eHealth services and Directive on Electronic Commerce 2000/31/EC

Jean-Marc VAN GYSEGHEM[1,2,1]
[1] *Senior researcher Research Centre on IT and Law (University of Namur, Belgium)*
[2] *Attorney at Law at the Bar of Brussels (Belgium)*

Abstract. We often restrict the analysis of eHealth services to a concept of privacy. In this article, we'll demonstrate that other legislation can apply to those services as Directive 2000/31/EC on Ecommerce. By creating telematic networks or infrastructure, eHealth services are offering information services. But what are the consequences with such concept? What are the duties and rights for the actors of the network(s)? We'll try to answer to some questions, even if it won't be exhaustive.

Keywords. Health Services, Public Health Informatics, Legal Liability, Consumer Health Information

1. Introduction

The medical practice is changing quickly and in this context, practitioners use new technologies to improve its efficiency. The use of these technologies raises new legal issues which are often misunderstood. That misunderstanding scares practitioners and patients as well.

The main technology used by hospitals is the Internet when relying on Internet-based networks to allow the sharing of data (medical, administrative, etc.) between several actors active in the Health sector. We are in the eHealth generation!

But, **what is an eHealth service**? Jean HERVEG and Yves POULLET explained that *"eHealth is characterized by the use of information and communication Technologies in Healthcare"*[1].

They add to their saying that "eHealth projects aim to create telematic networks or infrastructure at local, regional, national, European, international, or even worldwide level"[1].

The words "networks" and "infrastructure" involve the sharing of information as said before but involve also the concept of availability for a certain public. We also have to point that these eHealth services offer an added value to the data to the profit of the physicians by giving them a new perspective of use (short medical file for urgent action, hyperlinks, etc…), of the patient, of the researcher, etc…

[1] Special thanks to Jean HERVEG, Lecturer at the Faculty of Law (University of Namur) and senior researcher at the Research Centre on IT and Law (University of Namur) who has kindly red the text over.

The question which comes in mind is the following: in which extent can the sharing of data and the public access be qualified as a service of the information society in the meaning of Directive 2000/31/EC on Ecommerce [2]?

In this paper and due to a question of length, we'll analyze only some aspects of the Directive 2000/31/EC related to the concept of eHealth services. Therefore, we'll put some other points aside such as the internal market and free movement principles, the concept of sanction and the status of Education in relation to the Directive on eCommerce.

2. Directive 2000/31/EC on Ecommerce

By contrast to the usual approach of the eHealth service – focusing on the patient and the practitioner from a data protection point of view -, we propose to analyse the legal qualification of the network and the infrastructure.

2.1. Scope of the Directive

The Directive 2000/31/EC covers all information society services which include services between companies (B2B - business to business), between companies themselves and consumers (B2C - business to consumers) and free services delivered to recipients. It covers on-line services like databases, selling of medicines (ePharmacy) [3]. The aim of the Directive is to guaranty the transparency on the net [4].

The scope of the Directive is quite wide and concerns all information society services even in sector which has a high level of protection as public health, etc…

The Directive sets a minimum of requirements to be fulfilled in order to achieve its objective by eliminating disparities within the European Union[2]. That means that national laws transposing the Directive cannot be less strict. The article 1(5) of Directive 2000/31/EC sets up some exceptions to its application which are not relevant here from our point of view in this contribution.

Attention must be paid to the fact that this Directive doesn't deal with personal data - as mentioned in the Recital 14. Therefore this Directive 2000/31/EC is a regulation which juxtaposes with Directive 95/46/EC [5]and they may coexist as it often occurs in Privacy matters.

2.2. The information society service

The concept of information society services is *"any service, normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services"*[3].

The keywords are:

- The service must be provided **for remuneration**. It doesn't matter if the service is paid by the recipient himself or not. That means that the payment can come from another source (like advertising, etc.) than the recipient. We

[2] Recitals 6 and 10 of the Directive 2000/31/CE.

[3] Article 1(2) of Directive 98/48/EC of the European Parliament and the Council of 20.07.1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

have to consider that all activities are included in the concept of services (article 50 of the European treaty – version 97/C 340/03), except the ones offered by the State without economic consideration in accordance with its social, cultural, education, etc. duties before they are opened to payment[4].

Reading Article 50 of the European Treaty, we can set that all activities, except the ones realized by the Member State and related to its missions (i.e.: culture, justice, etc…), are likely to be "services" in the sense of Article 50 of the Treaty.

What about eHealth? We have to keep in mind it costs a lot to set up an eHealth services and has to be financed from a way or another. Therefore, it will need a financial support. In theory and in an economical point of view, services can be paid by the users of the service, advertisements, public funding, etc…. It's a question of choice and the source doesn't matter because the concept of remuneration is very broad. We therefore have to conclude that eHealth services will often be remunerated for in the sense of Article 50 of the European treaty, from a way or another.

- The service must be provided **at distance** which means that the parties are not physically and simultaneously present[5].

  That includes online databases or advices which does not request the presence of the patient. *A contrario, "medical examinations or treatment at a doctor's surgery using electronic equipment where the patient is physically present"*[6] won't be a service of the information society [3].

  What about eHealth? Obviously, the different parties dealing within an eHealth environment will never (or exceptionally) be physically or simultaneously present. Therefore, eHealth fulfils, most of the time, this criteria.

- The service has to be made **by electronic means** which means that *"the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) ad storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means"*[7].

  In the concept of electronic means, the recital 18 includes only the online services and not the offline one. In the hypothesis of both services, the Directive will apply to, and only, the online one.

  Are also excluded services which are not provided by electronic or inventory system as telefax services, voice telephony services, the supply consisting in material goods even if it implies the use of electronic means (for example: train ticket, money, etc…).

  What about eHealth? The entire eHealth environment is based on the Internet and/sometimes on the Grid technology, which means that the service

[4] See Recital 19 of the Directive 98/48/EC of 20.07.1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations. In this recital, we should understand article 50 instead of article 60 (European Treaty – version 97/C 340/03).

[5] See also Annex V to the Directive 98/48/EC of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

[6] Annex V to the Directive 98/48/EC of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

[7] Article 1(2) of Directive 98/48/EC of the European Parliament and the Council of 20.07.1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

is usually provided by electronic means. All the transmissions of data (which are in a numeric form) will obviously be realized through the Internet. Therefore, eHealth fulfils this criterion in this extent.

- The service must be provided at the **individual request of a recipient of services** which means that the service is provided through the transmission of data on individual request.
  That excludes all services provided without individual request as television and radio.
  What about eHealth? First of all, we have to define the notion of "recipient of services" in an eHealth environment. Actually, depending on the service, we may consider several recipients like the physicians, the patients, the researchers, etc. seeking information. Obviously, their request will take place in the offer of a service in response to their individual request when asking for a medical document, medical information, data for scientific research, etc. The individual request can occur at the beginning of the relation between the user and eHealth services. It means that the transmission of data to a user does not have to follow, at each time, a special request. The contract between eHealth service and the user can provide, for example, that the information will be sent as soon as there is an update, for instance.

We see that **eHealth services** fulfill, most of the time, the different criteria of information society services. The consequence is that most of the eHealth services falls within the scope of the Directive and must respect the obligations in matter of information and other duties concerning the conclusion of contracts by electronic means[8] and regarding commercial communications.

A way to get out of the scope of this Directive would consist in providing an off-line service excluding *de facto* all on-line services (see above), which obviously does not fit with the concept of the eHealth environment.

Concerning regulated profession as well as health on line, on line medicine in the surrounding of commercial communications, the Members States have to ensure that the use of such commercial communication *"is permitted subject to compliance with the professional rules regarding, in particular, the independence, dignity and honour of the profession, professional secrecy and fairness towards clients and other members of the profession"*[9].

2.3. Provider of a service of the information society

2.3.1. Definition and concept

Directive defines the service provider as *"any natural or legal person providing an information society service"*[10]. The definition is very broad since it includes all persons dealing with commercial activity[11]. The duties towards the recipient are mainly informational.

---

[8] Article 9 and following of the Directive 2000/31/EC.
[9] Article 8.1 of the Directive 2000/31/EC.
[10] Article 2(b) of the Directive.
[11] By commercial activity, we have to understand service for payment in the sense of the article 50 of the European treaty and the interpretation given by the European court of justice (*Cfr.* above).

At the level of eHealth, we have to consider it's a provider of a service of the information society as soon as it's a "*natural or legal person providing an information society service"*. We have seen above that eHealth includes information society services. Hence we have to precise this quality by saying it's a provider.

What about eHealth? The question is to know who can qualify as a provider of information society services in the eHealth environment. The "*natural or legal person providing an information society service"* could be the physician and/or the patient and/or the researcher and/or lab, etc. When could it be the case? We have to determine very carefully who really provides the service. Is this the physician or the patients? We can already set that could be hardly feasible for them in terms of administration and so on.

Obviously, physicians, patients and researchers transfer information (data) to each of them through or with the collaboration of eHealth services which give the infrastructure (see above). The physician makes available some patient's data to other physicians, patients, researchers, etc. through the eHealth network/service and *vice versa*. Therefore, there's a kind of services given by each one.

We have to check again the key words defining information society service which are service provided by remuneration, at a distance, by electronic means and at the individual request of a recipient of services. The main discussion is about the remuneration once we consider that the other elements are met.

We remind that by remuneration, we have to understand any kind of retribution. For sure, the physician gets retribution from the patient and, in some situation, from Member States. The question is to determine what kind of remuneration is got by the physicians. Is it for therapeutic purpose to the patient or to give the service of furnishing the information through the eHealth services? Giving an answer to this question is to resolve the question to know if he can be considered as provider or not. Actually, the physicians is paid, most of the time, to cure the patients and, in most of the European legislations, he is legally obliged to get information from other physicians and from the patient itself as he has to give information to other physicians and the patient. In a wider dimension, it can be useful for the patient to have his data sent to researchers. The physician does not get any specific remuneration, directly or not, for this specific service which is included in its therapeutic duties towards the patient[12][6]. Therefore, the physician cannot be considered as a service provider because the criterion of remuneration is missing. On the other hand, it would be different if he creates a website or will send, getting specific remuneration, data to other persons.

The same question is put forward for the researcher. Actually, he often gets remuneration from Member States, EU, etc. Following the example of the physician, we can consider this remuneration is given for the research and not for the availability of some results for physician and patient consisting in giving the results of the research to this last one which is part of its work of researcher. From our point of view, the remuneration cannot be considered in relation to the service.

What about the patient? It would be outrageous to consider that the patient takes remuneration to transfer information to his physician or to a researcher. Even the Directive 2001/20/CE of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct

[12] For opposite position, see Patrick Van Eecke, "Electronic Health Care Services and the E-Commerce Directive", *A Deacade of Research @ the Crossroads of Law and ICT*, Brussels, Larcier, 2001, p. 375.

of clinical trials on medicinal products for human use prohibits incentives or financial inducements except for compensation. That shows how it is impossible to consider the patient getting remuneration when sharing data in the matter of therapeutic services as an eHealth service.

At this point, we may consider that actors using eHealth services do not get most of the time, any remuneration for making available data through the eHealth infrastructure. Their remuneration is related to the therapeutic finality for the physician and a finality of research for the researcher and a finality of healthy life for the patient. Therefore, they can not be considered under scope of the Directive 2000/31/EC.

Who's the provider of service then? We should consider that the provider will be the natural or legal person who will set up the service such as an e-Health platform, a hospital opening the system to external physicians or labs, etc. and if such service is directly or indirectly paid. In each case, we'll have to check if there's such direct or indirect remuneration or not for such service (see above). It will be a factual analysis. If there's no remuneration, we'll not be fit the criteria of information society services.

2.3.2. information duties.

Article 5 specifies the kind of general information accessible by an easy, direct and permanent way in any case and in any service of the information society such as the name of the service provider, the details of the service provider, including his electronic mail address, which allow him to be contacted rapidly and communicated with in a direct and effective manner.

If the provider practices a regulated profession, he has to deliver some more information as decribed in the article 5, f.[13] such as any professional body or similar institution which the service provider is registered with.

Besides the general information, the Directive makes provisions for several more precise services as commercial communications and contracts concluded by electronic means.

What about eHealth? In its quality of provider, eHealth services have to respect this duty of information as any other provider.

In some cases, eHealth services can use commercial communication as a way to finance the service offered. In that hypothesis, it has to take care of the special informational duties.

What about contracts concluded by electronic means which request special information[14]? We have to start from the hypothesis that there will be contract between eHealth services and the actors using such services concerning duties and right of the different parties. Those contracts needed in a data protection framework designed for each eHealth service will, certainly, be concluded by electronic means and, often, between non consumer parties except with the patient.[15] That means, in practice, that the information given to the non consumer user can be reduced to nothing in the sense of the Directive 2000/31/EC if there's an agreement between the parties. Within the eHealth environment, this possible substantial reduction of information will facilitate the work...

[13] Article 5, f of the Directive 2000/31/EC.
[14] Article 10 of the Directive 2000/31/EC.
[15] Consumer is defined like "any natural person who is acting for purposes which are outside his or her trade, business or profession" (article 2(e) of the Directive.

Pay attention to the fact that this information is not required if the contract is concluded exclusively by exchange of electronic mail or by equivalent individual communications. The interpretation of this paragraph must be restrictive and concerns the process of the contract which is made entirely by Email or equivalent individual communication.

For practical reasons, the contracts within the eHealth services should be – if not yet – electronic.

2.4. Recipient of the service

The Directive defines the recipient of the service as *"any natural or legal person who, for professional ends or otherwise, uses an information society service, in particular for the purposes of seeking information or making it accessible"*[16]. The Directive wants to limit the concept of information society service to open networks, excluding "private" networks accessible only to the members of the legal entity[17].

What about eHealth? In the architecture and the purpose of any eHealth service, there will be several recipients acting at the same time or not or through the same eHealth service or not. Those recipients may be the physicians, the patients, the researcher, the labs, etc. and outside a one only and same legal person.

2.5. Liability and intermediary service providers

The Directive has created a special category of provider which is called *"intermediary service provider"*. No definition of this kind of provider is given by the Directive but each of the three kinds of such intermediary service provider is defined differently on the field of the liability.

The objective of this Directive 2000/31/EC in this particular matter is to reduce the civil and penal liability (for example: libel, pirating, forging, privacy, etc) of this actor working in the information society which will have to fit in a category to get the benefit from this reduction of liability[18].

The exemptions from liability set in this Directive cover only cases where the activity of the information society service provider is limited to the technical process of operating and giving access to a communication network over which information made available by third parties is transmitted or temporarily stored, for the sole purpose of making the transmission more efficient; this activity is of a mere technical, automatic and passive nature, which implies that the information society service provider has neither knowledge of nor control over the information which is transmitted or stored[19].

The conditions to benefit from this exception of liability depend on the kind of intermediary services offered:

- **Mere conduct**: A total absence of liability is set when an information society service is provided that consists of the transmission in a communication network of information provided by a recipient of the service, or the provision

[16] Article 2(d) of the Directive.
[17] See recital 20 of Directive 2000/31/EC.
[18] On the question of liability of the intermediary service provider, see Tribunal de grande instance de Paris, 3ème chambre, 1ère section, 15 avril 2008, www.juriscom.net/documents/tgiparis20080415-Lafesse.pdf; Tribunal de grande instance de Paris, 3ème chambre, 1ère section, 15 avril 2008, www.droit-technologie.org/upload/jurisprudence/doc/254-1.pdf;
[19] Recital 42 of Directive 2000/31/EC

of access to a communication network, if the provider does not initiate the transmission, does not select the receiver of the transmission and does not select or modify the information contains in the transmission[20]. The best example is the medical emailing by an Internet service provider.
That includes the automatic, intermediate and transient storage of the information transmitted in so far as this takes place for the sole purpose of carrying out the transmission in the communication network, and provided that the information is not stored for any period longer than is reasonably necessary for the transmission[21].

- Caching: Where an information society service is provided that consists of the transmission in a communication network of information provided by a recipient of the service, there is no liability for the automatic, intermediate and temporary storage of that information, performed for the sole purpose of making more efficient the information's onward transmission to other recipients of the service upon their request[22]. But to benefit from that exemption of liability, the provider has to prevent himself to modify the information, and to comply with conditions on access to the information, etc.[23] An example of such intermediary service is the system, server or proxy service.
- Hosting: Where an information society service is provided that consists of the storage of information provided by a recipient of the service (such as database storing information without producing any information), there is no liability for the information stored at the request of a recipient of the service, on condition that the provider does not have actual knowledge of illegal activity or information and, as regards claims for damages, is not aware of facts or circumstances from which the illegal activity or information is apparent; or , upon obtaining such knowledge or awareness, acts expeditiously to remove or to disable access to the information[24]. There is no exemption of liability when the recipient of the service is acting under the authority or the control of the provider[25].

The limitations of liability of intermediary service providers set in this Directive do not affect the possibility of injunctions of different kinds. Such injunctions can in particular consist of orders by courts or administrative authorities requiring the termination or prevention of any infringement, including the removal of illegal information or the disabling of access to it[26].

In order to benefit from a limitation of liability, the provider of an information society service, consisting of the storage of information, upon obtaining actual knowledge or awareness of illegal activities has to act expeditiously to remove or to disable access to the information concerned[27]. The removal or disabling of access has to

[20] Article 12,3 of Directive 2000/31/EC.
[21] Article 12,2 of Directive 2000/31/EC.
[22] Article 13.1 of Directive 2000/31/EC.
[23] Article 13,1 of Directive 2000/31/EC.
[24] Article 14,1 of Directive 2000/31/EC.
[25] Article 14,2 of Directive 2000/31/EC.
[26] Recital 45 of Directive 2000/31/EC.
[27] See Tribunal de grande instance de Toulouse, référé, 13 mars 2008, www.legalis.net/jurisprudence-imprimer.php3?id_article=2246; Tribunal de commerce de Paris, 8ème chambre, 20 février 2008, www.legalis.net/jurisprudence-decision.php3?id_article=2223.

be undertaken in the observance of the principle of freedom of expression and of procedures established for this purpose at national level. This Directive does not affect Member States' possibility of establishing specific requirements that must be fulfilled expeditiously prior to the removal or disabling of information[28].

The Directive encourages the non imposition of a general obligation on providers, when providing the services mere conduit, caching and hosting, to monitor the information that they transmit or store, nor a general obligation actively to seek facts or circumstances indicating illegal activity.

Meanwhile, it promotes an obligation for information society service providers promptly to inform the competent public authorities of alleged illegal activities undertaken or information provided by recipients of their service or obligations to communicate to the competent authorities, at their request, information enabling the identification of recipients of their service with whom they have storage agreements[29].

What about eHealth? Can we consider any eHealth service as an intermediary service provider and benefit from the reduction of liability set by the Directive (see above). Will it only store the information from the providers to give the opportunity to the recipient to get it?

The eHealth services make a kind of processing of the data coming from outside. For example, they change the structure of the information, they create a list containing hyperlinks to the information stored in another place as in a hospital, they create a short medical file for urgent action, etc. The qualification of the eHealth service towards Directive 2000/31/EC will be very factual and it's quite difficult to give an answer within this contribution. However, we can point even if the eHealth services won't change the content of a medical report they will process the data itself by organizing it (for example: hyperlinks[30] [7]) and extracting information (for example: short medical file for urgent action) in an objective of valorisation of the data. It's often one of the purposes of the service offered to the users. The eHealth service can also be intermediary service provider for a part of its activity and "full" service provider for another part of it [7]. In consequences, we have to consider that eHealth service can be both an intermediary service provider and a service provider. It depends on its real activity.

About the question of the liability of the eHealth services as service of information society provider, we'll have to return to the national regulations because the Directive 2000/31/EC doesn't deal with that issue. Obviously, this question will have to be analysed in another contribution.

2.6. Codes of conduct

The Directive also encourages[31] the drawing up of codes of conduct at Community level, by trade, professional and consumer associations or organisations, designed to contribute to the proper implementation of Articles 5 to 15 and the accessibility of these codes of conduct in the Community languages by electronic means.;

In the eHealth context, it would be an appropriate initiative to adopt a code of conduct at the European level to secure the users/actors.

---

[28] Recital 46 of Directive 2000/31/EC.
[29] Article 15, 2 of Directive 2000/31/EC.
[30] See Tribunal de grande instance de Paris, référé, 26 mars 2008, www.foruminternet.org/specialistes/veille-juridique/jurisprudence/IMG/pdf/tgi-par20080326.pdf.
[31] Article 16 of Directive 2000/31/EC.

3. Conclusion

In terms of conclusion, we certainly have to consider that any eHealth service will be considered as a service of the information society in the sense of Directive 2000/31/EC on Ecommerce and will have to respect the rules set by it.

The Directive is not a danger for the eHealth services and even can offer a security to the provider at the level of liability if he can be considered as an intermediary service provider. Concerning this last issue, we'll always have to analyze the real activity to work out either it's a "full" provider or an intermediary one. If it's a "full" provider, its liability will be regulated by common national law unlike for a intermediary provider.

As seen before, the difference between those two concepts is not only a question of words!

Apart from that, the duties for the provider is mainly informational with some variation depending on whether he's "full" provider or an intermediary one, whether he's in charge of contract by electronic means and if the contract are made between non consumers or not, etc.

We also want to attract the attention that the sanction of any breach of the Belgian eCommerce law (11 March 2003) can go up to 20.000 €.

Honestly and at this point of the study which is in progress, we don't see any way out to the Directive 2000/31, except if we offer an offline service, what would be a nonsense confronting to the whole concept of the eHealth services.

To close this contribution, we point out the fact that eHealth service do not play alone! Indeed, in this environment, several actors work together with a willing of respect of their own duties coming from other legislation. As whispered before, the developer of any eHealth service must also pay attention to other laws or legislations as Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data.

References

[1] Herveg Jean and Poullet Yves, "Wich Major Legal Concerns in Future e-Health", in The Information Society : Innovation, Legitimacy, Ethics and Democracy in Honor of Professor Jacques Berleur s.j., Boston, Springer, 2007, p. 159-160.

[2] Directive 2000/31 of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000L0031:EN:HTML.

[3] van Doosselaere Céline, Herveg Jean, Siber Denise and Wilson Petra, Legally eHealth. Putting eHealth in its European Legal Context, Legal and regulatory aspects of eHealth, study report March 2008, p. 21.

[4] Dumoulin Marie, "Information et transparence sur les réseaux", in le commerce électronique européen sur les rails? Analyse et proposition de mise en œuvre de la directive sur le commerce électronique, Bruxelles, Bruylant, 2001, p. 95.

[5] Directice 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML.

[6] Van Eecke Patrick, "Electronic Health Care Services and the E-Commerce Directive", A Deacade of Research @ the Crossroads of Law and ICT, Brussels, Larcier, 2001.

[7] Montero Etienne, "La Responsabilité des prestataires de service sur les réseaux", le Commerce électronique européen sur les rails, Cahier du Crid, 2001, p. 276