



e-HEALTH LEGAL CHALLENGES

European Integration and Healthcare Systems

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CONTROVERSIAL ISSUES

e-Health - synonym for dispute between lawyers, conflicts about whether and to what extent it interferes with public health policy and other policies

- Should be regulated separately from the more "traditional" healthcare?
- Law vs. Innovative Technology?
- Is it self-regulable?
- Is it legal?



OVERVIEW

- I. Legal Uncertainty
- II. Division of competences in the Public Health Policy
- III. e-Health's hybrid character
- IV. Effective communication in e-Health
- V. e-Health's definition
- VI. e-Health's market
- VII. Legal barriers towards e-Health market
 - Application of Personal Data Protection legislation to e-Health
 - Legal liability (Civil liability for defective goods and services)
 - Jurisdictional certainty
 - Cross-border healthcare



I. Legal Uncertainty (I)

- Legal certainty is a pre-requisite for businesses to invest in innovation and for providers and users to take up new products and services
- It is about knowing in advance who has legal responsibility for each aspect of an application
- The public authorities have a clear responsibility in providing such certainty



I. Legal Uncertainty (II)

- The 2006 Report "Creating an Innovative Europe" prepared by Mr. Esko Aho, explicitly acknowledged the importance of ICT in tackling specific challenges within the public health, and thus identified e-Health as an example of a key area where a market for innovation can operate and public policy can have a significant role



II. Division of competences in the Public Health Policy

Art. 152 -1

A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, ***which shall complement national policies***, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community ***shall complement the Member States' action*** in reducing drugs-related health damage, including information and prevention.



II. Division of competences in the Public Health Policy

Art. 152-2

The Community ***shall encourage cooperation between the Member States*** in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1.

The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.



II. Division of competences in the Public Health Policy

Art. 152-4

The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting:

- c) ***incentive measures*** designed to protect and improve human health, ***excluding any harmonisation of the laws and regulations of the Member States***



III. Hybrid character of e-Health

- Competences in health policy, ICT and R&D, data protection, consumer rights protection, internal market freedoms
- Multidisciplinary character of e-Health
- e-Health derives competences from competences of other Community policies



IV. Effective communication in e-Health (I)

- Horizontal communication and cooperation between all relevant sectors (national authorities responsible for health, research and development, information society, personal data protection, consumer protection etc).
- Vertical communication and cooperation towards regional and local structures (in decentralised Member States, e. g. Consejerías de Salud de las Autonomías, Spain)
- Effective communication inside of a Member State – promise of effective communication among all Member States (e. g. Recommendation on e-Health Interoperability)



IV. Effective communication in e-Health (II)

Recommendation on e-Health Interoperability

- *Dialogue*: Start a dialogue with the MSs on achieving a European health information space by 2015.
- *Agreement and engagement*: Indicate on what principles there should be a broad agreement and engagement in order to reach shared and interoperable e-Health systems by 2015.
- *Framework*: Form a 'framework' that enables all Member States to participate and to identify an appropriate role.
- *Interoperability*: Focus on interoperability between health information shared among different healthcare systems, and based on a limited range of applications in current existence and use in different Member States.
- *Semantic Interoperability*: Improve semantic interoperability by adopting a common terminology framework.



V. Multiple definition of e-Health (I)

Wikipedia

e-Health (also written **eHealth**) is a relatively recent term for healthcare practice which is supported by electronic processes and communication. The term is inconsistently used: some would argue it is interchangeable with health care informatics, while others use it in the narrower sense of healthcare practice using the Internet. The term can **encompass a range of services** that are at the edge of **medicine/healthcare** and **information technology**:

- **Electronic Medical Records:** enable easy communication of patient data between different healthcare professionals (GPs, specialists, care team, pharmacy)
- **Consumer Health Informatics** (or citizen-oriented information provision): both healthy individuals and patients want to be informed on medical topics.
- **Telemedicine:** includes all types of physical and psychological measurements that do not require a patient to travel to a specialist. When this service works, patients need to travel less to a specialist or conversely the specialist has a larger catchment area.
- **Evidence Based Medicine:** entails a system that provides information on appropriate treatment under certain patient conditions. A healthcare professional can look up whether his/her diagnosis is in line with scientific research. The advantage is that the data can be kept up-to-date.
- **Health knowledge management** (or specialist-oriented information provision): e.g. in an overview of latest medical journals, best practice guidelines or epidemiological tracking.
- **Virtual healthcare teams:** consist of healthcare professionals who collaborate and share information on patients through digital equipment (for transmural care)



V. Multiple definition of e-Health (II)

- e-Health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.
 - “stamping a definition on something like e-Health is somewhat like stamping a definition on 'the Internet': It is defined how it is used - the definition cannot be pinned down, as it is a dynamic environment, constantly moving“

Gunther Eysenbach in: *Journal of Medical Internet Research*, Vol. 3, No 2 (2001)



VI. Definition of the e-Health's market (I)

- **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



VI. Definition of the e-Health's market (II)

- e-Health is a system (SW+HW)
- Danger: According to the Consumer Sales Directive – a consumer good is a “tangible moveable item” which excludes SW and data related to e-Health from its scope
- No responsibility for possible damages and non conformity of such products with the contract and a low prevention of consumers to use remedies for non-conformity
- The IGC mandate for the next Treaty reforming the current Treaties contains a proposal on adoption of a declaration clarifying the internal market aspect of measures on the quality and safety standards for medicinal products and devices



VII. Legal barriers towards e-Health's market

- I. Application of Personal Data Protection legislation to e-Health
- II. Legal liability (civil liability for defective goods and services, criminal liability)
- III. Jurisdictional certainty
- IV. Cross-border provision on healthcare: Patient mobility & Telemedicine



VII.-/- Application of Personal Data Protection legislation to e-Health

- The fundamental right to the protection of personal data is based on Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms and on Article 8 of the EU Charter of Fundamental Rights.
- More precise protection:
 - **Directive 95/46/EC** of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
 - **Directive 2002/58/EC** of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector
 - Article 29 Working Party documents
 - **WP 131 Working Document** on the processing of personal data relating to health in electronic health records, 15.02.2007
 - **WP 105 Working Document** on data protection issues related to RFID technology, 19.01.2005



VII.-II- Civil liability for defective goods and services

- Liability for the quality and safety of e-Health goods is covered reasonably well by the general legislation in Europe on product safety and consumer protection (Directive 374/1985/EEC of 25 July 1985 on liability for defective products)
- Specific nature of e-Health - problem of civil liability (who is liable for what and how liability is split among different service providers)
- Possible solution - a principle of the law of the place where the person sustaining the damage has his/her residence, together with a 'foresee ability clause'
- Foresee ability clause aims to protect the producer against the application of the law of the place where the damage occurred if he was not able to foresee this solution.



VII.-III- Jurisdictional certainty

- Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels II)
- The 1980 Rome Convention on the law applicable to contractual obligations (Rome I)
- A draft Regulation on the law applicable to non contractual obligations (Rome II)



VII.-IV- Cross-border provision on healthcare

- is one of the four aspects of cross-border healthcare
- Approximately 1% of total healthcare expenses is spent each year on cross-border care, this tendency is growing
- Cross-border e-Health services (telemedicine, teleradiology, teleconsultancy, telecare, etc)
- Legal base for e-Health cross-border services
- Directive 2000/31/EC e-Commerce Directive v. Information Society Directive
- Information Society Service - "any service normally provided for a) remuneration, b) at a distance, c) by electronic means and d) at the individual request of a recipient of services" (Art. 1, par. 2)



CONCLUSIONS

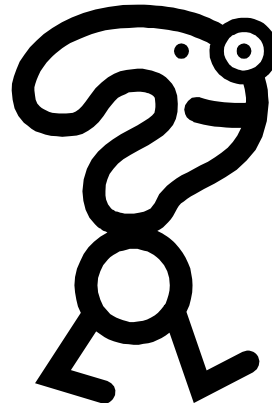
- e-Health is a dynamic environment
- e-Health derives its competences from competences of other policies
- e-Health is a driven tool in shaping policies
- e-Health is a system
- e-Health is a service

...because the alternative is not an option...



Audience patience's limit :-)

Questions and Answers



Thank you for your attention!!!!
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***e-Health* LEGAL CHALLENGES**

***e-Health* makes health better for all
e-Health against social exclusion**

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