

Legal workshop on telemedicine

Prague, 18 Feb. 2009

Luba Hromkova, DG INFSO



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



SWP Telemedicine – areas

- Definition of telemedicine as a service
- Licensing/authorisation
- Liability
- Conflict of jurisdiction
- Health data protection
- Reimbursement



Telemedicine freedom to provide services

- ECJ proclaimed - health service is service in the meaning of the Art. 49 EC Treaty – 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.
- eHealth service is a service
- Telemedicine is an information society service (ISS) in the meaning of e-Commerce Directive (Directive 2000/31/EC)
- Definition of ISS: at a distance, by electronic means and at the individual request of a recipient
- Excluded (Annex V a) - medical examinations or treatment at a doctor's surgery using electronic equipment where the patient is physically present (Directive 98/34/EC as amended by Directive 98/48/EC)



Telemedicine – challenges for:

- National setting
- Cross-border setting
- EU-Third country setting

