



# eHealth Study of the Month Legally eHealth

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## Making clear the legal and regulatory context of eHealth

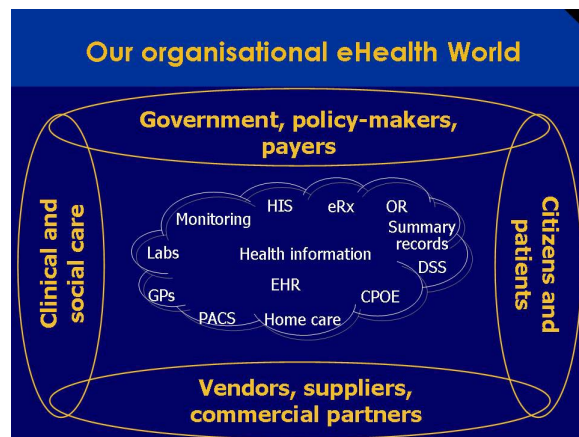
### 'Legally eHealth' aims to help remove legal and regulatory doubts at the EU level

Information and communication technologies are increasingly being used to improve the quality, provision and access to care while also bringing new elements to the reflection on the financial sustainability of health systems. However, questions exist over the legal and regulatory implications for eHealth services, especially as these can cross institutional boundaries and national borders. One initiative, 'Legally eHealth', aims to help remove those doubts at the EU level. The study forms part of the 'Good eHealth' cluster of studies that support the European eHealth Action Plan.

The growing interest in and implementation of eHealth systems - combined with other challenges such as an ageing population, patients and professionals moving across borders, and the current context of the consultation on Community action in the field of health services - makes this study all the more topical.

We have begun to 'do health' differently - what are the implications and how we can we enable patients to stay, more than ever, at the centre of the health system to ensure access, quality and sustainability? How can we ensure that, in this changing context, health professionals are as ever able to fulfil their duty of care and their duty of confidentiality?

Information and communication technologies have much to bring to the world of health. The diagram below brings to the fore the fact that new actors have entered the eHealth scene: industry and other commercial partners are now forming agreements not only with health services providers, but increasingly also directly with patients and 'consumers' of health services.



The Legally eHealth study has undertaken to make sense of how EU-level legislation applies to this eHealth world through three clusters of issues:

- Privacy, confidentiality, and security issues
- Product & service liability and consumer protection
- Trade and competition aspects of (e)health





host, the makers of HypnoNix, or another authority?

- Sandrine Sandeau has a congenital heart disease that requires medication in the form of patches and constant monitoring. Her doctor has prescribed her an eVest to wear. This wearable monitoring device is equipped with sensors that monitor her blood pressure, heart rate, and heart rhythm. It transmits the data to a medical centre that automatically notifies patients when they need to change their medicated patches. Sandrine fainted while off on holiday in the French Alps. The emergency response team noticed right away that her medicated patches were not operational. What part of the treatment process had failed Sandrine? What might the consequences be on the eVest provider, the monitoring centre, and the telecommunication provider in the Alps?

In the study, these clusters of legal issues are analysed by experts who look at Treaty texts, Directives and other EU-level legislations, as well as relevant case law. The appropriate issues are further unpacked through a series of case vignettes, or fictional short stories, that are compiled from current and possible future eHealth cases. The case vignettes not only decant some of the complexities of the legal issues, but also bring out other questions which, although they do not necessarily require a legal response, need further reflection and analysis. Here are four pertinent examples:

- The SoftMicro company wishes to diversify its health-related activities beyond records scanning. It has been informed that a couple of monitoring companies with strong potential in the field are ready to sell. The companies are based in Finland and, after just these few company purchases, SoftMicro soon owns 90% of the Finnish market. The Finnish health minister does not agree with a foreign company dominating the monitoring sector of the country and presents the case to the courts. What aspects of trade and competition law might be applicable to the health sector, and specifically to eHealth? How might they be applied?

- Dr. Caroline Carrington, in Scotland, wishes to digitise the current paper-based medical records of her patients. SoftMicro, a multi-national company, proposes to scan records in a local mobile unit and send the records to Pakistan for data entry and to populate a database hosted by a UK-based website. Is this something that she has a right to do? If so, under what conditions and what might be her duties towards her patients? What are the duties of the company, both in the UK and in Pakistan?

While Legally eHealth does not aim to provide all the answers to all these questions, its combination of legal analysis and case vignettes illustrates various situations in which different actors in the eHealth field might recognise themselves. In this way, the study aims to enable different actors to ask the right types of questions and to look in the right places for answers.

- 17-year old Ben Bemelmans snores and wishes to find treatment before going off to summer camp. On surfing the Internet, he finds an international online pharmacy offering HypnoNix, a one-week over-the-counter cure for snoring. He purchases the medication. While the accompanying leaflet is in a language he does not understand, he finds the treatment works for the six guaranteed months. When about to re-order, Ben notes on the website that HypnoNix can have negative effects on male fertility. Ben had not noticed the information previously and now wonders if it was already on the site when he first ordered the medicine. What recourse does Ben have? Should he have done anything differently? Who might be held liable in this situation – the online pharmacy, the website

The study will conclude in spring 2007. Its final deliverables will provide a description of the barriers, gaps, and any lack of legal or regulatory clarity for each of the three clusters of issues – that is, privacy, products, and trade and competition - in addition to concrete recommendations for solutions.

Study team:  
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 Basil Strategies

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## Links:

Study website: Legally eHealth [www.ehma.org](http://www.ehma.org)  
 Study overview: [http://ec.europa.eu/information\\_society/activities/health/docs/studies/legallyehealth-fp6book.pdf](http://ec.europa.eu/information_society/activities/health/docs/studies/legallyehealth-fp6book.pdf)  
 IST Results: [http://ec.europa.eu/information\\_society/activities/health/docs/projects/istresults/legally\\_eHealth20061106.pdf](http://ec.europa.eu/information_society/activities/health/docs/projects/istresults/legally_eHealth20061106.pdf)  
 Health Policy Relevance: [http://europa.eu.int/information\\_society/activities/policy\\_link/policy\\_cases/index\\_en.htm#Health](http://europa.eu.int/information_society/activities/policy_link/policy_cases/index_en.htm#Health)

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