cyprus", European Ethical-Legal Papers N°10, Leuven, 2007.

<sup>432</sup> See the introduction to this annex for a description of the patient rights directive.

Committee.<sup>433</sup> No explicit regulations on the right to compensation are included. The Cypriot patient rights act describes 17 different rights and a mechanism for the monitoring of potential violations and the resolution of patients' complaints. Despite the fact that the Patient Rights Act represents a great leap forward in the recognition and protection of patients' rights in Cyprus, the law does not cover malpractice.<sup>434</sup> This is instead pursued through criminal law.

#### 9.4.1.5 Privacy and data protection

Article 15 explicitly states that all information about the patient's medical condition (including all personal data) shall be kept confidential. This is also the case even after the patient dies.

#### 9.4.1.6 Implementation of Directive 95/46/EC

Cyprus adopted the Processing of Personal Data Law in 2001 (Νόμος που τροποποιεί τον Πери Επεξεργασίας Δεδομένων Προσωπικού Χαρακτήρα (Προστασία του Ατόμου) Νόμο του 2001, αρ. 37(I)/2003) to implement the Directive.<sup>435</sup>

## 9.5 Czech Republic

### 9.5.1 Patients' rights

The Czech Republic has an extremely fragmented system of protection of patient's rights legislation. One of the primary sources is Act Number 20/1966 on Healthcare.<sup>436</sup> This act has however been described as being 'outdated' and 'not covering all aspects of patients' rights'.<sup>437</sup> The Code of Ethics and Patients' Rights and the Ethical Code of Physicians of the Czech Medical Chamber were created in 1992. Whilst both of these documents provide important guidelines to medical professionals they are not legally binding.

#### 9.5.1.1 Consent

The Act on Healthcare (Article 23) states that the patient's agreement is necessary before the treatment may be implemented. The patient should be informed in an appropriate manner about the illness and about the necessary procedures.

#### 9.5.1.2 Health information

Czech law does not provide a right of information for patients as a specific and separate right. There is also no legislation available concerning the therapeutic exception (which would allow doctors to withhold information if it was perceived to be in the benefit of the patient concerned). The Ethical Code of the Czech Medical Chamber recognizes the possibility but the decision is up to the physician.

#### 9.5.1.3 Medical records

All healthcare establishments are obligated to keep medical files of their patients. This has been laid down in Art.6 of the Code of Ethics and Patients' Rights.

#### 9.5.1.4 Complaints

Czech law does not contain one specific system with regards to patient compensation. Rather, several possibilities exist according to the nature of the complaint<sup>438</sup>. Where problems occur with the settlement of disputes, an Ombudsman (as stated in the Healthcare Act) is available. Damage that occurs as a result of healthcare services can give rise to compensation according to the rules in the Czech Civil Code. The relevant rules are general and do not contain special provision on the liability when providing health services.

<sup>433</sup> Articles 22-23 of the Patients' Rights Law.

<sup>434</sup> See Eleftheriou., A, 'Patients Rights' Published by The Thalassaemia International federation No:7 ISBN 978-9963-623-42-6 "The law provides for a Patients' Rights Officer (PRO), responsible for investigating patient complaints, to be established in each of the main public hospitals in each administrative district. PROs must respond to patient complaints within 24 hours, or the complaint will be referred to the regional 5-member Complaints Examination Committee. The PRO is also responsible for advising patients on how to safeguard their rights, and for informing and training medical, paramedical and administrative staff. Public hospitals are required to take all measures necessary to comply with a PRO's requests regarding patients' rights; complaints from patients at private institutions are investigated by the relevant regional Complaints Examination Committee."

<sup>435</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#cyprus](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#cyprus)

<sup>436</sup> Act 20/1966 Coll. March 17, 1966. on Care of People's Health.

<sup>437</sup> See Patients' Rights in the European Union, The European Patients Forum (2009)

<sup>438</sup> See Patients' Rights in the European Union, The European Patients Forum (2009) – See the section concerning the Czech Republic.



#### 9.5.1.5 Privacy and data protection

In order to meet the necessary conditions for its Accession to the EU the Czech Republic adopted the act 'On Personal Data Protection'.<sup>439</sup> The Act replaced the 1992 Act on Protection of Personal Data in Information Systems.<sup>440</sup> The Act represents the key requirements of the EU's regime of Personal Data Protection. Healthcare professionals are required to maintain confidentiality about all the facts he/she was informed about in relation to the exercise of their occupation. This right is combined with the right regarding the medical records.

#### 9.5.1.6 Implementation of Directive 95/46/EC

The Czech Republic implemented the Personal Data Protection Act in 2000.<sup>441</sup>

## 9.6 Denmark

### 9.6.1 Patients' rights

Denmark, unlike many other European Member States has one primary piece of healthcare legislation that specifies patient rights. This instrument can apply in various ways that can impact on the provision of patient rights.<sup>442</sup>

#### 9.6.1.1 Consent

Patients have a right to be included in the involvement of decisions made concerning their health.<sup>443</sup> This also provides for informed consent. No treatment may be carried out without the informed consent of the patient, unless it otherwise established by law or regulation.

#### 9.6.1.2 Health information

The provision concerning the general right of access to treatments is covered in the same section as that relating to consent described above.

#### 9.6.1.3 Medical records

The Medical Practices Act contains a provision regarding the duty of physicians to keep medical records of their patients. A healthcare provider may forward information regarding the history of the illness, the cause of death and the way of death of a deceased patient to the nearest relatives, when this is not considered being against the wishes of the deceased.<sup>444</sup>

#### 9.6.1.4 Complaints

Patients' complaints are gathered by one organization, the Patient's Complaint Board. Patients may claim damages in connection with treatment through the Patient Insurance Scheme. Compensation can be demanded under specific circumstances under Article 20 of the Health Act. The Patients Complaints Board is a disciplinary board assessing cases of malpractice and violation of patients' rights.<sup>445</sup> It is an impartial public authority, and the decisions from the Board serve to establish whether a health care professional is guilty of malpractice.<sup>446</sup>

#### 9.6.1.5 Privacy and data protection

The Danish constitution (created in 1953) does not contain provisions on privacy. However, section 72 provides a procedural protection of the freedom of communication. A public authority may only intervene either on a basis of a court decision or with authority in a statute<sup>447</sup>. All patients have the right to confidentiality from healthcare professionals concerning information received or implied during

<sup>439</sup> Entered into effect on June 1, 2000

<sup>440</sup> Different Approaches to New Privacy Challenges, In Particular in the light of Technological Developments A2 Czech Republic Contract r: JLS/2008/C4/011 – 30-CE-0219363/00-28

<sup>441</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#czechrepublic](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#czechrepublic)

<sup>442</sup> See Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Denmark

<sup>443</sup> Health Act, Law No. 546 of 24 June 2005, Article 15

<sup>444</sup> See Patients' Rights in the European Union, The European Patients Forum (2009)

<sup>445</sup> This Organisation is regulated by Act on the Right to Complain and Receive Compensation within the Health Service 2005 (lov nr. 547 af 24 juni 2005 om klage og erstatning inden for sundhedsvæsenet)

<sup>446</sup> For more information see: Study on Legal Framework of Interoperable eHealth in Europe -

NATIONAL PROFILE DENMARK, European Commission Directorate General Information Society (SMART 2007/0059)

<sup>447</sup> A Comparative Study on the Different Approaches to New Privacy Challenges, In Particular in the light of Technological Developments A2 Denmark

Contract r: JLS/2008/C4/011 – 30-CE-0219363/00-28

the performance of their profession. Hospitals are permitted to inform a general practitioner about the treatment provided by the hospital without the explicit consent of the patient concerned. Rules concerning the protection of personal data in addition to the main data protection act<sup>448</sup>, can be found in many different legislative instruments. Some of these are shown below:

- The penal code (1068 of 6.11.2008)
- The statute on financial institutions (897 of 4.9.2008)
- The Public Administration Act (1365 of 7.12.2007)
- The Act on the central personal data register (1134 of 20.11.2006)
- The Act on social services (58 of 18.1.2007)
- The Marketing Act. (1389 of 21.12.2005)
- The act on the DNA profile register (434 of 31.5.2000)
- The Administration of Justice Act. (1069 of 6.11.2008)
- The Danish Data Protection Act

#### 9.6.1.6 Implementation of Directive 95/46/EC

The Data Protection Act is the main legislation concerning the processing of personal data<sup>449</sup>. The Act entered into force on the 1<sup>st</sup> of July 2000.

## 9.7 Estonia

After big political changes at the beginning of the 1990s the Estonian healthcare system has been successfully reformed.<sup>450</sup> Estonia was, for a time, regarded as a leader in the uptake and development of modern approaches in medicine, particularly eHealth, During the last years this process slowed down.<sup>451</sup> The Estonian Constitution grants a right to health protection.<sup>452</sup>

### 9.7.1 Patients' rights

Estonia does not have a specific law on patients' rights. Several attempts to create such a law have been stopped during the last two decades because of different stakeholder interests.<sup>453</sup> Patients' rights and obligations are now laid down in the Law of Obligations Act from 2001.<sup>454</sup> This Act has been inspired by Dutch law and therefore constitutes a treatment contract which is similar to the Dutch one.<sup>455</sup> It does rather focus on the rights of patients than on the duties of healthcare providers.<sup>456</sup>

#### 9.7.1.1 Consent

The right to informed consent is regulated by §766 of the Law of Obligations Act. Consent can be withdrawn given that there is a reasonable period between consent and withdrawal and that it is done in a way reproducible in writing.<sup>457</sup> Furthermore, rules on consent are laid down in Regulation N° 144 of 2001 and in §56 (1) of the Health Services Organisation Act.<sup>458</sup>

#### 9.7.1.2 Health information

Estonia has a National Health Information System which was implemented during the last years. It is part of the Health Services Organization Act and provides for digitalization of health information in

<sup>448</sup> Data Protection Act (429/2000) Transposing Directive 95/46

<sup>449</sup> The Act on Processing of Personal Data (Act No. 429) of 31 May 2000

<sup>450</sup> Doupi, E., Renko, E., Giets, S., Heywood, J. & Dumortier, J. (2010). eHealth Strategies. Country Brief: Estonia. Retrieved 08 March 2012: [http://ehealth-strategies.eu/database/documents/Estonia\\_CountryBrief\\_eHStrategies.pdf](http://ehealth-strategies.eu/database/documents/Estonia_CountryBrief_eHStrategies.pdf)

<sup>451</sup> Läänela, S. & Aaviksoo, A. (2008). National Health Information System in Estonia. *Health Policy Monitor*. Retrieved 8 March 2012 from: <http://www.hpm.org/survey/ee/a11/4>

<sup>452</sup> The Constitution of the Republic of Estonia (1992), § 28. Retrieved 08 March 2012 from: <http://www.legaltext.ee/text/en/X0000K1.htm>

<sup>453</sup> Nys, H., Goffin, T., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Estonia. *European Ethical-Legal Papers*, Leuven.

<sup>454</sup> Law of Obligations Act (2001). Retrieved 08 March 2012 from:

[http://www.legaltext.ee/en/andmebaas/paraframe.asp?loc=text&lk=et&sk=en&dok=X30085K2.htm&query=collateral&tyyp=SITE\\_X&ptyyp=l&pg=1](http://www.legaltext.ee/en/andmebaas/paraframe.asp?loc=text&lk=et&sk=en&dok=X30085K2.htm&query=collateral&tyyp=SITE_X&ptyyp=l&pg=1)

<sup>455</sup> Nys, H., Goffin, T., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Estonia. *European Ethical-Legal Papers*, Leuven.

<sup>456</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>457</sup> Law of Obligations Act (2001), §766(3) 'A patient may be examined and health care services may be provided to him or her only with his or her consent. A patient may withdraw his or her consent within a reasonable period of time after granting consent. At the request of a provider of health care services, such consent or an application to withdraw such consent shall be in a format which can be reproduced in writing.'

<sup>458</sup> Nys, H., Goffin, T., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Estonia. *European Ethical-Legal Papers*, Leuven.

Estonia.<sup>459</sup> The right to health information is regulated under the provisions for informed consent. There is a right not to know but no exception for therapeutic reasons.<sup>460</sup>

### 9.7.1.3 Medical records

The National Health Information System includes the establishment of an electronic patient record.<sup>461</sup> Those records are automatically created unless the patient objects to it. Patients can access and copy this file but cannot change it.<sup>462</sup> The Law of Obligations Act imposes the duty to document on healthcare providers. A provider of health care services shall document the provision of health care services to each patient pursuant to the requirements and shall preserve the corresponding documents. The patient has the right to examine these documents and to obtain copies thereof at his or her own expense, unless otherwise provided by law.<sup>463</sup>

### 9.7.1.4 Complaints

Filing complaints is possible under Regulation N° 144 on Quality Assurance Requirements for Health Services. Health care providers must not only develop procedures for complaints but also inform their patients about them.<sup>464</sup> Liability and compensation are provided for in §770 And 771 of the Law of Obligations Act.<sup>465</sup> Since the procedure can be cost intensive and time consuming it is not used very often.<sup>466</sup>

### 9.7.1.5 Privacy and data protection

Privacy and data protection are regulated in the Law of Obligations Act and the Personal Data Protection Act. The first contains a 'duty to maintain confidentiality'. Deviations are possible if otherwise harm for the patient could be anticipated.<sup>467</sup> The Medical Secrecy is regulated by the Penal Code.<sup>468</sup> Privacy is also included in §26 of the Constitution.<sup>469</sup>

### 9.7.1.6 Implementation of Directive 95/46/EC

Estonia passed and implemented a Personal Data Protection Act in 1996. After revisions in 2003 it complies with the requirements of the Directive.<sup>470</sup>

## 9.8 Finland

Nordic countries like Finland are often regarded as role models in the area of patients' rights.<sup>471</sup>

Finland was the first country which enacted a law on patients' rights.<sup>472</sup> Health care is granted as a general right in Finland.<sup>473</sup>

### 9.8.1 Patients' rights

Next to giving 'treatment guarantees'<sup>474</sup> the Nordic states are also securing the legal rights of patients.<sup>475</sup> Finland was the first country in the world adapting legislation on patient rights, the Act on the Status and Rights of Patients (785/1992), in 1992. Furthermore, the Act on the Status and Rights

<sup>459</sup> Läänelaid, S. & Aaviksoo, A. (2008). National Health Information System in Estonia. *Health Policy Monitor*.

<sup>460</sup> Law of Obligations Act (2001), §766.

<sup>461</sup> Läänelaid, S. & Aaviksoo, A. (2008). National Health Information System in Estonia. *Health Policy Monitor*.

<sup>462</sup> Doupi, E., Renko, E., Giets, S., Heywood, J. & Dumortier, J. (2010). eHealth Strategies. Country Brief: Estonia.

<sup>463</sup> Law of Obligations Act (2001), §769.

<sup>464</sup> Nys, H., Goffin, T., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Estonia. European Ethical-Legal

<sup>465</sup> Law of Obligations Act (2001), §770 & §771.

<sup>466</sup> Nys, H., Goffin, T., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Estonia. European Ethical-Legal

<sup>467</sup> Law of Obligations Act (2001), §768.

<sup>468</sup> Nys, H., Goffin, T., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Estonia. European Ethical-Legal Papers, Leuven.

<sup>469</sup> The Constitution of the Republic of Estonia (1992), §26.

<sup>470</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#estonia](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#estonia)

<sup>471</sup> Eleftheriou, A. (n.d.). Patients' Rights. Retrieved 07 March 2012 from:

[http://www.thalassaemia.org.cy/pdf/Patient\\_Rights\\_ENGLISH.pdf](http://www.thalassaemia.org.cy/pdf/Patient_Rights_ENGLISH.pdf)

<sup>472</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>473</sup> Ministry of Social Affairs and Health, Finland (1992). Act on the Status and the Rights of Patients (No 785/1992). Retrieved 05 March 2012 from: <http://www.finlex.fi/en/laki/kaannokset/1992/en19920785.pdf>

Section 3 'Every person who is permanently resident in Finland is without discrimination entitled to health and medical care required by his state of health within the resources available to health care at the time in question.'

<sup>474</sup> Eleftheriou, A. (n.d.). Patients' Rights. 'In practice, the care guarantee is an agreement between the State and the healthcare principal, a relationship to which the patient is not a party. He or she has no legal rights.'

<sup>475</sup> Ibid.

of Social Welfare Clients (812/2000) and the Act on Patient Injuries (585/1986) regulate patients' rights.<sup>476</sup>

#### 9.8.1.1 Consent

The right to self-determination is laid down in Section 6 of the Act on the Status and Rights of Patients. The patient's consent is required for treatment. Treatment can be refused.<sup>477</sup>

#### 9.8.1.2 Health information

Under the Act on the Status and Rights of Patients Finnish patients have the right to information. Section 5 of the Act explains that this information includes the treatment, possible alternatives and the risks. The information must be given in an understandable way. Patients have the right to access their health information.<sup>478</sup> This right can also extend to the patient's representative.<sup>479</sup>

#### 9.8.1.3 Medical records

Health care providers are required to keep medical records. These shall entail *'the information necessary for the arranging, planning, providing and monitoring of care and treatment for a patient.'*<sup>480</sup> Patients can access these files and have the possibility to correct them.<sup>481</sup>

#### 9.8.1.4 Complaints

Patients can file complaints to the director responsible for the health care unit. Appeal against his/her decision is possible at the health care authorities. In case liability arises this is dealt with in the Patient Injury Act (585/1986) and in the Act of Torts (412/1974).<sup>482</sup> The Act on the Status and Rights of Patients establishes an ombudsman who shall

1. *to advise patients in issues concerning the application of this Act;*
2. *to help patients in the matters meant in paragraphs 1 and 3 of section 10;*
3. *to inform patients of their rights; and*
4. *to act also otherwise for the promotion and implementation of patients' rights.*<sup>483</sup>

#### 9.8.1.5 Privacy and data protection

Section 13 of the Act on the Status and Rights of Patients further outlines concepts raised in the confidentiality of patient documents. Doctors have to act according to the medical secrecy.<sup>484</sup> The right to privacy is enshrined in the Finnish Constitution. This does include the privacy of communication.<sup>485</sup> Data protection is furthermore secured by the Data Protection Act.

#### 9.8.1.6 Implementation of Directive 95/46/EC

In 1999 Finland implemented the Finnish Personal Data Act (523/1999). It was amended in 2000. Furthermore, there is a Finnish Data Protection Act in Working Places from 2004.<sup>486</sup>

## 9.9 France

### 9.9.1 Patients' rights

France has a comprehensive system of patients' rights laid down in legislation. The concept of patients' rights had been recognized by the French legal system since the 1930s. The court stated that the patient had the right to expect treatment reflecting the scientific progress at the time, and the physician was responsible for his/her patient. It was not until 1974 that a French text referred to patient rights in a thorough manner. This charter focused on the duties on healthcare organizations, but not

<sup>476</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Finland. Retrieved 05 March 2012 from: <http://europatientrights.eu/countries/signed/finland/finland.html>

<sup>477</sup> Ministry of Social Affairs and Health, Finland (1992). Act on the Status and the Rights of Patients (No 785/1992), Section 6.

<sup>478</sup> Ibid, Section 5.

<sup>479</sup> Ibid, Section 9.

<sup>480</sup> Ibid, Section 12.

<sup>481</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Finland. Retrieved 05 March 2012 from:

[http://europatientrights.eu/countries/signed/finland/finland\\_rights\\_regarding\\_the\\_medical\\_file.html](http://europatientrights.eu/countries/signed/finland/finland_rights_regarding_the_medical_file.html)

<sup>482</sup> Ministry of Social Affairs and Health, Finland (1992). Act on the Status and the Rights of Patients (No 785/1992), Section 10.

<sup>483</sup> Ibid, Section 11.

<sup>484</sup> Ibid, Section 13.

<sup>485</sup> Ministry of Justice (1999/2011). The Constitution of Finland, Section 10. Retrieved 05 March 2012 from:

<http://www.finlex.fi/fi/laki/kaannokset/1999/en19990731.pdf>

<sup>486</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#finland](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#finland)

really on the rights of patients that used them. Thus, although it remains the first comprehensive text dealing with patients' rights in France, the charter has limited impact and is narrow in scope. This charter was later revised with a newer Charter issued in 1995, emphasizing a patient's right to access any public hospital service and to comment on their stay in healthcare establishments.<sup>487</sup> All hospitalized patients can request a copy of the Charter. Many patient rights are laid down in the Act No. 2002-303 of 4 March, 2002.<sup>21</sup> In addition, Act No. 2005-370 concerning Patients' Rights and the End of Life (produced in 2007) have now come into force. Each of these acts provides a wide range of patient rights in France.<sup>488</sup> The Right of informed consent is recognized by a number of provisions in the Code of Public Health<sup>489</sup> that stipulate that informed consent of the patient is required before any medical treatment can be started.<sup>490</sup>

#### 9.9.1.1 Consent and health information

The Code of Public Health<sup>491</sup> states that everyone has the right to be informed about their medical condition. This is described however in connection to the right to give informed consent.

#### 9.9.1.2 Medical records

The Code of Public Health<sup>492</sup> provides for everyone the right to access the data concerning their health that is kept in a medical file by healthcare providers or healthcare institutions.

#### 9.9.1.3 Complaints

The Code of Public Health<sup>493</sup> requires all healthcare services to have a committee ensuring the quality of the care provided. This committee permits patients to express their complaints. A form of strict liability is provided in some cases and a compensation mechanism for serious treatment accidents, under the principle of national solidarity has been established.

#### 9.9.1.4 Privacy and data protection

France was one of the first countries in Europe to adopt a data protection law: the Law on Informatics, Files and Freedoms.<sup>494</sup> This legislation entered into force in 1978. Although there is no specific data protection guarantee in the French Constitution, the first provision of this law (which has been retained unamended in the latest version discussed here) makes clear that the aim of the law and of data protection generally is to protect human rights in order to ensure that technical developments do not undermine human rights.<sup>495</sup> Additionally in 2004 the Law on Confidence in the Digital Economy<sup>496</sup> was adopted which, by amending certain provisions in the Code on Mail and Telecommunications, implemented the data protection requirements of the Directive on Privacy and Electronic Communications (Directive 2002/58/EC or DPEC, the successor to the Telecommunications Data Protection Directive, Directive 97/66/EC; hereafter the "e-Privacy Directive"). The Code of Public Health<sup>497</sup> also requires that all patients have the right for their privacy to be respected and the right that the data concerning him/her is kept secret.

#### 9.9.1.5 Implementation of Directive 95/46/EC

France implemented the Directive with Law 2004-801 which modified law 78-17 of 1978.<sup>498</sup>

<sup>487</sup> See Eleftheriou., A, 'Patients Rights' Published by The Thalassaemia International federation No:7 ISBN 978-9963-623-42-6 "Patients in France today have free choice of provider and can visit any GP or specialist practising privately or in hospital outpatient departments, without referral and without any limit on the number of consultations. Patients can be hospitalised in the public or private sector service of their choice, with some limitations due to financial barriers (co-payments) or problems with geographical accessibility in rural or suburban areas. Patients can be given authorisation for treatment abroad, if the treatment is medically justified and not available in France, with the exclusion of emergency care."

<sup>488</sup> See European Patients' Forum (2009). Patients' Rights in the European Union. - see the section referring to France

<sup>489</sup> Art. 11 of the Code of Public Health (Code de la santé publique)

<sup>490</sup> See Eleftheriou., A, 'Patients Rights' Published by The Thalassaemia International federation No:7 ISBN 978-9963-623-42-6 France has enacted several other laws addressing patients' rights, biomedical research, and the ethical implications of medical technological advancements. In 1996, the Social and Economic Council strongly recommended that patients' rights should be given high priority in national legislation.

<sup>491</sup> Art. L.1111-2 of the Code of Public Health Modified by LOI n°2009-879 of 21 July 2009 - Art. 37

<sup>492</sup> Art. L. 1111-7 of the Code of Public Health

<sup>493</sup> Art. L. 1112-3 of the Code of Public Health

<sup>494</sup> Loi du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés.

<sup>495</sup> Different Approaches to New Privacy Challenges, In Particular in the light of Technological Developments A2 France Contract □: JLS/2008/C4/011 – 30-CE-0219363/00-28

<sup>496</sup> Loi pour la confiance dans l'Économie Numérique du 21 juin 2004

<sup>497</sup> Art. L. 1110-4 of the Code of Public Health

<sup>498</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#france](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#france)

## 9.10 Germany

German law does not know specific legislation on patients' rights.<sup>499</sup> There are however plans to change the Civil Code to introduce patients' rights into the general legislation. The new concept proposes a treatment contract.<sup>500</sup>

### 9.10.1 Patients' rights

German patients' rights are at the moment constituted in different laws. Patients derive their rights from general provisions on data protection, liability and privacy rather than from one specific patient law.<sup>501</sup> The rights are embedded in the Basic Law,<sup>502</sup> the Federal Law on Data Protection<sup>503</sup> and the Charter of the Rights of Patients.<sup>504</sup>

#### 9.10.1.1 Consent

Rules on consent are laid down in the Federal Data Protection Act. Consent must be given freely and must be informed.<sup>505</sup> The German law applies all requirements of Directive 95/46/EC and is in some regards more stringent than the European approach.<sup>506</sup> The proposed law entails a provision about consent.<sup>507</sup>

#### 9.10.1.2 Health information

The proposal on the new law on patients' rights includes a right to information. Health professionals have to provide information about diagnosis, treatment, outcomes and adverse effects.<sup>508</sup> Derogations in emergency situations or because of therapeutic reasons are possible.<sup>509</sup> The right to information already exist but is not laid down in a specific patient law.<sup>510</sup> The information can also be given by a physician who is not executing the treatment. The one responsible for the treatment is however liable.<sup>511</sup>

#### 9.10.1.3 Medical records

Health care providers are obliged to record many treatments. This excludes routine checks.<sup>512</sup> According to the proposed legislation the medical record has to be kept for at least 10 years.<sup>513</sup> Patients can access their medical record (if this causes any costs they have however to be paid by the patient).<sup>514</sup>

#### 9.10.1.4 Complaints

Patients can use different bodies to file a complaint: the associations of doctors or dentists, health insurances, consumers' and patients' organizations, free institutions giving advice to patients and some hospitals have service points for complaints. With regard to a possible compensation it is advised to get a lawyer and use the existing points for mediation. Health insurances are obliged to

<sup>499</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>500</sup> Bundesministerium der Justiz & Bundesministerium der Gesundheit (2011). Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten (Patientenrechtegesetz). Retrieved 04 March 2012 from: [http://www.bmg.bund.de/fileadmin/dateien/Downloads/Gesetze\\_und\\_Verordnungen/Laufende\\_Verfahren/P/Patientenrechte/Referentenentwurf\\_Patientenrechte\\_BMJ\\_BMG\\_Endfassung\\_120116.pdf](http://www.bmg.bund.de/fileadmin/dateien/Downloads/Gesetze_und_Verordnungen/Laufende_Verfahren/P/Patientenrechte/Referentenentwurf_Patientenrechte_BMJ_BMG_Endfassung_120116.pdf)

<sup>501</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). Patient Rights in the EU.. Retrieved 02 March 2012 from: [http://europatientrights.eu/general\\_overview\\_patient\\_rights\\_legislation.html?LAN=E](http://europatientrights.eu/general_overview_patient_rights_legislation.html?LAN=E)

<sup>502</sup> Bundesministerium der Justiz (1949/2010). Grundgesetz für die Bundesrepublik Deutschland. Retrieved 04 March 2012 from: <http://www.gesetze-im-internet.de/bundesrecht/gg/gesamt.pdf>

<sup>503</sup> Bundesministerium der Justiz (1990/2009). Bundesdatenschutzgesetz. Retrieved 04 March 2012 from: [http://www.bfdi.bund.de/SharedDocs/Publikationen/GesetzeVerordnungen/BDSG.pdf?\\_\\_blob=publicationFile](http://www.bfdi.bund.de/SharedDocs/Publikationen/GesetzeVerordnungen/BDSG.pdf?__blob=publicationFile) An English translation can be found here:

[http://www.bfdi.bund.de/EN/DataProtectionActs/Artikel/BDSG\\_idFv01092009.pdf?\\_\\_blob=publicationFile](http://www.bfdi.bund.de/EN/DataProtectionActs/Artikel/BDSG_idFv01092009.pdf?__blob=publicationFile)

<sup>504</sup> Bundesministerium für Gesundheit & Bundesministerium für Justiz (2002). Patientenrechte in Deutschland. Retrieved 04 March 2012 from: <http://www.bzaek.de/fileadmin/PDFs/pati/BMG-G-G407-Patientenrechte-Deutschland.pdf>

<sup>505</sup> Bundesministerium der Justiz (1990/2009). Bundesdatenschutzgesetz, Articles 4 & 4(a).

<sup>506</sup> Korff, D. (2010). Comparative Study on different Approaches to New Privacy Challenges, in Particular in the Light of Technological Developments. Country Studies – Germany. Retrieved 04 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/docs/studies/new\\_privacy\\_challenges/final\\_report\\_country\\_report\\_A4\\_germany.pdf](http://ec.europa.eu/justice/policies/privacy/docs/studies/new_privacy_challenges/final_report_country_report_A4_germany.pdf)

<sup>507</sup> Bundesministerium der Justiz & Bundesministerium der Gesundheit (2011). Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten (Patientenrechtegesetz), Article 1 §630(d)

<sup>508</sup> Ibid, Article 630(c)(2).

<sup>509</sup> Ibid, Article 630(c)(4)1.-4.

<sup>510</sup> Bundesministerium für Gesundheit & Bundesministerium für Justiz (2002). Patientenrechte in Deutschland.

<sup>511</sup> Ibid.

<sup>512</sup> Ibid.

<sup>513</sup> Bundesministerium der Justiz & Bundesministerium der Gesundheit (2011). Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten (Patientenrechtegesetz), Article 1§630(f)

<sup>514</sup> Ibid, Article 1§630(g).

give free advice to patients who suffered from an error in treatment. Questions of compensation are normally regulated by civil law.<sup>515</sup> The new law contains definitions about errors in treatment and defines the burden of proof.<sup>516</sup>

#### 9.10.1.5 Privacy and data protection

Germany has a long tradition in data protection. In 1970 the German Land Hessen adopted the first data protection law in the world. A federal Law was implemented in 1977.<sup>517</sup> Due to the federal system Germany does not just have one law on data protection. Next to the federal act each of the 16 Länder implemented own legislation.<sup>518</sup> In general, data protection and the right to privacy are guaranteed on constitutional level. Article 10 of the Basic Law protects privacy of mail and communication.<sup>519</sup> A right to self-determination is given in Article 2.<sup>520</sup> Germany gives a high level of protection to personal data under its Basic Law. This is found to have implications for the minimum requirements of EU law in order to avoid conflicts between national and EU law.<sup>521</sup>

The German Data Protection Act recognizes the general principle of data processing. In the case of sensitive personal data processing is only allowed under certain circumstances. This includes medical data which are processed by health professionals.<sup>522</sup> German legislation on privacy includes the medical secrecy.<sup>523</sup>

#### 9.10.1.6 Implementation of Directive 95/46/EC

Directive (95/46/EC) was implemented by amending the Federal Data Protection Law from 1990. The Federal Data Protection Act came into force in 2001 and was amended in 2009.<sup>524</sup> Due to the federal structure of the system it was necessary to change the respective laws of the Länder as well. This has happened in 14 of the 16 Länder in between 1999 and 2002.<sup>525</sup>

### 9.11 Greece

Greece has not, as of yet, introduced comprehensive legislation on patients' rights. The provisions are laid down in different laws.<sup>526</sup>

#### 9.11.1 Patients' rights

Patients' rights in Greece can be found in the Act on Modernisation and Organisation of the Health System (No. 2071/92), Article 47), the Code of Ethics (No. 3418/2005) and the Code of Practice of Medicine. Some rights can be derived from the Constitution.<sup>527</sup> The Act of Modernisation and Organisation of the Health System directly addresses patients' rights.<sup>528</sup>

##### 9.11.1.1 Consent

The Greek Constitution establishes the right of consent by emphasizing dignity and integrity.<sup>529</sup> It is furthermore laid down in the Hospital Law<sup>530</sup> and the Code of Medical Ethics.<sup>531</sup> An important aspect of consent is the sufficient provision of information which is highlighted in both the Hospital Law (Article

<sup>515</sup> Bundesministerium für Gesundheit & Bundesministerium für Justiz (2002). Patientenrechte in Deutschland.

<sup>516</sup> Bundesministerium der Justiz & Bundesministerium der Gesundheit (2011). Entwurf eines Gesetzes zur Verbesserung der Rechte von Patientinnen und Patienten (Patientenrechtegesetz), Article 1§630(h).

<sup>517</sup> Korff, D. (2010). Comparative Study on different Approaches to New Privacy Challenges, in Particular in the Light of Technological Developments. Country Studies – Germany.

<sup>518</sup> Ibid.

<sup>519</sup> Bundesministerium der Justiz (1949/2010). Grundgesetz für die Bundesrepublik Deutschland., Article 10.

<sup>520</sup> Ibid, Article 2.

<sup>521</sup> Korff, D. (2010). Comparative Study on different Approaches to New Privacy Challenges, in Particular in the Light of Technological Developments. Country Studies – Germany.

<sup>522</sup> Bundesministerium der Justiz (1990/2009). Bundesdatenschutzgesetz. Article 13(7).

<sup>523</sup> Bundesministerium für Gesundheit & Bundesministerium für Justiz (2002). Patientenrechte in Deutschland.

<sup>524</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#germany](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#germany)

<sup>525</sup> Ibid.

<sup>526</sup> Goffin, T., Nys, H., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Greece. *European Ethical-legal Papers N°6*, Leuven.

<sup>527</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>528</sup> Eleftheriou, A. (n.d.). Patients' Rights.

<sup>529</sup> The Constitution of Greece (1975). (Unofficial English Translation), Articles 2 & 5. Retrieved 06 March 2012 from:

<http://www.cecl.gr/RigasNetwork/databank/Constitutions/Greece.html>

<sup>530</sup> Goffin, T., Nys, H., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Greece. *European Ethical-legal Papers N°6*, Leuven.

<sup>531</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

47) and the Code of Medical Ethics (Article 12). There are exemptions to the obligation for doctors to get consent and patients have the possibility to withdraw their consent.<sup>532</sup> With regard to consent as it is established in the data protection law there is a slight difference from the Data Protection Directive since Greece has higher requirements with regard to information and introduces a possibility to withdraw at any time.<sup>533</sup>

#### 9.11.1.2 Health information

Medical information is not only an important aspect of consent. The access to information is a right on its own. Again the Hospital Law and the Code of Medical Ethics provide for the right to information. This information needs to be given by the health care provider and includes for example information about treatment, alternatives, side-effects and the possible outcome. A therapeutic exception exists.<sup>534</sup>

#### 9.11.1.3 Medical records

Greek patients have the right to access their medical file which contains all important information about the health status and treatment of patients. The medical file can be copied.<sup>535</sup>

#### 9.11.1.4 Complaints

The Greek law provides for a right to complain. An ombudsman is responsible for complaints about health care and welfare.<sup>536</sup> According to Article 47 of the Hospital Act patients have the right to submit complaints. Besides a national committee for complaints, each hospital has a service point for handling complaints. Physicians can be held liable for tort and for contract breaches with regard to the provision of medical services. Physicians might have to pay compensation. The burden of proof is shared between patients and health care providers.<sup>537</sup>

#### 9.11.1.5 Privacy and data protection

Article 9A of the Greek Constitution enshrines the principle of data protection.<sup>538</sup> Data obtained in violation of this Article cannot be used as evidence.<sup>539</sup> The privacy of communication is guaranteed in Article 19 of the Greek Constitution.<sup>540</sup> Since the Greek law on data protection is very similar to Directive 95/46/EC the same provisions apply. There are only small deviations from the Directive.<sup>541</sup> Greek physicians are bound by the medical secrecy and have to respect the privacy of their patients.<sup>542</sup>

#### 9.11.1.6 Implementation of Directive 95/46/EC

The Directive was implemented in 1997. Law 2472 transposes it into Greek law.<sup>543</sup> The Law reproduces the Directive and takes over many provisions without adapting them.<sup>544</sup>

## 9.12 Hungary

### 9.12.1 Patients' rights

The principal legislative instruments concerning patient rights are the Parliamentary Act No. CLIV of 1997 on health care and the Parliamentary Act No. XLVII of 1997 on the processing and the protection of health care data and associated personal data.<sup>545</sup> The first of these created a substantial package of

<sup>532</sup> Goffin, T., Nys, H., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Greece. *European Ethical-legal Papers N°6*, Leuven.

<sup>533</sup> Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (1997). Retrieved 06 March 2012 from: [http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH\\_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-APRIL010-EN%20\\_2\\_.PDF](http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/ENGLISH_INDEX/LEGAL%20FRAMEWORK/LAW%202472-97-APRIL010-EN%20_2_.PDF)

<sup>534</sup> Ibid.

<sup>535</sup> Goffin, T., Nys, H., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Greece. *European Ethical-legal Papers N°6*, Leuven.

<sup>536</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>537</sup> Goffin, T., Nys, H., Borry, P. & Dierickx, K. (2007). Patient Rights in the EU – Greece. *European Ethical-legal Papers N°6*, Leuven.

<sup>538</sup> The Constitution of Greece (1975/2001), Article 9(a). Retrieved 06 March 2012 from: <http://www.unhcr.org/refworld/docid/4c52794f2.html>

<sup>539</sup> Ibid, Article 19.3.

<sup>540</sup> Ibid, Article 19.1.

<sup>541</sup> Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (1997).

<sup>542</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>543</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#greece](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#greece)

<sup>544</sup> Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (1997).

<sup>545</sup> S.DEFLLOOR, et al., "Patient Rights in the EU - Hungary", *European Ethical-Legal Papers N°11*, Leuven, 2007.



rules for health care. The Act includes the rights and obligations of patients<sup>546</sup> and health care workers.<sup>547</sup> The Act also introduced the concept of patient autonomy together with enforceable rights for patients. This was in contrast to the more paternalistic vision that had reigned beforehand.

#### 9.12.1.1 Consent

Self-determination as a right is provided for in the Health Act Described above.<sup>548</sup> The patient has the right to be involved in decisions concerning examination and treatment. A patient must provide his or her informed consent to perform all procedures unless specially guaranteed by the law.

#### 9.12.1.2 Health information

In Hungary patients have a right to receive information in an individualized form taking into account their own circumstances. This is also governed by the Healthcare Act. The concept of the therapeutic exception does not exist as such. If certain data is missing from a patient's healthcare records or if some data is imprecise, the patient has the right to ask for the data to be completed or corrected.

#### 9.12.1.3 Medical records

The patient has the right to access his/her medical file. The Health Act contains the general rule that all patients have the right to be given information about their health care records, to inspect them and have copies of them made at their own cost.<sup>549</sup> The main principles of the EU's data protection framework are implemented by Act LXIII of 1992 on the Protection of Personal Data and Public Access to Data of Public Interest.<sup>550</sup>

#### 9.12.1.4 Privacy and data protection

The Health Act provides for a right to privacy for the patient in Sections 24 and 25. A patient has the right to have his/her examination and treatment taken under strict private circumstances. Furthermore, the patient has the right to have only those persons present whose involvement is necessary.<sup>551</sup>

#### 9.12.1.5 Implementation of Directive 95/46/EC

Hungary implemented the Protection of Personal Data and Public Access to Data of Public Interest in 1992 (1992. évi LXIII. törvény a személyes adatok védelméről és a közérdekű adatok nyilvánosságáról).<sup>552</sup>

### 9.13 Ireland

#### 9.13.1 Patients' rights

In Ireland the existence of patient rights cannot be attributed to a single source. It is rather divided amongst several legislative acts. Prominent examples are the Health Act 2005, the Mental Health Act 2001 and the Medical Practitioners Act 2007.<sup>553</sup>

##### 9.13.1.1 Consent

For consent to be valid it must be informed consent. The informational requirements that apply to medical professionals before consent can be considered valid is not completely clear. Consent is only clearly legally defined for the purposes of psychiatric treatment<sup>554</sup> but not for other treatments.

##### 9.13.1.2 Health information

The Freedom of Information Act, 2003 requires that all government departments, including the Health Service Executive (HSE) and local authorities are required to publish information on their activities and to make personal information available to citizens, including those who request such information in the capacity of being patients.

<sup>546</sup> chapter II

<sup>547</sup> chapter VI

<sup>548</sup> Section 5

<sup>549</sup> Drotár., A, Heuer., O, Ivicz., J, Németh., A, 'Patients' Rights in Hungary – Rules and Practice' Published by the Hungarian Civil Liberties Union January 2002

<sup>550</sup> 1992. évi LXIII. törvény a személyes adatok védelméről és a közérdekű adatok nyilvánosságáról

<sup>551</sup> Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Poland.

<sup>552</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#hungary](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#hungary)

<sup>553</sup> See Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Ireland

<sup>554</sup> Mental Health Act 2001

### 9.13.1.3 Medical records

Patient have the right of full access to their medical record if they so desire.<sup>555</sup>

### 9.13.1.4 Complaints

There are various options for complaints in Ireland. The patient can file a complaint at one of these institutions (depending on the complaint): the Ombudsman, the Medical Council or the Nursing Board.

### 9.13.1.5 Privacy and data protection

The Irish Charter of Patient's Rights confirms that the patient has the right to have their privacy respected. The patient has the right to total confidentiality in respect to the medical records.

### 9.13.1.6 Implementation of Directive 95/46/EC

The main act implementing the EU's data protection directive is the Data Protection Act (1998). This Act entered into force on the 1<sup>st</sup> July 2003.<sup>556</sup>

## 9.14 Italy

### 9.14.1 Patients' rights

Italy's National Health Service was established in 1980. At the heart of the service were several important principles including that citizens are free to choose their doctor from a list of accredited GPs within the health service, free to choose the ambulatory unit or out-patient service for their medical examinations, free to choose the hospital itself. Services are free of charge for those over 60 and those under 10.<sup>557</sup> Various forms of State financial support are available for those who fall in between. The Code on Medical Ethics provides guidance on patient rights. It should be noted however that this Code is not legally binding. Although there is no concrete and separate patients' rights legislation in Italy, patients still enjoy certain rights, some of which are described below.<sup>558</sup>

#### 9.14.1.1 Consent

The Italian Constitution guarantees the physical integrity of the individual. Consent for medical treatment is required according to the Constitution.<sup>559</sup> According to the provisions in the constitution nobody can be forced to undergo any particular medical treatment, unless under the provision of the law.

#### 9.14.1.2 Health information

In Italian law the right of the patient to information about their health does not exist as a standalone right. The Code of Medical Ethics specifies where information must be granted in the context of informed consent.<sup>560</sup>

#### 9.14.1.3 Medical records

The Code of Medical Ethics does not provide this right. This right may be deducted from section 92 of Article 96/2003 on data protection.<sup>561</sup>

#### 9.14.1.4 Complaints

In case of routine operations, medical professionals are subject to strict liability. In case of complex operations the courts call for a high level of professional care and attentiveness. The Tribunal for the Rights of Patients was launched, in Italy in 1980, to protect the health and welfare rights of citizens and to help to achieve a more humane and functional health service. It is an organization that monitors the existence of patient rights in Italy. It includes ordinary citizens, healthcare workers and professionals, who provide their services on a voluntary basis. It has local units throughout Italy.<sup>562</sup> Amongst European countries, Italy has the highest number of physicians subject to criminal proceedings related to medical malpractice. This is changing the approach to medical practice. The

<sup>555</sup> Data Protection Act 2003

<sup>556</sup> The Act was also amended by the Data Protection (Amendment) Act 2003 enacted on 10 April 2003

<sup>557</sup> Eleftheriou., A, 'Patients Rights' Published by The Thalassaemia Internaitonal federation No:7 ISBN 978-9963-623-42-6

<sup>558</sup> Katholieke Universiteit Leuven.. European Centre for Biomedical Ethics and Law. Patients Rights Legislation in Italy. (2008).

<sup>559</sup> Constitution of the Italian Republic (*Costituzione della Repubblica italiana*), Article 32(2)

<sup>560</sup> Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Italy.

<sup>561</sup> Ibid

<sup>562</sup> Eleftheriou., A, 'Patients Rights' Published by The Thalassaemia Internaitonal federation No:7 ISBN 978-9963-623-42-6

Italian health system has paid increasingly higher insurance premiums and is having difficulty finding insurance companies willing to bear the risk of monetary claims alleging medical malpractice.<sup>563</sup>

#### 9.14.1.5 Privacy and data protection

The concept of professional secrecy is governed by Italian criminal law.<sup>564</sup> The Code of Medical Ethics also enforces the professional confidentiality.

#### 9.14.1.6 Implementation of Directive 95/46/EC

In 1996 Italy implemented the Protection of individuals and other subjects with regard to the processing of personal data Act no. 675. The New Data Protection Code entered into force in 2004.<sup>565</sup>

### 9.15 Latvia

The patient rights legislation of Latvia differs somewhat from its Baltic neighbours. Not all patients' rights are covered in Latvia yet.<sup>566</sup> A protection of health and the right to basic care are however laid down in the Constitution.<sup>567</sup>

#### 9.15.1 Patients' rights

Next to the provision in the Constitution, the Law on Pharmaceuticals, the Law on Medical Care and the Medical Treatment Law regulate health care. Only the latter contains specific legislation on patients' rights.<sup>568</sup>

##### 9.15.1.1 Consent

Consent is required by the Latvian law. A physicians needs to provide information on diagnosis and treatment. Treatment can be refused.<sup>569</sup>

##### 9.15.1.2 Health information

Latvian patients have a right to receive information about their health. This includes their health status, the diagnosis and the treatment. There is derogation for therapeutic reasons. Physicians can withhold information if this would otherwise worsen the situation of the patient.<sup>570</sup>

##### 9.15.1.3 Medical records

The Medical Treatment Act obliges health care providers to record health information. These must be accessible for patients.<sup>571</sup> There are specific regulations on the information of the sexual health of patients. Patients can access their medical file and ask for rectification.<sup>572</sup>

##### 9.15.1.4 Complaints

The State Health Inspectorate is responsible for dealing with complaints. Those complaints can be transferred to a prosecutor. Furthermore, the Law on Medical Care provides for penalization of health care providers. A compensation system is lacking. Current practice is based on case law.<sup>573</sup>

##### 9.15.1.5 Privacy and data protection

The rights to privacy in general and to the privacy of communication in particular are included in the Latvian Constitution.<sup>574</sup> Medical treatment is confidential and the information about the health of a

<sup>563</sup> Traina., M, (2009) 'Medical Malpractice: The Experience in Italy', Clin Orthop Relat Res. 2009 February; 467(2): 434–442.

<sup>564</sup> Art. 622 of the Italian Criminal Code

<sup>565</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#italy](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#italy)

<sup>566</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>567</sup> Constitution of the Republic of Latvia (1922/2009), Article 111. Retrieved 07 March 2012 from:

<http://www.satv.tiesa.gov.lv/?lang=2&mid=8>

<sup>568</sup> European Patients' Forum (2009). Patients' Rights in the European Union

<sup>569</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Latvia. Informed Consent. Retrieved 07 March 2012 from:

[http://europatientrights.eu/countries/signed/latvia/latvia\\_right\\_to\\_informed\\_consent.html](http://europatientrights.eu/countries/signed/latvia/latvia_right_to_informed_consent.html)

<sup>570</sup> Ibid. Right to information about his or her health. Retrieved 07 March 2012 from:

[http://europatientrights.eu/countries/signed/latvia/latvia\\_right\\_to\\_information\\_about\\_his\\_or\\_her\\_health.html](http://europatientrights.eu/countries/signed/latvia/latvia_right_to_information_about_his_or_her_health.html)

<sup>571</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>572</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Latvia. Rights regarding the Medical File. Retrieved 07 March 2012 from:

[http://europatientrights.eu/countries/signed/latvia/latvia\\_rights\\_regarding\\_the\\_medical\\_file.html](http://europatientrights.eu/countries/signed/latvia/latvia_rights_regarding_the_medical_file.html)

<sup>573</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

patient can only be communicated under specific circumstances (e.g. information to other physicians, informed consent).<sup>575</sup>

#### 9.15.1.6 Implementation of Directive 95/46/EC

Latvia has the Personal Data Protection Law (Fizisko personu datu aizsardzības likums) which was amended by the Law of 24 October 2002.<sup>576</sup>

### 9.16 Lithuania

The healthcare system of Lithuania has been significantly reformed from the soviet model which did not acknowledge patients' rights. Many problems which can be related to this old system still remain however.<sup>577</sup>

#### 9.16.1 Patients' rights

Even though patients' rights are well-known in Lithuania and health care professionals are aware of them there are violations of these rights. Patients are believed to be not assertive enough with respect to their rights.<sup>578</sup> Patients' rights are enshrined in the Constitution, the Civil Code and Law on the Rights of Patients and Compensation of the Damage to their Health.<sup>579</sup>

##### 9.16.1.1 Consent

In both the Civil Code and the Law on the Rights of Patients the right to informed consent is established. Consent is necessary for treatment. According to Article 8 of the Law on the Rights of Patients, doctors need to provide patients with sufficient information about the treatment in order to give informed consent. Withdrawal of consent is possible.<sup>580</sup>

##### 9.16.1.2 Health information

The same laws that apply in the case of consent also provide legislation on health information. Article 6 (1) of the Law on the Rights of Patients and Article 6.727 (1) of the Civil Code states that there is a right to health information.<sup>581</sup> Therapeutic exceptions are possible.<sup>582</sup> The right not to know also exists in Lithuanian law.<sup>583</sup>

##### 9.16.1.3 Medical records

Patients in Lithuania can directly access their medical records. Healthcare providers are obliged to keep medical records.<sup>584</sup> Their content is not regulated. However, there is a right to access to the medical file and also a right to be given a copy of the medical file.<sup>585</sup>

##### 9.16.1.4 Complaints

The Law on the Rights of Patients and Compensation of the Damage to their Health already clarifies through its name that there is a possibility to file complaints and receive possible compensation. The regulations for the complaint procedure are therefor rather specific and even contain time limits. There is the possibility of compensation.<sup>586</sup>

<sup>574</sup> Constitution of the Republic of Latvia (1922/2009), Article 96 & 100.

<sup>575</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Latvia. Right to Privacy. Retrieved 07 March 2012 from:

[http://europatientrights.eu/countries/signed/latvia/latvia\\_right\\_to\\_privacy.html](http://europatientrights.eu/countries/signed/latvia/latvia_right_to_privacy.html)

<sup>576</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#latvia](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#latvia)

<sup>577</sup> Nys, H., Defloor, S., Dierickx, K. & Goffin, T. (2007). Patient Rights in the EU – Lithuania. European Ethical-legal Papers, Leuven.

<sup>578</sup> Eleftheriou, A. (n.d.). Patients' Rights.

<sup>579</sup> Nys, H., Defloor, S., Dierickx, K. & Goffin, T. (2007). Patient Rights in the EU – Lithuania. European Ethical-legal Papers, Leuven.

<sup>580</sup> Ibid.

<sup>581</sup> Ibid.

<sup>582</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>583</sup> Nys, H., Defloor, S., Dierickx, K. & Goffin, T. (2007). Patient Rights in the EU – Lithuania. European Ethical-legal Papers, Leuven.

<sup>584</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>585</sup> Nys, H., Defloor, S., Dierickx, K. & Goffin, T. (2007). Patient Rights in the EU – Lithuania. European Ethical-legal Papers, Leuven.

<sup>586</sup> Ibid.

### 9.16.1.5 Privacy and data protection

Lithuania also has a specific data protection law (implementation of Directive 95/46/EC). It is criticized that there is a lack of concrete guidelines enacting this legislation.<sup>587</sup> Processing of health data by health professionals is allowed. Medical secrecy is stipulated by Lithuanian Law. *'All the information concerning the condition of the patient's health, diagnosis, prognosis and treatment, and also all the other information of a personal nature concerning the patient, must be held as confidential, even after the patient's death.'*<sup>588</sup>

### 9.16.1.6 Implementation of Directive 95/46/EC

In 2003 the Law on Legal Protection of Personal Data (Asmens duomenų teisinės apsaugos įstatymas) has been published. It has been amended in 2004.<sup>589</sup>

## 9.17 Luxembourg

Luxembourg is one of the smallest of the EU Member States but has a stable economy and a good health care system.<sup>590</sup>

### 9.17.1 Patients' rights

There is no specific act on patients' rights in Luxembourg. Patients' rights are acknowledged in the Act on Hospital Establishments and in the Code of Medical Ethics. Whereas the first rather focuses on the rights of hospitalized patients, the latter takes a more general approach.<sup>591</sup>

#### 9.17.1.1 Consent

The right to informed consent is in both the Act on Hospital Establishments and the Code of Medical Ethics. Physicians are obliged to provide patients with all necessary information to make an informed decision. Deviations in emergency situations are possible.<sup>592</sup>

#### 9.17.1.2 Health information

The rights on health information in the Act on Hospital Establishments are related to the legislation on informed consent.<sup>593</sup> On the contrary the Code of Medical Ethics is more precise and recognizes a right not to know.<sup>594</sup>

#### 9.17.1.3 Medical records

Patients have the right to access their medical files and to make copies of it.<sup>595</sup>

#### 9.17.1.4 Complaints

Hospitals are obliged to establish a complaint mechanism.<sup>596</sup> There is an ombudsman who is working on patients' rights and also on complaint resolution.<sup>597</sup>

#### 9.17.1.5 Privacy and data protection

Confidentiality need to be ensured with regard to the medical record.<sup>598</sup> Furthermore, the medical secrecy must be guaranteed.<sup>599</sup> Luxemburg directly transposed Directive 95/46/EC. With regard to data protection therefore the provisions of the directive which are described in the main text apply.

<sup>587</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>588</sup> Law on the Rights of Patients and Compensation of the Damage to their Health (2004), Article 10(2).

<sup>589</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#lithuania](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#lithuania)

<sup>590</sup> Jakubowski, E. & Busse, R. (1998). Health Care Systems in the EU – A Comparative Study. Retrieved 08 March 2012 from:

[http://www.europarl.europa.eu/workingpapers/saco/pdf/101\\_en.pdf](http://www.europarl.europa.eu/workingpapers/saco/pdf/101_en.pdf)

<sup>591</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>592</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Luxembourg. Right to informed consent.

[http://europatientrights.eu/countries/signed/luxembourg/luxembourg\\_right\\_to\\_informed\\_consent.html](http://europatientrights.eu/countries/signed/luxembourg/luxembourg_right_to_informed_consent.html)

<sup>593</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>594</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Luxembourg. Right to Information about his or her Health. Retrieved 08 March 2012 from:

[http://europatientrights.eu/countries/signed/luxembourg/luxembourg\\_right\\_to\\_information\\_about\\_his\\_or\\_her\\_health.html](http://europatientrights.eu/countries/signed/luxembourg/luxembourg_right_to_information_about_his_or_her_health.html)

<sup>595</sup> Ibid, Rights regarding the Medical File. Retrieved 08 March 2012 from:

[http://europatientrights.eu/countries/signed/luxembourg/luxembourg\\_rights\\_regarding\\_the\\_medical\\_file.html](http://europatientrights.eu/countries/signed/luxembourg/luxembourg_rights_regarding_the_medical_file.html)

<sup>596</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>597</sup> Ombudsman. [http://www.ombudsman.lu/page-son\\_role.html](http://www.ombudsman.lu/page-son_role.html)

### 9.17.1.6 Implementation of Directive 95/46/EC

Luxemburg did not transpose the Directive but approved in in 2002. After it was published in Memorial A 91 of 13 August 2002 it entered into force on December 1<sup>st</sup> 2002.<sup>600</sup> The Luxemburgish data protection law is therefore directly derived from the Directive.

## 9.18 Malta

The Maltese healthcare system has been extensively reformed during the last years. The focus of the healthcare system is on enhancing equity in access to care, the promotion of quality and excellence and sustainability.<sup>601</sup>

### 9.18.1 Patients' rights

The Maltese provisions on patients' rights can be found in the Patients' Rights Charter, the Patients' Charter National Hospital, the Data Protection Act and the Criminal Code (Art. 257).<sup>602</sup> With regard to enforcement a vertical approach is taken.<sup>603</sup>

#### 9.18.1.1 Consent

The Data Protection Act defines consent as '*any freely given specific and informed indication of the wishes of the data subject by which he signifies his agreement to personal data relating to him being processed*'.<sup>604</sup> For processing medical data consent is necessary. Consent can be withdrawn.<sup>605</sup> Also according to patients' rights legislation consent is necessary before starting treatment.<sup>606</sup>

#### 9.18.1.2 Health information

The right to health information is included in the rights on informed consent.

#### 9.18.1.3 Medical records

There are medical files in Malta. Regulation on this is however limited and the format is up to the physicians.<sup>607</sup>

#### 9.18.1.4 Complaints

The complaint procedure has two different levels: public and private. The latter requires an approach to the Medical Council of Malta. In the public sector one has to file the complaint with the Customer care of the Maltese Health Department.<sup>608</sup>

<sup>598</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). General National Patient Rights Protection – Luxembourg, Rights regarding the Medical File. Retrieved 08 March 2012 from:

[http://europatientrights.eu/countries/signed/luxembourg/luxembourg\\_rights\\_regarding\\_the\\_medical\\_file.html](http://europatientrights.eu/countries/signed/luxembourg/luxembourg_rights_regarding_the_medical_file.html)

<sup>599</sup> Ibid, Right to Privacy. Medical Secrecy. Retrieved 08 March 2012 from :

[http://europatientrights.eu/countries/signed/luxembourg/luxembourg\\_right\\_to\\_privacy\\_medical\\_secrecy.html](http://europatientrights.eu/countries/signed/luxembourg/luxembourg_right_to_privacy_medical_secrecy.html)

<sup>600</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#luxembourg](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#luxembourg)

<sup>601</sup> Restall, B., Giets, S., Dumrtier, J. & Artmann, J. (2010). eHealth Strategies. Country Brief: Malta. Retrieved 08 March 2012 from: [http://ehealth-strategies.eu/database/documents/Malta\\_CountryBrief\\_eHStrategies.pdf](http://ehealth-strategies.eu/database/documents/Malta_CountryBrief_eHStrategies.pdf)

<sup>602</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>603</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). Patient Rights Legislation. Horizontal/Vertical. Retrieved 08 March 2012 from: [http://europatientrights.eu/types/contractual\\_horizontal.html](http://europatientrights.eu/types/contractual_horizontal.html)

<sup>604</sup> Data Protection Act (2001), Article 2. Retrieved 07 March 2012 from :

[http://ec.europa.eu/justice/policies/privacy/docs/implementation/malta\\_en.pdf](http://ec.europa.eu/justice/policies/privacy/docs/implementation/malta_en.pdf)

<sup>605</sup> Ibid, Article 10 & 12.

<sup>606</sup> European Patients' Forum (2009). Patients' Rights in the European Union

<sup>607</sup> Ibid.

<sup>608</sup> Ibid.

### 9.18.1.5 Privacy and data protection

The right to privacy can be found in the Maltese Constitution.<sup>609</sup> The Data Protection Act takes into account the basic principles of data processing. The processing of sensitive data is not allowed. Medical data can be exempted from this rule if the principle of necessity is fulfilled and if processing is done by a health professional.<sup>610</sup> Furthermore, rules on confidentiality are enshrined in Article 257 of the Criminal Code.<sup>611</sup>

### 9.18.1.6 Implementation of Directive 95/46/EC

Malta implemented the Directive in the Data Protection Act of December 14 2001 (Act XXVI of 2001) which was amended by Act XXXI of 2002 and entered into force July 15, 2001.<sup>612</sup>

## 9.19 The Netherlands

The Netherlands, has a progressive reputation with regard to patients' rights. Privacy and data protection are both acknowledged as fundamental rights and enshrined in the constitution.

### 9.19.1 Patients' rights

The Netherlands is regarded as a pioneer country with regard to patients' rights and served as model for the legislation in this area for some other European countries.<sup>613</sup> It was the first country to implement a 'treatment contract' similar to a contract for services between patient and service provider.<sup>614</sup> The Dutch approach is the incorporation of a special law on patients' rights in the general body of legislation. In 1995 the Act on the medical treatment contract (Wet op de geneeskundige behandelingsovereenkomst) was adopted. It forms part of the Dutch Civil Code.<sup>615</sup> The Act reflects a horizontal approach with the opportunity to invoke the patients' rights against the care provider.

#### 9.19.1.1 Consent

The Dutch law applies the principle of informed consent and therefore relates consent and health information. Both can be found in the same provision.<sup>616</sup> Consent is required for medical treatment. Both implicit and explicit consent are possible under Dutch law.<sup>617</sup>

#### 9.19.1.2 Health information

The Dutch law knows only one provision on health information and consent. The provision on health information can therefore be found in the Act on medical treatment contract in Article 448 concerning also the right to consent. Care providers are obliged to provide patients with all necessary information about the medical proceedings. The information can be requested in writing. Derogations might however apply if the care provider believes that informing the patient could have serious medical consequences. Furthermore, patients can express the wish to not be informed.<sup>618</sup> In practice it has proven that particularly in the area of health information there are uncertainties. Patients and care providers have a different understanding on the way information is provided and the level of detail which is required.<sup>619</sup>

<sup>609</sup> Constitution of Malta(1964/2007), Article 32(c). Retrieved 08 March 2012 from:

<http://legislationline.org/documents/section/constitutions>

<sup>610</sup> Data Protection Act (2001), Article 15.

<sup>611</sup> European Patients' Forum (2009). Patients' Rights in the European Union.

<sup>612</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#malta](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#malta)

<sup>613</sup> Goffin, T., Borry, P., Dierickx & Nys, H. (2008). Why Eight EU Member States Signed but Did not Ratify the Convention for Human Rights and Biomedicine. *Health Policy* 86(2/3), 222 – 233.

<sup>614</sup> Katholieke Universiteit Leuven, Centre for Biomedical Ethics and Law (2008). Patient Rights in the EU. Nominate/Innominate Treatment Contract. Retrieved 02 March 2012 from: <http://europatientrights.eu/types/nominate.html>

<sup>615</sup> Roscam Abbing, H. (2006). Recent Developments in Health Law in the Netherlands. *European Journal of Health Law* 13, 134.

<sup>616</sup> De Minister van Justitie (1994). Wet van 17 november 1994 tot wijziging van het Burgerlijk Wetboek en enige andere wetten in verband met de opnemng van bepalingen omtrent de overeenkomst tot het verrichten van handelingen op het gebied van de geneeskunst. Retrieved 02 March 2012 from: [http://wetten.overheid.nl/BWBR0007021/geldigheidsdatum\\_02-03-2012](http://wetten.overheid.nl/BWBR0007021/geldigheidsdatum_02-03-2012)

Minister van Justitie. Burgelijk Wetboek 7. Article 448. Retrieved 02 March 2012 from:

[http://wetten.overheid.nl/BWBR0005290/Boek7/Titel7/Afdeling5/Artikel454/geldigheidsdatum\\_02-03-2012](http://wetten.overheid.nl/BWBR0005290/Boek7/Titel7/Afdeling5/Artikel454/geldigheidsdatum_02-03-2012)

<sup>617</sup> Ibid, Article 448.

<sup>618</sup> Ibid, Article 448.

<sup>619</sup> Nivel (2000). De Wet op de Geneeskundige BehandelingsOvereenkomst. Article 448. Retrieved 02 March 2012 from: <http://www.nivel.nl/oc2/page.asp?PageID=431>

### 9.19.1.3 Medical Records

In the Netherlands care providers are obliged to keep medical files which have to be stored for 15 years. Patients can request access to the file or copies of it.<sup>620</sup> The right to access derives from the right to privacy in the Dutch Constitution.<sup>621</sup> Furthermore, patients can ask to have those documents destroyed.<sup>622</sup> A right to be forgotten is therefore already implemented in Dutch patient law.

### 9.19.1.4 Complaints

Dutch patients have the opportunity to complain to a complaint committee of the institute for healthcare or to the healthcare provider. A file for compensation is possible. The burden of proof however lies with the patient.<sup>623</sup>

### 9.19.1.5 Privacy and data protection

Privacy and data protection are constitutional rights in the Netherlands. Next to recognizing them by ratifying human rights conventions they are therefore enshrined in the Dutch Constitution. Furthermore, the Netherlands transposed Directive 95/46/EC into national law.

Article 10 of the Dutch Constitution states that '*Rules to protect privacy shall be laid down by Act of Parliament in connection with the recording and dissemination of personal data*' and '*Rules concerning the rights of persons to be informed of data recorded concerning them and of the use that is made thereof, and to have such data corrected shall be laid down by Act of Parliament.*'<sup>624</sup>

Personal data are furthermore protected under the Personal Data Protection Act (Wet Bescherming Persoonsgegevens) from 2000.<sup>625</sup> This law applies to those acts of data processing which take place in the Netherlands.<sup>626</sup> General principles like consent,<sup>627</sup> purpose specification,<sup>628</sup> data minimization,<sup>629</sup> limitation in time<sup>630</sup> and quality are part of the law. The processing of sensitive data is not allowed.<sup>631</sup>

There are specific regulations with regard to the protection of medical data. Article 21 allows for derogations for medical data from the prohibition to process sensitive data.<sup>632</sup>

The right to privacy is laid down in the Dutch Constitution in Articles 10, 12 and 13. Article 10<sup>633</sup> relates to privacy in general, Article 12<sup>634</sup> describes the right to privacy at home and Article 13<sup>635</sup> relates to privacy to correspondence regardless if in oral or written form.

Medical secrecy is laid down on the Act on medical treatment contract. Care providers are not allowed to provide information about medical conditions to third parties. However, there is the possibility that a patient gives consent for the disclosure of medical information.<sup>636</sup> Medical secrecy is related to the right on privacy.

<sup>620</sup> Minister van Justitie. Burgelijk Wetboek 7, Article 454.

<sup>621</sup> Minister van Justitie (1815/1983). Grondwet voor het Koninkrijk der Nederlanden. Article 10. Retrieved 02 March 2012 from: [http://wetten.overheid.nl/BWBR0001840/geldigheidsdatum\\_02-03-2012](http://wetten.overheid.nl/BWBR0001840/geldigheidsdatum_02-03-2012).

An English translation can be found at [http://www.servat.unibe.ch/icl/nl00000\\_.html](http://www.servat.unibe.ch/icl/nl00000_.html)

<sup>622</sup> Minister van Justitie. Burgelijk Wetboek 7, Article 455.

<sup>623</sup> European Patients' Forum (n.d.). Patients' Rights in the European Union. Retrieved 02 March 2012 from: [http://www.eu-patient.eu/Documents/Projects/Valueplus/Patients\\_Rights.pdf](http://www.eu-patient.eu/Documents/Projects/Valueplus/Patients_Rights.pdf)

<sup>624</sup> Minister van Justitie (1815/1983). Grondwet voor het Koninkrijk der Nederlanden. Article 10.2 & 10.3.

<sup>625</sup> De Minister van Justitie (2000). Wet van 6 juli 2000, houdende regels inzake de bescherming van persoonsgegevens (Wet bescherming persoonsgegevens). Retrieved 02 March 2012 from: [http://wetten.overheid.nl/BWBR0011468/geldigheidsdatum\\_02-03-2012](http://wetten.overheid.nl/BWBR0011468/geldigheidsdatum_02-03-2012)

<sup>626</sup> Ibid, Article 4.

<sup>627</sup> Ibid, Article 8.

<sup>628</sup> Ibid, Article 11.

<sup>629</sup> Ibid, Article 9.

<sup>630</sup> Ibid, Article 10.

<sup>631</sup> Ibid, Article 16.

<sup>632</sup> Ibid, Article 21.

<sup>633</sup> Minister van Justitie (1815/1983). Grondwet voor het Koninkrijk der Nederlanden. Article 10.

<sup>634</sup> Ibid, Article 12 '1. *Entry into a home against the will of the occupant shall be permitted only in the cases laid down by or pursuant to Act of Parliament, by those designated for the purpose by or pursuant to Act of Parliament.*

*2. Prior identification and notice of purpose shall be required in order to enter a home under the preceding paragraph, subject to the exceptions prescribed by Act of Parliament.*

*3. A written report of the entry shall be issued to the occupant as soon as possible. If the entry was made in the interests of state security or criminal proceedings, the issue of the report may be postponed under rules to be laid down by Act of Parliament. A report need not be issued in cases, to be determined by Act of Parliament, where such issue would never be in the interests of state security.'*

<sup>635</sup> Ibid, Article 13 '1. *The privacy of correspondence shall not be violated except in the cases laid down by Act of Parliament, by order of the courts.*

*2. The privacy of the telephone and telegraph shall not be violated except, in the cases laid down by Act of Parliament, by or with the authorisation of those designated for the purpose by Act of Parliament.'*

<sup>636</sup> Minister van Justitie. Burgelijk Wetboek 7, Article 447.



### 9.19.1.6 Implementation of Directive 95/46/EC

Directive 95/46/EC was approved by the Dutch Senate on the 6<sup>th</sup> of July 2000. It entered into force at the 1<sup>st</sup> of September 2001.<sup>637</sup> In Directive is transposed into Dutch law in the Personal Data Protection Act (Wet Bescherming Persoonsgegevens) from 6<sup>th</sup> of July 2000.<sup>638</sup>

## 9.20 Poland

### 9.20.1 Patients' rights

In Poland there are numerous legislative acts that are active in the area of patient rights. Patient rights are contained within separate legislative packages, the following groupings can be observed; the medical profession, health care providers, the National Health Fund (NHF) functioning, the Institute for Patient's Rights and Health Education activity.<sup>639</sup> The most important legislative act concerning patient rights is The Healthcare Institutions Act which was the first to specify the fundamental rights of patients.<sup>640</sup> The Polish Constitution also provides for general and specific rights concerning healthcare.<sup>641</sup> In the general sense the constitution provides for a general right to health care, in the more specific sense the constitution provides for the protection of privacy and the right to life.

#### 9.20.1.1 Consent

The Act on Healthcare Institutions affirms and combines the right to informed consent and the right to patient information. The patient has the right to express his/her consent to accept health services or to refuse them after receiving the sufficient amount of information. The center for Biomedical Ethics and Law has produced the following list of rights that can be found in Polish law with respect to consent.<sup>642</sup>

- (i) Patients have the right to express their consent to undergo health services or to refuse them if they have been given appropriate information. An individual's consent is the main basis for a physician to act.
- (ii) Physicians are required to obtain the patient's consent for both therapeutically and diagnostic interventions.
- (iii) Consent in cases of higher risk must be in writing. Physicians' may only carry out an operation or apply a treatment or diagnostic method, that increases patient risk, if he has obtained the patient's written consent. The patient however is not required to provide written consent each and every time the procedure is carried out. Oral consent is acceptable for procedures of low risk.
- (iv) The burden of proof that an informed consent was given rests on the physician. There is no provision with regards to the withdrawal of consent in the case of a normal medical treatment.

#### 9.20.1.2 Health information

A right to health information is considered as required in order to give informed consent within the meaning contained in the Act on Healthcare Institutions<sup>643</sup>.

#### 9.20.1.3 Medical records

Organizations must maintain a medical record, which patients are entitled to access.

#### 9.20.1.4 Complaints

The main institution regarding the right to complain is the Ombudsman. In the case where a patient's rights are infringed, the court may require the physician (hospital) to pay pecuniary compensation to the injured person for the harm caused. The Polish system of patient complaints has been severely criticized because cases are handled by special medical courts that are under the control of medical chambers (these are professional organizations that represent nurses, midwives and doctors).<sup>644</sup> The

<sup>637</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from: [http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#netherlands](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#netherlands)

<sup>638</sup> De Minister van Justitie (2000). Wet van 6 juli 2000, houdende regels inzake de bescherming van persoonsgegevens (Wet bescherming persoonsgegevens).

<sup>639</sup> Mokrzycka, A, 'Patients' Rights Law - the new MoH project', Institute of Public Health, Jagiellonian University Medical College, Krakow Survey no: (16)2010

<sup>640</sup> Act of 15 April 2005 on public aid and restructuring of public health care institutions.

<sup>641</sup> The Constitution of the Republic of Poland - *Konstytucja Rzeczypospolitej Polskiej*

<sup>642</sup> The Centre is based at the Catholic University of Leuven. The relevant information can be found at [http://europatientrights.eu/about\\_us.html](http://europatientrights.eu/about_us.html)

<sup>643</sup> Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Poland.

<sup>644</sup> Mokrzycka, A, 'Patients' Rights Law - the new MoH project', Institute of Public Health, Jagiellonian University Medical

system means that patients have no recourse to approach the courts themselves but depend upon the representation of a third party which controls the case. This system disadvantages patients. Normal civil courts are only active in the most serious and spectacular of cases. In such cases the patient is also disadvantaged as he must pay legal and administrative fees at the start of the claim.

#### 9.20.1.5 Privacy and data protection

Privacy is guaranteed as a right by the Polish constitution.<sup>645</sup>

#### 9.20.1.6 Implementation of Directive 95/46/EC

The Act of August 29, 1997 on the Protection of Personal Data is used for the transposition of the Directive. It was amended in 2004.<sup>646</sup>

## 9.21 Portugal

### 9.21.1 Patients' rights

The Basic Law on Health 48/90 of 24 August 1990 provides for a modest selection of patient rights. Further provision can be found in the Mental Health Act 36/98, the Law 12/2005 on Health Information, the Law 60/2003 on Primary Healthcare and the Law 281/2003 on Continuous Healthcare. Each of these includes several issues related to patients' rights.<sup>647</sup>

#### 9.21.1.1 Consent

Patients are provided with the right to accept or to refuse healthcare. In addition, there also exists the right to be informed about their situation, the possible alternatives of treatment and the probable evolution of their condition.

#### 9.21.1.2 Health information

As with other states, Portugal also has linked this concept with the right to informed consent. However, the therapeutic exception should be interpreted in a very restrictive way. It may only be used if the disclosure of information would aggravate cardiac or psychic illnesses. The treatment provider must inform the patient on the objective, nature, consequences, benefits, costs, risks and alternatives of diagnosis and treatment, as well as of delay or refusal of the proposed treatment. Information must be in simple and clear language tailored to the patient.<sup>648</sup>

#### 9.21.1.3 Medical records

All medical information must be kept in medical records by the physician treating the patient. The Portuguese Constitution stipulates that all citizens have the right to access the data related to them. However, there is no specific right of access to one's medical file in Portugal.<sup>649</sup>

#### 9.21.1.4 Complaints

There are no specific legal provisions concerning the rights of patients to complain about their treatment in Portugal.<sup>650</sup> Medical liability in Portugal is fault-based. The treatment provider must act like a competent, wise and sensible qualified treatment provider according to the circumstances.<sup>651</sup>

#### 9.21.1.5 Privacy and data protection

Persons responsible for the processing of health information are responsible for ensuring that confidentiality is protected<sup>652</sup>. Under the Health Information Act, health information is defined as any information that can be linked directly or indirectly to the present or future health status of a person, either living or deceased, including clinical and family history. Such information is considered the

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College, Krakow Survey no: (16)2010 General rights of patients are stated in Chapter II (Rights and obligation of patients) and Chapter VI (Rights and obligation of healthcare workers) of the Health Act CLIV of 1997

<sup>645</sup> The Constitution of the Republic of Poland - Konstytucja Rzeczypospolitej Polskiej, Articles 41 and 49

<sup>646</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#poland](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#poland)

<sup>647</sup> Katholieke Universiteit Leuven. European Centre for Biomedical Ethics and Law. Patients' Rights Legislation in Portugal. (2008) and Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Portugal.

<sup>648</sup> Nys, H. (2008). Patient Rights in the EU – Portugal. European Ethical-Legal Papers N°13, Leuven.

<sup>649</sup> Ibid.

<sup>650</sup> Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Portugal.

<sup>651</sup> Barendrecht, M. (2007). *Principles of European Law. Service Contracts*, Sellier, European Law Publishers, 2007, 826. In

Nys, H. et al. (2008). Patient Rights in the EU - Portugal European Ethical-Legal Papers N°13, Leuven.

<sup>652</sup> Law 12/2005 on Health Information

property of the person to whom it corresponds. This information may not be used for purposes other than healthcare and research unless otherwise defined by the law.

#### 9.21.1.6 Implementation of Directive 95/46/EC

Portugal implemented the Directive in 1998 in the Act on the Protection of Personal Data (Lei da protecção de dados pessoais).<sup>653</sup>

## 9.22 Romania

### 9.22.1 Patients' rights

In 2003 Romania enacted legislation specifically concerned with Patient Rights, which is called the Patients' Rights Act (2003).<sup>654</sup> There are also other pieces of legislation that impact upon this area including most notably the Romanian Constitution (1991);<sup>655</sup> the Health Reform Law (2005); the Mental Health Law (2002) the Public Health Law (1998) and the Deontological Code of Medical Profession.<sup>656</sup>

#### 9.22.1.1 Consent

According to the law on patient rights, patients are entitled to give informed consent before treatments may commence. A committee of arbitration can in certain circumstances allow this principle to be circumscribed.

#### 9.22.1.2 Health information

The patient has the right to be informed completely and in an accessible manner as laid down in the Patient's Rights Act.

#### 9.22.1.3 Medical records

According to the Patient Rights Act a medical record needs to be updated so as to be accurate. Furthermore, the patient has the right to access this record. The Romanian law 46/2003 of patients' rights, allows the family of a deceased access to his or her medical records only where express consent has been previously provided. It has been alleged that on occasion this practice is used to hide malpractice from a deceased person's family.<sup>657</sup>

#### 9.22.1.4 Complaints

According to the Patients' Rights' Act, the patient has the right to complain and appeal. The procedures that govern these rights have been the subject of criticism from the US State Department amongst others.<sup>658</sup>

#### 9.22.1.5 Privacy and data protection

The patient has the right to privacy and confidentiality. Also the data from the medical records need to be kept secret. There can be no disclosure without the authorization of the patient. The right to privacy is laid down in the Romanian Constitution. It recognizes the rights of privacy, inviolability of domicile, freedom of conscience and expression.<sup>659</sup>

#### 9.22.1.6 Implementation of Directive 95/46/EC

Law no. 677/2001 of 21st of November 2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data implements the Directive. In 2005

<sup>653</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#portugal](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#portugal)

<sup>654</sup> This is often known as Law 46, see: Milevska-Kostova., 'N, Patients' Rights as a Policy Issue in South Eastern Europe' CPS Internaitonal Fellowship Programme 2005/2006

<sup>655</sup> Constituția României (In Romanian)

<sup>656</sup> Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Hungary.

<sup>657</sup> See for example <http://roncea.ro/2010/03/07/revista-romana-de-bioetica-despre-cazul-george-pavel-vuza-similar-cazurilor-toni-tecuceanu-si-cezar-ivanescu-familia-pacientului-intre-dreptul-la-adevar-si-secretul-medical/> This case concerned a Romanian Professor of Mathematics that was refused access to his deceased parent's health record and was thus consequently unable to reconstruct the treatment he had been subject to before his death.

<sup>658</sup> See 2010 Human Rights Report: Romania Bureau of Democracy, Human Rights and Labour 2010 Country Reports on Human Rights Practices Report April 8, 2011

<sup>659</sup> Milevska-Kostova., 'N, Patients' Rights as a Policy Issue in South Eastern Europe' CPS Internaitonal Fellowship Programme 2005/2006

the Law no. 102/2005 regarding the setting up, organisation and functioning of the National Supervisory Authority for Personal Data Processing was adopted.<sup>660</sup>

## 9.23 Slovakia

### 9.23.1 Patients' rights

Slovakia has an extensive legal system concerning the rights of Patients. The sources of these rights include the Slovak Constitution, the healthcare reform package of six Acts of 2004 and especially Act No. 576/2004 on healthcare and healthcare-related services are the main legal documents.<sup>661</sup> According to the Constitution of the Slovak Republic, the state provides its citizens with the right to quality health care, health protection, safety, privacy and health information. The system of patient rights in Slovakia was largely modeled on the Dutch patient rights system.<sup>662</sup>

#### 9.23.1.1 Consent

The right of patients to informed consent is guaranteed in Slovakia. Such consent must always be given by patients before treatment, or by their legal representative if they are unable to give such consent.

#### 9.23.1.2 Health information

Article 11 of Act No 576/2004 covers this right as a separate right. It states that individuals have the right to be informed about their health status.<sup>663</sup>

#### 9.23.1.3 Medical records

Article 18 and 19 of Act No 576/2004 are devoted to this right and give the definition of a medical record. Healthcare providers must maintain healthcare records in an up to date and correct manner. In order to implement the EU data protection directive, Slovakia implemented the Protection of individuals and other subjects with regard to the processing of personal data Act no. 675.<sup>664</sup>

#### 9.23.1.4 Complaints

This right is well known and much used in Slovakia. The patient has several options to file a complaint. Most of them are filed with the Healthcare Surveillance Authority. Concerning infringement of the patients' rights Act No 576/2004 makes a reference in Article 11. A patient that feels that his/her rights have been violated is obligated to seek court protection. The general provisions with regard to civil liability of the Act 40/1964 of the Civil Code will apply. Some rights that are stated in legislation may in reality be difficult to secure. The right to choose a satisfactory general practitioner or healthcare facility is a good example where the right concerned is hindered by a lack of suitable information. The situation is made more difficult by the existence of a large lingual minority of Hungarian speakers who are often not well catered for.<sup>665</sup>

#### 9.23.1.5 Privacy and data protection

Confidentiality is a strict legal requirement of all healthcare workers. The Act on Healthcare assures that the right of professional secrecy that must be afforded to all patients.

#### 9.23.1.6 Implementation of Directive 95/46/EC

Slovakia adopted the Act No. 428/2002 on Protection of Personal Data which was amended in 2004 and 2005.<sup>666</sup>

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<sup>660</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#romania](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#romania)

<sup>661</sup> The National Council of the Slovak Republic. Act. No. 576/2004 Coll. On Healthcare and Healthcare-related Services. (2004) in Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Slovakia.

<sup>662</sup> Brazinová, I, Janská, E, Jurkovič, R, (2004) 'Implementation of patients' rights in the Slovak Republic' *Eubios Journal of Asian and International Bioethics* 14, 90-91.

<sup>663</sup> Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Slovakia

<sup>664</sup> This entered into force on the 8th May 1997

<sup>665</sup> Brazinová, I, Janská, E, Jurkovič, R, (2004) 'Implementation of patients' rights in the Slovak Republic' *Eubios Journal of Asian and International Bioethics* 14, 90-91.

<sup>666</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#slovakia](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#slovakia)

## 9.24 Slovenia

Slovenia recognizes a right to health care in its constitution.<sup>667</sup> Furthermore, health insurance is obligatory and must be provided by the state. In 2008 an act on patients' rights (Zakon o pacientovih pravicah, ZPacP 15/2008) was passed.<sup>668</sup>

### 9.24.1 Patients' rights

The new Act on Patients' Rights was welcomed as a necessary instrument to legalize patients' rights.<sup>669</sup> Considering fundamental principles like non-discrimination, dignity and self-determination, the Act regulates basic questions of access, quality, the right to information, and the possibilities of complaints.<sup>670</sup>

#### 9.24.1.1 Consent

The right to consent is given by the Slovenian Constitution through its provisions on personality and integrity and dignity.<sup>671</sup> The Patients' Rights Act additionally provides a more detailed description of this right stating that consent must be free, willful and informed.<sup>672</sup>

#### 9.24.1.2 Health information

Under the Personal Data Protection Act data subjects have a right to information about their own data. Furthermore, data can be supplemented, corrected, blocked or erased.<sup>673</sup> The right to revise and correct data can even be found in the Constitution.<sup>674</sup> The Patients' Rights Act further elaborates on the right to information and establishes in Article 20 that a right to be informed about the health status exists with an exemption for therapeutic reasons in Article 22.<sup>675</sup> This covers information about the success of the treatment, possible complications and the progress.<sup>676</sup>

#### 9.24.1.3 Medical records

The right to a medical record is established in the Health Services Act.<sup>677</sup> This has to be updated and stored by health professionals. Access is guaranteed under the Patients' Rights Act but also under the Personal Data Protection Act (in future eventually with an electronic health card). Whereas it is in general possible to amend data, changes are not allowed for the medical record.<sup>678</sup>

#### 9.24.1.4 Complaints

The right to complaint and to receive compensation are regulated in the Patients' Rights Act. Taking place under civil law the procedure can involve an ombudsman who is responsible for monitoring patients' rights.<sup>679</sup>

#### 9.24.1.5 Privacy and data protection

Privacy is guaranteed under Article 35 of the Slovenian Constitution.<sup>680</sup> Furthermore, the privacy of correspondence and communication is protected.<sup>681</sup> Article 38 of the Constitution establishes a right to data protection. *'The protection of personal data shall be guaranteed. The use of personal data contrary to the purpose for which it was collected is prohibited. The collection, processing, designated use, supervision and protection of the confidentiality of personal data shall be provided by law. Everyone has the right of access to the collected personal data that relates to him and the right to judicial protection in the event of any abuse of such data'*.<sup>682</sup> Slovenia has a Personal Data Protection

<sup>667</sup> The Constitution of the Republic of Slovenia (1991). *Official Gazette RS*, Nos. 33/91-I, 42/97, 66/2000 and 24/03, Article 51.

<sup>668</sup> Drnovsek, S., Giest, S., Dumortier, J. & Artmann, J. (2010). eHealth Strategies. Country Brief: Slovenia. Retrieved 06 March 2012 from: [http://ehealth-strategies.eu/database/documents/Slovenia\\_CountryBrief\\_eHStrategies.pdf](http://ehealth-strategies.eu/database/documents/Slovenia_CountryBrief_eHStrategies.pdf)

<sup>669</sup> Tit Albreht. "Patient rights to be enacted". *Health Policy Monitor*, October 2006. Available at <http://www.hpm.org/survey/si/a8/1>

<sup>670</sup> The Constitution of the Republic of Slovenia (1991). *Official Gazette RS*, Nos. 33/91-I, 42/97, 66/2000 and 24/03. Article 40.

<sup>671</sup> *Ibid.*, Articles 34 & 35.

<sup>672</sup> Znidarsic Skubic, V., Nys, H. (ed.)(2008). Patient Rights in the EU – Slovenia. European Ethical Legal Papers N° 16, Leuven.

<sup>673</sup> Personal Data Protection Act (2004). Articles 30 – 32 (Unofficial English translation). Retrieved 06 March 2012 from: [http://ec.europa.eu/justice/policies/privacy/docs/implementation/personal\\_data\\_protection\\_act\\_rs\\_2004.pdf](http://ec.europa.eu/justice/policies/privacy/docs/implementation/personal_data_protection_act_rs_2004.pdf)

<sup>674</sup> The Constitution of the Republic of Slovenia (1991). *Official Gazette RS*, Nos. 33/91-I, 42/97, 66/2000 and 24/03.

<sup>675</sup> European Patients' Forum (n.d.). Patients' Rights in the European Union.

<sup>676</sup> Znidarsic Skubic, V., Nys, H. (ed.)(2008). Patient Rights in the EU – Slovenia. European Ethical Legal Papers N° 16, Leuven.

<sup>677</sup> *Ibid.*

<sup>678</sup> Drnovsek, S., Giest, S., Dumortier, J. & Artmann, J. (2010). eHealth Strategies. Country Brief: Slovenia.

<sup>679</sup> European Patients' Forum (n.d.). Patients' Rights in the European Union.

<sup>680</sup> The Constitution of the Republic of Slovenia (1991). *Official Gazette RS*, Nos. 33/91-I, 42/97, 66/2000 and 24/03. Article 35

<sup>681</sup> *'The inviolability of the physical and mental integrity of every person, his privacy and personality rights shall be guaranteed.'*

<sup>682</sup> *Ibid.*, Article 37.

<sup>682</sup> *Ibid.*, Article 38.

Act transposing Directive 95/46/EC which applies the general principles with regard to data processing.<sup>683</sup> This Act prohibits the processing of sensitive data. However, a derogation exists with regard to medical data.<sup>684</sup>

#### 9.24.1.6 Implementation of Directive 95/46/EC

The Directive was implemented by the Personal Data Protection Act. First published in 1990 this ACT was renewed and replaced several times during the last two decades. The actual version is of 2004. Furthermore, Slovenia implemented an Information Commissioner Act.<sup>685</sup>

### 9.25 Spain

Next to the national legislation, the 17 autonomous regions of Spain have their own healthcare systems.<sup>686</sup> The system is completely decentralised but some strategic powers remain on national level.<sup>687</sup> This often leaves a gap between the regional and the national level.<sup>688</sup> The right to health protection is guaranteed by the Spanish Constitution.<sup>689</sup>

#### 9.25.1 Patients' rights

The Spanish law recognises patients' rights in the Basic Law 41/2002 on the Autonomy of the Patient and the Rights and Obligations with regard to Information and Clinical Documentation and the General Law on Public Health 14/1986. The new Basic Law has replaced the section on patients' rights from the law of 1986.<sup>690</sup>

##### 9.25.1.1 Consent

Chapter 4 of the Basic Law on Patient Rights regulates the right to consent. This consent has to be informed, free and conscious. This means that comprehensible information needs to be provided and that the decision must be voluntary. Consent can be withdrawn in writing.<sup>691</sup> In risky cases consent has to be given written.<sup>692</sup>

##### 9.25.1.2 Health information

Patients have the right to information. This concerns all information regarding their own health but also epidemiological information. The information can be given orally.<sup>693</sup> There is an exemption for therapeutic reasons.<sup>694</sup>

##### 9.25.1.3 Medical records

Patients have a right to a medical record. This should have, according to the Basic Law on Patients' Rights, details about the treatment process and about the involved care providers. Patients can access and copy their record. However, the new law is lacking provisions on a possible correction or deletion of the file.<sup>695</sup>

##### 9.25.1.4 Complaints

The new Patients' Rights Law does not cover complaints. The General Law on Public Health however grants the right to file a complaint. In case of compensation the General Consumers Protection Act needs to be used.<sup>696</sup>

<sup>683</sup> Personal Data Protection Act (2004). (Unofficial English translation).

<sup>684</sup> Ibid, Article 13.

<sup>685</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#slovenia](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#slovenia)

<sup>686</sup> Eleftheriou, A. (n.d.). Patients' Rights.

<sup>687</sup> Defloor, S., Nys, H., Dierickx, K. & Goffin, T. (2008). Patient Rights in the EU – Spain. *European Ethical-Legal Papers N°15*, Leuven.

<sup>688</sup> Eleftheriou, A. (n.d.). Patients' Rights.

<sup>689</sup> Spanish Congress & Senate (1978/1992). Spanish Constitution, Section 43. Retrieved 07 March 2012 from:

[http://www.senado.es/constitu\\_i/indices/consti\\_ing.pdf](http://www.senado.es/constitu_i/indices/consti_ing.pdf)

<sup>690</sup> Defloor, S., Nys, H., Dierickx, K. & Goffin, T. (2008). Patient Rights in the EU – Spain. *European Ethical-Legal Papers N°15*, Leuven.

<sup>691</sup> Ibid.

<sup>692</sup> Medinilla Corbellini, A., Giest, S., Artmann, J., Heywood, J. & Dumortier, J. (2010). eHealth Strategies. Country Brief : Spain. Retrieved 06 March 2012 from: [http://ehealth-strategies.eu/database/documents/Spain\\_CountryBrief\\_eHStrategies.pdf](http://ehealth-strategies.eu/database/documents/Spain_CountryBrief_eHStrategies.pdf)

<sup>693</sup> Ibid.

<sup>694</sup> European Patients' Forum (n.d.). Patients' Rights in the European Union.

<sup>695</sup> Defloor, S., Nys, H., Dierickx, K. & Goffin, T. (2008). Patient Rights in the EU – Spain. *European Ethical-Legal Papers N°15*, Leuven.

<sup>696</sup> European Patients' Forum (n.d.). Patients' Rights in the European Union.

### 9.25.1.5 Privacy and data protection

The rights to privacy and data protection can be found in different laws. The Basic Law on Patients' Rights includes a right to privacy including medical secrecy.<sup>697</sup> Additionally, this right is established in the Spanish Penal Code.<sup>698</sup> Privacy is also laid down in Section 18 of the Constitution which also restricts data processing to protect privacy.<sup>699</sup> The Spanish Law on the Protection of Personal Data provides for the processing of medical data under specific conditions. Limitations as purposefulness, necessity and medical secrecy must be taken into account. The data must be processed by a health professional.<sup>700</sup>

### 9.25.1.6 Implementation of Directive 95/46/EC

Spain introduced a data protection law which implemented the Directive in 1999 (Ley Orgánica 15/1999, de 13 de diciembre de Protección de Datos de Carácter Personal).<sup>701</sup>

## 9.26 Sweden

### 9.26.1 Patients' rights

The notion of Patients' rights in Sweden are covered by several pieces of legislation<sup>702</sup>. The Health and Medical Personal Duties Act, in addition to the Code on Parents, Guardians and Children are two important sources. Patient rights are also contained in a Charter by the Federation of County Councils. This charter has no force however as a legally binding instrument.<sup>703</sup>

#### 9.26.1.1 Consent

All medical treatments demand the consent of the patient.<sup>704</sup>

#### 9.26.1.2 Health information

The Health and Medical Services Act states that patients must be informed of their state of health and of the treatment methods available within the county council area. This includes diagnostic methods available within the district. This requirement is also provided in the Health and Medical Personnel Act (1994:953). This Act demands that healthcare professionals will, to the greatest extent possible, cooperate with the patient when planning the treatment and when carrying out that treatment. This requires that the individual concerned is furnished with information about their condition and the treatment options that are available.<sup>705</sup>

#### 9.26.1.3 Medical records

The patient has a right to access their own medical dossier. The Patient Journal Act states that the patient also has the right to obtain a copy of this journal.

#### 9.26.1.4 Complaints

Every county council must have a local advisory committee where patients can file complaints. The Patient Insurance Act contains provisions regarding the right of patients to compensation when suffering an injury. Additionally the Tort Liability Act covers this section. Sweden has had a patient insurance system to compensate patients for health-related injuries since 1975. This system was

<sup>697</sup> Ibid.

<sup>698</sup> European Patients' Forum (n.d.). Patients' Rights in the European Union.

<sup>699</sup> Spanish Congress & Senate (1978/1992). Spanish Constitution, Section 18. *'The law shall restrict the use of data processing in order to guarantee the honour and personal and family privacy of citizens and the full exercise of their rights.'*

<sup>700</sup> ORGANIC LAW 15/1999 of 13 December on the Protection of Personal Data (1999). (Unofficial English Translation), Article 7(6). Retrieved 07 March 2012 from:

[http://www.coe.int/t/dghl/standardsetting/dataprotection/National%20laws/SPAIN\\_Organiclaw\\_15\\_99.pdf](http://www.coe.int/t/dghl/standardsetting/dataprotection/National%20laws/SPAIN_Organiclaw_15_99.pdf)

<sup>701</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from:

[http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#spain](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#spain)

<sup>702</sup> Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Sweden

<sup>703</sup> Katholieke Universiteit Leuven. European Centre for Biomedical Ethics and Law. Patients' Rights Legislation in Sweden. (2008) in Patients' Rights in the European Union, The European Patients Forum (2009) – see section concerning Sweden

<sup>704</sup> A brief description of how the derivation of the Informed Consent in various circumstances can be found at [http://europatientrights.eu/countries/signed/sweden/sweden\\_right\\_to\\_informed\\_consent.html](http://europatientrights.eu/countries/signed/sweden/sweden_right_to_informed_consent.html) e.g. "Included in the duty of the medical personnel to treat the patient with consideration and respect is also the requirement that no patient must be forced to take a certain treatment or care. This means that all methods, interventions and, medical care demand the consent of the patient. Health and Medical services shall be conducted so as to meet the requirements of good care - one such requirement being the obligation to respect the patient's self determination. Care and treatment shall as far as possible be designed and conducted in consultation with the patient."

<sup>705</sup> Ibid

initially based on a voluntary patient insurance solution but, in 1997, the Patient Insurance Act replaced it<sup>706</sup>. The law contains provisions regarding the right to injury compensation and the duty of the care provider to carry patient insurance that covers compensation for injuries. In Sweden the county councils are responsible for most medical services and are therefore the target of most compensation claims.

#### 9.26.1.5 Privacy and data protection

Several Acts and Laws provide the right of privacy in Sweden. Among them are the Health and Medical Services Act, the Secrecy Act and the Care Registrations Act. Both medical secrecy and privacy issues are tackled within these documents.

#### 9.26.1.6 Implementation of Directive 95/46/EC

Sweden implemented the Directive through the Personal Data Act in 1998.<sup>707</sup>

### 9.27 United Kingdom

#### 9.27.1 Patients' rights

There is no one general legally binding patient rights instrument for the UK. The awareness of patients' rights began to emerge as strong force during the 1990's. The Patients' Charter was created in 1991. It linked ideas of individual rights and quality of service with the organizational reforms of the National Health Services (NHS). The Patients' Charter outlined rights and national standards, including the right to healthcare; physical security; freedom of choice; information; privacy; and the right to complain, the idea being to improve service quality and to give more value to the views of patients and care givers<sup>708</sup>. The recognition of the European Convention of Human Rights<sup>709</sup> has allowed patients to secure these rights through the UK's civil court system<sup>710</sup>. In addition to this case law, the NHS Constitution<sup>711</sup> also gives some direction of patients' rights in the UK and represents the latest version of what was started in the Patients' Rights Charter. The General Medical Council has produced numerous guidelines stating that consent should be sort before treatment is started. This has also been upheld in court with regard to patient human rights in court.<sup>712</sup>

##### 9.27.1.1 Consent and health information

This right is thus intertwined with the right to informed consent. Directive 95/46/EC (the Data Protection Directive on which the UK Data Protection Act is based) defines 'the data subject's consent' as 'any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed'. This means that in order for individuals to give a valid consent to a possible treatment option they should be adequately informed.

##### 9.27.1.2 Medical records

The right of access is contained in the Data Protection Act of 1998. Patients consequently have a right of access to their medical record at all times. The right of access has however been defined in a limited manner in *Durant v. The Financial Services Authority*.<sup>713</sup> There, the court stated that the right of access is primarily connected to the idea of determining accuracy and ensuring that the privacy<sup>714</sup> of the individual has been protected. The Act does not provide a general right of discovery that can for example be used in litigation to search for information on liability.

<sup>706</sup> Johansson., H, (2010) 'The Swedish system for compensation of patient injuries' *Ups J Med Sci.* 115(2): 88–90.

<sup>707</sup> European Commission (2010). Status of Implementation of Directive 95/46 on the Protection of Individuals with regard to the Processing of Personal Data. Retrieved 02 March 2012 from: [http://ec.europa.eu/justice/policies/privacy/law/implementation\\_en.htm#sweden](http://ec.europa.eu/justice/policies/privacy/law/implementation_en.htm#sweden)

<sup>708</sup> See Eleftheriou., A, 'Patients Rights' Published by The Thalassaemia Internaitonal federation No:7 ISBN 978-9963-623-42-6

<sup>709</sup> Human Rights Act 1998

<sup>710</sup> Cases of note include: *Regina (Hooper and Others) v Secretary of State for Work and Pensions* Court of Appeal, 18 June 2003; *House of Lords*, 5 May 2005, *R (Burke) v General Medical Council (Disability Rights Commission interested party)* High Court, 30 July 2004, *Glass v UK European Court of Human Rights*, 9 March 2004, *Bernard v Enfield High Court*, 25 October 2002. For a comprehensive review Equality, Dignity and Discrimination under Human Rights Law; selected cases

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<sup>711</sup> For England the relevant document is The NHS Constitution for England – 21 January 2009

<sup>712</sup> See for example *R (Burke) v General Medical Council (Disability Rights Commission interested party)* High Court, 30 July 2004

<sup>713</sup> *Durant v FSA* Court of Appeal, 8 December 2003, Case No: B2/2002/2636.

<sup>714</sup> The defined information that affects an individual's privacy as "information that affects [a person's] privacy, whether in his personal or family life, business or professional capacity"



### 9.27.1.3 Complaints

Complaints can be filed within the National Health Service. If this does not lead to a satisfying reply the Ombudsman can also be advised. Individuals also have the right to an administrative review of decisions and if justified redress to the court system where legal rights are violated.

### 9.27.1.4 Privacy and data protection

The Common Law covers the relationship regarding doctors and patients and the need for confidentiality. Doctors are required to respect the confidentiality of the patients. Rights connected to privacy better protected through the Data Protection Act.

### 9.27.1.5 Implementation of Directive 95/46/EC

The Data Protection Act, produced in 1998 is the primary element of the UK's data protection approach.<sup>715</sup>

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<sup>715</sup> The Data Protection Act (1998). The Act is 86 pages long (including no less than 16 Schedules) and is supplemented by a series of Orders, Rules and Regulations. The Act was adopted on 16 July 1998, but did not come into force until 1 March 2000, after the first subsidiary regulations had been issued.