Setting the legal context for telemedicine in the EU

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"Current and emerging challenges of eHealth
– privacy, law, ethics, governance and beyond"

eHealth Workshop
Middlesex University, Trent Part Campus, London, UK
16-17 June 2011

Overview

- Distribution of competencies in the area of telemedicine
- Commission actions in the area of legal aspects of telemedicine
- Ongoing regulatory initiatives relevant for telemedicine

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Division of competences in the Public Health Policy

- The legal basis is justified by both the **objectives** and the **content** of telemedicine

- Art. 168(7) TFEU - MS have primary responsibility for organisation and delivery of healthcare

- Art. 114 (3) TFEU – The Commission, in its proposals concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking into account in particular of any new development based on scientific facts

- COM should observe the subsidiarity principle Art 5(3) TEU

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Hybrid character of telemedicine

- Interferes competences in health policy, ICT and R&D, data protection, consumer rights protection, internal market, social and employment policy
- telemedicine derives competences from competences of other Community policies
- Areas where EU level action is needed relate to cross-border issues and free movement in the internal market

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Legal aspects of telemedicine- EC actions

- *Studies* published by the EC on legal aspects of eHealth covering both the EU and the national levels

- Commission **Communication on Telemedicine** COM (2008) 689 emphasizing the need to bring legal clarity

- Preparation of a Staff Working Document mapping existing EU legislation that could apply to telemedicine
- 2 workshops on legal issues of telemedicine in 2009 and 2010

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EC's Commitment

- A Staff Working Document on the applicability of existing EU legislation to telemedicine services

Purpose:

– Mapping existing EU legislation that could apply to telemedicine

– Identifying the open issues

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Focus areas

> **licensing, registration, authorisation of health professionals**

> **liability**

> **reimbursement**

> **conflict of jurisdictions**

> **personal data protection**

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Starting point – legal qualification

- Is TM a "service" within the meaning of the Treaties?

  > If yes - principle of freedom to provide services in the internal market applies

- Is TM an "information society service" within the meaning of the Transparency Directive?

  > If yes - eCommerce Directive applies

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Telemedicine as a "service" within the meaning of the Treaties

- "**Services**" within the meaning of the Treaties = **services which are normally provided for remuneration** (Art. 57 TFEU). Services shall in particular include activities of the professions.

- Overarching **principle of freedom to provide services** in the internal market – Art. 56 TFEU

- **medical services fall within the scope Art. 57 of TFEU** (ECJ, *Smits and Peerboms* - C-157/99)

- **Services provided at a distance fall within the scope Art. 57 of TFEU** (ECJ, *Alpine Investment* - C-384/93)

- Telemedicine services are defined as medical services provided at a distance

- the provisions of the Treaty regarding the free movement of services should apply to telemedicine services

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Telemedicine services as information society services (ISS)

- Definition of information society services (Art. 1(2) Transparency Directive)

   "any service normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of service"

- Most telemedicine services fall within this definition

- Exceptions: telemedicine services provided by traditional telephone, services provided in the presence of the patient (see Annex V of Transparency Directive)

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Licensing/registration of health professionals

- **In a cross-border telemedicine scenario, does the telemedicine professional need to be licensed/registered also in the MS of the patient?**
  - TM is a service within the meaning of the Treaties => freedom to provide services, derogations possible for imperative reasons relating to the public interest (e.g. public health)

  - If telemedicine is an ISS => E-Commerce directive is applicable –> country of origin principle – exceptions to be observed (e.g. public health) – obligation to notify

  - Directive 2005/36 is not applicable – requires physical presence of the health professional in the patient's country

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Reimbursement(I)

- **Cross-border level**
  - EU legislation on coordination of social security (Regulation 883/2004) systems does not seem to be applicable, because designed for physical movement of the patient
  - Directive 2011/24/EU on patients' rights in cross-border healthcare – based on ECJ case-law on reimbursement of health services
  - No case-law on reimbursement of telemedicine services yet

- **National level**
  - National legislation of Member States governing reimbursement according to their health systems
  - In some MS, telemedicine is not recognised as a proper medical act for reimbursement purposes

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Reimbursement(II)

Directive 2011/24/EU on patients' rights in cross-border healthcare
- Scope of the Directive is wide enough to include telemedicine services
- General principle of reimbursement is applicable to telemedicine – rules on prior-authorisation should be observed
- Telemedicine is specifically mentioned in Art 3(d) and Art 7(7)
- Article 14 on eHealth

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Liability

- Medical liability and services liability
  - no EU legislation
  - National legislation applies
  - Applicable national law needs to be determined

- EU consumer protection legislation

- No liability of intermediaries (ex. Internet service providers) for "mere conduit", "caching" or "hosting" (e-Commerce Directive)

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Conflict of jurisdictions and conflict of laws

- Conflict of jurisdictions
  - Regulation 44/2001
  - ECJ rulings C-144/09 *Alpenhof* and C-585/08 *Pammer* (on the interpretation of « directed activities» in Art 15(1)(c) of the Regulation)
- Conflict of laws
  - Regulation 593/2008 on the law applicable to contractual obligations ("Rome I")
  - Regulation 864/2007 on the law applicable to non-
    contractual obligations (Rome II)

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Health data protection(I)

- Art. 8 ECHR and Art. 8 EU Charter of Fundamental Rights
- General principles of data processing (Data Protection Directive)
- Health data – sensitive data – prohibition to process – exceptions
- Obligation of the data controller to implement appropriate security measures to protect personal data (sensitive data like health data require stricter measures of protection)
- E-Privacy Directive 2002/58, as amended by Directive 2009/136 – notification obligation for personal data breaches

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Health data protection (II)

- Reform of the European Data protection rules
  ongoing
  - Commission Communication 'A comprehensive approach on
    personal data protection in the European Union'
    COM(2010) 609

    http://ec.europa.eu/justice/policies/privacy/review/index_en.
    htm

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Thank you !

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http://ec.europa.eu/information_society/activities/health/index_en.htm