Regulating Telemedicine: the EU perspective

ETSI eHealth workshop

On telemedicine

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Céline Deswarte, Policy officer
Unit Health and Well-Being

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1) Legal aspects

**SWD on Telemedicine**

- No EU legislation specifically on telemedicine
- Telemedicine is at the crossroad of various topics: health policy, ICT, data protection

**Purpose of SWD:**

- Mapping existing EU legislation that applies to cross-border telemedicine
- Providing legal clarity to actors
1) Legal aspects

Telemedicine: Focus areas

- licensing, registration, authorisation of health professionals
- reimbursement
- personal data protection
- liability
1) Legal aspects

Licensing/registration of health professionals

- Health professionals only have to comply with the authorization and registration requirements of their Member State of establishment.
- No need for a license in the patients' country
- Laid down in eCommerce Directive (2000/31/EC) and Directive on patients' rights in cross-border healthcare (2011/24/EU)
1) Legal aspects

Reimbursement

**National level**
It is up to the Member States to decide whether telemedicine is reimbursed.

**Cross-border level (when CB dimension)**
Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare:
- covers telemedicine services
- patients receiving healthcare in another Member State have to be reimbursed up to the level of reimbursement applicable for the same treatment in their country. (express mention of right of reimbursement applicable to eHealth and in recital 26)
1) Legal aspects

Data protection (I)

- **General principles of data processing in Data Protection Directive 95/46/EC:**

  - Health data are sensitive data – prohibition to process – **exemption:**
    - preventive medicine, medical diagnosis, the provision of care or the management of healthcare services + professional secrecy
    - explicit consent from data subject
    - in the vital interest of the data subject
1) Legal aspects

Data protection (II)

- Obligation of the data controller to implement appropriate security measures to protect personal data (sensitive data like health data require stricter measures of protection)

- European Data protection rules currently being reviewed: General data protection draft regulation due to be adopted in 2015
1) Legal aspects

Liability

- **Medical liability and services liability**
  - no EU legislation
  - national legislation applies
  - applicable national law needs to be determined

- **EU consumer protection legislation**: liability for defective products
2) Policy aspects

How does the EU contribute to the large-scale deployment of telemedicine?

a) Digital Agenda for Europe

b) eHealth Action Plan

c) Dissemination of best practices
2) Policy aspects

a) Digital Agenda for Europe (DAE)

The DAE includes three specific actions on eHealth aimed at:

- **Action 75** - widespread deployment of telemedicine
- **Action 75** - patients' access to their health data and
- **Action 77** - interoperability.

**Context**

- Despite the economic crisis, the global telemedicine market grew from $9.8 billion in 2010 to $11.6 billion in 2011, while the global mHealth market is set to grow to $27.3 billion a year by 2016.
2) Policy aspects

b) eHealth Action Plan 2012-2020

Specific telemedicine actions:

• The Commission will under Horizon 2020 support activities for professionals on developing evidence-based clinical practice guidelines for telemedicine services.

• To achieve wider interoperability, the Commission will with the endorsement of the eHealth Network propose an eHealth interoperability framework.
The European Commission favours the **exchange of best practices** between Member States and stakeholders in the field of eHealth, e.g.:

- Importance of the eHealth Network
- eHealth Stakeholder Group – recent reports on telemedicine and interoperability
- Funding of website: [http://www.epractice.eu/](http://www.epractice.eu/)
The Renewing Health project aims at:

- implementing large-scale real-life test beds for the validation and evaluation of telemedicine services using a patient-centred approach and an assessment technology.

- giving patients a central role in the management of their own diseases while helping detect early signs of worsening of pathologies.

Projects (II) – "Chain of trust"

The Chain of Trust project aims at:

• assessing the **views, needs, benefits and barriers related to telemedicine** from the perspective of patients and health professionals

• increasing awareness of users' perspective on telehealth amongst patients' and health professionals' organisations and health authorities at EU and national level.

• [http://www.chainoftrust.eu/](http://www.chainoftrust.eu/)
Projects (III) – "Momentum"

- The Momentum Thematic Network is a platform of key players sharing knowledge and experience in deploying telemedicine services into routine care to build a body of good practice and:
  - assist countries and telemedicine practitioners in their telemedicine implementations
  - propose a set of policy recommendations to create the enabling environments to accelerate overall telemedicine deployment in Europe.

http://www.telemedicine-momentum.eu/
Projects (IV) - TELESCOPE

- Telescope aims to develop a comprehensive Code of Practice for Telehealth Services.
- It will, through establishing service standards, help establish relationships of trust between patients and providers and contribute to overall health and well-being.
- The standards will provide a quality benchmark for service regulation in Member States.
- [http://www.telehealthcode.eu/](http://www.telehealthcode.eu/)
PHC 26 -2014) Self-management of health and disease: citizen engagement and mHealth

Scope

focus on patients or healthy persons
health management addressed in a holistic approach
(i) citizen engagement in health, wellbeing and prevention of diseases

• Creation of a supportive environment for healthy behaviour
• Health promotion, health literacy and disease prevention
• Development of a multi-stakeholder ecosystem
• A migration path towards comprehensive solutions that could be incorporated into health care processes
PHC 26 -2014) Self-management of health and disease: citizen engagement and mHealth

Scope

(ii) mHealth apps for disease management

co-designing and user needs as a key driver; knowledge management systems; guidance for patients, care-givers, families and patients' social environment; patient adherence to and compliance with medical recommendations; economic aspects; secondary prevention; addressing avoidable negative health and wellbeing outcomes; screening for pre-frailty states; public health or health promotion interventions addressed to large sectors of population through mHealth applications and; co-operative ICTs to support co-operative management of health and disease among patients and eco-health systems.
EC Commission Staff Working Document on the existing EU legal framework applicable to telemedicine (06.12.2012):

http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=9155
Thank you!

Celine.Deswarte@ec.europa.eu

Digital Agenda for Europe
http://ec.europa.eu/digital-agenda

Have your say: Green Paper on mHealth
12-14 May 2014 eHealth Forum in Athens (#eHF14)

Website: http://bit.ly/EUeHealth
Newsletter: http://bit.ly/eHealthinFocus