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### Legal Aspects of Telemedicine



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#### **Key Points**

- Telemedicine is high on the European political agenda;
- By 2020 telemedicine will be widely available across the EU;
- There are two types of telemedicine - as a medical act, and tele monitoring (e.g. for home care);
- Existing EU legislation is complex but clear.

The European Union has a vision for telemedicine. The *Ehealth action plan 2012-2020* is part of the EU's Digital Agenda for Europe. The goal is that by 2020 every European citizen has access to, and can use a computer, regardless of education, age and income. The goal is that there will be a widespread deployment of telemedicine services, with personal health services available for every European citizen and patient by 2020. This should be one response to the imbalance of growing health needs and sparse resources in health and social care.

There is some misunderstanding and misconception of the legal aspects of telemedicine, which includes teleradiology. Even at the government level, member states are sometimes not well informed, and still believe there are some limitations. In practice there are almost no limitations on telemedicine. That is why the EU compiled the Staff Working Document (European Commission 2012), which took three years to compile, to bring clarity to this area. It takes into account advice from various Directorates-General (DGs), among them DG Connect, DG Sanco and others and legal advisers. Some will say that a Staff Working Document is not a legally binding document. By definition that is true, but the content is legal, as it refers to existing directives and regulations, which are legally binding. Of course, in a trial, it is for the judge to decide.

We need to differentiate in telemedicine between two types of telemedicine services. Firstly, those considered as a medical act, this means that it is an extension of the existing practice of medicine, performed by healthcare professionals – the ‘teleologies’ such as teleradiology, teleneurology, telecardiology and so on. By default these are services provided by medical doctors or other healthcare professionals. Secondly are telemonitoring services, these services are remote monitoring technologies that provide health professionals or call centre personnel with biological parameters of the patient/ citizen. The analysis of the data can even be done by computers. The European Society of Radiology (ESR) is looking at applications of telemedicine as a medical act.

### **EC Staff Working Document on the Legal Framework**

The European Commission last year published the Commission staff working document on the applicability of the existing EU legal framework to telemedicine services (European Commission 2012). There is European regulation, which is complex but clear. The so-called subsidiarity principle means that telemedicine is the responsibility of the national government when undertaken within the borders of that country and subject to legal constraints within that country. It changes when you talk about cross-border telemedicine, when EU regulations are involved. Many member states (MS) do not even have legal instruments dealing specifically with telemedicine in their own country, and only a few have regulations or guidelines.

The basic principle is that telemedicine is both a health service and an information society service. The patient is free to seek telemedicine services from any other European MS. The patient can choose where to go for treatment, whether that’s a physical or a telemedical service. It is also an information society service, which is a service provided for remuneration, normally provided by electronic means at the individual request of a patient. Patient rights on cross-border health also apply when being treated by a ‘teleologist’. The teleologist does not need the authority of the MS of residence of the patient when delivering services from his/her country of residence. Many are not aware of this or even have some doubts, but it is sure. It is only in cases when physicians provide physically services in another MS, then they might need to request authorisation from another country.

### **Licensing**

For example, you are a teleradiologist in country X, doing services in country Y. You are registered in country X, but then the teleradiologist moves physically to country Y, and he then needs to be registered in country Y. Where you as a teleradiologist physically are, and are working out of, you need to be registered in that country. If the teleradiologist complies with the legislation and regulations of his own MS in principle you are free to provide services in all other MS. So for example, a Spanish radiologist does not need to be registered in the UK to provide teleradiology services to the UK, but if he moves to Portugal, he would need to be registered in Portugal. There is the country of origin principle – only paperwork is needed to change the country.

### **Patients’ Rights**

Patients have three main rights when it comes to telemedicine: the right to be reimbursed, the right of access to the report and the opportunity to check the quality of services. The same as if they were going to their own local healthcare facility.

Patients have the right to receive treatment in another MS and to be reimbursed. If you are reimbursed in your own country for that service, you will also be reimbursed if you seek healthcare in another country. If you are not reimbursed in your own country for teleradiology, which is the case in the majority of MS, then you cannot be reimbursed for teleradiology services in another country. That is why most telepathology/teleradiology companies are contracted on a stipend basis. There is no governmental reimbursement.

### **Processing of Health Data**

The EU legal framework on the protection of personal data is being revised. There will be a new regulation to apply to all MS once accepted. The Commission's reform proposals were passed by the Committee for Civil Liberties, Justice and Home Affairs of the EU Parliament in October 2013. The next stage is adoption by the European Parliament and by the Member States in the Council with a view to the legislative reform being agreed before the May 2014 European Parliament elections. The reform proposals include rights such as the right to be forgotten, that data needs to be minimal, not anonymised. People have the right to demand that all personal data will be erased. Today healthcare/sensitive personal data can only be processed/transferred with patient consent, for the benefit of the patient, if there is a medical need and if the data controller falls under professional secrecy.

### **Other Issues**

The teleologist has to inform the patient of his/her identity. The patient must be able to verify the quality of the service and be able to contact the doctor who delivered the service. The name of the teleradiologist and his/her contact details must be included on the report and also details of the professional registration in the MS where the service is based.

### **Liability**

Liability can be of a professional nature or relate to defective equipment. EU legislation only harmonises rules relating to liability and defective equipment, and it does not relate to medical liability. The liability regime of teleology is not consistent across the MS, but the patient has always the possibility of suing the healthcare professional in his or own country of residence.

### **Conclusion**

The staff working document is clear and complete. There will not be a new directive on telemedicine. Existing directives such as those on information society services (including ecommerce), the directive on patients' rights in cross-border healthcare, directives on consumer protection, data protection, medical devices and medicinal products already apply. Only two things will change. The changes will be in a new regulation on data transmission and privacy. There is also planned an update on professional qualifications – for the 7 professions named (architects, dentists, doctors, nurses, midwives, pharmacists and veterinary surgeons), it will be even easier to move to another country to practise and to deliver their professional services and practise their profession within the EU. It will be voluntary and involve a card – the European Professional Card.

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