

## Creating Legal Certainty for e-Health across the European Union

*“The legal and regulatory issues in implementing a fully functional e-health system are a considerable challenge to healthcare providers and national regulators. With the Legally e-Health Study, Cisco IBSG has helped us significantly in identifying the key questions and highlighting the opportunities for EU-level action to drive greater legal certainty in e-health.”*

—Gérard Comyn, acting director, ICT Addressing Societal Challenges, DG Information Society and Media, European Commission

### In Brief

In its e-health Action Plan of 2004, the European Commission highlighted the importance of establishing legal certainty for e-health. During 2007 and 2008, in collaboration with the European Health Management Association, the University of Namur, and Basil Strategies, the Cisco Internet Business Solutions Group (IBSG) undertook an in-depth study of the European legal framework for e-health. The study resulted in an EU Commission publication in May 2008, “Legally e-Health: Putting e-Health in Its European Legal Context,” which has been made available to the health ministries of all 27 EU member states, as well as to a wider public audience through the EU Commission website, and a number of key e-health conferences and meetings. The study has been extensively discussed in the i2010 Committee on Information Society working groups on e-health. This study now contributes to the baseline of the commission’s next steps in adapting existing regulatory measures to e-health, and in introducing new regulatory measures where appropriate.

### Customer

European Commission,  
ICT Addressing Societal Challenges,  
DG Information Society and Media

### Industry

Healthcare

### Challenges

- Mapping the European legal landscape of e-health.
- Raising awareness of legal challenges in implementing e-health systems.
- Outlining the potential for further European Community action on creating legal certainty in e-health.
- Creating the right regulatory environment for the growth and adoption of network-based solutions for healthcare provision.
- Developing trust and promoting increased use of e-health solutions.
- Bringing a detailed industry perspective to the need for interoperability in e-health.



Cisco Internet Business Solutions Group (IBSG)

## Solutions

- Three detailed reports for the European Commission, as well as the published summary report that focuses on core legal questions central to the implementation and exploitation of e-health: privacy, confidentiality, and security of health and personal information; product / service liability and consumer protection; and trade and competition law applicable to cross-border e-health procurements.
- Each report provided an in-depth analysis of applicable EU-level legislation, as well as a series of case studies that clarify the application of law relating to e-health in Europe.
- The study concluded with a series of recommendations for regulations and policies to help create legal certainty and confidence in e-health across the European Union.

## Next Steps

- The European Commission has welcomed the report and used it as a baseline for further research, as well as in its ongoing policy actions on e-health—notably, the 2008 paper, “Recommendation for Interoperability in Electronic Health Record Systems,” and the forthcoming “Communication on Telemedicine in Chronic Disease Management.”

## Results / Benefits

- “Legally e-Health: Putting e-Health in Its European Legal Context” has been widely disseminated as an EU Commission publication and is available at <http://www.cisco.com> and [http://ec.europa.eu/information\\_society/activities/health/docs/studies/legally-e-health-report.pdf](http://ec.europa.eu/information_society/activities/health/docs/studies/legally-e-health-report.pdf)

## Best Practices / Lessons Learned

- The adoption of e-health has been hindered significantly by the lack of legal certainty in the applicability of EU-level legislation.
- The importance of developing a sound understanding of the legal and regulatory landscape in which a new technology will operate is fundamental to build trust in—and acceptance of—that technology, and to promote its adoption.

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