

# Patient Safety in e-Health and Telemedicine\*

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**Abstract:** Information and communication technologies provide opportunities for medical practice at a distance, including medical information, consulting, diagnosis, or even surgeries. Technologies can overcome physical distances and boundaries and promote wider access to health care. However, telemedicine raises issues of patient safety. The risk of malpractice may increase as both doctors and patients are not physically present, technologies may be unreliable or at least require special training to be operated by electronic means at a distance. Safety and confidentiality of communications are also sensitive questions. How does the legal system cope with the technological challenge? Are there specific rules for telemedicine? This paper addresses the European and national legal framework on telemedicine concerning licensing requirements, reimbursement, jurisdiction and applicable law. It has supported the communication to the IV European Conference on Health Law, which took place in Coimbra, Portugal, from October 9th to 11th, 2013,

## 1. Introduction

1.1. *Telemedicine projects.* Telemedicine is emerging as an alternative or a complement to traditional medical practice. In the European Union, the strategic document ‘A Digital Agenda for Europe’<sup>2</sup>, aims widespread deployment of telemedicine by 2020. In the US the American Telemedicine Association<sup>3</sup> presents itself as ‘the leading international resource and advocate promoting the use of advanced remote medical technologies’, and the U.S. Department of Health and Human Services’

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\* *Lex Medicinæ – Revista Portuguesa de Direito da Medicina, N.º Especial* (2014), p. 95-106.

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<sup>2</sup> COM(2010)245 final.

<sup>3</sup> <http://www.americantelemed.org/>

Health Resources and Services Administration (HRSA) Office for the Advancement of Telehealth has funded the Telehealth Resource Centers (TRCs).<sup>4</sup>

On this side of the Atlantic, Norway has launched a leading project on telemedicine as a response to problems of very low population density, long distances to see a doctor, and ageing population. The Norwegian Centre for Telemedicine (NST) is located in the city of Tromsø in the north of Norway. The Centre's mission is to produce and provide knowledge about telemedicine and e-health, both nationally and internationally. The goal is to ensure the integration of telemedicine services into health care. It is internationally well-known and has been a World Health Organization (WHO) Collaborating Centre for Telemedicine since 2002.<sup>5</sup>

In Portugal, telemedicine is already connecting five districts in the Centro Region, notably Guarda, Coimbra, Viseu, Aveiro and Leiria, networking circa 50 units of healthcare. The telemedicine program also provides access to medical specialities, in particular pediatrics, cardiology, radiology, dermatology, endocrinology, and psychiatric medicine. There are also specialized private operators, such as the Institute of Telemedicine LLP ("Instituto de Telemedicina, Lda."), which provides medical services and consulting, diagnosis and therapeutics, by telemedicine.<sup>6</sup>

*1.2. Advantages of telemedicine and the emerging market for eHealth services.* Telemedicine has many advantages for healthcare systems, in particular reducing hospitalisation costs, saving on unnecessary emergency visits, shortening waiting times, improving access to healthcare by patients living in remote areas, and facilitating cross border healthcare.

Telemedicine is also a new economic opportunity. The global market for eHealth is estimated to have a potential value of €60 billion, of which Europe represents one third, i.e. €20 billion. The combined global value of the telehome and telehospital market in 2011 was estimated at €8.8 billion in 2011, which will climb to €20.7 billion in 2016, according to a BCC Research study of March 2012.<sup>7</sup>

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<sup>4</sup> <http://www.telehealthresourcecenter.org/>. There are a total of 14 TRCs which include 12 Regional Centers, all with different strengths and regional expertise, and 2 National Centers which focus on areas of technology assessment and telehealth policy. The website of TRCs has a module on legal and regulatory concerns raised by Telehealth, especially regarding cross-state practice and reimbursement.

<sup>5</sup> [http://www.ehealthservices.eu/project\\_partners/nst](http://www.ehealthservices.eu/project_partners/nst)

<sup>6</sup> <http://www.i-telemedicina.pt/>

<sup>7</sup> Commission Staff Working document on the applicability of the existing EU legal framework to telemedicine services, SWD(2012) 414 final, Brussels, 6.12.2012.

1.3. *Definition of telemedicine and e-health services and the problem of lack of legal security.* Telemedicine is defined as "the provision of healthcare services, through the 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"<sup>8</sup>. Examples of telemedicine services are teleradiology, teleconsultation, telemonitoring, teleophthalmology, telesurgery and teledermatology. In broad sense telemedicine also includes other e-health services, notably health information portals, online pharmacy<sup>9</sup>, electronic health record systems, electronic transmission of prescriptions or referrals (e-prescription, e-referrals), and e-prescription.

There is no uniformity of regulations among EU Member States concerning telemedicine services. This lack of legal security is considered an obstacle to the development of eHealth market.<sup>10</sup> Most Member States do not have legal instruments specifically dealing with telemedicine, and only a few have adopted national regulations or professional and ethical guidelines concerning the provision of telemedicine services. Some national legal systems, such as Poland, require the physical presence of the patient and health professional at the same time and in the same place, for a medical act to be legally valid<sup>11 12</sup>.

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<sup>8</sup> See Commission Communication on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689; and Commission Staff Working document on the applicability of the existing EU legal framework to telemedicine services, SWD(2012) 414 final, Brussels, 6.12.2012.

<sup>9</sup> In Portugal online pharmacy has been authorized by Decree-Law No 307/2007 of 31 August, implemented by Ministerial Order No 1427/2007 of 2 November.

<sup>10</sup> Legal concerns raised by telemedicine include, notably, licensing requirements for delivering cross-border telemedicine (1), compliance with data protection regulations (2), conditions and rights for reimbursement (3), liability (4), jurisdiction and applicable law (5).

<sup>11</sup> EU legal framework to telemedicine services, SWD(2012) 414 final. This paper provides a synopsis of the document, addressing legal issues of telemedicine such as the free provision of services in the internal market, telemedicine as cross-border healthcare and information society services, licensing, and jurisdiction.

<sup>12</sup> Albeit not covered by this paper, protection of data and privacy in electronic communication is also a relevant issue of telemedicine. In fact, telemedicine by its nature involves personal data processing through the generation and/or transmission of personal data related to health. Article 8 of the EU Charter of Fundamental Rights, which has become legally binding, guarantees the fundamental right to the protection of personal data and it is enshrined in Article 16(1) of the Treaty on the Functioning of the EU (TFEU). According to the Directive on the application of patients' rights in cross-border healthcare the Member State of treatment must ensure that the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Directive 95/46/EC (currently under review) is the general EU law on the protection of personal data, which sets the rights of data subjects and establishes criteria for the legitimacy of processing personal data, including "personal data on health". It prohibits the processing of personal data related to health unless certain conditions are fulfilled (Article 8 of the Directive). According to the European Court of

## 2. The principle of freedom to provide telemedicine services in the internal market

**2.1. General rule.** Telemedicine is a service and as such falls under the provisions of the Treaty on the Functioning of the European Union (TFEU).<sup>13</sup> The European Court of Justice has consistently held that health services fall within the scope of the freedom to provide services (Article 56 TFEU)<sup>14</sup> and that neither the special nature of health services nor the way in which they are organised or financed removes them from the scope of this fundamental freedom.<sup>15</sup> This includes citizens' freedom to seek and receive health and care services from another Member State, regardless of how the service is delivered, i.e. including through telemedicine, as the Court expressly recognised that the freedom to provide services applies to services, which a provider supplies without moving from the Member State in which he is established, to recipients in other Member States.<sup>16</sup>

**2.2. Possible restrictions.** Member States are, however, allowed to maintain or introduce restrictions to the free movement of services, provided that these are justified by imperative reasons of public interest (e.g. public health), do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules.<sup>17</sup>

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Justice, the notion of "data concerning health" must be given a wide interpretation, so as to include information concerning all aspects, both physical and mental, of an individual's health (European Court of Justice, Judgment of 6 November 2003, Case C-101/01 - *Bodil Lindqvist*, 50 and 51). The Article 29 Data Protection Working Party provided further interpretation of this concept by recommending that health data should cover: a) any personal data closely linked to the health status of a person only, such as genetic data or data on consumption of medicinal products, alcohol or drugs; b) any other data contained in the medical documentation concerning the treatment of a patient – including administrative data (social security number, date of admission to hospital, etc.), so that any data that is not relevant for the treatment of the patient, should not be included in the medical files. On the other hand, Directive 2002/58/EC lays down specific requirements in connection with the provision of publicly available electronic communications services in public communications networks to ensure confidentiality of communications and security of their networks.

<sup>13</sup> EU legal framework to telemedicine services, SWD(2012) 414 final.

<sup>14</sup> ECJ judgment of 31 January 1984 in joined cases 286/82 and 26/83 *Luisi and Carbone*.

<sup>15</sup> See in particular ECJ judgment of 28 April 1998, in case C-158/96 *Kohll*; ECJ judgment of 12 July 2001 in case C-368/98, *Vanbraekel*; ECJ judgment of 13 May 2003 in case C-385/99, *Müller-Fauré and Van Riet*; ECJ judgment of 12 July 2001 in case C-157/99, *Smits and Peerbooms*; ECJ judgment of 16 May 2006 in case C-372/04, *Watts*.

<sup>16</sup> ECJ judgement of 10 May 1995 in case C-384/93 *Alpine Investments*.

<sup>17</sup> ECJ judgment of 02 March 2011 in case C-108/91 *Ker-Optika*, 58 until 76. ECJ judgement of 4 December 1986 in case 205/84, *Commission v Germany*, paragraphs 27 and 29; ECJ judgment of 26

It means, in short, that, in principle, Member States should not adopt any national law, which would prevent service providers from exercising their freedom to provide telemedicine services. Any obstacle to the freedom to provide services across borders is prohibited, unless it is justified by imperative reasons of public interest, for example on grounds of public health. Administrative and reimbursement difficulties might represent obstacles in this regard, and Member States should prove that they are justified.

Does telemedicine have sensitive concerns which may justify, under the rule of reason, protective regulations at national level against cross-border telemedicine?

**2.3. *The Portuguese Deontological Regulation of Telemedicine.*** In Portugal, the Medical Deontological Code<sup>18</sup> has a chapter on telemedicine. Telemedicine is not prohibited, but it does not appear to be a preferential or privileged mode of medical practice.

To begin with, the Code provides the principle of freedom of doctors to use telemedicine. This principle is enshrined in a provision on doctor's liability (Art. 95), and means that doctors are free and completely independent to decide whether to use or to refuse telemedicine (Art. 95/1). A doctor who asks the opinion from a colleague is liable for treatment as well as for decisions and recommendations given by him to the patient (Art. 95/2). Moreover, tele-consulted doctors have no obligation to issue an opinion where they have not knowledge or enough information on the patient to give a reasoned opinion, but they are liable for it if they give it (Art. 95/3).

On the other hand, the Code provides that telemedicine must respect the doctor-patient relationship (Art. 94), preserving mutual trust, independence of doctor's opinion, patient's autonomy and confidentiality (Art. 94/1). Where the patient requests a supervision consultation by means of telemedicine, this must not replace the doctor-patient relation and shall only be given if the doctor has a clear and justifiable idea of the clinical situation of the patient (Art. 94/2).

Then, doctors who use means of telemedicine and do not physically observe the patient in presence must carefully evaluate the received information, and they can only give opinions, recommendations or take medical decisions where the quality of the received information is enough and relevant (Art. 94/3). In telemedicine emergency

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February 1991 in case C-180/89, *Commission v Italy*, paragraphs 17 and 18; and ECJ judgement of 20 May 1992 in case C-106/91, *Ramrath*, paragraphs 30 and 31.

<sup>18</sup> Enacted by Regulamento n.º 14/2009 of 13 January 2009 - <http://dre.pt/pdf2sdip/2009/01/008000000/0135501369.pdf>

situations it is allowed that the opinion of the tele-consulted doctor be based upon incomplete information, but the assistant doctor shall be liable for the decision to be taken (Art. 94/4).

On the other hand, the Code contains a special provision of patient's security in telemedicine (Article 96). It provides that doctors shall only use telemedicine provided that they make sure that the team in charge of its performance assures a level of quality sufficiently high which works in a proper way and complies with established regulations (Art. 96/1). In particular, doctors must use supporting systems, quality controls and evaluation procedures to monitor the accuracy and the quality of the received and transmitted information (Art. 96/2). Moreover, doctors can only use telemedicine once they have made sure that the system used and its users assure medical secret, namely by means of encryption of names and other identifying data (Art. 96/3).

Confidentiality is a sensitive issue of telemedicine. Concerning collaborators who are not doctors and take part in the transmission or reception of data, doctors must make sure that the education and skills of such professionals are adequate, so that they can assure an appropriate use of telemedicine and the preservation of medical secret (Art. 95/4). Telemedicine practitioner doctors clarify the patient and obtain his consent according to Articles 44 to 48 of the Deontological Code (Art. 95/5), and they must assure the application of security measures established to protect the patient's confidentiality (Art. 95/6).

Concerning clinical records, doctors using telemedicine must register in the clinical file the methods of identification of the patient as well as information requested and information received (Art. 97/1). Tele-consulted doctors must register in the clinical file the opinions which they have issued and the information upon which they have based their opinions (Art. 97/2). Computerized methods of storage and transmission of the patient's data may only be used where enough measures have been adopted to protect confidentiality and security of stored or exchanged information (Art. 97/3).

In short, the deontological Code allows doctors to use telemedicine, provided that it respects the doctor-patient relation, patient's security and confidentiality.

Do these special concerns of the deontological Code prevent the provision of telemedicine by doctors established in another Member State to patients located in Portugal?

In principle it should not have a restrictive effect on the freedom to provide medical services within the internal market. But it is possible that the telemedicine concerns may justifiably obstacle an absolute freedom of telemedicine.

### **3. Telemedicine as (possible) cross-border healthcare and as information society service**

3.1. EU Directive 2011/24 on the application of patients' rights in cross-border healthcare<sup>19</sup>, due to be transposed by 25 October 2013<sup>20</sup>, codified the jurisprudence of the European Court of Justice on EU patients' rights to be reimbursed for medical treatment in other EU Member States<sup>21</sup>, including through eHealth and telemedicine.<sup>22</sup>

Telemedicine services fall within the scope of this Directive when they are health services provided by health professionals<sup>23</sup>. It contains two express references to telemedicine (Article 3(d) and Article 7(7)) and its scope covers “the provision of healthcare to patients, regardless of how it is organised, delivered or financed” (Article 1(2)). This Directive clarifies patients' rights to be reimbursed for the provision of cross-border health services, including cross-border telemedicine services. The key applicable provisions are the following:

- a) Rights are established to ensure that the essential information on prices, quality and safety of care are accessible to the patient to ensure an informed decision;
- b) The Member State of treatment (that in case of telemedicine is the Member State where the service provider is established) must ensure that the healthcare in question is provided in accordance with its legislation (Article 4(1));
- c) The principle of non-discrimination with regard to nationality is recognised and applies both to access and to fees charged for medical services (Article 4(3) and (4)).

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<sup>19</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

<sup>20</sup> A proposal for the implementation of Directive 2011/24/EU has been open to public discussion - <http://www.portaldasauade.pt>

<sup>21</sup> E.g. judgment of 27 October 2011, C-255-09, Commission v. Portugal.

<sup>22</sup> EU legal framework to telemedicine services, SWD(2012) 414 final.

<sup>23</sup> Health care professional, as defined in Article 3(f) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, “means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment”.

d) In principle, the Member State of affiliation of the patient ('home-country') shall reimburse the costs of cross-border healthcare if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

3.2. EC Directive 2000/31 on electronic commerce<sup>24</sup> creates a legal framework to ensure the free movement of information society services. It sets information requirements for information society service providers, rules on commercial communications, contracts concluded by electronic means and the liability of intermediary service providers<sup>25, 26</sup>.

In order for a telemedicine service to qualify as an information society service, it needs to be a "service normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of service"<sup>27</sup>.

The main provisions of the eCommerce Directive that apply to cross-border telemedicine are the following:

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<sup>24</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce').

<sup>25</sup> The specific liability regime of intermediaries of information society services provided for the eCommerce Directive does not apply to the providers of telemedicine services as they are not considered "intermediaries" in the meaning of Articles 12-15 of the eCommerce Directive.

<sup>26</sup> See Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee - First Report on the application of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), COM(2003)702 final.

<sup>27</sup> Article 2(a) and Article 1(2) of Directive 98/34/EC (Regulatory Transparency Directive) and whereas 17 of eCommerce Directive. The notion of information society services has four elements: for remuneration (1), at a distance (2), by electronic means (3), at the individual request of a recipient (4). "Remuneration" is to be considered in relation to the service in question, regardless of who effectively pays for the telemedicine service. "At a distance" means that the service is provided without the parties being simultaneously present. All telemedicine services are by definition provided at a distance. "By electronic means", i.e. the service also has to be sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by means of wire, radio, optical means or other electromagnetic means. This means that the following health services are not information society services: a) services provided in the physical presence of the provider and the recipient, such as medical examinations at a doctor's premises, even if using electronic equipment; b) services which are not using online telecommunication services, such as a telephone or telefax medical consultation or medical call-centers providing services through traditional *voice telephony*. "At the individual request of a recipient" means that services falling under the definition of information society service are those provided in response to an individual request from the recipient. Telemedicine services are usually provided at the individual request of a recipient. Patients *being* treated by a doctor using telemedicine services (e.g. teleradiology), implicitly accept such services and this constitutes the individual request. Examples of services supplied on individual request can be found in the Vade-mecum to the Regulatory Transparency Directive, which include "*doctors (computer medicine), etc., access to databases, data and file management, consultation, diagnosis etc.*"

a) The *country of origin principle* provides that the law applicable to an information society service will be the law of the Member State in which the service provider is established, i.e. the place in which a service provider effectively pursues an economic activity using a fixed establishment for an indefinite period. The Member States may however under certain circumstances and procedural conditions and on a case-by-case basis take measures to restrict the provision of a particular online service from another Member State (Article 3).

However, according to the Regulatory Transparency Directive<sup>28</sup>, Member States wishing to adopt a regulation on telemedicine services as information society services will have to notify it to the Commission and to other Member States before adoption. This requirement seeks to verify that the future regulation will not create obstacles to the free movement of information society services and to the freedom of establishment (of information society service providers) within the internal market.

b) The principle of *free access to the electronic market* means that Member States cannot subject the taking up and the pursuit of the activity of an information society service provider to prior authorisation or any other requirement having an equivalent effect (Article 4 (1)).

c) Concerning *duties of information and freedom of commercial communications*, information society service (ISS) providers, including telemedicine providers, have to render easily, directly and permanently accessible to the recipients of the service a set of information, such as their identity and contact details on their website. Regulated professions have to provide additional information concerning, for instance, their professional body or registered institution, professional title and the Member State where it has been granted.

Telemedicine providers have to comply with some specific requirements when using commercial communications for the promotion of e-Health services or products (Articles 6 and 7), for instance, ensuring they are clearly and unambiguously identifiable as such. The rules on unsolicited commercial communications were

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<sup>28</sup> Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, as modified by Directive 98/48/EC.

complemented by new rules in Directive 2002/58, amended by Directive 2009/136<sup>29</sup>. The principle is the requirement of prior consent and the right to opt-out.

Members of regulated professions may use commercial communications online, subject to compliance with such professional rules governing the independence, honour and dignity of the profession. Restrictions are allowed but a total ban of commercial communications is to be removed by Member States according to Article 24(1) of Directive 2006/123/EU on services in the internal market.

#### **4. Licensing**

In order to provide telemedicine cross-border within the EU, do healthcare professionals also need to be licensed or registered in the Member State of the patient? The 'country-of-origin principle' answers to this question.

**5.1.** Licensing is required at the source, i.e. in the country of origin. In most Member States, the competence to accredit professionals wishing to deliver health services is delegated to an appointed licensing or registration body.

In Portugal this body, concerning doctors, is the *Ordem dos Médicos* (Doctors' Association). Registration is restricted to graduates in medicine by a Portuguese medical school or, where recognized, by a foreign medical school. Upon being licensed/registered, the health professional will have to abide by the rules and regulations established by the licensing authority (the professional body) and to be subject to disciplinary sanctions in case of non-compliance.

**5.2.** The Member State of establishment is the Member State of provision of telemedicine. In fact, Directive 2001/24/EU provides that the Member State of treatment is that of the service provider's Member State of establishment, and that "healthcare is considered to be provided in the Member State where the [telemedicine] healthcare provider is established" (Articles 3 (d) and 4(1)(a)).

The application of the legislation of the service provider's Member State of establishment (as the 'country-of-origin principle') is also enshrined in the e-Commerce

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<sup>29</sup> Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws.

Directive (Article 3(1) and 3(2) of Directive 2000/31/EC). It means that Directive 2005/36/EC on the recognition of professional qualifications<sup>30</sup> does not apply to healthcare professionals providing cross-border telemedicine.<sup>31</sup> Article 5(2) of this Directive provides that it is only applicable to situations where the service provider actually moves to the territory of a host Member State to pursue a regulated profession. As indicated above, telemedicine services are provided without the actual movement of the telemedicine provider health care professional.

## **5. Reimbursement**

Cross-border telemedicine services are, in principle, entitled to reimbursement. According to Directive 2011/24/EU, patients are entitled to be reimbursed by their Member State of affiliation, for the healthcare received in another EU Member State, if the healthcare in question is among the benefits to which the insured person is entitled in his home country.

The Directive 2011/24/EU makes it clear that cross-border healthcare services using e-Health services are also to be reimbursed (Recital 26). The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through the use of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities as it would impose if this healthcare were provided on its territory (Article 7(7)).

On the other hand, reimbursement of cross-border healthcare, cannot, as a rule, be subject to prior authorisation (Article 7(8)). Member States may however introduce a system of prior authorisation only for certain types of healthcare and under strict conditions (Article 8(2)), such as planning requirements and the use of highly specialised and cost-intensive medical infrastructure or medical equipment. Such a system has to be restricted to what is necessary and proportionate to the objective to be achieved. Member States should notify to the European Commission of the set-up of a prior authorisation system and make publicly available which healthcare is subject to such system.

The Directive also limits the conditions under which the Member State of affiliation may refuse to grant prior authorisation to an insured person (Article 8(6)).

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<sup>30</sup> Directive 2005/36/EC of the Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications.

<sup>31</sup> EU legal framework to telemedicine services, SWD(2012) 414 final

## **6. Jurisdiction and applicable law in case of damage**

An important issue is the determination of the competent court and the applicable law where the patient seeks compensation for damages suffered due to telemedicine.<sup>32</sup>

**6.1.** For civil and commercial matters, the rules determining the *competent jurisdiction* in a cross-border situation are provided in Regulation 44/2001<sup>33</sup>.

To begin with, parties are free to designate, by written agreement, which court should be competent to resolve a possible conflict arising between them (Article 23). However, consumer protection limits the possibility for such a designation in the case of a consumer/ professional contractual relationship is (Article 17).

Where parties do not contractually define the court of their choice, as a general rule jurisdiction is to be exercised in the Member State in which the defendant is domiciled, regardless of his/her nationality. However, in certain circumstances a defendant may be sued in the courts of another Member State.

In matters involving a non-contractual relationship, the competent courts are those of the place where the harmful event occurred or may occur (Article 5(3)). This includes the place where either the act causing harm or the direct damage occurs. In cross-border telemedicine, the place where the act causing the damage occurs is located in the Member State where the professional is when delivering the service (a); and the place where the damage arises is located in the Member State where the patient was when he received the medical advice or treatment (b).

In matters involving a contractual relationship a distinction is made between contracts between professionals only (B2B) and contracts between professionals and consumers (B2C).

In B2B contracts, the competent courts are the courts in the Member State where, under the contract, the services were provided or should be provided (Article 5(1)(b)). In B2C contracts, where the professional's activity is 'directed to the Member State of the consumer's domicile or to several States including that Member State', the consumer may only be sued (e.g. over a dispute concerning an unpaid bill) before the competent courts of the Member State of his domicile, and he has a choice to sue either in the

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<sup>32</sup> EU legal framework to telemedicine services, SWD(2012) 414 final.

<sup>33</sup> Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters hereinafter "Regulation Brussels I".

Member State where the other party is domiciled or in the Member State where he is himself domiciled (Article 15(1)(c) and Article 16). In the rulings *Alpenhof* and *Pammer*<sup>34</sup>, the European Court of Justice clarified the notion of ‘directed activities’ in the context of the internet, holding that to determine whether a trader's website is ‘directing’ its activity to the Member State of the consumer’s domicile, it should be ascertained whether, before the conclusion of any contract, it was apparent from the website and the trader’s overall activity that he was foreseeing business opportunities in that Member State<sup>35</sup>. Accordingly, “the mere accessibility of the trader’s or the intermediary’s website in the Member State in which the consumer is domiciled is insufficient”, for ex. where a Portuguese consumer requests from a Swedish telemedicine provider services available only in Swedish.

If the activity is not directed to the Member State of the consumer's domicile, the competent courts are the courts in the Member State where, under the contract, the services were provided or should be provided (Article 5(1)(b)). In cross-border telemedicine scenarios, it is argued by the European Commission that, by analogy with the case-law concerning the delivery of goods, it could be reasonably be the Member State where the patient was when he received the advice or treatment<sup>36</sup>. However, according to Directive 2011/24/EU: “In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established” (Article 3(d)).

**6.2. Concerning *law applicable to contracts*, Regulation Rome I<sup>37</sup> provides rules on the applicable law to civil and commercial contracts.**

Concerning contracts between professionals (B2B), the general rule is the freedom of choice of the parties, meaning that the applicable law to the contract will be the one expressly chosen by the parties. In the absence of choice, the default rule for services contracts shall apply, according to which contracts for the provision of services are

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<sup>34</sup> ECJ Rulings C-144/09 and C-585/08 of 7 December 2010.

<sup>35</sup> The Court also formulates a non-exhaustive list of matters from which it may be concluded that the trader’s activity is directed to the Member State of the consumer’s domicile: “*the international nature of the activity, mention of itineraries from other Member States for going to the place where the trader is established, use of a language or a currency other than the language or currency generally used in the Member State in which the trader is established, mention of telephone numbers with na international code, outlay of expenditure on an internet referencing service to facilitate access to the trader's site or that of its intermediary by consumers domiciled in other Member States etc.*”.

<sup>36</sup> EU legal framework to telemedicine services, SWD(2012) 414 final.

<sup>37</sup> Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I Regulation).

governed by the law of the Member State where the service provider has his habitual residence (Article 4(1)(b)), i.e. the home-country of the telemedicine provider.

Concerning contracts between professionals and consumers (B2C), the parties are also free to choose the applicable, but the consumer may not be deprived of the protection afforded to him by the provisions of the law of his country that cannot be derogated from (due to their importance) through agreement. In case there's no choice of law agreement, the law applicable is either the law of the country where the consumer has his habitual residence (Article 6) in case the healthcare professional directs its activities to the Member State where the consumer has his habitual residence or to several countries including that country (i), or the law of the Member State where the service provider has his habitual residence (Article 4(1) b)) in case the healthcare professional does not direct its activities to the Member State where the patient has his habitual residence (ii).

**6.3.** As for *law applicable to torts*, Regulation Rome II<sup>38</sup> applies to situations involving a conflict of laws regarding non-contractual obligations in civil or commercial matters.

The law applicable to torts is the law of the country in which the damage occurs, i.e. the Member State where the patient was when he received the treatment. This law applies irrespective of the country in which the event giving rise to the damage occurred (i.e. the Member State where the healthcare professional was when he delivered the advice/treatment) and irrespective of the country or countries in which the indirect consequences of that event occur (Article 4(1)). Notwithstanding, under certain conditions, the parties may choose another applicable law by an agreement entered into after the event giving rise to the damage occurred (Article 14).

In what concerns the relationship between the applicable law and the country-of-origin principle, Article 4 of Directive 2011/24/EU provides that cross-border healthcare shall be provided in accordance with the legislation of the Member State of treatment and the standards and guidelines on quality and safety laid down by that Member State (Article 4 of Directive 2011/24/EU), i.e. treatment must be carried out in a way that complies with the provider's local law.

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<sup>38</sup> Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II Regulation).

However, this does not derogate from the rules set out in the Rome I and II Regulations on applicable law (Article 2(q) of the Directive 2011/24/EU), as the law applicable to civil liability may be of a different Member State than the one of the healthcare provider. The scope of Article 4 of Directive 2011/24/EU is limited to public law issues, and goes hand-in-hand with Article 17 of the Rome II Regulation, according to which in assessing the conduct of the person claimed to be liable, account shall be taken of the rules of safety and conduct in force in the place of the event giving rise to liability.<sup>39</sup> For example, if the Member State of treatment is Portugal because it is the country of origin of the telemedicine provider but the parties have chosen Spanish law, the latter will apply to civil liability between the parties despite the standards imposed by Portuguese law are still relevant in determining whether a surgeon has complied with local requirements on standards and guidelines on quality and safety applicable to telemedicine.

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<sup>39</sup> EU legal framework to telemedicine services, SWD(2012) 414 final.