E-ENERCA

WP6

TELEMEDICINE PROJECT

LEGAL ASPECTS

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SUMMARY

1. Introduction. Aims and scope of the report

According with the Commission *Communication on telemedicine for the benefit of patients, healthcare systems and society*, Telemedicine is defined as "the provision of healthcare services, through the use of ICT (Information and Communication Technology), 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".

Telemedicine could involve medical actions as diagnosis (including a medical second opinion), treatment or follow up of patients.

The European Commission has adopted a favourable vision concerning telemedicine as a tool to improve healthcare and quality of life, to short waiting times, and to optimise the use of available resources.

As it was agreed in the e-enerca WP6 First internal meeting, in the field of our project telemedicine and tele-expertise are defined as:

Telemedicine, use of an interface in view to help at a distance non expert physicians making a diagnosis and giving advices to monitor and treat their patients; all data are anonymized.

Tele-expertise, use of an interface for remotely asking for second opinion by exchange of anonymized data between scientists.

The aims of this report are two:

a) The analysis of the legal framework of telemedicine services in the European Union (EU)

b) The description of the legal requirements for the establishment of a telemedicine platform withing e-enerca project in the terms agreed.

2. European legal framework of telemedicine services in the EU

This analysis is based on the Commission staff working document on the applicability of the existing EU legal framework to telemedicine services (Brussels, 6.12.2012. SWD(2012) 414 final).

2.1. Telemedicine as a healh care service

If telemedicine is understood as a service (an action performed to satisfy a need or to fulfill a demand of a client), it falls into the scope of article 56 of the Treaty on the Functioning of the European Union (Treaty of Lisbon, 2007): "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. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure, may extend the provisions of the Chapter to nationals of a third country who provide services and who are established within the Union".

This means that European citizens are free to seek and receive health care services from another Member State, including Telemedicine. Member States can regulate the free movement of services. In the case of telemedicine a further regulation is in the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare as it covers *"the provision of healthcare to patients, regardless of how it is organised, delivered or financed"* (Article 1(2) of the Directive).

The Directive refers to the issue of patient´s right to be reimbursed after receiving a health service abroad.

Healthcare is defined as:"health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices".

Member State of treatment is defined as 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".

Member State of affiliation is the State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State or the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State.

"The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources" (Article 7(7) of the Directive)

In conclusion, as stated in the Directive, patients have the right to be reimbursed for the telemedicine services in the same conditions provided for cross border health care in general.

The key applicable provisions are the following:

- Rights are established to ensure that the essential information on prices, quality and safety of care are accessible to the patient to ensure informed decision.
- The Member State of treatment must ensure that the healthcare in question is provided in accordance with its legislation (Article 4(1) of the Directive).
- The Directive provides that, in principle, the Member State of affiliation of the patient 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.

- In the case of rare diseases, patients can be referral to other Member State even for diagnosis and treatments which are not available in the Member State of affiliation (Article 13 of the Directive)
- Health care may be subject to prior authorization when:

  (a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:

  (i) involves overnight hospital accommodation of the patient in question for at least one night; or

  (ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;

  (b) involves treatments presenting a particular risk for the patient or the population; or

  (c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

2.2. Data protection

2.2.1. Relevant provisions in the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Directive 95/46/EC 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". Directive 95/46/EC is currently

under review[1] with the aim to modernise and clarify the EU legal system for the protection of personal data, strengthen individuals' rights, while at the same time reducing administrative formalities to ensure a free flow of personal data within the EU and beyond.

As regard to its scope of application, Directive 95/46/EC establishes that "personal data" means any information related to an identified or identifiable natural person (the "data subject"; Article 2 a) of the Directive). An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

"Processing of personal data" means any operation or set of operations, which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction (Article 2 b) of the Directive).

These definitions are similar in The European Parliament legislative resolution of 12 March 2014 on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation):

“"Data subject means an identified natural person or a natural person who can be identified, directly or indirectly, by means reasonably likely to be used by the controller or by any other natural or legal person, in particular by reference to an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person”;

“Pocessing means any operation or set of operations which is performed upon personal data or sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, erasure or destruction”.

[1] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0212+0+DOC+XML+V0//EN

Special protection for personal data related to health

According to Directive 95/46/EC the processing of personal data related to health is prohibited unless certain conditions are fulfilled (Article 8 of the Directive and in a similar way Article 9.1 of the Proposal of General Data Protection Regulation).

Exemptions to this prohibition principle are laid down in the Directive, in particular if processing is *required* for specified medical and healthcare purposes. The general prohibition of processing such personal data does not apply where, among other circumstances, the data subject has given his explicit consent to the processing; or where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy (Article 8(3) of the Directive and in a similar way Article 9.2 of the Proposal of General Data Protection Regulation).

General principles for the processing of personal data

The processing of personal data related to health must comply with the following general data protection principles established by legislation. Some of the key principles are outlined in the following summarised table:

Personal data must:

- Only be collected for specific, explicit and legitimate purposes and not be kept for longer than necessary (Article 6(1)(b) of the Directive 95/46/EC).
- Be limited to the relevant data for the specific purposes they are intended to fulfil, e.g. by obtaining appropriate contractual or other commitments from the entities in the third countries (Article 6(1)(c) of the Directive 95/46/EC)

Data controllers must:

- Provide certain information to data subjects on the identity of the controller and recipients of data, the purposes of the processing, and the existence of a right of access (Articles 10 and 11)
- Allow data subjects access to their personal data

Patients who have received cross-border healthcare treatment (including through telemedicine) are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this (See Articles 4(f) and 5(d) of Directive 2011/24/EU).

– Implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or unauthorised disclosure. Such measures shall ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected (Article 17)

In telemedicine, the health data first have to be processed according to the law of Country of the patient as the data controller is a healthcare provider from that country. The controller will have to ensure that the processing was legitimate according to Article 8 of the Data Protection Directive 95/46/EC and the Country law transposing the Data Protection Directive. Once the health data of the patient are transferred to other Country, any further processing must comply with the law of that Country (e.g. legitimate grounds for processing, information to data subject, access to data, security requirements, etc.).

2.2.2. Relevant provisions in the Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector

Directive 2002/58/EC (as lastly amended by Directive 2009/136) 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.

The Directive regulates issues raised in the context of electronic communications. Data protection Directive 95/46/EC is applicable but there are further provisions concerning security in the elecronic mail, spam, cookies, etc.

The directive obliges the providers of services to erase or anonymize the traffic data processed when no longer needed. Data may be retained upon a user's consent for marketing and value-added services. For both previous uses, the data subject must be informed why and for how long the data is being processed. Article 13 prohibits the use of email addresses for marketing purposes.

The Directive provision applicable to cookies is Article 5(3). Member States shall ensure that the use of electronic communications networks to store information or to gain access to information stored in the terminal equipment of a subscriber or user is only allowed on condition that the subscriber or user concerned is provided with clear and comprehensive information in accordance with Directive 95/46/EC, inter alia about the purposes of the processing, and is offered the right to refuse such processing by the data controller. This shall not prevent any technical storage or access for the sole purpose of carrying out or facilitating the transmission of a communication over an electronic communications network, or as strictly necessary in order to provide an information society service explicitly requested by the subscriber or user. The regime so set-up can be described as opt-in, effectively meaning that the consumer must give his or her consent before cookies or any other form of data is stored in their browser.

2.3. Legal protection of the platform

The creation of the telemedicine platform has as an undoubted requirement the creation of a website capable of allowing the development a set of activities. This website is the tool that will allow the development of a fluid exchange of information between experts in Rare Anaemias in order to perform a series of tasks such as diagnosis, second opinion, treatment, etc.

In this sense, we have to keep in mind that this tool (the website) is composed of a set of independent elements. Some of these elements have a different kind of legal protection:

i. User interface (designs or graphic appearance).

ii. Content (domain, logo/trademark, text, graphics, photographs, videos, animations and sounds).

iii. Software: Source code (collection of computer instructions written using some human-readable computer language, usually as text).

In this section we will analyze and identify the most appropriate mechanisms for the legal protection of every element which compose the telemedicine platform (website): mechanism of registration, intellectual property protection, ownership of the various elements and finally the possibility of patenting the system.

The study will take into account the specific circumstances in which the E-Enerca's Research Team is (lack of legal personality) and the geographic scope to be achieved (at least, at European level), so it will be necessary to perform an analysis of the possibility of providing protection to the website from the European Institutions and Agencies (Office for Harmonization in the Internal Market —Trademarks and Designs—).

In order to develop such study, it would be important to elaborate a list of objects that will be part of the content:

- Logo/trademark: We need to establish if the E-ENERCA Telemedicine Platform will have a different logo/trademark than the E-ENERCA Project's Logo (see: http://www.enerca.org/),
- New domain: We need to establish if the E-ENERCA Telemedicine Platform will work on the internet under a different domain than the E-ENERCA Project (http://www.enerca.org/),
- Text,
- Graphics,
- Photographs,
- Other kind of pictures,
- Videos, etc.

To establish the content of said list we will need the cooperation of all members of the Steering Committee, and specially of the researchers involved in the Work Package 6 (ENERCA Expert advice: Tele-expertise and Tele-medicine services for rare anaemias) given that such team is in charge of the creation of the E-ENERCA Telemedicine Platform.

We must point out that the mechanisms of intellectual property's protection developed in the EU are the specific tools which rewards innovators and enables them to benefit from their achievements. It is important to note that mere thoughts and ideas do not

qualify for such purposes. According with the dispositions of the "Council Regulation (EC) No 6/2002 of 12 December 2001 on Community Designs", intellectual property dispositions define and protect the following human innovations and creations:

- Designs (specify how products look).
- Trade marks (signal the origin of products to consumers).
- Copyright (relates to artistic creations, such as books, computer programs, databases, music, paintings, sculptures, films) and
- Patents (protect technical inventions in all fields of technology).

In accordance with the Article 2 of the mentioned "Council Regulation (EC) No 6/2002 of 12 December 2001 on Community Designs", the Office for Harmonisation in the Internal Market (Trade Marks and Designs), instituted by "Council Regulation (EC) No 40/94 of 20 December 1993 on the Community Trade Mark" shall carry out the tasks related to the process of registration.

The Office (based in Alicante, Spain) is the trademark and designs registry for the internal market of the European Union and have as a principal task the promotion and management of the "Community Trade Marks" and "Community Designs" within the European Union. It carries out registration procedures for titles to EU industrial property and keeps public registers of these titles. It shares with the courts in Member States of the European Union the task of pronouncing judgment on requests for invalidation of registered titles. Such Institution is a public establishment which enjoys legal, administrative and financial independence. The Court of Justice of the European Union is responsible for overseeing the legality of the Office's decisions. The Office is responsible for balancing its budget from its own revenue, which is derived mainly from registration fees and fees for the renewal of trade mark protection.

As we have noted, a website is basically composed of a set of elements that can be grouped into three different categories: ***a.*** User interface, ***b.*** Content, and ***c.*** Software (source code). Given that the protection of the content of one of this categories have a different kind of legal arrangement we will divided this section into three parts in order to describe the details of every category.

2.3.1. The protection of the user interface

In general terms, the user interface is the space where interaction between humans and machines (computers, for our purposes) occurs. The principal aim of this kind of interaction is the effective operation and control of the machine focused on the human purposes, and the feedback from the machine, which aids the operator in making operational decisions. Examples of this broad concept of user interfaces include the interactive aspects of computer operating systems, handtools, heavy machinery operator controls, and process controls. The design considerations applicable when creating user interfaces are related to or involve such disciplines as ergonomics and psychology.

Sometimes, the user interface includes hardware (physical) and software (logical) components (source code). We will focus on the questions related to the source code in the part ***c)*** of this section.

As has been indicated, user interfaces exist for various systems, and provide a means of:

Input, allowing the users to manipulate a system, and Output, allowing the system to indicate the effects of the users' manipulation.

Web-based user interfaces or web user interfaces (WUI) that accept input and provide output by generating web pages which are transmitted via the Internet and viewed by the user using a web browser program (explorer, chrome, firefox, etc.). Administrative web interfaces for web-servers, servers and networked computers are often called “control panels”. For our purposes, we have to keep in mind that the user interface of the E-ENERCA Telemedicine Platform will be represented by the designs or graphic appearance.

In this sense, and given that the object we aim to protect is, indeed, the platform design, it is quite important to delimitate the content of the term “design”. According with the article 3.a of the “Council Regulation (EC) No 6/2002 of 12 December 2001 on Community Designs”, a "design" means the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.

E-ENERCA must start the process of registration of all these elements in the Office for Harmonisation in the Internal Market -Trade Marks and Designs- (Europa Avenue, 4, E-03008 Alicante, Spain. Information Centre: +34 965 139 100). It is important to note that it must be submitted one application per web page.

a) Systems of user interface's protection

Said norm establish that there are two ways to protect such design:

- ***i.*** To protect the design with the Office for Harmonisation in the Internal Market (Trade Marks and Designs) before its commercialization and obtaining a "registered Community design" (RCD) or, alternatively,
- ***ii.*** To commercialise the design directly without registration by relying on what is known as the "unregistered Community design" (UCD) right.

In both cases the registration must be carried out in the manner clearly provided in the mentioned Council Regulation (EC) No 6/2002. Office for Harmonisation in the Internal Market (Trade Marks and Designs) recommends that the option we eventually choose will depend on the impact that it has on our design portfolio strategy. In addition we must point out that both pathways offer the following protection:

- ***i.*** Manufacturing a product incorporating a protected design (or to which the design is applied) without the consent of its proprietor would be considered illegal;
- ***ii.*** Putting a product on the market incorporating the protected design (or to which the design is applied) without the consent of its proprietor would be considered illegal;
- ***iii.*** Offering a product for sale incorporating a protected design without the consent of its proprietor would be considered illegal;
- ***iv.*** Marketing a product incorporating the protected design without the consent of its proprietor would be considered illegal;
- ***v.*** Importing/exporting a product incorporating the protected design without the consent of its proprietor would be considered illegal.

However, it is remarkable that RCDs and UCDs are quite different in terms of scope of protection and duration.

b) Requirements for protection

According to the article 4 of the Council Regulation (EC) No 6/2002, a design shall be protected by a Community design to the extent that it is new and has individual

character. Same norm also indicate that a design applied to or incorporated in a product which constitutes a component part of a complex product shall only be considered to be new and to have individual character:

i. if the component part, once it has been incorporated into the complex product, remains visible during normal use (use by the end user, excluding maintenance, servicing or repair work) of the latter; and

ii. to the extent that those visible features of the component part fulfil in themselves the requirements as to novelty and individual character.

On the other hand, Article 5 of the Council Regulation (EC) No 6/2002, deals the issue of "Novelty" and establish that a design shall be considered to be new if no identical design has been made available to the public:

i. in the case of an unregistered Community design, before the date on which the design for which protection is claimed has first been made available to the public;

ii. in the case of a registered Community design, before the date of filing of the application for registration of the design for which protection is claimed, or, if priority is claimed, the date of priority.

According with said norm, designs shall be deemed to be identical if their features differ only in immaterial details.

Finally, Article 6 establish that a design shall be considered to have individual character if the overall impression it produces on the informed user differs from the overall impression produced on such a user by any design which has been made available to the public:

i. in the case of an unregistered Community design, before the date on which the design for which protection is claimed has first been made available to the public;

ii. in the case of a registered Community design, before the date of filing the application for registration or, if a priority is claimed, the date of priority.

c) Scope and term of protection

The scope of the protection conferred by a Community design shall include any design which does not produce on the informed user a different overall impression. In assessing the scope of protection, the degree of freedom of the designer in developing his design shall be taken into consideration (see Article 10 Council Regulation (EC) No 6/2002).

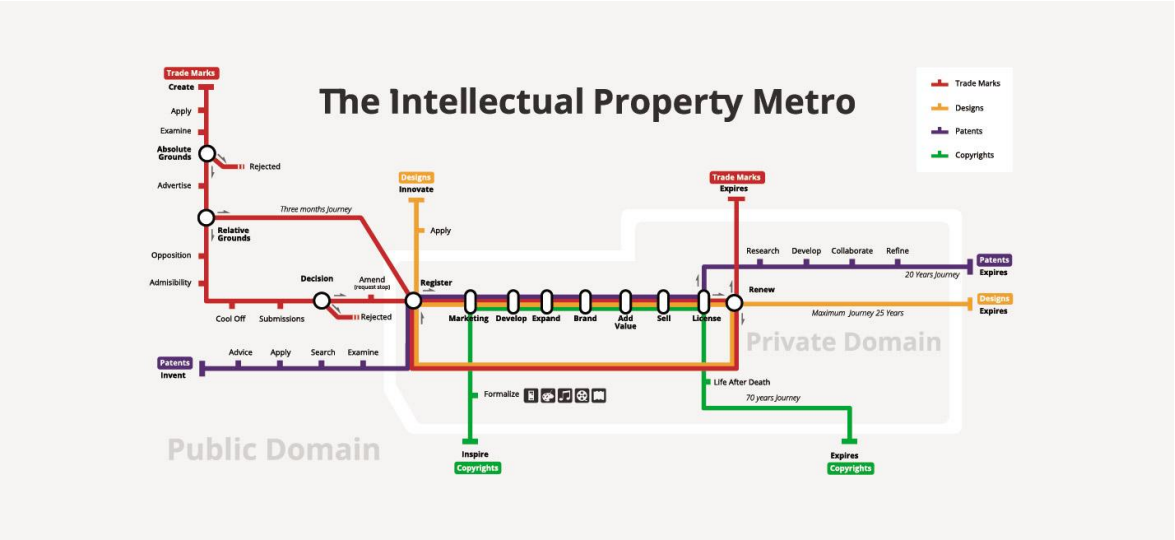
Concerning the commencement and term of protection of the unregistered Community design, the mentioned Council Regulation establish that a design which meets the requirements demanded shall be protected by an unregistered Community design for a period of three years as from the date on which the design was first made available to the public within the Community.

On the other hand, upon registration by the Office, a design which meets the requirements under Section 1 of the Council Regulation (EC) No 6/2002, shall be protected by a registered Community design for a period of five years as from the date of the filing of the application. The right holder may have the term of protection renewed for one or more periods of five years each, up to a total term of 25 years from the date of filing.

2.3.2. The protection of the website's content

Website's content is composed of the domain, logo/trademark, text, graphics, photographs, videos, animations and sounds. Available mechanism to protect such content, basically, is the same that the mechanism described in Section 2.1 of this report. Same occurs with the issues related to the requirements, scope and term of protection.

E-ENERCA must start the process of registration of all these elements in the Office for Harmonisation in the Internal Market -Trade Marks and Designs- (Europa Avenue, 4, E-03008 Alicante, Spain. Information Centre: +34 965 139 100). It is important to note that it must be submitted one application per element (graphic, logo/trademark, etc.).



The "Intellectual Property Metro" is a graphic created by the Office for Harmonization in the Internal Market to explain the steps we must follow in order to register the designs and trademarks in the EU.

2.3.3. The protection of the software: source code

Computer software is the non-tangible component of computers. It contrasts with computer hardware, which is the physical component of computers. Computer hardware and software require each other and neither can be realistically used without the other.

Computer software includes all computer programs regardless of their architecture; for example, executable files, libraries and scripts are computer software. Yet, it shares their mutual properties: software consists of clearly defined instructions that upon execution, instructs hardware to perform the tasks for which it is designed.

In this sense, we must point out that E-ENERCA website will be created by the development of one specific part of the software: the website`s source code (as we have explained the source code is a collection of computer instructions written using some human-readable computer language, usually as text). At European level, legal protection for new websites' source code has been regulated by the European Patent Convention which provides a legal framework for the granting of European patents, via a single, harmonised procedure before the European Patent Office. A single patent application, in one language, may be filed at the European Patent Office at Munich, at its branches at

The Hague or Berlin or at a national patent office of a Contracting State, if the national law of the State so permits.

Regarding E-ENERCA website's source code, we must indicated that we don't think is possible to apply for a patent given that the Convention (Article 52.2.c) establish that programs for computers shall not be regarded as patentable inventions. Nevertheless there is an exception for this rule, and this is the case which occurs when the source code causes a further technical effect going beyond the "normal" physical interaction between the program (software) and the computer (hardware). An example of a further technical effect is where the program serves to control a technical process or governs the operation of a technical device (see How to get a European Patent, Guide for Applicants, European Patent Office, Munich, 2013, p. 17; European Patent Convention, Article 52.1: European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application). Given that the E-ENERCA website's source code will not cause another effect than the "normal" physical interaction (we must note that the website only will allow the development of a fluid exchange of information between experts in Rare Anaemias in order to perform a series of tasks such as diagnosis, second opinion, treatment, etc.) we conclude indicating that a possible application for a patent probably will be rejected by the European Patent Office.

2.4. Health professional liability

As is described in the 'Study on the Legal Framework for Interoperable eHealth in Europe' (http://ec.europa.eu/information_society/activities/health/docs/studies/legal-fw-interop/ehealth-legalfmwk-final-report.pdf) the liability rules of the Member States with regard to the provision of healthcare are complex and diverse.

When the patient suffers a harm related to the telemedicine service in cross border health care, two diferent legislations could be applicable and two jurisdictions could be competent.The uncertainty with regard to the outcome of these complicated legal questions is without any doubt an important obstacle for interoperable eHealth in Europe, as it is said in the forementioned Study (p.44). Responsibility can rise also from the relation between two professionals.

The Directive 2011/83/EU on Consumer Rights applies to any contract concluded between a trader and a consumer. Service contract' means any contract other than a sales contract under which the trader supplies or undertakes to supply a service to the consumer and the consumer pays or undertakes to pay the price thereof. It expressly excludes healthcare from its scope. The Directive states that "Healthcare requires special regulations because of its technical complexity, its importance as a service of general interest as well as its extensive public funding" (recital 30). Article 3 excludes from the scope of this Directive the healthcare as defined in point (a) of Article 3 of Directive 2011/24/EU, whether or not they are provided via healthcare facilities.

According to Directive 2011/24/EU the services shall be provided in accordance with the legislation of the Member State of treatment and the standars and guidelines on quality and safety lay down by that Member State (article 4). But this provision refers to the rules for the health treatment not to the law applicable to solve conflict of jurisdiction or law regarding liability issues.

Nevertheles, there are some important requirements in the Directive dealing with internal law that are relevant to the possible responsibility:

> Member State of Treatment wich is the one where the service provider is establishes shall ensure:
>
> - Transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive (Article 4.2.c).
>
> - Systems of professional liability insurance or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk for treatment provided on their territory (Article 4.2.d).
>
> - Patients are entitled to a written or electronic medical record of the treatment, and access to at least a copy of this record (Article 4.2.f). This document could help in the determination of responsibilities.

The Directive 2011/24/EU shall apply without prejudice to 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 (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) and other Union rules on private international law, in particular rules related to court jurisdiction and the applicable law (article 2).

2.4.1. Competent jurisdiction

In Europe the relevant regulation in this field is the Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters ("Brussels I Regulation").

There are two different scenarios depending on the existence or not of a contractual relationship between the actors involved.

A. Contractual relationship

- If the parties, one or more of whom is domiciled in a Member State, have agreed that a court of a Member State are to have jurisdiction to settle any disputes which have arisen or which may arise in connection with a particular legal relationship, that court shall have jurisdiction (article 23).

- If such agreement does not exist:

In the case of professional to consumer contract: if the services is offered directly to the Member State of the consumer, the consumer can choice the courts of the Member State where he is domiciled or of the Member State where the other party is domiciled (articles 15 and 16 of the Regulation).

In other case (contracts between professionals) the competent court is the one of the Member State of performance of the obligation (article 5, 1°, b of the Regulation).

B. Non contractual relationship

According to article 5.3 of the Regulation, in this case the competent court is the one of the place where the harmful event occurred or may occur.

According to the CommisionWorking Document on telemedicine services, the place where the act causing the damage occurs is where the professional is when delivering

the service, and where the patient was when he received the medical advice or treatment.

2.4.2. Applicable Law

The rules to determine the applicable law in international obligations are the 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) and the 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).

A. Contractual relationship

Parties can choose the applicable law. In the absence of choise the applicable law:

- If the parties are two professionals

In the absence of choise the applicable law is the one of the country where the service provider has his habitual residence (Article 4.1.b of Rome I Regulation).

- If the parties are a consumer and a professional

In the absence of choise the applicable law is the one of the country of the consumer if that professional pursues his commercial or professional activities in the country where the consumer has his habitual residence. In other case, the applicable law will be the law of the country where the service provider has his habitual residence (Article 4.1.b of Rome I Regulation).

B. Non-contractual relationship

In general, the applicable law in this case is the law of the country in which the damage occurs. The place of damage is the place where "damage occurs irrespective of the country in which the event giving rise to the damage occurred and irrespective of the

country or countries in which the indirect consequences of that event occur" (Article 4.1 of the Rome II Regulation).

2.4.3. Responsibility for the use of medical devices

The Commission Staff Working Document on telemedicine, mentioned, deals with the issue of the responsibility for the use of medical devices in the provision of a telemedicine service.

When a telemedicine system falls within the definition of a medical device or of an *in vitro* diagnostic medical device[2], the product must be in conformity with the legal requirements set out in Directive 90/385/EEC or Directive 98/79/EC, in order to protect the health and safety of patients. Liability for defective products is regulated at EU level by Directive 85/374/EEC which applies to any product manufactured in or imported into the European market.

Some examples of telemedicine products that could fall within the definition of medical devices are: Patient monitoring devices measuring vital signals such as ECG, heart rate, breathing etc.; Telemonitoring devices transmitting data between patients and doctors; Components of communication infrastructure facilitating the transfer of data (e.g. digital images) between health centres.

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[2] Acording to Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - investigation, replacement or modification of the anatomy or of a physiological process, — control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Acording to Directive 98/79/EC off 27 October 1998 on in vitro diagnostic medical devices, In vitro diagnosis medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: - concerning a physiological or pathological state, or - concerning a congenital abnormality, or - to determine the safety and compatibility with potential recipients, or - to monitor therapeutic measures. Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles` are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination. Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

3. Legal requirements for the stablishment of a telemedicine plataform withing e-enerca project

3.1. E-enerca telemedicine platform as a healhcare service

The objective of E-enerca telemedicine platform is to provide expert opinion to physicians. The Directive 2011/24/EU defines healthcare as a right of european citizens in this terms: health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.

The service in the e-enerca telemedicine platform in not a second opinion given to the patient after his / her request (wich is a right in several Member States Health Care Systems), as a matter of fact, the e-enerca telemedicine platform is not conceived as a service to patients in the terms of the Directive 2011/24/EU, but as a tool for professionals (see the aims of the platform in the introduction of this resport). In conclusion, it seems this service does not fall into the scope of the Directive as a healthcare service.

Neverthless, in the particular case of Rare Diseases, Directive 2011/24/EU includes special provisions taking into account the characteristics of these diseases, in order to facilitate diagnosis and treatment. According to Article 8.4 of Directive: "When a patient affected, or suspected of being affected, by a rare disease applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice". So this is stated a provision of requesting scientific advice and in this sense tools should be implemented to facilitate this posibility".

E-enerca telemedicine Platorm will be one of this useful tools as well as a deliverable of an European reference network that may be supported by Member States according to Articles 12 and 13 of the Directive. In this sense economic support of national healthcare systems would be perfectly demanded and justified, but concrete negotiations should be carried out for this aim.

3.2. Data protection in E-enerca telemedicine platform

In the report of the first internal meeting of the e-enerca WP6, it is said that all the data that are going to be sent betweeen professionals to get the advice will be anonymized. Anonymized data do not fall into the scope of Directive 95/46/EC. It is important to take into account that if the data is related to an identified or identifiable natural person in the sense of the directive, cannot be considered as anonymized information. Regulation is not homogeneous in all the European countries concerning the meaning of this concept, nor concerning the requirements to process health data. If the physician sending the data knows who is the patient, in some countries data protection principles will apply (*Study on the Legal Framework for Interoperable eHealth in Europe*, p.60). National law of the country of the patient must be applied when sending information to other physicians (for example, ask for consent if it is required for coded data, or if it is required for the use outsite the national health system, etc… (See legal report delivered in WP1 Enerca project: Stablishing a network for Rare and Congenital Anaemias. Comparative report on legal issues).

These differences will disappear someway with the entry into force of the Regulation on Data Protection. In the Proposal, coded data are considered as personal information within the scope of the Regulation, so conditions to process personal data related to health would apply: "Pseudonymous data means personal data that cannot be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organisational measures to ensure non-attribution" (Article 4).

As it has been said article 9 of the Proposal states that, personal data concerning health, can be processed when (a) the data subject has given consent (…) , or (h) processing of data concerning health is necessary for health purposes and subject to the conditions and safeguards referred to in Article 81". Article 81 states that "(…) processing of personal data concerning health must be on the basis of Union law or Member State law which shall provide for suitable, consistent, and specific measures to safeguard the data subject's interests and fundamental rights, to the extent that these are necessary and proportionate, and of which the effects shall be foreseeable by the data subject, for: (a) the purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or

another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies (…)".

In conclusion, coded data related to health will be considered as personal data in all Member States. This means that security mesures should be implemented. Hoewer, with adequate guarantees, express consent of the patient won't be a requisite to send clinical information to a phisician in other Member State for diagnosis purposes.

According to the WMA Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine (http://www.wma.net/en/30publications/10policies/t3/index.html), the physician must aim to ensure that patient confidentiality and data integrity are not compromised. Data obtained during a telemedical consultation must be secured through encryption and other security precautions must be taken to prevent access by unauthorized persons.

Other issues arised concerning the data of the users of the electronic communications (the physicians) and the provisions of Directive 2002/58/EC must be applied.

3.3. Legal protection of E-enerca telemedicine platform

The application of the European system of website's protection to the E-ENERCA Telemedicine Platform must face and solve a set of pendent issues:

- ***i.*** E-Enerca's Research Team does not have "legal personality". This situation must be solve in order to establish who (person or institution) could be the intellectual property rights' owner. However it would be advisable to think about the possibilities that the European Reference Network on Rare Anaemias promoted by E-ENERCA could be in the near future an institution with "legal personality" requirements to register all the objects of protection described in the Section 2.3 of this report.
- ***ii.*** Since the geographical scope of the E-ENERCA Telemedicine Platform will be, at least, the European Community, it will be advisable to obtain the mechanism of website's protection from the European Institutions and Agencies: in particular from the Office for Harmonization in the Internal Market (Trademarks and Designs) and the European Patent Office (if Steering Committee considers appropriate).

iii. We need to determine the specific content of the E-ENERCA Telemedicine Platform, in particular the issues related with the logo/trademark (does the Platform will have a different logo/trademark than the E-ENERCA Project?), domain (will be a different one that the ENERCA's domain) and other graphics, pictures or videos (platform will have some of this content?).

We assume that E-ENERCA Steering Committee, and specially researchers involved in the Work Package 6 (ENERCA Expert advice: Tele-expertise and Tele-medicine services for rare anaemias), will contribute to specify this questions.

3.4. Liability derived from the activities in E-enerca telemedicine platform

As the platform establishes a relation between professsionals, and patients are not involved in this relation, responsibility of the diagnosis, treatment and follow up concerns the physician in charge of the health service to the patient.

Actors involved in the relations as well as functions of the platform must be well identified.

Within the platform a non contractual relationship is established between two professionals, and responsibility could arise in this framework. International private law rules would be applied.

As is said in the WMA Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine mentioned before, the physician asking for another physician's advice or second opinion remains responsible for treatment and other decisions and recommendations given to the patient. Physician whose advice is sought through the use of telemedicine should keep a detailed record of the advice he/she delivers as well as the information he/she received and on which the advice was based.

4. Other issues. A website offering health related information

Other issues are raised when a platform is considered as a website offering health related information. Even the telemedicine platform within E-enerca WP6 does not offer health information to the public, but only under request and between professionals, some criteria mentioned in the Communication from the European Commission concerning Quality Criteria for Health related Websites in are suitable to be taken into account. As a matter of fact, these criteria are designed to be applicable to the development and maintenance of a health related site irrespective of the type of information or audience to whom the information is targeted. However, one essential quality criterion is that a health-related web site should state clearly what is its target audience and that care should be taken to ensure that both the style and nature of the information, and its presentation, are appropriate for the chosen audience. The criteria are the following:

"**Transparency and Honesty**

- Transparency of provider of site – including name, physical address and electronic address of the person or organisation responsible for the site (see Article 5 and 6 Directive 2000/ 31/ EC on Electronic Commerce).
- Transparency of purpose and objective of the site
- Target audience clearly defined (further detail on purpose, multiple audience could be defined at different levels).
- Transparency of all sources of funding for site (grants, sponsors, advertisers, non-profit, voluntary assistance).

Authority

- Clear statement of sources for all information provided and date of publication of source.
- Name and credentials of all human/ institutional providers of information put up on the site, including dates at which credentials were received.

Privacy and data protection

- Privacy and data protection policy and system for the processing of personal data, including processing invisible to users, to be clearly defined in accordance with community Data Protection legislation (Directives 95/ 46/ EC and 2002/ 58/ EC).

Updating of information

- Clear and regular updating of the site, with date of up-date clearly displayed for each page and/ or item as relevant. Regular checking of relevance of information.

Accountability

- Accountability -user feedback, and appropriate oversight responsibility (such as a named quality compliance officer for each site).
- Responsible partnering -all efforts should be made to ensure that partnering or linking to other websites is undertaken only with trustworthy individuals and organisations who themselves comply with relevant codes of good practice.
- Editorial policy -clear statement describing what procedure was used for selection of content.

Accessibility

- Accessibility -attention to guidelines on physical accessibility as well as general findability, searchability, readability, usability, etc".

In relation with the "Transparency and Honesty" criteria, it should be taken into account that any conflict of interest should be declared in the website, as well as in the communications between professionals.

5. Conclusions

FIRST. The service in the e-enerca telemedicine platform in not a second opinion given to the patient after his / her request, as a matter of fact, the e-enerca telemedicine platform is not conceived as a service to patients in the terms of the Directive 2011/24/EU, but as a tool for professional. It seems this service does not fall into the scope of the Directive as a healthcare service.

However, e-enerca telemedicine platform will be a useful tool created by an expert network within the framework of diagnosis and treatment for patients with rare diseases. In this sense is a tool encouraged by the Directive and economic support of national healthcare systems would be perfectly demanded and justified, but concrete negotiations should be carried out for this aim.

SECOND. Coded data related to health will be considered as personal data in all Member States after the entry into force of the Proposal General Data Protection Regulation, it is approved in its actual version. This means that security measures should be implemented. However, with adequate guarantees, express consent of the patient won't be a requisite to send coded clinical information to a physician in other Member State for diagnosis purposes.

THIRD. All the professionals participating in the platform must aim to ensure that patient confidentiality and data integrity are not compromised. Data must be secured through security precautions to prevent access by unauthorized persons.

FOURTH. Concerning the legal protection of the Platform: It has been established that it would be advisable to enable some mechanisms for the legal protection of the E-ENERCA Telemedicine Platform. In order to develop this task we have to keep in mind that the platform (a website) is composed of a set of independent elements and that some of these elements have a different kind of legal protection (***i.*** User interface, ***ii.*** Content, ***iii.*** Software: Source code).

At European level, legal protection for User Interface and Content has been provided by the Council Regulation (EC) No 6/2002 of 12 December 2001 on Community Designs. E-ENERCA must start the process of registration of all these elements in the Office for Harmonisation in the Internal Market -Trade Marks and Designs- (Europa Avenue, 4, E-03008 Alicante, Spain. Information Centre: +34 965 139 100).

On the contrary, and regarding E-ENERCA website's source code (Software), we don't think it will be possible to apply for a patent given that European Patent Convention (Article 52.2.c) establish that programs for computers shall not be regarded as patentable inventions and our website does not have the particular characteristics to fit in the exceptions for this rule (when the source code causes a further technical effect going beyond the "normal" physical interaction between the software and the hardware).

FIFTH: Concerning the legal requirements for the establishment of the telemedicine plataform, we have concluded that it would be necessary to previously solve a couple of difficulties: E-Enerca's Research Team does not have "legal personality". This situation must be solve in order to establish who (person or institution) could be the intellectual property rights' owner. It is necessary to determine the specific content of the E-ENERCA Telemedicine Platform (logo/trademark, graphics, pictures, videos, etc.).

SIXTH. As the platform establishes a relation between professsionals and patients not involved in this relation, responsibility of the diagnosis, treatment and follow up concerns the physician in charge of the health service to the patient.

Actors involved in the relations as well as functions of the platform must be well identified.

Within the platform a non contractual relationship is established between two professionals, and responsibility could arise in this framework. International private law rules would be applied.

SEVENTH. As a website offering health related information, the criteria stated in the Communication from the European Commission concerning Quality Criteria for Health related Websites are suitable to be taken into account. A relevant one is that a health-related web site should state clearly what is its target audience and that care should be taken to ensure that both the style and nature of the information, and its presentation, are appropriate for the chosen audience.

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Relevant EU Law

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