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ISSUES OF LIABILITY AND CONSUMER PROTECTION

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eHEALTH GOODS & SERVICES: ISSUES OF LIABILITY AND CONSUMER PROTECTION

OVERVIEW

As consumers of goods and services, we expect the law to protect us from potential harm from using 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 chapter in the "Legally eHealth" study 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. In this context we look at the changing nature of professional relationships in healthcare and the wide range of actors implicated in any eHealth relationship.

In the traditional healthcare context, liability for medical care and treatment was restricted to the relationship between the patient and the health practitioner (usually a doctor). When a patient was harmed as a result of medical negligence or error, the solution was quite simple: the patient introduced a civil or criminal lawsuit against the doctor.

However, as the professionalisation of healthcare grew, a new actor appeared in case of medical negligence or error: the insurance company of the health practitioner or indeed healthcare professionals when the patient is treated by a team of health practitioners or by a hospital service.

As the relationships became more complicated lawyers were frequently asked: Who is liable - the health practitioner, the team of health practitioners, the hospital? And what about the liability of the author of a second opinion? And does the patient have a part in this? If so, what is it?

And what about the liability of the State, i.e. in the organisation and the monitoring of the health activities? Should we also consider the liability of pharmaceutical or medical device companies, or that of the power companies or the telephone provider in case of failure?

If medical liability continues to be considered first in the relationship between the patient and the health practitioner (i.e., the patient sues the health practitioner and the health practitioner then, if appropriate, sues the person responsible for the damage), the multiplication of intermediaries in the field of health services and the number of these with whom the patient has direct contact is changing the way in which the liability of the various actors is engaged. The problem arises from the fact that the manners in which these liabilities vary, thus potentially creating imbalances, gaps, or incoherences in the application of rules to eHealth goods and services.

With the advent of the 'empowered patient', more and more citizens are becoming increasingly in charge of their own health, without the intervention of a health practitioner. In such cases, with the health practitioner entirely out of the picture, the patient stands 'alone' against the service provider (whether that is a special services operator, a medical device manufacturer or a pharmaceutical company), which might be subject to entirely different liability rules altogether. Furthermore, if the patient benefits from particular provisions under medical liability laws taking into consideration the vulnerabilities specific to the context of health, liability rules applying to these other service providers who are not usually associated with health might not provide the same types of safeguards for patients.

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 to provide consumers with a legal guarantee of a high level of quality of products and services, and legal redress for any damages resulting from sub-standard products or services. The legal texts do not apply exclusively to

eHealth, but are instead applied with a general context of service provision and product delivery, whether by traditional or via electronic means.

This paper will explore the range of EU level consumer protection legislation which could apply to eHealth systems and services, exploring issues such as dissemination of information via websites, electronic advertising, contracting online, and delivering of products or services.

The document is divided into four parts:

Part I: A summary description of the key principles of EU level product and services liability legislation. Here you will find an outline of the key principles of the legislation with some healthcare based examples.
Part II: A detailed step-by-step analysis of the directives covering: sale of goods, medical devices, eCommerce and electronic signatures. The analysis includes a description of all the relevant articles of legislation as well as links and references to the source documents.
Part III: A series of case vignettes, which show the way in which the legislation works. The fictional cases will show examples of eHealth applications and explore the data protection duties that they imply for the healthcare providers and other actors.
Part IV: A Source Reference list, where you will find links and reference to all the legal source documents discussed in Parts I, II and III.

PART I: KEY PRINCIPLES

Introduction

The concept of the eHealth product is a difficult one because in practice most eHealth products will be either 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). In this chapter we take a broad definition of an eHealth product or services 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; or even just a simple health information portal. Pure medical devices, such as a blood pressure monitor are excluded from our definition unless an 'e' interface is used.

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

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

At a most simple level the sale of any product – be it eHealth or any other, sold to a consumer or professional – 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 which will allow the purchaser to pay less or to return the goods. Similarly national legislation based on the **EC product liability directives** (Directive 2001/95/EC and Council Directive 85/375/EEC as amended by Directive 1999/34/EC) will ensure that the purchaser has redress if the goods are not fit for the purpose sold, while other EC legislation such as **Directive 2002/95/EC on the Use of Hazardous Substances** will provide the purchaser with certainty about certain aspects of a product's quality.

In general therefore in the eHealth arena, one will need to make reference to the relevant national legislation based on **Directive 1999/44/EC on the Sale of Consumer Goods and associated guarantee**.

According to this directive, when consumer goods are sold under a contract, the seller must deliver goods in conformity of the contract of sale. Moreover, when a commercial guarantee exists, the seller or producer who has offered the goods for sale will have to respect some rules and will be legally 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 some information. Anyone selling an eHealth product would 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?

Directive 2001/95/EC on General Product Safety imposes a general safety requirement for any product put on the market for **consumers or likely to be used by them**. Indeed, the producers must put on the market only safe products which are not likely to cause any threat (or only a reduced threat in accordance with the nature of use of the product) and which is acceptable in view of maintaining a high level of protection for the health and safety of persons. 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…). The distributors must also comply with other duties, such as keeping the relevant documents to help trace the products.

Although most of this legislation is well known to anyone operating in the business world, it is fair to say that eHealth products are still rather new and therefore little legal guidance exists on, for example, the type of information that is necessary and relevant to allow a purchaser to assess the risks of using a product.

However, national authorities have been established to monitor product safety and to take appropriate measures to protect consumers. An information system has been put in place that imposes collaboration between distributors, producers and the national authorities but also between Member States and the European Commission. One such system is RAPEX[1], a European rapid alert system for dangerous non-food products. It ensures information about dangerous products identified in the Member States is quickly circulated between the Member States and the Commission. When a product (e.g. a toy, a childcare article or a household appliance) is found to be dangerous, the competent national authority takes appropriate action to eliminate the risk. It can withdraw the product from the market, recall it from consumers or issue warnings. The designated national contact points then informs the European Commission (Directorate-General for Health and Consumer Protection) about the product, the risks it poses for consumers and the measures taken by the authority to prevent risks and accidents. The European Commission publishes weekly overviews of dangerous products and the measures taken to eliminate the risks on the Internet.

Could eHealth applications and tools be considered medical devices?

Any eHealth device placed on the market and designated as a medical device by the manufacturer will be subject to the specific additional rules regarding the medical devices. The medical devices sector is covered by three Directives, covering a wide scope of products. The first Directive (90/385/EEC), dealing with active implantable medical devices, was adopted in 1990. The second Directive (93/42/EEC), adopted in 1993, deals with medical devices in general, while the third Directive (98/79/EC), adopted in 1998, deals with in vitro diagnostic medical devices.

The General Directive (93/42/EC) concerning medical devices aims notably to safeguard the health and safety of the 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,

[1] http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

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.

When the products manufactured are electrical or electronic equipment, like IT or telecommunications equipment, they must respect Directive 2002/95/EC, known as the "Restrictions on the use of Hazardous Substances in electronic equipment" (or RoHS), bans the sale of new electrical and electronic equipment containing more than agreed levels of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants. This law requires manufacturers to find new materials and develop new engineering processes for the creation of common electronic equipment.

The Directive does not currently apply to medical devices even if the definition of a medical device could cover electronic equipment and software. The question of applicability of the RoHS Directive on eHealth hardware manufacturers is controversial: a possible interpretation would be that hardware sold to medical equipment manufacturers to run medical equipment but which retain all of the normal functions of a computer will have to respect the RoHS Directive. However, computer or other components installed into medical equipment as components that do not act as a separate computer but only operate the medical device are considered as medical device and are not concerned by RoHS Directive.

The Directive relating to active implantable medical devices states that active medical devices and active implantable medical devices may be placed on the market and put into service only if they do not compromise the safety and health of patients and users. Member States must take appropriate measures to withdraw dangerous devices from the market.

The Directive on In Vitro Diagnostic Medical Devices imposes that in vitro medical devices and their accessories, the latter considered as in vitro diagnostic medical devices as such, may be placed on the market and put into service only if they comply with some requirements. This induces the obligation of Member States to monitor the security and the quality of these devices. Member States must take appropriate measures to withdraw dangerous devices from the market.

Directive 2001/83 on the Community code relating to medicinal products for human use imposes that no medicinal product may be placed on the market unless a marketing authorisation has been issued by the national competent authority.

Finally, it should be noted that national, European and international standards bodies are developing standards that apply to eHealth products. A particular example is the CEN standard for EHRs (CEN ENV 13606) or the American HL7 standard for EHR or indeed the industry DICOM standard for medical digital images[2]. 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.

[2] see http://www.openehr.org/standards/t_cen.htm

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

Council Directive 85/374/EEC on Defective Products will apply to eHealth products in the same way as it applies to any product sold on the European market. This Directive aims at ensuring a high level of consumer protection against damage caused to health or property by a defective product. It aims also to reduce the disparities between national liability laws, which distort competition and restrict the free movement of goods. It implements a system that extends the producer's liability ('strict liability') in order to protect consumers.

Council Directive 85/374/EEC establishes the principle of objective liability or liability without fault of the producer, importer and under some conditions the supplier, for damage caused by a defective product. As a result, the producer, importer or supplier will be liable and must pay compensation for damages caused to persons or properties resulting from a defect. The injured person does not have to prove that the producer was at fault or negligent; he 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 (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, but will just have to prove that he was injured, not the fact that the software does not provide the safety which a patient is entitled to expect as well as the 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. Indeed, under some particular circumstances, the producer may be exonerated from all liability. Moreover, the liability is not unlimited but rather a limited period of liability has been set 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 ten years after the producer has put the product into circulation.

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 good. Thus if an error exists in a 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 is currently, however, 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 by wholly 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.

Who is legally responsible for Health related websites?

From the moment a service is proposed via Internet at the individual request of a recipient of services and that this service is normally provided for remuneration, it is considered as an information society service, and accordingly the information duties established by the eCommerce Directive have to be respected.

Thus, a doctor or other party running a health related website, will have to inform the users of his identity, address, VAT number, etc. These information duties aim to enable the recipient of the service (professionals or not) to identify properly the service provider and to ensure transparency of his/her activities.

In essence the purpose of these information duties is to allow the ultimate 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 also included within the Commission Communication (COM(2002)667) on Quality Criteria for Health related Websites. This Communication aims to increase the reliability of health related websites and also include other quality criteria that health related web sites must 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 commercial communications (any type of communications promoting the goods, services or the image of a company), the eCommerce Directive imposes additional duties. It requires, among other things, that 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.

In the context of health related websites it should be noted that Directive 2001/83/EC explicitly prohibits direct-to-consumer-advertising (DTCA) of prescription medication. This applies whether the advertisement is made on paper or electronically. However, given that direct to consumer advertising of prescription medication is permitted in the USA, many European citizens find American advertising on the Internet and buy directly from the USA.

Moreover, a health related website might advertise services or products not covered by the ban on advertising of prescription only pharmaceuticals. In these cases, Directive 2005/29/EC concerning unfair business-to-consumer commercial practices may apply. According to this directive, any commercial practice (including advertising) directly connected with the promotion, sale or supply of a product (including service) to consumers must be fair. This Directive explains when a practice should be considered as unfair. All practices breaching the professional diligence requirements that materially distort the behaviour of the average consumer will be considered as unfair, and therefore banned.

For instance, it is forbidden to promote a medicinal product as 100% guarantee without any side effects when the trader must reasonably know that the tests made cannot completely exclude the possibility of all potential side effects.

Directive 2005/29/EC thus bans unfair commercial practices such as misleading practices, failing to provide the consumer with the information needed or with false information, and aggressive practices, like harassment, coercion or undue influence. The directive provides a black list of prohibited practices. It lists the practices that will be considered as unfair in all circumstances, such as unsolicited supply or use of bait advertising (for instance when the lower-price product is not available).

Directive 2005/29/EC integrates the previously existing EU level rules applicable to business-to-consumer transactions. These rules were established by the directives on misleading and comparative advertising (84/450/EEC as modified by 97/55/EC), which are still applicable to business-to-business relationships. These directives prohibit misleading advertisings and fix the conditions allowing comparative advertising.

When the advertisements made on websites concern medicinal products, some particular rules apply. Directive 2001/83 on the Community code relating to medicinal products for human use authorises the advertising of medicinal products only if some conditions are respected (obtaining of marketing authorisation, no marketing for medicines only available on medical prescription or requiring intervention of a medical practitioner,…). Moreover, the advertising must encourage the rational use of the medicinal product through an objective and reasonable presentation of its properties.

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

Much eHealth business will necessarily involve the conclusion of contracts. On the whole, normal national contract law will apply, transposing where applicable EU level directives. The conclusion of eHealth contracts could occur for the delivery of eHealth products and for the provision 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 a 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 have already been adopted to ensure that parties to such contracts can know in advance under which jurisdiction any eventual dispute will be solved. The "Brussels Regulation" (Council Regulation 44/2001 of 22 December 2000) 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 at EU level.

A further area of legislation could apply to a contract concluded by electronic means. When the possibility of online contracting is offered, Directive 1997/7/EC on distance contracts applies, as well as some rules of the eCommerce Directive (2000/31/EC). It should be noted that the Directive on distance contracts applies when the contract is concluded between a professional

and a consumer, while the eCommerce Directive applies to business-to-consumer transactions and to business-to-business transactions.

If either directive applies to an eHealth transaction, they may impose on eHealth professionals a duty to provide consumers/patients/users with some information. The Distance Contracts Directive (1997/7/EC) imposes on the supplier a duty to provide the recipient with written information (or another durable medium such as an e-mail or an online information), prior to the conclusion of the contract, relative to his identity, the product or service and the price. The eCommerce Directive provides for a list of information relative to the formation of the contracts, such as the different technical steps to follow in order to conclude the contract or relative to the technical means proposed to identify errors.

Can electronic signatures be used to conclude eHealth contracts?

eHealth professionals may use electronic signatures in order to authenticate their identity, their profession, as well as the fact that they are registered with a professional body. A particular example of the use of eSignatures in health will arise in the case of electronic prescriptions, where it will be necessary to ensure that the signatory has the title of doctor and probably also that he is registered with the social security body, which allows the reimbursement of the medical fees.

An electronic signature aims to allow the person receiving electronic data (like an e-mail, an ePrescription, etc.) to be able to identify the origin/author of the information/data (identification) as well as to verify that the information has not been altered during its communication (integrity).

Different kinds of electronic signatures exist, from the very simple ones (the insertion of a scanned hand-written signature within an electronic document), to the most sophisticated ones, such as the signatures based on public key cryptography. This last kind of signatures implies the intervention of a trusted third party (Certification Service Providers) who creates certificates in order to allow the recipient to check the identity of the sender and the integrity of the message.

Directive 1999/93/EC on electronic signatures provides the conditions for the legal recognition of any electronic signature. When the signature is based on a public key cryptography system (advanced electronic signature), for example, it has to be accepted and recognised, including in a court of law. But every kind of electronic signature may benefit from some legal effects.

The main principle of the Directive is the introduction of a legal equivalence between the hand-written signature and the advanced electronic signature based on a qualified certificate meeting certain requirements. When the conditions are met, the advanced electronic signatures are considered as having the same effect as a hand-written signature.

Moreover, the legal equivalence cannot be *a priori* denied for any electronic signature as such. The fact that a signature is in electronic form and does not meet the requirements that make it possible to affirm automatically its equivalence with the hand-written signature does not allow the judges to refuse it. The legal effectiveness and admissibility in legal proceedings of an electronic signature cannot be refused simply because it is in electronic form or because it does not enjoy the conditions of an advanced electronic signature. Therefore, the legal value of a non-advanced eSignature must be determined case by case and may not be rejected *a priori*.

For instance, if a doctor uses his scanned signature for an ePrescription and after, in the framework of a trial, it must be proved that the prescription was coming from him/her, the judge

cannot *a priori* refuse to consider this type of signature but will have to analyse, possibly with the help of experts, the evidence value of this signature. The advantage of the use of 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 hand-written signature.

Conclusion

From the discussion above we can see that although a wide range of legislation will apply to the provision of eHealth services and goods, there is no EU level legislation targeted especially at such transactions. In general, consumers will be protected if they suffer harm from an eHealth good just as they are protected if they suffer harm from any other good. This means that any consumer can expect reasonable levels of safety, and can sue for damages using the strict liability rules.

We have noted also that the provision of eHealth services as such are regulated primarily through national contract law, which will apply to domestic as well as cross-border contracts. Special rules may apply when the eHealth good or service consists of or uses a medical device or if it is made using certain hazardous substances.

We have noted also that if an eHealth good or service advertised on a website and a contract for such a good or service is concluded online, then special rules about eCommerce and distance contracting will apply to eHealth goods and services as they apply to any other good or service – this includes also the prohibition of the sale of prescription medication except by authorised providers and the direct to consumer advertising of such pharmaceuticals.

It should be noted, however, that there is no special legislation at EU level covering eHealth goods and services and that moreover there is only limited legislation that regulates the quality of services as opposed to goods (with the exception of financial services).

Having set out the general landscape with respect to liability for eHealth goods and services the following section gives a detailed analysis of the various EU Directives described above.

PART II: DETAILED ANALYSIS OF THE LEGAL TEXTS

I. DIRECTIVE 1999/44 ON THE SALE OF CONSUMER GOODS AND ASSOCIATED GUARANTEES

A. Key concepts

1. CONSUMER

The consumer is the same as in Directive 1997/7: it is any natural person who, in the contracts covered by this Directive, is acting for purposes which are not related to his trade, business or profession.

2. CONSUMER GOODS

Consumer goods are any tangible movable item (except goods sold by authority of law, water and gas where they are not put up for sale in a limited volume or set quantity, and electricity).

3. SELLER

The seller is any natural or legal person who, under a contract, sells consumer goods in the course of his trade, business or profession.

4. PRODUCER

The producer is the manufacturer of consumer goods, the importer of consumer goods into the territory of the Community or any person purporting to be a producer by placing his name, trademark or other distinctive sign on the consumer goods.

5. GUARANTEE

A guarantee is any undertaking by a seller or producer to the consumer, given without extra charge, to reimburse the price paid or to replace, repair or handle consumer goods in any way if they do not meet the specifications set out in the guarantee statement or in the relevant advertising.

This term covers only commercial guarantees, which may be voluntarily proposed by the sellers and not the 'legal guarantee', which exists without the need of the will of the seller, just by effect of the law. The commercial guarantee offers protection in addition to that due by law. The legal guarantee is described in this Directive as the 'principle of conformity with the contract'.

Comment [C1]: = in french « volontee » ?

6. REPAIR

Repair means bringing consumer goods into conformity with the contract of sale.

B. Principle of conformity with the contract

The seller has to deliver to the consumer goods that are in conformity with the contract of sale.

Consumer goods are presumed to be in conformity with the contract if they:

(a) comply with the description given by the seller and possess the qualities of the goods which the seller has held out to the consumer as a sample or model;
(b) are fit for the purposes for which goods of the same type are normally used;
(c) are fit for any particular purpose for which the consumer requires them and which he

made known to the seller at the time of conclusion of the contract and which the seller has accepted;

(d) show the quality and performance which are normal in goods of the same type and which the consumer can reasonably expect, given the nature of the goods and taking into account any public statements on the specific characteristics of the goods made about them by the seller, the producer or his representative, particularly in advertising or on labelling.

C. Liability of the seller in case of lack of conformity and exemptions

1. PRINCIPLE

The seller shall be liable to the consumer for any lack of conformity that exists at the time the goods were delivered.

Any lack of conformity that becomes apparent within six months of delivery of the goods shall be presumed to have existed at the time of delivery unless proved otherwise or if this presumption is incompatible with the nature of the goods or the nature of the lack of conformity.

Where the final seller is liable to the consumer because of a lack of conformity resulting from an act or omission by the producer, a previous seller in the same chain of contracts or any other intermediary, the final seller shall be entitled to seek action against the person responsible.

2. EXEMPTION OF LIABILITY

The seller is not liable if, at the time the contract was concluded, the consumer was aware, or could not reasonably be unaware of, the lack of conformity, or if the lack of conformity has its origin in materials supplied by the consumer.

The seller shall not be bound by public statements, as referred to in point B (d), if he:

- shows that he was not, and could not reasonably have been, aware of the statement in question,
- shows that, by the time of conclusion of the contract, the statement had been corrected, or
- shows that the decision to buy the consumer goods could not have been influenced by the statement.

3. CONSUMER'S RIGHT

In the case of a lack of conformity, the consumer shall be entitled:

- to have the goods brought into conformity free of charge by repair or replacement, within a reasonable time and without any significant inconvenience to him or her, or
- to have an appropriate reduction made to the price or the contract rescinded if repair or replacement is impossible or disproportionate, or if the seller has not remedied the shortcoming within a reasonable period of major inconvenience to the consumer.

The consumer is not entitled to have the contract rescinded if the lack of conformity is minor.

4. LIMIT OF PERIOD OF LIABILITY

In order to benefit from the protection, the consumer must inform the seller of the lack of conformity within a period of 2 months from the date on which he detected such lack of conformity.

Moreover, the seller's liability is limited to a two-year period from the date of the delivery of goods.

D. Rules relating to the commercial guarantees

Any commercial guarantee offered by a seller or producer will be legally binding under the conditions laid down in the guarantee document and the associated advertising.

The guarantee shall:

- state that the consumer has legal rights under applicable national legislation governing the sale of consumer goods and make clear that those rights are not affected by the guarantee,
- state its contents in plain intelligible language and indicate the conditions for making claims under the guarantee, notably the duration and territorial scope of the guarantee as well as the name and address of the guarantor.

On request by the consumer, the guarantee shall be made available in writing or feature in another durable medium available and accessible to him or her.

II. DIRECTIVE 2001/95 ON GENERAL PRODUCT SAFETY

A. Key concepts

1. PRODUCT

The term 'product' means any product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

Therefore, products initially reserved for professional use that are subsequently made available to consumer are also considered as product.

This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.

2. SAFE PRODUCT

A safe product is any product which, under normal and reasonably foreseeable conditions of use including duration, and where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

Some elements should be taken into consideration:

- the characteristics of the product, such as its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- the categories of consumers at risk when using the product, in particular children and the elderly.

3. DANGEROUS PRODUCT
A product is dangerous when it does not meet the definition of 'safe product'.

4. SERIOUS RISK
Serious risk means any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities.

5. PRODUCER
The producer is:

- the manufacturer of the product, when he is established in the Community, and any other person presenting him or her self as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product;
- the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product;
- other professionals in the supply chain, insofar as their activities may affect the safety properties of a product.

6. DISTRIBUTOR
The distributor is any professional in the supply chain whose activity does not affect the safety properties of a product.

7. RECALL
Recall is any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor.

8. WITHDRAWAL
Withdrawal is any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer.

B. Scope of the General Product Safety Directive

The Directive applies to any product insofar as no specific provisions among the European Community laws governing the safety of the product are concerned or if sectoral legislation is sufficient.

The provision of services is excluded from the scope of the Directive but the products supplied to consumer in the context of a service are covered.

C. General safety requirement

1. PRINCIPLE

Producers are obliged to place only safe products on the market for consumers or likely to be used by them.

2. HOW TO ASSESS THE COMPLIANCE WITH THE SAFETY REQUIREMENT?

Some criteria are proposed in order to assess if a product complies with the safety requirement:

- A product is deemed safe once it conforms to the specific Community provisions governing its safety;
- In the absence of such provisions, the product must comply with the specific national regulations of the Member State in which it is being marketed or sold;
- In the absence of such provisions, it must conform to the voluntary national standards which transpose the European standards;
- In the absence of these, the product's compliance is determined according to different elements (such as the reasonable consumer expectations concerning safety, the state of the art and technology, codes of good practice, Commission recommendations, …).

D. Other obligations of producers and obligations of distributors

The producers must provide consumers with the relevant information to enable them to assess the risks inherent in a product, particularly when these are not obvious. They must also indicate, by means of product or its packaging, the identity and details of the producer and the product reference.

The producers must also take measures to avoid such risks, such as withdrawing the products from the market, informing consumers, recalling products that have already been supplied to consumers, etc.

The distributors are obliged to supply products that comply with the general safety requirements, to monitor the safety of products placed on the market, to keep and provide the documentation ensuring that the products can be traced, and to collaborate with competent authorities to avoid the risks.

E. The duty of the Member States to put in place National Authorities

National authorities are established or designated by the Member States in order to monitor the product safety and to take appropriate measures as regards risky products.

This national authority must ensure that producers and distributors comply with their duties and are entitled to ensure the product safety by organising checks on safety properties, by imposing producers to warn adequately on the possible risks, by prohibiting dangerous products to be marketed, by alerting consumers on the risks of a product already marketed and by organising recalls and destruction of products when necessary.

F. Information system

Directive 2001/95 aims to create an efficient information system in order to help Member States, national authorities and consumers to react quickly in order to avoid or reduce any harm to the health and safety of persons.

The producers and distributors who discover that a product is dangerous must notify the competent national authority and collaborate with it.

The European Commission is in charge of reinforcing cooperation between the national authorities and of promoting exchange of information and expertise by setting up a European product safety network between the national authorities.

When a national authority adopts a measure for the reason of a serious risk that may have an effect beyond its territory, it shall inform the European Commission via Rapex (a system for the rapid exchange of information between the Member States and the European Commission) of the identity of the product, the risks, the measures taken and the information on the distribution, including the destination countries. This information will be communicated to the other Member States.

The European Commission can also approve rapid measures at Community level when it becomes aware of a serious risk in various Member States. After consulting the Member States and a scientific committee when scientific questions arise, the Commission may adopt a decision (like the recall of the product, for instance) to be implemented by the Member States within less than 20 days.

III. COUNCIL DIRECTIVE 85/374/EEC CONCERNING LIABILITY FOR DEFECTIVE PRODUCTS

A. Key concepts

1. PRODUCT

A product is all movables, which have been industrially produced, even though incorporated into another movable or into an immovable. It includes, since the modification of the Directive in 1999, primary agricultural products, but it does not include immovables.

2. PRODUCER

The 'producer' means:

- the manufacturer of a finished product,
- the producer of any raw material or the manufacturer of a component part,
- any person who, by putting his name, trade mark or other distinguishing feature on the product presents him or her self as its producer. Therefore, there is no loophole of protection if the name that appears on the product is not the one of the real manufacturer or if the product is anonymous.

Moreover, the importer who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive.

3. DEFECTIVE PRODUCT

A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

- the presentation of the product;
- the use to which it could reasonably be expected that the product would be put;
- the time when the product was put into circulation.

Therefore, the safe nature of the product must be judged at the time the product was put into circulation. A product will not be considered as defective for the sole reason that a better product is consequently put into circulation. The safety is assessed by excluding any misuse of the product not reasonable under the circumstances.

B. The principle of liability without fault

1. WHO IS LIABLE?

The producer is liable for damage caused by a product defect even without fault. The producer is submitted to these rules of liability without fault from the moment when he put the product into circulation. According to the European Convention on products liability in regard to personal injury and death of 27 January 1977, a product has been 'put into circulation' when the producer has delivered it to another person.

The person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer and will therefore be responsible as a producer. The underlying idea is to protect the consumer even if the producer is a foreigner and is not established in the Community.

If the producer (or the importer) cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him or her with the product.

There are therefore different levels of persons' liability: primary (for the producer or the importer that will be treated like the producer) or subsidiary (supplier).

If more than one person is liable for the same damage, there will be joint liability.

2. WHAT HAS TO BE PROVED?

The injured person has to prove:

- the actual damage; and
- the defect of the product; and
- the causal relationship between the damage and the defect.

It is not necessary to prove the negligence or the fault of the producer or the importer. The producer (or the importer, the supplier) will be liable even he did not made any fault. The European Convention on products liability in regard to personal injury and death of 27 January 1977 introduced this principle since it was considered that the notion of "fault" no longer constituted a satisfactory basis for the system of products' liability in an era of mass-production, where technical developments, advertising and sales methods had created special risks, which the consumer could not be expected to accept.

3. EXEMPTION OR REDUCTION OF LIABILITY

The Directive establishes a list of hypotheses under which, the producer may be exempted from liability. The producer will have to defend him or her self successfully by proving that:

- he did not put the product into circulation (for instance, it was put into circulation by a person who stole it); or
- that the defect causing the damage did not exist when the product was put into circulation or that the effect came into being afterwards (the producer therefore prove that the defect was not attributable to him or her); or
- that the product was not manufactured or distributed for profit-making sale or in the course of his business; or
- that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or
- that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered; or
- in the case of a manufacturer of a component of the final product, that the defect is attributable to the design of the product in which component has been fitted or to the instructions given by the product manufacturer.

The producer's liability is not reduced when the damage is caused both by a defect in the product and by the act or omission of a third party. In this case, the producer may try to recover his loss against the third party.

However, when the damage is caused both by the defect of the product and the fault of the injured person or any person for whom the injured person is responsible (like the legal representative, the employee or the children), the producer's liability may be reduced or disallowed.

The producer is not allowed to limit or exclude his liability by contractual provisions.

C. The damage covered

The producer shall be liable to pay compensation for:

- the damage caused by death or personal injuries;
- the damage to an item of property ordinarily intended for private use or consumption or used by the injured person mainly for his own private use or consumption, with a threshold of EUR 500.

The damage caused to the defective product itself is not covered. The Directive does not prevent Member States from establishing compensation to non-material damages.

D. Limit of period of liability

The injured person has a limitation period of three years to seek compensation. This period starts from the day on which the plaintiff became aware, or should reasonably have become aware of the damage, the defect and the identity of the producer. After that, no further compensation will be possible.

Moreover, in any case the producer's liability is limited to a period of ten years from the date on which the producer put the product into circulation. This time limit is intended to preserve a balance between consumers' and producers' interests.

IV. DIRECTIVE 90/385/EEC RELATING TO ACTIVE IMPLANTABLE MEDICAL DEVICES

A. Key concepts

1. MEDICAL DEVICE

Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means;

2. ACTIVE MEDICAL DEVICE

Active medical device means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3. ACTIVE IMPLANTABLE MEDICAL DEVICE

Active implantable medical device means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

4. CUSTOM-MADE DEVICE

Custom-made device' means any active implantable medical device specifically made in accordance with a medical specialist's written prescription which gives, under his responsibility, specific design characteristics and is intended to be used only for an individual named patient.

5. DEVICE INTENDED FOR CLINICAL INVESTIGATION

Device intended for clinical investigation' means any active implantable medical device intended for use by a specialist doctor when conducting investigations in an adequate human clinical environment.

6. INTENDED PURPOSE

Intended purpose means the use for which the medical device is intended and for which it is suited according to the data supplied by the manufacturer in the instructions.

7. PUTTING INTO SERVICE

Putting into service means making available to the medical profession for implantation.

B. Authorisation and Evaluation of Active Implantable Medical Devices

Where an active implantable medical device is intended to administer a medicinal product, that substance shall be subject to the system of marketing authorization for medicinal product.

Where an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product, that device must be evaluated and authorized.

C. Principle

Active Medical Device and Active Implantable Medical Device may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly implanted, maintained and used in accordance with their intended purposes.

D. Essential Requirements for Active Implantable Medical Devices

Active Medical Device and Active Implantable Medical Device and Custom-made Device must satisfy the essential requirements set out in the Annex 1 of the Directive, which shall apply to them account being taken of the intended purpose of the devices concerned.

E. Withdrawal of dangerous devices

Where a Member State finds that an Active Medical Device or an Active Implantable Medical Device, correctly put into service and used in accordance with their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or their being put into service.

In this case the Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to meet the essential requirements, where the device does not meet in full or in part the standards referred to in Article 5;
(b) incorrect application of those standards;
(c) shortcomings in the standards themselves.

F. Information system on dangerous devices

Member States shall take the necessary steps to ensure that information brought to their knowledge regarding the incidents mentioned below involving a device is recorded and evaluated in a centralized manner:

(a) any deterioration in the characteristics and performances of a device, as well as any inaccuracies in the instruction leaflet which might lead to or might have led to the death of a patient or to a deterioration in his state of health;

(b) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

G. CE Mark

In principle Active Implantable Medical Device must bear the CE Mark of Conformity.

The EC mark of conformity must appear in a visible, legible and indelible form on the sterile pack and, where appropriate, on the sales packaging, if any, and on the instruction leaflet.

It must be accompanied by the logo of the notified body.

V. DIRECTIVE 2001/83 ON THE MEDICINAL PRODUCTS FOR HUMAN USE

A. Key concepts

1. MEDICINAL PRODUCT

A medicinal product is any substance or combination of substances presented for treating or preventing disease in human beings or which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions.

2. MEDICINAL PRESCRIPTION

A medicinal prescription is any medicinal prescription issued by a qualified professional person.

3. ADVERTISING OF MEDICINAL PRODUCTS

Advertising of medicinal products is any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. It includes in particular:

- advertising of medicinal products to the general public,
- advertising of medicinal products to persons qualified to prescribe or supply them,
- visits by medical sales representatives to persons qualified to prescribe medicinal products,
- the supply of samples,
- the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,
- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,
- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

B. Scope

Directive 2001/83 applies to industrially produced medicinal products for human use intended to be placed on the market in Member States.

C. Principle of authorisation

No medicinal product may be placed on the market, distributed, manufactured of imported unless a marketing authorisation has been issued by the competent authorities of the relevant Member State. A marketing authorisation may only be granted to an applicant established in the Community.

Before issuing an authorisation, the competent authority will check if the outer packaging, the immediate packaging and the package leaflet contain the necessary information (such as the name of the product, route of administration, adverse reactions, expiry date etc.).

An authorisation holder may submit a request for recognition of this authorisation to other Member States.

D. Advertising

No advertising may be made for a medicinal product for which a marketing authorisation has not been granted (except in the case of homeopathic medicines).

The advertising must encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties and the advertising shall not be misleading.

All parts of the advertising of a medicinal product must comply with the particular specifications listed in the summary of product characteristics (article 11 of the Directive), for instance, the name of the medicinal product, information for the correct use, pharmaceutical form, contra-indications, adverse reactions, special precautions for use, posology and method of administration, special warnings, etc. Some specific information must appear when the advertising is made to the general public and other type of information when the advertising is made to the persons qualified to prescribe or supply such products (doctors, pharmacists, …).

Some additional requirements are established when the advertising is made to the general public (and not only to the persons qualified to prescribe or supply medicinal products). In this case, it may not concern medicinal products that are available only on medical prescription, that contain psychotropic or narcotic substances or that may not be advertised to the general public because, by virtue of their composition and purpose, they are intended and designed for use only with the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

Some therapeutic indications may not be mentioned in advertising to the general public, such as tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other tumoral diseases, chronic insomnia, diabetes and other metabolic illnesses.

Direct distribution of medicinal products to the public for promotional purposes is prohibited as well as advertising the cost of which may be reimbursed.

The advertising of medicinal products to the general public may not include any information which:

- gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
- compares the medicinal products with other treatments or products;
- suggests that the health of the subject can be enhanced by taking the medicine or affected by not taking it;
- is directed exclusively or principally at children;
- refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body;
- mentions that the medicinal product has been granted a marketing authorisation.

VI. COUNCIL DIRECTIVE 1993/42 CONCERNING MEDICAL DEVICES

A. Key concepts

1. MEDICAL DEVICE

According to the Directive, 'medical device' "means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means".

The accessories which is not a medical devices as such but is intended specifically to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device is shall be treated as medical devices in their own right.

Electronic equipment and software are included within the definition of medical device when they are manufactured or promoted for medical purpose. According to the Guidelines relating to the Medical Devices Directives, software related to the functioning of a medical device is an accessory or a device on its own right if it is placed on the market separately from the related device. When the software helps for the diagnostic (like image enhancing software for diagnostic purposes), or is a therapeutic tool, then it is considered as a medical device. This is not the case for software used for the administration of general patient data.

When a product has multiple purposes (such a PC, printer, screen, etc.), it could be considered as a medical device only if a specific medical purpose is assigned to them.

2. MANUFACTURER

'Manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.

B. General safety requirement

Manufacturer are obliged to place on the market or to put into service only medical devices that do not compromise the safety and health of patients users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.

The manufacturer must design and manufacture medical devices in such a way that some 'essential requirements' are met, such as to take into account the generally acknowledged state of the art and to eliminate or reduce risks as far as possible (like the risks linked to the toxicity of the materials and their incompatibility with biological tissues and cells, or the risks of contamination for persons involved in the transport, storage and use of the devices, and for patients).

Devices which are in conformity with national provisions transposing the existing harmonised standards will be presumed by Member States to comply with the essential requirements laid down by the Directive.

Devices other than those which are custom-made or intended for clinical investigation must bear a CE conformity marking when they are placed on the market.

C. Possibility for the MS to withdraw medical devices from the market

Where a Member States ascertains that a medical devices may compromise the health and/or safety of patients, users or, where applicable, other persons, it must take all appropriate measures to withdraw such devices. Such decision must be motivated and notified to the manufacturer.

The Member State must also inform the European Commission of any such measures, indicating the reasons for its decision.

If the Commission, after a consultation with the parties concerned finds that the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States. When the Commission considers that the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community.

D. Information system in case of incidents

Member States must ensure that incidents arising following placing of devices on the market will be recorded and evaluated centrally, for instance by requiring medical practitioners or the medical institutions to inform the competent authorities of any incidents.

After carrying out an assessment, if possible together with the manufacturer, Member States shall, inform the Commission and the other Member States of the incidents for which relevant measures have been taken or are contemplated.

VII. DIRECTIVE 98/79 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES

The Directive applies to in vitro diagnostic medical devices and their accessories that are treated as in vitro diagnostic medical devices in their own right.

A. Key Concepts

1. MEDICAL DEVICE

Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

2. IN VITRO DIAGNOSTIC MEDICAL DEVICE

In vitro diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or

- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles` are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

3. ACCESSORIES

Accessory means an article that, while not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.

For the purposes of this definition, invasive sampling devices or devices that are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall not be considered to be accessories to in vitro diagnostic medical devices.

4. DEVICE FOR SELF-TESTING

Device for self-testing means any device intended by the manufacturer to be able to be used by lay persons in a home environment;

5. DEVICE FOR PERFORMANCE EVALUATION

Device for performance evaluation means any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises.

6. MANUFACTURER

Manufacturer means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.

7. AUTHORIZED REPRESENTATIVE

Authorised representative means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive.

8. INTENDED PURPOSE

Intended purpose means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use and/or in promotional materials.

9. PLACING ON THE MARKET

Placing on the market` means the first making available in return for payment or free of charge of a device other than a device intended for performance evaluation with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished.

10. PUTTING INTO SERVICE

Putting into service means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose.

11. CALIBRATION AND CONTROL MATERIALS

Calibration and control materials refer to any substance, material or article intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device.

B. Principle

Such devices may be placed on the market and/or put into service only if they comply with the requirements laid down in the Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.

This involves the obligation of Member States to monitor the security and quality of these devices.

There must not be any obstacles to the placing on the market or the putting into service of devices bearing the EC marking.

C. Essential Requirements

Devices must meet the essential requirements set out in the Annex I of the Directive, taking account of the intended purpose of the devices concerned.

D. Dangerous Devices

Where a Member State ascertains that the devices, when correctly installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, 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 Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance is due to:

(a) failure to meet the essential requirements;
(b) incorrect application of the standards referred to in Article 5, insofar as it is claimed that the standards have been applied;
(c) shortcomings in the standards themselves.

E. Registration duty

Any manufacturer who places devices on the market under his own name shall notify the competent authorities of the Member State in which he has his registered place of business:

- of the address of the registered place of business,
- of information relating to the reagents, reagent products and calibration and control materials in terms of common technological characteristics and/or analytes and of any significant change thereto including discontinuation of placing on the market; for other devices, the appropriate indications,
- in the case of devices covered by Annex II and of devices for self-testing, of all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Annex I, part A, section 3, the outcome of performance evaluation pursuant to Annex VIII, certificates and any significant change thereto, including discontinuation of placing on the market.

VIII. DIRECTIVE 2000/31 ON ELECTRONIC COMMERCE

A. Key Concepts

1. INFORMATION SOCIETY SERVICES

An information society service is any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services (like the Internet). It covers services between enterprises or between enterprises and consumers, which are paid directly from the recipient (on-line transactions) or which are financed by indirect means, like by 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;
- On-line selling of medicines (ePharmacy);
- On-line 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;
- On-line 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).

2. SERVICE PROVIDER

A service provider is any natural or legal person providing an information society service.

3. RECIPIENT OF THE SERVICE

The recipient of the service is any natural or legal person who, for professional ends or otherwise, uses an information society service, in particular for the purposes of seeking information or making it accessible.

4. COMMERCIAL COMMUNICATION

Commercial communications are any form of communication designed to promote, directly or indirectly, the goods, services or image of a company, organisation or person pursuing a

commercial activity. Information allowing direct access to the activity of the company, organisation or person, in particular a domain name or an e-mail address is not a commercial communication.

B. The principle of country of origin

The country of origin principle 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 health care service provider, established in Italy, provides on-line information to doctors in different places in Europe, it will fall under the Italian law.

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

C. Information duty for information society services

1. GENERAL INFORMATION

In addition to other information requirements, the Information Society Service provider has to render easily, directly and permanently accessible to the recipients of the service and competent authorities, at least the following information:

- the name of the service provider;
- the geographic address at which the service provider is established;
- the details of the service provider, including his electronic mail address, which allow him 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 in that register;
- where the activity is subject to an authorisation scheme, like the sale of pharmaceutical products, the particulars of the relevant supervisory authority.

2. REGULATED PROFESSIONS

Regulated professions have to provide more additional information when delivery information society services:

- any professional body or similar institution with which the service provider is registered,
- the professional title and the Member State where it has been granted,
- a reference to the applicable professional rules in the Member State of establishment and the means to access them.

3. VALUE ADDED TAX NUMBER

The Value Added Tax number has to appear when offering information society services whether the service provider undertakes an activity subject to VAT.

4. PRICE INFORMATION

Finally, where information society services refer to prices, these prices are to be indicated clearly and unambiguously and, in particular, must indicate whether they are inclusive of tax and delivery costs.

D. Commercial communications: possibility and information duty

The provider of an Information Society Service has to comply with some special conditions when using commercial communications or unsolicited commercial communications for promoting eHealth services or products. There are also special rules applicable to commercial communications from regulated professions.

1. General Conditions to Commercial Communications

In addition to other information requirements, when the commercial communication is part of, or constitutes, an information society service, some additional information have to appear:

- the commercial communication has to be clearly identifiable as such;
- the natural or legal person on whose behalf the commercial communication is made has to be clearly identifiable;
- promotional offers, such as discounts, premiums and gifts, where permitted in the Member State where the service provider is established, has to be clearly identifiable as such, and the conditions which are to be met to qualify for them has to be easily accessible and be presented clearly and unambiguously;
- promotional competitions or games, where permitted in the Member State where the service provider is established, has to be clearly identifiable as such, and the conditions for participation has to be easily accessible and be presented clearly and unambiguously.

2. Special Conditions to Unsolicited Commercial Communications

Additionally where unsolicited commercial communication by electronic mail are used by the provider of an eHealth Service and are permitted by the Member State where the service provider is established, such commercial communication has to be identifiable clearly and unambiguously as such as soon as the unsolicited commercial communication is received by the recipient.

The providers of an eHealth Service undertaking unsolicited commercial communications by electronic mail has to consult regularly and respect the opt-out registers in which natural persons not wishing to receive such commercial communications can register themselves.

3. Special Conditions to Commercial Communications from Regulated Professions

Regulated professions (like lawyers, doctors, and dentists, amongst others) are allowed to make use of commercial communications. But to benefit from this authorisation these professionals must comply with the professional rules regarding in particular, the independence, dignity and honour of the profession, professional secrecy and fairness towards clients and other members of the profession.

Regarding this issue, professional associations and bodies are encouraged to establish codes of conduct at European level in order to determine the types of information that can be given for the purposes of commercial communication in conformity with the rules regarding in particular, the independence, dignity and honour of the profession, professional secrecy and fairness towards clients and other members of the profession.

If the commercial communication conforms to these rules, the service provider must still comply with the general conditions applicable to commercial communications and with the special conditions applicable to unsolicited commercial communications i.e. he should clearly identify it as such. Moreover, the natural or legal person on whose behalf the commercial communication is

made shall also be clearly identifiable. Promotional offers and promotional competitions shall also be clearly identifiable.

E. The conclusion of contract by electronic means

The conclusion of contract by electronic means is allowed in eHealth - regarding the provision of products and services. However, it does not change special rules applicable in the healthcare sector as for example these concerning the prescription of medicines.

But the conclusion of contract by electronic means has to comply with some special conditions. These conditions are applicable in eHealth.

1. PRINCIPLE

All the Member State Legal Systems have to allow the conclusion of contracts by electronic means. In particular no legal requirements applicable to the contractual process may create obstacles for the use of electronic contracts nor deprived these contracts of legal effectiveness and validity on account of their having been made by electronic means.

2. EXCEPTIONS

Nevertheless Member States may decide that some contracts may not be concluded by electronic means such as those falling into one of the following categories:

- contracts that create or transfer rights in real estate, except for rental rights;
- contracts requiring by law the involvement of courts, public authorities or professions exercising public authority;
- contracts of suretyship granted and on collateral securities furnished by persons acting for purposes outside their trade, business or profession;
- contracts governed by family law or by the law of succession.

3. THE CONCLUSION OF CONTRACTS BY ELECTRONIC MEANS

The online conclusion of contract follows a kind of "two step procedure":

(a) information to provide the recipient of the service with and
(b) the placing of the order.

(a) Information from the service provider to the service recipient

(a.1) Information regarding the contractual process

(a.1.1) Business to consumer

In addition to other information requirements and prior to the placing of the order by the service recipient, the service provider has to provide the service recipient with at least the following information clearly, comprehensibly and unambiguously:

- the different technical steps to follow to conclude the contract;
- whether or not the concluded contract will be filed by the service provider and whether it will be accessible;
- the technical means for identifying and correcting input errors prior to the placing of the order;
- the languages offered for the conclusion of the contract.

(a.1.2) Business to business

Parties who are not consumers may agree otherwise on the information to provide regarding the contractual process.

(a.1.3) Exception

The information duty regarding the contractual process does not apply to contracts concluded exclusively by exchange of electronic mail or by equivalent individual communications.

(a.2) Indication and information regarding codes of conduct

(a.2.1) Business to consumer

The service provider must indicate any relevant codes of conduct to which he subscribes and information on how those codes can be consulted electronically.

(a.2.2) Business to business

Parties who are not consumers may agree otherwise on the indication and information regarding codes of conduct.

(a.2.3) Exception

The indication and information duty regarding codes of conduct does not apply to contracts concluded exclusively by exchange of electronic mail or by equivalent individual communications.

(a.3) Availability of Contract Terms and General Conditions

Contract terms and general conditions provided to the service recipient must be made available in a way that allows him or her to store and reproduce them. This duty equally applies to contracts concluded exclusively by exchange of electronic mail or by equivalent individual communications.

(b) Placing of the order

(b.1) Acknowledgement receipt of the order and of the moment of the reception of the order

(b.1.1) Business to consumer

In cases where the service recipient places his order through technological means, the following principles apply:

- the service provider has to acknowledge the receipt of the recipient's order without undue delay and by electronic means,
- the order and the acknowledgement of receipt are deemed to be received when the parties to whom they are addressed are able to access them.

(b.1.2) Business to business

Parties who are not consumers may agree otherwise on the principles applicable to the acknowledgement of the order and to the moment of the reception of the order and of the acknowledgement receipt.

(b.1.3) Exception

The service provider has not to acknowledge the receipt of the recipient's order without undue delay and by electronic means in case of contracts concluded exclusively by exchange of electronic mail or by equivalent individual communications.

(b.2) Possibility of prior identification and correction of input errors

(b.2.1) Business to consumer

Prior to the placing of the order the service provider has to make available to the recipient of the service appropriate, effective and accessible technical means allowing him to identify and correct input errors.

(b.2.2) Business to business

Parties who are not consumers may agree otherwise on the possibility to identify and to correct input errors prior the placing of the order.

(b.2.3) Exception

The possibility to identify and to correct input errors prior the placing of the order does not apply to contracts concluded exclusively by exchange of electronic mail or by equivalent individual communications.

F. Liability of intermediary service providers

The Directive establishes a special exoneration system of liability for some categories of Internet intermediaries (mere conduit, caching and hosting) in detailed circumstances.

1. MERE CONDUIT

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; and
- 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 in so far 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.

This liability exemption does not affect the possibility for a court or administrative authority of requiring the service provider to terminate or prevent an infringement.

For example, if the electronic communication operator or Internet access provider plays only a passive role in transmitting information from a third party, he won't be liable.

2. CACHING

The "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" service, 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. To benefit from this exemption, the provider has to comply with several cumulative conditions:

- the provider does not modify the information;
- the provider complies with conditions on access to the information;
- the provider complies with rules regarding the updating of the information, specified in a manner widely recognised and used by industry;
- the provider does not interfere with the lawful use of technology, widely recognised and used by industry, to obtain data on the use of the information; and
- the provider acts expeditiously to remove or to disable access to the information it has stored upon obtaining actual knowledge of the fact that the information at the initial source of the transmission has been removed from the network, or access to it has been disabled, or that a court or an administrative authority has ordered such removal or disablement.

This liability exemption does not affect the possibility for a court or administrative authority of requiring the service provider to terminate or prevent an infringement.

3. HOSTING

The "Hosting" service consists of the storage of information provided by a recipient of the service.

When providing such "Hosting" service, the service provider is not liable for the information stored at the request of a recipient of the service. To benefit from this exemption, the provider has to comply with several cumulative conditions:

- the provider does not have actual knowledge of illegal activity or information and, as regards claims for damages, is not aware of facts or circumstances from which the illegal activity or information is apparent; or
- the provider, upon obtaining such knowledge or awareness, acts expeditiously to remove or to disable access to the information.

The service provider may not benefit from this exemption when the recipient of the service is acting under the authority or the control of the provider.

This liability exemption does not affect the possibility for a court or administrative authority of requiring the service provider to terminate or prevent an infringement, nor does it affect the possibility of establishing procedures governing the removal or disabling of access to information.

For example the Internet service provider that gives server space for a company's or an individual's website will not be liable for the information stored when he does not know about the illegality of the information or if he does know it, he prevents any access to it.

When the provider has a control on the information (acting like an editor), he cannot benefit from this exoneration system.

4. NO GENERAL OBLIGATION TO MONITOR INFORMATION

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

But they may be obliged to promptly inform the competent public authorities of alleged illegal activities undertaken or information provided by recipients of their service or obligations to communicate to the competent authorities, at their request, information enabling the identification of recipients of their service with whom they have storage agreements.

IX. DIRECTIVE 1999/93 ON A COMMUNITY FRAMEWORK FOR ELECTRONIC SIGNATURES

A. Key concepts

1. ELECTRONIC SIGNATURE

An electronic signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication.

2. AN ADVANCED ELECTRONIC SIGNATURE

An advanced electronic signature is an electronic signature that meets the following requirements:

(a) it is uniquely linked to the signatory;

(b) it is capable of identifying the signatory;

(c) it is created using means that the signatory can maintain under his sole control; and

(d) it is linked to the data to which it relates in such a manner that any subsequent change of the data is detectable.

3. THE SIGNATORY

The signatory is the person who holds a signature-creation device and acts either on his own behalf or on behalf of the natural or legal person or entity he represents.

4. A CERTIFICATE

A certificate is an electronic attestation that links signature-verification data to a person and confirms the identity of that person.

5. A QUALIFIED CERTIFICATE

A qualified certificate is a certificate that meets the requirements laid down in Annex I of the Directive 1999/93 on a Community framework for an electronic signature and is provided by a certification-service-provider who fulfils the requirements laid down in Annex II of the same Directive.

6. A CERTIFICATION SERVICE PROVIDER

A certification-service-provider is an entity or a legal or natural person who issues certificates or provides other services related to electronic signatures.

B. Legal recognition of electronic signatures

1. ADVANCED ELECTRONIC SIGNATURES

An advanced electronic signature (which is uniquely linked to the signatory; is capable of identifying the signatory; is created using means that the signatory can maintain under his sole control; and is linked to the data to which it relates in such a manner that any subsequent change

of the data is detectable) will enjoy the same evidence value of an handwritten signature if complying with the following requirements:

- It must be based on a qualified certificate;
- The certificate must have been issued by a service-provider who possesses the requirements foreseen in Annex II to the Directive;
- It must be created by a secure-signature-creation device which meets the requirements laid down in Annex III;

This type of electronic signature constitutes an implicit reference model for the Community legislator. By using this type of eSignature, which may be accredited by a national body, the signatory does not take the risk that his signature will not be accepted as evidence in a court procedure.

2. NON ADVANCED ELECTRONIC SIGNATURES

A non-advanced electronic signature or which does not comply with the requirements allowing the automatic legal equivalence with a hand-written signature does also produce legal effects.

Indeed, the Directive includes a non-discriminatory principle that states that an electronic signature could not be legally discriminated solely on the grounds that it is:

- in electronic form, or
- not based upon a qualified certificate, or
- not based upon a qualified certificate issued by an accredited certification-service-provider, or
- not created by a secure signature-creation device.

In practice, when a conflict occurs, the admissibility as well as the evidence value cannot be *a priori* rejected by the judge, simply for the reason that it is a signature in a electronic format or because it does not respect the conditions of an advanced electronic signature.

The main objective of the European legislator was to be technologically neutral and not to exclude electronic signatures that are not considered as the most sophisticated ones.

The appreciation of the legal value will have to be considered case by case by the judges, depending on the particular circumstances.

X. DIRECTIVE 2005/29 CONCERNING UNFAIR BUSINESS-TO-CONSUMER COMMERCIAL PRACTICES

A. Key concepts

1. BUSINESS-TO-CONSUMER COMMERCIAL PRACTICES

Business-to-consumer commercial practices are any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a trader, directly connected with the promotion, sale or supply of a product to consumers.

2. PRODUCT

A product is any good or service including immovable property, rights and obligations.

3. PROFESSIONAL DILIGENCE

Professional diligence is the standard of special skill and care which a trader may reasonably be expected to exercise towards consumers, commensurate with honest market practice and/or the general principle of good faith in the trader's field of activity.

4. TO DISTORT MATERIALLY THE BEHAVIOUR OF THE AVERAGE CONSUMER

Using a commercial practice to impair appreciably the consumer's ability to make an informed decision, thereby causing the consumer to take a transactional decision that he would not have taken otherwise.

5. UNFAIR COMMERCIAL PRACTICES

A commercial practice is unfair when:

- it is contrary to the requirements of professional diligence; and
- it materially distorts or could materially distort the economic behaviour of the average consumer.

In particular, commercial practices shall be unfair if they are misleading or aggressive.

6. MISLEADING PRACTICES

A commercial practice may mislead by action or by omission.

A practice is misleading by action if it gives false information or deceives or is likely to deceive the average consumer, even if the information is factually correct.

A practice is misleading by omission if it omits material information that the average consumer needs prior to take a decision on the transaction or it provides unclear, ambiguous information and therefore distorts the transactional decision that the average consumer would have taken otherwise.

7. AGGRESSIVE COMMERCIAL PRACTICES

Aggressive commercial practices are commercial practices using harassment, coercion, including the use of physical force, or undue influence, that impairs significantly or is likely to impair significantly the average consumer's freedom of choice or conduct and thereby causes him or her or is likely to cause him or her to take a transactional decision that he would not have taken otherwise.

8. THE BLACK LIST OF PROHIBITED PRACTICES

Annex I of Directive 2005/29 provides a list of the commercial practices that must be considered, in all circumstances, as unfair and therefore prohibited, such as:

- pretending to be a signatory to a code of conduct or to have a trust mark or quality mark when it is not true,
- using bait advertising (when the low-priced product is not available)
- stating that a product can legally be sold when it cannot.
- using 'advertorial' (avertising made in a form of an editioral copy)
- making persistent and unwanted solicitations by telephone, fax, e-mail or other remote media except in circumstances and to the extent justified under national law to enforce a contractual obligation.

B. General prohibition of unfair commercial practices

The Directive bans unfair commercial practices in the European Union. This principle applies when a practice is contrary to the requirements of professional diligence and when it distorts or could distort the behaviour of the average consumer.

Some additional criteria are provided in order to assess if a commercial practice is unfair. The Directive defines the misleading practices and the aggressive practices, but also provides a black list of the commercial practices that must be prohibited in all the Member States.

Consumer groups considered as vulnerable receive a higher level of protection in order to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to unfair commercial practices. Indeed, where a commercial practice specifically targets a particular group, such as children, the impact of the commercial practice must be assessed from the perspective of the average member of that group.

XI. DIRECTIVE 1997/7 ON THE PROTECTION OF CONSUMERS IN RESPECT OF DISTANCE CONTRACTS

A. Key concepts

1. DISTANCE CONTRACT

A distance contract is any contract concerning goods or services concluded between a supplier and a consumer under an organised distance sales or service-provision scheme run by the supplier, who, for the purpose of the contract, makes exclusive use of one or more means of distance communication up to and including the moment at which the contract is concluded.

2. CONSUMER

A consumer is any natural person who, in contracts covered by this Directive, is acting for purposes which are outside his trade, business or profession.

3. SUPPLIER

A supplier is any natural or legal person who is acting in his commercial or professional capacity.

4. MEANS OF DISTANCE COMMUNICATION

Means of distance communication are any means that, without the simultaneous physical presence of the supplier and the consumer, may be used for the conclusion of a contract between those parties.

B. Information duty

Prior to the conclusion of any distance contract, the supplier must provide the consumer with the following information:

- the identity of the supplier and, in the case of contracts requiring payment in advance, his address;
- the main characteristics of the goods or services;
- the price of the goods or services including all taxes;

- delivery costs, where appropriate;
- the arrangements for payment, delivery or performance;
- the existence of a right of withdrawal;
- the cost of using the means of distance communication, where it is calculated other than at the basic rate;
- the period for which the offer or the price remains valid;
- where appropriate, the minimum duration of the contract in the case of contracts for the supply of products or services to be performed permanently or recurrently.

Those information shall also be confirmed by writing or in another durable medium available (i.e. electronic format or an email) to the consumer, in good time during the performance of the contract (for instance, just after the conclusion of the contract), and at the latest at the time of delivery, unless the information has already been given to the consumer prior to conclusion of the contract in writing or on another durable medium available and accessible to him or her.

The written confirmation must include also:

- the conditions and procedures for exercising the right of withdrawal;
- the place to which the consumer may address any complaints;
- the information on after-sales services and guarantees;
- the conditions under which the contract may be rescinded.

C. Right of withdrawal

When a consumer enters a contract at distance, he must benefit from a right of withdrawal allowing him or her to cancel the contract during 7 days without any penalty.

When the supplier does not inform the consumer on this right of withdrawal, the period is extended to 3 months.

If the consumer exercises his right of withdrawal, the supplier has to repay the amounts already paid within 30 days. The only charge that may be made to the consumer because of the exercise of his right of withdrawal is the direct cost of returning the goods.

The right of withdrawal does not apply to some types of contract, such as:

- for the provision of services if performance has begun, with the consumer's agreement, before the end of the seven working day period;
- for the supply of goods or services the price of which is dependent on fluctuations in the financial market and which cannot be controlled by the supplier;
- for the supply of goods made to the consumer's specifications or clearly personalized or which, by reason of their nature, cannot be returned or are liable to deteriorate or expire rapidly;
- for the supply of audio or video recordings or computer software which were unsealed by the consumer;
- for the supply of newspapers, periodicals and magazines.

PART III: CASE VIGNETTES

Introduction

We have so far provided a general overview of the principles of liability and consumer protection in the EU and their application to eHealth (Part I) and a detailed analysis of the key legislation (Part II). Part III will look at those principles and definitions in practice by using a series of fictional cases.

Each case vignette has been constructed on the basis of fictional case histories to outline the way in which legislation 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 the reality of medical practice.

In order to make best use of the case vignettes the reader should refer back to Part II to ensure that a correct interpretation of the legal terms is understood.

CASE VIGNETTE 1

Bert Bemelmans, a 38-year old Belgian, was born with the rare disease, Nafram syndrome, which he inherited from his father. As the son of a Nafram Syndrome patient, Bert was diagnosed early on. Barring the limitation on strenuous athletic activity incurred by Nafram Syndrome, Bert enjoys a regular life.

Bert's mother's career as an economist took the family from Belgium to the UK in 1986. But Bert Jr. returned for his masters' degree and settled down in Liège, while his parents remained in Bristol. Bert Bemelmans Senior passed away in 2004 in the UK. Bert Jr and his wife Barbara have two children, Ben 18 and Beverly 16.

Ben is a computer addict, spending most of his waking moments online. His health is generally good, as Ben is fortunate not to have inherited Nafram Syndrome. But, Ben does have one problem that occurs in certain rare forms of Nafram Syndrome, sleep apnoea, which is characterized by loud snoring and more seriously by respiratory difficulty while sleeping. Last summer, Ben's stay at summer camp was marred by his tent-mates making fun of the noise. 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

Young Ben thought he just found the perfect solution to his snoring problem after reading an advertisement for HypnoNix on the website of an international pharmaceutical company which warehouse is established on Cyprus. In theory he should have been cured for at least six months after a one-week cure. HypnoNix was delivered over the counter (OTC) and the product leaflet was written in Greek, a language he does not understand. The snoring stopped but one month later Ben developed breathing problems and nosebleeds. He returned to the website and 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.

1. DIRECTIVE ON ECOMMERCE

The first question is to know if we are in presence of an information society service falling under the scope the eCommerce Directive (online promotion and sale of HypnoNix).

We may assume that the online offering (without the need of an over-the-counter medication which required no prescription by a medical professional) of a one week cure for snoring is an information society service, since it does not seem to require the physical examination of the patient. This is however dependant on the drug not requiring a prescription to be sold, since in many EU countries an on-line prescription may only be made 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.

If however HypnoNix is not a prescription drug and is not offered on the basis of a medical consultation, we have a simple eCommerce relationship in which the pharmaceutical company would be the service provider of this information society service and Ben would be the recipient of the service.

The information society service also includes a commercial communication as it is promoting the sale of HypnoNix - a medicinal product.

We assume that the service provider is established in Cyprus . Hence the Cypriot Law will apply to this eCommerce activity according to the principle of country of origin. This means that first we need to establish is the service provider has complied with his duties as an information society service provdier. These duties refer mainly to the information which must be given to the consumer and to the procedure of purchasing medicinal products by electronic means.

a. Information duties

The advertisement for Hypnonix should comply with the general information due for any information society service (i.) and with the conditions applicable to any commercial communication (ii.).

i. General information duty

The following information should have appeared on the website:

- 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 Cyprus ;
- the details of the service provider, including his electronic mail address, which allows him 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 in that register ;
- where the activity is subject to an authorisation scheme, like the sale of pharmaceutical products, the particulars of the relevant supervisory authority.
- The Value Added Tax number should also appeared 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.

ii. Conditions applicable to the commercial communication

The online advertisement is a commercial communication regarding the eCommerce Directive. Hence the advertisement should comply with further conditions such as i.e.:

- the commercial communication has to be clearly identifiable as such;
- the natural or legal person on whose behalf the commercial communication is made has to be clearly identifiable;
- promotional offers, such as discounts, premiums and gifts, if permitted in Greek Law, has to be clearly identifiable as such, and the conditions which are to be met to qualify for them has to be easily accessible and be presented clearly and unambiguously.

b. Purchase of HypnoNix by electronic means

Ben is allowed to purchase HypnoNix by electronic means according to the eCommerce Directive. But this does not prevent the application of other rules (Greek or Belgian) opposing the sale of medicine through the Internet i.e. for public health safety reasons or requiring a medical prescription.

If the conclusion of the contract by electronic means is allowed by the local laws, it will have to comply with special conditions: prior to placing the order, Ben should have received some information regarding the contractual procedure (the applicable codes of conduct and the contract terms and the general conditions).

i. Prior information on the contractual procedure

If the online OTC sale of HypnoNix is lawful in Greece and in Belgium, the pharmaceutical company still has to provide Ben with some information regarding the contractual procedure leading to the purchase of the medicine, prior the placing of the order. This information must be clear, understandable and unambiguous:

- the different technical steps to follow to conclude the contract;
- whether or not the concluded contract will be filed by the pharmaceutical company and whether the contract will be accessible;
- the technical means for identifying and correcting input errors prior to the placing of the order;

- the languages offered for the conclusion of the contract.

ii. Prior information on codes of conduct

The pharmaceutical company must indicate any relevant codes of conduct to which it subscribes and information on how those codes can be consulted electronically.

iii. Contractual terms and General conditions

The contractual terms and general conditions must be made available in a way allowing Ben to store and reproduce them.

iv. Placing of the order

Prior to the placing of the order the pharmaceutical company has to make available to Ben appropriate, effective and accessible technical means allowing him to identify and correct input errors (for instance the number of ordered doses or cures, the delivery address, the credit card to be charged).

Then the pharmaceutical company must acknowledge the receipt of Ben's order without undue delay and by electronic means.

2. DIRECTIVE ON BUSINESS-TO-CONSUMER COMMERCIAL PRACTICES

Considering the Directive on Business to Consumer Commercial Practices, the question to address is to know if the online promotion and sale of HypnoNix might constitute unfair commercial practices. The question is delicate. We could consider several hypotheses.

First the advertisement could constitute an unfair commercial practice if the website states that HypnoNix may be sold online OTC when it is not true regarding Greek or Belgian Law.

The commercial communication might also be an unfair commercial practice if the website refers to a code a conduct or a trustmark with whom the site does not comply.

The unfair practice could also result from the use of advertising under the form of a medical editorial. In the same logic the company has to avoid misleading the consumer when providing false or incomplete information. Therefore the phrasing of the advertisement should be carefully reviewed.

In summary the company has to be very cautious when promoting HypnoNix through its website. Otherwise the company could face lawsuits according to the national measures taken when transposing the directive in Belgian Law (i.e., complaint by the Belgian Ministry of Economics Affairs or of Public Health).

3. DIRECTIVE ON DISTANCE CONTRACTS

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

- the identity of the supplier and, if payment in advance is required, his address;
- the main characteristics of HypnoNix;
- the price of HypnoNix including all taxes;
- delivery costs;
- the arrangements for payment and delivery;
- the existence of a right of withdrawal;

- the period for which the offer or the price remains valid.

Ben should have received a written confirmation or in another durable medium available (i.e. electronic format or an email) of the order, unless the information has already been given prior to conclusion of the contract.

The written confirmation must include also:

- the conditions and procedures for exercising the right of withdrawal;
- the place to which the consumer may address any complaints;
- the information on after-sales services and guarantees;
- the conditions under which the contract may be rescinded.

If Ben had chosen to exercise his right of withdrawal the pharmaceutical company should have repaid him the price within thirty days. But Ben could be charged with the cost of the returning.

4. DIRECTIVE ON CONSUMER GOODS

Under this Directive Ben is entitled to receive a medicine conform to the description given by the pharmaceutical company. HypnoNix must show the quality and the regular performances of such medicine and 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 seller of HypnoNix will be liable for any lack of conformity existing at the time of the delivery. The final seller is entitled to suit previous seller of the product.

The pharmaceutical company could try to escape from her liability notably by claiming that Ben could not be unaware of the lack of conformity.

But the remedy for the lack of conformity will not necessarily satisfy Ben. Indeed if he succeeds in his action, the Directive only entitles him to ask for a conform product or an appropriate reduction to the price or the cancellation of the contract.

5. DIRECTIVE ON GENERAL PRODUCT SAFETY

The Directive on General Safety Product could be interesting for Ben. Indeed HypnoNix should not present any risk for Ben 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. In this case we could argued the company should have withdrew HypnoNix from the market and informed consumers and recalled the products already supplied to consumers. There should have been a monitoring of the product safety and a collaboration with the competent authorities to avoid the risks.

National authorities also have a role to play in the monitoring of the product safety and they have to take appropriate actions regarding dangerous products such as HypnoNix.

6. DIRECTIVE CONCERNING DEFECTIVE PRODUCTS

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 which 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 assign 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. 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.

7. DIRECTIVE ON MEDICINAL PRODUCTS FOR HUMAN USE

HypnoNix is a medicinal product. Hence it cannot be put into the market without a prior marketing authorization granted by the national competent authorities.

Once granted with a marketing authorization the advertisement for HypnoNix have to comply with numerous rules. If HypnoNix did not receive a marketing authorization, no advertising might be done except if it is considered as a homeopathic medicine. If HypnoNix is not a homeopathic medicine and was granted with a marketing authorization, its advertising should comply with several conditions (encouraging rational use, objective presentation of its properties, etc.) including special warning on side effects.

No advertising is allowed for HypnoNix if its delivery requires a medical prescription or the intervention of a medical practitioner of a pharmacist.

CASE VIGNETTE 2

Sophie and Sandrine Sandeau are identical twins with a congenital cardiac disorder that led to the implantation of their first pacemakers at age 40.

Sophie is a biologist with the French Medical Research Institute in Paris, and Sandrine is a mystery novelist, well known in the Bordeaux area for her vineyard murder series. Both sisters support the work of the French Association of Congenital Cardiac Disorders.

Six years after the first pacemakers, Professor Serge Simon, the head cardiac surgeon at a state of the art French hospital performed an innovative surgical technique on the sisters at six month intervals, first Sophie and then Sandrine.

Professor Simon and his cardiologist colleague Dr. Samuel Stephane next recommended that Sophie and Sandrine be equipped with the latest devices, one implantable, the other wearable.

Sophie was monitored remotely thanks to 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.

Sandrine, on the other hand, was prescribed, e-Vest®, a "wearable" electronic monitoring device, implanted in a special lightweight sleeveless vest. The sensors imbedded in the vest, continuously monitored Sophie's, heart rate, heart rhythm and medication requirements and transmitted the data to the same cardiac centre.

Dr Stephane was very pleased with the initial results. The Sandeau sisters were much less anxiety-ridden than they had been prior to use of the monitoring systems. They hoped nonetheless that they would not have to remain under monitoring surveillance in twelve months' time.

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

This case covers the situation of Sophie and Sandrine Sandeau. We are going to review the main rules applicable to their respective situations and highlight the possible remedies for Sophie.

Sophie's cardiac implant

Sophie benefits from an implantable cardiac medical device with a drug distribution function, coupled with a telemonitoring service.

1. THE TELEMONITORING SERVICE

The telemonitoring service constitutes an information society service. The telemonitoring service is covered by the French Law according to the principle of country of origin since the service

provider is established in France and will thus have to respect the French law developed under the eCommerce Directive as well as French contract law.

First we have to highlight the duties that fall upon the service provider regarding the rules applicable to this information society service. 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 telemonitoring service:

- the name of the service provider ;
- the geographic address at which the service provider is established : the company seems to be located on France ;
- the details of the service provider, including his electronic mail address, which allow him 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 in that register ;
- where the activity is subject to an authorisation scheme, like the provision of healthcare service, the particulars of the relevant supervisory authority.
- The Value Added Tax number should also be indicated,
- The price of the telemonitoring service should appear and indicate if it is inclusive of tax.

2. THE IMPLANTABLE MEDICAL DEVICE WITH THE DRUG DISTRIBUTION FUNCTION

Sophie suffered a malfunctioning of her implantable medical device combined with a drug distribution function. Happily the nurse at the monitoring centre reacted quickly and on an appropriate way.

But what kind of liabilities could arise in this case regarding the European Legal Framework if the nurses had not acted so quickly?

a. Directive on the sale of consumer goods

Under this Directive, 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 and which Sophie could reasonably expect given the nature of the product and 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 suit 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 only to ask for a conformant product or an appropriate reduction to the price of the one she has or the cancellation of the contract.

b. Directive on General Product Safety

The Directive on General Safety Product could be useful to Sophie. The Implant should not have presented any risk for Sophie or only the minimum risks compatible with its use. Here the Implant had a defect. Hence it could be argued that the 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 a monitoring of the product safety and a collaboration with the competent authorities to avoid such risks.

National authorities also have a role to play in the monitoring of the product safety and they have to take appropriate actions regarding dangerous products such as the Implant.

c. Directive concerning Defective Products
If the Implant is industrially produced it falls under the scope of the Defective Product Directive.

The PhysioImplant® could be regarded as a defective product if it does not provide the safety which a person is entitled to expect taking all circumstances into account. In this case it is likely that the Implant is defective.

If the Implant 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 in 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.

d. Directive relating to active implantable medical devices
Sophie bears an active implantable medical device administering a medicinal product. The medicinal product has to have been granted a marketing authorization 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 had compromised the health of Sophie, the French government must take all appropriate measures to withdraw the device from the market. The French Government must also inform immediately the European Commission of the measure and indicates its reasons. The information regarding such incident has to be recorded and evaluated in a centralized manner.

Sandrine's wearable medical device in her sleeveless vest

Sandrine benefits from a wearable cardiac medical device with a medication requirement function, coupled with the same telemonitoring service as her sister Sophie.

1. THE TELEMONITORING SERVICE
The telemonitoring service constitutes an information society service regarding the eCommerce Directive. The service provider is the cardiac monitoring centre in Paris. Sandrine is the recipient of the telemonitoring service. The telemonitoring service is covered by the French Law according to the principle of country of origin if the service provider is well established in France.

The cardiac monitoring centre in Paris has a duty as service provider which concenrn primarily information it must make available to the recipient of the service.

The service provider has to provide Sandrine with at least the following information concerning the telemonitoring service:

- the name of the service provider ;
- the geographic address at which the service provider is established : the company seems to be located on France ;
- the details of the service provider, including his electronic mail address, which allow him 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 in that register ;
- where the activity is subject to an authorisation scheme, like the provision of healthcare service, the particulars of the relevant supervisory authority,
- the Value Added Tax number should also be indicated,
- the price of the telemonitoring service should appear and indicate if it is inclusive of tax.

2. THE WEARABLE MEDICAL DEVICE WITH THE MEDICATION REQUIREMENT FUNCTION

Sandrine's eVest is a medical device that must comply with several rules.

a. Directive on the sale of consumer goods

Under this Directive Sandrine is entitled to expect a medical device (the eVest) which conforms to the description given by the seller. The eVest must show the quality and the regular performances of such product and which Sandrine could reasonably expect given the nature of the product and taking into account any public statements on the specific characteristics of the eVest made by the seller particularly in advertising and on labelling.

The seller of the eVest 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.

b. Directive on General Product Safety

The eVest should not present any risk for Sandrine or only the minimum risks compatible with its use. Here the eVest does not seem to be dangerous. The company should provide Sandrine with enough information to enable her to assess the risks linked with the use of the eVest. In case of an incident the company should consider the withdrawal of the Vest from the market and the information of the consumers and the recall of the products already supplied to consumers. There should be a monitoring of the product safety and a collaboration with the competent authorities to avoid the risks.

National authorities also have a role to play in the monitoring of the product safety and they have to take appropriate actions regarding dangerous products.

c. Directive concerning Defective Products

If the eVest is industrially produced it falls under the scope of the Defective Product Directive.

The eVest 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 the eVest does not seem to be defective.

If the eVest appears to be defective, Sandrine could sue the producer for damages caused by personal injuries arising from reasonable use of the eVest. She would have to introduce her suit in 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.

d. Directive relating to active implantable medical devices

The eVest does not qualify as an implantable medical device, since it is a near body device rather than one physically implanted into the body.

CASE VIGNETTE 3

Dr Caroline Carrington is a general practitioner who recently arrived in a busy group practice, in Loch Harlow, Lannockshire, Scotland. Caroline replaced Dr. Charles Cramer, when he retired in May 2006, inheriting his carefully handwritten records. Dr Carrington, a pragmatic professional, wanted to switch to digital records as quickly as possible, before multiplying her own additions to the files.

Dr Carrington also wanted to acquire a properly authorized electronic signature and begin to generate e-prescriptions. The scanned signature that she used for transmitting certain correspondence did not satisfy Dr Carrington. She wanted the pharmacists (chemists) to be certain that she and she alone had authorized the prescription. Since Dr Carrington wasn't sure that either of the SoftMicro® devices, the pen tablet or the digital pen were truly stabilized, Dr Carrington decided to go with a simple encryption signature software that she purchased online from a Loch Harlow internet service provider.

Dr Carrington was looking forward to her first day of ePrescribing with the electronic signature. Unfortunately that day she had to attend to the German national ping-pong team whose bus tour took them through Lannockshire on their way to France. Half of the team needed an antibiotic that would have to be ordered for delivery the next day in Lille, and Dr Carrington did not know how to ePrescribe beyond the borders of Scotland…

Fortunately, Dr Carrington's last patient of the day, Lana Lipton, was a Lannockshire resident and Dr Carrington was able to "write" her first ePrescription for Lana's anti-ulcer treatment and sign it electronically. Lana was pleased that she did not have to wait at the pharmacy (chemist's), because her order was ready when she got there.

Dr Carrington's next project was to set up her own blog to promote the use of eHealth tools to her colleagues. But, when would she find the time to write the articles?

Legal analysis

Dr Carrington wishes to use an authorized electronic signature for ePrescription in her Member State and within Europe.

To benefit from the same recognition as a hand-written signature, the electronic signature must be an advanced signature complying with the following requirements:

- It must be based on a qualified certificate;
- The certificate must have been issued by a service-provider who possesses the requirements foreseen in Annex II to the Directive on Electronic Signature;
- It must be created by a secure-signature-creation device which meets the requirements laid down in Annex III of the Directive on Electronic Signature;

As we already know an electronic signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication. And an advanced electronic signature is an electronic signature that meets the following requirements:

(a) it is uniquely linked to the signatory;

(b) it is capable of identifying the signatory;

(c) it is created using means that the signatory can maintain under his sole control; and

(d) it is linked to the data to which it relates in such a manner that any subsequent change of the data is detectable.

A certificate is an electronic attestation which links signature-verification data to a person and confirms the identity of that person and a qualified certificate is a certificate which meets the requirements laid down in Annex I of the Directive on electronic signature and is provided by a certification-service-provider who fulfils the requirements laid down in Annex II of the same Directive.

In this case it is not sure that the solution used by Dr Carrington is satisfactory enough for producing ePrescriptions. She really needs an advanced electronic signature and a qualified certificate. She also has to comply with national rules applicable to medical prescription and their administrative aspects.

To know if she could have prescribed antibiotics to the German ping-pong team to be delivered in France she should have consulted the French Law regarding the recognition of her medical education (professional equivalence) and regarding the issue of the intervention of the French social security system to allow the reimbursement of the antibiotics.

If she wants to promote eHealth through the creation of a blog, she has to consider if it constitutes an information society service. If the answer is positive (and it is likely going to be positive) she has to comply with the conditions applicable to such service.

CASE VIGNETTE 4

Wilhelm Wolfgang, 50, a building construction manager in Stuttgart, has suffered from multiple allergies both respiratory and dermatological, since he began working on construction projects at age 18. Wilhelm, a non-smoker, has generally been in good health, other than the recurrent allergies. Unfortunately his most recent routine x-ray has revealed some suspicious areas on the upper right lung.

Wilhelm's sister Wanda also suffered from allergies, and in particular pollen-related ones. She decided to look around on the Internet for solutions to her problems. Three web sites caught her attention.

The first was called "Allergies and Yoghurt". On this page, she learned of the existence of a special Bulgarian yoghurt reputed for its anti-allergic properties. Wanda noted that the web site displayed a quality trustmark from the Bulgarian Dairy Association and found the articles interesting. But, she decided to eliminate that web site from her sources, when she realized that there was no contact information or even company name for the sponsor of the web site. She wondered if the Bulgarian Dairy Association would not have a conflict of interest regarding the yoghurt's health qualities.

The second web site was the "Austrian national allergy web site", on which she noticed a product that was not available in Germany. The web site offered product information regarding an over-the-counter (OTC) allergy treatment from an Austrian company that had been started by German owners, hoping to avoid German regulations. Wanda wondered whether it was legal for her to order such a product from Austria.

Wanda also noted that the web site offered a 24 hour help number. She phoned the service and found the line busy, so that it took her several hours to get through. When she did get through, the nurse was cheery. However, the nurse's main task of determining whether Wanda required an immediate medical appointment could not be achieved, since the web site was reserved to Austrian nationals. Ever the optimist, Wanda decided she would at least tell her Austrian cousin Wilhelmina about the web site, since Wilhelmina also suffered from allergies.

The third web site was titled "Testing for Allergies". It presented information about the various tests that an allergy-sufferer could find in pharmacies or by contacting a physician. She noted that this web site was produced by a pharmaceutical manufacturer who provided full contact information; secondly, the German Allergy Association displayed its logo on the site. Wanda printed out the page and planned to bring it to her pharmacist the next day. Her pharmacist was pleased to see that Wanda came in to enquire about the new tests.

Legal analysis

Wolfgang's sister looked at three websites in order to find a solution to her allergic problems.

The three Health related websites consulted by Wanda should at least comply with the Quality Criteria applicable to the Health Related Websites (COM (2002)667final, 29 nov.2002). In short these criteria are the following:

Transparency and honesty

- Transparency of the provider including the name, mail address and email of the person or organisation in charge of the website;
- Transparency of the purpose and objective of the website;
- Clear definition of the targeted audience;
- Sources of funding of the website.

Authority

- Clear statement of source for all information provided and date of publication of sources
- Name and credentials of all information providers including dates at which credentials were received

Privacy and data protection

- Data protection must be ensured including protection against invisible data processing

Updating of information

- Clear and regular updating of the website with date of up-date clearly displayed for each page and / or item as relevant + regular checking of relevance of information

Accountability

- Accountability - User feedback and appropriate oversight responsibility
- Responsible partnering - All efforts should be made to ensure that partnering or linking to other websites is undertaken only with trustworthy individuals and organisations who themselves comply with relevant codes of good practices
- Editorial Policy – clear statement describing what procedure was used for the content selection

Accessibility

- Attention to guidelines on physical accessibility as well as general findability, searchability, readability, usability, etc.

Although the guidelines are not legally binding, many of the principle in the guidelines are reflected also in the legislation that is examined in more detail below.

1. ALLERGIES AND YOGHURT WEBSITE

If we consider the website Allergies and Yoghurt as an information society service (this qualification is due at first view mainly to the promotion of Bulgarian Yoghurt on the website), it has to comply with several rules from the eCommerce Directive.

The law applicable to this information society service will be the law of the country where the service provider is established. In the present case we ignore the service provider location. If the service provider is established outside Europe there could be another problem in the determination of the applicable law.

Normally in Europe the service provider should give at least the following information:

- his name;
- the geographic address at which he is established;

- his details, including his electronic mail address, which allow him/her to be contacted rapidly and communicated with in a direct and effective manner;
- where he is registered in a trade or similar public register, the trade register in which he is entered and his registration number, or equivalent means of identification in that register;
- where the activity is subject to an authorisation scheme, the particulars of the relevant supervisory authority.

In this case there is no information concerning the service provider.

On the other hand it must be questioned if the website does not promote directly or indirectly the goods of a company. If the answer is positive the information society service constitutes a commercial communication and hence it has to comply with some additional rules:

- the commercial communication has to be clearly identifiable as such;
- the natural or legal person on whose behalf the commercial communication is made has to be clearly identifiable;
- promotional offers, such as discounts, premiums and gifts, where permitted in the Member State where the service provider is established, has to be clearly identifiable as such, and the conditions which are to be met to qualify for them has to be easily accessible and be presented clearly and unambiguously.

In the present case there is no information on the person on whose behalf the commercial communication is made.

Then we could discuss the quality trustmark from the Bulgarian Dairy Association displayed on the website as an unfair commercial practice.

Finally we could consider the dangerousness of the promotion of the yoghurt as an efficient medicine against allergies. More especially we could wonder if the yoghurt should not, as a consequence of its presentation as a possible cure for allergies, be subject to a marketing authorization as a medicinal product. We have to remember that no advertising may be made for a medicinal product for which no marketing authorization has been granted except if the yoghurt may be seen as a homeopathic medicine. If the yoghurt is a homeopathic medicine or is an authorized medicinal product, the advertising has still to comply with special rules regarding the advertisement of medicinal product (encourage the rational use of the medicinal product, objective presentation of its properties, etc.). Some medicinal products may not be subject to advertising notably such as those requiring the intervention of a medical practitioner or of a pharmacist.

2. AUSTRIAN NATIONAL ALLERGY WEBSITE

The Austrian National Allergy Website offers information on an Over The Counter allergy treatment from an Austrian Company started by Germans willing to avoid German Regulations.

The website is thus an information society service including commercial communication as it promotes a special product.

The law applicable to this information society service is the law of the country where the service provider is established – here the Austrian Law. There might be exceptions to this principle in Germany i.e. for the protection of public health.

Normally the service provider should give at least the following information:

- his name;
- the geographic address at which he is established;
- his details, including his electronic mail address, which allow him/her to be contacted rapidly and communicated with in a direct and effective manner;
- where he is registered in a trade or similar public register, the trade register in which he is entered and his registration number, or equivalent means of identification in that register;
- where the activity is subject to an authorisation scheme, the particulars of the relevant supervisory authority.

Some additional requirements have to be met regarding the commercial communication:

- the commercial communication has to be clearly identifiable as such;
- the natural or legal person on whose behalf the commercial communication is made has to be clearly identifiable;
- promotional offers, such as discounts, premiums and gifts, if permitted in Austria, has to be clearly identifiable as such, and the conditions which are to be met to qualify for them has to be easily accessible and be presented clearly and unambiguously.

Finally we could consider the dangerousness of the promotion of the treatment regarding the fact it has been banned in Germany. More especially we could question if the treatment should not, as a consequence of its presentation as a possible cure for allergies, be subject to a marketing authorization as a medicinal product. We have to remember that no advertising may be made for a medicinal product for which no marketing authorization has been granted except if the treatment may be seen as a homeopathic medicine. If the treatment is a homeopathic medicine or is an authorized medicinal product, the advertising has still to comply with special rules regarding the advertisement of medicinal product (encourage the rational use of the medicinal product, objective presentation of its properties, etc.). Some medicinal products may not be subject to advertising notably such as those requiring the intervention of a medical practitioner or of a pharmacist.

3. TESTING ALLERGIES WEBSITE

The last website visited by Wanda is the Testing Allergies Website. As it presents information on various allergic tests and is produced by a pharmaceutical company, this is an information society service including commercial communications.

The law applicable to this information society service is the law of the country where the service provider is established – here the German Law.

Normally the service provider should give at least the following information:

- his name;
- the geographic address at which he is established;
- his details, including his electronic mail address, which allow him/her to be contacted rapidly and communicated with in a direct and effective manner;
- where he is registered in a trade or similar public register, the trade register in which he is entered and his registration number, or equivalent means of identification in that register;
- where the activity is subject to an authorisation scheme, the particulars of the relevant supervisory authority.

Some additional requirements have to be met regarding the commercial communication:

- the commercial communication has to be clearly identifiable as such;
- the natural or legal person on whose behalf the commercial communication is made has to be clearly identifiable;
- promotional offers, such as discounts, premiums and gifts, if permitted in Austria, has to be clearly identifiable as such, and the conditions which are to be met to qualify for them has to be easily accessible and be presented clearly and unambiguously.

Finally we could question if the treatment should not, as a consequence of its presentation as a possible cure for allergies, be subject to a marketing authorization as a medicinal product. We have to remind that no advertising may be made for a medicinal product for which no marketing authorization has been granted except if the treatment may be seen as a homeopathic medicine. If the treatment is a homeopathic medicine or an authorized medicinal product, the advertising has still to comply with special rules regarding the advertisement of medicinal product (encourage the rational use of the medicinal product, objective presentation of its properties, etc.). Some medicinal products may not be subject to advertising notably such as those requiring the intervention of a medical practitioner or of a pharmacist.

In this case the website does not seem to sell allergic tests directly to the consumer. Here Wanda went with the collected information to her pharmacist.

PART IV: LEGAL SOURCES

Product safety, liability and consumer protection issues relating to eHealth are on some aspects regulated by European regulations that may be presented in three categories:

A. 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')

B. 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.

C. 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