Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

ETHICS, HEALTH AND NEW INFORMATION TECHNOLOGIES

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Introduction

The new information technologies constitute and metaphorically make up a territory that by now seems, *wrongly*, familiar, whilst it is still not only largely unexplored, but mostly undefined in its real boundaries. If it is true that communication represents the horizon of experience that more than any other marks post-modernity and if it is true that the *network* today is the essential core of global communication, it is also true that the potential of this method of communication still seems (aside from all the technical and operative implications) epistemologically ambiguous. The network, in fact, does not only multiply, almost indefinitely, the possibility of communication, but it alters its *quality* and probably its identity. And therefore, consequently, we start to perceive how human identity itself is altered, according to dynamics that only few are, today, able to foresee, but that already reveal themselves to be highly incisive. From this point of view, it is easy to understand how even medicine is challenged by the new information technologies and how it inevitably suffers, because of them, *pressure* capable of changing its essence. It is enough to justify the bioethical interest on the issue that is the object of reflection by the *National Bioethics Committee* and that already gives substance to the document presented here.

It is thanks to Prof. Adriano Bompiani that, during the plenary meeting of the 23rd of April 2004, agreements were collected to start a Working Group aimed at elaborating a document to study in more depth the bioethical aspects of the use of the internet in the medical-healthcare sector. When creating the Working Group, the Committee unanimously asked Prof. Bompiani to become its moderator.

The relevance of this topic explains the significant number of Committee members who decided to take part in the Group's work: Prof. Amato, Prof. Battaglia, Prof. Binetti, Prof. Borgia, Prof. Caporale, Prof. Coghi, Prof. Marini, Prof. Neri and Prof. Umani Ronchi. Prof. Eusebi also actively intervened in later meetings. The Group, which met altogether eight times, worked from the 17th of June 2004 to the 16th of March 2006, using also the contribution of "experts", who generously answered our invitation to collaborate positively. They are: Dr. Giovanni Buttarelli, General Secretary of the Privacy Guarantor Authority, Prof. Angelo Serio, professor of statistics and healthcare information technology at "La Sapienza" University of Rome; Dr. Eugenio Santorio, Responsible for the Laboratory of Healthcare Information technology at the Institute for Pharmacological Research "Mario Negri" in Milan; Dr. Paola Mosconi, Responsible for the Research Laboratory on Citizens' Involvement in Healthcare at the "Mario Negri" Institute; Dr. Giovanni Alopone, Responsible for the Oncology Transactional and Outcome Research Laboratory, at the same Institute; Dr. Maurizio Bonati, Responsible for the Laboratory for Maternal and Infant Health, also at the "Mario Negri" Institute in Milan and finally Col. Umberto Rapetto, Commander of the *Nucleo speciale frodi telematiche* part of the Guardia di Finanza. The draft of the document, written by Prof. Bompiani, Prof. Amato and in particular Prof. Marini, was then presented to the attention of the Committee gathered in plenary meeting, which, after in depth discussion, approved it unanimously in the Plenary meeting of the 21st of April 2006.

As highlighted in the same document, the NBC text follows the initiatives of other supranational bodies that elaborated similar documents on this issue,

which have been the object of careful evaluation by the Committee. Here we must recall in particular:

- The *European Group on ethics in sciences and new technologies* operating as part of the European Commission (EGE), which, on the 30th of July 1999 issued an *Avis* titled *Ethical Issues of the Use of Personal Health Data in the Information Society;*
- The Council of Europe (C.E.) that, after promoting the *Convention on Information and Legal Cooperation concerning the "Information Society Services"*, produced further materials, amongst which we must mention those destined more specifically to the healthcare sector and in particular the two *Recommendations* of the Committee of Ministers to Member States, the R(97)5 relative to the protection of medical data and the R(99)5, on the protection of privacy when using the Internet;
- The Recommendation Project by the CDSP, European Health Committee which should – if approved by the Committee of Ministers – regulate the impact of informatics in the healthcare sector, with particular attention to the use of the Internet (SP-IMP/TECH).

Although we don't presume to have carried out this task without oversights, but being aware of its quality, the *National Bioethics Committee* recommends reading this document to the public, not only bioethicists, and more in general to all those who are interested in the newer and more urgent healthcare issues, but also to those who know well how urgent it is by now to seriously question ourselves about the boundaries of the *post-human*.

Prof. Francesco D'Agostino
President of the *National Bioethics Committee*

CHAPTER I

GENERAL OUTLINES OF MEDICAL INFORMATICS

1.1 – *Premise*

The concepts of information and communication have general anthropological characteristics in each human activity, and particular characteristics in each activity considered. Information and communication today enjoy instruments that have multiplied a great deal the possibilities of increasing, storing, analysing, disseminating, etc. the information available, therefore multiplying the ability to communicate. So, information technology is born, which is a specialised human activity that elaborates models, creates systems and finally operates with appropriate tools in the information sector.

In this document we will examine some aspects of the application of informatics to medicine.

Governments and healthcare organisations believe that the spreading of information technology can improve patients' safety, guide clinical choices and eliminate at least some of the imbalances existing in the distribution and fruition of healthcare services. These are "positive", bioethically relevant objectives; however internet communication (which today is the most common method – but not the only one – of informatics communication) in pursuing these objectives can be the source of danger/harm for the user, like any other system of information can be, after all, when used inappropriately.

From this dual point of view, the issue also interested the NBC, which believed it was appropriate to examine the various aspects of the dissemination of informatics communication in today's society, in view of the right to the protection of health, seen – as known – as a human right.

This analysis will tackle, after having looked briefly at "medical informatics", especially "internet communication", which has a particular role in the use of informatics also in the healthcare sector and for health protection, in the widest sense of the term.

Coherently with the aims and the style adopted in previous NBC documents, this work also wants to present public opinion a series of information and reflections on the use of this widespread means of communication in the healthcare sector, in a clear and informative way.

In particular, we will focus on the ethico-legal aspects of the correct use of the internet, highlighting not only the positive features, but also the risks of an irresponsible use.

1.2 *Some definitions*

Not focusing, at the moment, on broader reflections regarding the stated autonomy of medical informatics as a discipline, it seems appropriate to recall – however – the definition of medical informatics that does not seem – reductively – to refer to the mere (instrumental) use of calculators in medicine.

1. Definitions

This cultural and operative area, according to the World Health Organisation, must in fact be intended as all the applications of the appropriate methods and techniques to the sciences of information, computerisation, network organisation and communication with the objective of supporting healthcare and the disciplines concerning it, like medicine, dentistry, nursing sciences, pharmacy, etc. (Power, 1999).

An equivalent, shorter, definition is that of TALMON and HASMAN:

Medical informatics can be defined as the discipline concerned with the systematic processing of data, information and knowledge in the cultural field of medicine through appropriate technical means.

Its "domain" extends to the computational and informational aspects of the processes involved in medicine and healthcare.

It has a dual use:

a) giving solutions to problems connected to data processing, information and knowledge, produced by medical "procedures";

b) studying the general principles applied to this processing (TALMON and HASMAN, 2002).

According to this perspective, medicine involves activities that can be broken down into their individual processes (biological, communicative, decisional, educational/formative, organisational, computational, etc.) and in each of them informatics can intervene with appropriate models and algorithms.

For the concept of processing, it is better to use the broad definition found in the recent "Personal data protection code" (enabling Act No. 127/2001), which states:

processing shall mean any operation, or set of operations, carried out with or without the help of electronic or automated means, concerning the collection, recording, organisation, keeping, interrogation, elaboration, modification, selection, retrieval, comparison, utilisation, interconnection, blocking, communication, dissemination, erasure and destruction of data, whether the latter are contained or not in a data bank.

According to some, the numerous fields of intervention – indicated by the Italian legislation but fully in line with international Regulations – would make medical informatics a transversal "medical" (or at least biomedical-healthcare) discipline, whilst according to others medical informatics remains closer to "engineering", "ontologically", than to medical sciences (SHAHAR, 2002). In any case, it must be considered at least as inter-disciplinary.

According to SCHORTLIFFE, 2001, medical informatics as a discipline concerns not only the treatment and use of biomedical information, but also the study of the "nature" of medical information, and this is a task that (at least today) we assign to medical epistemology.

1.3 *A general illustration of the current applications of medical-health informatics*

Abandoning, at the moment, this area of reflection, we will now try, in a preliminary and certainly not exhaustive way, to make a list of the currently more widespread applications of medical informatics.

This immediately demands some clarifications:

Medical informatics:

- concerns all citizens, in general, but more directly (according to the programmes activated) healthcare administrators, healthcare personnel at any level, biomedical researchers, teachers and students in training courses, patients, etc.
- its main objectives are the participation to programmes of:

1. Health protection and treatment of illness
2. Management of healthcare systems
3. Facilitation of biomedical research.

This broad presence of informatics in healthcare can be found, necessarily, with those "sensitive data" that, according to their definition are, with regards to medicine, in particular "personal data able to reveal health and sex life", but more in general also those classified as sensitive but not medical, which, in the exercise of the profession, can become known to the doctor (e.g. racial and ethnical origin, religious, philosophical, or other kinds of beliefs, etc.).

Finally, we must clarify that medical informatics concerns most of all, but not exclusively, "personal data of the individual", but can involve also eventually "sensitive" information regarding other forms in which the legal concept of person is expressed. In the already mentioned Code, they are indicated as data regarding "Any information relating to natural or legal persons, bodies or associations that are or can be identified, even indirectly, by reference to any other information, including a personal identification number".

Concluding this preliminary information, we will say that what characterises this cultural and operative sector, from an ethical point of view, is the ethically correct use of information.

We therefore arrive to that definition of medical informatics that is more restrictive – in a way – but appropriately finalised to this aspect, given by the Manchester University Medical Information Working Group: *"medical informatics involves a responsible use of information in support to healthcare"*.

This is the definition that – beyond the recurrent discussions about the epistemological and disciplinary autonomy of informatics and of medical informatics in particular – interests the doctor as any citizen and any patient, because it highlights a responsible and finalised use of informatics, as a group of methodologies, algorithms and instruments that process data and information in support of those particular models of relations between individuals that are health, illness and the organisation of healthcare.

1.4 *Opportunities and difficulties in the development of health informatics; the arrival of the internet*

An Opinion (surprising, from a certain point of view) has been expressed that the Information and Communication industry in general is sceptic about the

profitability of the healthcare market, seen as hospital and basic medicine IT systems do not operate for profit, and doctors tend to use computers – especially personal ones – more for memorising their patients' personal data than for a necessary and quality support to their daily work through "expert systems", etc.

On the other hand, what has been stated by MUSEN (2001) is just as true, namely, that modern software systems have become so complex that they demand personnel, resources and economic support capabilities that only profit-making, large-scale software engineering organisations can guarantee.

It must be recognised that medical informatics is particularly complex, as the analysis of its components, the memorisation and the processing of the elements that constitute it, have a series of highly hierarchical levels, if we want to achieve a high and correct clinical use (BLOIS, 1984), levels that require particularly expert personnel. However, there has been progress since the time BLOIS expressed these views.

Interesting applications for the integral, multimedia memorisation of the data, have since been acquired as part of the intra-hospital's management of the patient, so that the possibility of elaborating information on various lines of research becomes increasingly more concrete and current: e.g. according to nosography (WEED, 1968, 1971); symptomatology (ARANDA, 1974); therapeutic choices (e.g. ACHESON, 1972; FERRI, 1995, etc.).

The development of these large intra-hospital "archives" will certainly allow positive progress in epidemiological research, but also contribute to the analysis of the efficacy-efficiency of the patient's treatment (FERRI at al. 1998; STACCINI et al. 1999, etc.), an argument that today is at the centre of the debate on the organisation of healthcare.

Currently, the more extensive and detailed support of the user's requests/needs (doctor and patient) in the context of the policy of health is seen as the most important development opportunity for medical informatics; in addition, we identify outlines of development in the fact that informatics is increasingly integrated with the processes of molecular medicine as they are clarified, becoming not only support systems, but also new fields of research for biologists and clinical doctors (KULIKOSKI 2002).

The "tout court" challenge of informatics – as a specific field of research – would be to identify organisational and application principles in support of the different disciplines that intervene in the knowledge of health and of relative promotional behaviours, in order to develop specific systems to follow the various problems at the different levels and help resolve them: consequently we move, for some, from the concept of medical informatics to that of "healthcare informatics", which would better express this complexity and broadness of applicative horizons.

CHAPTER II

THE POTENTIAL OF THE INTERNET IN THE HELATHCARE SECTOR

2.1 *The specificity of internet communication*

We must recognise that the progress of the last few decades in the informatics sector have allowed the manifestation of a growing trend of using electronic technologies in the "exchange" of information between people. The exchange of information regards in practice any sector of associative life and it contributes to the so-called "globalisation process" of society.

An optimistic attitude has appeared towards the tumultuous development of the internet, in the context of which "healthcare information", exchanged with the public by those responsible for the healthcare system at different levels, also partially happens.

The advent of the Internet, a system based on the interconnection of numerous (and heterogeneous) communication networks, created for military research projects in the 60s and immediately welcomed as an easy means of communication amongst a restricted "network" of university researchers, in a few years has demonstrated such usefulness that it has extended to any sphere of worldwide communication.

According to G. Gottardi (2003) "*From a technical point of view the internet can be defined as all the technologies and solutions that allow the interconnection and exchange of data between computers. Its importance however is in the applications that it is able to hold. (…) The total freedom of access, without ties and technical mediations, at virtually no cost, and the continuous improvement of its performance has led to a growth in the infrastructure and in the number of users to levels unimaginable until a few years ago.*

Currently, the growth is linked especially to the increase of business applications that the network is able to support".

The growing success recorded in the dissemination of the services offered by the internet is in fact due to factors that are quite simple and appreciated by the users: the substantial simplicity of the technology (limited volume of the appliances, limited cost of purchase and use, the possibility of connecting through the usual phone lines or consolidated systems of communication like ADSL, etc.), the possibility of learning to use it with relative ease already as teenagers, the widespread network connection, which opens direct and specific possibilities of dialogue between individuals that were unseen until now; the ease with which, from home and without having to face the convulsive rhythms of the metropolis, we can carry out many operations of daily life, finance and even culture.

The *freedom of expression*, according to some sociologists, is the main success factor of the internet, because it allows the open communication of our ideas and feelings, (anonymously, if we want), directed to "global" interlocutors, even far and unknown, who come into contact with the communicator.

There are some authoritative monographs illustrating these phenomena in detail, but they also offer different opinions in their interpretation. On the one hand the value of the INTERNET as a "cult of the freedom of expression" is

highlighted – focusing on the personality of the individual who presents him/herself to an international audience – with a freedom that provoked, in some contexts, also the "maniacal cult" of the INTERNET (on which focused THEODOR ROSZAK, 1986; A. MATTERLART, 1999; PH. BRETON, 2000; Kimberly Young, 2000, and others), interpreting the Internet almost as a new religion of existence. On the other hand, are highlighted the risks for the more normal and traditional associative life, based on personal encounters, where, as well as the ideas expressed we value the words, the looks, the movements, etc., all means of communication that – it has been said (PH. BRETON, 2000) – are even repugnant to the obsessive "surfer", sunk in loneliness.

The NBC does not mean, with this document, to focus on these phenomena – which are certainly also deserving of ethical consideration – but it chooses to reflect on a more common use of web communication, namely, a *"useful tool"* to pursue individual interests, and amongst them we must mention "health protection", which so much occupies and/or preoccupies people, especially in mature societies.

2.2. *A general look at the dissemination of websites and the reasons for the growing use of the internet in healthcare;*

The Censis-Forum for biomedical research placed, in 2001, an estimate by JUPITER et al (2000) of the foreseeable number of European "internauts" at around 129 millions in 2002 (equal to 34.3% of the population). The Italian Internet observatory estimated 10 million internauts at the end of 2000 (18% of the population), and the CENSIS-FORUM estimated them at 20 millions in 2005 (equal to 42.7% of the adult population).

In a few years, there has been a considerable increase in the questions regarding health in the information transmitted via the Internet, and in the same way the offer of health services by doctors, healthcare organisations, etc. has increased (WYATT, 1997; JADAD and GAGLIARDI, 1989, etc.) especially in countries with a free healthcare market.

It has been estimated that the number of websites that – on the planet – offer healthcare information, already in 1999 was 100,000 (EYSENBACH G. and Diepgen data, 1999), number agreed upon by a communication of the European Commission in November 2002.

The HEALTH on the NET FOUNDATION in 2003 estimated that 35% of European users were patients searching for medical-healthcare information, and the CENSIS-FORUM RBM estimated at 4 millions the Italians searching for healthcare information on the web (26% of the total users in 2005).

When it concerns critical pathologies, these numbers are even higher, as shown by a 2003 research estimating that 39% of the cancer patients directly researched information on the Internet, along with another 15%-20% of patients for whom this research was carried out by third parties, generally family or friends (EYSENBACH CA CANCER J CLIN 2003).

Without prejudice for the accuracy and the revision of the numbers, the breadth of the phenomenon allows the creation of the concept of "web as medical-healthcare consultant".

The reasons of this growing interest can be listed as follows (CENSIS-FORUM, 2001):

- *The easy and immediate access* to a practically unlimited source of information;
- *the possibility of comparing different versions and points of view* on the same topic (the growing request for a second opinion);
- *the possibility of surfing through levels of differentiated in depth studies*, according to personal needs;
- *the possibility of reaching niches of the market* which are, for various reasons, difficult to access, in order to know, compare or simply test the market;
- *the possibility of contacting bodies,* associations or people in various ways involved in the topic of interest, able to redirect the user's choices and opinions.

Sociological investigation allows distinguishing the interest of the consumer from that of the healthcare manager as follows:

From the consumer's point of view:

- the Internet offers, indubitably, many facilitations in accessing medical and healthcare information, and it contributes to "equal opportunities" between citizens and the "ubiquity" of information, which crosses frontiers. It can act, therefore, as an increment to the freedom of choice.

There are, in addition, advantages also from the point of view of the healthcare organisation.

- Correlated to precise territorial areas; information via the Internet is useful in finding available services, what is on offer on the market, and – if the descriptions are correct – supplies knowledge of waiting times and booking methods, and anything else that can be useful to the user.

From the point of view of the healthcare administrator:

- In general, healthcare administrators are in favour of the dissemination of health information in particular sectors, because information meets expectations positively and supports the citizens' healthcare education by those responsible for care institutions. In fact, through the Internet we can achieve a capillary dissemination of the notion of healthcare prevention, vaccinations, diagnostic tests, etc., aimed at large and indeterminate strata of the population using the web. Also it supports information on the services offered.

In conclusion, the Internet can contribute to the maintenance and increase of the level of individual health, promoting as much as possible personal autonomy and strengthening the right to health protection.

2.3 *Assessing the quality of information*

There are many websites that are structured in a variety of ways according to the finality pursued also in the health sector.

Naturally, this immediately poses the question of the "quality" of information transmitted through this tool of information/ production/distribution.

As rightly stated by C. PRINS and M. SCHELLEKENS (2004), looking at the rapid increase in the number of messages (information) and users following the years after the 1999 evaluation, we must harbour the founded doubt of whether the information coming from such an extensive tool is always correct, complete and legitimate.

These Authors highlight the frequent lack of clear details about the source, name, address and credentials of the "provider" supplying the information, and

about who compiled it, the date and the constant updating of it, the procedures and criteria adopted to select it.

Studies carried out in various medical sectors, in addition, highlight how scientific information supplied by medical websites is often lacking (EYSENBACH et al 2002), even arriving at suggesting remedies that are not coherent with the main international guidelines in tackling simple situations like managing a child's cough (PANDOLFINI at al 2000) and temperature (IMPICCIATORE et al 1997).

Assessing the "quality" of healthcare information represents the first problem at the centre of most of the NBC's bioethical reflection.

As well as the observations, regarding this, found in literature, documenting its incompleteness in particular cases, a further in depth study can come from investigating the "guidelines" by international organisations, regarding the deontology of those operating through the internet, which all recommend accurate information.

The methods to measure and guarantee the quality of the medical information put on the web, develop following three outlines (E. SANTORO of the "Mario Negri" Institute 2001): a) the use of self-regulation codes (or guidelines) by those creating the site, b) the use of control services through reviews/revisions of the sites, c) the adoption of PICS (Platform for Internet Content Selection) to describe the content of the sites.

Self-regulation codes comprise a number of principles that, although they do not evaluate a site, give rules that allow the assessment of its reliability and accuracy.

The first self-regulation code suggested by the scientific community is that developed in 1997 by the main international biomedical journals (International Committee of Medical Journal Editors JAMA 1997).

This code identifies as reliable those sites that require the following information: the author's name, his/her credentials and the declaration of eventual conflicts of interest, the organisation he/she belongs to, the editor's name, the bibliography used, information about the ownership and copyright of the site, date and modification of the document.

The HON code (called HON code and proposed in 1997 by the Health on the Net Foundation) includes many criteria indentified by the International Committee of Medical Journal Editors and it is the system of self-certification (which in the last few years has become a system of certification that the owners of the sites require and that the organisation gives only after verifying that the criteria are followed correctly – verification that is carried out annually) which is most used today (http://www.hon.ch/HONcode/Conduct.html). With regards to the previously illustrated code, the HON code also guarantees a verification support of the certification that the user can eventually use.

The principles suggested by these codes can be used also as guidelines by citizens, to assess the reliability and accuracy of a site, even though this does not have any self-certification system. It is on the basis of these considerations, that in recent years the development of useful tools for this purpose has proliferated, increasingly aimed at the consumer/citizen. Amongst the better known ones, it is possible to mention the DISCERN project (http://www.discern.org.uk) by the Oxford University and, in Italy, the tool "Misurasiti" in the portal "Partecipasalute".

There can be two types of services reviewing/revisioning medical sites:

- general services, comprising known research engines like Google, which cover a wide range of topics, with selection and assessment criteria that are in general quite vague.
- specialist services (amongst the Italian examples we can cite the tools developed by the Institute for Pharmacological Research "Mario Negri" called ONCO.CARE – http://www.omcocare.it – and CARDIO.CARE – http://www.cardiocare.it) which give formal criteria and precise rules in the selection and assessment of the medical resources to bring to the citizens' attention.

There are also "rating" systems expressing the quality with a number (Star System) between 0 and 5, established by an Editorial Committee on the basis of elements like reliability, completeness of information, use of multimedia, public access typology.

The PICS labels, created at the end of the 1990s to filter information on the network, have then been suggested to select medical resources on the internet. The labels, compiled according to certain criteria of guarantee, indicate whether and which documents to access. The European Union funded, between 2000 and 2003, research projects on the applicability of these systems to websites containing healthcare information. Amongst the most interesting projects we can mention MedCERTAIN (http://www.medcertain.org) and MedCIRCLE (http://www.medcircle.org), which studied and implemented a vocabulary called HIDDEL vocabulary ("Health Information Disclosure, Description and Evaluation Language") based on the MedPICS system ("Medical Platform for Internet Content Selection), an extension of PICS. However, these systems are still in the experimental phase and have never found, even in recent years, a solid application.

Despite these efforts, it seems evident that – currently – many websites do not offer sufficient guarantee of "transparency", as the adoption of certification criteria is still limited.

Recently, C.PRINS and M. SCHELLENS (2004) wondered what legal aspects are taken into account in the initiatives of full "transparency": they risk becoming a source of complaint and compensation requests by those who expose themselves on the internet by name, whilst this does not happen to those who maintain their anonymity.

If this interpretation is true, we understand (although it cannot be justified from the point of view of the "consumer") the lack of support for the "guidelines".

2.4 *Risks of the improper use of the internet in clinical medicine*

But, as known, the exercise of clinical medicine itself, aimed at the individual, can be changed by the use of the internet, which allows the patient to consult the doctor "from a distance" and this fact can be the source of advantages (at least in some circumstances) if the individual who is (clinically) well known to the trusted doctor, but it can be the source of serious problems if the individual is unknown, or has symptoms that can be necessarily interpreted only with a clinical examination.

Some investigations tried to identify the reasons for the citizens' growing interest in healthcare communication via the internet, attributing it to the dissatisfaction they still feel after talking to the doctor "face to face" (SPIELBERG, 1997/1998), to being less uneasy and more open in the way they express themselves anonymously via the internet due to the nature and the method of posing the questions (BOROWITZ and WYATT, 1998); to the desire of having a second opinion (also from unknown doctors) about their ailments (EYSENBACH G., DIEPGEN., 1999), without their GP knowing, etc.

It seems difficult to establish how frequent these "motives" are, but the fact that they have been mentioned invites doctors to take them into account, in order to stimulate a "friendly", "empathic" and non-paternalistic behaviour towards the patient, in line with the well known and widespread bioethical principle of the correct "therapeutic alliance".

Concluding these quick observations, it must be highlighted that many authors focused on the opportunities offered by the internet for the protection of health, amongst which we mention M.D.C. ROSCAM ABBING (2000), C. PRINS and M. SCHELLENS (2004) – members of authoritative International Organisations – who however did not hesitate to warn against the problems of its use, which are due, at least in part – to the lack of (or just started) development of the quality criteria for the management of health websites. The field of "marketing", which appears to become increasingly important (through, for example, the offer of "DIY" tests for the HIV infection (ROSCAM – ABBING, 2000), but the same problem can be seen for some genetic tests) cannot fail to raise apprehension, if it's not balanced by a great "transparency" on the origin of the information and the "reliability" on the indications (scientific and/or practical, behavioural etc.) suggested on the internet.

The growing request to receive information via the internet about the illnesses and care strategies contested in many countries, involves the increase of the responses on the net, which must be scientifically accurate and appropriate, to avoid risks of harm or even harm due to inaccurate information. This, which is a general problem of communication, tackled also by civil law both theoretically and practically (see for example BUSINELLI, 1997), has a growing relevance from the point of view of public healthcare. In fact, it has been noted for some time that the number of consumers ("internet surfers") who believe they can find direct answers to their health problems on the internet, without medical help, is rapidly increasing (FERGUSON, 1998); therefore, it seems appropriate for the healthcare authority to be vigilant, so that the information given to the patients is adequate and leads to a choice that is not shaped by commercial speculation, which can be harmful to health. But most of all it is considered inappropriate for the profession (and a source of risk both for the patient and for the organised healthcare structure) that some doctors can derive evident financial gain from this kind of communication with patients they do not know directly (see FERGUSON, 1998), they have never examined and have contacted outside of the rules codified by their profession.

Scientific societies should also collaborate towards the objective, cited by many, to protect the quality of information and the professional orders by being vigilant of marketing behaviours. However, it is still to be established with which chances of success, in sectors where business competition with regards to offer is very open and anonymity is allowed. In conclusion, we believe that the screening and validation process of medical information (contents, presentation methods and sources) and healthcare marketing still require considerable

reflection in its social and technical aspects (MORRIS et 1997; BROWN et al. 2000, etc.), and these points will be discussed more in depth later, in the following part of the text, from a legal point of view.

Finally, it has been mentioned, more than once – in literature – not only the extreme dishomogeneity in the quality of information, but also the uncertainty in the protection of privacy (JADAD 1998, 1999; EYSENBACH and DIEPGEN, 1998; SILBER et al.; Federal Trade Commission, etc.).

We must appreciate the initiative of the American Medical Informatics Association, aimed at developing guidelines for the use of internet information, and the adoption of them by the Association's websites (AMIA), guidelines that are proposed also by other independent "providers" (not linked to the Association: Winker et al., 2000). Also appreciated is the initiative of the same American Medical Informatics Association, which has developed guidelines (immediately adopted by the American Medical Association) regulating the doctor-patient relationship in case electronic mail is used (Kane at al J Am Med Inform Assoc, 1998).

2.5. *The situation in Italy*

Although not many investigations have been carried out so far, the situation in Italy does not seem to be very different from the general situation just illustrated.

A recent CENSIS-FORUM R.B.M. (2005) study classifies as follows a sample of 190 sites on the basis of their founding characteristics and the services on offer:

Institutional sites – created by individuals who work in Italy in the organisation and management of healthcare policies and by bodies representing healthcare institutions (26.30%).

Pharmaceutical industry sites: sites of companies producing and/or marketing medicines in Italy (22.60%).

Patients' Associations sites: they collect the requests/interests of the individuals affected by definite pathologies (26.80%).

Wide-ranging sites: involved, regardless of the nature of the individual, in the dissemination of information in the health sector (24.20%).

The institutional sites in Italy are mostly those managed by organisations like the Istituto Superiore di Sanita', the Ministry of Health, the Italian Medicines Agency, Regional Healthcare Services Agencies, medical-scientific societies and Italian universities.

Amongst international sites, particularly qualified are those of the European Medicines Agency (EMEA), which comprises the Council of Europe, the WHO, where we can find information about the cure and prevention of main illnesses, the American National Institutes of Health (NIH), one of the main American medical organisations, the National Library of Medicine (NLM), responsible for the development of databases like Medline and PubMed and systems of healthcare information distribution to the public like MedlinePlus, that of the Food and Drug Administration (FDA), the authority responsible for the registration of drugs in the United States, and that of the Centres for Disease Control and Prevention, the American centre responsible for the prevention and control of illnesses.

Pharmaceutical industry sites generally offer different information for three categories of users (doctors, patients, journalists).

Patients' Associations sites are generally reliable, easy to use and often equipped with tools that allow patients to talk to each other.

Wide-ranging sites, although not active in the healthcare world, give information relative to health. This is a very broad category of sites offering different types of information: "encyclopaedic" (through medical dictionaries and health manuals), scientific by giving appropriate "lists" of data found in medical journals, "legal" offering useful information for legal questions linked to health.

With regards to the direction of the information supplied on medical sites, the Censis-Forum RBM 2005 investigation offers the following outline:

1) Updated information on healthcare issues 76 %
With reference to authoritative sources 72 %
With the chance of further study and support 62 %
2) References and codes of conduct for the protection of privacy 19 %
3) Business marketing in the health/healthcare sector 18 %
4) Initiatives of social interest 13 %
5) Explicit references to ethical implications and issues 8 %
6) Offer of on-line psychological advice 5%

With regards to the "consumption" of information, in Italy (Censis-Eurisko 2005 data) 26% of research carried out on the web involves issues linked to health and well-being, and this could suggest a slightly lower percentage than the European trend, estimated at 35% of users by the Health On The Net Foundation (2003). This last research also highlights that these users search especially for information and more in depth studies on illnesses and, even though they are not doctors, they most frequently use specialist sites (70%).

64% of the content of the information, for what can be derived from Censis data, regards research and Congresses, 43% information on specific pathologies, 42% communications between doctors or patients, 28% pharmacotherapy, 25% prevention.

In Italy, the Institute for Pharmacological Research "Mario Negri", within the research project "*PartecipaSalute - Costruire un'alleanza strategica tra associazioni di pazienti&cittadini e comunità medico scientifica*" – tackled, on the project's site (http://www.partecipasalute.it), the issue of the quality of the sites dealing with health issues. In particular, on the site, on the basis of some assessment tools already existing in literature, the reader is presented with a self-assessment grid to establish the quality, accuracy and updating of the information on the net (http://www.partecipasalute.it/informati-bene/misura-siti.php). The grid is regularly applied to medical and health sites, selected and collected under the heading "Good site of the week".

The 10 questions on which "Misurasiti" is based are:

1. Are the authors of the content named?
2. Are the sources of the information indicated?
3. Is there a date for the updating of the content?
4. Is it clear who the site "belongs" to?
5. Are eventual sponsors mentioned?
6. How is advertising presented? Is it separated from the rest of the content?
7. Are eventual conflicts of interest declared?

8. Are the site's objectives clear?
9. Does the site give details on other sources of information?
10. Does the site help the user to make in choices and decisions regarding his/her health?

On the basis of previous experience, within the research project "Internet as a tool of research and information on chronic pain in the cancer patient" there is an adaptation of the methods and tools of "Evidence Based Medicine" to the resources available on the internet on the issue of chronic pain in cancer patients. The project is taking shape through a collection of qualitative-quantitative data to apply to internet resources and to therefore assess the results obtained.

The CENSIS-FORUM R.B.M. (2005) investigation also proposes four parameters that could be used to build an assessment "model" for the quality of the site, with relative overall point index, that is:

- Reliability of information.
- Ease of use (the ease with which the users gain the required information).
- Variety of the content presented on the website.
- Genericity (level of the answers).

In the Italian situation, as examined by this investigation and on the basis of an index from 0 to 20, we would have the following votes:

SITE CLASSIFICATION	**PARAMETERS**			
	RELIABILITY	**EASE OF USE**	**VARIETY OF CONTENT**	**GENERICITY**
ISTITUTIONAL	11,6	11,4	9,1	5,3
PHARMACEUTICAL INDUSTRY	10,0	9,6	5.5	5,6
PATIENTS' ASSOCIATIONS	12,0	9,4	9,8	4,2
WIDE-RANGING	10,4	9,5	9,0	6,3
OVERALL AVERAGE INDEX	11,1	10,0	8,5	5,3

The investigation allowed the verification of: a) a considerable variety of content; b) the good quality, in general, of medical-healthcare information on Italian websites, from the point of view of their reliability, and of the ease of use; c) the reduced variety that can be found on the sites managed by the industry due to the higher specialisation of the content; d) the higher "genericity" of the

information given by generalist sites and the lower “genericity” of the information given by patients’ associations (especially for specific pathologies).

Certainly, the values of the genericity index (around 5-6 out of 20) highlight the fact that there still are a certain number of sites that do not give very in depth information, without any reference to authoritative sources, which do not explain their title and aims or guarantee privacy.

The investigation has also verified that the certification given by the Health On The Net Foundation is declared only on 7.4% of the sites in the Countries taken into account, whilst only the 19.5% of them explain their privacy policy to the user and guarantee that the data relative to research or issues explored by the users will not be disseminated (76.8%).

2.6 *Conclusions*

Waiting to develop wider bioethical reflections at the end of this discussion, it seems appropriate to reach a first conclusion: the negative implication of the abovementioned genericity is even worse if it appears on sites that also cover pathology, as the presence of unreliable or not updated information for those users who are not doctors can worsen the user’s emotive state, who does not find what he/she needs in the doctor-patient communication and can turn to wrong or inadequate behaviours.

There are here two points of considerable bioethical relevance: the need to guarantee the quality of information the users can access and the need to train them so that they can recognise the most authoritative sources. This would avoid the risk of the uncontrolled dissemination of vague knowledge confusing (or, worse, harming) the users, especially if they are not doctors. On the portal of the Partecipasalute project (http://partecipasalute.it) there are for example links that help surfing, giving, at the same time, useful tools to understand the typology and quality of the sites.

We must not underestimate the risk that overturning, also chronologically, the doctor-patient relationship, exposes those looking for information on their own or a loved one’s state of health, to a serious emotive involvement, both for the difficulty of giving the information its proper importance, as well as for not being able to share – as is the case in a good doctor-patient relationship – his/her anxiety with someone who can keep it in check.

CHAPTER III

INFORMATION TECHNOLOGY AND INTERNET AS TRAINING TOOLS IN MEDICINE

This commitment of ICT to give information from afar is, maybe, the best known one in the medical sector, but it also is not devoid of problems.

In particular, we will focus on the use of the INTERNET, which represents the way in which a considerable amount of the information used in the programmes of medical training is shared.

Some evaluations can be – briefly – summarised as follows:

3.1 *Teaching materials*

A debate that is increasingly intense, at least in some Countries (e.g. the USA), concerns the costs, the intellectual ownership, the preservation and the long-term validity of the teaching material supplied in informatics (BUTLER CAMPBELL, 2002; NAZIONAL ACC. PRESS, 2000; MCROY and MAUX, 2002; LINDBERG, 2002).

The costs seem constantly growing, and various measures have been taken – by some journals and organisations producing IT materials – to make the various products more accessible to the members of the same organisations (e.g., in the case under examination the IMIA, namely, the International Medical Informatics Association), including amongst the facilitations the purchase of software for doctors and students, the access to "guidelines" for IT research, etc.

With regards to intellectual ownership, generally we think that once the author publishes the work on a scientific journal, even if on-line, and gives up the copyright requested by the editor, the work can be reproduced by third parties on condition that it is not used for profit and commercialisation, citing, in any case, its origin. We will later focus on some legal aspects regarding this issue.

3.2 *The learning of basic facts*

In the learning of basic facts in formative curricula based on the discipline's system, medical informatics teaching has by now a considerable importance, next to "frontal" or magisterial teaching, in almost all the Faculties and degree/diploma Courses. Appropriately organised (and eventually managed by a "tutor" for the research of the sources) it can broaden the angle of the information and raise more cognitive interest (curiosity) from the pupil, facilitate the guided link between different topics, etc., but a great part of its success depends on the quality of the programmes on offer (HADAD and GAGLIARDI, 1998; LINDBERG and HUMPHREYS B., 1998, etc.). Very useful is the following verification, an interactive discussion, in small groups, with the "tutor", of the experience had and the knowledge achieved.

In this type of teaching, generally the student – at least if belonging to the most recent generations – uses means (internet, videos, etc) he already knows how to use.

3.3 *"Problem solving" methods*

In learning with the "problem based learning" criterion, based on the identification of all of the cultural, social, professional, technical etc. aspects linked to the solution of specific medical problems usually found in the profession (on issues decided by the teaching staff, but left to the choice of the students to a certain extent), the recourse to information technology seems even more independent and distinctive compared to the traditional method: reading, comprehension, mnemonic learning, etc, whilst the teaching work of support, assessment, criticism etc. appears more intense and structured.

In this type of learning, the use of the means is more elaborate, asking the students to perfect also the use of the method through stimulations, self-assessments, etc. (HASMAN and BOSHUIZEN, 2001, etc).

3.4 *Creating the programmes*

All these developments, in any case, whether they have a teaching-learning content or whether they are based on the "problem-based solving" criterion, require a considerable effort in organising and updating the IT programmes available in the teaching centre and the teachers' and students' full knowledge of how to use them, which is tested in certain centres (see for example DORMAN et al. 2003, FOSTER and DORMAN, 2003, etc.).

Positive experiences in the use of IT in medical education have been highlighted also by Italian schools (DE SALVO et al., 1991; MERIGLIANO and DA LIO, 1991; VALDENASSI et al., 1991; MOLINO, 1990; MERIGLIANO, 1987; ALBANO, 1987; CARTABELLOTTA and NOTARBARTOLO, 1997); and others. The interactive relationship with the student-user, possible with IT methods, facilitates learning, the methodology of clinical reasoning; alternative diagnosis; self-assessment. A. ROMANINI (1987) stresses, in particular, not only the breadth of the applications, but also the need for the teacher to be prepared to elaborate and manage techniques of information technology in his/her subject.

MARCHISIO and CURTONI (1999) assess the chances to "train" the students to the appropriate research of information (also for their following permanent learning) offered by the use of the internet. The increasingly widespread dissemination of the tool and the growing network of sites regarding medicine cannot be – in the end – ignored any longer, but the student must learn to find the sources and evaluate their reliability (that is, how serious and scientific they are).

3.5 Teachers' training and behaviour

The development and use of informatics in teaching also create the need to change the training and behaviour of the teacher (see in general P. C. RIVOLTELLA, 2002).

These changes could be identified as follows:

- A re-definition of the role (less hierarchical, less "frontal" and more "lateral" towards the student);
- An increase of the workload (more structured organisation of the work, preparation of on-line material, management of communication tools – mailing, forum, chat);
- The need, in view of the previous point, to build and manage teaching teams with diversified responsibilities (tutoring, problem solving, more in depth study of the subject);
- Moving the core of education from the teaching to the student's learning;
- The progressive increase of a culture of monitoring and assessment as the usual habitus of teaching rather than as an isolated, summarising final moment.

We in any case stress the importance of being competent – as a teacher – in the various actions that identify the teaching process in its various places (classroom, web, video-conference, on-line course, etc.), to better use the teaching potential.

3.6 Verification of the literature available in the profession exercised

In some Countries, electronic communication in the profession has had a considerable development, which is based on the immediate verification of the literature available in order to reach the best clinical decision possible in certain circumstances, in the patient's interest. On the other hand, on the internet there are a variety of sources of this kind (often accessible for free) like bibliographic databases (for example Medline - http://www.pubmed.gov), registers of clinical trials (for example Clinicaltrials.gov - http://www.clinicaltrials.gov), guidelines databases (for example the National Guidelines Programme - http://www.pnlg.it), the Cochrane Library (http://www.thecochranelibrary.com), and the articles published in international biomedical journals (http://www.pubmedcentral.com). This could be called an "immediate teaching" tool that the GP can use to bring him/herself up to date, when needed.

The increasingly widespread use of computers also in GP surgeries (for example in the United Kingdom, in 2000, 99% of General Practitioners – GPs – had computers, used by 85% of GPs in prescriptions) makes the use of this criterion possible, which however – in the study by ROBINSON et al., 2003 – seems still limited, despite the fact that it could be the opportunity for the doctor to learn and improve whilst working. Even though in most of the current clinical activity medical judgement is based on the "memorisation" of that illness and on the "experience" of the observed cases, which lead him/her to "facilitated" diagnostic and therapeutic conclusions, there are circumstances in which the doctor feels the need to compare his/her knowledge with the experience of others and with the wider knowledge of the scientific literature available. For

this reason, the quick availability, in the place of work, of this information can have its optimal realisation through informatics.

3.7 Training for IT operators in the medical sector

With regards to the creation of specific roles of IT operators in the medical sector, various suggestions have been made in connection with the increasingly specialist development of technologies in particular subject areas (HOFFMAN and ASCH, 2001, COVVEY et al., 2001, etc.) or with the needs to use calculators in the IT support to nursing (STAGGERS et al., 2001) or of programmes for healthcare IT operators at the administrative or executive level, etc.) (YASNOFF et al., 2001).

According to DOUGLAS and HOVENGA (2002) there still is no general consensus on the level of competence needed for each of these "roles" in the IT profession in the medical-healthcare sector, but there is agreement on the usefulness of having operators with this kind of training.

3.8 Conclusions: the generalised need for IT training for healthcare personnel

It seems clear that the issue of training is – today – of major interest. We can share the two main avenues of development stated by HOUX (2002):

- Training programmes in medical and healthcare informatics for all health operators, seen as users of information technology as part of school teaching programmes. An appropriate "modulation" of the complexity and the objectives seems necessary.
- Specialist programmes for specialist IT operators, for a personal professional "career" in Universities, Research institutes, hospitals, industries in this sector, etc., as "producers" of new applications and/or hardware managers.

In conclusion, we have seen the doctors' growing interest towards the use of the internet both as an instrument of professional training, competitive [for reasons of ease and cost also in comparison to the conventional professional training meetings: WIECHA (2004)], as well as for a generic monitoring of patients' homecare.

However, this still meets with considerable difficulties regarding its acceptability by patients and technology providers (ATACK et al., 2004), but also for the still insufficient medical training in the use of the web as part of the doctor's university studies (JONES and M. CLARKE (2004); WIECHA (2004). This must be increased not only from the point of view of the dissemination and correct technical use, but also from a deontological perspective of ethical responsibility.

CHAPTER IV

OUTLINES OF INTERNATIONAL LAWS

4.1 *Introduction: a general look at the legal problems raised by the dissemination of the internet*

The dissemination of the internet has raised a series of legal problems which have caused an in depth and still current debate. Some of these problems, in truth, are not specific to the Internet, even though the dissemination of the "Web of webs" strengthened them and forced the attention of the wider public on them.

This can be said, first of all, of the introduction of IT communication in private and commercial law (particularly with regards to the electronic document and the digital signature) and for the issues relative to the so-called "distance contracts" (perfecting the contract or the consumer's protection, for example, even though on the Web the strategies of commercial communication can be much more invasive than traditional ones), as they are mostly events that precede the arrival of the internet.

The penal profiles on the internet are similarly devoid of truly new elements, as they are essentially linked to the problem of repressing, using traditional means, behaviours characterised by the extreme difficulty of location. These are behaviours belonging to two large categories, according to whether the IT programme is used to commit common crimes or is, in itself, the object of transgression. A hybrid and very widespread type of transgression is illegal duplication (the so-called software piracy), however, amongst them, more worrying are the behaviours leading to the dissemination on the Web of illicit images, especially regarding child pornography. In this field, as also in the wider context of the protection of privacy for internet users, the need to resolve, at its origin, the conflict between legal rights that are in some ways in contrast, is keenly felt: the protection of the sexual modesty and the freedom of information, in the first case *privacy* and in the second freedom of communication.

With regards to the fields under consideration, therefore, it is possible to state that the conflict between different needs of protection has highlighted the true nature of the internet, that is, a simple but effective sounding board for ideas, principles and solutions found in the real world.

More new elements are offered, instead, by the field of intellectual property, with particular reference to the registration of the so-called domain names and the counterfeit use of the company's distinctive logo in domain names. This aspect, truly peculiar of the internet, highlights the fundamental problem of creating Web regulations that are in line with its nature of international means of communication, identifying, for this purpose, adequate methods and tools. And this is the field in which the law becomes more uncertain, taking into account the relative unfamiliarity of the internet with some traditional legal principles and rules and, in particular, the aversion shown by the same operators and users towards any form of regulation of Web applications, both internationally and in Italian legislation. This has led to a growing number of technical regulations and elaborate standard programmes in

cyberspace, accepted and used consensually by internet users, for the main purpose of ensuring the interconnection and universal interoperability of the Web, that is: "*in extreme synthesis – the link between different IT and/or telecommunication systems according to particular technical methodologies, in order to allow the elaboration and transmission of data and information*".

In this chapter, the NBC intended to inform the reader about the main international and European legal documents, recalling the need for a correct management of the internet/processing of sensitive data/health relationship.

The issue of buying medicines for human consumption through the internet will then be given particular mention, as it highlights some critical aspects that are truly peculiar of the application of the internet to the medical sector.

The development of new technologies and the potential shown by their use in medicine and healthcare, first of all highlighted the need to ensure adequate legal protection to healthcare information, answered by the measures adopted internationally by the World Health Organisation, by the Council of Europe and by the European Community. These are measures that identify some fundamental principles for the collection and processing of personal data, proposing to find the balancing point between contrasting subjective positions, and defining the transformation of the main instrument for the protection of personal information from a generic obligation to abstain from intrusive behaviours in the personal sphere to a much more penetrating power of control on the flow of information that is continually generated. Regarding this, it is important to stress that the need to have more incisive forms of protection is mostly felt with regards to personal information intimately connected with individual, family and inherited biological identity, the handling of which can be particularly harmful to fundamental rights: to the consolidated category of the so-called sensitive data, concerning the state of health, racial or ethnic origin, political opinions, religious beliefs and sexual preferences, we have to add the new category of "extremely sensitive data" which is, in particular, genetic information. However, the same international regulations allow the distinction, with regards to positive discipline, between "generic data" and "medical data", and it is at the second category of data that the following considerations are aimed.

4.2 *The protection of medical data with international legal tools*

a) *Universal International Legislation*

With regards to this, we must highlight, from the point of view of universal international legislation, the **"eHealth" Resolution** adopted by the 58th World Assembly of the World Health Organisation, on the 16th-25th of May 2005[1], in which the WHO asked the member states to create centres of excellence for the development of telemedicine practices, to consider the opportunity to create and develop national electronic systems for public healthcare and to improve, by incrementing the availability of information, the ability to monitor and control pathologies and healthcare emergencies. The principles inspiring this resolution were already the object of the **eHealth Code of Ethics**, approved on the 18th of May 2000 by an international association of healthcare operators in

[1] Cf. Resolution WHA58.28.

telemedicine (Internet Healthcare Coalition) within the eHealth Ethics Initiative, carried out with the support of the World Health Organisation. This document stated that the use of the internet for reasons concerning the state of health should not prejudice the principles safeguarding needs of general interest, like transparency and privacy. From the point of view of the protection of privacy in particular, the document recognised the right of the individual to be adequately informed in order to be able to be in control of the processing of his/her personal information, as well as the possibility to exercise the right to correct, integrate and delete his/her healthcare information. Finally, the document hoped for the encryption of all healthcare data used, as well as the traceability of the use of the same data.

More recently, another body operating internationally, the International Working Group on Data Protection in Telecommunications (IWGDPT)[2], has created a working document, the **Draft Working Paper on Electronic Health Record**, on the processing of healthcare data by making electronic clinical records available *on-line*.[3] The document presents the first experiences realised in some legislations in order to link, nationally, the individual healthcare structures (public and/or private), also extending the access to healthcare information to all professional operators. However, as well as the advantages of these technological solutions, in particular due to the lower cost of processing healthcare information, the integral accessibility of the data for the patient's advantage, and the overall efficiency of the healthcare system, the document highlights also the risks relative to the use of the internet, especially in the framework of the protection of privacy of the healthcare data processed and professional secrecy. In particular, the document highlights that one of the first limitations to the functioning of *on-line* clinical records, comes from the need to have the consent of the interested party every time an individual different from his/her GP wants to access the patient's healthcare information.

b) *European regional law*

As to European regional laws, the **Oviedo Convention** recognises inArt. 10 the individual right to the protection of private life in relation to information about his or her state of health, as well as the right to know or ignore said information[4]. This directive is the synthesis of the activity carried out by the Council of Europe about to the protection of privacy when processing healthcare data, protection that finds its general basis in Art. 8 of the 1950's European Convention for the Protection of Human Rights and Fundamental Freedoms. In this context, we must first of all recall that the Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data, in force since the 1st of October 1985[5], which gives special protection to

[2] This organisation, created in 1983 within the International Conference of Data Protection and Privacy Commissioners, groups together the representatives of the national authorities for personal data protection, of the international organisations overseeing the issue of privacy and of the scientists and experts in privacy and telecommunications.

[3] This document was approved during the 38th meeting in Berlin on the 6th-7th September 2005.

[4] The Convention however accepts, exceptionally and in the exclusive interest of the patient, that national legislations can restrict access to the exercise of those rights (Art. 10, paragraph 3).

[5] The convention was adopted by the Committee of Ministers in the Council of Europe on the 17th of December 1980 and it was open to the signature of the member states on the 28th of January 1981 in Strasburg. Italy ratified the Convention with Law No. 98 of the 21st of February 1989 (in Gazzetta Ufficiale, Ordinary Supplement, number 66 of the 20th of March 1989).

sensitive data, in consideration of the discriminatory use of them (Art. 6), and authorises the processing of such data only with appropriate safeguards given by domestic regulations[6]. The agreement also sanctions the right to access personal data, which allows the interested party to check the accuracy, level of update and pertinence of the information collected, in line with the declared purposes (Art. 8).

In this context we must also recall the **Recommendations of the Committee of Ministers of the Council of Europe with regards to the processing of healthcare data**. First of all, we highlight *Recommendation R(97) 5, of the 13th of February 1997, relative to the automated processing of healthcare data* (which substituted Recommendation R(81) 1, of the 23rd of January 1981)[7]. This Recommendation establishes the rules on the collection and automated processing of all medical data; it determines the principles to safeguard genetic data and it contains definitions allowing the distinction, for the purposes of positive discipline, between medical data and genetic data. In particular, on the basis of the Recommendation, we intend as medical data all personal data regarding the health of the individual, including data with a clear and close link with health, and as genetic data, instead, all data, of any kind, referring to the hereditary characteristics of an individual or regarding the genetic inheritance of a group of individuals[8].

More recently, *Recommendation R(2004) 17 relative to the impact of information technology on the protection of health – "The patient and the Internet"* was adopted. This Recommendation recognises the citizens' fundamental right to access information on healthcare issues; asks for the review of policies, laws, and general practice limiting the patient's access to information disseminated through the internet or other means of communication; asks for the development at the international level of common approaches for the optimal use of the internet by patients and citizens, promoting criteria for the transnational exchange of information between

[6] See, for Italy, Legislative Decree number 196 of the 30th of June 2003 "Code on the Protection of Personal Data" (in *Gazzetta Ufficiale*, No. 174 of the 29th of July 2003, *Ordinary Supplement* number 123), as well as the authorisations of the Guarantor for the Protection of Personal Data relative to the handling of data revealing the state of health and sex life, adopted since November 1997 (finally, see authorisation number 2/2004 of the 30th of June 2004, in *Gazzetta Ufficiale* number 190 of the 14th of August 2004). Exceptions to the general tone of the Convention are presented in Art. 9, referring to the necessary measures, in a democratic society, to ensure the prevalence of the relevant public interests, the safeguard of the interested party and the protection of the rights and freedoms of others.

[7] We recollect, with regards to this, that this Recommendation discusses the processing of healthcare data, with particular reference to data found in medical registers, defining "medical data" any data that includes information relative to the psychological and physical health of an individual in the past, present or future.

[8] The cited document can be found in Textes du Conseil de l'Europe en matiére de bioéthique, Strasbourg, 2005. It is important to remember, in addition, that the activity of the Council of Europe with regards to the protection of privacy in the automated processing of personal data extends, amongst others, to the insurance sector [Recommendation R(2002) 9, on the protection of personal data collected and handled for insurance purposes], the internet [Recommendation R(99) 5 of the 23rd of February 1999, including the guidelines for the protection of people with regards to the collection and processing of personal data in information], statistical research [Recommendation R(97) 18, of the 30th of September 1997], social security [Recommendation R(86) 1, of the 23rd of January 1986], public safety [Recommendation R(87) 15, of the 15th of September 1987], work [Recommendation R(89) 2, of the 18th of January 1989] and penal justice [Recommendation R(92) 1, of the 10th of February 1992].

patients and doctors; and it hopes for the resolution of conflicts, real and potential, between the legislation on data protection and the patients' freedom of access to information beyond national boundaries. With regards to the guidelines attached to the Recommendation, the document by the Council of Europe states the principle according to which confidentiality measures must be introduced to guarantee the patient's right to self-determination, anticipating that the legal basis for the processing can be found in the consent, the contract or the law; it also recommends that the patient's identification is not required in order to access healthcare information on the internet, unless the individual's identity is not prevented, for example, from accessing a healthcare service, for medical-legal or financial reasons; finally, in order to guarantee the users' confidentiality and safety, it recommends the member states to promote the dissemination of digital signatures and digital identities and it asks for the institution of authorities and committees responsible for the elaboration of specific privacy and safety criteria in member states.

4.3 *The protection of medical data in European Community laws*

The legal protection of information regarding the state of health is ensured, in European Community laws, by the **Directive of the European Parliament and Council number 95/46 of the 24th of October 1995, relative to the protection of individuals with regard to the processing of personal data and on the free movement of such data[9].**

This directive completes and integrates the principles of the Convention of the Council of Europe, recalled above, reinforcing significantly the protection given by the Convention to the interested parties, as well as in a different legislation. In fact, whilst international agreements state the principle of the free movement of personal data and recognise to the individual a simple power of control on the accurate automated processing of these data, legitimate in itself, the directive attributes to the interested parties the right to authorise or not the

[9] In Guce number L281 of the 23rd of November 1995, p. 31, integrated by the Commission's decision number 2002/16, of the 27th of December 2001, relative to the typical contractual clauses for the transferral of personal data to those responsible for the processing resident in other countries, according to directive 95/46 (in Guce number L6 of the 10th of January 2002, p. 52). We recall that other acts by the European Community regulate specific aspects of the protection of privacy in relation to the processing of personal data, like regulation number 45/2001 of the 18th of December 2000 of the European Parliament and of the Council, on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (in Guce number L8 of the 12th of January 2001, p.1), which was put into force by Council deliberation number 2000/31, of the 8th of June 2000, on certain legal aspects of information society services, in particular electronic commerce, in the internal market: the so-called directive on electronic commerce (in Guce number L178 of the 17th of July 2000, p. 1), and the directive of the European Parliament and of the Council number 97/66, concerning the processing of personal data and the protection of privacy in the telecommunications sector (in Guce number L24 of the 30th of January 1998, p. 1), abrogated and substituted by the directive of the European Parliament and of the Council number 2002/58, of the 12th of July 2002, concerning the processing of personal data and the protection of privacy in the electronic communications sector (in Guce number L201 of the 31st of July 2002, p. 1).

processing itself (not only when automated), the legitimacy of which is in this way subordinated to the guarantees sanctioned by European Community law[10].

In this context, the directive establishes the general principle of the unequivocal consent of the data subject to the processing of personal data, intended as manifestation of free, specific and informed will (articles 2 and 7). In particular, for what concerns the processing of the so-called sensitive data (amongst which, as we have said, we can include those relative to the state of health), the directive requires the explicit consent of the data subjects (Art. 8). Dispensations to the general legitimate management of the processing of information are anticipated for cases, clearly listed in the directive, in which the interest towards the movement of data is believed to be prevalent (for prevention, medical diagnostic and administration of care), on condition that the processing of data is carried out by a healthcare operator sworn to professional secrecy (Art. 8, paragraph 2 and 3)[11].

In matters of electronic healthcare we also recall, with regards to political trends, the **Ministerial Declaration of the Member States of the European Union, of the Acceding and Associated Countries, adopted in the framework of the e-Health 2003 Conference.** This Declaration, in defining e-Health as the use of modern information and communication technologies to meet the needs of citizens, patients, healthcare professionals and healthcare providers, as well as policy makers, recognises that efficient national planning and evaluation of health policies require speedy, accurate and comprehensive exchange of data between member states with regards to communicating relevant best practices, and recommends that the accessibility to appropriate healthcare information is guaranteed by the use of secure and shared e-Health applications[12]. In this perspective, the project eHealth Impact, funded by the European Commission, developed a large database concerning 100 case studies relative to the application of procedures to supply healthcare services through the use of telematic networks[13].

In the perspective of the adoption of a specific discipline in the European Community with regards to electronic healthcare, we also find the Communication of the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Regional Committees on **"Electronic Healthcare – making healthcare better for European citizens: an action plan for a European e-Health Area"** [document COM(2004) 356 def.], adopted on the 30th of April 2004. The Action plan indicates, amongst the concrete measures for the creation of a "European electronic healthcare area", the use of information and telematics technologies for prescriptions, medical records, patient identification and health cards, as

[10] Note that the field of material applications for the directive is broader than that of the Convention of the Council of Europe, because the European Community act concerns public and private archives both manual and automated.

[11] For a comment on the European Community directive see also L. Boulanger et al., La protection des données à caractère personnel en droit communautaire, in Journal Trimestrielle de Droit Européen, 1997, n. 40, p., 121 and following., n. 41, p. 145 and following, n. 42, p. 173 and following, and Y. Callens, The Privacy Directive and the Use of Medical Data for Research Purposes, in European Journal of Health Law, 1997, p. 309 and following.

[12] Note that eHealth is part of the objectives of the 2005 eEurope Action Plan, adopted with the Communication of the Commission to the European Council, the European Parliament, the European Economic and Social Committee and the Regional Committees, of the 28th of May 2002, "eEurope".

[13] Cf. site: www.ehealth-impact.org.

well as the dissemination of broadband networks destined to manage healthcare systems. The aim is to agree, before the end of 2006, uniform methods among the member states for the identification of patients and to define norms for the interoperability of clinical data and on-line medical records.

We must finally recall the opinion adopted by the European Group on Ethics in Science and New Technologies (EGE), relative to **"Ethical issues of healthcare in the information society"** of the 30th of July 1999, which states the principles of the patient's consent to the collection and processing of medical data, to the confidentiality of healthcare information, even after the death of the data subject, to professional secrecy. The opinion of the EGE also requires the creation of a system of accreditation for those who carry out the processing of medical data in healthcare, due to the sensitivity of these operations and the peculiar responsibilities of the individuals working in the medical-healthcare field, and it excludes direct access by third parties, like employers or insurance companies, to the medical information of the employee or the insured: in this perspective, setting up suitable safety mechanisms, like for example encrypting information, or the adoption of close circuit systems, becomes of significant importance. The document also requires that the information found in electronic healthcare paperwork is only that for which the interested party has given his/her consent and that he/she can restrict access to some of the information contained in it and finally hopes for the adoption of some regulations in the European Community, like a directive on the protection of medical data and a Recommendation including a Charter for the European Patient, introducing a specific discipline with regards to the issues considered[14].

4.4 Medicines and the Internet

An issue of particular importance is that relative to the purchase of medicines for human consumption on-line, thanks to the electronic network (so called virtual pharmacies).

The main legal problems linked or due to this habit, quickly spreading in the United States of America as well as Europe, can be found first of all in the difficulty for consumers to verify if the medicine purchased on-line has, both in its country of origin (where it was made) and in the country of destination (where the consumer resides), the authorisation for its introduction on the market, which generally is aimed at ensuring the conformity of the medicine to the criteria of quality, safety and efficacy required by law. Specific relevance is given, from the point of view indicated, to the problems relative to the qualification of the products marketed on-line (which in some legislations can be included in the category of medicines for human consumption, whilst others can classify them, for example, "food supplements" or "nutritional products") and to the violation of eventual, further requirements mentioned in the appropriate regulation, both in the country of origin and in the country of destination (mainly the obligation to have a doctor's prescription for the delivery of the drugs). The peculiar characteristics of the internet, and in particular the absence of direct contact between the doctor (or the pharmacist) and the patient, can also increase the risk of undesirable or adverse effects deriving

[14] Cf. the site: http://www.eu.int/comm/european_group_ethics/index_en.htm.

from the interaction between medicines, from taking medicines incorrectly or different from those necessary to treat certain pathologies. Finally, particular risks can be posed with regards to the state of preservation of the medicines sold and ordered on-line, as well as the eventual confusion (rectius, counterfeiting) of the medicines on sale, which could contain active ingredients or components different from those required or completely ineffective[15].

The problems described have been tackled in some countries at the national level, both from a legislative and legal perspective, but it is on the results achieved by the regulations of the European Community that we will focus in the following pages, in consideration of the characteristics of the internet and, particularly, of the **transnationality of *on-line* commercial transactions.** With regards to this, it is appropriate to highlight immediately that, in the legislation under consideration, the evaluation of the problem discussed has been carried out in line with the objective of favouring as much as possible the liberalisation of business exchanges, a fundamental aim of the process of integration in the European Community.

To summarise the regulations of the European Community applicable to the sale, supply and advertising of medicines, we must first of all recall the **Directive of the European Parliament and of the Council number 2001/83 of the 6th of November 2001, on the so-called Community Code relating to medicinal products for human use[16].** This directive, confirming the discipline introduced by the better known Council directive number 65/65 of the 26th of January 1965[17], establishes that no medicine can be put on the market without the "authorisation… by the competent (national) authorities… in accordance with this Directive or… in accordance with Regulation number 2309/93" (cf. Art. 6, number 1)[18]. With regards to the supply of medicines, the discipline in the European Community code, confirming what anticipated by Council Directive number 92/26 of the 31st of March 1992[19], establishes the conditions according to which the medicines authorised to be put on the market are subject to a compulsory doctor's prescription, like medicines that "are likely to present a danger either directly or indirectly, even when used correctly, if utilised without

[15] It is enough to access some internet sites to realise the wide range of ways to buy *on-line* offered by virtual "pharmacies", even for medicines subject to a doctor's prescription: some sites allow the consumer to "self-prescribe" medicines, "clicking" certain options or filling *on-line* forms, whilst others simply require financial guarantees (like the credit card number) for purchasing any medicine.

[16] In *Guce* number L311 of the 28th of November 2001, p. 67. The directive has not been adopted in Italy yet.

[17] Directive number 65/65, repealed and substituted by the 2001 code, on the approximation of provisions laid down by law, regulation or administrative action of the member states relating to medicinal products (in *Guce* number L22 of the 9th of February 1965, p.369/65).

[18] We recall that the Council regulation number 2309/93 of the 22nd of July 1993, relative to European Community procedures for the authorisation and control of medicines (in *Guce* number L214 of the 24th of August 1993, p. 1), was modified by the Commission regulation number 649/1998 of the 23rd of March 1998 (in *Guce* number L88 of the 24th of March 1998, p. 7). It is significant to highlight that the European Community procedure established with regulation number 2309/93 does not prejudice the competences of the member states with regards to fixing the price of medicines, or those relative to the inclusion of medicines in the application field of the national systems of illness insurance on the basis of health, economic and social considerations.

[19] Repealed and substituted by the 2001 code, directive number 92/96 on the classification of the supply of medicines for human use (in *Guce* number L113 of the 30th of April 1992, p.5).

medical supervision" (cf. Art. 71)[20]. With regards, instead, to advertising medicines, the European Community code follows the discipline introduces by Council directive number 92/28, also repealed and substituted by the 2001 act[21]. The current regulation makes it compulsory for member states to prohibit any advertising of medicinal product in respect of which a marketing authorisation has not been granted (Art. 87); member states shall also prohibit advertising "to the general public" of medicinal products which are available on medical prescription only (Art. 88)[22].

Other relevant regulations about the on-line sale of medicines are those found in article 14 of the **Directive of the European Parliament and of the Council number 97/7 of the 20th of May 1997, on the protection of consumers in respect of distance contracts[23],** which allows member states to ban "in the general interest, the marketing on its territory of certain goods or services, particularly medicinal products", and Art. 14 of the directive of the European Parliament and Council number 97/36 of the 30th of June 1997 on the so-called teleshopping, which expressly forbids the "telesales of medicines subject to authorisation to be put on the market…, as well as the telesales of medical treatments"[24].

We must mention the **Directive of the European Parliament and Council number 2000/31 of the 8th of June 2000, "on certain legal aspects of information society services, in particular electronic commerce, in the internal market (directive on electronic commerce").** This directive is clearly intended to favour the development of electronic commerce, leaving however untouched the level of protection for public healthcare and consumers that is guaranteed by some regulations of European Community law, like those on the advertising of medicines for human use (considering 11)[25]. It is important

[20] According to the directive mentioned, the compulsory medical prescription extends to medicines often used and, largely, correctly used, if they present a direct or indirect danger to human health, if those medicines contain substances or preparations, the activity and/or adverse reactions of which require further investigation, without exceptions, if those medicines are prescribed by a doctor to be administered parenterally.

[21] In *Guce* number L113, *cit.*, p. 13. Note that directive number 92/28, on the advertising of medicinal products for human use, did not regulate the labelling and the instructions for use of medicines for human consumption: these aspects were the object of the regulation introduced by Council directive number 92/27 (in *Guce* number L113, *cit.,* p. 8), also repealed and substituted by the 2001 European Community code.

[22] Part of the prohibition mentioned includes also advertising medicines containing psychotropics or narcotics, as well the mention of the following in the therapeutic instructions: tuberculosis; sexually transmitted diseases; other serious infective illnesses, cancer and other tumors; chronic insomnia; diabetes and other metabolic illnesses (cf. Art. 888, number 2, subsection 2).

[23] In *Guce* number L144 of the 4th of June 1997, p. 19. Directive No. 97/7 was amended and integrated a variety of times, lastly with the directive of the European Parliament and of the Council No. 2005/29 of the 11th of May 2005 (in *Guce* number L149 of the 11th of June 2005, p. 22). The act was adopted in Italy with Legislative Decree number 185 of the 22nd of May 1999, published in the *Gazzetta Ufficiale* number 143 of the 21st of June 1999.

[24] Directive No. 97/36 is aimed at amending directive No.89/552 of the Council relative to the coordination of certain provisions laid down by law, regulation or and administrative action in member states concerning the pursuit of television broadcasting activities (in *Guce* number L 202 of the 30th of July 1997, p. 60). The Act was adopted in Italy with Law No.223 of the 6th of August 1990 and with Law No. 122 of the 30th of April 1998.

[25] In Guce number L.178 of the 17th of July 2000, p. 1. The directive was adopted in Italy with Legislative Decree No. 70 of the 9th of April 2003, published in the *Gazzetta Ufficiale* No. 87 of the 14th of April 2003, Ordinary Supplement number 61. For a comment about European Community regulations applicable to the phenomenon of electronic commerce, see L. Marini,

however to clarify that the field regulated by directive number 2000/31 only includes the requirements for on-line activities (like on-line information, on-line advertising, on-line sales and on-line contracts) and it does not include the legal requirements established by member states with regards to goods (like regulations about security, labelling obligations or regulations concerning product responsibility) or to the delivery and transport of the goods themselves, "including the distribution of medicinal products" (considering 21).

As it is easy to observe, the directive on electronic commerce has a peculiar importance in this matter, even though the predictions found in the preamble to the act do not seem to be in line with the need to ensure, in the European Community, an ordered and safe development of the activity of selling medicines on-line. The European Parliament seems to have realised this, and since 2000 asked the Commission about the risk that the global nature of the internet allows the advertising and sale of medicines to European consumers by operators working from other countries, in this way, getting around the guaranteed protection of European Community regulations[26].

The European Community Judiciary Court also passed judgement on this issue, and, with the sentence of the 11th of December 2003, in the Case **Deutscher Apothekerverband v. DocMorris NV**, interpreted all the European Community laws applicable to the distance selling of medicines[27]. In effect, the Dutch pharmacy DocMorris, since June 2000, supplied via the internet to German citizens medicines for human use authorised to be put on the market by German authorities and the authorities of other member states[28].

The Deutscher Apothekerverband association of German pharmacists (representing around 19,000 pharmacies) has therefore brought DocMorris to the Frankfurt tribunal, contesting both the *on-line* offer of medicines and their international delivery by mail, on the basis of national bans which forbid in Germany the distance sale of medicines available exclusively in a pharmacy[29]. According to the acting association, the bans mentioned would not be restrictions to business exchanges forbidden by Art. 28 of the Treaty of Rome and would be compatible with Art. 30 of this Treaty, being aimed at ensuring imperative needs (the protection of life and the safeguard of European citizens' health) and therefore prevailing compared to the principle of the freedom of circulation guaranteed by the Treaty by having an internal market and liberalising the exchange of productive factors (especially goods)[30]. Because

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Electronic Commerce. Aspects of European Community Law, Padova, 2000, in particular p. 131 and following.

[26] See the written interrogation E-3077/00 of the 2nd of October 2000 and the answer of the European Commission on the 23rd of November 2000, with which this institution announced the beginning of awareness campaigns for European consumers, as well as the promotion of ad hoc codes of conduct (in Guce number C151 of the 22nd of May 2001, p. 58).

[27] Case C-322/01, in *Raccolta della giurisprudenza della Corte* (following: *Raccolta*), 2003, p. I-14887. For a first comment about the sentence see R. Manno, Europa: via libera all'e-commerce dei farmaci, in htpp://www.interlex.it.

[28] In particular, DocMorris qualified the medicines as subject to a doctor's prescription according to Dutch law or the law of the consumer's place of residence: in this case, the delivery of the medicine would happen only after the presentation of the original doctor's prescription and the medicine could be collected in person by the customer or by courier.

[29] In particular, they took into consideration the prohibitions present in German law with regards to medicines for human use (Arzneimittelgesetz-AMG) and to the advertising of healthcare professions (Heilmittelwerbegesetz-HWG).

[30] Art. 28, 29 and 30 of the Treaty of Rome, pillars of the internal market, prohibit quantitative restrictions to import and export, as well as measures "having equivalent effect" to quantitative

DocMorris contested this point, the German judge suspended the main case, deferring to the Court of Justice the solution of a series of extremely important prejudicial questions, which in substance can be summarised as follows: do national bans to the cross-border distance sale of medicines to be sold exclusively in a pharmacy violate the principles of the free circulation of goods found in Art. 28 of the Treaty of Rome? Can the national ban on advertising for the distance sale of medicines to be bought only in pharmacies be extended to the internet site of an established pharmacy in another European Community member state which describes the medicines (indicating name, methods of delivery and cost) and also offers the possibility of buying them *on-line*?

Largely in line with the conclusions of the advocate general, the judges of the Court of Justice established that there is no legitimate reason to justify an absolute ban to the distance sale of medicines that do not require a doctor's prescription. The interest to guarantee correct information and personalised professional advice, asked for by Deutscher Apothekerverband, has not been believed to be enough to justify such a ban and the restriction of exchanges within the European Community that would derive from it: on the contrary, according to the Court, buying *on-line* can have advantageous aspects for European consumers, who can ask the virtual pharmacy, through the *web* pages and *links* offered, any kind of useful or relevant information. The information available on-line, which should be accessed by consumers before a distance buy, has been deemed suitable by the Court to dispel even the potential risks linked or due to the incorrect use of medicines bought *on-line*. According to the Court, therefore, the ban of distance sale could find a legitimate basis only with reference to medicines requiring a doctor's prescription: in this case, in fact, the risks linked to taking these medicines need a stricter control and the observance of eventual bans posed by national laws seems functional to the protection of fundamental and mandatory legal interests.

With regards to the second issue, using again the distinction between medicines needing a doctor's prescription or not (according to the distinction also made by the European Community code relative to medicines for human use in 2001, abovementioned), the Court of Justice noticed that the ban on advertising is justified in relation to medicines needing a doctor's prescription and that in Art. 88 of the European Community code is against national bans on the advertising of medicines that do not need a doctor's prescription (the so-called over the counter medicines or medicines without need of prescription)[31]. Essentially, therefore, the Court of Justice denied that the ban to the distance selling of medicines that can only be bought in pharmacies is a "way of selling", and as such fits into the parameters established by law[32], clarifying that a ban

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restrictions, except national bans and restrictions justified, amongst other things, by reasons of "protection human health and life". These prohibitions shall not, however, constitute "a mean of arbitrary discrimination, or a disguised restriction on trade between member states".

[31] They are also called OTC (*over the counter*) or NP (no prescription) medicines. These medicines can be sold freely, without the need for a doctor's prescription, but it must be remembered that in Italy the use of the expression "over the counter medicines" seems improper, because the current law demands that the pharmacist gives the medicines and, in the same way, forbids the consumers to autonomously take "from the counter" the required medicines: recurring to his/her famous imagination, the Italian legislator has therefore preferred to create the expression "self-medication medicines".

[32] See in particular sentence *Keck* of the 24th of November 1993, Cases C-267/91 and C-268/91, in *Raccolta*, 1993, p. I-6097.

similar to that under consideration in the national case would bring a more significant prejudice towards pharmacies outside of Germany than to those on German soil. The Court stated, on this point, that "if with regards to… (German pharmacies) it is difficult to contest that this ban deprives them of a supplementary or alternative way to reach the German market of medicines' consumers, nonetheless they still can sell the medicines in their pharmacies. On the contrary, the internet would be a more important tool for the pharmacies that are not on German soil, to directly reach such a market. A ban that affects those pharmacies established outside of the German soil more, could hinder the access to market of products from other member states more than that of national products"[33].

From the sentence recalled, it appears evident that the Court of Justice favours the internet and, more in general, the application of communication technologies in the healthcare services sector, which seems to be in line with the need to support as much as possible the creation of an internal market and therefore, as mentioned above, the main objective of the integration of the European Community.

We must also clarify that, if the sentence of the Court is mainly effective in the German legislation[34], it will have significant repercussions also in other member states, like Italy, in which the regulations about the distribution and advertising of medicines seems to be incoherent with the spirit of the sentence examined. In Italy, in fact, the distance sale of medicines is banned tout court: see, about this, the directives in the **1934 Collection of Healthcare Laws**[35], according to which the sale of medicines must happen exclusively in pharmacies, and Art. 25 of the deontological code of the pharmacist profession, which forbids giving medicines, with or without prescription, via the internet or other informatics systems[36]: only for the so-called self-medication medicines, Art. 3 of Legislative Decree number 541 of the 30th of December 1992, allows the advertising to the public in the prescribed forms[37]. Incompatibilities of the Italian legislation compared to the interpretative principle established by the Court of Justice with the sentence Deutscher Apothekerverband appear, therefore, with regards to the distance sale and advertising of "medicines without prescription".

In light of the considerations made, the elaboration of a discipline of the *on-line* sale of medicines for human consumption seems impossible to delay, also to support the positive applications of such a controversial phenomenon[38]. With regards to this, it seems easy to share the trend aimed at supporting, for the internet and its applications, the development of a broad regulatory framework, based on the adaptation of the traditional legal principles and

[33] Cf. point 56 of the sentence *Deutscher Apothekerverband* .

[34] And in fact the German Ministry for Health announced the inevitable reform of the regulations applicable to the distribution of medicines in Germany.

[35] Cf. R.D. number 1265 of the 27th of July 1934, in *Gazzetta Ufficiale* number 186 of the 9th of August 1934.

[36] Approved by the National Council of the Federation of the Order on the 13th of December 2000.

[37] In *Gazzetta Ufficiale* number 7 of the 11th of January 1993.

[38] Think, for example, to particularly rare illnesses and to the related difficulty of identifying and finding the most appropriate medicines for these pathologies, which often, because of the reduced economic perspectives deriving by the small number of interested patients, are not produced or marketed (so-called orphan medicines). In these cases, the internet could be a valid (and cheap) tool to disseminate the relevant information, not only within the scientific community, but also for the benefit of the interested patients.

regulations and in part on the elaboration of codes of conduct and self-regulating "good practice" techniques[39]. Resolution WHA51. 9 adopted in May 1998 by the 51st Assembly of the World Health Organisation, was already going in this direction, as it asked for the Organisation's Director general to elaborate a guide relative to "**Medical Products and the Internet**" for the purpose of giving the member states a homogeneous model of reference to help internet users to obtain reliable, independent information, comparable on line, on medicines for human use[40].

[39] This is the case of the so-called quality certification, which generally should allow, on the one hand, to assess the organisational and functional efficiency of those subjects offering goods and services on the Web and, on the other hand, to reassure the consumers about the quality, safety, privacy and reliability of the information received and of *on-line* business transactions.

[40] The guide, elaborated on the basis of the contribution given by national authorities, independent experts, consumers' organisations and representatives of the pharmaceutical industry, is published also in Italian: cf. V. REGGI, *Farmaci e Internet. Guida per la ricerca di informazioni attendibili*, Casalnoceto, 2000.

CHAPTER V

OUTLINE OF ITALIAN LAWS

5.1 *Pragmatic internet regulations*

These are rules dictated by experience, true "norms of good practice", capable, amongst other things, of adapting more easily than legal regulations to the evolution of the internet. The development of individual behavioural rules and of other forms of private self-regulation, widespread today also in sectors different from telematics (like for example in the biomedicine and biotechnology sector) is then stressed by the globalisation process, to which corresponds the progressive erosion of state sovereignty deriving from consolidating power and transversal dynamics to the states.

The fact that the technical norm has become the rule in the community of Web users – with such committed agreement that it has led to "*considering the internet as a real model of social organisation*" (RODOTA', 1998)[41] if on the one hand allows us to respond with the necessary speed to the solicitations deriving by the application of new technologies, on the other hand it presents articulated and often contradictory possibilities, from which come complex legal problems.

For example, taking into account the universal importance of the global dissemination of the internet as a means of communication, we can say that the phenomenon of retreat of the legal norm described above, poses the premises to state the autonomous status of the person from an international point of view, favouring a sort of re-evaluation of the individual dimension of the freedom of expression, already sanctioned as a fundamental human right by important instruments of international law[42], but that can have – in some – as already stated in the introduction, general exasperated and maniacal forms of behaviour.

However, it cannot be denied that the globalisation process highlights a distancing between science and society in which science tends to become, cross-nationally, a power devoid of the common foundations of legitimacy. As it is easy to guess, this poses new challenges for the protection of fundamental rights and in particular of the so-called new generation ones, coming from the advent of new technologies. In this framework, the need to assess *cum grano salis* the suitability of the technical rule to overlap with the legal norm, in order to overcome the gaps in the legislation, seems evident, therefore creating a normative fact.

It is important to ask, in particular, if technical rules are able to have a function that is more typically that of the law, with the same efficacy, ensuring to the individual adequate forms of guarantee and safeguarding their effectiveness in a certain social context.

The changes highlighted are so relevant that they have induced those analysing the internet as a global phenomenon to wonder whether the Web is

[41] Rodota' S.

[42] Suffice to remember the 1948 Universal Declaration of Human Rights, the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms and the 1966 International Covenant on Civil and Political Rights.

not a new form of law. It is undoubtedly an opinion that can be agreed upon, even though it is necessary to clarify that the development of this new dimension makes the creation of laws for the current process of globalisation of the law even more urgent (FLICK, 2000)[43].

5.2 *The protection of privacy in Italian legislation and the personal data protection code*

After this general premise, it is important to recall some aspects of the Italian legislation regarding the protection of the individual in the processing of personal data, amongst which we find – as sensitive data – those about health. These data, in fact, can be processed with IT methods, including via the intranet/internet.

We must recognise that the Italian situation, from a legal protection point of view, is now completely regulated, following Law No.675/1996, the norms deriving from it, the creation of the Guarantor Office and the recurring intervention of the Guarantor for the protection of personal data.

The issuing of the Code on personal data protection completed the framework of reference for the regulations on the public processing also of healthcare data, considered, as we have said, as "sensitive data"[44].

The *Code* dedicated Title V to the specific problem of personal data processing in healthcare, indicating the general principles (Art. 76) and the methods to access information and consent (Articles 77-84), identifying the aims of relevant public interest and defining the role of the National Healthcare Service (articles 85-86), regulating the form and method for drawing up doctor's prescriptions (Art. 87), the processing of genetic data with particular reference to bone marrow (Art. 90), the processing of all data to determine the state of health or sex life (clinical records, certificates of care at childbirth, databanks, archives, registers and files) (Articles 91-94). It must be highlighted that, for the purpose of the information to be given to the patient, the "system" is based on assigning this task mainly to the GP or paediatrician of choice (Art. 78), who however can use/or be temporarily substituted by another professional or by another individual who can give specialist care, when requested by the GP or the paediatrician, or can supply the prescribed medicines.

As well as the indirect and generic reference to the possibility of using electronic cards for the preservation of data, it is important to quote subsection 5 to Art. 78, which says:

"The information provided pursuant to this section shall highlight, in detail, processing operations concerning personal data that may entail specific risks for the data subject's rights and fundamental freedoms and dignity, in particular if the processing is carried out:

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[43] FLICK A.M., *Diritti fondamentali, regole e istituzioni nella prospettiva della globalizzazione*, script of the lectio magistrale at the Universita' Cattolica del Sacro Cuore in Milan, on the 24th of November 2000, p. 23.

[44] It is not possible here to recall the Italian doctrinal and legal debate regarding the general protection of personal data, which preceded the issuing of the Code.
Important mentions can be found in BUTTARELLY 1997; COIERA E., 1999, CIRILLO (in LO IOCIDE and SANTARIELLO, 2000), CIACCI (in LO IODICE and SANTARIELLO).

a) For scientific purposes, including scientific research and controlled clinical drug testing, in compliance with laws and regulations, by especially pointing out that the consent, if necessary, is given freely;

b) Within the framework of tele-aid or tele-medicine services;

c) To supply other goods or services to the data subject via electronic communication network".

From these elements we can identify some fundamental principles:

a) All processing must guarantee the patients' dignity, privacy and decorum, especially in case of serious or terminal illnesses and pathologies afflicting minors or people without capacity for discernment (article 2 of the Code);

b) Information systems and IT programmes will have to be homogenised so that the use of personal data and identification data is kept to a minimum, in order to avoid their processing when the aims in each individual case can be achieved, respectively, through anonymous data or suitable methods that allow the identification of the subject's data only in case of need (necessity principle Art. 3 of the Code).

c) Personal data must be processed in line with the principles of legitimacy and correctness, that is, respecting the normative framework of reference, without malicious intent or to prejudice the data subject (Art. 11 of the Code).

d) The transparency, uniformity and suitability of the information must be protected through the promotion, by the Guarantor, of deontological and good conduct codes for personal data processing (Art. 133);

e) The collection of personal data must also happen in the respect of the principles of pertinence, non-excess and indispensability, which obliges to only collect personal data that are strictly necessary to achieve the aims pursued. With regards to this, we must keep in mind that, according to Art. 11, subsection 2 of the Code, personal data processed in violation of the relevant directive on personal data processing, cannot be used;

f) According to Art. 13 of the Code, the patient must be clearly informed of the aims and methods of the processing, of the eventuality that it might be compulsory and, in particular, of the identity of the individuals who will have access to his/her personal data, as well as the person or individual they can contact to exercise the rights listed in Articles 7 and following of the Code. With regards to the content and methods with which the information must be passed on to the data subject, we also observe that, given what is stated in Art. 78, subsection 5, letter b) and c) of the Code, the information will have to highlight in detail the processes carried out within tele-aid or tele-medicine and those aimed at supplying other goods or services via electronic communications networks, which can present specific risks for the rights, the fundamental freedoms and the dignity of the data subject;

g) The data subject's consent must be collected in line with the requirements listed in Articles 23, 26, 81 and 84 of the Code. With regards to the way in which the interested party's consent is presented, it is necessary to highlight that Art. 81 of the Code anticipates that the data to determine the state of health can be documented by a notice written by the healthcare professional or the public healthcare body (the so-called witnessed consent), in which

h) Personal data processed with the new technologies mentioned above must be protected by appropriate security measures, in order to reduce to a minimum the risks of destruction, loss, even accidental, of unauthorised access or unlawful processing not in line with the aims for the collection (see Articles 33 and following of the Code and Technical disciplines – annex B) to the Code);

i) In relation to what said in Art. 37, subsection 1, letter b), of the Code, individuals who collect data disclosing health and sex life, for the purpose of delivering healthcare services on-line relative to databanks or the supply of goods, must notify the Guarantor;

j) Art. 84 of the Code anticipates that personal data disclosing the state of health must be made known to the data subject or owner. The second subsection of this regulation states that the owner or the person responsible can authorise in writing persons or healthcare professionals other than physicians who, to fulfil their respective duties, have direct contacts with patients and are in charge of processing personal data disclosing the state of health, to communicate said data known to data subjects;

k) According to Art. 26, subsection 5 of the Code, the dissemination of data disclosing the state of health of the data subject must never be allowed (for example by the possibility that an indeterminate public of users would access some web pages in which the patient's healthcare data can be viewed);

l) The processing – also through electronic cards – of data disclosing the state of health or sex life, shall only be allowed if carried out by following the measures and precautions laid down by the Guarantor in a preliminary verification (the so-called prior checking) and respecting the necessity principle (Art. 91 of the Code).

5.3 The sanction against illegal behaviour and health protection

The legal framework offered by the Code with regards to personal data protection, stresses the values of privacy and informed consent, linking them to the particular situations brought about by the electronic management of data and by the dissemination of information via the internet through a series of alterations due, in particular, to the necessity principle, which recommends reducing to a minimum the collection of personal and identification data, to the pertinence principle, which allows the acquisition only of the information indispensable and not in excess, and to the principle of mediated acquisition of the right to information, which demands the indispensable mediation of a doctor in the transmission of data to the data subject. We tend to reach a difficult balance between increasingly pressing, detailed, impersonal, mainly centralised information and occasional, personal and mainly individualised services. The protection regards only the acquisition and processing of data and the remedies are exclusively administrative. The guarantor can order the termination of the illegal behaviour (Art. 150), block completely or in part the processing of data (Art. 143), make provisions for a fine for the use of information (Art. 162).

There isn't instead a specific discipline (which was definitely not the task of a Code on personal data protection to issue) on the problem of the quality of

information that guarantees an adequate protection for the different profiles of the right to health, which can be prejudiced by an indiscriminate and unchecked offer of information and services. This protection regards both the penal aspects in the case of malicious behaviours likely to cause injury and the civil aspects relative to the identification of the responsibility for a defect in the information.

Currently, *on-line* regulations are the same as those also valid *off-line* and, therefore, a restricted number of completely generic criminal hypothesis, very difficult to adapt to that heterogeneous plurality of data that characterises the dissemination of news on the internet. We often find an inextricable confusion between the communication of data and the supply of the service (ZENO ZENKPVICH 2004), scientific dissemination and business advertising, offer of information and offer of advice, offer of services and offer of medicines. The ease and speed of access is, in abstract, a positive data for the users who can utilise, without limitations of time and space, a large number of data, having access to often highly qualified sources that would otherwise be precluded to them. In concrete, there is no chance of guaranteeing the quality of information and relate it to the user's ability to understand problems that could imply delicate choices about his/her health. Together with the unquestionable usefulness, the possible situations of risk increase.

a) *From a penal point of view*

If we examine any site mentioned in specialist publications, we find a wide array of offers: a diagnostic journey to keep in check our health (*Clinics*), a specialist medical advice service for those who want a second opinion (*second opinion*), a web platform to book appointments and tests, receive the results of clinical analysis, consult the medical dictionary (*Internet service provider*) (MUNICO PARK, 2003). These are activities that, *off-line*, would have involved different professionals (doctors, hospitals, laboratories, pharmacies) requiring, both in acquiring the data and in obtaining the services, a whole series of mediations. Each of these mediations requires, in our legal system, a specific accreditation in order to guarantee a preventive protection of professional ability and quality control of the service. The direct and indiscriminate access to the offer of anonymous and generalised medicine could avoid any filter without offering different or alternative forms of protection. As we have observed previously, Art. 84 of the Code on personal data protection tries to create a balance between the impersonal mass of data found on the internet and the individuality and peculiarity of their use, forcing the principle of mediated acquisition of the right to information. The GP should have the central role in guaranteeing control on the quality and methods of the news that are assimilated. It is, however, a norm that has a limited scope and it does not cover a large part of the services that can be obtained on-line. It also presumes a clear professional relationship in which it is possible to identify the individuals responsible and the methods of service. In practice the opposite happens: we have an indiscriminate offer which everyone accesses without any limitation.

All this should impose a specific regulation allowing the repression of frauds and the creation of clear rules to identify those responsible. Instead, in our legal system, we can find, with some difficult adaptations, few repressive legislations (MANNO, 2005), linking to Art. 440 of the penal code on the

adulteration and counterfeiting of food, Art. 443 of the penal code on the trade or administration of out-of-date medicines, Art. 445 of the penal code on the administration of medicines dangerous to public health and Art. 348 of the penal code on the abusive exercise of a profession. The doctrine tends to broaden their scope, defining them as crimes of danger and not of damage, and therefore putting the moment of crime in the objective beginning of the threat and not in the effective damage. The identification and repression of this hypothetic situation of danger is particularly serious *on-line* for the great amount of people that can be reached immediately, but it is difficult to estimate. The limits of the current regulation, and maybe of any possible law, emerge from at least two points of view: the identification of the regulations to apply; the identification of those responsible.

From the first point of view, the structural delocalisation of the mass of news circulating on the internet hinders a clear identification of the legal procedure to apply, so that we don't know if we need to recur to the regulations of the place in which the service is offered or that in which it is required. To understand if the exercise of a profession is abusive or if the sale of a medicine is allowed, we should first of all solve the problem of whether it is the doctor going, virtually, to the patient or the patient going to the doctor. In the United States, Medical Colleges chose the second solution, stating that what is necessary is the qualification to exercise the profession in the patient's State (STEVEN et al, 2003). We hope for the introduction of a specific "licence", valid for all the States of the Union, so that it guarantees a uniform protection to those who intend to use the services offered by tele-medicine. This solution, which seems the most obvious, makes us understand how it is extremely complex to be able to create adequate legal regulations valid in all countries, because anyone and anybody can offer cures and services in any part of the world. How can we expect to guarantee a minimum level of quality?

Should the danger or illegality of the service offered be proven, there would still be no repressive or preventive instruments. From the point of view of identifying responsibilities, we must take into consideration that in the dissemination of news via the internet at least four different subjects intervene: the material authors of the content of the data put on-line (so-called *content providers*), the owners of the telecommunications infrastructures (so-called *network providers*), those who offer the possibility of accessing the network and to use certain functions (so-called *access providers*), the suppliers of services that allow the user to link to the network (so-called *service providers*). Even if we could reconstruct it in all of its parts, this complex chain of services operates as much in close connection, because each passage is indispensable to the realisation of the final product, as in absolute autonomy, because the individual *providers* can belong to different countries, operate in different countries, each ignoring the specific work of the other. Without discussing the different forms of responsibility in abstract, it is extremely difficult to prosecute subjects different from the *content provider*, which is also the element that is most fleeting and difficult to identify (SEMINARA, 1998). In our legal system there isn't a specific duty of the *provider* to check the information disseminated. There isn't a norm like Art. 5 of the German Law of the 22nd of July 1997 on information and communication services that explicitly requires the service providers to be responsible for other people's materials when they make them available, but "only if they know their content and blocking their availability is technically possible and can be expected". And it clarifies that "service providers are not

responsible for other people's materials if they only supplied the access. An automatic and short retention of other people's materials, following the request of users, is to be considered as supplying access".

Even with a specific regulation of agreement between the content providers and the network managers, it is extremely difficult to determine when a provider has a real knowledge and possibility of intervention. Due to the huge mass of data and their rapid changeability any form of control that is preventive or immediately follows the input of the data on the network seems extremely difficult and it is therefore difficult to hypothesise a repressive action leading both to the identification and incrimination of those responsible, and the immediate cancellation of information dangerous to health, and to deter *network providers*, *access providers* or *service providers* from disseminating this type of news.

b) *From a civil law point of view*

What has been said about the repression of relevant behaviours in penal law is also valid for the eventual solutions in civil law. The need for protection emerges at different levels: we are responsible for the dissemination of erroneous information (*information tort*), the responsibility relative to the telematics marketing of provisions and services and, finally all the vast sector of pharmaceutical marketing (IZZO, 2000).

Also in this case, working out the responsibility is particularly difficult. Tele-medicine, with the plurality of services that it makes available, could be particularly affected by the fluctuation of the law to ascertain the professional responsibility in team medicine. The principle of custody would call into cause each of the healthcare professionals involved within the limits of the specialist contribution to the therapy (in this case also to the informative process overall), but the need to guarantee quick interventions aimed at amending eventual errors would lead to favouring the identification of a care "supervisor", with powers of control and therefore responsible overall for all the activities carried out. The tendency to the impersonality of the information offered on-line would maybe make it desirable to identify, like in administrative law, someone who is overall responsible for the procedure with the specific obligation to verify both the accuracy of the information and the proper functioning of all the individual passages.

We must also observe that generally, it is believed that the Legislative Decree of the 22nd of May 1999, put in place by Directive 97/7/CE, is applicable also to healthcare services offered *on-line*, with it, through the discipline of the so-called distance selling, particularly important obligations of information and specific contractual solutions have been introduced for the consumer's protection (PASQUINO). The importance of these norms must not however be found in the legal protection, maybe even more difficult and complex than penal protection, but in the indirect impact that it could have in prefiguring the fundamental guidelines for the issuing of self-regulating codes allowing the selection of different offers of services. The only practicable avenue to protect the right to health, in fact, seems that of anticipating forms of accreditation, a sort of hallmark, given by scientific bodies recognised internationally, starting with the quality, transparency and reliability of the information. It has been suggested, for example, using PICS labels (*Platform for Internet Content*

Selection), requiring for each medical resource the filling of a suitable label including fundamental data (author's name, creation and updating date, judgement on the quality and extensiveness of the information) (SANTORO, 2000). This labelling could be accompanied by *rating* systems giving the different sites quality points on the basis of homogeneous and transparent criteria. It would be desirable that, with time, specialist and accredited "infomediaries" were created, which users could refer to in order to obtain reliable, selected and highly qualified information. The user should, through this cross system of accreditations and evaluations, be in the condition of making a conscious choice, avoiding with a minimum of caution giving way to false and fraudulent proposals.

It is plausible to imagine that the growth of the level of accreditation and notoriety of some sites will lead to a reduction in frauds. To reinforce this form of self-protection, a network of hot-lines, national and European, could be created, to which any situation that seems dangerous or illegal can be reported, in order to force providers into a specific obligation to suppress news that do not supply adequate guarantees. It would be possible, for national healthcare services or consumers associations, to go even further and organise "Patient's advocacy on-line": legal agencies specialised in identifying and persecuting anyone who gives health information or services without authorisation, not suitably reliable or even dangerous. Considering the evident limitations of penal repression and the extreme peculiarity of the administrative and civil sanctions, it should be the telematics system itself to elaborate its own internal corrective measures, fighting the excess of information with the quality of information, through the creation of filters following different strategies (self-regulation codes, quality accreditation, rating systems, hot-lines) so that the evident lack of the one is corrected through the work of the other. If it is easy, in an IT network, to avoid controls and alter quality accreditations, it could become extremely complex, and therefore financially unadvisable, to try and overcome the filters operating at different levels, through a variety of bodies and with particular specialisations.

CHAPTER VI

SYNTHESIS AND CONCLUSIONS: BIOETHICAL PROFILE OF THE USE OF THE INTERNET IN HEALTHCARE COMMUNICATION

The NBC wanted to present a systematic analysis of the relationship between the ethics of communication and the ethics of health, but suggest some reflections with regards to the use of one of the tools that – in today's technologically advanced world – have a growing role in ensuring the communication in the healthcare sector, that is, the internet.

This tool – belonging to the traditional classification of the family of synchronic systems of communication[45], together with ordinary electronic mail (e-mail), mailing lists and electronic conferences (news groups) – although strictly different from the tools of "tele-medicine", has come to have a growing role of interest and use that the NBC wanted to evaluate with this document.

1. The NBC recognises – generally – that the exceptional development of informatics has greatly increased the communication capabilities of some privileged people or groups, able to use the internet in many sectors of private and public life thanks to their means, professional education and technical knowledge.

The internet can help people to responsibly use science and technology, expand the range of choices available in different aspects of life, broaden their cultural and educational horizons. The growing dissemination of images and words on the global scale is transforming not only the relationship between populations from a scientific, political and financial point of view, but the understanding of the world itself.

This phenomenon offers a variety of possibilities, if based on shared values, rooted in the person's nature.

Therefore, the intercultural dialogue, made possible by the internet and other means of social communication, can be the preferred tool to build unity and diversity, and from this point of view the NBC cannot but appreciate the growing dissemination of the internet in Italy as well.

However, paradoxically, what leads to better communication can also bring an increase in egocentrism. The internet can be used (consciously or unconsciously) to bring people together, but it can also divide them, both as individuals and as groups suspicious of one other and separate in ideology, politics, passions, race, ethnic origins, intergenerational differences and even religion. It has already been used aggressively, almost as a weapon of war, and there is already talk of the danger represented by "cyber-terrorism".

From this point of view, the NBC can silence some preoccupations, which have already appeared especially internationally, but that can be shared also amongst unequal economic areas, within the individual nations.

[45] Communication is defined as synchronic when the interlocutors are present and linked to the network at the same time; asynchronic when the messages are exchanged and updated with delays ranging from a few minutes and some days: the interlocutors can participate to the discussion afterwards, according to times and moments more suitable to them (see L. PACCAGNELLA, *La comunicazione al computer,* ed. Il Mulino, Bologna 2000, p. 16).

Amongst the most important is what we call today the “digital-divide”, a form of discrimination that divides the rich from the poor, between nations and within them, on the basis of the access or impossibility of access to new IT technologies. In this sense, it is an updated version of the old gap between the rich and the poor of information.

The expression “digital-divide” highlights the fact that individuals, groups and nations must have access to new technology in order to keep up with the fast use of information, and be penalised in enjoying the benefits promised by globalisation and development. It is necessary that the gap between those who benefit from the new tools of information and expression and those who don’t yet have access to them does not get out of hand, as a further source of inequality and discrimination.

From this point of view, the NBC appreciates the initiatives – national and international – of those governments that facilitate the dissemination of the internet, on the basis of the equality principle.

The Unesco also dedicates a specific Programme to the problem, emphasising that the true challenge is the human dimension of the *digital divide*[46], rather than the technological aspects. In this sense, it highlights how there cannot be information for all if there’s no education for all.

The “Communication and Information” Programme includes a variety of worldwide and regional projects that have as main strategic objectives: “the promotion of a free exchange of ideas and universal access to information; the promotion of the expression of pluralism and cultural diversity in media and worldwide information networks; the promotion of the access to ICT for all”.

2. If these considerations can be aimed at the competencies and responsibilities of the public authority, others – still from a general point of view – must turn to the same powers as well as the citizens, called to be “user” and “consumer” of internet communication.

Complex and source of further preoccupations – for the NBC – in fact, is the issue of the freedom of expression on the internet, which regards first of all human beings.

The freedom to search and know the truth is a fundamental human right and the freedom of expression is a cornerstone of democracy. All this means that, respecting the moral order and common usefulness, it is possible to freely investigate, examine the truth about public and scientific events, establish also spontaneous groups on the internet for the study of particular problems etc.; in conclusion, to express and disseminate our opinions according to principles that numerous international documents, and the Italian Constitution, dictated for the development of communication in society.

However, also the freedom of expression and communication of thought on the internet cannot avoid the rules that already in oral, written (on paper) or televised communication have been elaborated by civil and penal codes, for the protection of human dignity, honour, public morality and public order.

The individual active network of “users” – that is, those who organise and send messages and select information they believe useful for the community –

[46] The Resolution of the United Nations Economic and Social Council (July 2000) on the “Role of IT in the context of a global economy based on knowledge” and the Millennium Declaration (September 2000) are two texts that suggest the creation of an international cooperation aimed at overcoming the digital divide.

must take into account that the "public" nature of internet communication, which differentiates it from "private (face to face) communication between two interlocutors who are voluntarily away from the influence of others (as for example happens in the communication between doctor and patient in the privacy of the surgery). Two interlocutors on the internet can happily, expressly (if they want) give up their "privacy", but they cannot commit acts that interfere with someone else's privacy.

We have to highlight, in addition, that the deliberate omission of the name of the writer of the message, or the use of pseudonyms and encrypted contents, is sometimes used on the internet for communications that have illegal aims in the objectives pursued.

In this way, if the objective of sheltering from repression is achieved, remains – at least potentially – the damage to third parties.

Public authorities should be vigilant about the accuracy (in the terms indicated) of the "traffic via the internet and not simply act – on a notification – to repress illegalities, but try and prevent (with methods that the NBC also recognises difficult to identify) the abuses that can happen with this means of communication.

3. These general reflections seem particularly coherent and punctual when the use of the internet is seen as a "service" to the citizen, with the objective of protecting and promoting health.

There is no doubt that also the recurring expectation – advanced by some – of attributing the internet to the "virtual world" (in which often dominates the free expression of feelings, the ideal images of vital situations, the surfacing of profound moods and free thought to share with strangers etc.) rather than to "the real world" (as it's expressly stated by the extremist positions of internet lovers) collapses necessarily when the tool is used either to obtain scientific news from an informatics library, or to ask a doctor a "clinical opinion", or finally to buy a medicine.

It is on this aspect of pragmatic usefulness that the NBC has mostly focused, that is, on the use of an "indirect" means of communication between citizens and health workers, in a sector where for centuries there have been specific rules and traditions with regards to "direct" communication, so-called "face to face", as in the sector of clinical medicine.

In any case, these are rules and habits that – in the evolution of interpersonal doctor/patient relationships[47], or amongst healthcare organisations and the citizen and/or between auxiliary personnel operating in healthcare and citizens – were established first of all by deontological evaluations, but also legal evaluations, based on some principles, amongst which emerges "the subject's autonomy" (from which derives the need of an explicit consent to the medical procedure preceded by exhaustive information) and the respect of "professional secrecy", extended today to the principle of the protection of the patient's privacy.

If these are the fundamental principles (although not all) regulating "face to face" communication in the healthcare sector, there are some consequences also for the use of the internet, which seems appropriate to explain further:

[47] The concept of "patient" is international and it expresses each individual's right (independently from being a "citizen" in a certain community) to access healthcare, where there's the need (ONU Declaration of Amsterdam (WHO) on patients' rights).

a) As “information” vehicle on health

No objection – generally – can be made on this use, either in the public or private sector.

From the point of view of a “social” ethical profile – in which great relevance is given to the initiative, the regulating power and the financial support that the healthcare administrator offers with choices in healthcare policies – the NBC cannot but appreciate those ideas (translated sometimes in concrete initiatives with structures, personnel and means) with which we tend to develop a policy of public information on health, prevention of illnesses, education to healthy behaviours also through the internet.

However, this information has now become redundant in some sectors (for the evident intervention of commercial reasons), lacking in others, and not always reliable.

This information must be “truthful”, it must not be “ambiguous” or “partial” or “vague” to cover, in some cases, the proponent’s unclear interests, that is “triumphalist”, and “falsely reassuring” in other cases, which are a part, most of the times, of the business objective.

The need for accurate internet messages with regards to health – as it has been amply discussed in the text – has been felt for a long time and measures of “quality accreditation” have been suggested (but only partially activated), based in part on the voluntary agreement of those creating the message with behavioural codes shared by the community and in part on the recognition – carried out by authoritative Accreditation agencies – of the quality of the messages.

The NBC recognises the complexity of this activity, not easy to pursue with the necessary range and efficacy. In the same way, it recognises that – from a legal point of view – the various instances called “Privacy guarantees” have, in Europe, created rules for the protection of privacy of internet messages; but we must stress that it is still widespread today the feeling that in some sectors these rules are not taken into account.

But most of all there still is no policy to induce “providers” and in general “active” site users (those who give messages regarding health are not always “experts”) to accept self-regulating codes for the “quality” of the messages, the dissemination of which should be in line with shared “reliability” criteria and subjected to verifications – although occasional – by competent external requests.

This does not mean forcing the producers to exclusively adopt criteria of high scientific content for each message – which would not be fully compatible with the average cultural capability – and it does not mean stopping the dissemination of less elaborate texts, more attuned to the consumer’s understanding (the citizen receiving the message on the internet); but make sure that the consumer can be at least reassured on the “reliability” of the message received and in any case know the date of completion, the name of the organisation and the writer.

It is also true that the “sites’ ownership” – where declared in the messages transmitted as belonging to Scientific Society and Institutions or Hospitals – already operates (at least indirectly) in this effort of transparency, reassurance and “public” effort in the use of the internet; however, from sample surveys (cited in the text), both international and national, the number of sites transmitting health messages where it is not possible to identify the writer is still

too high and it can instead be hypothesised, from the content, that the initiative aims at a financial gain.

More rigid regulations should be adopted, therefore, for the qualification of the sites and for the identification of those who write the message.

In this direction go also the documents (reported in the appendix) of the European Community EGE Group and the suggestions of the Council of Europe's Working Group, which the NBC shares.

b) As a vehicle of healthcare advertising

The NBC, examining the various aspects of healthcare advertising and finding that the internet has been progressively more used, for the vastness of its "target", like a potent advertising tool dominating in the globalisation of the market – it must highlight a considerable lack of rules expressly dedicated to healthcare advertising on the internet, both in the offer of professional activities, and in the sale of medicines, nutritional supplements, medical instruments and anything else that is part of the healthcare market.

It is also true that we can state that the regulations currently in force in Italy both for healthcare advertising and the repression of the unauthorised exercise of healthcare professions (for example Law No.175 of the 5th of February 1992, titles "*Norms on healthcare advertising and the repression of the unauthorised exercise of healthcare professions*"[48]), both for the advertising of medicines for human consumption (for example Legislation Decree number 541 30/12/1992 "*Carrying out Directive 92/28CEE on the advertising of medicines for human use*[49]) apply – for their general character – also to the use of the internet as an advertising "channel" in our country; however an explicit updating in this sense of both the legislative decrees would help clarity and would strengthen the work of repression of possible transgressions, work that is certainly difficult on the internet because of the facilitations in remaining anonymous, or avoiding what is compulsory by law, offered by making business via the internet. We refer – on the one hand – to ambiguous professional titles, doubtful in nature and reliability, present on the internet, and on the other to the lack of prescriptions for medicines that by law should only be sold with one.

c) As loss of a full communication between doctor and patient

It is maybe this bigger "danger" that the professional activity on the internet is exposed to, real danger and of such potential gravity that it has induced some states to forbid carrying out the medical profession "from a distance" for unknown patients and which the doctor has not examined objectively (except for urgent tele-medicine situations due to the lack of real, different situations: see the case of remote places in Australia, Norway, African Countries, etc. found in literature)[50].

It has been observed numerous times, in literature, a dual effect:

- A generic one, of all the internet messages, namely, of the loss of a full "interpersonal communication" between users and consumers, as the internet is more an interface tool of progressive messages, than a contextual development of a communication made not only by verbal expressions, but

[48] Published on the G.U. number 50 of the 29th of February 1992.
[49] Published on G.U. number 7, Ordinary Supplement of the 11th of January 1993.
[50] This use finds similar elements with the naval medical service, radiotelephonic, established a long time ago for those sailing.

also by visual perceptions of the interlocutors' attitudes (gesture codes); voice intonations; body language, etc[51].

- A specific feature of the art of medicine, relative to the loss of that group of objective signs (general look of the patient, posture, deambulation, objective examination by inspection, palpitation, auscultation, percussion, etc.) which, together with elements of emotive perception, guide the diagnostic process in the context of the correct medical semeiotic on the physicality of the person.

With regards to the risk of depersonalising the doctor-patient relationship, various authors have focused their attention on it for some time (for example EVANS, 1993; MILLER, 2002; 2003 etc.) in particular in those organisations of distance medical consultation services, called "DOT.com", many of which developed in the USA to satisfy public demand, but are of doubtful safety and financial advantage (WOOTTON, 2001).

Also, in other situations (for example in subjects with psychiatric disorders or sexually transmitted diseases) the greater anonymity that can be obtained – according to the patient – with an internet consultation seems to encourage reluctant personalities to start tests and treatments and undertake even the use of videoconferences, which would relieve the patient's uneasiness caused by a "face to face" with the doctor (MC LAREN, et al., 1995).

4. The NBC – finally – stresses the opportunity to intervene, with suitable measures and on the line of the reviewed international Recommendations, and increase the safety factor of the use of the internet in a "sensitive" sector, like that of health, in order to make it easier for the consumer to select, amongst a myriad of information received today, those that are really useful.

We should – from the point of view of public health and the relative "responsibility" of the administrators – ensure not only a greater homogeneity of the "right to be informed" for all citizens, but also a greater ability to control the "quality" of the information exchanged on the internet regarding health problems.

5. Concluding the review of the issue, the NBC expresses in synthesis the main advantages and problematic aspects (at least potentially) of the use of the internet in healthcare as follows:

<u>Advantages</u>

- It can reduce the costs and waiting times of some health services. For example, it is possible to reduce waiting times at the counter, an increased availability of information, the delocalisation of the supply of services, etc.
- It can facilitate the access to treatments and offer higher level advice services to citizens living in areas with poor healthcare services, especially if linked to tele-medicine services.
- It can simplify both the monitoring and control of the patient after beings dismissed, once the acute phase has passed (follow-up), maintaining with him/her periodical contact, as well as eventual consultations and further treatments (second opinion and consensus conference). For example, the

[51] Read, with regards to this, the analysis of the literature carried out by L. PACCAGNELLA, *La comunicazione al computer,* Il Mulino, Bologna, 2000.

“electronic slide”, elaborated within the “tele-pathology project” of the National Institute for the Study and Treatment of Tumors in Milan, is significant.

- It can facilitate people’s education to discern – in the current news regarding medicine – what has scientific foundation and what belongs to hopes for the future.
- It can offer an empathic support, link and help to carry out bureaucratic practices for particular categories of patients and their families.

Problematic aspects

- Possible depersonalisation of the doctor-patient relationship with an emphasis on the risk of feeling cut off.
- Breakdown of the anthropocentric view of medicine as multisensory contact with the patient and – in extreme cases – reduction of the physicality to the network.
- Without the doctor-patient direct relationship, it appears extremely difficult both collecting the informed consent and identifying the subject deontologically responsible for the information process.
- In the case of medicine sales or any other form of support for forms of self-medication and self-diagnosis, there is a serious risk of abuse or erroneous use of tests and medicines.

Recommendations

For the “ambiguities” in the use of the interned mentioned above, the person must be “educated” to understand and evaluate the aspects of the healthcare management of the internet.

Nationally, it seems appropriate to elaborate codes of conduct and guidelines – linked to international experiences – so that explicitly backing them would give reliability to the operators and users in the healthcare sector.

The support action for the patients and their families must be appreciated, when correctly carried out in the spirit of sharing and solidarity, also on the net, by voluntary organisations.

The doctor and in general the healthcare operator must be allowed – since their primary medicine and/or healthcare studies – to use all the cultural and practical potential offered also by this means of communication, without giving up other forms of cultural and professional training, and exercising a critical evaluation of the available information .

In the training of a doctor, specialist and healthcare personnel, it will be important to insist also on ethico-legal problems concerning the protection of “privacy” and caution in the preservation, processing and transmission via the internet etc. of the patient’s health data, according to international and national binding regulations.

The doctor and in general the health operator, when required and interested in professional communication on the internet, must, deontologically, keep sight of the “human” complexity of the doctor/patient relationship and must never give up – in the correct exercise of the profession – the richness of direct communication.

The same deontological rules, aimed at protecting the dignity and professional reliability also with regards to healthcare advertising already in force in other sectors of communication (newspapers, television, etc.) must be applied to the internet; public authorities and professional Orders – in their respective competences – must set up and exercise “adequate control” actions after having – if it is necessary – expressly updated the traditional legal tools regarding advertising also in the sector of internet communication.

In light of the considerations above, the elaboration of a discipline on the on-line sale of medicines for human consumption seems impellent, in order to boost those applications that appear positive even in the context of a controversial phenomenon.

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ATTACHMENTS

EUROPEAN INITIATIVES FOR THE CORRECT USE OF THE INTERNET, IN PARTICULAR IN THE HEALTHCARE SECTOR

We believe that it is appropriate, in attachment, to examine some documents that contributed, for being authoritative, to define the guidelines for the development of the regulations (especially European and national) regarding the internet.

The initiative of the EGE Group for the protection of personal health data in the European Union

The European Group for the ethics of science and new technologies operating at the European Commission (EGE/GEE) on the 30th of July 1999, issued an AVIS titled "Ethical issues of the use of personal health data in the information society", which, because of the its ethico-legal formulation and its contents, is an important premise to the possible legislation of medical informatics in the European Union.

Recalling the preamble to the treaties by the European Union protecting fundamental rights, health and consumer's protection and the many Directives issued by the EC to regulate the processing of personal data, the EGE group wanted to "lay a bridge" between the need for the protection of privacy of the individual and the interest to see the rights to health protection and promotion ensured in the same way, harmonising them with those of the economic-social development aimed at by the European Union.

The following documents had already focused attention on this issue:

- The ***Council of Europe*** (Convention 108 on the protection of individuals with regard to automatic processing of personal data, 20th of January 1981; Recommendation R(97)5 on the protection of medical data, 13th of February 1997 and the Convention on human rights and biomedicine, Oviedo, 4th of April 1997);
- The ***UNESCO*** (Universal declaration on the human genome and human rights, 11th of November 1997, approved by the ONU, General assembly, 9th December 1998);
- The ***OCDE*** (Directive guidelines on the protection of privacy and trans-border flows: Recommendation of the OCDE Council, 23rd of September 1980).

The AVIS of the EGE group, first of all defines the nature of sensitive personal data, taking into account not only anamnestic, biochemical and therapeutic ones, but also "sensitive" individual ones, like for example those about the personal physical state, data regarding hospital admissions and discharges, insurance covers and other financial data.

It then states that the use of personal health data stops at the doctor-patient dual, direct relationship, but extends to all those who – healthcare and administrative personnel – are in contact with them.

The rules suggested by the AVIS apply when the person the data refers to is identified or can be identified; it does not apply to anonymous data.

In particular, it lists the technologies used in the collection, preservation and processing of personal medical data, that is:

- Electronic medical record (EMR)
- The dissemination of medical data via the internet
- Advice through tele-medicine
- Electronic healthcare cards
- Expert systems for medical decisions
- Databases of health banks

Add the healthcare information of educational programmes via the internet.

If we accept that the development of “information society” caused profound changes in the traditional doctor-patient relationship, widening the sphere of the people who come into contact with the information, the AVIS recalls to the need of absolute confidentiality, which can guarantee the exchange of medical-healthcare information as long as it is in the user/patient’s interest, either because the information is of therapeutic interest to the patient or because they help the development of medicine.

It is interesting, in this context, the statement that personal health data are an attribute to the personality of the individual, the identity of whom they reflect, whatever the use of them.

These data cannot be completely disassociated from the person they refer to.

From these considerations come legal needs of protection, deriving from the general principle of the protection of privacy stated by European Union Directive n. 95/46/CE.

With regards to the ethical aspects of this argument, the EGE Group Councillors identify some issues that worry people:

- Little understanding of the potential invasiveness of information technologies;
- Lack of transparency in medical practices and in doctor-patient practices;
- Risk of violating privacy, which others, ill-intentioned and strangers to the healthcare system, could carry out;
- Difficulties in guaranteeing the safety of the system, as the opportunities to access it are now widespread;
- Inequalities of results, deriving from the different abilities to use the informatics system.

From this, derive conflicts of values, so listed:

- Efficacy against confidentiality;
- Protection of privacy against public interest needs;
- Optimisation of treatment (through standardised protocols) against the doctor’s professional independence;
- (economic) efficiency against beneficiality in individual cases.

The fundamental ethical principles proposed to overcome these antinomies are traditional, already adopted a number of times in the EGE Group’s “opinions”, that is:

- Human dignity (it involves the right to privacy, confidentiality of medical data, respect of professional secrecy);
- The individual's autonomy (right to self-determination, participation to personal and also collective choices regarding healthcare);
- Justice (fair distribution of limited resources);
- Beneficiality/non-harmfulness (application of the budget criterion cost/benefit also in the informatics sector);
- Solidarity (every citizen's right to care implicates duties towards the most vulnerable people and groups).

Having said all this, the EGE Group arrives, in short, to an "AVIS" with the following content:

1. Personal health data form part of the personality of the individual, and must not be treated as mere objects of commercial transaction.
2. The respect for private life requires that confidentiality of personal health data is guaranteed at all times, forcing us to subordinate the collection and transmission of data to the informed consent of the individual. The collection of and access to, personal health data is limited to treating medical practitioners and to those third parties (administrators, etc.) who can demonstrate a legitimate use. The confidentiality principle, equivalent to the professional duty of medical secrecy, must be observed by the people or bodies authorised to process personal health data: exceptions to this rule must be strictly limited and provided by legal rule. Medical secrecy does not only respond to the patient's interest, but to a public interest that constitutes - in itself – an ethical value. The respect for personal health data continues after the death of the person.
3. The respect of the patient's self-determination principle involves that:
- Data should be collected directly from the citizen whenever possible.
- Citizens must know and determine which personal data can be collected and recorded and the purpose of their use, and have the right to correct data if necessary.
- The citizen has the right to oppose the use of his/her personal health data for secondary purposes not provided for by law.
- The use of personal health data for the purpose from which society as a whole benefits must be justified in the context of the above individual rights.
4. The "networking" of health data fosters new responsibilities for the informatics professionals, which must be answered, and more in particular:
- An accountability equivalent to that of healthcare professionals should be established for those who use medical data (not anonymised)
- When health managers use health data for the purposes of services planning and management, they are accountable for such data uses.
5. The collection and processing of personal health data should be guided by the finality principle, which implies the existence of a strict relationship between the abovementioned operations and the legitimate purpose to which those data are used. If third parties, or insurers or employers, need information on the state of health of the subject data, they must in no case have direct access to personal health data.
6. The security of ICT for personal health data is an ethical imperative; therefore:

- The system must, as much as possible, use the encryption of the data, the use of closed networks or all other organisational measures believed to be appropriate;
- European security standards should be observed wherever an electronic transfer of person identifiable data occurs;
- The systems' safety must be rigorously monitored.

7. The notion of accountability has to be extended to the providers of health information suppliers on the internet.
- Business transactions of health goods and services made on the internet should be regarded as personal health data.
- The access of healthcare information on the internet must not be used for constructing personal profiles of the patient, or be transferred to third parties.

8. Health cards. Every application of them must observe the citizens' rights to self-determination and participation.
- No personal health data may be included on the card without the holder's prior informed consent.
- The holder must be able to readily restrict – as he/she believes appropriate – access to third parties of all or some of the information held on the card.

9. Participation. The right to participate in the medical decision-making process is a key part the notion of citizen, as a stakeholder. The European citizen must have access his/her electronic health record. Appropriate initiatives and procedures have to be developed to encourage the participation of citizens' collectives and healthcare professionals in the idea of electronic healthcare data "systems".

10. Transparency. The standardisation is inherent to electronic healthcare data systems. It is even more so in the applications to clinical treatment, where the coding in widespread use. These standards – which are not neutral, but embody value-related choices – must be made more transparent and should be the subject of evaluation by independent bodies (for example ethical committees, patients' organisations, etc.).

11. Evaluation. Qualitative and quantitative evaluation studies focus on the core implications of ICT systems, should be undertaken at the European level.

12. Education and training. The realisation of the patient's right to self-determination presumes that healthcare professionals are able to inform patients directly of their rights without a direct request for such information.

It is important to promote, in the European Community, programmes of information, education and training destined both to the citizens and to the healthcare professionals and the systems designers with guidance on the ethical implications of ICT in healthcare, its potential, limitations and appropriateness of use.

The AVIS of the EGE Group concludes with two "Recommendations" on what to do:
- Create a Directive on medical data protection, within the legal framework of the Data Protection Directive to address the possibility of computerising such data;
- Adopt at the same time a European Patient's Charter, covering the above aspects, possibly by means of a Recommendation.

Council of Europe initiatives

As already mentioned, the Council of Europe (E.C.) has already intervened a number of times to suggest to the member states a coherent discipline in the information sector. It is the Convention on Information and Legal Cooperation concerning the "Information Society Services", followed by the Plan of Action of the 11th October 1997, by the Convention on Cybercrime and by Recommendation n. R(2001)8 on the self-regulation of cyber-contents.

More specifically for the healthcare sector, we must look at Recommendation of the Committee of Ministers of member states R(97)5 on the protection of medical data and R(99)5 for the protection of privacy on the internet.

With the proclamation of the Convention on Human Rights and Biomedicine (Oviedo, 1997) – which contains general regulations stating the supremacy of human dignity, interest and wellbeing over the interest of society or science (Art. 2), as well as regulations so that the protection of health is carried out in accordance with relevant professional standards and obligations (Art.4), recognising also that the individual is entitled to know any information collected about his/her health (Art.10), this field of European Community law has become part of the "bio-law" that the Council of Europe (currently made up of 45 States) is progressively putting together.

The work carried out by a Directive Committee of experts in the health sector (CDSP) recently produced a Recommendation Project, which should – if approved by the Committee of Ministers – regulate the impact of informatics in the healthcare sector, with particular focus on the use of the internet (SP-IMP/TECH).

The objectives of the Recommendation Project "The impact of informatics and the use of the internet in healthcare (SP-IMP/TECH)

The content of the Recommendation Project can be summarised as follows:

1. Recognising the citizens' right to access information regarding their health, also encouraging the development of information services on the internet, harmonising national laws, creating databases and monitoring to make sure that only information of proven efficacy in the protection of health and prevention are disseminated;
2. Supporting the production of scientifically accurate and up-to-data information tools, to be made available both for the training of healthcare professionals and citizens;
3. Promoting the international collaboration on-line of Research institutes, organisations and patients' associations, in order to improve the quality of messages, endorse services, support the transborder exchange of information between patients and physicians, identify frauds and fakes on the internet, ensure the confidentiality of data and the patients' freedom to access the internet, in the framework of a specific legal competence;
4. Anticipating a regular review of the objectives mentioned in the Recommendation with regards to healthcare information, the quality of services, legal competences, compatibility with documents by the Council of Europe and other pertinent documents.

Finally, the States are requires to disseminate the objectives of the Recommendation, stressing in an Annex the operative methods that are considered adequate.

Operative methods

They are identified as summarised:

a) The state cannot have unique and exclusive responsibility of the internet, as this is a global *governance* system, but it is responsible for its applications on its territory. The state should ensure the freedom of development with regards to biotechnology, not limit health information but verify its quality.

b) The relationship between patients and health professionals must remain “private” and protected in any situation. The access to the internet must be open to all: governments should identify the obstacles to this and remove them. The needs of particular groups should be taken into account. The States should find ways to check the impact of healthcare in the liberalisation of health information on the internet, in particular with regards to patients’ emancipation and the improvement of the interactions with health providers.

c) Measures to ensure the citizens’ confidentiality in the responsible access to internet services must be developed, but the providers of information and communication services in the healthcare sector must always be immediately identifiable and easy to find. Suitable technical systems for the protection of confidentiality in the communication between national governments and industry will have to be developed.

The national institution of a guarantor authority (or a guarantor committee), responsible for the development and updating of confidentiality and safety regulations, will have to be promoted.

d) In the education sector, the considerable opportunities offered by the internet to improve the population’s health must be studied, even through a public debate.

e) Governments must be aware that the biggest difficulty will be in finding the means to guarantee the distinction between good or bad quality information. Self-regulating codes will have to be encouraged. All internet sites will have to make the following information explicit:

- Intellectual property of the content and ownership of the content on the site;
- Attribution of the content and precise information on the person (or persons) who carried out the work;
- Declarations of impartiality of the information , or admission of any conflicts of interest;
- Dating of the content, or of the last revision, accompanied by the source for an additional verification of authenticity.

f) Governments should ensure the quality through criteria (fixed by regulations) on the information provided with regards to health and in particular on:

- The specialist knowledge that the patients share with the doctors;
- Information on the performances of the lenders, paying customers and other subjects in healthcare;

- Information regarding groups of interest operating in healthcare, by consumer protection associations;
- Information on illnesses and health, including those relevant for public health;
- Information on the procedures, rules, guidelines, methods used by clinical practices;
- Information on the medications, healthcare centres, differentiated or complementary treatments;
- Patients' opinions and needs.

g) Governments should support the healthcare professionals in improving their knowledge of the opportunities created by the internet in supporting new relationships with patients and citizens, reinforcing educational programmes in this regard.

Healthcare professionals should better understand the notion of confidentiality and respect of privacy on the internet and the impact of the patient's management of the clinical consultation in their plan for clinical practice.

h) Suitable measures to gain maximum advantage from the internet must be developed, namely:

- Support public training on media and individual health;
- Create a culture of information on the quality of care;
- Help individuals to organise action groups on healthcare issues, share experiences and information with others, participate to policies and healthcare planning in society; allow third parties to act as intermediaries and support the choices, as healthcare consultants.

i) Telecommunications tariffs should be reviewed, in order to really allow the universal access to the services, eliminating social exclusion for financial reasons; supporting the development of new technologies also by accelerating financially competitive pilot projects, etc.

j) Member states should anticipate the creation of a permanent Transborder Health Commission, entrusted with establishing the guidelines to be adopted:

- For the accurate transborder trade of goods and health services, like medications, informatics tele-surveillance, etc.
- For quality regulations recognised internationally;
- For the knowledge and transborder communication between groups of patients;
- For the transborder circulation of health data (tele-measures) and information (medical records);
- For transborder training.

k) Each state should establish the breadth of the information network to consider legally authorised (??). Patients' organisations and ONG should be encouraged to play an active role in evaluating, regulating, accrediting health information available on the internet.

Member states should take every precaution to defend patients from frauds, exchanging information on episodes that have occurred.

Patients should make use, as consumers, of the various internet services (booking, payment, buying medicines with a prescription, special foods, medical assistance, etc.). We must act so that individuals are able to personally use the internet (also through financial help, etc.), but "councillors", acting as trusted

intermediaries in the transactions between different parties, must also be available.

The Recommendation Proposal of the Council of Europe (CDSP) Working Group concludes indicating, in summary, the role of the parts: government, patients and citizens, health personnel for the issues under examination.

Interesting is the proposal, to health personnel, to create tele-healthcare companies, “benefiting from the necessary freedom to create responsible bodies ensuring tele-healthcare services”.

Finally, various research programmes are identified, amongst which the study of the impact the explosive development of mobile tele-communication can have in healthcare and the study of the behaviour of patients in healthcare and the study of the behaviour of patients towards the use of new technologies.