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The EU legal framework on e-health

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1. Introduction

The European single market in health care is developing despite the existence of many different health care systems. With cross-border activities in health care increasing, patients tend to be treated in other Member States more often than in the past, especially since there are waiting lists in some countries. Moreover, doctors ask for more and varied telematic information from their colleagues than previously, and health care professionals, hospitals and laboratories use more and more information and communication technology (ICT) applications to communicate health data for treatment and other purposes. Many health care players (like sickness funds, hospitals, laboratories, etc.) are European health care actors and feel the need to communicate health data between Member States for treatment and other purposes. Consumers, on the other hand, use the Internet to search for medical information or to order medicinal products from pharmacies that are located in other countries. Many of these developments are related to e-health.¹ E-health describes the application of information and communication technologies across the whole range of functions that affect the health care sector. According to the European Commission, e-health comprises the following four interrelated categories of applications: (a) clinical information systems; (b) telemedicine and home care, personalized health systems and services for remote patient monitoring, teleconsultation, telecare, telemedicine and teleradiology; (c) integrated regional/national health information networks, distributed electronic health record systems and associated services such as e-prescriptions or e-referrals; and (d) secondary usage of non-clinical systems (such

¹ See S. Boillat and S. Callens, 'The sale of medicinal products by mail-order in Europe', *Yearbook of European Medical Law* (2005), 57–62.

as specialized systems for researchers, or support systems such as billing systems).²

Despite the fact that health services are excluded from the application of the Directive on Services in the Internal Market (Directive 2006/123/EC of 12 December 2006),³ it is obvious that the Commission has enacted many rules related to health care and that these rules have an important impact on health care systems, including the creation of an EU legal framework for e-health. This chapter aims to describe this legal framework and some European policy initiatives on e-health. It will not analyse whether or not e-health is having an important effect on health care systems,⁴ but rather how European rules have been created that are important for the functioning of e-health, and therefore also for health care players and health care systems.⁵ It is clear that e-health in itself has an impact on health care. Health care systems are part of wider systems, such as social welfare systems and society. Therefore, evolutions in society, such as developments regarding information and telecommunication technology, as well as rules related to ICT, will influence health care systems. Section two describes some important European rules that may apply to e-health but which often are not known by actors in the health care system. These relate to the processing of personal data, the delivery of information society services, the use of medical devices, the conclusion of contracts at a distance and agreements that may have an influence on the competition between undertakings. Section three deals with European Union policy related to e-health. Despite the fact that many existing rules can be applied to e-health and despite the attention given to it by the Commission, there are still important issues that have to be clarified at the EU level in order to ensure that e-health

² eHealth Taskforce, 'Accelerating the Development of the eHealth Market in Europe', eHealth Taskforce Report (2007), p. 10.

³ European Parliament and Council Directive 2006/123/EC on services in the internal market, OJ 2006 No. L376/36.

⁴ For the impact of some e-health developments, see www.ehealth-impact.org. See also E. Mossialos, S. Thomson and A. Ter Linden, 'Information technology law and health systems in the European Union', *International Journal of Technology Assessment in Health Care* 20 (2004), 498.

⁵ It is clear that other legal rules may be important for e-health, such as the rules on intellectual property rights or the Notification Directive 98/34/EC. Since these rules do not pose specific issues related to e-health, they are not described in this chapter.

will play an even more important role in health care systems than is the case today. Therefore, section four lists some key issues and provides suggestions for legal initiatives at the EU level.

2. European legal instruments related to e-health

A. *The Data Protection Directive*

On 24 October 1995, the Council adopted 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 (the Data Protection Directive).⁶ The Directive contains several important principles that require compliance from e-health actors that process personal data concerning health. If national health care systems or other e-health actors create health grids, electronic national records or information systems that may be used for treatment, quality review or research purposes, they have to comply with the principles of the Data Protection Directive.

The Data Protection Directive aims to protect individuals with regard to the processing of personal data, and at the same time allows the free movement of such data. The Directive applies to the processing of personal data wholly or partly by automatic means, and to the processing of personal data by other means, which form part of a filing system or are intended to form part of a filing system. Article 8 of the Directive prohibits the processing of personal data concerning health. However, this prohibition does not apply where the processing of health data⁷ is required, for example, for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment

⁶ The 'Data Protection' Directive, Council 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, OJ 1995 No. L281/31.

⁷ Case C-101/01, *Lindqvist* [2003] ECR I-12971. The ECJ stated in *Lindqvist* that the act of referring, on an Internet page, to various persons and identifying them by name or by other means constitutes 'the processing of personal data wholly or partly by automatic means' within the meaning of Article 3(1) of the Data Protection Directive (above n.6). Such processing of personal data in the exercise of charitable or religious activity is not covered by any of the exceptions in Article 6(2). In this case, the fact that it was mentioned on the Internet that an individual had injured her foot and was on half-time leave on medical grounds constitutes personal data concerning health within the meaning of Article 8(1) of the Data Protection Directive.

or the management of health care services, and where such data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional confidentiality or by another person also subject to an equivalent obligation of confidentiality.

According to the Data Protection Directive, personal data used in e-health projects must be processed fairly and lawfully. Furthermore, data must be collected for specified, explicit and legitimate purposes and not further processed in a way that is incompatible with those purposes. The data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and must be kept in a form that permits identification of data subjects for no longer than is necessary and only for the purposes for which the data was collected or is required for further processing. Data subjects also have to be informed about the processing of their personal data.

Regarding the transfer of data between Member States, for example, for treatment purposes, in the case of e-health projects a data controller established in the territory of one Member State can be sure that in transferring data to another controller established in another Member State this data will be correctly protected, since the second Member State will provide for a similar level of protection of personal data.⁸ With regard to the transfer of data to third countries, the Directive stipulates that the Member States shall provide that the transfer of personal data that are undergoing processing, or are intended for processing after transfer, may take place only if, without prejudice to compliance with national provisions adopted pursuant to the other provisions of the Directive, the third country in question ensures an adequate level of protection.⁹ The adequacy of the level of protection afforded by the third country will be assessed in light of all the circumstances surrounding a data transfer operation or set of data transfer operations. Particular consideration is given to the nature of the data, the purpose and duration of the proposed processing operation or operations, the country of origin and country of final destination, the rules of law, both general and sectoral, in force in the third

⁸ Article 25, 'Data Protection' Directive, above n.6.

⁹ See also H. Rowe, 'Data transfer to third countries: the role of binding corporate rules', *Computer Law & Security Report* 19 (2003), 490–496.

country in question, and the professional rules and security measures that are complied with in that country.¹⁰

Since personal data (including personal data concerning health) is often transferred between the EU and the United States, and since there was uncertainty about the impact of the 'adequacy' standard on personal data transfers from the European Community to the United States, the United States Department of Commerce issued the 'Safe Harbor Principles' under its statutory authority to foster, promote and develop international commerce. The European Commission has recognized these Safe Harbor Principles in Decision 2000/520/EC of 26 July 2000.¹¹ These principles were developed in consultation with industry and the general public to facilitate trade and commerce between the United States and the European Union. They are intended for use solely by United States organizations receiving personal data from the European Union for the purpose of qualifying for the 'Safe Harbor' and the presumption of 'adequacy' it creates. The Safe Harbor Principles consist of seven principles and a few frequently asked questions (FAQs). FAQ 14 deals with the relationship between the Safe Harbor Principles and pharmaceutical and medical products. If personal data is collected in the EU and transferred to the United States for pharmaceutical research or other purposes, Member State law applies to the collection of the personal data and to any processing that takes place prior to the transfer to the United States. However, the Safe Harbor Principles apply to the data once they have been transferred to the United States. It should be noted that research

¹⁰ For exceptions to Article 25 of the 'Data Protection' Directive, see Article 26(1) and Article 26(2) of the Directive; see also I. Andoulsi *et al.*, 'Bottlenecks and challenges and RTD responses for legal, ethical, social and economic aspects of healthgrids', Roadmap I 2008, p. 21, <http://eu-share.org/deliverables.html>. The Data Protection Directive also states that Member States may authorize a transfer or a set of transfers of personal data to a third country that does not ensure an adequate level of protection of personal data, where the controller adduces adequate safeguards through appropriate contractual clauses between the sender and the recipient of the personal data. In this context, the European Commission has proposed standard contractual clauses that ensure an adequate level of protection of transferred personal data.

¹¹ Commission Decision 2000/520/EC pursuant to European Parliament and Council Directive 95/46/EC on the adequacy of the protection provided by the safe harbour privacy principles and related frequently asked questions issued by the US Department of Commerce, OJ 2000 No. L215/7.

data are often uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects, and pharmaceutical companies sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he/she can identify the research subject under special circumstances. Therefore, the transfer of data coded in this way from the European Union to the United States does not constitute a transfer of personal data that is subject to the Safe Harbor Principles.¹²

B. The E-commerce Directive

Directive 2006/123/EC on services in the internal market does not apply to non-economic services of general interest and to health care services. Nevertheless, health care actors that utilize e-health may be considered to be providing information society services and may have to comply with another important directive related to services, the Directive 2000/31/EC on certain legal aspects of information society services in the internal market (the so-called 'E-commerce Directive').¹³

The E-commerce Directive applies to information society services that are defined as any service normally provided for remuneration, at a distance, by electronic means,¹⁴ for the processing (including digital compression) and storage of data, and at the individual request of a recipient of a service.¹⁵ 'At a distance' means that the service is provided without the parties simultaneously being present.¹⁶ Since the economic activities of an information society service can consist of

¹² Commission Decision 2000/520/EC, above n.11, Annexe II – frequently asked questions 14, 1 and 7. The issue of data transfer is a delicate issue as the SWIFT has shown; see Article 29, Data Protection Working Party, 'Opinion 10/2006 on the processing of personal data by the Society for Worldwide Interbank Financial Telecommunication (SWIFT)', WP 128, 22 November 2006.

¹³ The Directive on Electronic Commerce, European Parliament and Council Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal market, OJ 2000 No. L178/1. For more guidance on the Directive, see S. Callens, 'Telemedicine and the E-Commerce Directive', *European Journal of Health Law* 9 (2002), 93–109.

¹⁴ Communication by phone, fax or mobile phone does not fall under the Directive.

¹⁵ The recipient can be a patient or a physician asking for an opinion.

¹⁶ P. Van Eecke, 'Electronic Health Care Services and the E-Commerce Directive', in J. Dumortier, F. Robben and M. Taeymans (eds.), *A decade of research@the crossroads of law and ICT* (Ghent: Larcier, 2001), p. 369.

services giving rise to online contracting, several e-health applications can be the subject of an information society service. The E-commerce Directive may apply to online medicine purchases, as well as to services consisting of the transmission of information via a communication network, or that provide access to a communication network. The E-commerce Directive may also be applicable to the use of electronic research registers by physicians who pay a fee to access a file, to physicians who use a web site to promote their activities, or for the sending of medical information among physicians against remuneration.¹⁷

The Directive obliges e-health actors who act as an information society service to provide the recipients of the service and competent authorities with easily, directly and permanently accessible information on the service providers and, where their activity is subject to an authorization scheme, the particulars of the relevant supervisory authority, any professional body or similar institution with which they are registered, as well as which professional titles they have obtained, which Member State has granted these titles, which applicable professional rules in the Member State of establishment are applicable and what means exist to access them. According to the Directive, Member States must ensure that e-health actors who act as information society services indicate any relevant codes of conduct to which they subscribe and information on how those codes can be consulted electronically.¹⁸

Member States have to ensure that the take-up and pursuit of the activity of an information society service provider (including an e-health actor) may not be made subject to prior authorization or any other requirement having equivalent effect (Article 4(1)). Article 4(1) shall be without prejudice to authorization schemes that are not specifically and exclusively targeted at information society services, or that are covered by Directive 97/13/EC on a common framework for general authorizations and individual licences in the field of

¹⁷ See also *ibid.*, p. 375.

¹⁸ In order to facilitate the free provision of services in general, there are specific rules aimed at the abolition of obstacles to the free movement of persons and services, which extend the possibility of pursuing professional activities under the original professional title. European Parliament and Council Directive 2005/36/EC on the recognition of professional qualifications, OJ 2005 No. L255/22, can also be applicable. Yet the Directive does not cover the situation where the health professional and the patient are not simultaneously present. (European Commission, 'Telemedicine for the benefit of patients, healthcare systems and society', Commission Staff Working Paper, SEC (2009) 943, June 2009); see Chapter 14 in this volume.

telecommunications services. This very important principle, as laid down in Article 4 of the E-commerce Directive, is a major challenge for national e-health networks or telemedicine projects for which the competent public authorities want to provide reimbursement under certain conditions.

C. Medical Device Directives

The Medical Device Directives¹⁹ harmonize the rules pertaining to the free circulation of medical devices in the EU. Products that fall within their scope must meet all applicable essential safety and administrative requirements and must bear an EC-conformity mark to show that they comply with the Directive. Such products may then be sold throughout the European Economic Area without, in principle, being the subject of additional national legislation. These Medical Device Directives are of importance for the e-health sector, especially with regard to medical software that is used in many e-health applications. The Medical Device Directives define a medical device as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specially for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for, among other things, the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap and the control of conception. Software for general purposes, when used in an e-health project, is not a medical device. However, software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device.

In the context of the Directive, manufacturers are obliged to place on the market or to put into service only medical devices that do not compromise the safety and health of patients, users and other persons, when properly installed, maintained and used in accordance

¹⁹ European Parliament and Council Directive 2007/47/EC amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EEC concerning the placing of biocidal products on the market, OJ 2007 No. L247/21.

with their intended purpose. The manufacturer must design and manufacture medical devices in such a way that some essential requirements are met, such as taking into account the generally acknowledged state-of-the-art and to eliminate or reduce risks as much as possible. Devices that are in accordance with national provisions that have transposed the existing European harmonized standards will be presumed by EU Member States to be compliant with the essential requirements laid down by the Directive.²⁰ Devices other than those that are custom-made or intended for clinical investigation must bear an EC-conformity mark when placed on the market.²¹ Clinical evaluation is also required and it will remain to be seen how this obligation will be fulfilled by medical software vendors. Directive 2007/47/EC of 5 September 2007, amending Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices,²² Council Directive 93/42/EC concerning medical devices²³ and Directive 98/8/EC concerning the placing of biocidal products on the market²⁴ clarify that clinical evaluation is needed for every medical device.²⁵ This clinical evaluation can be done in different ways – for instance, by means of a critical evaluation based on the scientific literature in that area or by means of results from a clinical investigation, or by combining both methods.²⁶ For active implantable devices and Class III devices, there must always be a clinical investigation.²⁷ Therefore, clinical investigation will be necessary for medical implantable software or software listed under Class III.²⁸

D. Directive on Distance Contracting

E-health business may involve the conclusion of contracts. These contracts contain the description of the various parties' obligations and,

²⁰ Article 5, Directive 93/42/EC concerning medical devices, OJ 1993 No. L169/1.

²¹ Article 4, *ibid.* ²² Directive 2007/47/EC, above n.19.

²³ Directive 93/42/EC, above n.20.

²⁴ Directive 98/8/EC concerning the placing of biocidal products on the market, OJ 1998 No. L123/1.

²⁵ Directive 2007/47/EC, above n.19, Recital 8. ²⁶ *Ibid.*, Annexe 10, 1.1.

²⁷ *Ibid.*

²⁸ Medical devices are divided into classes. For the classification rules, see Directive 93/42/EC, above n.20, Annexe IX.

often, special clauses. A contract related to e-health concluded between a professional and a consumer (for example, a contract between a patient and a tele-expert or a contract between a patient and a pharmacist regarding the delivery of medicinal products) may be the subject of a contract at a distance. The Directive on Distance Contracting²⁹ will apply to any contract concerning goods or services concluded between a supplier and a consumer under an organized distance sales or service-provision scheme run by the supplier, who, for the purpose of the contract, makes exclusive use of one or more means of distance communication up to and including the moment at which the contract is concluded. In good time prior to the conclusion of any distance contract, the consumer shall be provided with sufficient information on the identity of the supplier, the main characteristics of the services, the price of the services, the arrangements for payment, delivery or performance, and the existence of a right of withdrawal. Consumers must receive written confirmation or confirmation in another durable medium available and accessible to them of the information mentioned above, in good time, during the performance of the contract, unless the information already has been given, with the same provisos, prior to conclusion of the contract. For any distance contract, consumers will have a period of at least seven working days in which to withdraw from the contract without penalty and without giving any reason.

E. Directive on Electronic Signatures

E-health projects often require the use of electronic signatures. Essential in an information society, the European Union has promoted the use of electronic signatures, which are to be treated as equal to hand-written signatures. An electronic signature is a generic technology-neutral term covering the methods by which electronic records can be signed and can be created by different technologies. The electronic signature is a key tool to ensure confidentiality, integrity and authenticity in the transfer of health data between electronic sources. Article 3(7) of the Directive on Electronic Signatures³⁰ states

²⁹ European Parliament and Council Directive 97/7/EC on the protection of consumers in respect of distance contracts, OJ 1997 No. L144/19.

³⁰ European Parliament and Council Directive 1999/93 on a Community framework for electronic signatures, OJ 2000 No. L13/12.

that Member States may make use of electronic signatures in the public sector subject to possible additional requirements. However, such requirements shall be objective, transparent, proportionate and non-discriminatory, and shall relate only to the specific characteristics of the application concerned. Such requirements may not constitute an obstacle to cross-border services for citizens.

F. Competition law

The European Union seeks to create a single internal market characterized by open competition. Therefore, a system of competition law has been developed whose central aim is to prevent the disruption of free competition or to neutralize any such disruption.³¹

Community competition rules prohibit undertakings from participating in anti-competitive activities, such as agreements to set prices or abuse of dominant position.³² Article 81 of the EC Treaty prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices that may affect trade between Member States and that have as their object or effect the prevention, restriction or distortion of competition within the common market. Article 82 prohibits abuse of a dominant position by one or more undertakings. Article 86 of the EC Treaty is also important in the area of health care, permitting as it does partial exemption from the competition rules for some undertakings. This article states that undertakings entrusted with the operation of services of general economic interest shall be subject to the rules contained in this Treaty, in particular the rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Community.

The rules of European competition law, for example, can apply to electronic networks. Independent health care practitioners may have a common computer server to exchange patient information. Such collaboration does not come under the prohibition of cartels, if some

³¹ For a detailed description of the competition rules, see Chapters 7 and 8 in this volume.

³² Articles 81 and 82 EC.

conditions are fulfilled. Firstly, the electronic system in principle may not be used for the exchange of competitively sensitive information about prices, turnover,³³ etc., as the exchange of such information can lead undertakings to no longer compete with one another. Secondly, an information network, in principle, has to be open. If the participants of a network benefit from this network and these economic benefits cannot be achieved by others who do not participate, a situation will be created where it will be very hard for health care practitioners to establish themselves in the market.³⁴

3. EU policy related to e-health and its impact on health care systems

The Commission was and still is aware that e-health and/or telemedicine may contribute to delivering better quality of care and to a better involvement of patients in the management and follow-up of their health condition.³⁵

In December 1999, the Commission launched the so-called ‘e-Europe initiative’ (‘e-Europe – an information society for all’). The initiative was a political enterprise to ensure that the European Union would fully benefit from the changes brought about by the burgeoning information society. The e-Europe Action Plan initially identified ten areas where action at a European level would add value. These actions were revised in view of the Lisbon European Council in 2000,³⁶ and the actions were clustered around three main objectives: first, a cheaper, faster and secure Internet; second, investing in people and skills; and, third, stimulating the use of the Internet. This initiative saw the start

³³ See also A. Beurden, ‘The European perspective on e-health’, in S. Callens (ed.), *E-health and the law* (Den Haag: Kluwer, 2003), pp. 106–8.

³⁴ Dutch National Competition Authority, ‘Richtsnoeren voor de Zorgsector’, Report of the Dutch National Competition Authority (2001), www.zemagazine.nl/dsc?c=getobject&s=obj&objectid=11882&!sessionid=11zySrobBaqs7154qVBDU@t5G78Ld!zmQ!2Az1JIodvhoUhcP3M4aGxJh@OuGEX&!dsname=bsl.

³⁵ European Commission, ‘Questionnaire, tele-medicine’, I2010 eHealth sub group Members (2007), p. 2; European Commission, ‘A lead market initiative for Europe’, COM (2007) 860 final, 21 December 2007, p. 5.

³⁶ The e-Europe Action Plan 2002 was adopted by the Commission on 14 June 2000 and endorsed by the European Council in Feira, Portugal on 19–20 June 2000, http://ec.europa.eu/information_society/eeurope/2002/action_plan/pdf/actionplan_En.pdf.

of the Health Online Action, underlining that the European Union recognizes the strategic importance of fully exploiting new technologies in health care.³⁷ Policy actions detailed under the Health Online Action were as follows: to ensure that primary and secondary health care providers have a health telematics infrastructure in place, including regional networks; to identify and disseminate best practice in electronic health services in Europe, and to set benchmarking criteria; to establish a set of quality criteria for health-related web sites; to establish health technology and data assessment networks; and to publish a Communication on the 'legal aspects of e-health'.³⁸

The High Level Committee on Health has established a Working Group on Health Telematics. This Working Group was asked to review the introduction of information and communication technology (ICT) in the health sector, the factors promoting or inhibiting its development, and areas where Community legislation could be beneficial. The Group considered particular applications of ICT in health; namely, health cards, virtual hospitals and provision of health-related information to health professionals and patients. Their report was accepted by the High Level Committee on Health in April 2003.³⁹

E-health still receives a great deal of attention at the EU level, and the Commission has invested in several research programmes related to this area.⁴⁰ Moreover, in 2004, it established an Action Plan for a European E-health Area,⁴¹ in which health and health care formed a key part of the Commission's vision for an information society where a new generation of computerized clinical systems, advanced telemedicine services and health network applications improve health, continuity of care and allow citizens to be more involved in, and assume greater responsibility for, their own health. The Commission believed that e-health would be an instrument for restructured, citizen-centred health care systems, which, at the same time, respects the diversity of Europe's multicultural,

³⁷ Beurden, 'The European perspective', above n.33, pp. 99–103. See also http://ec.europa.eu/information_society/eeurope/ehealth/index_en.htm.

³⁸ See the e-Europe Action Plan 2002, above n.36.

³⁹ http://ec.europa.eu/health/ph_overview/Documents/hlch_health_telematics_final_report_en.pdf.

⁴⁰ European Commission, 'eHealth portfolio of projects', European Commission Information Society and Media (2007), http://ec.europa.eu/information_society/activities/health/docs/publications/fp6upd2007/fp6intro1.pdf.

⁴¹ European Commission, 'e-Health – making healthcare better for European citizens: an action plan for a European e-Health Area', COM (2004) 356 final, 30 April 2004.

multilingual health care traditions.⁴² The Commission was and still is of the opinion that e-health can be an important tool for creating a citizen-centred health system,⁴³ and that it can facilitate cooperation between health actors⁴⁴ in Europe. According to the Commission, e-health will enable higher-quality, effective health care that is safe, empowering and accessible for patients and cost-effective for governments.⁴⁵ It is of no surprise that, in its report of 21 December 2007, the Commission considered e-health to be one of the six leading markets in Europe.⁴⁶

Nevertheless, the Commission has observed a low take-up of telemedicine applications in real-life medicine. It is now identifying the barriers and triggering factors for greater use of e-health applications, and has issued, on 4 November 2008, a Communication on telemedicine for the benefit of patients, healthcare systems and society.⁴⁷ According to the Commission, Member States should have assessed and adapted by the end of 2011 their national regulations enabling wider access to telemedicine services. Issues such as accreditation, liability, reimbursement, privacy and data protection should be addressed.⁴⁸ The Commission has also drawn up a report on accelerating the development of the European e-health market, stating that the prospective return on e-health investment is relatively high when compared to the costs inherent in the health sector.⁴⁹ In its recent proposal for a directive on the application of patients' rights in cross-border health care,⁵⁰ the

⁴² *Ibid.* ⁴³ *Ibid.*

⁴⁴ See also the recent European Commission, 'Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health records', C (2008) 3282 final, 2 July 2008.

⁴⁵ European Commission and Member States, 'eHealth Conference 2007 Final Declaration', 17 April 2007. See also European Commission, 'A lead market initiative', above n.35.

⁴⁶ European Commission, 'A lead market initiative', above n.35.

⁴⁷ European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society', COM (2008) 689 final, 4 November 2008.

⁴⁸ The Working Paper of the Commission, European Commission, 'Telemedicine for the benefit of patients, healthcare systems and society', above n. 18, aims to provide additional information supporting the communication of 4 November 2008.

⁴⁹ eHealth Taskforce, 'Accelerating the Development', above n.2, p. 5.

⁵⁰ European Commission, 'Proposal for a European Parliament and Council Directive on the application of patients' rights in cross-border healthcare', COM (2008) 414 final, 2 July 2008.

Commission referred also (albeit rather briefly) to e-health. Article 16 of this proposal states that the Commission shall:

[A]dopt specific measures necessary for achieving the interoperability of information and communication technology systems in the health care field, applicable whenever Member States decide to introduce them. Those measures ... shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.

Despite the attention given to several legal issues related to e-health at the EU level, it is our opinion that a more detailed legal framework is needed to allow the use of this activity in health care systems, and one that takes into account all the interests at stake, such as data protection, public health, quality of care, cost-effectiveness, etc. The issues that need more European involvement are related to legal provisions (for example, rules are needed on liability and reimbursement matters; see section four, subsections B and C below) and to new technical developments (for example, the existence of health grids, electronic health records, e-health platforms, and further use of genetic data and tissue; see section four, subsection A).

4. Legal challenges to promote e-health

A. *New challenges due to new e-health applications*

Electronic health records and e-health platforms

Several Member States are shifting from using electronic health insurance cards to electronic health records or e-health platforms⁵¹ in order to

⁵¹ In Belgium, a new law establishing an 'e-health platform' was passed on July 2008 and published in the Official Journal on 13 October 2008. The e-health platform will be a protected electronic exchange platform where all healthcare practitioners can exchange information with due regard for privacy rules. The e-health platform aims to optimize the quality and continuity of health care, optimize the safety of patients, promote administrative simplification, and support health policy-making. The aim is to exchange information among all actors in the health care sector, with guarantees for information safety and privacy protection. In contrast to an electronic health record, the e-health platform will be a decentralized way of storing and exchanging medical data. The e-health platform itself does not contain much data but indicates nevertheless the places where relevant data can be found.

make available health data for medical treatment and allied purposes. It is argued by public authorities that electronic health records may improve quality of care⁵² and patient safety and they also can be used as an instrument to control the rising demand for (and cost of) health services.⁵³ Electronic health records should facilitate the appropriate treatment of patients by providing health professionals with a better knowledge of a patient's history and previous interventions by other medical practitioners.⁵⁴ According to the Commission, improvements in patient safety can be achieved if information concerning patients is managed in a more systematic manner by everyone involved in health care provision or standards.⁵⁵ However, the use of electronic health records that contain data supplied by several health actors poses new risks, with some legal consequences (see below).

The Data Protection Commission at the European level, the so-called Article 29 Data Protection Working Party,⁵⁶ has adopted an interesting document on the processing of personal data relating to health in electronic health records (EHR).⁵⁷ This document aims to provide guidance on the way to apply the data protection legal framework to electronic health record systems. The analysis of the Working Party is certainly necessary, since many health care players do not always seem to know how to comply with the Data Protection Directive. The Working Party also has made an important recommendation for politicians, in that it recommends the laying down of special safeguards for the electronic health record system within a special

⁵² However, secure and fast access to patient information will require the interoperability of health records.

⁵³ European Commission, 'e-Health', above n.41, p. 5. The lack of standards has pushed up the cost of development and customization, which has held back the e-health industry from more substantial investment in e-health solutions. See European Commission, 'e-Health', above n.41, p. 13.

⁵⁴ *Ibid.*, p. 8.

⁵⁵ European Commission and Member States, 'eHealth Conference 2007 Declaration', above n.45.

⁵⁶ See Articles 29 and 30, 'Data Protection' Directive, above n.6. Article 29 sets up a Working Party on the protection of individuals with regard to the processing of personal data, hereinafter referred to as 'the Working Party'. The Working Party advises and makes recommendations on all matters relating to the protection of persons with regard to the processing of personal data in the Community.

⁵⁷ Article 29 Data Protection Working Party, 'Working document on the processing of personal data relating to health in electronic records', WP 131, 15 February 2007.

comprehensive legal framework. This framework has to provide for, among other things, the following safeguards: it should be possible for patients, at any time, to prevent the disclosure of, and access to, their personal data; only relevant information should be entered into an EHR and it might be useful to create different data modules within an EHR system with different access requirements; a special arbitration procedure should be set up for disputes over the correct use of data in EHR systems; and a single special institution must be given responsibility for the proper handling of access requests.⁵⁸

Together with the Working Party, we believe that new European general principles and data protection preconditions for establishing a nationwide EHR system or an e-health platform, as well as their applicable safeguards, are welcome, since this area poses potential new risks. The data contained in electronic health records or e-health platforms are used increasingly for purposes other than treatment, and health care actors are becoming more global (for instance, they are becoming part of European groups). Therefore, there are more opportunities to process health data among several Member States and/or third parties. There is also the risk that data may be more readily available to a wider circle of recipients.⁵⁹ In compiling existing medical information about an individual from different sources, with the result of allowing easier and more wide-spread access to this sensitive information, EHR systems introduce a new risk scenario. More categories of people may gain access to data if hospitals, pharmacies, laboratories, sickness funds, etc., that process health data become members of (international) groups. The Article 29 Working Party has stated that explicit consent must be given in order to process health data in an EHR.

It is true that the Data Protection Directive does allow for the processing of health data without explicit consent. Article 8(3) of the Data Protection Directive, for example, allows for processing by a health professional subject to confidentiality rules for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services. However, the Working Party is of the opinion that Article 8(3) cannot serve as the sole legal basis

⁵⁸ *Ibid.*, p. 13.

⁵⁹ *Ibid.*, p. 5. See also European Commission, 'Commission Recommendation', above n.44, p. 18.

for the processing of personal data in an EHR system. EHR systems provide direct access to a compilation of existing documentation about a person's medical treatment from different sources (hospitals, health care professionals, etc.) and throughout their lifetime. These systems transgress the traditional boundaries of the individual patient's direct relationship with a health care professional or institution. Therefore, it is not certain whether the processing of health data in an EHR system can be allowed without the explicit consent of the patient. The Article 29 Working Party is not convinced that relying only on the obligation to practise professional confidentiality provides sufficient protection.⁶⁰ If more people are allowed access to records because such records are kept by European actors, more specific safety measures must be taken and patients must be asked for consent as to which categories of people may have access to their records.

We not only need to reflect on the impact of Article 8(3) of the Directive⁶¹ in light of patient rights related to EHR systems, we also need to reflect on the legal rules regarding the processing of personal health data for purposes other than treatment purposes, such as research and quality review. Better and more specific provisions in the Directive for the further use of health data are needed, as the use of such data takes place increasingly within a globalized context of health care actors, and in several Member States where national rules regarding certain types of processing differ. Indeed, globalization in health care has become a reality, since not only pharmaceutical companies but also sickness funds, patients groups, research institutes, hospitals and laboratories are becoming part of an increasing number of European-wide organizations or groups.

This globalization of health care actors requires more harmonized rules for health data processing, particularly as the exchange of data between European e-health actors will not be limited to the treatment

⁶⁰ Article 29 Data Protection Working Party, 'Working document', above n.57, p. 12.

⁶¹ Article 8(1), 'Data Protection' Directive, above n.6, prohibits the processing of personal data. Article 8(1) 'shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy'. Article 8(3), 'Data Protection' Directive.

of patients – the data also can be processed for evaluation, research or statistical purposes. Currently, harmonized rules in this area are lacking. Several Member States have formulated strict rules for the processing of medical data for research purposes, while other Member States have more flexible rules. Article 8 of the Directive leaves too much room for different legislation in the Member States, which is not good for the establishment of an internal market in which international quality review projects, epidemiological studies, clinical trials and post-marketing surveillance projects are emerging. It is regretful that Article 8 does not contain more specific rules for the processing of medical data for research purposes, as more specific rules at the European level are needed.⁶²

Health grids

Initiatives to analyse the impact of health grids in health care systems have existed for several years. A grid is a new technology that aims to enhance the services already offered by the Internet. It offers rapid computation, large scale data storage and flexible collaboration by harnessing the power of a large number of commodity computers or clusters of other basic machines. The grid was devised for use in scientific fields, such as particle physics and bioinformatics, in which large volumes of data, or very rapid processing, or both, are necessary.⁶³ A grid has also been used in some ambitious medical and health care applications.⁶⁴ However, there is a tension between the spirit of the grid paradigm and the requirements of medical or health care applications. On the one hand, the grid stores data in the most convenient way according to performance criteria. On the other hand, a hospital or other health care institution is required to maintain control of the

⁶² Since EHR systems may contain a large amount of data over a long period of time, the new European legal framework should also foresee, among other things, the need for a comprehensive logging and documentation of all processing steps that have taken place within the system, combined with regular internal checks and follow-up on correct authorization, and regular internal and external data protection auditing. See also European Commission, 'Commission Recommendation', above n.44, Point 14(k). It will also be an important challenge for legislators to guarantee that all groups in society (including single parents, homeless persons, the elderly and disabled, isolated communities, etc.) have equal access to electronic health records. See also European Commission, 'e-Health – making healthcare better', above n. 41, p. 15.

⁶³ See www.initiative.healthgrid.org.

⁶⁴ *Ibid.*

confidential patient data and to remain accountable for its use at all times.⁶⁵ Health grids provide doctors, researchers and health system planners with the opportunity to support areas of health care such as medical imaging and image processing, modelling the human body for therapy planning, pharmaceutical research and development, epidemiological studies and genomic research, and treatment development. However, in order to be truly effective, such grid applications must draw together huge amounts of data from disparately located computers – which implies data sharing across jurisdictions and the sharing of responsibilities by a range of different data controllers.⁶⁶ The Supporting and Structuring HealthGrid Activities and Research in Europe (SHARE) Report⁶⁷ illustrates the applicability of the European Data Protection Directive to grids. Since not all Member States have transposed the Directive in the same way, and since the Directive itself allows Member States to adopt legislative measures to restrict the scope of some obligations and rights, there are differences in the level of protection granted to personal data between EU Member States, which might be a problem for the implementation of the health grid technology throughout the whole territory of the European Union.⁶⁸ According to the SHARE project, if health grids are really to grow to their full potential and deliver their promises, adjustments must be made to national and supranational legislation. This implies the development and adoption of robust guidelines developed specifically for the health grid context, which address the balancing of interests between an individual's privacy and medical advancement.⁶⁹

Further use of genetic data and tissue

E-health will create the situation where the difference between human tissue and computer data that refer to human tissue becomes very small. Since DNA sequences of samples can be analysed via and stored

⁶⁵ *Ibid.*

⁶⁶ SHARE, 'Bottlenecks and challenges and RTD responses for legal, ethical, social and economic aspects of healthgrids', Roadmap I (2008), p. 19. SHARE is a European initiative supporting the grid concept and the introduction of new technologies in the medical sector that involve e-health or e-infrastructures in medical research. Its main goal is to ensure the successful take-up of health grids by creating a roadmap for essential technology development in the future. See www.healthgrid.org.

⁶⁷ *Ibid.* ⁶⁸ *Ibid.*, p. 19. ⁶⁹ *Ibid.*, p. 25.

on computers, the distinction between the processing of human tissue and the processing of health data diminishes. E-health will enhance this further use of human tissue and genetic data as human tissue and blood, and the (genetic) data derived from tissue, is increasingly being used and stored for treatment and other purposes, such as research. The pharmaceutical industry, for example, collects human tissue when carrying out clinical trials on certain medicinal products. This is the issue of storing pharmacogenetic samples. Pharmacogenetics is the study and understanding of the genetic variation between individuals underlying differential responses to drug treatment.⁷⁰ University centres also often store blood and human tissue samples that can be used for research purposes, and countries collect biological samples on a very large scale and create population banks.⁷¹ Several European documents already refer to the use of human tissue, such as Directive 2004/23/EC on setting quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells⁷² and Regulation 1394/2007/EC on advanced therapy medicinal products.⁷³ However, these documents remain too vague to provide health care systems with clear and detailed rules on the further use of genetic data and tissue. It will be a challenge for Europe to provide a more detailed legal framework with rules governing the (further) processing of tissue and data, an issue

⁷⁰ European Commission Group of Experts, 'Ethical, legal and social aspects of genetic testing: research, development and clinical applications', Report of the Independent Expert Group (2004), http://ec.europa.eu/research/conferences/2004/genetic/pdf/report_En.pdf.

⁷¹ J. A. Bovenberg, *Property rights in blood, genes and data. Naturally yours?* (Leiden: Martinus Nijhoff Publishers, 2006), p. 23.

⁷² Directive 2004/23/EC on setting quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ 2004 No. L102/48.

⁷³ Regulation 1394/2007/EC of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation 726/2004/EC, OJ 2007 No. L324/12. At the level of the Council of Europe, we can refer to the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24 January 2002, in force 1 May 2006, ETS No. 186, <http://conventions.coe.int/treaty/en/treaties/html/186.htm>; as well as to Recommendation Rec(2006)4 on research on biological materials of human origin, Strasbourg, 15 March 2006, <https://wcd.coe.int/ViewDoc.jsp?id=977859>. Rules regarding the use of human tissue and blood often differ between the Member States.

that goes beyond national boundaries and is becoming a European, and also an international, concern.

B. Towards more guidelines on the reimbursement criteria for telemedicine

The E-commerce Directive does not regulate the reimbursement of telemedicine services, which falls under the competence of the Member States.⁷⁴ European and international telemedicine projects have often failed because they are too expensive for patients, and reimbursement by their health insurance funds⁷⁵ is not possible.⁷⁶ The recent Commission Communication on telemedicine for the benefit of patients, health care systems and society of 4 November 2008 states clearly that the lack of legal clarity with regard to, for example, reimbursement is a major challenge for telemedicine and that, in some Member States, for a medical act to be legally recognized as such, the presence of the patient and the health professional in the same place is required.⁷⁷

An essential condition for reimbursement is indeed never fulfilled in the domain of telemedicine since reimbursement requires the physical presence of the (tele) physician with the patient at the moment of performing the medical action. This refusal to reimburse medical costs if there is no physical presence might have been reasonable in a period without ICT. It could be argued that a physician who only listens to a patient on the telephone cannot indeed make a good diagnosis, and therefore reimbursement by public authorities for this kind of service could be refused. However, the revolution in the ICT sector today makes it sometimes possible to collect the required medical information for a diagnosis at a distance without being physically

⁷⁴ If there is a cross-border element, the European rules on free movement will be engaged.

⁷⁵ S. Callens, 'Tele-medicine and European law', *Telehealth Law* 2 (2002), 34–40.

⁷⁶ The Standing Committee of European Doctors has recommended a reimbursement of telemedical services by national social security systems in the same way as any other form of medical service. Standing Committee of European Doctors, 'The practice of tele-medicine in Europe: analysis, problems and CPME recommendations', 2002M/027 (2002), p. 18.

⁷⁷ European Commission, 'Communication from the Commission', above n.47, p. 8.

present. The question is then whether, under those circumstances, it is still reasonable to refuse reimbursement just because a physician does not see a patient physically.

The question arises as to whether or not the criterion of physical presence for the reimbursement of treatment forms an obstacle to the free movement of services – that is, whether there is a barrier to the free movement of services if the telemedicine treatment or diagnostic services carried out by a physician in country X on a patient situated in country Y is not reimbursed due to the physical presence requirement. The counter-argument may be that it is an issue of objective public interest and that the Member States should decide themselves whether or not the criterion of physical presence is needed for the reimbursement of medical interventions. The Member States can, indeed, owing to a lack of harmonization at Community level, determine for themselves the conditions under which a person can or must subscribe to a social security regime and under which the right to benefits exists.⁷⁸

However, the Court of Justice has regularly stressed that Member States also have to comply with Community law in the implementation of social security systems.⁷⁹ Simple mention of a rule of social security law does not exclude the application of Articles 49 and 50 of the EC Treaty.⁸⁰ In the *Kohll* case, the Court of Justice stressed that the requirement of prior consent by the insured person's health insurance fund, before the patient can claim (ambulatory) medical costs in another Member State, is a barrier to the free delivery of services.⁸¹ In the case of telemedicine, Member State legislation that requires a physical presence for reimbursement purposes does not forbid a patient from having recourse to a telephysician established in another Member State. It only makes the reimbursement thereof impossible. In a certain sense, the physical presence condition may impede medicine at a distance by a physician established abroad, as

⁷⁸ H. D. C. Roscam Abbing, 'Public health insurance and freedom of movement within the European Union', *European Journal of Health Law* (1999), 1–6.

⁷⁹ See, for example, Case C-120/95, *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR I-1831, para. 23; Case C-158/96, *Kohll v. Union des Caisses de Maladie* [1998] ECR I-1931, para. 19; Case C-157/99, *Geraets-Smits and Peerbooms* [2001] ECR I-5473.

⁸⁰ See also Chapter 11 in this volume.

⁸¹ Case C-158/96, *Kohll*, above n.79, para. 35.

well as the possibility, for example, of a Belgian patient consulting a telephysician in another European country. However, the condition of physical presence applies both to telemedicine treatment carried out by Belgian or foreign physicians, as well as to traditional medical treatments applied in situ. Thus, the measure is applicable without exception and is therefore not a formally discriminatory measure. However, it may still fall within Articles 49 and 50 EC, as it constitutes a deterrent to the cross-border provision of services.⁸² Alongside the justifications mentioned in Article 46 of the EC Treaty (in particular, public health reasons), Member States may view the physical presence condition as an imperative reason in the common interest that justifies an obstacle to the trade in services.⁸³

However, whether or not the reimbursement of medicine at a distance does in fact have an important effect on the financial balance of social security systems still needs to be examined. It seems to us that the reimbursement of certain types of telemedical interventions will have to be accepted. If the safety of patients is guaranteed and if the telemedical treatment is cost neutral, it is to be expected that exceptions to the physical presence requirement will have to be allowed under Community law.⁸⁴ It is obvious that guidance (at the European level) can be given as to the criteria that (tele) health sessions will have to comply with for reimbursement purposes.⁸⁵ However, these criteria must always comply with the principle of Article 4 of the E-commerce Directive (see above).

⁸² See Case C-55/94, *Gebhard* [1995] ECR I-4165; Case C-384/93, *Alpine Investments* [1995] ECR I-1141.

⁸³ Case C-158/96, *Kobll*, above n.79, para. 41; S. Callens, 'International tele-medicine and the law', in *Proceedings of the 13th World Congress on Medical Law*, Vol. 1 (Helsinki: World Congress on Medical Law, 2000).

⁸⁴ Concerning the reimbursement of medical treatment received abroad, see Chapter 12 in this volume.

⁸⁵ The recent proposal for a directive on the application of patients' rights in cross-border health care, European Commission, 'Proposal', above n.50, refers in its Article 16 to e-health, but this article remains quite vague. It states that the Commission 'shall adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures ... shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.'

C. Towards a European legal framework on liability and telemedicine

One of the important questions in cases of liability and telemedicine will be whether or not the telemedical transaction is the most suitable approach for the treatment of patients. Physicians must always consider whether or not telemedicine poses an increased risk for a patient – for instance, in an emergency situation where a delay in providing the necessary medical intervention would pose a greater risk to the patient than a prompt intervention with telehealth. On other occasions, however, telehealth might not offer the best method,⁸⁶ since telemedicine might not allow the physician to effectively resolve problems during the transaction. Furthermore, telemedicine makes it difficult to alter the course of a procedure in order to address complications that may surface during surgery.⁸⁷ One has to take into account that an online session can be disrupted or fail during the procedure without any direct access by the tele-expert to the patient. It can well be expected that, compared to traditional medical treatments, a greater variety of people undoubtedly will be held liable if something goes wrong during the telemedical session. The technical failure of some devices used during a telemedical session can lead to liability claims against software producers or Internet providers. In the case of a defective medical device, the Product Liability Directive⁸⁸ has to be considered. This Directive establishes the general principle that a producer is liable for damages caused by a defect in its product. A product is defective when it does not provide the safety that a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it reasonably could be expected to be put and the time at which the product was put into circulation.⁸⁹

⁸⁶ D. A. Crolla, 'Health care without walls: responding to telehealth's emerging legal issues', *Health Law in Canada* 19 (1998), 6.

⁸⁷ *Ibid.*

⁸⁸ Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ 1985 No. L210/29.

⁸⁹ Telemedicine might sometimes, however, make it easier to know who made a mistake, since tele-operations may be taped and be kept together with the file. This could facilitate answering the question of what went wrong during the session. B. Sluyters, 'Telegeneeskunde', *Tijdschrift voor Gezondheidsrecht* (1999), 273.

The issue of liability becomes very important in the case of ‘telemonitoring’, whereby medical devices are implanted to monitor and follow the patient. We might think, for example, of patients suffering from cardiac conditions.⁹⁰ These devices send electronic messages about the patient’s health situation to the doctor in charge at specific regular intervals. However, the device may not always contain an alarm system for emergency situations and does not always include twenty-four-hour assistance. The question then is whether physicians should hesitate to use these new medical methods, despite their technological efficiency, for fear of the burden of unclear liability. Would the doctor be held liable for not responding immediately to a message received during his absence? Written and oral information about the patient using the device and how information received by the doctor will be handled is important. Patients will have to be informed accurately – and in such a way that they can understand – of the doctor’s limited availability and, for example, that the medical device has no alarm. Doctors are obliged to ensure the continuity of health care for any treatment undertaken, including postoperative care and follow-up. Doctors must take all the necessary measures during their absences to guarantee the quality of their health care services to their patients. Therefore, it is preferable for doctors to organize their practices so that they inform their patients of absences, permit a suitably competent colleague to access their professional mailbox during any absence – albeit with due respect for professional confidentiality and privacy – and inform patients of the possibility of contacting this substitute.

We believe that the EU should play an important role even with regard to the liability issue if e-health actors are submitted to different liability schemes.⁹¹ Some countries, like France and Belgium, recently enacted so-called ‘no-fault’ legislation related to health care.

The no-fault issue is already contained in the Product Liability Directive⁹² but is increasingly being expanded to other domains,

⁹⁰ For the importance of teleradiology in Europe, see European Commission, ‘Communication from the Commission’, above n.47, p. 4.

⁹¹ It is a good thing that the Commission has stated in European Commission, ‘Communication from the Commission’, above n.47, p. 9, that, by the end of 2011, Member States should have assessed and adapted their national regulations enabling wider access to telemedicine services and that issues such as liability and reimbursement should be addressed.

⁹² For the relationship between e-health and product liability and medical devices see C. Van Doosselaere *et al.*, ‘eHealth ... But is it legal?’, *Eurohealth* 13 (2007), 2.

such as the delivery of health care. However, many countries do not use the no-fault standard with regard to the treatment of patients by health care professionals. No-fault liability rules state that if a patient is harmed, he/she is compensated regardless of the intent or negligence of the health care practitioner. If something goes wrong during a medical intervention, adequate compensation for patients might indeed be considered to be an important right. It is not good for patients or health care professionals if this right is regulated differently across the European Union, as this will not promote the use of telemedicine and the access to health care it allows. Therefore, EU legislation should require Member States to provide similar rules for compensation, which would enhance the free movement of patients and of health care services, and, in the final analysis, also access to health care and e-health. The no-fault rules should also cover damage caused in country X by a tele-expert located in country Y. Currently, some no-fault laws, such as the Belgian law, only apply to damage caused in Belgium. However, it is questionable whether this rule conforms to the EU Treaty, since it will not regulate damage caused in Belgium by a tele-expert working from abroad in the same way as the damage caused in Belgium by a tele-expert working in Belgium.

5. Conclusion

Many health care players (such as sickness funds, hospitals, laboratories, etc.) are now European health care actors and may feel the need to communicate health data between Member States for treatment and other purposes. Through the enactment of European rules that can be applied to e-health, the Commission has created quite an important legal framework for e-health, and therefore also for health care systems. Moreover, the Commission has given specific attention to e-health through the launch, in 1999, of its e-Europe initiative – ‘e-Europe – an information society for all’ – which included the Health Online Action. The Commission has also invested in several research programmes and, in 2004, established an Action Plan for a European E-health Area. The Commission continues to refer to the importance of e-health,⁹³ as well as the legal barriers to effective

⁹³ See Article 16 of European Commission, ‘Proposal for a European Parliament and Council Directive’, above n.50. See also European Commission, ‘Commission Recommendation’, above n.44.

e-health.⁹⁴ Some European instruments – such as the Data Protection Directive, the E-commerce Directive, the Medical Devices Directives and the Distance Contracting and Competition Rules Directive – play an important role for health care systems, through the use of e-health applications.

However, despite these rules and policy attention, the existing legal framework is not yet complete. The current European rules often remain too vague. The issues confronting health care players have to be addressed at the European level, as some important legal issues, as well as technological developments, need a clear legal answer. Regarding the legal issue, specific attention should be given to the need to enact European criteria on the reimbursement of e-health activities and on the (no-fault) liability issue. Before e-health can play an important role for health care players and health care systems, while respecting the interests of patients, health care providers and public authorities, the European Union will also have to provide a clear answer to the challenges caused by new technical developments, such as e-health platforms, electronic health records, health grids and the further use of genetic data and tissue.

⁹⁴ See European Commission, ‘Communication from the Commission’, above n.47.