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Global Forum - Citizens Centered e-Health & m-Health

Legal and Regulatory Issues with e-Health & m-Health

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Regulatory Developments with EU e-Health & m-Health

- E-Health - making healthcare better for European citizens: an action plan for a European e-Health Area COM (2004) 356
- E-Health Taskforce Report (2007) - Accelerating the Development of the e-Health Market in Europe
- WP 29 No. 131 of 15 February 2007 on the processing of personal data relating to health in Electronic Health Records
- Commission Communication on Telemedicine COM (2008) 689 emphasising the need to bring legal clarity
- Commission Recommendation on cross-border interoperability of EHR systems of July 2008
- Legal and Regulatory aspects of e-Health – Study Report March 2008
- MOU between US and EU on Health Information Technologies – December 2010
- Directive 2011/24/EU on patients' rights in cross-border healthcare refers to telemedicine and e-health
- Reform of the EU Data Protection Directive 95/46/EC with a new proposal due early in 2012

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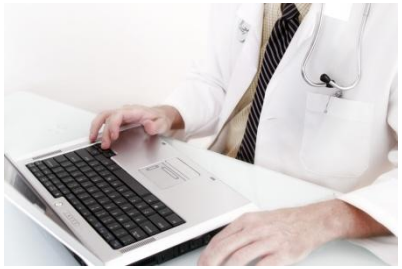
Processing Health Data in e-Health

- Processing of health data which identifies a living individual is subject to the Data Protection Directive 95/46/EC which is in the process of being revised
- The Data Protection Directive has been interpreted and applied differently by Member States particularly in relation to health data leading to national law inconsistencies
- It is often unclear when de-identified health data is considered to be personal data and not anonymous data
- There is uncertainty over the legal grounds to process health data including whether consent is valid and what other legal grounds can be used e.g. for preventative medicine
- There are difficulties with the cross-border transfer of health data from the EU due to national law differences and inflexible data transfer solutions e.g. model contracts



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Buying and Using e-Health

- E-Health products and services are subject to a myriad of consumer protection laws including EU product liability directives and product safety directives
- E-Health devices are also subject to directives in the medical device sector which aim to harmonise conditions for placing medical devices on the market
- A number of standards are also being developed such as the European Standards Agency (CEN) standard for EHRs
- E-Health services provided via the Internet may be subject to the e-Commerce Directive, Distance Selling Directive and e-Signatures Directive
- Legal and administrative limitations in EU Member States on reimbursement of e-health services is also problematic

Ways to Improve Legal Certainty with e-Health

- One of the key issues identified by the Commission is to provide greater legal clarity to the provision of e-health
- The Legally e-Health Report of 2008 recommends:
  - a definition of duties and rights of all actors involved in an e-Health system
  - clarifying the rules of data protection to balance patient rights to privacy and the need for data sharing in e-Health
  - standardisation of the infrastructure and security of e-Health services
  - assessment of impact of competition law on uptake of e-Health
- As stated in the ten step plan in the Commission's Communication on Telemedicine other areas where legal certainty is still required include accreditation, liability and reimbursement.
- By end of 2011 Member States are meant to have adapted national laws to enable wider access to telemedicine services with the Commission to publish a policy strategy paper on interoperability of telemonitoring systems

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Comments/Questions

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