

# Introduction to legal framework for eHealth

Seminar SEeHealth: The Roadmap from  
Concept to Practice

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Catalina DIMA, Legal Officer  
ICT for Health Unit , DG Information Society and Media



## Definitions of eHealth in *the acquis* - eHealth Action Plan (2004)

- e-Health **tools** or **solutions** include **products**, **systems** and **services** that go beyond simply Internet-based applications. They include **tools** for both health authorities and professionals as well as personalised health systems for patients and citizens. Examples include health information networks, electronic health records, telemedicine **services**, personal wearable and portable communicable **systems**, health portals, and many other information and communication technology-based **tools** assisting prevention, diagnosis, treatment, health monitoring, and lifestyle management.



## Definitions of eHealth in *the acquis* - Lead market Initiative (2007)

- **Clinical information systems and specialised tools** for health professionals within care institutions (e.g., hospitals). Examples are Radiology Information Systems, Nursing Information Systems, Computer Assisted Diagnosis, Surgery Training and Planning Systems
- **Clinical information systems for primary care** and/or for outside the care institutions such as general practitioner and pharmacy information systems
- **Integrated regional/national health information networks** and distributed electronic health record systems and associated services such as e-prescriptions or e-referrals
- **Systems for health education and health promotion of patients/citizens** such as health portals or online health information services
- **Telemedicine and homecare**, personalised health **systems** and **services**, such as disease management services, remote patient monitoring (e.g. at home), tele-consultation, tele-care, tele-medicine, and tele-radiology
- **Specialised systems for researchers** and public health data collection and analysis such as bio-statistical programs for infectious diseases, drug development, and outcomes analysis
- **Support systems** such as supply chain management, scheduling systems, billing systems administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals



## Division of competences in the Public Health Policy

- The legal basis is justified by both the **objectives** and the **content** of eHealth
- Art. 168 of the Treaty on the functioning of the European Union - a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities
- – MS have primary responsibility for organisation and delivery of healthcare
- Art. 114 (3) – 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



## Hybrid character of eHealth

- Interferes competences in health policy, ICT and R&D, data protection, consumer rights protection, internal market, social and employment policy
- eHealth derives competences from competences of other Community policies



## "Soft law" on eHealth

- Communication on eHealth – making healthcare better for European citizens: **An action plan for a European eHealth Area**, COM(2004) 356 final, April 2004
- Communication on **A lead market initiative for Europe**, COM(2007) 860 final, December 2007
- Recommendation on **cross-border Interoperability of Electronic Health Record systems**, COM(2008) 3282 final, July 2008
- Communication **on telemedicine** for the benefit of patients, healthcare systems and society, COM(2008) 689 final, November 2008
- Staff Working Paper **on telemedicine** for the benefit of patients, healthcare systems and society, SEC(2009)943 final, June 2009



# Recent developments

- Council Conclusions on Safe and efficient healthcare through eHealth, 1 December 2009
- On-going discussions on the Draft Directive on the application of patients' rights in cross-border healthcare, COM(2008) 414 final
  - Art. 16 "E-health" of the initial proposal:

"The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data in accordance with the applicable law. They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services."
- Draft Staff Working Paper (SWP) on the applicability of existing EU law to telemedicine services



## SWP on Telemedicine- objectives

- to provide legal clarity to telemedicine, in particular to teleradiology and telemonitoring
- to provide legal responses to the most universal situations common to all telemedicine providers

### ***Steps:***

- to raise awareness about the *acquis communautaire* in Member States
- to analyse and list the provisions of the EC legislation applicable to telemedicine
- provide case studies





## SWP Telemedicine – areas to be covered

- Freedom to provide telemedicine services
- Definition of telemedicine as an information society service
- Licensing/authorisation
- Reimbursement
- Liability
- Health data protection



# Freedom to provide telemedicine services

- Overarching principle of freedom to provide services in the internal market – Art. 56 and 57 of the Treaty on the functioning of the European Union
- ECJ - medical services fall within the scope Art. 57 of the Treaty on the functioning of the European Union (*Smits and Peerboms* - C-157/99)– neither the special nature of health services, nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement.
- “Article 59 (currently Art. 56) of the Treaty applies to services which a provider supplies without moving from the Member State in which he is established to recipients established in other Member States” (*Alpine Investment* - C-384/93)
- Telemedicine services are defined as healthcare services provided at a distance
- the provisions of the Treaty regarding the free movement of services should apply to telemedicine services



# Telemedicine services as information society services (ISS)

- Definition of information society services (Art. 1(2) of Directive 98/34, as amended by Directive 98/48)
  - "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 Directive 98/34, as amended by Directive 98/48)



# Consequences of Telemedicine as an ISS

- General obligation to inform (eCommerce directive) – general information + specific information for regulated professions (professional body with whom they are registered, professional title, applicable professional rules)
- MS and COMM encourage drawing up of Codes of Conduct at Community level – soft law
- Any national legislation specifically directed at ISS should be notified to the Commission (Directive 98/34, as amended by Directive 98/48)



# Licensing/authorisation

- E-Commerce directive – country of origin principle
  - Exceptions, namely public health: any measure should be proportionate, taken against a serious risk and prior notification of the MS and of the Commission
- Harmonisation of qualifications of health professionals - Directive 2005/36 – in case of temporary provision of services – no authorization, only a simple notification
- Directive 2005/36 is not applicable – requires physical presence of the health professional in the patient's country
- Are MS entitled to require the obligatory registration of a health professional who is teleworking to another MS?
- Prohibition to impose a specific prior authorisation for telemedicine services (e-Commerce directive)



# Reimbursement

- ECJ case law to be codified by the Draft Directive on patients' rights– applicable in cross-border situations - non-hospital planned healthcare – should be reimbursed up to the level of costs that would have been assumed if the service would have been provided in the MS of affiliation
- Regulation No. 1408/71 of the Council on coordination of social security schemes
- 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
- Analogy to the similar traditional treatment should be envisaged



- Medical liability and services liability – national law – in cross-border situations, applicable law to be identified using Rome I/Rome II Regulation (contractual/non-contractual obligations) and e-Commerce Directive
- Product liability – EU legislation on no fault liability for defective products as implemented in national law
- No liability of intermediaries (ex. Internet service providers) for “mere conduit”, “caching” or “hosting” (e-Commerce Directive)
- Draft Directive on patients’ rights – MS of treatment shall ensure the following are in place:
  - systems of professional liability
  - systems for making complaints



# Health data protection

- General principles of data processing (Data Protection Directive)
- Art. 29 Data Protection Working Party document on processing of health data in EHRs  
[http://ec.europa.eu/justice\\_home/fsj/privacy/docs/wpdocs/2007/wp131\\_en.pdf](http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf)
- 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)
- Authentication procedures – eSignature Directive is relevant
- Differences in the implementation of the Data Protection Directive in the MS





## Conclusions

- eHealth is a dynamic legal environment
- eHealth derives its competences from competences of other policies
- eHealth is a tool, a solution, a system, a product, a service
- eHealth does not constitute any specific branch of health law
- eHealth is already covered by EC law



# Further reading

- Legally eHealth - study on legal and regulatory requirements of eHealth

[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)

- Study on the Legal framework of Interoperable eHealth in Europe

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



**Thank you for your attention!!!!**  
**Catalina.dima@ec.europa.eu**

