Study on Legal and Regulatory aspects of eHealth "Legally eHealth" : deliverable 1 work programme

Herveg, Jean

Publication date:
2006

Document Version
Publisher's PDF, also known as Version of record

European Commission
Contract # 30-CE-0041734/00-55

Study on Legal and Regulatory aspects of eHealth

"*Legally* eHealth"

DELIVERABLE 1
WORK PROGRAMME

Start date:	**1st January 2006**
Commencement date of contract:	**1st January 2006**
Duration:	**12 months**
Contractor:	**European Health Management Association**
Version:	**09 (Final)**

TABLE OF CONTENTS

PART I - SUMMARY

1. Description

OBJECTIVE

The study on Legal and Regulatory aspects of eHealth has the central objective of contributing to the Actions of the eHealth Communication and Action Plan that address the need to establish greater legal certainly in Europe with respect to the practice of eHealth service delivery and the use of eHealth tools within the context of the existing legal framework on product liability legislation and other relevant EU level legislation.

The study has four key objectives:

- To analyse the existing EU level legal framework pertaining to the use of eHealth tools, systems and services.
- To develop an accessible knowledge base on legal and regulatory aspects of eHealth covering all pertinent EU level legislation and case law, and selected relevant national level legislation. The knowledge base will take on a Wiki[1]-style format in the form of electronic documents with internal and external hyperlinks.
- To develop a series of case study vignettes to explore and elucidate the practical implications of the identified legislative issues in the use of eHealth tools, systems and services.
- To make recommendations on such legislative and regulatory lacunae as may exist.

METHODOLOGY

The study uses both traditional legal research methods and the case study method. The researchers will use standard European legal databases including EurLex, CeLex, and the records of the European Court of Justice, as well as wider European regulations databases such as those of the Council of Europe and the European Court of Human Rights, as well as selected national databases.

As well as cataloguing and analysing the EU level legal aspects of eHealth, this study explores the extent of their impact on the delivery of healthcare using eHealth tools, systems and services through a series of composite case vignettes built from a range of real event reports. The case vignettes are used to bring to life the complex nature of key legal concepts such as data protection, data ownership, and product and service liability, through the telling of compelling stories.

SCOPE

The study undertakes a thorough assessment of all EU level legislation, regulations and guidelines that may be applicable to the use of eHealth tools, services and applications in healthcare delivery. Healthcare delivery is, in this case, construed widely to include institutional care (primary and secondary care), remote care, professional medical advice, and non-professional health advice. It covers services delivered by all levels of health professionals as well as those working on a voluntary basis. The study will include assessments of selected examples

[1] See, for example, Wikipedia on http://en.wikipedia.org/wiki/Main_Page

of national transpositions of relevant EU legislation in areas such as data protection, electronic commerce and product liability.

The case vignettes developed will also select specific national examples in order to demonstrate the application of the EU level rules at national and cross-border level. The examples will be selected to demonstrate legal issues across the range of different health systems current in Europe: national health systems, social insurance systems, community health insurance systems, and direct payments to patients, and private insurance based systems.

Based on the two elements described a series of recommendations will be made on meeting such legislative and regulatory needs as may be found to exist.

2. Contractor and Partners

The study is co-ordinated by the European Health Management Association (EHMA), represented in this study by both senior and junior staff.

Mr Philip Berman, Director of EHMA, will manage the study, with the assistance of Ms Celine van Doosselaere, EHMA's Head of Brussels Office / EU Affairs[2].

Three further highly experienced experts in health law and health policy will assist EHMA in the study through separately concluded subcontracts. Professor Yves Poullet, Mr Jean Herveg and Ms. Isabelle Vereecken, of the Research Centre for Computers and Law, University of Namur and Ms. Denise Silber of Basil Strategies, a long established consultancy in eHealth with an established record in Management Consultancy on eHealth to providers (hospitals) and policy makers (Health Ministries).

As well as relying on the expertise of the three sub-contracted researchers the EHMA team will make use of the extensive membership of EHMA (which comprises over 240 institutions) to develop and validate the case studies. EHMA will also make use of its active membership of the European Health Policy Forum to involve other EU level non-governmental organisations and interest groups in informal expert advice and quality assurance through the Advisory Board, covering the healthcare provider perspective (Georges Pompidou Hospital, Paris), the business perspective (Deloitte and Touche[3]), the academic perspective (IESE Business school, Barcelona) and the not-for-profit sector perspective (European Public Health Alliance).

[2] NOTE: At the time of tender submission Dr Petra Wilson, legal expert, was employed by EHMA. In March 2006 Petra Wilson left EHMA to take up employment with Cisco Systems (Internet Business Solutions Group). Petra will continue to act as advisor to EHMA on the Legally eHealth Study within the framework of a wider no-fee consultancy relationship between Cisco IBSG and the ICT for Health Unit of the European Commission.

[3] NOTE: In the course of 2006, the study's contact person at Deloitte and Touche changed employment to Agfa.

PART II – LEGALLY EHEALTH

1. Introduction

The concept of eHealth and its reality in daily medical practice fundamentally challenges our understanding of the practice and regulation of healthcare in terms of the relationship between practitioner and patient, between practitioner and institution as well as between institutions.

In the traditional model, patient access to the healthcare delivery system has been limited to predetermined points of entry, such as through a primary care physician. From the entry point, the patient's progress through the system has been relatively linear and often dictated by the health system's reimbursement systems. Similarly, processes such as diagnosis, treatment and care have involved physical presence and personal interaction between providers and patients and of course, such physical presence requires some sort of identification (i.e., lack of anonymity). Finally, in traditional health delivery, consumers pay for all aspects of their healthcare information, treatment and care, either directly or through increasingly complex reimbursement systems.

eHealth, however, is premised on a fundamentally new patient experience that is unconstrained by familiar points of entry and structures or traditional channels for delivering information or care. For one thing, anonymity or pseudonymity can be preserved much more easily. Not surprisingly, therefore, the eHealth revolution has as many serious implications for healthcare regulators and lawyers as for medical professionals.

Although policy makers have noted at both European and national level that a lack of legal certainty about the use of eHealth tools and services exists, little has been done to study the issue in detail. Certain projects[4] funded under the Framework Programmes have looked at the general legal issue concerning the use of information society technologies (IST), while others have included work packages looking at the legal aspects of a particular technology or application[5]. Others still have looked at one particular issue, such as confidentiality, in greater detail[6]. However, it would seem that no work has been undertaken to date to look across the whole range of legal issue relevant to the use of IST tools and services in healthcare and to draw conclusions about the regulatory needs which may exist.

As long ago as 1999, when the European Commission launched the eEurope initiative with the adoption of the Communication 'eEurope – An Information Society for All' (COM(1999)687 final, of 8.12.1999), it was noted that although the market for technological applications in the clinical domain was developing rapidly in Europe, and although the increase of health related information and education material available on the internet was of growing significance, the full exploitation of both sectors of eHealth was hindered by a *lack of legal clarity and certainty*. The communication noted specifically that, in the clinical (including commercial) eHealth applications domain **"uncertainty persists in the health telematics related industry about responsibility and data protection, the legality of providing on-line medical opinions as well as on-line pharmaceutical information and product supply."**

The issue was raised again in the 2004 Action Plan for a European eHealth Area (COM(2004)356). This stated that despite adoption of EU legislation on issues such as Data Protection (95/46/EC), Electronic Signatures (99/93/EC), eCommerce (2000/31/EC),

[4] see for example Legal IST- FP6-IST

[5] see for examples NEXTGRID - FP6-IST or EUROGENTEST - FP6-LIFESCIHEALTH

[6] see for example EUROSOCAP – Quality of Life Programme (FP5)

Distance Contracting (97/7/EC) and the existing legislation on General Product Liability (92/59/EEC) and on Medical Devices (93/42/EEC), considerable uncertainty on the legal aspects of the use of eHealth applications, tools and services still continues. Accordingly the Action Plan proposes that by 2009 the European Commission shall "provide a framework for greater legal certainty of eHealth products and services liability within the context of existing product liability legislation."

In this context, the Commission called for the present study in order to establish a base-line report on existing EU level legislation, its impact on the delivery of eHealth and an analysis of the legal lacunae which may exist.

2. Objective and Scope of the Study

This study analyses the legal framework existing at EU level pertinent to the use of eHealth tools, systems and services. The objective is to explore the wide range of settings in which eHealth tools, systems and services can be used and to map them onto the existing EU level legislation as well as selected examples from Member State level legislation.

To make the concepts readily understandable, case study vignettes will be used to group eHealth tools and services into four overlapping categories, which in their turn explore three clusters of legal and regulatory issues.

A series of case vignettes will be developed to cover four eHealth application clusters:

- Public access information systems including health portals providing information for citizens on health education, disease prevention and public health issues;
- Administrative support systems including electronic health records, booking systems and care planning systems;
- Patient support tools and services, including remote monitoring and personal medical data collection devices (wearables and implantables);
- Clinical devices, including decision support tools and telematic medical devices.

The case studies will thus lend themselves to **exploring three clusters of legal issues**:

- Data Protection, confidentiality and security in the context of the collection and sharing of person identifiable data for healthcare and advice;
- Product and Liability and Consumer Protection in the use of eHealth tools, devices and services in both traditional healthcare delivery; eCommerce and distance contracting (including ePharmacy and advertising).
- Trade and Competition in the context of using use of eHealth tools in health services planning and delivery in traditional, remote or cross-border healthcare delivery.

Alongside the case vignettes, the study will develop **a structured, searchable knowledge base** in the form of Wiki-style electronic documents with internal and external links. The documents will cover all the EU level legal, regulatory and policy issues in the three legal clusters, which can be explored through practical case studies developed to include all four eHealth application clusters. The deliverables will thus provide both an easily updateable knowledge base and a series of educational case studies that clearly convey the complexities of the practical implications of the regulations.

The study will clarify for EU and national policy makers the extent to which existing EU level legislation is sufficient to regulate eHealth, and will **highlight any issues that may require legal clarification, or indeed new legal responses**.

It will also, **through the case vignettes, provide an educational tool that may be used by health service regulators to develop confidence and trust** in both healthcare providers and consumers in the use of eHealth tools, systems and services.

Finally, based on the research undertaken, the study will **develop recommendations on meeting any legislative and regulatory needs that may be found to exist.**

3. Methodology

The study will use a mixture of traditional legal research methodology alongside the case study method commonly used in executive education.

TRADITIONAL LEGAL RESEARCH

The researchers will use standard European legal databases including EurLex, CeLex, and the records of the European Court of Justice, as well as wider European regulations databases such as those of the Council of Europe and the European Court of Human Rights.

Research of the databases will be used to define and describe key legal concepts and also to provide a non-exhaustive list of current European legislation and regulatory responses relevant to the use of eHealth systems, tools and services in healthcare delivery. The study will include all hard law (regulations and directives) while also covering soft law and policy guidelines adopted by European Union and International Bodies (such as the European Group on Ethics or the Working Parties of the Council of Europe). Where relevant, EU level case law will be described in detail to clarify the application of the EU Directives and Regulations in this field.

The use of institutional databases as well as academic research methods will ensure that the researchers are constantly up-to-date with developments and that the reports presented as project deliverables represent the state of the art. In the course of the research, a knowledge base will be developed which can easily be updated by the Commission services or other contractors after the end of this project. In the spirit of the Wiki approach, this could also be made open access by the Commission services if it so wished.

CASE STUDY VIGNETTES

In addition to cataloguing and analysing the EU level legal aspects of eHealth, this study will explore the extent of their impact on the delivery of healthcare using eHealth tools, systems and services through a series of composite case study vignettes built from a range of real event reports.

The case method has for many years been one of the key tools used in law schools for teaching students to apply the knowledge gained in the study of many areas of law to complex real life situations. It has also become the method of choice in business and management education,

because of its appeal to mature students who are able to draw on a wide range of practical and personal experiences.

Case studies have been accepted as important pedagogical tools in many fields of study and knowledge transfer, Naumes and Naumes (1999)[7] have argued that there is always an element of "active learning" in any story; the listener or reader cannot simply jump to the end of the tale to find the right answer, but must learn it from the details of the narrative. Case studies have been used in medicine, psychology, sociology and law since the nineteenth century. A case tells the story of an event, individual, group, or decision, and usually describes the results of an action and the action itself.

A case is a "factual description of events that actually happened at some point in the past" (Naumes and Naumes, 1999)[8]. A case presents facts and real people; in other words, it is not fictional. They differ from research case studies, insofar as they do not try to develop or test a hypothesis, but tell "real life" stories; and not the issues presented but remain neutral. They might not have the same intellectual or academic.

Case studies allow participants to participate actively in the learning process allowing the participant to learn as she goes, by stimulating analysis and discussion. A case does not provide a "perfect" account of events but gives facts that are relevant for the case objectives providing condensed information that is focused on the issue by creating a focal point for the exchange of experience and discussion.

Cases studies in management education can be used with a variety of different objectives: to develop concepts; to understand techniques; or to acquire skills - in using techniques, in analysing problems, or in formulating action plans. They are used in the belief that management is a skill rather than a collection of techniques, and that the best way to acquire management skills is to practice them in a case session. This is an important aspect in the transfer knowledge as complex as the one related to eHealth practices

The case method will be applied in this study in a slightly truncated version. Rather than using long cases the study will develop a series of case vignettes to draw together many legal issues into a series composite case examples which will be developed from a range of real event reports. The case vignettes will be used to bring to life the complex nature of, for example, data protection, data ownership, product liability and professional mobility through the telling of a case story. This method is particularly useful in alerting the reader to the fact that a 'case' may have a range of possible outcomes and that legal issues are not always readily evident or solvable.

The case vignettes to be developed for this project will be based on real-life experiences drawn from EHMA's members, and supplemented with details from established case studies which will be obtained from the European Case Clearing House as well as other established Case Clearing Houses, especially that of Harvard Business School.

[7] Naumes, W., & Naumes, M. J. (1999). The Art & Craft of Case Writing. Thousand Oaks, CA: Sage Publications.

[8] Idem.

4. Project Management

Overall Project Management Principles

EHMA project management is based on recognised standard methodologies, such as the Project Management Body of Knowledge of the Project Management Institute.

Management Meetings

Management meetings will be held with the Commission Steering Committee at the end of each project phase on the basis of the relevant report.

The role of the management meetings will be to review the work undertaken in the project and to update the work plan for the next stage if required, having considered the underlying reasons for any deviation and agreed corrective action.

The management meetings will also consider the feedback from the Advisory Board and will invite the Advisory Board Members to meetings if appropriate.

Project Monitoring and Quality Assurance

Regular internal progress reviews will be held, based on reviewing achievements at predefined, regular control points. These reviews will check progress against plans for the past period and evaluate work for the coming period. A brief report will be prepared for each review and will be made available to the Commission.

In general, reviews will be held every two months. During certain key activities, however, they may be held more frequently. Items covered by the reports will be:

- Progress
- Achievements
- Problems
- Actions from last review

Quality Assurance of each stage of the project and of each deliverable will be undertaken by the Projects advisory board. The Advisory Board covers the perspectives of healthcare providers (Georges Pompidou Hospital, Paris), business (Deloitte and Touche / Agfa), academia (IESE Business school, Barcelona) and the not-for-profit sector (European Public Health Alliance).

Reporting

The project deliverables will include six reports as follows:

- D.1: Work Programme: detailing the project plan.
- D.2: (legal cluster 1) "Data Protection, Privacy and Confidentiality": identifying legal and regulatory aspects relating to legal cluster 1 and including legal analysis of relevant case vignettes.

- D.3: (legal cluster 2) "Product Liability and Consumer Protection": identifying legal and regulatory aspects relating to legal cluster 2 and including legal analysis of relevant case vignettes.
- D.4: (legal cluster 3) "Trade and Competition Law": identifying legal and regulatory aspects relating to legal cluster 3 and including legal analysis of relevant case vignettes.
- D.5: Final Report: providing a final draft of full legal issues report in both Wiki-style and paper formats and including all case vignettes; providing the draft conclusions and recommendations to the Commission with respect to clarifying the legal and regulatory aspects of eHealth.

5. Contractor and Resources

STUDY TEAM

The study is co-ordinated by the European Health Management Association (EHMA), represented in this study by both senior and junior staff.

Mr Philip Berman, Director of EHMA, will manage the study, with the assistance of Ms Celine van Doosselaere, EHMA's Head of Brussels Office / EU Affairs[9].

Three further highly experienced experts in health law and health policy will assist EHMA in the study through separately concluded subcontracts. Professor Yves Poullet, Mr Jean Herveg and Ms. Isabelle Vereecken of the Research Centre for Computers and Law, University of Namur and Ms. Denise Silber of Basil Strategies, a long established consultancy in eHealth with an established record in Management Consultancy on eHealth to providers (hospitals) and policy makers (Health Ministries).

As well as relying on the expertise of the three sub-contracted researchers the EHMA team will make use of the extensive membership of EHMA (which comprises over 240 institutions) to develop and validate the case studies. EHMA will also make use of its active membership of the European Health Policy Forum to involve other EU level non-governmental organisations and interest groups in informal expert advice and quality assurance through the Advisory Board, covering the healthcare provider perspective (Georges Pompidou Hospital, Paris), the business perspective (Deloitte and Touche / Agfa), the academic perspective (IESE Business school, Barcelona) and the not-for-profit sector perspective (European Public Health Alliance).

[9] NOTE: At the time of tender submission Dr Petra Wilson, legal expert, was employed by EHMA. In March 2006 Petra Wilson left EHMA to take up employment with Cisco Systems (Internet Business Solutions Group). Petra will continue to act as advisor to EHMA on the Legally eHealth Study within the framework of a wider no-fee consultancy relationship between Cisco IBSG and the ICT for Health Unit of the European Commission.

Name of Expert/ Affiliation	Role in the study team	Primary background/ Specific competences
Philip Berman EHMA	Project leader	Health Management, European Union policy analysis, project management.
Petra Wilson EHMA, later Cisco IBSG	Project manager, then expert	Educated to doctor level in Health Law, direct experience in assessing legal aspects of eHealth in EU policy development.
Céline van Doosselaere EHMA	Core team	eHealth tools and services assessments; project execution.
Yves Poullet CRID	Expert sub-contractor	eHealth Law
Jean Herveg CRID	Expert sub-contractor	eHealth Law
Isabelle Vereecken CRID	Expert sub-contractor	eHealth Law
Denise Silber Basil Strategies	Expert sub-contractor	eHealth and Management.
Véronique Lessens Deloitte & Touche, later Agfa	Advisory Board	Quality Assurance assessment in healthcare, eHealth solutions and tools.
Magdalena Rosenmöller IESE	Advisory Board	Strategic consulting on eHealth.
Lara Garrido-Herrero EPHA	Advisory Board	Public Health.
Line Kleinebreil Pompidou Hospital	Advisory Board	Healthcare Delivery.

PART III - DELIVERABLES AND WORK PACKAGE OUTLINES

1. Work Packages

WP No	Work Package Description	Start	End	Milestones and Deliverables
WP A	Project management	M1	M12	o Project plan o **Work programme (D.1)** o Project meetings (D.1(1), D.1(3), D.1(4), D.1(5)) o Quality reviews (D.1(2), D.1(6))
WP B	Legal Issues	M2	M10	o "Data Protection, Privacy, Security" (D.2(1)) o "Product Liability and Consumer Protection" (D.3(1)) o "Trade and Competition Law" (D.4(1))
WP C	Case Vignettes	M3	M10	o "Data Protection, Privacy, Security" (D.2(2)) o "Product Liability and Consumer Protection" (D.3(2)) o "Trade and Competition Law" (D.4(2))
WP D	Legal Recommendations	M7	M10	o **"Data Protection, Privacy, Security" (D.2)** o **"Product Liability and Consumer Protection" (D.3)** o **"Trade and Competition Law" (D.4)**
WP F	Final Reports	M 8	M12	o **Final Report (D.5)**

2. Deliverables

Del. No.	Deliverable title	Delivery date	Nature
D.1 (1)	First meeting of Steering Committee	end M1	Meeting (2/2/06)
D.1	**Work Programme**	**end M1**	**Report**
D.2 (1)	First draft legal issues report outlining all Data Protection related issues in EU law and extracts from Data Protection Directive transposition	end M2	Internal report
D.2 (2)	First draft case vignettes exploring issues related to legal cluster 1 (data protection, confidentiality, privacy)	mid M3	Internal report
D.1 (2)	Second meeting of Steering Committee Quality review	end M3	Meeting (10/3/06)
D.2	**Report** identifying all the legal and regulatory aspects relating to legal cluster 1 and including a series of case vignettes to explore those issues and make recommendations	**end M3**	**Report**
D.3 (1)	First draft legal issues report outlining all issues related to product liability and consumer protection in (e)Health	end M6	Internal report
D.1 (3)	Third meeting of Steering Committee	mid M7	Meeting (10/7/06)
D.3 (2)	First draft case vignettes exploring issues related to legal cluster 2 (product liability and consumer protection)	mid M8	Internal report
D.3	**Report** identifying all the legal and regulatory aspects relating to legal cluster 2 and including a series of case vignettes to explore those issues and make recommendations	**end M9**	**Report**
D.1 (4)	Fourth meeting of Steering Committee	mid M9	Meeting (25/9/06)
D.4 (1)	First draft legal issues report outlining all issues related to trade and competition law	early M10	Internal report
D.4 (2)	First draft case vignettes exploring issues related to legal cluster 3 (trade and competition law)	end M10	Internal report
D.1 (5)	Fifth meeting of Steering Committee	mid M11	Meeting (14/11/06)

D.4	**Report** identifying all the legal and regulatory aspects relating to legal cluster 3 and including a series of case vignettes to explore those issues and make recommendations	**end M11**	**Report**
D.5(1)	Draft Final Report including recommendations and incorporating finalised Deliverables 2, 3, and 4.	beg M12	Internal report
D.1 (6)	Sixth Meeting of the Steering Committee Quality Review	mid M11	Meeting (20/12/06)
D.5	**Final Report** on full legal issues with case vignettes and including final recommendations	**end M12**	**Report**

3. Description of the work per work package

WP 'A': PROJECT MANAGEMENT AND DIRECTION

Start date:	M1
End date:	M12

Objectives

WP 'A' is project management. This includes:

- Project planning and monitoring
- Milestones and deliverables management
- Conflict resolution
- Final reporting
- Financial reporting
- Quality assurance

Description of work

The following tasks are executed by the Project Management team (the Project Manager and the Quality Assurance (QA) Board):

- Manage team resources, task allocation, progress control
- Information flow: within the project team, with the EC and the Steering Committee (the Project Management team and subcontractors)
- Ensuring timely delivery of outputs
- Quality control: e.g., organising the quality review of all deliverables
- Financial control and management of resource utilisation
- Regular progress reporting

Deliverables

Type	Name	Del	Date
Int	Quality assurance meetings	D.1(1) D.1(2) D.1(3) D.1(4) D.1(5) D.1(6)	M1 M3 M7 M9 M11 M12
Pub	Work Programme	D.1	end M1

WP 'B': LEGAL ISSUES

Start date:	M2
End date:	M10

Objectives
To develop a report and Wiki-style knowledge base content covering all key EU level legislation applicable to eHealth

Description of work
WP 'B' will lead to several paper reports, ultimately to be synthesized into one report covering the following legal issues:

- Data Protection, confidentiality and security in the context of the collection and sharing of person identifiable data for healthcare and advice
- Product and Liability and Consumer Protection in the use of eHealth tools, devices and services in both traditional healthcare delivery; eCommerce and distance contracting (including ePharmacy and advertising)
- Trade and Competition in the context of using use of eHealth tools in health services planning and delivery in traditional, remote or cross-border healthcare delivery

Deliverables

Type	Name	Del	Date
Int	Legal Cluster 1: Data Protection, Privacy, Confidentiality	D.2(1)	end M2
Int	Legal Cluster 2: Product Liability and Consumer Protection	D.3(1)	end M6
Int	Legal Cluster 3: Competition and Trade Law	D.4(1)	early M10

WP 'C': CASE VIGNETTES

Start date:	M3
End date:	M10

Objectives
To develop a series of case vignettes to illustrate the legal issues identified in the legal issues report.

Description of work
Using national and regional reports as well as legal cases and reported practice to develop a series of composite fictional case vignettes that tell the story of the potential legal barriers to the use of eHealth tools and services across four eHealth tools and services applications covering:

- Public access information systems including health portals providing information for citizens on health education, disease prevention and public health
- Administrative support systems including electronic health records, booking systems and care planning systems
- Patient support tools and services, including remote monitoring and personal medical data collection devices wearables and implantables)
- Clinical devices, including decision support tools and telematic medical devices

Deliverables			
Type	**Name**	**Del**	**Date**
Int	Legal Cluster 1: Data Protection, Privacy, Confidentiality	D.2(2)	mid M3
Int	Legal Cluster 2: Product Liability and Consumer Protection	D.3(2)	mid M8
Int	Legal Cluster 3: Competition and Trade Law	D.4(2)	early M10

WP 'D': LEGALLY EHEALTH – CONCLUSIONS AND RECOMMENDATIONS

Start date:	M6
End date:	M10

Objectives
To prepare a report, including recommendations for legislative or regulatory action, on each of the legal clusters identified in the study.
To prepare for the Final Report of the study.

Description of work
To highlight legal lacunae and issues raised in Work Packages B and C and to make recommendations for possible responses at Community level.

Deliverables			
Type	**Name**	**Del**	**Date**
Pub	1st Recommendations Report: Legal Cluster 1	D.2	M3
Pub	2nd Recommendations Report: Legal Cluster 2	D.3	M9
Pub	3rd Recommendations Report: Legal Cluster 3	D.4	M11

WP 'E': LEGALLY EHEALTH - REPORTS

Start date:	M2
End date:	M12

Objectives
To deliver all public reports.

Description of work
To finalise three public reports:

- D.2: Legal cluster 1 "Data Protection, Privacy and Confidentiality": including legal analysis, case vignettes, identification of legal lacunae and obstacles, and proposed recommendations.
- D.3: Legal cluster 2 "Product Liability and Consumer Protection": including legal analysis, case vignettes, identification of legal lacunae and obstacles, and proposed recommendations.
- D.4: Legal cluster 3 "Competition and Trade Law": including legal analysis, case vignettes, identification of legal lacunae and obstacles, and proposed recommendations.

in order to deliver final study report:

- D.5: Final Report: providing a final draft of full legal issues report in both Wiki-style and paper formats and including all case vignettes; providing the draft conclusions and recommendations to the Commission with respect to clarifying the legal and regulatory aspects of eHealth; incorporating any comments from the Commission services made on previous drafts.

Deliverables

Type	Name	Del	Date
Pub	Final Report	D.5	End M12