European Commission’s latest activities on Telemedicine

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The three Instruments used by the Commission:

- Policy instruments
- Deployment and support to policies
  - CIP call in 2008
- RTD (FP7)
  - Personal Health Systems
"Telemedicine for the benefit of patients, healthcare systems and society"


1. Building confidence and acceptance of telemedicine services

2. Bringing legal clarity

3. Solving technical issues and facilitating market development
2. Bringing legal clarity:

- Member States to share information on current/future national legislative frameworks relevant to telemedicine

- and adapt national legal framework to allow telemedicine to be used

- Analysis of the European legal framework applicable to telemedicine services
A Staff Working Document on the applicability of existing EU legislation to telemedicine services

**Purpose:**

- Clearly identifying *scope, depth and borders of the applicability to Telemedicine* of the existing Community legal framework.
Proposed approach

• **Cross-referencing:**

  A. the *existing Community law* that can be related to Telemedicine from a general perspective

  to:

  B. the *specific Telemedicine applications* that are currently on the verge of *entering the mainstream* of the care delivery process

• Legal voids, overlapping and redundancies will be underlined
Areas covered

- licensing, accreditation and registration of professionals
- liability
- reimbursement
- conflict of jurisdictions
- personal data protection
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
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
• 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)
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
  - If telemedicine is an ISS => E-Commerce directive is applicable -> country of origin principle – exceptions to be observed
  - Directive 2005/36 is not applicable – requires physical presence of the health professional in the patient’s country

- Can MS require/impose a specific license for practicing telemedicine?
  - Prohibition to impose a specific prior authorisation which is specifically and exclusively targeted at ISS (e-Commerce directive)
  - No special license for providing telemedicine services can be imposed
  - The normal medical license should suffice
• **Cross-border level**
  – EU legislation on coordination of social security systems not applicable, because designed for physical movement of the patient
  – Mechanism of reimbursement of health services established by ECJ case-law
  – No case-law on reimbursement of telemedicine services

• **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
• 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)
Health data protection

- 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)
- Directive 2002/58 – processing of data in the electronic communications sector
Workshop Legal Aspects of Telemedicine

- Organised by DG INFSO, ICT for Health Unit with the help of ePractice

- 71 participants

- Main points on the Agenda:
  - General presentation of the draft SWP
  - 2 use cases – teleradiology and teleconsultation (Handling patients with chronic foot wounds & leg ulcers)
  - 4 problematic areas: license/registration, reimbursement, liability, data protection
Workshop Legal Aspects of Telemedicine – key findings

• Licensing/registration/accreditation
  - B2B – clear, no license required
  - B2C – uncertainty – MS may impose specific requirements
    Suggestion for a directive setting the limit for MS intervention
  - Accreditation – need for a harmonised accreditation of a telemedicine act at EU level?
    Suggestion to draft European level guidelines

• Reimbursement
  - MS to work out at national level what kind of TM services to reimburse
    How? – either by separate nomenclature for TM services or by recognising that certain interventions have TM aspects within their conduct (RPM for diabetes management)
    Sufficient evidence and sound business cases of TM are necessary

• Liability
  - EU level consumer protection legislation applicable to telemedicine
  - Local legislation on liability
  - Hospital liability - MS level – may be different
    In some MS it is clear that for any service received in a hospital, the hospital can be sued regardless if the professional is self-employed or employed by the hospital
    Suggestion to harmonise no fault liability for this at EU level

• Data protection
  - Good legal basis for handling personal data within a telemedicine service
  - Patients’ right to know what happens to the data, who has access to it and for what purposes
    basis for patients’ confidence
Temporary Conclusions on legal clarity

- EU legislation: still to be adapted to telemedicine services
- MS actions to be identified in view of eliminating existing barriers to the provision of telemedicine services
- What’s next
  - Consider concrete situations and legislative implications
An additional EC Commitment

• ‘The Commission will support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including **effectiveness and cost-effectiveness**. This will be based on the work of experts in the field, Commission-supported studies, large-scale pilot schemes and relevant research projects’.
Measuring Impact of telemedicine services

• HTA adapted to telemedicine
  – The MethoTelemed methodology
  – A study to be delivered in May 2010

• CIP call on telemedicine assessment
  – RENEWING HEALTH project
  – 9 participating regions
  – 8000 patients involved
  – Using Metho Telemed
  – Producing a systematic and multidisciplinary assessment on the impact of the integrated telemedicine services
Personal Health Systems: the bigger picture

Data acquisition
- Sensors for multi-parametric monitoring

Data processing & analysis
- Other data: clinical, images, lab, genomics
- Medical expertise
- Support to diagnosis decision & treatment

Intelligent analysis

Health / call Centre

Hospital

Data communication and feedback
Aspects and areas covered:

1) Mainly **Chronic disease management**, some on **prevention**
   - (a) Cardiovascular diseases
   - (b) Diabetes
   - (c) Respiratory diseases
   - (d) Renal failure
   - (e) ICT-enabled Artificial Organs
   - (f) Mental disorders (depression, bipolar, stress)
   - (g) Point-of-Care diagnostics

2) **Support Actions** on:
   - RTD roadmap on Personal Health Systems
   - Roadmap on ICT for disease prevention
   - Interoperability of Personal Health Systems
Moving to “pHealth”

- Enrich information
  - from surrounding environment, activities, emotions, genetic ...
- Account for measurements in non-clinically controlled environments
  - give “context” to a value, i.e. under which conditions it was measured
- Adapt to specific characteristics of the individual
  - we are all different from each other
  - a blood pressure level may be high for person X but normal for person Y
- Consider all the above in:
  - reducing false alarms
  - medical decision making
  - providing services
- PHS research moves in this direction
  - ... but we are not quite there yet
• Systematic support to R&D so far has helped to:
  ➢ realise the first generations of prototype PHS
  ➢ overcome many technological challenges

• Early evidence suggests significant benefits to healthcare systems and individuals

• Two parallel streams of activities:
  ➢ Assistance towards the wide deployment/integration of first PHS generations in healthcare systems
  ➢ Continued research activities towards new PHS generations: moving to personalised care