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Telemedicine is not e-commerce!

At a time when the health industry is legitimately researching a long-term business vision of digital applications in the vast field of Health, and when health professionals are engaging in new care organisations structured by telemedicine, it is important to reiterate the legal and regulatory frameworks of e-health (A) and telemedicine (B) and to analyse why e-health can be, in certain areas, a subset of the European Directive on e-commerce (C), while clinical telemedicine cannot (D).

A) e-health: an ambiguous concept from its creation

The idea that the Internet would revolutionise organisation and access to care was born in Australia in 1999 after a government study demonstrated that “the increasing use of information and telecommunications technologies (ICT), including Internet technologies, has emerged as a key tool to drive efficiency and effectiveness in Australia’s health system." John Mitchell from Sydney, author of this Australian study, presented this vision of the development of digital health at the 7th International Congress on Telemedicine, which took place in London in November 1999. In order to illustrate his words, he used the term "e-health." E-health was defined by Mitchell as being "much broader than telemedicine or telehealth. It covers the use of digital data transmitted electronically - for clinical, educational and administrative applications - both locally and at a distance. Hence, e-health is the overall field that encompasses telemedicine." This new concept immediately gave rise to several articles and editorials on "the death of telemedicine." For the authors, e-health replaced telemedicine. Additionally, "e-health was taken to be a subset of e-commerce" driven by non-health professionals, while telemedicine was driven only by medical health professionals. The craze for this new concept was such that several English-language telemedicine journals added this new term to their title. The European Directive on Electronic Commerce of 8 June 2000, which had been in preparation since 1997, also took into account this new concept, and stated in the introduction that information society services covered by this directive included “the on-line sectors and activities in particular: newspapers, databases, financial services, professional services (solicitors, doctors, accountants, estate agents), entertainment services (video on demand, for example), direct

¹ President of the National Association of Telemedicine (ANTEL)
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³ Preamble to the Constitution of the World Health Organization, International Health Conference, New York, 19-22 June, 1946: “Health is a state of complete physical, mental and social well-being and is not merely the absence of disease or infirmity”
⁹ Telemedicine Journal and eHealth
marketing and advertising and internet access services." The French government of the time was marked by the emergence of this new concept as it launched, at the beginning of 2000, an "e-Health 2000" plan, worth €20 million, that was supposed to kick-start in France the development of e-health, which nevertheless integrated telemedicine. Lawyers subsequently analysed the European Directive of 22 June 1998, defining the information society services as applying to telemedicine, and not to telephone doctor consultations, as "undeniably, telemedicine falls within the scope of an Information Society service, that is to say, a service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services." The legal framework for services of the information society has been specified in the Directive of 8 June 2000. It is thus stated in Article 3 that "each Member State shall ensure that the information society services provided by a service provider established on its territory comply with the national provisions applicable in the Member State in question which fall within the coordinated field." The Directive, in Article 2, provides a certain number of definitions: the "service provider" (any natural or legal person who provides an Information Society service), the "established service provider" (provider who exercises an effective economic activity through a fixed establishment for an indefinite period), and the "coordinated field" (the requirements set by the legal systems of the Member States and applicable to providers of information society services or information society services, that are general in nature or have been specifically designed for them). The Directive further stipulates that "the coordinated field concerns requirements with which the service provider has to comply in respect of the taking up of the activity of an information society service, such as requirements concerning qualifications, authorisation or notification and the pursuit of the activity of an information society service such as requirements concerning the behaviour of the service provider, requirements regarding the quality or content of the service including those applicable to advertising and contracts, or requirements concerning the liability of the service provider." Finally, in Article 8 concerning the regulated professions using these services, the Directive states in paragraph 1 that "Member States shall ensure that the use of commercial communication which are part of, or constitute, an information society service provided by a member of a regulated profession 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," and in paragraph 2 that, "without prejudice to the autonomy of professional bodies and associations, Member States and the Commission shall encourage professional associations and bodies to establish codes of conduct at Community level in

11 DHOS Circular November 1999 to the ARH for the development of telemedicine
14 Pierre Desmarais. La télémédecine... c’est de l’e-commerce ! 14 October 2013 http://avocats.fr/space/pierre.desmarais
15 ref. 8
order to determine the types of information that can be given for the purposes of commercial communication in conformity with the rules referred to in paragraph 1." If we consider that these two Directives on information society services and legal rules of electronic commerce must apply to telemedicine, specifying the country of origin of the provider, the duty to provide prior information, the commercial communications which must comply with the provisions of the legislation, such as the code of ethics, this would lead to an amalgamation of telemedicine with an information society service, such as e-health more generally, and that consequently, it should respect the legal framework of e-commerce. The ambiguity of the analysis is obvious, since the very concept of telemedicine is not evoked at all in these two Directives, which mention only services of regulated professions, including doctors, who fall under information society services.

It was not until the Communication from the European Commission (EC) to the Parliament and the Council of 8 November 2008 that the EC provided a definition of telemedicine services: 16 "Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients." This definition was included in the Communication of 6 December 2012, a working document of the Commission services on the applicability of the European Union (EU) legal framework to telemedicine services. 17

This document describes the legal framework applicable to telemedicine services. Firstly, when telemedicine is considered a health care service, Articles 56 and 57 of the European Treaty consolidated in May 2008 18 on the free movement of services can be cited. Article 56 states that "within the framework of the provisions set out below, restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended," and Article 57 states that "services shall be considered to be ‘services’ within the meaning of the Treaties where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons. ‘Services’ shall in particular include: activities of an industrial character; activities of a commercial character; activities of craftsmen; activities of the professions." The Directive 2011/24/EU on cross-border healthcare, 19 in Articles 3(d) and 7(7), also forms part of the EU legal framework for telemedicine as a care service. When

17 Analysis of the European Commission in the working document of the Commission services on the applicability of the legal framework of the EU to telemedicine services, SWD(2012) 414 final. https://www.google.fr/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CDQQFjAA&url=http%3A%2F%2Fec.europa.eu%2Finformation_society%2Fnewsroom%2Fpdf%2Fdocument.cfm%3Fdoc_id%3D1251&ei=2yLTQV8mW9g9zqYQJNnvY6 dp%3Fsig%3DSCWTS%3Fvt%3D8x1bB54XnxbNmOMW0ajlO%3Bmv%3Db %3B6643336.d.d2k
telemedicine is considered as an Information Society service, the document refers to Directive 2000/31/EC on electronic commerce, otherwise known as the "e-commerce Directive" and Directive 98/34/EC, otherwise known as the "Directive on regulatory transparency." In this document the working group of the EC distinguishes the EU legal framework that falls under a health care service from that which falls under an Information Society service. The authors state that the EC has given until 2020 to develop a legal framework for telemedicine that is shared by all Member States, after taking into account the laws and regulations that some Member States have already implemented.

In 2004, the European Commission predicted that "e-health, including the Internet, to deliver patient care is also growing and should be a common occurrence at the end of the decade for health professionals, patients and the public." The Erkki Liikanen report presented before the EC even stated that "the challenges of health care in Europe required a bold response and thus the increased use of technology and services, such as internet as a partner in improvement of health care, should be encouraged." The report also showed that e-health was becoming the new industry of public health with an annual turnover of €11 billion, alongside pharmaceutical products and medical devices.

This semantic and cultural revolution, driven in the early 2000s by the information systems industry, and taken over by the EC, was not subject to a general consensus among health actors, as evidenced by two subsequent studies. The first, published in February 2005, studied how the new term "e-health" had included individuals, health professionals, academics and organisations. A broad review of the international scientific literature 1999-2004 revealed 51 different definitions covering the term "e-health" five years after the creation of the concept, demonstrating the absence of a clear consensus on this term. The second study, published in December 2012, was a bibliometric analysis of the terms 'telemedicine,' 'telehealth' and 'e-health' used in the international scientific literature up until the end of 2011. Of 11,644 documents consulted, 8,028 concerned telemedicine in 126 countries, 2,573 concerned e-health in 99 countries and 1,679 concerned telehealth in 55 countries. The authors showed that telemedicine remained the dominant term in published scientific studies and that the differing usage of these three terms suggested ambiguity or a lack of clarity of the concepts to which they referred.

The WHO, in its 2010 report on telemedicine, also revealed ambiguities in the terms telehealth and telemedicine, preferring finally to use only the term "telemedicine" that it had defined in 1997. However, Dr Fernando Antezana, Director-General of the WHO wished to complete this

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20 Ref.8
21 ref.11
24 Oh H et al. What is eHealth : a systematic review of published definitions. J Med Internet Res. 2005 Feb 24;7(1)e1
definition in December 1998, stating that the clinical field was attributed to telemedicine while the broader field of public health fell under telehealth. Finally, in an analysis published in July 2013 on the methodologies used in some 25 general reviews and meta-analyses on home telemonitoring, the Assessment Centre of HEC Montreal emphasised the negative impact that the ambiguous definitions of these three terms could have on the reliability of the results presented.

B) Clinical telemedicine: a clear concept for health professionals

In developed countries, telemedicine is mainly clinical, corresponding to a real remote medical act, while in developing countries telemedicine is more informative. Medical or clinical telemedicine is "an activity of health care service that implements digital means of communication allowing doctors and other medical staff to perform remote medical procedures for patients." By contrast, informative telemedicine is defined as "as an information society service that organizes interactive audiovisual dissemination of knowledge and medical protocols for management of patients and care in order to support and improve medical practice." France legalised the practice of clinical telemedicine on 22 July 2009 in the law on "Hospital, patients, health, territories" (Hôpital, patients, santé, territoires – HPST). The legal definition of telemedicine is contained in Article 78 of this law, and in the Code of Public Health, Article L.6316.1. This definition is unambiguous regarding the clinical character of telemedicine. The law article describes remote medical practice, which is divided into five clinical procedures in Decree 2010-1229 dated 19 October 2010 related to telemedicine. The conditions under which these acts are implemented are specified in the decree. They have been described in great detail in the recent HAS (Haute autorité de santé - French national authority for health) study published in July 2013, dedicated to helping developers achieve a high-quality and secure clinical telemedicine project. The decree and this HAS study reiterate the conditions for the exercise of clinical telemedicine: respect for patients’ rights with regard to information on their condition and treatment for which, also in

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28 In December 1998 in Geneva, Dr. Fernando Antezana, Director General of the WHO specified the following definitions of telehealth and telemedicine: "If telehealth is understood to mean the integration of telecommunications systems into the practice of protecting and promoting health, while telemedicine is the incorporation of these systems into curative medicine, then it must be acknowledged that telehealth corresponds more closely to the international activities of WHO in the field of public health. It covers education for health, public and community health, health systems development and epidemiology, whereas telemedicine is oriented more towards the clinical aspects."


30 Ref. 14

31 JM Croels. Le droit des obligations à l'épreuve de la télémédecine. PU d'Aix-Marseille, 2006, p.38

32 Id. p.39

33 Art. L.6316.1 du CSP : "Telemedicine is a form of remote medical practice using information and communication technologies. It connects, with each other or with a patient, one or more health professionals, which must include a medical professional and, where appropriate, other professionals providing their care to the patient. It helps establish a diagnosis, to provide, for a patient at risk, preventive or post-treatment monitoring, to request specialist advice, to prepare a therapeutic decision, to prescribe medication, prescribe or to perform services or acts to conduct monitoring of the patient’s condition. The definition of telemedicine procedures and their conditions for implementing and financial provision are determined by decree, taking into account the deficiencies in the provision of care due to geographic isolation and insularity."

34 Décret n° 2010-1229 du 19 octobre 2010 relatif à la télémedecine
terms of free choice of care, consent and confidentiality of personal health data must be obtained beforehand, the need for access to the medical record especially when the patient is suffering from a chronic disease, and the possibility of requesting a competent third party by tele-expertise when the patient's doctor judges it necessary. In the practice of clinical telemedicine, as in that of face to face medicine, telemedicine is obliged to comply with the Code of Medical Ethics, as reiterated by the CNOM (Conseil national de l'ordre des médecins - French national medical council) in January 2009 in its White Paper on Telemedicine.35

The use of the internet, for realising telemedicine acts, may be considered only if all the conditions for implementation specified in the decree are met. Thus the decree does not consider free or paying medical e-consultancy as acts of telemedicine. The CNOM warns doctors who might practice medical e-consultancy that it is a business practice prohibited by the Code of Medical Ethics (Article R4127-19 of the Code of Public Health). When medical e-consultancy is customized and remunerated, the CNOM has specified how the medical service might comply with the Code of Medical Ethics.36 Personalized e-consultancy could still be considered as an act of telemedicine only if the conditions for its realisation allowed the doctor to retain his or her full professional independence (art. R4127-5) with regards to the organizer of the telemedicine activity, and have a payment method involving remuneration per call, which is prohibited (art. R4127-53). Remuneration per call would link personalized internet e-consultancy to an e-health commercial medical activity related to e-commerce,37 prohibited by the Code of Ethics (Article R4127-19). In the case of personalized, medical e-consultancy given by the emergency services call centre doctor, an act included in the decree of telemedicine, the doctor has full professional, independent practice with regards to the organizer of the activity (public health establishment) and is an employee of the institution.

Therefore there cannot be any confusion or amalgam between clinical telemedicine and e-health. Telemedicine fulfils a need for remote medical provision and aims to improve equal access to high-quality care, a provision governed by the Code of Medical Ethics. E-health fulfils a need for an industrial provision aiming to develop a health industry market in order to improve the well-being and/or the well-ageing of persons, as defined by the WHO in 1946, which in France is more commonly called "telehealth."

C) Some fields of e-health or telehealth may be subject to EU Directive on electronic commerce

As has been previously mentioned, the common element of many definitions of e-health is the constant reference to a health industry market that has been developing in Europe for a decade and that is regularly evaluated by the EC. It is mostly personal services related to the information society, particularly electronic commerce. This includes most notably social home telemonitoring.

36 Télémédecine : les préconisations du CNOM, janvier 2009. www.conseil-national.medecin.fr/.../telem...
implemented to help maintain home support, prevent falls, improve conditions of isolation and equip the environment with various sensors to make it safer for individuals who are disabled or living alone (smart buildings or home automation). It also includes tele-compliance with medical devices by healthcare providers for patients treated at home and all that digital technologies can offer to improve the health information of individuals, whether on approved internet sites or the numerous medical applications on smartphones or digital tablets that contribute to the health education of individuals (Quantified Self) and thus the primary or secondary prevention of diseases. All these applications of e-health and more recent concepts such as Mobile Health or Living Labs may be governed by EU law. There are many other commercial services related to e-health and m-health, but the purpose of this article is not to be exhaustive. The reader may consult general journals on these topics.38 39

The field of information systems in the coordination of healthcare is also a subset of e-health. If it is indeed a service of the Information Society, from which the different actors and patients benefit, the European Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market states, in paragraph 22 of its preamble, that "the exclusion of healthcare from the scope of this Directive should cover healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided."40 Patients' medical records, whether professional, personal, as well as the pharmaceutical record, are shared records in various e-health activities and some telemedicine acts (teleconsultation, tele-expertise, telemonitoring). This domain may thus correspond to health care and pharmaceutical services because they are pivotal for better coordination of care delivered to patients by medical and non-medical health professionals.

Directive 2011/24/EC of 9 March 2011 on the application of patients' rights in cross-border healthcare41 allows care providers of a Member State in which a patient wishes to receive care access to electronic medical records hosted, if any, in the Member State to which the patient is affiliated. For this area within e-health, the Directive applies without prejudice to Directive 2000/31/EC of 8 June 2000 on certain legal aspects of information society services, particularly electronic commerce in the domestic market. Article 3, paragraph d, also states that "the 'Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established." Some lawyers suggest that the reference to telemedicine in this directive would amend national law on the grounds that "in EU law, this form of medical practice is a service of the Information Society, and it means that the intracommunity telemedicine is now possible, without a telemedicine contract being necessary."42 As discussed later, this assimilation of

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the act of cross-border telemedicine services with an information society service, id est an act of e-commerce, seems unfounded to the extent that the EC distinguishes in its communication dated 6 December 2012, the EU legal framework for telemedicine that is part of a health care service, from telemedicine that is part of the information society.43

D) The field of clinical telemedicine cannot fall within the scope of the Directive on electronic commerce

Is clinical telemedicine subject to the Directive on electronic commerce on the grounds that “the medical provision of telemedicine can be likened to a service provided against remuneration, remotely by electronic means and at the individual request of a recipient of services”? This is the legal issue regularly debated since France adopted legislation and regulation for the exercise of telemedicine. We would like to demonstrate that with the current state of the law and French legislation, such a change is not possible, firstly because the practice of clinical telemedicine in France cannot be a business (1), secondly because the exercise of clinical telemedicine cannot be equated with a service of the information Society (2) and thirdly because in the present state of EU law, there is no clear legal framework of telemedicine applicable to all Member States, with the exception of the cross-border telemedicine framework (3).

1) Clinical telemedicine, which is only medicine at a distance, whether exercised privately or publicly, is governed by the Code of Medical Ethics 44 which prohibits practising medicine as a business (art. R4127-19), providing personalised e-consultancy priced per act (art. R4127-53) and renouncing professional independence (art. R4127-5), for example by practising in an e-health agency that has commercial objectives.

2) Telemedicine structures an organisation of care services remotely using information and communication technology. The European Directive of 12 December 2006 on services in the internal market, specifies in Article 2 that it does not apply “to health care services, whether or not insured under healthcare facilities, and regardless of the how they are nationally organized and financed or whether they are public or private.” 45 All telemedicine organizations, whether in the hospital or self-employed sectors, are health care services and therefore excluded from the scope of this Directive. In addition, the EC Communication of 6 December 2012 clearly distinguishes what is clinical telemedicine, such as health care services, from what is informative telemedicine, such as Information Society services.


45 Télémédecine : les préconisations du CNOM, janvier 2009. www.conseil-national.medecin.fr/.../telem...
3) Regarding telemedicine, the EC adopted a position of support for the Member States requesting, in the communication of 4 November 2008,\textsuperscript{46} that they assess their needs and priorities by the Interministerial Conference on Health in late 2010. This communication also states that "before 2011, Member States should undertake to adapt their regulatory framework for authorizations, professional responsibility, judicial competence and administrative practices relating to refunds. Confidentiality of acts and patient safety must be guaranteed." France was one of the few member states to meet the demand of the EC since the article of the law on the exercise of telemedicine was enacted on 22 July 2009, the decree governing its implementation on 19 October 2010 and the national strategy for the development of telemedicine was adopted by the Council of Ministers on 8 June 2011.

In the communication of 6 December 2012,\textsuperscript{47} the EC intends to "develop a clear legal framework for medical acts provided through telemedicine systems" for all Member States by 2020, taking into account pre-existing laws and regulations in some Member States.

Finally, under the 2011/24/EC Directive on cross-border healthcare, Article 1, paragraph 4, states that "this Directive shall not affect laws and regulations of the Member States in terms of organization and financing of health care in situations unrelated to cross-border care." There is therefore no need to review the legislation and regulations on the practice of telemedicine within the Member State. However, in transposing this Directive into French law, it will be necessary to define the practice of cross-border telemedicine.

In conclusion, nearly 15 years after the emergence of the concept of e-health, which for some would replace that of telemedicine,\textsuperscript{48} it is clear that the concept and its sphere of operation still remain ambiguous. If it is recognized that e-health refers to "all digital aspects of remote or direct health" and that this corresponds to the "digital content related to health, also called e-health or telehealth," whether it is "the application of information and communication technology to all activities related to health in its broadest sense," that its issues are "numerous and cover various sectors of our society" of which economically it is "the emergence of a specific market growth generator and engine for economic gain," the ambiguous definition of its sphere of operation prevents a clear strategy for its development, as "telemedicine, prevention, home maintenance, monitoring of chronic disease at bay, electronic medical records, home automation, smart textiles, information and training, etc." are all jumbled together.\textsuperscript{50} Faced with such nebulous boundaries, the legal approach to e-health and telehealth remains complex. Hence the trend today in France to implement the national legal framework for telemedicine to e-health,\textsuperscript{51} which leads to an

\textsuperscript{47} Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 4 November 2008 on telemedicine for the benefit of patients, health care systems and society (COM 2008 689). http://europa.eu/legislation_summaries/public_health/european_health_strategy/sp0003_fr.htm
\textsuperscript{48} Ref. 42
\textsuperscript{49} Ref. 4 and 5
\textsuperscript{51} Id
erroneous amalgam of the practice of clinical telemedicine with e-commerce. Expressing a growing awareness of this ambiguity by the professional health community involved in the deployment of telemedicine, both in France and in some European countries, the CNOM and ANTEL collaboratively publish this analysis of European and national legal texts in order to demonstrate that the practice of professional clinical telemedicine, as defined by French law and regulations, or specified by the codes of medical ethics from several member countries of the European Union, cannot in any case fall under e-commerce. The practice of clinical telemedicine should be clearly distinguished from other legal services in the field of e-health. Indeed, the commercial activity borne by the digital health industry, which is governed by the European Directive of 8 June 2000 on information society services, id est e-commerce, does not fall within the scope of the practice of medicine, even when this practice uses information and communication technology tools.

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56 The German company telemedicine (DG telemed) reiterated during his Congress 2013 (6-8 November in Berlin), one of the obstacles to the development of telemedicine in Germany is the perception of German health professional that organizations advocated by the health industry, especially for home telemonitoring, are part of a commercial strategy about which German doctors were not consulted and to which the German Code of ethics does not allow them to adhere. http://www.dgtelemed.de/de/ueber-uns/highlights.php?lang=en
57 At the meeting of the Ambient Assisted Living Joint Programme (AAL JP) which was held in Stockholm 9 October 2013 on the theme of ‘ageing well’, the necessary distinction between eHealth and telemedicine was recalled. http://www.aal-europe.eu/
58 The National Association of Telemedicine (ANTEL) is a scientific society gathering the health professionals involved in the deployment of telemedicine in France, whose main purpose is to assess the medical service given to patients by the practice of clinical telemedicine. www.antel.fr