

## The applicability of existing Community legal framework to telemedicine services

A Staff Working paper



**Telemedicine can help increase accessibility to healthcare for patients living in remote geographical areas, allow patients with chronic diseases to be monitored at home and involve patients in the management of their own healthcare.**

**However, despite the potential benefits identified and the potential for growth of the market, the use of telemedicine applications in everyday medicine is still relatively low. One of the reasons identified is the lack of legal clarity. In view of enhancing legal clarity regarding telemedicine services, the Commission will publish a Staff Working Paper (SWP) on Community legal framework applicable to telemedicine in 2010.**

### Telemedicine definition

Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.

Telemedicine encompasses a wide variety of services. Those most often mentioned in peer-reviews are teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology. Other potential services include call centres/online information centres for patients, remote consultation/e-visits or videoconferences between health professionals.

### Background

On 4 November 2008 the Commission adopted the Communication on **telemedicine for the benefit of patients, healthcare systems and society**<sup>1</sup>. In this Communication the Commission undertook to publish, in cooperation with Member States, an analysis of the Community legal framework applicable to telemedicine services. This was listed in the Communication as an action aimed to bring legal clarity to telemedicine.

The Communication was followed by an explanatory document [Commission Staff Working Document - SEC(2009)943 final]<sup>2</sup> that includes details of the extensive consultation process which led to the Communication.

Also relevant as a background for the present EC initiative are two studies on legal aspects of eHealth available on the website of the Commission<sup>3</sup>. The 'Legally eHealth'<sup>4</sup> study addresses the need to establish greater legal certainty in Europe with respect to the practice of

<sup>1</sup><http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF>

<sup>2</sup>[http://ec.europa.eu/information\\_society/activities/health/docs/policy/telemedicine/telemedecine-swp\\_sec-2009-943.pdf](http://ec.europa.eu/information_society/activities/health/docs/policy/telemedicine/telemedecine-swp_sec-2009-943.pdf)

<sup>3</sup>[http://ec.europa.eu/information\\_society/activities/health/studies/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/studies/index_en.htm)

<sup>4</sup>[http://ec.europa.eu/information\\_society/activities/health/docs/studies/legally-ehealth-report.pdf](http://ec.europa.eu/information_society/activities/health/docs/studies/legally-ehealth-report.pdf)

**Telemedicine can help increase accessibility to healthcare for patients living in remote geographical areas**

eHealth service delivery and the use of eHealth tools focusing on the existing legal framework of relevant EU legislation. The study on the 'Legal framework of Interoperable eHealth in Europe'<sup>5</sup> focuses more on individual Member States' legislation. It identifies and analyses the range of legal and regulatory frameworks for electronic health delivery and services in each Member State and proposes recommendations to facilitate cross-border service provision via eHealth applications. It also provides ten use cases of telemedicine services (such as the NHS Direct Telephone Line or the Barcelona Telemedicine Clinic).

### Objective of the initiative

The main objective of this initiative is to enhance legal clarity for providers of telemedicine services by clearly identifying the scope, depth and borders of applicability of existing Community legal framework to telemedicine services. The dialogue with healthcare providers disclosed that awareness about which rules and norms currently apply to telemedicine is a primary precondition to boost wider deployment of telemedicine services both within and across Member States' borders.

### Issues to be addressed

During the consultations with the stakeholders on the subject of telemedicine, several legal issues have been identified. These include: licensing, accreditation and registration of health professionals providing telemedicine services; reimbursement of costs for telemedicine services; liability; personal data protection and conflict of jurisdictions. The present EC initiative will provide guidance for telemedicine users on the Community legal framework applicable to these areas.

### Envisaged structure of the SWP

The SWP will be composed of two main parts. The first part will present the Community legislation applicable to telemedicine services structured around the main problematic areas identified above. The second part will comprise a practical approach. It will present several cases of telemedicine services. These cases will be analysed by cross-reference to the relevant Community legislation presented in the first part.

**Telemedicine can allow patients with chronic diseases to be monitored at home**

<sup>5</sup>[http://ec.europa.eu/information\\_society/activities/health/docs/studies/legal-fw-interop/ehealth-legal-fmwk-final-report.pdf](http://ec.europa.eu/information_society/activities/health/docs/studies/legal-fw-interop/ehealth-legal-fmwk-final-report.pdf)

**The EU Member States have the prime responsibility for protecting and improving the health of their citizens.** As part of that responsibility, it is for them to decide on the organisation and delivery of health services and medical care. **However, when exercising these competences, Member States nonetheless have to comply with Community law.**

There are a **number of examples in the health area** on which Member States cannot act alone effectively and **where cooperative action at the EU level is indispensable**, especially regarding issues with a **cross-border dimension** or relating to the **free movement of persons** within the internal EU market. Both existing and emerging disparities in Member States' legislation and case-law concerning healthcare impair the development of cross-border services.

### Documents of reference:

- [Articles 49 and 152 of the Treaty establishing the E.C.](#)
- [Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare](#) (2008/0142 (COD))
- [European Parliament resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market](#) (2006/2275(INI))
- [e-Health - making healthcare better for European citizens: an action plan for a European e-Health Area](#) COM(2004) 356 final
- [Recommendation on cross-border interoperability of electronic health record systems](#)
- [Directive 2000/31/EC \(known as the e-Commerce Directive\)](#)
- [Directive 2005/36/EC on the recognition of professional qualifications](#)
- [Directive 95/46/EC \(known as the Data Protection Directive\)](#)
- [Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector](#)
- [Regulation No. 1408/71 of the Council on coordination of social security schemes](#)
- [Transparency Directive \(98/34/EC\) as amended by Directive 98/48/EC](#)
- [Regulation 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, as amended](#)

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