

eHealth – moving target: Legal challenges for eHealth

Today eHealth becomes a more and more powerful word. eHealth is not health in the next century, or a James Bond invention. "Stamping a definition on something like eHealth 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 moving¹." It is here and now, a rapidly growing trend, and a moving target. The primary eHealth definition which was more or less restricted to the use of Internet in health systems, is not valid anymore, though health related websites are among the most widely used websites on the Internet. We are facing many definitions of eHealth which broadly characterize this notably booming area. Over the course of time eHealth revolutionised in many areas; in spite of an indisputable impact on research and industry, it has become a frightening topic for many lawyers who are constantly asking what to do with it. It has become a synonym for dispute between lawyers, conflicts about whether and to what extent it interferes with public health policy and should be regulated separately from the more "traditional" healthcare. A very close collaboration and mutual perception between research and law are needed to cut this Gordian knot, but unfortunately the legal and regulatory environment has not progressed as rapidly as technology. A good legal system should reflect the social reality, and especially be able to regulate issues which cannot be self-regulated. Today one of the alarming issues is how to achieve the synergy between the evolution of innovative technology and the legal systems. This consequently provokes a question about a flexibility of the legal system and tolerable space for non regulation of eHealth.

The importance of this issue was also raised by the Report "Creating an Innovative Europe"², prepared by Mr. Esko Aho, who recommended the development of innovation-friendly markets in a more targeted way by creating conditions to facilitate the translation of technological and non-technological innovation into commercial products. The Report explicitly acknowledged the importance of information and communication technologies (ICT) in tackling specific challenges within the public health, and thus identified eHealth as an example of a key area where a market for innovation can operate and public policy can have a significant role³.

Legal uncertainty around eHealth was identified among the most compelling barriers to eHealth market's potential. Legal certainty is a pre-requisite for businesses to invest in innovation and for providers and users to take up new products and services for which they know in advance who has legal responsibility for each aspect of an application. The public authorities have a clear responsibility in providing such certainty. In order to give a satisfactory response to the legal uncertainty issues, we should also analyse the motives that mostly provoked this situation.

This presentation attempts to provide an overview of the legal environment through which the eHealth must pass and point out some critical issues which should be addressed, if we agree that eHealth is not a domain which can be left for self-regulation. Its complex and special

¹ Gunther Eysenbach in: *Journal of Medical Internet Research*, Vol. 3, No 2 (2001).

² Esko Aho, "Creating an Innovative Europe: Report of the Independent Expert Group on R+D and Innovation Appointed Following the Hampton Court Summit", available at: http://ec.europa.eu/invest-in-research/pdf/download_en/aho_report.pdf

³ The European Commission currently prepares to issue a Communication on A Lead Market Initiative for Europe where one thematic part is devoted to a Lead Market Initiative for eHealth.

nature raises many legal issues, and this presentation is not intended to be a comprehensive analysis but a piece to highlight some legal aspects of eHealth. Particularly it will deal with:

- Division of competences between Member States and Community in the Public Health Policy;
- Hybrid character of eHealth which consists in competences in health policy, ICT, R&D, personal data protection, consumer protection etc.;
- Multiple definition of eHealth and perception of eHealth in the framework of the EU single market;
- legal barriers *per se* towards eHealth market:
 1. Application of Personal Data Protection legislation to eHealth;
 2. Civil liability for defective goods and services;
 3. Jurisdictional certainty;
 4. Patient mobility.

e-Health is a synonym of new health culture. It can make life of many patients easier, safer, flexible, less painful and more comfortable. It strengthens the constitutional protection of human life. Therefore innovative technologies in healthcare should be adequately addressed in all public policy strategies. It is necessary underline that e-Health should not create differences between patients, nor to become a matter only for wealthy citizens. We must ensure that e-Health overcomes social exclusion and will serve to all of us.