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Legal and regulatory aspects of eHealth : Putting eHealth in its European Legal Context

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Legally eHealth

Putting eHealth in its European Legal Context



Legal and regulatory aspects of eHealth
Study report March 2008



European Commission
Information Society and Media

About the Report

This report has been prepared on the basis of work undertaken for the European Commission, Directorate General Information Society and Media in the context of a study awarded to the Legally eHealth team after a call for tenders on the exchange of good practices in eHealth (No. 2005/S 137-135419) and executed under contract number 30-CE-0041734/00-55.

The Legally eHealth Team brought together for the purposes of this study were: Celine van Doosselare of the European Health Management Association; Jean Herveg of the Centre de Recherche Informatique et Droits at the University of Namur (Belgium); and Denise Silber of Basil Strategies (France).

The Team also was assisted by Petra Wilson of Cisco Systems (Internet Business Solutions Group), whose expertise in eHealth provided valuable input to both the study and this report.



Legally eHealth

Putting eHealth in its European Legal Context

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Prepared by: Celine van Doosselaere (EHMA), Jean Herveg (CRID),
Denise Silber (Basil) and Petra Wilson (Cisco)

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Foreword

Healthcare systems, as we know them, currently are evolving. The technological adjustment introduced by ICT systems dramatically has altered the way players, citizens, patients, clinicians, care providers, policymakers, governments, vendors, and suppliers interact. Privacy and confidentiality, personal data, and data protection issues are becoming highly relevant when discussing eHealth in its European legal and regulatory context.

Legal certainty is a prerequisite for businesses to invest in innovation, and for providers and users to take up new products and services. As long as the eHealth market is characterised by lack of regulation and legal certainty, barriers to the progress of eHealth will persist.

The added value of eHealth is about developing a concerted and focused prospective approach of regulatory and other policy instruments to allow a varied set of technologies and innovative business models to rapidly meet demand and to benefit from the mobilising effect generated.

Key to the success of the eHealth initiative is a debate at regional and national level concerning the conflicts about whether and to what extent the current legislation regarding eHealth interferes with public health policy. Legal liability and jurisdictional certainty are at the heart of this discussion, as well as cross-border provision on healthcare. The aim of this booklet is to present an overview of how the current EU-level registration can meet demands of regulating the emerging eHealth markets of Europe.

I hope that this booklet *'Legally eHealth; Putting eHealth in its European Legal Context'* can act as guidance for all players in the European health sector.



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The Legally eHealth team also owes a debt of gratitude to the attendees of the various conferences at which this work was presented for their insightful questions, which contributed significantly to the development of this work.

However, this report reflects solely the views of its authors, and is not the officially endorsed opinion of any of the companies or institutions for which they work.



Executive Summary

“

What is e-health? eHealth characterizes 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.

*G. Eysenbach
(Journal of Medical
Internet Research
2001;3(2):e20).*

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The term eHealth, although now quite current in Europe and, indeed, throughout the world, still is rather new, making its first appearances in the scientific and policy literature around 1999. Its predecessors, however, date back to the 1960s when the concepts of health informatics and bio-medical computing began to occupy the minds of academic physicists, mathematicians, and medics.

The 1960s and 1970s saw the development of computing technology for mathematical modeling applied to the healthcare setting, along with highly specialized, tailor-made programmes for complex medical models. The early 1990s saw the beginnings of the IT revolution, which took us from the back roads to the super highway. With the development of Internet technology, eHealth became a potential reality not only for healthcare practitioners but for every citizen.

It was, however, not until the late 1990s that layers and administrators began to question the extent to which existing legislation was sufficient to cover the use of eHealth tools in the provision of healthcare to citizens. Over the past decade, a number of articles, reports, and studies have established that the use of ICTs in healthcare does raise a number of legal questions, but few have looked, in detail, at the extent to which European legislation could provide good answers.

The Legally eHealth Report, therefore, seeks to examine some keys of the legal questions raised by the adoption of eHealth tools in healthcare. It looks at how EU legislation on data protection, product and services liability, and trade and competition law applies.

In considering the law of privacy, the report examines the European Directives on Data Protection Directive, Privacy in Electronic Communications, as well as the European Convention of Human Rights against the backdrop of a number of scenarios exploring data transfer for the purposes of better care provision both across European and international borders, as well as for commercial purposes.

The report also addresses the vexed issue of liability of eHealth goods and services, covering both simple eCommerce-like health services transacted over Websites, as well as much more complex issues such as multiple and split liability for services provided through a series of co-operating providers is also explored. Finally, noting that eHealth is a significant, emerging European industry, the Legally eHealth report questions the extent to which European trade and competition law might apply to eHealth.

The overall objective of the report is to widen the audience of legal questions in eHealth since, until these issues are tackled head-on in real cases, we will not begin to change the legal landscape in order to provide fertile ground for new developments. eHealth is not just about technology, but about changing the everyday practice of healthcare for every healthcare professional and every patient.



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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, between practitioners and institutions on one hand and, on the other hand, bodies involved in the funding (social security) and monitoring (public health control) of healthcare.

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 processes. Similarly, processes, such as diagnosis, treatment, and care, have involved physical presence and personal interaction between providers and patients. Of course, such physical presence requires some sort of identification (i.e., lack of anonymity).

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 brought about as many serious implications for healthcare regulators and lawyers as for medical professionals.

Although policy makers have noted at both the 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,¹ funded under the Framework Programmes, have looked at the general legal issues 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.² Others have looked at one particular issue, such as confidentiality, in greater

detail.³ It would seem, however, that little work has been undertaken to date to look across the range of legal issues relevant to the use of IST tools and services in healthcare and to draw conclusions about the regulatory needs that may exist.

In order to fill this gap, a study⁴ was conducted between January 2006 and May 2007 to investigate the extent to which European Community legislation, contained in various Directives, provided sufficient legal certainty to allow eHealth to prosper in Europe. This current report draws together the results of that study, focusing particularly on the challenges of compliance with rules on data protection and privacy, questions of product and services liability, and on the role of EU competition law on the development of the eHealth industry within the European internal market.

The objective of this report is to provide the reader with an overview of the extent to which current EU-level legislation can meet the demands of regulating the nascent eHealth markets of Europe. It does not purport to give legal answers, but rather to give the reader a basis from which to examine your own eHealth situations and to arm you with appropriate questions to ask within the relevant national or regional legislations.

1. see for example: Legal IST- FP6-IST

2. see for examples: NEXTGRID – FP6-IST or EUROAGENTEST – FP6-LIFESCIHEALTH and FP5- GEMSS

3. see for example: EUROSOCAP – Quality of Life Programme (FP5)

4. Legally eHealth: A Study on the Legal and Regulatory Aspects of eHealth Contract 30-CE- 0041734/00-55

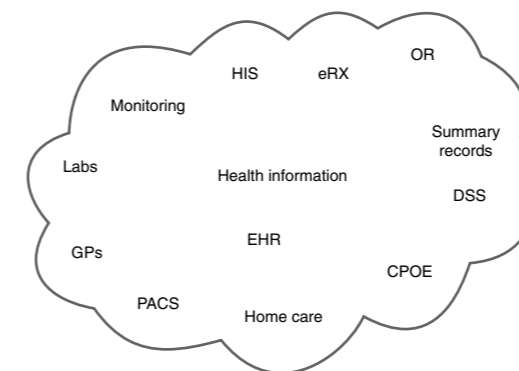


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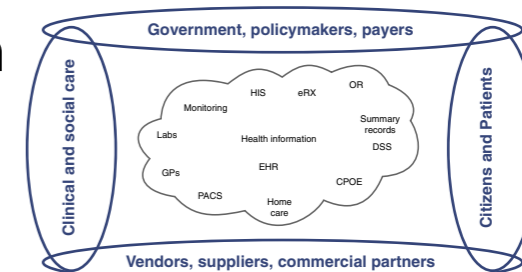
Setting the scene:

eHEALTH in its European Legal Context

eHealth is a very broad term and encompasses many concepts. For this study, we have taken the term to include the wide range of information technology-based applications found in hospitals and primary care settings. These include administrative tools, such as hospital information systems (HIS), summary records, and discharge letters; clinical technical applications, such as picture archiving and communications systems (PACS); as well as clinical support systems, such as operating theatre systems, decision support systems (DSS), and systems linking institutions such as General Practitioners Systems; and electronic prescribing systems linking general practitioners with pharmacies (eRx). At the heart of our eHealth world is the elusive holy grail of eHealth – the fully interoperable cradle-to-grave Electronic Health Record.

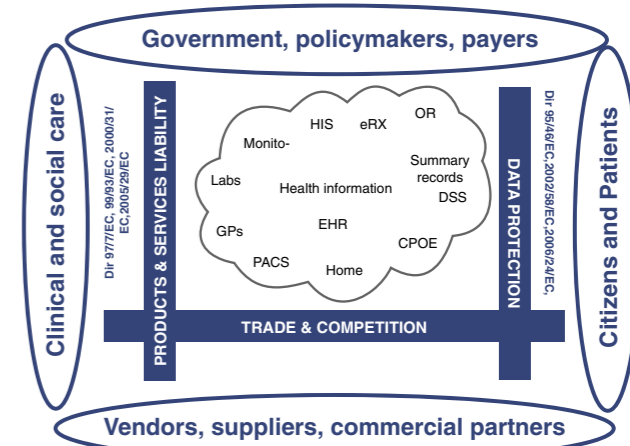


The stakeholders in the world of eHealth may be classified into four groups of actors: Citizens and patients; clinicians and care providers; payers, policy makers and governments; and vendors, suppliers, and commercial partners. All four groups have highly significant but not always equal roles to play in healthcare. We look, in particular, at the tensions that can arise between clinician and patient with respect to privacy and confidentiality or between government and vendor with respect to competition in the healthcare market.



While a wide range of legal issues are relevant to eHealth, ranging across contract law, employment law, and even criminal law, it was felt that three areas of law are particularly difficult to interpret in the context of eHealth. Given that eHealth intrinsically is dependent upon the collection and sharing of patient data, it is important to examine the extent to which data protection and privacy laws impact upon its practice (see for example the discussion on Directive 95/46/EC on Data Protection). Similarly, since eHealth frequently will be used in order to facilitate collaboration between different care providers funded from different budgets and with varying levels of responsibility to the patient, it is important to examine to what extent current rules on liability for goods and services cover the provision of healthcare using eHealth tools (see for example the discussion on Directive 97/7/EC on Distance Contracting).

Finally, in order to allow eHealth to prosper, it is important to ensure that trade and competition law, as it currently stands in Europe, does not pose any problems for this nascent industry. Accordingly, we also look at the implications of EU-level competition law (see for example the discussion on Articles 81 and 82 of the Treaty on the European Communities).



2 Processing Medical Data in eHealth



Data Protection, Confidentiality and Security

Introduction

eHealth applications, whatever their nature, frequently will involve the processing of information relating to an identified or identifiable patient. Such information legally is known as personal data and is subject to data protection legislation in the European Union. In Europe, such data are protected by legal rules found in a number of legal sources, the most important of which is the Directive on Data Protection (Dir. 95/46/EC), which now has been transposed into national data protection legislation across the EU.

The following pages provide a very quick overview of key aspects of the European Data Protection Directive. The full Directive can be downloaded at http://ec.europa.eu/justice_home/fsj/privacy/ where each Member State's national legislation transposing the Directive also is available.

What is the purpose of the Data Protection Directive?

The primary purpose of the EU Directive on Data Protection (95/46/EC) is to protect the fundamental rights and freedoms of natural persons, which are real people, as opposed to legal persons or entities such as companies or societies. Within the legislation, such a natural person is referred to as a data subject – in other

words, the person to whom the personal data relate. The Directive, however, has a further purpose: To allow the free movement of personal data within the European Union in the context of the internal market. On the one hand, its object is to protect the privacy of individuals while, on the other hand, it is to allow freedom of movement of data across the European Union in order that the internal market might prosper.

To what types of data does the Directive apply?

In order to establish if data are covered by the Directive, one first must ask if the data are such that they allow the identification of a particular natural person. Second, is the data going to be processed by someone (a legal or natural person). Thus, the laboratory result of a blood sample test, giving the count of various markers in the blood, will be covered by this legislation if the identification of the originator of the blood is possible using reasonable means. The Directive applies also if the laboratory results are stored with coded identifiers, such as a patient number. The basic principle here is that if a piece of information can be linked to a person either by reasonably simple means, by or with the help of a third person, then the data is considered as identifiable and, therefore, in the scope of the Directive. If the information refers to a group, or if it is so complete or so unique as to make it applicable to only a very small number of people (e.g., disease profile, age, gender, postcode, profession all held together), then the data could be classified as identifiable even if no actual identifier were used.

Who has data protection duties?

The data protection rules are addressed primarily to the data controller – the person who decides the purpose and the means of the processing and who has the legal duty to ensure that data are handled appropriately. In most professional cases, this will be a senior staff member who is named as the person responsible for data collection and storage by an organisation.

In the case of small companies or self-employed individuals (such as many General Practitioners), the data controller generally will be the person who has legal and tax liability for the organisation. It should be noted that organisations need not be businesses or legally constituted to be covered by the legislation; a disease self-help group will fall within the legislation and its data controller will be its president or other lead person.

What are the main duties of a person who controls personal data?

Any personal data that the controller needs to process for the purposes of his or her professional activity must meet certain levels of quality, and must comply with different principles concerning data collection and processing.

The data must be collected for specified, explicit, and legitimate purposes. This principle requires that, prior to processing personal data, the controller has to define clearly and precisely the purpose(s) for which the data are to be processed. Moreover, the processing should be transparent. The data controller will, therefore, have to

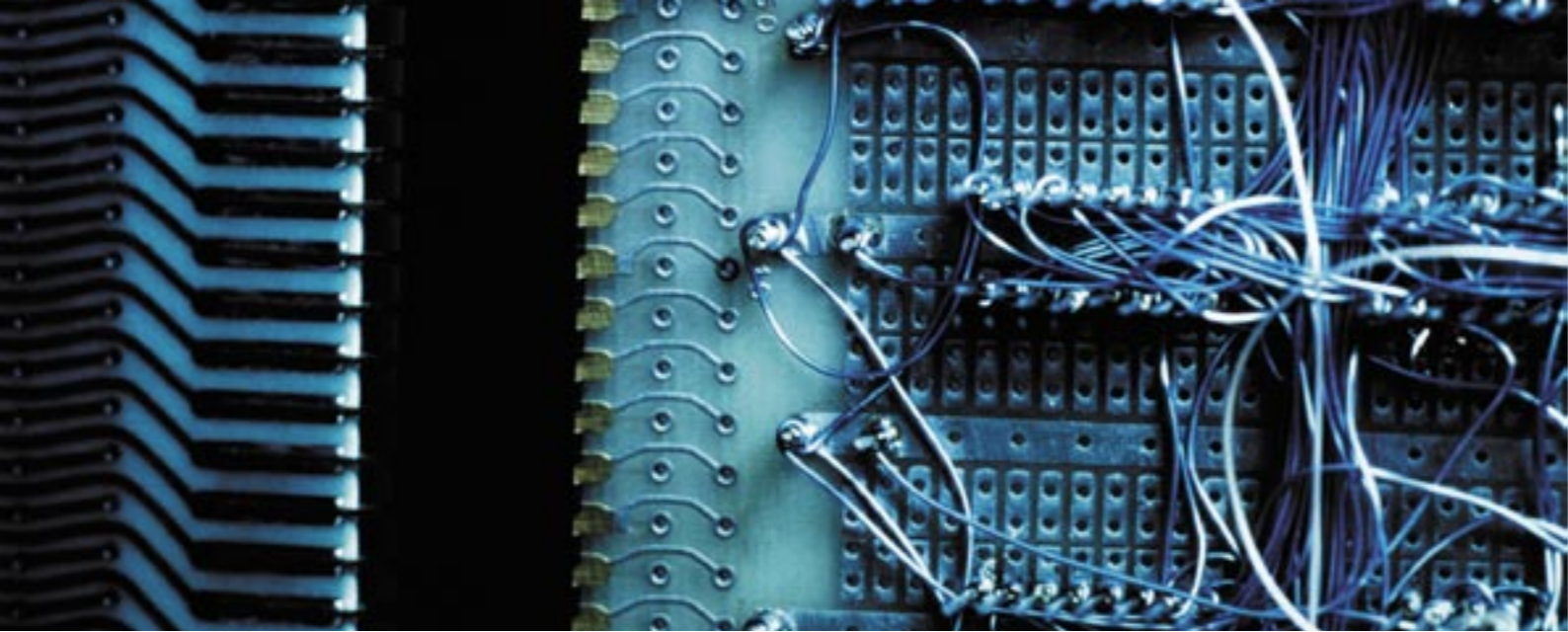
provide the relevant national data supervisory authority and the data subject with certain information regarding the processing, and may only process the data for the purposes for which it was collected.

Thus, a doctor who may share patient identifiable data with another doctor for the purposes of treating the patient may share that same information with another healthcare professional for the purpose of conducting medical research if that purpose originally was given as one of the final uses of the data. It also would apply if this is compatible with the latter (especially if the data subject has given his or her consent to the communication) or if appropriate safeguards are met for processing personal data for medical research viewed as a scientific purpose (i.e., reasonable steps are taken to hide the true identity of a data subject). If the personal data are anonymised by the doctor, there is no problem to communicate the anonymous data to a third party for scientific purposes, including medical research safe for other special rules in National Law (i.e., medical secrecy). Also, they must be processed fairly and lawfully so that if a researcher collects data in order to carry out a specified research project, he or she may not collect and process other data that are not necessary for that particular study but might be useful at some later date. The controller also must ensure the data are kept up-to-date while they are needed, and not kept longer than necessary.

What rights do data subjects have?

Data protection law not only gives duties to data controllers, but also rights to data subjects, such as patients. Laws in EU countries grant access rights to all data subjects to data held about them, which allows them to request specific information about their own personal





3 Data processing Case Vignettes

data; the right to ask for data to be rectified when they are incomplete or inaccurate; and, under some conditions, the right to object to the processing. On the basis of these duties, most EU countries have introduced legislation that allows patients to access their medical records and to demand a rectification of those records.

Are medical data treated differently from other data?

All the principles described above are general principles that may alter very slightly when the data are regarded as especially sensitive. Data concerning a person's health, religion, trade union activity, as well as data revealing racial or ethnic origin and judicial information, are amongst the data regarded by the Directive as especially sensitive and, therefore, subject to special rules. For this reason, data that are capable, by their nature, of infringing fundamental freedoms or privacy of the data subject normally should not be processed.

The ban on processing sensitive or medical data aims to ensure the fundamental rights and freedoms of the data subject regarding the processing of his or her medical data. The ban is, of course, not absolute, so all EU countries hold, by principle, that medical data may be collected or processed only for certain purposes and following certain guidelines, including notably:

- That the explicit informed consent of the data subject is obtained
- To protect the vital interest of the data subject or of another person when the data subject is physically or legally incapable of giving consent
- For the purposes of preventive medicine, medical diagnosis, the provision of care or treatment, or the management of healthcare services, if the data are processed by a health professional subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

Introduction to case vignettes

In order to place the general overview of the principles of EU data protection in its eHealth context, a series of fictional case vignettes have been constructed on the basis of reported case histories. These outline the way in which data protection rules might be applied in practice. The case vignettes are not real cases as such, but are informed by reports of real cases and are grounded in medical practice reality.

CASE VIGNETTE 1: SECOND MEDICAL OPINION FROM A COLLEAGUE IN ANOTHER EU COUNTRY

Wilhelm Wolfgang, 50, a building construction manager from Stuttgart, has suffered from multiple allergies both respiratory and dermatological, since he began working on construction projects at age 18. Other than the recurrent allergies, Wilhelm, a non-smoker, generally has been in good health.

Unfortunately, his most recent routine X-ray revealed some suspicious areas on the upper right lung. Wilhelm's specialist, Dr. Willy Weiss, would like to ask a second opinion regarding the images and the case. He identified Prof. Alexander Artemis, a world expert of pulmonary imaging in the detection of rare lung diseases, located in Greece.

Dr. Weiss wonders whether the digital X-ray images can be transferred safely and securely to Prof. Artemis. A conversation with Prof. Artemis reassures him on that score. In addition, Prof. Artemis is quite happy to provide his analysis free of charge.

Wilhelm is hoping that Prof. Artemis can provide his opinion from a distance, although he is willing to fly over, if expenses can be reimbursed. Wilhelm thinks that two opinions give more credibility to the decisions that will follow.

The legal analysis

In this case, we see a typical doctor-patient relationship. However, since the story includes the transfer of medical data, we can use it to look carefully at the legal duties of doctors wishing to collaborate, over a distance, using standard tools for sharing electronic medical reports and records.

In order to establish which rules apply to the proposed transfer of data from Germany to Greece, a number of questions must be asked:

HAVE THE DATA BEEN LAWFULLY COLLECTED?

The answer would seem to be positive since Wolfgang has agreed to the X-ray and to its possible transmission to Prof. Artemis. Given that the data are medical data, Dr Weiss will be subject to the special rules concerning the processing of sensitive data.

IS IT LEGITIMATE TO PROCESS THE MEDICAL DATA?

Again, the answer would seem to be yes since Dr. Weiss processes Wilhelm's medical data as a registered medical practitioner and, as such, is entitled to collect and process such data as it is needed for medical diagnosis and the provision of care or treatment to Wilhelm. In this case, the medical data have to be processed by a health professional subject under national law or rules established by national competent bodies to the obligation of secrecy or by another person also subject to an equivalent obligation of secrecy.

CAN THE MEDICAL DATA BE SENT TO ANOTHER COUNTRY?

Yes. Prof. Artemis is a medical doctor, in a European Union country, and the data is communicated for the purposes of providing medical diagnosis. Note, however, that Dr Weiss has a legal duty to ensure that Prof. Artemis and his hospital provide sufficient guarantees on technical and organisational security measures.





4 Buying, selling, and using eHEALTH Tools and Services

WHAT LEGAL DUTY DOES THE THIRD-PARTY DATA RECIPIENT HAVE?

Prof. Artemis will be processing the personal data on behalf of Dr. Weiss and will be therefore, considered as a data processor who must act only on instructions of Dr. Weiss. He must take the appropriate technical and organisational measures of protection.

CASE VIGNETTE 2: PROCESSING OF MEDICAL RECORDS OUTSIDE THE EU

Dr. Caroline Carrington is a general practitioner who recently arrived in a busy group practice, in Loch Harlow, Lannockshire, Scotland. Dr. Carrington replaced Dr. Charles Cramer, who retired in May 2006, inheriting his carefully handwritten records.

Dr. Carrington wanted to switch to digital records as quickly as possible, before multiplying her own additions to the files.

Dr. Carrington's problem on how to digitalise Dr. Cramer's files seemed to find a providential answer when she opened an envelope from SoftSupport Ltd, multinational software specialists. Inside there was a prospectus indicating that International Medical Records Coordinators (IMRC) Ltd., a division of SoftSupport, would be stopping in Loch Harlow over the summer to provide record scanning services.

Founded by Dr. Gautam Gandhi, a practicing physician in the UK, IMRC had been sold to SoftSupport in 2005. IMRC's business was based on Dr. Gandhi's connections between the UK and India. IMRC scans patient records in a mobile unit stationed outside British practices, then sends them to IMRC offices in India for data entry to populate a database held in the practice.

Dr. Carrington wonders if she can make use of the offer of IMRC Ltd.

The legal analysis

IS IT LEGALLY ACCEPTABLE TO DIGITIZE PAPER RECORDS?

The legal question here is whether such processing of the patients' medical data is compatible and necessary with the initial purpose for which the data were collected, i.e., treating patients. It would seem to be the case since digital records will allow Dr. Carrington to treat her patients more efficiently.

CAN DIGITIZATION OF PAPER RECORDS BE OUTSOURCED DOMESTICALLY?

The legal duty of care to the patient, respect to privacy, and confidentially remains with Dr. Carrington, or with the practice, which legally are designated as the data controllers. IMRC would be acting as a data processor for Dr. Carrington, who will have to ensure that IMRC can provide sufficient guarantees on technical and organisational security measures and to sign a contract to that effect.

CAN FURTHER PROCESSING BE OUTSOURCED OUTSIDE THE EU?

IMRC intends to do more than simply digitise records. Once scanned, the digitised medical files will be sent to India (thus outside the European Union) in order to populate a searchable database of medical records located in the UK. The transfer of data to India could only be permitted if India ensures an adequate level of protection. Today, India does not seem to ensure such level of protection. Such transfer of data to India would be permitted either on the basis of the unambiguous consent from the patient or on the basis of a contract signed between Dr. Carrington and the recipient of the personal data, imposing on the latter the conditions of the data processing based on the standard contract terms available from the European Commission. The recipients of the communication have to be subject to confidentiality rules equivalent to those incumbent to health care professionals. Again, to ensure a fair data processing, Dr. Carrington or the practice should inform the patients that the digitalized medical records have been sent to be encoded for a database located in the UK.

PRODUCT AND SERVICES LIABILITY

Introduction

As consumers of goods and services, we expect the law to protect us from potential harm from poor goods or services by having strong requirements of high quality and to provide us with adequate means for redress if we are harmed in some way. The object of this section is to investigate how far, at a European level, the existing legislation on consumer protection is adequate to protect users of eHealth systems, tools, and services.

It is clear that the provision of eHealth products, systems, and services must comply with certain levels of quality. Different legal texts have been agreed upon to provide consumers with legal guarantees for any damages resulting from sub-standard products or services. The legal texts do not apply exclusively to eHealth, but instead are applied with a general context of service provision and product delivery, whether by traditional or via electronic means. We will explore the range of EU-level consumer protection legislation that could apply to eHealth systems and services, exploring issues such as dissemination of information via Websites, electronic advertising, contracting online, and delivery of products or services.

The concept of the eHealth product is sometimes difficult to understand because, in practice, most eHealth products either will be software packages and interfaces (electronic health record, decision support tool) or they might be hardware devices with embedded software (radio frequency identification location trackers for locating people and objects; remotely controlled medical devices). We take a broad definition of an eHealth product or service to include anything sold to a medical

practitioner or directly to a consumer that uses an Internet-enabled component to deliver benefit. As such, it might be an electronic record to be used by the doctor, or a monitoring device that includes a Web-based interface. It might even be just a simple health information portal. Pure medical devices, such as blood pressure monitors, are excluded from our definition unless an 'e' interface is used.

It is important to note that at present, no specific legislation exists at an EU level that specifically targets such eHealth services and products. Legally, these products will be covered by a range of legislation.

It is important to note that at present, no specific legislation exists at an EU level that specifically targets such eHealth services and products. Legally, these products will be covered by a range of legislation.

Does the sale of consumer goods legislation apply to eHealth goods and services?

At a most simple level, the sale of any product – be it eHealth or any other – will be covered by standard contracts for sale of goods. Thus, if the eHealth product fails to arrive or arrives late, the standard clauses in the contract will apply. These allow the purchaser to pay less or to return the goods. Similarly, national legislation based on the EC general product liability directives (Directive 2001/95/EC and Directive 1999/34/EC), ensures that the purchaser has redress if consumer goods are not fit for the purpose sold, as well as the relevant national legislation based on Directive 1999/44/EC on the Sale of Consumer Goods.

According to these EU directives, when eHealth tools are sold as consumer goods, the seller must deliver goods

as described in the contract of sale. Moreover, when a commercial guarantee exists, the seller or producer who has offered the goods for sale legally will be bound to that guarantee, as well as to the associated advertising. Any such commercial guarantee will have to be made available in writing (or another durable medium, such as an e-mail) and will have to contain certain information. Anyone selling an eHealth product as a consumer good would, therefore, have to comply with these rules and, conversely, a purchaser of an eHealth product would have redress under them.

Is there general product safety legislation that applies to eHealth goods and services?

The General Product Safety Directive (2001/95/EC) imposes a general safety requirement for any product put on the market for consumers. In addition, they must provide consumers with relevant information enabling them to assess the risks inherent to the product, particularly when it is not obvious, and take appropriate actions to avoid these risks (withdrawal from the market, warning to the market consumers, recall products already supplied, etc.). To assist consumers, national authorities have established systems to monitor product safety and to take appropriate measures to protect consumers. Such a system also exists at the EU level in RAPEX, a European rapid alert system for dangerous non-food products, which ensures that information about dangerous products identified within the Member States is quickly circulated between the Member States and the Commission. To date, no eHealth products have been listed in RAPEX, but as consumer products in eHealth become more common, this will serve a useful purpose in the eHealth sector.

Could eHealth applications and tools be considered medical devices?

Any eHealth device placed on the market, which is designated by its manufacturer as a medical device, will be subject to the specific additional rules regarding medical devices. The medical devices sector is covered by three directives, covering a wide scope of products. The first Directive, (90/385/EC), deals with active implantable medical devices, the second Directive, (93/42/EC), deals with medical devices in general, while the third Directive, (98/79/EC), deals with in vitro diagnostic medical devices.

The General Directive (Dir. 93/42/EC) concerning medical devices aims to safeguard the health and safety of patients and users by harmonising the conditions for placing medical devices on the market and putting them into service. The medical devices must be designed and manufactured in such a way that their use does not compromise the safety and health of patients, users, and other persons when properly installed, maintained, and used in accordance with their intended purpose. If a Member State notes that a medical device conforming to the Directive compromises the health and/or safety of patients, users, or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.

The Directive on In Vitro Diagnostic Medical Devices provides that such devices may be placed on the market and put into service only if they comply with some requirements. This obliges Member States to monitor the security and the quality of these devices and to take appropriate measures to withdraw dangerous devices from the market. Where a medical device is used to dispense a medicinal product, Directive 2001/83/EC on Medicinal Products for Human will require that any such compound dispensed by the device is covered by a marketing authorisation issued by a national oversight authority.

Although early eHealth devices frequently were not designated as medical devices, the growing market in personal health monitors or any medical support tools, such as wearable and implantable monitors, will ensure that more and more such eHealth tools are designated as Medical Devices so that this legislation will grow in importance.

Finally, it should be noted that national, international, and European standards bodies are developing standards that apply to eHealth products. Examples include the European Standards Agency (CEN) standard for EHRs (CEN ENV 13606), the American HL7 standard for EHR, or, indeed, the industry standard for the communication of medical digital images (DICOM).⁵ While these standards are not legally binding, they do provide a baseline against which disputes about the quality of an eHealth product, covered by a standard, might be assessed.

How will consumers and professional users be protected if an eHealth product or services causes damage?

Directive 85/374/EC on Defective Products will apply to eHealth products in the same way as it applies to any other product sold on the European market. This Directive aims to ensure a high level of consumer protection against damage caused to health or property by a defective product. It also aims to reduce the disparities between national liability laws, which distort competition and restrict the free movement of goods. The Directive establishes the principle of no-fault liability for damage caused by a defective product and, as a result, the producer, importer, or supplier will be liable and must pay compensation for damage caused to persons or property resulting from a defect. The injured person does not have to prove that the producer was at fault or negligent, but simply needs to prove that damage arose, that a defect in the product exists, and that there is a causal relationship between defect and damage (this is known as the concept of 'strict liability').

For example, if defective software used to drive an infusion pump causes an incorrect dosage to be administered, and the patient is caused harm, then the patient will not need to prove the fault of the manufacturer of the software. He would just have to prove that he was injured, not the fact that the software does not provide the safety that a patient is entitled to expect. Nor does the patient have to show a link between the dosage error and the injury.

However, in order to strike a reasonable balance between the interest of the consumer and the need to encourage innovation and technological development, there are some rules protecting the producer. Therefore, the period of liability has been limited to three years from the moment the consumer becomes aware of the damage, the defect, and the identity of the producer. And the liability is limited to ten years after the producer has placed the product on the market.

What about liability for an eHealth service?

An eHealth service might be passive, such as delivering general medical information through a Website, or might be active in giving medical advice or specific decision support to clinicians, or might involve the collection of biomedical data for remote monitoring by a clinician. Such a service might conceivably cause damage to someone relying on the service. A citizen might follow

bad advice and fall ill, or even die; a clinician might follow the recommended procedure after using a decision support tool and might harm a patient; or a remote monitoring service might fail to transmit relevant data, thereby putting a patient's life at risk.

In many such cases, a causal link will exist between the harm suffered and a defective product. Thus, if an error exists in decision-support software, the doctor who relied on the software would have a claim based in Council Directive 85/374/EEC, as described above.

There currently is no general European harmonisation of liability rules for services in which no defect can be found in a device. Therefore, liability for services is governed by ordinary rules of law applicable in the Member States. An exception to this may exist if a service is supplied wholly by electronic means, in which case the eCommerce Directive (Directive 2000/31/EC) might apply. These issues are further considered below, looking at questions on health-related Websites and health-related eCommerce.

What about eHealth services provided to patients via the Internet?

Any eHealth services provide via the Internet will be subject to the national legislation derived from the eCommerce Directive if they meet the qualities of an information society service. That is any service normally provided for remuneration, at a distance, by electronic means, and at the individual request of a recipient of services (such as through the Internet). It covers services between enterprises or between enterprises and consumers, which are paid directly from the recipient (online transactions) or those financed by indirect means, such as advertising income or sponsoring.

Activities, which by their very nature, cannot be carried out at a distance and by electronic means, such as medical advice requiring the physical examination of a patient, are not information society services. When the physical examination of the patient is not necessary, then the service may be considered as information society service, such as:

- Websites of doctors promoting their activities
- Online selling of medicines (ePharmacy)
- Online advice that does not require the physical examination of the patient if a fee is paid or if it is financed by advertising or sponsorship
- Online databases of information accessible for medical professionals or consumers if a fee is paid or if it is financed by advertising or sponsorship (even indirectly).

What duties and rights arise from an eHealth services provided via the internet?

A doctor or other party running a health-related Website, whether it is a passive information site or one supplying services, will have to inform the users of his identity, address, and VAT number, if applicable. If the service is provided by a doctor, or other profession subject to rules of professional registration, the full registration details applicable in the country of registration also must be provided. These information duties aim to enable the user of the Website (passive or active) to identify the service provider and to ensure transparency of activities. In essence, the purpose of these information duties is to allow users to know against whom they can seek redress if they should need to do so.

This principle of transparency of provider of site is included within the Commission's Communication on Quality Criteria for Health-related Websites (COM 2002/667), which seeks to increase the reliability of health-related Websites and also include other quality criteria that health-related Websites should comply with, such as transparency of the purpose of the Website, respect of privacy, accessibility adapted to the target audience, etc. Those quality criteria may serve as reference in the development of quality initiatives for health-related Websites.

If a health-related Website includes any type of communication promoting goods, services, or the image of a company, the eCommerce Directive imposes further duties that require that any such commercial communication should be clearly identifiable as such and the person on whose behalf the commercial communication is made must be clearly identifiable as well. The purpose is to avoid any confusion between advertising and any other type of information. The eCommerce Directive does not replace other legal texts that impose particular rules or restrictions relative to advertisement concerning regulated professions, such as doctors or dentists. Therefore, the advertising of prescription-only medication still is prohibited on European-registered Websites (Directive 2001/83/EC). However, given that direct-to-consumer advertising of prescription medication is permitted in the United States, many European citizens find American advertising on the Internet and buy directly from these American sellers.

If a health-related Website is offering services or products not covered by the ban on advertising of prescription-only pharmaceuticals, further consumer protection laws will apply, notably those derived from Directive 2005/29/EC on Unfair Business to Consumer Practices. This includes, for example, a ban on promoting a medicinal

service or product as 100% effective, and without any side effects, when the trader must reasonably know that the tests made cannot completely exclude the possibility of all potential side effects.

Which countries rules apply to services offered via the Internet?

In general, the rules of the country in which the service provider is registered will apply. That is why information on the service provider must be given on the Website. This is known as the country of origin principle, which provides that the law applicable to an eCommerce activity will be the law of the country in which the service provider is established. For example, if an electronic healthcare service provider, established in Italy, provides online information to doctors in different places in Europe, it will fall under Italian law.

However, there are exceptions to the country of origin principle. Most notably, Member States have the right to derogate from this principle if, for example, it is necessary for the protection of public health.

Does the Internet Services Provider (ISP) have any special duties?

The eCommerce Directive establishes a special exoneration system of liability for some categories of Internet intermediaries (mere conduit, caching, and hosting) in detailed circumstances. The "Mere Conduit" is an information society service consisting of:

- The transmission in a communication network of information provided by a recipient of the service or
- The provision of access to a communication network

When providing such "Mere Conduit" service, the service provider is not liable for the information transmitted. To benefit from this exemption, the provider has to comply with several cumulative conditions:

- The provider does not initiate the transmission
- The provider does not select the receiver of the transmission
- The provider does not select or modify the information contained in the transmission

The acts of transmission and of provision of access include the automatic, intermediate, and transient storage of the information transmitted insofar as this takes place for the sole purpose of carrying out the transmission in the communication network, and provided that the

information is not stored for any period longer than is reasonably necessary for the transmission.

Caching is an information society service consisting of the transmission in a communication network of information provided by a recipient of the service. When providing such caching services, the service provider is not liable for the automatic, intermediate, and temporary storage of that information, performed for the sole purpose of making more efficient the information's onward transmission to other recipients of the service upon their request.

When providing these three information services (Mere Conduit, Caching, or Hosting), providers can not be obliged to monitor the information that they transmit or store, nor to actively seek facts or circumstances indicating illegal activity.

Are there any special rules for contracts for eHealth goods or services?

Much eHealth business necessarily will involve the drawing up of contracts. On the whole, normal national contract law will apply, transposing where applicable EU-level directives. The agreement of eHealth contracts could occur for the delivery of eHealth products or for the provisioning of eHealth services. The latter includes the online provision of medical care, such as tele-monitoring.

Generally, such a contract will be governed by normal national contract law, being simply a contract for service. Where such a contract is made between parties in different European countries, the usual rules about cross-border contracting will apply. This means that the contracts will be drawn up under the law of the state in which either the purchaser or provider resides. A number of legislative instruments at the EU level already have been adopted to ensure that parties to such contracts can know, in advance, under which jurisdiction any eventual dispute will be resolved. The Brussels Regulation (Regulation 44/2001/EC) concerning jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, and the 1980 Rome Convention on the law applicable to contractual obligations, are the reference points for EU-level contracts.

A further area of legislation could apply to a contract concluded by electronic means. Directive 1997/7/EC on Distance Contract imposes on the supplier a duty to provide the recipient with written information (or another durable medium such as an e-mail or online information) prior to the conclusion of the contract concerning the supplier's identity, the product or service, and the price. In such contracts, the rules on electronic signatures also will apply (Directive 1999/93/EC). This provides that national-level legislation must ensure a legal equivalence between the handwritten signature and advanced electronic signatures based on a qualified certificate. A simple form of eSignature, such as a scanned handwritten signature, may be used, but if a dispute arises, experts would need to advise on the evidence value of this signature. The advantage of the advanced electronic signature is that, in the context of a trial, this type of signature is directly considered as having the same evidence value as the handwritten signature.

5 Product and Services Liability

Case Vignettes

Introduction

In order to place the general overview of the principles of product and services liability of the European Union in its eHealth context, a series of fictional case vignettes have been constructed on the basis of reported case histories. These will outline the way in which the data protection rules might be applied in practice. The case vignettes are not real cases as such, but are informed by reports of real cases and are grounded in medical practice reality.

CASE VIGNETTE 1: BUYING A MEDICINAL PRODUCT ON-LINE

Ben Bemelmans, an 18-year old Belgian, is a keen Internet user, spending most of his waking moments online. Last summer, Ben's stay at summer camp was marred by his tent-mates making fun of his snoring. Ben was determined to put an end to the problem without telling his family.

Late one night, Ben Googled "snoring treatment" and found an advertisement for an international online pharmacy, offering a one-week, over-the-counter (OTC) cure for snoring. The effect of the treatment was guaranteed to last a minimum of six months. Ben used his credit card to order the item.

The product, named HypnoNix, arrived at the Bemelmans' home in Liège in only three days, despite the fact that the international pharmacy warehouse was situated on Cyprus. Ben was a little bit surprised to note that the product leaflet was in Greek, but the information on the Website in English was more than sufficient. In any event, Ben was very happy with his purchase, because he recorded his sleep between two and three in the morning and noted that he no longer snored.

However, one month into the treatment, Ben developed sudden and severe shortness of breath and

nosebleeds. Wondering whether HypnoNix could be responsible for this, he returned to the Website and read the fine print. HypnoNix can induce a variety of respiratory ailments. Ben had not noticed that information the first time around and wondered if it had indeed appeared on the site when he ordered the product.

Legal Analysis

Introduction

Ben thought he found the perfect solution to his snoring problem after reading an advertisement for HypnoNix on the Website of an international pharmaceutical company, which is established in Cyprus. In theory, he should have been cured for at least six months after the one-week HypnoNix cure. HypnoNix was delivered over-the-counter and the product leaflet was written in Greek, a language Ben does not understand. The snoring stopped but, one month later, Ben developed breathing problems and nosebleeds. He returned to the Website, read the fine print, and discovered that HypnoNix could have side effects such as respiratory problems. He is not sure that this information was on the Website when he ordered the HypnoNix cure.

What went wrong in this case? To answer this question, we have to consider the different regulations applicable to Ben's situation.

IS BUYING A MEDICINAL PRODUCT ON LINE SUBJECT TO ECOMMERCE LAW?

Offering an over-the-counter medication for snoring is an information society service, since it does not seem to require the physical examination of the patient. Note, however, that this is dependent on the drug not requiring a prescription to be sold, since in many EU countries, an online prescription may be made only where the doctor and patient have an existing relationship in which the doctor has previously met with the patient face-to-

face. In some countries, medical advice by electronic communication (e-mail or Website) is never permitted, even if such a relationship already exists.

We may assume that the service provider is established in Cyprus; hence Cypriot Law will apply to this eCommerce activity according to the principle of country of origin. This means that we need to establish that the service provider has complied with his duties as an information society service provider, principally that all the required information is provided:

- The name of the service provider (the pharmaceutical company making HypnoNix, or the vendor)
- The geographic address at which the service provider is established, in this case Cyprus
- Details of the service provider, including its e-mail address, which allows it to be contacted rapidly and communicated with in a direct and effective manner
- Where the service provider is registered in a trade or similar public register, the trade register in which the service provider is entered, and his registration number or equivalent means of identification
- Where the activity is subject to an authorisation scheme, such as the sale of pharmaceutical products and the particulars of the relevant supervisory authority
- The Value Added Tax number also should appear on the advertisement
- The price of the HypnoNix cure should appear on the Website and should indicate if it is inclusive of tax and delivery costs, as the product will be sent from Cyprus to Belgium.

DOES THE LAW ON DISTANCE CONTRACTING APPLY TO A THE PURCHASE OF A MEDICINAL PRODUCT ON-LINE?

Ben purchased HypnoNix by a distance contract. Prior to the conclusion of this distance contract, the pharmaceutical company should have provided him with the following information:

- Identity of the supplier and, if payment in advance is required, supplier's address
- The main characteristics of HypnoNix
- HypnoNix price, including all taxes
- Delivery costs
- Arrangements for payment and delivery
- Existence of a right of withdrawal
- The period for which the offer or the price remains valid.

If Ben had chosen to exercise his right of withdrawal, the pharmaceutical company should have repaid him the price within thirty days.

DO GENERAL RULES ON CONSUMER GOODS APPLY TO THE SALE OF MEDICINAL PRODUCTS ONLINE?

Under the Directive on General Product Safety (and national laws resulting from the Directive), Ben is entitled to receive a medicine conforming to the description given by the pharmaceutical company. HypnoNix must show the quality and the regular performances of such medicine and of which Ben could reasonably expect given the nature of the product and taking into account any public statements on the specific characteristics of HypnoNix made by the pharmaceutical company, particularly in advertising or on labelling.

The Directive on General Safety Product could be useful to Ben, since he has a right to assume that HypnoNix would not present any risk or only the minimum risks compatible with its use. Here, HypnoNix presented severe side effects. Hence, it could be argued that HypnoNix is a dangerous product. In any case, the company should have provided Ben with enough information to enable him to assess the risks linked with the use of HypnoNix. Furthermore, if HypnoNix is industrially produced, it falls under the scope of the Defective Product Directive. HypnoNix could be regarded as a defective product if it does not provide the safety that a person is entitled to expect taking all circumstances into account. In this case, it is likely that HypnoNix is defective. If HypnoNix is

defective, Ben may sue the producer for damages caused by personal injuries. He must introduce his suit in a three-year period starting from the day on which he became aware, or should reasonably have become aware, of the damage, the defect, and the identity of the producer. Finally, since HypnoNix is a medicinal product, the seller must comply with national rules on market authorisation.

CASE VIGNETTE 2: AN IMPLANTED EHEALTH DEVICE

Sophie Sandeau was born with a congenital cardiac disorder that led to the implantation of her first pacemaker at age 40. Six years later, Professor Serge Simon, the head cardiac surgeon at a state-of-the-art French hospital, and his cardiologist colleague, Dr. Samuel Stephane, recommended that Sophie be equipped with the latest implantable cardiac care device.

Sophie now is monitored remotely using the PhysioImplant®, an implantable Finnish monitoring and dosage device. PhysioImplant provides early warning of cardiac failure and adjusts medication dosages accordingly. Measurements are taken automatically, and data communicated continuously to the cardiac monitoring centre in suburban Paris.

Unfortunately, after two months, Sophie suddenly developed cardiac oedema and had to be hospitalised. Receiving too little medication because of a defect in the PhysioImplant system, Sophie required immediate hospitalisation. Fortunately, the night nurse at the cardiac monitoring centre acted quickly. The implant was removed and the situation improved within twenty-four hours.

Legal analysis

Sophie benefits from an implantable cardiac medical device with a drug distribution function, coupled with a tele-monitoring service. Who is liable if something goes wrong?

IS REMOTE CARDIAC MONITORING AN INFORMATION SOCIETY SERVICE COVERED BY ECOMMERCE LAW?

Sophie's tele-monitoring service constitutes an information society service. The tele-monitoring service is covered by French law according to the principle of country of origin since the service provider is established in France and will have to respect the French law developed under the eCommerce Directive, as well as French contract law. As such, the fact that this service is reimbursed by social security should not influence the qualification of this monitoring service as an information society service.

WHAT LEGAL DUTIES DOES A REMOTE MONITORING SERVICE PROVIDER HAVE?

The duties of the service provider are set out in the applicable law on information society services. These duties refer mainly to the information to be provided to the recipient of the service. The service provider has to give to Sophie at least the following information concerning the tele-monitoring service:

- Name of service provider
- Geographic address at which the service provider is established
- Details of the service provider, including his e-mail address, thereby allowing rapid contact and communication in a direct and effective manner
- Where the service provider is registered in a trade or similar public register, the trade register in which the service provider is entered, and his registration number or equivalent means of identification in that register
- Where the activity is subject to an authorisation scheme, like the provision of healthcare service or the particulars of the relevant supervisory authority
- The Value Added Tax number should be indicated
- The price of the tele-monitoring service should appear and indicate if it is inclusive of tax.

WHO IS RESPONSIBLE IF AN IMPLANTED MEDICAL DEVICES MALFUNCTIONS?

Sophie suffered a malfunction of her implantable medical device, which included a drug distribution function.

Under the Directive on Sale of Consumer Goods (Dir 1999/44/EC), Sophie is entitled to receive a device conformant to the description given by the seller. The implant must show the quality and the regular performances of such a device, taking into account any public statements on the specific characteristics of the implant made by the seller, particularly in advertising and on labelling.

The seller of the implant will be liable for any lack of conformity existing at the time of the delivery. The final seller is entitled to sue the previous seller of the product. But the remedy for the lack of conformity will not necessarily satisfy Sophie. Indeed, if she succeeds in an action, the Directive only entitles her to ask for a conformant product, or an appropriate reduction to the price of the one she has, or the cancellation of the contract.

However, the Directive on General Safety Product could be more useful to Sophie. The implant should not have presented any risk for Sophie, or only the minimum risks compatible with its use. The implant, however, had a defect. Hence, it could be argued that PhysioImplant is a dangerous product. The company should have provided Sophie with enough information to enable her to assess the risks linked with the use of the implant. In this case, we could argue that the company should have withdrawn the PhysioImplant from the market, informed consumers,

and recalled the products already supplied to consumers. There should have been monitoring of product safety and collaboration with the proper authorities to avoid such risks.

Furthermore, since the implant is almost certainly industrially produced, it likely falls under the scope of the Defective Product Directive. PhysioImplant could be regarded as a defective product if it does not provide the safety that a person is entitled to expect, taking all circumstances into account. In this case, it is likely that the implant is defective. If it is defective, Sophie may sue the producer for damages caused by personal injuries she suffered as a result of using the defective product. She must introduce her suit within a three-year period, starting from the day on which she became aware, or should reasonably have become aware, of the damage, the defect, and the identity of the producer. In any case, the producer's liability is limited to a ten-year period from the date on which the producer put the product into circulation.

HOW DOES THE LAW ON IMPLANTED MEDICAL DEVICES PROTECT USERS OF IMPLANTED REMOTE MONITORING TOOLS?

Sophie employs an active implantable medical device administering a medicinal product. The medicinal product has to have been granted a marketing authorisation as set out in the Directive on Implantable Medical Devices. The medical device must comply, at least, with the essential requirements set out in the Annex 1 of the Directive relating to active implantable medical devices.

In this case, as the device has compromised the health of Sophie, the French government must take all appropriate measures to withdraw the device from the market. The French government immediately must inform the European Commission of this measure and indicate its reasons. The information regarding such an incident has to be recorded and evaluated in a centralised manner.



6 Trading in eHEALTH

THE ROLE OF EUROPEAN COMPETITION LAW

Introduction

Competition policy is one of the cornerstones of the internal market, which is, in itself, one of the central *raison d'être* of the European Union. The concept of the internal market is to allow European businesses to compete on a level playing field between and across all the Member States of the Union. The role of competition policy and legislation is to ensure that such competition is allowed to prosper unhindered by anticompetitive practices on the part of companies, public bodies, or national authorities. Its central purpose is to prevent one or more organisations from improperly exploiting an economic power over weaker organisations through an abuse of a dominant position, as well as to prevent Member States' governments from distorting competition through state aid. Its function, in short, is to encourage a market economy while still safeguarding the interests of European consumers.

When eHealth services are offered on an open market by commercial undertakings, they will, of course, be governed by the rules of competition law. Thus, if a company offers a diabetes monitoring service, which incorporates a physical device and a Web-based monitoring service to people suffering from diabetes, directly on the open market, then such a company will be subject to the rules on abuse of dominant position and on state aid, which regulates the extent to which national programmes may be used to support companies operating in the public domain.

On the face of it, this should not cause any problems since an eHealth company is not necessarily any different from a hotel group or a car manufacturer. However, the context

in which eHealth organisations operate might make them significantly different from other organisations, not least because an eHealth company will, in many cases, be selling its services not directly to the consumer, but to a public health services provider who, in turn, makes the eHealth services available to patients and citizens in the course of their usual provision of care.

It should be noted that, historically and socially, the provision of healthcare services has been hidden from the purview of competition law not only because of its public nature, but also because healthcare generally is conceived of an intellectual service provided by professionals whose services comprise a range of skills not classified into separate activities subject to competition. As a result, healthcare, historically, has not attracted the attention of competition lawyers to any very significant extent.

Since health services are, in most EU countries, funded through some form of taxation, and organised to some degree by public bodies, the extent to which competition law applies to them is somewhat unclear and may be limited. In particular, it is unclear in how far the rules of competition apply at all to publicly funded bodies, how far the concept of Services of General Interest apply to health services, and the extent to which health services are, on the basis of the rules on Services of General Economic Interest as provided for in the Treaty, exempted from the provisions of European competition law.

However, as healthcare services change to incorporate more and more technical services furnished by specialised providers who are not necessarily medical practitioners, the role of competition law will become more important as those providers seek to ensure that they function within an open market. Similarly, as more and more health services are purchased by private individuals, especially in long-term elderly care, a direct contractual relationship between the consumer and the health service provider will require that such care provision is amenable to the control of public competition authorities.

European Competition Law: A bird's eye view

The principles of free trade and competition are among the most important economic principles supported by the European Community. It is not surprising that the European Community has adopted a wide range of legislation to support competition through a legal system prohibiting any disloyal practices that might restrict competition.

The basis of European competition law is found in Article 3(g) of the Treaty establishing the European Community (TEC). The article aims to establish "a system ensuring that competition in the internal market is not distorted." In that context, the Treaty includes a number of articles that provide that agreements and concerted practices come within the jurisdiction of the European Community authorities if they affect trade between Member States. It is important to note that the role of the European Community is limited to issues affecting intra-community trade; consequently, the coexistence of community and national competition law sometimes causes the two to be applied simultaneously.

European Community competition law is found in Articles 81-89 of the Treaty and falls into the following categories:

- Rules on undertakings (Articles 81-82)
- Rules on specific sectors and Services of General Interest (Article 86)
- Rules on state aid (Articles 87-89)
- Rules on regulation of competition
 - Article 83 provides that the Commission shall propose directives and regulations to give force to Articles 81 and 82
 - Articles 84 and 85 specify the respective powers of the Commission and the authority of Member States to apply Articles 81 and 82 during the transitional period (until the entry into force

of the provisions adopted by the Council under Article 83).

The core of European competition law is found in the rules applying to private firms or undertakings in Articles 81 and 82. Article 81 prohibits agreements and concerted practices with an anticompetitive object or effect on the market, while Article 82 prohibits abuse of a dominant position. Article 86(2) states that the rules on competition also apply to public undertakings as long as, "the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them."

The law encapsulated in the key articles above, as well as a wide range of case law coming from the European Court of Justice (ECJ), is established to allow fair and open competition between companies (known in the jurisdiction as 'undertakings') operating in the European Union. The purpose of the legislation is to ensure that trade across EU borders can take place on a level playing field in which all may compete fairly, regardless of European country of origin. In order to understand the way in which it applies to healthcare, if at all, we must first establish what an undertaking is, since the law applies only to undertakings. The first key question for the purposes of healthcare providers is, therefore, whether they are deemed to be undertakings, and, therefore, subject to competition? Or are they public entities not subject to such regulation?

In order to clarify the current law, we must ask three key questions:

- What is an undertaking and can a public body be classified as an undertaking?
- What is a Service of General Economic Interest and do the rules on Services of General Economic Interest apply to healthcare?
- What is state aid?

WHAT IS AN 'UNDERTAKING' AND CAN A PUBLIC BODY BE CLASSIFIED AS AN UNDERTAKING?

First, it is important to note that the term undertaking is not defined in the EC Treaty, but its meaning has been set out in community case law. An undertaking includes any natural or legal person engaged in economic activity, regardless of legal status or the way it is financed. It includes companies, firms, businesses, partnerships, individuals operating as sole traders, non-profit organisations, and, in some circumstances, public entities that offer goods or services in a given market.

The key consideration in assessing whether an entity is an undertaking is whether it is engaged in economic activity. An entity may engage in economic activity in relation to some of its functions but not others – thus a long-term care facility may be regarded as undertaking economic activity for the 'hotel' services it provides to residents, since these will be contracted for on the open market, but may not be acting as an undertaking in the healthcare it supplies if this is supplied as part of a public health system.

In the recent case of the Federación Española de Empresas de Tecnología Sanitaria (FENIN), the Court of First Instance of the EU found that a Spanish health service organisation should not be deemed to act as an undertaking simply because it was purchasing large quantities of goods or services from competitive markets. In the FENIN case, an association of businesses that market medical goods and equipment used in Spanish hospitals complained to the European Commission that several public bodies that run the Spanish national health system were abusing a dominant position by paying sums invoiced to them only after an average 300-day delay.

The European Court of Justice ruled that a purchasing activity is not subject to competition law if it is undertaken for a purely social purpose rather than as an economic purpose, such as a supply of goods or services on a market. The Court accepted the argument that, in this case, the Spanish hospitals operated according to the principle of solidarity in that they were funded from social security and state contributions, providing free-of-charge services on the basis of universal cover, so they were found not to be engaging in economic activity. The Commission's argument summarised in paragraph 24 of the ECJ judgment (and accepted by the Court) makes the point in a concise way: "[It is] the act of placing goods or services on a given market that characterises the concept of economic activity and not purchasing activity as such."

The current situation is that most healthcare providers who are supplying goods or services in the execution of an exclusively social function; on a non-profit making basis; on the principle of solidarity; and where the entitlement to services is not dependent on the amount of contributions are unlikely to be legally classified as an undertaking conducting an economic activity. Their

interactions with private bodies from which goods or services are purchased for the purposes of providing healthcare will not be subject to the rules on abuse of dominant position. A healthcare provider, however, operating outside those strict criteria, could well be classified as an undertaking and, therefore, subject to competition law.

WHAT IS A SERVICE OF GENERAL ECONOMIC INTEREST, AND DO ITS RULES APPLY TO HEALTHCARE?

In the cases where a healthcare provider is classified as an undertaking, it might be possible for the healthcare provider to operate outside the rules of Articles 81 and 82 if it has been entrusted by a public body to supply Services of General Economic Interest. Article 86 of the Treaty provides for certain types of undertakings to be classified as providing Services of General Economic Interest (SGEIs) that may be exempted from the rules of competition if the application of the rules would obstruct the performance, in law or in fact, of the particular tasks assigned to them.

The first step in applying the rules on SGEIs is to establish that the undertaking has been duly entrusted to provide Services of General Economic Interest. The act of entrustment may be by way of legislative measures or regulation. An undertaking also may be entrusted through the grant of a concession⁶, or licence governed by public law.⁷

Next, we must establish if the service can be classified as SGEI. The Treaty does not define SGEI. Instead, Member States define what they consider to be SGEI. The European Commission and Court will review the definition of a service as a SGEI only if they consider that a Member State has made a manifest error. A SGEI usually is a service that:

- The market does not provide or does not provide to the extent, or at the quality, required by the State
- is in the general interest, i.e., it is delivered to the public at large and not to a specific sector of industry.

The service must be capable of being carried out on a commercial basis. Examples include public service broadcasting, public transport, postal services, and the provision of gas, electricity, and telecommunications services.

Finally, any undertaking wishing to benefit from the exemption of competition law would have to establish that the application of the law to its provision of an SGEI would obstruct its ability to meet its duties as entrusted to it by a public body.

WHAT IS STATE AID?

For the health sector, it is important to think not only about the application of the rules on abuse of dominant position, and the possible exemptions of SGEIs, but also

about state aid, since many health service providers will be funded directly through state aid. If the state grants financial aid that includes special tax exemption, modification of credit conditions, or state contribution to capital financing, to an undertaking entrusted with delivering SGEIs, then the state must comply with the rules as set out in Article 87 of the Treaty.

Article 87 states that any aid granted by a Member State, or through state resources, in any form whatsoever, that distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, insofar as it affects trade between Member States, be considered as incompatible with the common market.

Despite the categorical tone of Article 87, the European Commission has the power to decide that where state aid has a social character and is granted to individual consumers (e.g., state aid to assist consumers who have suffered loss due to the collapse of a major industry) or where state aid is used to repair the damages caused by natural disasters, then such state aid may be considered as compatible with the common market. The Commission also may permit some specific aids.

In general, any project of state aid must be notified in advance to the Commission. Some state aid, however, in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (e.g., hospitals) are not considered as incompatible with the common market and need not be notified.

Commission Decision of 28 November 2005 sets out the conditions under which state aid can be considered as compatible with competition rules.⁸ These conditions notably allow that aid of any amount granted for hospitals and social housing is allowable. It also provides that service providers that deliver a SGEI whose annual turnover in the last two financial years was less than 100 million euros may be granted annual aid of up to 30 million euros.

If any one of these conditions is not met, then the payment or other benefits granted from state resources is a state aid for the purposes of Article 87(1) and subject to the other provisions of Article 87 and, therefore, not permissible.

As well as Article 87 on state aid, it should be noted that Article 10 of the EC Treaty requires Member States to take all appropriate measures to ensure the fulfilment of the obligations arising out of the Treaty and to abstain from any measure that could jeopardise the attainment of the objectives of this Treaty. If an undertaking is found to be in breach of Articles 81 or 82, a Member State can be found to have infringed Article 10 if the state favours or reinforces this anti-competitive agreement.

6. Case C-159/94 and C-160/94 EC Commission v the French Republic [1997] ECR I-05815.

7. Case C-393/92 Municipality of Almelo and Others v NV Energiebedrijf IJsselmij [1994] ECR I-1477.

8. Commission Decision of 28 November 2005, O.J., L 312 of 29 November 2005, pp. 67-73.

eHealth **Trading** Case Vignette

Introduction

We have, so far, provided a general overview of the aspects of competition and trade law having a potential impact on the implementation of eHealth. We now will use a case vignette constructed on the basis of fictional case histories to outline the way in which legislation might be applied in practice. The compilation is not a real case as such, but is informed by reports of real cases and grounded in the reality of medical practice.

SoftSupport Ltd., multinational software specialists, has a division called International Medical Records Coordinators (IMRC) Ltd. (acquired in 2005 as the beginning of a healthcare strategy roll-out), which provides record scanning services. Founded by Dr. Gautam Gandhi, a practicing physician in the UK, IMRC's business was based on Dr Gandhi's connections between the UK and India. IMRC scans patient records in a mobile unit stationed outside British practices and then sends them to IMRC offices in India for data entry to populate a database hosted on a UK Website.

Business developed well over the first eighteen months when suddenly, and without warning, the National Health Service (NHS) began to offer the same service to physician practices, at one-third the price. The NHS had bought out a British record-scanning company in order to offer the service cheaply and accelerate the number of records being scanned in the UK. Dr Gandhi's personal financial situation was considerably weakened. He had to make most of his employees redundant. IMRC and SoftSupport wondered if the NHS entry in the scanning market, in this way, was legal at a European level.

Legal Analysis

This case raises the question as to the lawfulness of the NHS' competition.

HOW IS THE ROLE OF NATIONALISED HEALTH SERVICE PROVIDERS IN THE OPEN MARKET REGULATED?

In the case vignette, the legal question arises from the fact that IMRC now has to compete with the new NHS service offered at one-third the price. The legal issue is whether this is an abuse of dominant position.

The key question is whether the NHS is classified as an undertaking or not, since only if it is an undertaking will the rules on competition apply.

WHEN IS A HEALTH SERVICE PROVIDER AN UNDERTAKING IN TERMS OF COMPETITION LAW?

The answer will depend on the activity in question. Legally, it is possible that the same organisation could be considered an undertaking for some of its activities but not for others.

We must examine whether the provision of record-scanning services performed by the NHS should be considered an economic activity, which would place the NHS under the definition of an undertaking as per the Treaty.

In this case, the NHS may be considered to be an undertaking if it is performing an economic activity that could be conducted by a private company or if there is no reason why a private company could not perform this activity. The fact that the activity is carried out by a private company (IMRC in this story) in certain Member States shows the economic character of this activity. Therefore, it may be argued that the record-scanning service is an economic activity that the NHS is an undertaking for this activity, and that competition rules do apply to it for this activity.

WHEN MAY A HEALTH SERVICE PROVIDER DEROGATE FROM THE RULES ON COMPETITION?

A public entity, such as the NHS, may apply for derogation from the rules. Article 86.2 EC provides for the possibility of derogation from competition rules for undertakings that are entrusted with the provision of services of general economic interest. It states that those undertakings are subject to the rules contained in the Treaty, in particular to the rules on competition, only insofar as the application of such rules does not obstruct the performance of the particular tasks assigned to them. On the other hand, the development of trade must not be affected to such an extent as would be contrary to the interests of the community.

Here we could argue that the application of competition rules does not obstruct the performance of the record-scanning services, so derogation from competition rules is, therefore, not possible (i.e., competition rules apply).

HOW DO THE RULES ON ABUSE OF DOMINANT POSITION APPLY?

Having established that, for this activity, the NHS is an undertaking, we need to examine whether it is abusing its dominant position when charging a lower price than its competitors. In order to do so, we have to identify the relevant product⁹ and the geographic market.¹⁰ This must be done on a case-by-case basis, with instruments, such as price effect analysis, to determine the impact on consumers.

To assess dominance, two elements generally are analysed: the type of entry barriers and the importance of market shares. Some very important market shares may be considered as a dominant position (e.g., 75% or more). A typical case of a dominant position is when an undertaking has a significant market share and there are high entry barriers. The existence of a dominant position is not forbidden, as such. It is only the abuse of this position that is unlawful. Considering this, the application of an unfair price could be qualified as an abuse of dominant position if the low price is not justified. In this case, the

NHS would have to argue in court that the low price it proposes is justifiable.

BUT IS HEALTHCARE NOT DIFFERENT - IS IT NOT CONTROLLED AT MEMBER STATE LEVEL?

It must be remembered that community action, including competition rules, have to respect the Member States' responsibilities for the organisation and provision of health services and medical care, as per Article 152 of the Treaty. Thus the NHS might provide the counter-argument that in the interests of maintaining an efficient and effective public health system, its functioning in this particular issue (record management) should be taken outside the scope of EU competition law because to apply the rules would compromise its ability to meet the health needs of the people it serves.

9. A relevant product market comprises all products and/or services that are regarded as interchangeable or substitutable by the consumer by reason of the products' characteristics, its price, and intended use.

10. A relevant geographic market comprises the area in which the concerned firms are involved in the supply of products or services, and in which the conditions of competition are sufficiently homogeneous.

8 Conclusions



Through the case vignettes described in this report we have seen that eHealth products and services raise numerous new legal questions. Among these, the “Legally eHealth” report has looked in particular data protection, liability and consumer protection, and some aspects of competition law as being the most significant issues at this time.

A reading of the report will confirm that generally European law provides the Member States with a significant number of harmonised answers and solutions to integrate eHealth tools into daily medical practice.

However, presentation of the study described in this report at various conferences and meetings has revealed that there is a lack of legal certainty amongst health actors necessary to support wide implantation of eHealth.

Accordingly it is recommended that actions are taken at European and Member State level addressing the following issues:

- A definition of duties and rights of all actors involved in an eHealth system, including clarification of the rules on data protection to ensure a proper balancing between the patient’s right to privacy and the need for adequate data sharing in a modern eHealth enabled healthcare system.
- A formal standardisation of the interoperability of the infrastructure and of eHealth products and services.
- A formal standardisation of the security requirements for both the infrastructure and the eHealth products and services.
- An assessment of the impact of competition legislation on the uptake of eHealth applications, with a view to addressing such legislation to encourage the growth of eHealth markets in the European Union.



LEGAL SOURCES ON DATA PROTECTION

- Directive 95/46/CE of the European Parliament and of the Council of 25 October 1995 on the protection of individuals with regards to the processing of personal data and on the free movement of such data
- Directive 2002/58/CE 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
- Directive 2006/24/CE of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks. Amending Directive 2002/58/EC
- Regulation (EC) No. 45/2001 on the protection of individuals with regard to the processing of personal data by the Community, institutions, and bodies, and on the free movement of such data
- European Convention on Human Rights
- Charter of fundamental rights of the European Union
- The Convention n°108 of the Council of Europe for the Protection of Individuals with regard to Automatic Processing of Personal Data, adopted on 28 January 1981
- Convention n°164 for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine and its Additional Protocols
- Recommendation (97) 5 of the Committee of Ministers to Member States on the protection of medical data, adopted on 13 February 1997
- Recommendation (83) 10 of the Committee of Ministers on the protection of personal data used for scientific research and statistics, adopted on 23 September 1983
- Recommendation (97) 18 of the Committee of Ministers of Members States concerning the protection of personal data collected and processed for statistical purposes, adopted on 30 September 1997
- Recommendation (99) 5 of the Committee of Ministers of Members States for the protection of privacy on the Internet, adopted on 23 February 1999
- Communication 2004 (356) from the Commission to the Council, the European Parliament, the European economic and social committee, and the committee of the regions, “eHealth - Making Healthcare Better for European Citizens: An Action Plan for a European eHealth Area”
- Some opinions or recommendations made by the Data Protection Working Party
- Opinion n°13 (1999) of the European Group on ethics in science and new technologies on ethical issues of healthcare in the information society

LEGAL SOURCES ON PRODUCT AND SERVICES LIABILITY

Legal Sources Concerning Information Society

- Directive 1999/93/EC on a Community framework for electronic signatures
- Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (‘Directive on electronic commerce’)

Legal Sources Concerning Business and Consumer Protection

- Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (Unfair Commercial Practices Directive). This Directive replaces the business-to-consumer rules in the misleading and comparative advertising Directives (Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising as modified by Directive 97/55/EC of European Parliament and of the Council of 6 October 1997 concerning misleading advertising so as to include comparative advertising). Those two Directives still apply to business-to-business activities.
- Directive 97/7/EC on the protection of consumers in respect of distance contracts
- Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees
- Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
- European Convention on products liability in regard to personal injury and death of 27 January 1977 (NB: Council of Europe)
- Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products as modified by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

- RoHS Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Legal Sources Concerning Health-care

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

LEGAL SOURCES ON COMPETITION LAW

Legally Binding Texts:

- Article 81 of the Treaty establishing the European Community prohibiting agreements and concerted practices between undertakings with an anticompetitive object or effect on the market
- Article 82 of the Treaty establishing the European Community prohibiting the abuse of undertakings in a dominant position that affects free trade
- Article 86.1 of the Treaty establishing the European Community on the liability of Member States for unlawful practices made by public undertaking or undertaking that received special or exclusive rights
- Article 86.2 of the Treaty establishing the European Community providing exceptions on the application of the competition rules for undertakings entrusted with the operation of general economic interest
- Article 87 of the Treaty establishing the European Community prohibiting direct or indirect state aid that may distort competition by favouring certain undertakings
- Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation)
- Commission decision of 28 November 2005 on the application of Article 86(2) of the EC Treaty to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, O.J., L 312 of 29 November 2005, pp. 67-73.

Commission

Communications:

- Communication from the European Commission on social services of general interest in the European Union, SEC 2006/516.
- Commission communication on ‘Professional Services’ of 5 September 2005, COM 2005/405.

Relevant Case Law of European Court of Justice (ECJ):

- United Brands v. Commission, 14 February 1978, Case C-27/76
- Höfner and Elser v Macrotron, ECJ, 23 April 1991, Case C-41/90
- Poucet and Pistre v Assurances Générales de France and Others, ECJ, 17 February 1993, Joined cases C-159/91 and C-160/91
- SAT Fluggesellschaft mbH v Eurocontrol, 19 January 1994, Case C-364/92
- Fédération Française des Sociétés d'assurance, Société Paternelle-Vie, Union des Assurances de Paris-Vie and Caisse d'Assurance et de Prévoyance Mutuelle des Agriculteurs v Ministère de l'Agriculture et de la Pêche, 16 November, Case C-244/94
- Pavel Pavlov and Others v Stichting Pensioenfonds Medische Specialisten, 12 September 2000, Joined cases C-180/98 to C-184/98
- Cisl di Battistello Venanzio & C. Sas contre Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (INAIL), 22 January 2002, Case C-218/00
- Federación Española de Empresas de Tecnología Sanitaria (FENIN), formerly Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental, v. Commission of the European Communities, 11 July 2006, Case C-205/03 P
- Competition Act 1998 Decision of the Office of Fair Trading No CA98/09/2003 BetterCare Group Ltd/ North & West Belfast Health & Social Services Trust (Remitted case), 18 December 2003 (Case no CE/1836-02)

Legally eHealth

Putting eHealth in its European Legal Context

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