Collaborative Patient Centred eHealth
E. De Clercq et al. (Eds.)
IOS Press, 2008

doi:10.3233/978-1-58603-922-6-47

Legal aspects of E-HEALTH

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Abstract. Cross-border activities in health care in the European single market are increasing. Many of these cross-border developments are related to e-Health. E-Health describes the application of information and communication technologies across the whole range of functions that affect the health care sector. E-health attracts a growing interest on the European level that highlights the sharp need of appropriate regulatory framework able to ensure its promotion in the European Union. Some Directives constitute a step in this direction. Both the Data Protection Directive, the E-Commerce Directive, the Medical Device Directive and the Directive on Distance Contracting are some of the most important European legal achievements related to e-Health. Although the directives are not adopted especially for e-health applications, they are indirectly very important for e-Health. Firstly, the Data Protection Directive applies to personal data which form part of a filing system and contains several important principles that have to be complied with by e-Health actors processing personal data concerning health. Secondly, the E-commerce Directive applies to services provided at a distance by electronic means. Many e-Health applications fall within this scope. Thirdly, the Medical Devices Directive is of importance for the e-Health sector, especially with regard to e.g. the medical software that is used in many e-health applications. Finally, the Directive on Distance Contracting applies to contracts for goods or services which make use of one or more means of distance communication; E-Health business may involve the conclusion of contracts.

Despite these Directives more developments are needed at the European level in order to make sure that e-Health will play an even more important role in health care systems than is the case today. The new e-Health applications like electronic health records, e-health platforms, health grids and the further use of genetic data and tissue involve new legal challenges. Several member states are introducing electronic health records or e-Health platforms. The use of electronic health records that contain data of several health actors poses new risks with some legal consequences. Recently, grids are being used in some ambitious medical and healthcare applications. 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. E-Health will also enhance the further use of human tissue and genetic data. More and clear guidelines on the reimbursement criteria for telemedicine and on liability would also be very useful. Guidance at the European level can be given as to the criteria that (tele-) health sessions will have to comply with for reimbursement purposes, since it is still unclear when e-Health sessions will be reimbursed. It is clear that the existing European legal framework is not finished yet and that more specific European rules are needed.

Keywords. e-Health, legal aspects, telemedicine.

1. Introduction

The European single market in health care is developing despite the existence of many different health care systems. Cross-border activities in health care are increasing. Many of these cross-border 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[1].

E-Health gets a lot of attention at the EU level. This is not new and not so surprisingly. In the action plan for a European e-Health Area of 2004[2] health and health care formed a key part of the Commission's vision of an information society in which a new generation of computerized clinical systems, advanced tele-medicine services, and health network applications improve health, continuity of care and allow citizens to be more involved in and assume more greater responsibility for their own health. The Commission believed that e-Health would be an instrument for restructured, citizen-centred healthcare systems and, at the same time, respecting the diversity of Europe's multi-cultural, multi-lingual healthcare traditions[3]. It is obvious that the Commission, because of the existence of e-Health, is enacting more and more rules that are related to health care and that these rules have an important impact on the health care systems. Through enacting these European rules on e-Health, the Commission is creating a legal framework for the health care systems.

In this presentation 4 [2], we will describe some important European legal achievements related to e-Health (section II). In spite of the existing legal rules, there is still a lot of work to do challenges to promote E-Health on the European level (section III).

2. European legal achievements related to E-HEALTH

This section highlights some European rules regarding e-Health that are of importance for health care systems. These European rules have an impact on national health care systems and are often not known by the health care actors. Both the Data Protection Directive, the E-Commerce Directive, the Medical device Directive as the Directive on Distance Contracting will be described shortly.

The *Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data*[5] contains several important principles that have to be complied with by e-Health actors that process personal data concerning health. If national health care systems or other e-Health actors will create health grids, electronic national records, information systems that may be used for treatment purposes, quality review purposes, research purposes, etc. they have to

[1] See also: European Commission, 'Accelerating the Development of the eHealth Market in Europe', eHealth Taskforce Report 2007, p. 10.

[2] European Commission, Communication from the Commission. E-Health-making healthcare better for European citizens: An action plan for a European e-Health Area, COM (2004) 356 final; See also: http://ec.europa.eu/information_society/activities/health/policy/index_en.htm.

[3] European Commission, Communication from the Commission. E-Health-making healthcare better for European citizens: An action plan for a European e-Health Area, COM (2004) 356 final.

[4] This presentation is based on an article of S. Callens: "Analysis and evaluation of the EU legal framework on e-health".

[5] 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 L 281/31.

comply with the principles of the Data Protection Directive. Article 8 of the Directive prohibits the processing of personal data concerning health. However, this prohibition does not apply where the processing of health data[6] is required e.g. 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. 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 incompatible with those purposes. The data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and the data must be kept in a form which permits identification of data subjects for no longer than is necessary and for the purposes for which the data was collected or for which they are further processed. The data subject has also to be informed about the processing of his personal data.

Health care actors that are applying e-Health may be considered as information society services and may have to comply to the European Directive on certain legal aspects of information society services in the Internal Market (the so-called *Electronic Commerce Directive*)[7] [3]. The E-Commerce Directive applies to information society services. Information society services are defined as any service normally provided for a remuneration, at a distance, by electronic means for the processing (including digital compression) and storage of data, and at the individual request of a recipient of a service[8]. The E-Commerce Directive may apply to online medicine as well as to services consisting of the transmission of information via a communication network, or in providing access to a communication network [4]. The Directive obliges the e-Health actors who act as an information society service to render easily, directly and permanently accessible to the recipients of the service and competent authorities, information on the service provider, where his activity is subject to an authorization scheme, the particulars of the relevant supervisory authority, any professional body or similar institution with which he is registered, which professional title he has obtained, which Member State has granted this title, 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 he subscribes and information on how those codes can be consulted electronically.

[6]ase C-101 Lindqvist [2003] ECR I-12971: The European Court of Justice stated in the Lindqvist case 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 Directive 95/46. Such processing of personal data in the exercise of charitable or religious activity is not covered by any of the exceptions in paragraph 2 of that article. The fact mentioned on the internet that an individual has injured her foot and is on half-time on medical grounds constitutes personal data concerning health within the meaning of Article 8(1) of the Directive.

[7] Directive 2000/31 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), OJ L 2000 178/1. For more guidance on the Directive see reference 3.

[8]At a distance means that the service is provided without the parties being simultaneously being present.

The *Medical Device Directive*[9] harmonizes the rules pertaining to the free circulation of medical devices in the EU. This Medical Device Directive is of importance for the e-Health sector, especially with regard to e.g. the medical software that is used in many e-health applications[10]. In the Directive's context, 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 with their intended purpose. The manufacturer must design and manufacture medical devices in such a way that some essential requirements are met, such as to take 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 the national provisions transposing the existing European harmonised standards will be presumed by EU member states as compliant with the essential requirements laid down by the Directive[11].

E-Health business may involve the conclusion of contracts. These contracts contain the description of the various parties' obligations and, often, special clauses. A contract related to e-Health concluded between professionals and consumers may be the subject of a contract at a distance. The *Directive on Distance Contracting*[12] 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 e.g. the identity of the supplier, the main characteristics of the services, the price of the services, the arrangements for payment, delivery or performance, the existence of a right of withdrawal etc. The consumer must receive written confirmation or confirmation in another durable medium available and accessible to him of the information mentioned above, in good time during the performance of the contract, unless the information has already been given to the consumer prior to conclusion of the contract in writing or on another durable medium available and accessible to him. For any distance contract the consumer shall have a period of at least seven working days in which to withdraw from the contract without penalty and without giving any reason.

[9] Article 1 Directive 90/385 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ 2007 L 247/21; Article 1 Directive 93/42 concerning medical devices as modified by Articles 1 and 2 of the Directive 2007/47 amending Council Directive 90/385 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ 1993 L 169/1, Directive 93/42 concerning medical devices, OJ 1993 L 169/1 and Directive 98/8 concerning the placing of biocidal products on the market, OJ 1998 L 123/1.

[10] The Medical Device Directive defines 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.

[11] Article 5 Directive 93/42 concerning medical devices.

[12] Directive 97/7 on the protection of consumers in respect of distance contracts, OJ 1997 L 144/19.

3. Legal challenges to promote E-HEALTH

Many recent developments still need to be clarified at the EU-Level in order to make sure that e-Health will play an even more important role in health care systems than is the case today. The new e-Health applications such as electronic health records, e-health platforms, health grids and the further use of genetic data and tissue involve new legal challenges. More and clear guidelines on the reimbursement criteria for telemedicine and on liability would also be very useful.

3.1. New challenges because of new e-Health applications

3.1.1. 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 platforms* in order to have[13] an availability of health data for medical treatment and allied purposes. It is argued by public authorities that electronic health records or e-Health platforms may improve quality of care[14] and patient safety and also can be used as an instrument to control the rising demand for (and cost of) health services[15] [16]. They should facilitate appropriate treatment of patients by providing health professionals with a better knowledge of the patient's history and of previous interventions by other colleagues[17]. According to the Commission improvement of patient safety can be achieved if information concerning patients is managed in a more systematic manner by everyone concerned with health care provision or standards[18]. Nevertheless, the use of electronic health records that contain data of several health actors poses new risks with some legal consequences.

The Data Protection Commission at the European level, the so-called Article 29 Data Protection Working Party[19], has adopted an interesting document on the

[13] In Belgium, a draft proposal of law is proposed in April 2008 which will set an "e-Health platform". The e-Health platform aims to optimize the quality and continuity of the healthcare, to optimize the safety of the patient, to promote the administrative simplification, and to support the health policy. This aim is to exchange information between all actors in the healthcare sector, organised with guarantees for the safety of the information and the privacy protection. The e-Health platform will, contrary to an electronic health record, be a decentralized way to store and exchange medical data. The E-Health platform does not contain the data itself, but is a place for healthcare actors where the data can be found. The patient will have to give his explicit written informed consent before his data will be added to the platform (Privacy Commission, advice nr. 14/2008 of 2 April 2008 "regards the draft law on e-health p. 10-11 en 25).

[14] Secure and fast access to patient information will, however, require the interoperability of health records.

[15] European Commission, Communication from the Commission. E-Health-making healthcare better for European citizens: An action plan for a European e-Health Area, COM (2004) 356 final, p. 5.

[16] The lack of standards has pushed up the cost of development and customisation, which has held the e-Health industry back from more substantial investment in e-Health solutions (European Commission, Communication from the Commission. E-Health-making healthcare better for European citizens: An action plan for a European e-Health Area, COM (2004) 356 final, p. 13).

[17] European Commission, Communication from the Commission. E-Health-making healthcare better for European citizens: An action plan for a European e-Health Area, COM (2004) 356 final, p. 8.

[18] European Commission and Member States, EHealth Conference 2007 Declaration, 17 april 2007 (available at: http://ec.europa.eu/information_society/activities/health/docs/events/ehealth2007/eh_declaration20070417_en.pdf).

[19] See articles 29 and 30 Data protection Directive: 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.

processing of personal data relating to health in electronic health records (EHR)[20]. The Working Party recommends to lay down special safeguards for the electronic health record system in a special comprehensive legal framework. This framework has to provide for, amongst others, the following safeguards: a patient should at any time have the possibility to prevent the disclosure of and the access to his/her 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 about the correct use of data in EHR systems; a single special institution must be made responsible towards the data subject for the proper handling of access requests[21].

EHR systems and e-Health platforms introduce a new risk scenario. More categories of persons may get access to data if hospitals, pharmacies, labs, sickness funds etc. that are processing health data are becoming members of (international) groups. The Article 29 Working Party has stated that consent to process health data in EHR must be explicit. 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 secrecy 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 this Article 8.3 cannot serve as the sole legal basis for the processing of personal data in an EHR system. Too much persons can have access to health data (such as allied hospitals, the general practitioner etc.). Moreover, EHR's can be used for several purposes. Therefore, we need a reflection on the impact of Article 8.3 of the Directive[22] and also on the legal rules regarding the processing of personal data concerning health for other purposes than treatment purposes such as research, quality review, etc. Several Member States formulated for the processing of medical data for research purposes strict rules whereas other Member States enacted more flexible rules. Article 8 of the Directive leaves too much room for different legislation in the Member States. This is not good for the establishment of on internal market in which international quality review projects, epidemiological studies, clinical trials and postmarketing surveillance projects are emerging. It is regretful that article 8 of the Directive does not contain more specific rules for the processing of medical data for research purposes. More specific rules at the European level are needed. [23]

[20] Article 29 Data Protection Working Party, 'Working Document on the processing of personal data relating to health in electronic records (EHR)', 00323/07/EN, WP 131; This document aims to provide guidance on the way to apply the data protection legal framework to electronic health record systems.

[21] Article 29 Data Protection Working Party, 'Working Document on the processing of personal data relating to health in electronic records (EHR)', 00323/07/EN, WP 131, p. 13.

[22] The first paragraph of article 8 of the Privacy Directive prohibits the processing of personal data. This paragraph 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 of the Privacy Directive).

[23] Since EHR systems may contain many data for 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 which have taken place within the system, combined with regular internal checks and follow-up on correct authorisation, regular internal and external data protection auditing (See also EUROPEAN COMMISSION, Draft Recommendation on eHealth interoperability, 16 July 2007, Annexe 1, p. 15). It will also be an important challenge for the legislator to guarantee that all groups in society (including lone parents, homeless persons, elderly and disabled persons, isolated communities etc.) have equal access to the electronic health record.

3.1.2. Health grids

Since several years initiatives are taken to analyse the impact of health grids24 in health care systems. *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. A *grid* has also been used in some ambitious medical and healthcare applications[25]. However, there is a tension between the spirit of the *grid* paradigm and the requirements of medical or healthcare applications. On the one hand the *grid* stores data at the most convenient way according to performance criteria. On the other hand, a hospital or other healthcare institution is required to maintain control of the confidential patient data and to remain accountable for its use at all times[26]. 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[27] [28]. The SHARE report[29] shows the applicability of the European Data Protection Directive to health grids. Since not all Member States have transposed the Directive in the same way and since the Directive itself allows the 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 on the whole territory of the European Union[30]. If health grids are really to grow to their full potential, robust guidelines developed specifically for the health grid context will have to be developed and adopted[31].

3.1.3. Further use of genetic data and tissue

E-Health will make sure that the difference between human tissue and computer data that refer to the human tissue becomes very small. E-Health will enhance the further use of human tissue and genetic data. The Human tissue and blood and the (genetic) data derived from tissue are increasingly being used and stored for treatment and other purposes such as research purposes [5]. Several European documents already refer to the use of human tissue such as the 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 and the Regulation on Advanced Therapy

[24] A grid is a new technology which aims to enhance the services already offered by the internet. It offers rapid computation, large scale data storage and flexible collaboration by harnessing together the power of a large number of commodity computers or clusters of other basic machines.

[25] See www.healthgrid.org.

[26] See www.healthgrid.org.

[27] SHARE, 'Bottlenecks and challenges and RTD responses for legal, ethical, social and economic aspects of healthgrids', Roadmap I, 2008, p.19 (available at http://eu-share.org/deliverables.html).

[28] SHARE is a European initiative defending the Grid concepts and the introduction of new technologies in the medical sector, involving e-health or e-infrastructures into medical research. Its main goal is intended to ensure the successful take-up of HealthGrid by creating a roadmap for essential technology development in the coming years (See www.healtgrid.org).

[29] SHARE, 'Bottlenecks and challenges and RTD responses for legal, ethical, social and economic aspects of healthgrids', Roadmap I, 2008.

[30] SHARE, 'Bottlenecks and challenges and RTD responses for legal, ethical, social and economic aspects of healthgrids', Roadmap I, 2008, p. 19.

[31] 31 SHARE, 'Bottlenecks and challenges and RTD responses for legal, ethical, social and economic aspects of healthgrids', Roadmap I, 2008, p. 25.

Medicinal Products[32]. However, these documents remain too vague to provide health care systems 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 to the (further) processing of tissue and data which is becoming an international issue (and no longer a national one).

3.2. Towards more guidelines on the reimbursement criteria for tele-medicine

The E-Commerce Directive does not regulate the reimbursement of tele-medicine services, which falls under the competence of the Member States. European and international tele-medicine projects have often failed because they were too expensive for the patients and reimbursement by their health insurance funds [6]was not possible[33]. An essential condition for reimbursement was never fulfilled in the domain of tele-medicine, i.e. 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. Nowadays 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. 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 benefit exists[34] [7]. The Court of Justice has, however, regularly stressed that the Member States also have to comply with Community law in the implementation of a social security system. It is not just because mention is made to a rule of social security law that Articles 49 and 50 of the EC Treaty cannot be applied when judging a provision of social security law[35]. The legislation of European Member States which requires physical presence for reimbursement does not forbid a patient from having recourse to a tele-physician established in another Member State. It only makes the reimbursement thereof impossible. Alongside the justification mentioned in Article 46 EC Treaty (in particular the public health), the Member State may see it as an imperative reason of common interest by which an obstacle to the trade in services can be justified[36] [8]. However, whether or not the reimbursement of medicine at a distance does in fact have an important effect on the financial balance of the social security system it still needs to

[32]At the level of the Council of Europe, we would refer to the additional protocol on tissues of human origin to the Biomedicine Convention, as well as to Recommendation 2006/4 on research on biological materials of human origin. Rules regarding the use of human tissue and blood do differ often between the Member States.

[33] The Standing Committee of European Doctors is pleading for a reimbursement of tele-medical services by the national social security system 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), p. 18).

[34]The Court of Justice has, however, regularly stressed that the Member States also have to comply with Community law in the implementation of a social security system: see e.g. Case C-120/95 Decker [1998] ECR I-1831, para 23; Case C-158/96 Kohll [1998] ECR I-1931, para 19; Case C-157/99 Smits-Peerbooms [2001] ECR I-5473.

[35]In the Kohll case the Court of Justice has stressed that the requirement for preliminary consent of 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 (Case C-158/96 Kohll [1998] ECR I-1931, para. 35).

[36]Case C-158/96 Kohll [1998] ECR I-1931, para. 41; S. CALLENS, 'International Tele-medicine and the Law', in Books of proceedings I of the 13th World Congress on Medical Law (Helsinki, 2000).

be examined. It seems to us that the reimbursement of certain types of tele-medical interventions will have to be accepted. If the safety of the patient is guaranteed and if the tele-medical treatment is cost neutral, it is to be expected that exceptions to the physical presence requirement will have to be allowed under Community law. 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.

3.3. Towards a European legal framework on liability and tele-medicine

One of the important questions in cases of liability and tele-medicine will be whether or not the tele-medical transaction is the most suitable approach to treat the patients. Physicians must always consider whether or not tele-medicine poses an increased risk for the patient, for instance, in an emergency situation where a delay of the necessary medical intervention would pose a greater risk for the patient than a prompt intervention with telehealth. It can well be expected that more and other type of persons than in a classic medicinal treatment will undoubtedly be held liable, if during the tele-medicinal session something goes wrong. The technical failure of some devices used during a tele-medicinal session can lead to liability claims against software producers or Internet providers. In the case of a defective medical device, the European Directive on product liability[37] has to be considered. This Directive establishes the general principle that the producer is liable for damages caused by a defect in his product[38] [39] [9]. The EU should play an important role even with regards to the liability issue if the e-Health actors are submitted to different liability schemes. Some countries like France and Belgium recently enacted so called no-fault legislation related to health care [11]. The no-fault issue is already known in the EU Directive on products liability [10] but is increasingly expanded to other domains like the delivery of health care[40]. However, many countries do not use the no-fault issue with regard to the treatment of a patient by a health care professional. It is not good for patients or health care professionals if this right is regulated all over Europe in a different way. This will not promote the use of tele-medicine and access to health care. Therefore, EU legislation should enforce Member States to provide similar rules for compensation which would enhance the free movement of patients and of health care services and at the end the access to health care and e-Health.

[37] Directive 85/374 of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ 1985 L 210/29.

[38] A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that the product would be put and the time when the product was put into circulation.

[39] Tele-medicine might, however, make it sometimes 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 (see reference 9).

[40] On this moment there exist no European rules concerning the no fault liability for all types of health care. The Member States apply their own liability rules. This results in different liability rules in the different Member States. At the European level the no fault liability has only be introduced for certain specific issues related to health care.

4. Conclusion

Many health care players (like sickness funds, hospitals, labs) are being part of a European network of health care actors and may feel the need to communicate between Member States health data for treatment and other purposes. Through enacting European rules on aspects of e-Health, the Commission created a legal framework for the health care systems. Some Directives, like the Data Protection Directive and the E-Commerce Directive play an important role for health care systems, through the use of e-Health applications. However, the existing legal framework is not finished. The current European rules remain often too vague. It is obvious that the issues which health care players may deal with, have to be addressed at the European level. Some important legal issues as well as technological developments need a clear legal answer.

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