COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Brd/160302/7/EN/fr

At its Board meeting, Brussels, March 16th, 2002, the CPME adopted the following policy : **The practice of telemedicine in Europe : analysis, problems and CPME recommendations** (CPME 2002/027 Final EN)

THE PRACTISE OF TELEMEDICINE IN EUROPE
Analysis, problems and CPME recommendations

Following the initiative of president Äärimaa the Executive Committee of the Standing Committee of European Doctors CPME decided in January 2001 to prepare a guidebook for the practise of telemedicine. One aim of the project was to study the current situation of the practise of telemedicine in the EU/EEC Member States. For the purpose a questionnaire was prepared covering 6 different aspects of telemedicine. The questionnaire was circulated in March to the national member associations of the CPME. Before the distribution of the questionnaire the Executive Committee and the European Commission's Working Group on e-commerce on health were consulted about it.

All together 16 countries answered the questionnaire, one of them an EU-candidate country and one an EFTA-country. These countries were Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Italy, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden and the UK. EU Member States which did not reply were Ireland and Luxembourg.

This paper presents the results of the study and the relevant EU legislation. As important aspects of telemedice are not yet covered by legislation, guidelines or established practises the paper proposes new CPME policy in order to make telemedicine a safe and effective tool for doctors.

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STRUCTURE OF THE PRESENTATION

The results of the study are presented under ten headings covering the different fields of the analysis. When appropriate, the text under each main heading is divided under following subheadings;

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1. THE EXTENT OF THE PRACTISE OF TELEMEDICINE

Definitions

As defined by the CPME telemedicine is practise of medicine over distance. The definition does not restrict purposes for which telemedicine is used, or methods which can be applied. As a matter of fact, letters, telefaxes and telephones have been used for decades to give medical assistance. The modern electronic telecommunication has boosted the development, as well as innovations e.g. in video conferencing and robotics, which have made also remote operations possible. Today telemedicine can used in many different fields of medicine, and in radiology, in pathology and psychiatry telemedical methods belong in some areas in routine practises.

Description of the topic

In order to find out the current situation in the EU countries we studied:

- in which countries telemedicine was practised.
- for which purposes telemedicine was used.
- differences between public and private health care in the use of telemedicine.
- whether telemedicine was practised in a country and internationally

Results of the study

Extent of use

Telemedicine was practised in all the countries of the EU/EEA and Slovenia. Austria stated that it will use telemedicine for the transfer of medical data while the use of telemedicine was not possible in the direct doctor-patient relationship.
Notice: Information was not obtained from Ireland and Luxembourg.

Purpose of the use

Telemedicine was used for:

- diagnosis and treatment (11 countries),
- occupational health (5 countries; e.g. Netherlands specified this as health services given to the sailors at the sea. Other countries were Belgium, Finland, Iceland and Spain),

- insurance medicine (3 countries; France, Iceland and Spain),
- other purposes indicated by the countries (6 countries): education (Norway, Sweden), consultation (Sweden), second opinion (Slovenia, Sweden), and to provide health information (Netherlands), and community health (the UK, a pilot scheme).

Use in public/private health care
Telemedicine was practised by public health care in most countries (12/14): Finland, France, Germany, Greece, Italy, Iceland, Netherlands, Norway, Portugal, Spain, Sweden and the UK as well as by private health care (13/14): Belgium, Finland, France, Germany, Greece, Iceland, Italy, Netherlands, Norway, Portugal, Slovenia, Spain and Sweden.

According to these results telemedicine was used only in public health care in the UK and only in private health care in Belgium and Slovenia.

Use within a country/cross border
Public health care services were mainly performed within the country (9/9): Finland, Germany, Greece, Iceland, Italy, Netherlands, Portugal, Spain and Sweden, but in some countries also to abroad (4/8): Greece, Italy, Iceland and France.

Private telemedicine services were mainly delivered within the country (11/12: Belgium, Finland, Germany, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, and Sweden), but also to abroad (6/12): Finland, France, Germany, Greece and Iceland.

Notice: There were some controversial answers like Italy which has private telemedical services, but stated that private service were neither given within the country nor to abroad.

Relevant EU regulations

Treaties establishing European internal markets set four principles: free movement of goods, services, labour and capital. These freedoms can be easily exploited by telemedicine, with which medical services can be effortless sold and bought over the national borders. European secondary legislation realises these principles of the internal markets. So called directives ensure Europe-wide recognition of medical diplomas and ensure the possibility of doctors to practise in another EU country. Europeans have the right, based on Community legislation, to be employed, to be established and to provide services in another country. Citizens have the right to obtain services from other member countries of the EU. According to the principle of subsidiarity, member states can restrict the freedom of buying medical services abroad. Tertiary legislation of the Community, i.e., interpretation of Community legislation by the European Court of Justice (ECJ), has clarified the freedom of buying medical services over the borders. According to recent rulings of the ECJ, both ambulatory and institutional medical services are commercial services, which should be freely available for patients to buy over national borders. Restrictions can be imposed only in order to maintain the national health care system or to economise it. Restrictions must however not harm the patient causing for example undue delay. ECJ rulings are suggestive and a slow means to provide answers for indistinctness. They are done case by case and later on interpreted nationally.

Directive 2000/31/EC[1] on certain legal aspects of information society services, in particular electronic commerce, in the internal markets, states that Member States(of EEC) cannot restrict the freedom to provide information society services established in another member (if they comply with the applicable provisions of that Member State). Exception is possible for e.g. for protection of public health (Article 3.1.-2.).

The position of telemedicine in European legislative framework, whether and where the Community legislation or national legislation applies, will have an indicative impact, when the case of DocMorris, Dutch online pharmacy, is judged by the European Court of Justice. DocMorris took advantage of the price divergence between Netherlands and Germany and sold pharmaceuticals, also non-authorised products, via internet to German consumers. It delivered the goods via mail, this act being against German law. DocMorris was sued by the German Pharmacist Association and several drug companies, and sentenced by several German provincial Courts. However, the regional Court of Frankfurt took the case of DocMorris into the European Court of Justice. The questions asked for interpretation of Community law apply to the fundamental rights of internal market: Freedom of movement of goods.

Several legislation (and rights) of the EU can be restricted for the safety of public health, so it shall be seen in the near future, what will happen to this type of online service raising several unsolved questions when practising its activity in the virtual and real world. Certainly the Courts attitude will be suggestive for other types of telemedical services.

Proposed CPME policy

The practise of telemedicine should be encouraged, also over national borders. In order to make it safe and feasible international rules or rules between concerned countries should be established to guide appropriate practises.

2. LEGISLATION GOVERNING THE PRACTISE OF TELEMDICINE

Description of the topic

In general, legislation on the practise of medicine is relevant also for the practise of telemedicine. Additional legislation is however required to cover special aspects telemedicine. Use of non-legislative measures, such as guidelines and codes of conduct are essential to complete the framework offered by legislative measures. International co-operation in regulative framework for telemedicine is necessary to ensure functioning and safety of cross border practise.

[1] EU Directives mentioned in this document are available by their number from: http://www.europa.eu.int/eur-lex/en/search/search_lif.html

We studied:
- whether special legislative measures were applied to the practise of telemedicine
- whether special legislative measures were applied to the equipment used

Results of the study

Special legislation on telemedicine
Four countries informed that telemedicine was recognised by laws or regulations. In Finland legislative measures were applied to electronic prescriptions; In Germany regulations on teleradiology were under preparation. Portugal said that telemedicine was recognised by legislation establishing health information net and emergency care; Norway did not specify the legislation. Of the remaining 11 countries, 4 stated that general legislation on health care applied to telemedicine. These countries were: Denmark, Netherlands, Spain and Sweden. This is probably the case in all of the countries.

Telemedical equipment
No specific legislation on the quality of telemedical equipment exists on any of the countries. Iceland stated that other laws and regulations applied to telemedicial equipment such as Act on Medical Devices NO 16/2001. The quality of transfer of data in telemedicine was specifically legislated in 2 countries, Belgium, France, and the rest of the countries, 10 together, stated that there were no specific legislation on this issue. Some of them said that general legislation applied. This is likely to be the case in the other countries, too.

Relevant EU regulations

Several EU directives and regulations are relevant for the practise of telemedicine. The two directives establishing a framework for telemedical services are:

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal market.
Directive 1997/7/EC on the protection of consumers in respect of distance contracts.

These directives will be described later on in relevant chapter.

Individual data protection in electronical communication, applying also data processed in telemedicine:

Directive 1995/46/EC on protection of individuals when processing personal data and on free movement of such data.
Directive 1997/66/ECon processing of personal data and protection on privacy in telecommunications sector.

These directives will be described later on in relevant chapter.

Telemedical equipment:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
establishes quality requirements standards and procedural measures prior to placing the equipment onto the internal market. All the devices have to fulfil requirements to gain a common CE-mark.

Proposed CPME policy

(1) Conventional health care legislation shall be reviewed and , if found insufficient, extended to cover telemedicine.
(2) The CPME should identify areas where further guidance is required for safe and high quality practise of telemedicine.

3. GUIDELINES FOR THE PRACTISE OF TELEMEDICINE

Description of the topic

Professional associations have shown concern on the practise of telemedicine. Gaps in legislation and the uncertainty of rules applying cross-border practise pose a legal risk for both the doctors and their patients. International professional organisations have developed codes of conduct for the practise of telemedicine to guide individual doctors. CPME established its ethical guidelines on telemedicine in 1997. Later on in 1999 the World Medical Association (WMA) developed its ethical guidelines for the practise of telemedicine, the point of view being the same as in the CPME's. A few national medical associations have adopted these guidelines and some have even produced their own guidelines.

The problem with non-legislative measures such as guidelines is that they are not legally binding. In some countries their value may be higher and the medical supervising authorities respect the guidelines as a professional norm that has to be followed but this is not the case in all the countries.

We studied:
- whether non-legislative measures were adopted for the practise of telemedicine.

Results of the study

Guidance at national level
Three countries reported that legislative or non-legislative measures (guidelines) exist on national level for the practise of telemedicine. These countries were: Finland (used the CPME guidelines for telemedicine, adopted by the Finnish Medical Association), France and Norway (did not specify the used measures). Denmark stated that the Ministry of Health currently studied telemedicine in order to offer official guidance. In Germany, Bundesärzekammer (German Medical Association) had an opinion on general questions on health telematics. Sweden and Iceland stated that general laws and regulations on health care applied to telemedicine; this view is probably the attitude of all the countries where telemedicine is used even though not mentioned by other countries

Professions guidance
National medical associations in five countries had accepted telemedicine guidelines produced by the CPME (5: Belgium, Finland, Germany, Slovenia and Spain), by the WMA (4: Belgium, Finland, Germany and Spain), produced by their own (4: Belgium, France, Germany, Spain) and other (3, Belgium, Slovenia (AEMH's guidelines) and Spain). All the four alternatives of guidelines were reported to be used in Belgium and Spain.

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets establish framework for information society services. The Directive defines 'information society service as any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services' (Art. 2a).

The Directive states minimum for information about the service provider and about the contract the service provider has to provide to the service recipient.

The Directive also gives the possibility to professional bodies to establish Community level codes of conduct to determine the information that can be used in commercial communication (Art. 8.2). Member States are given the responsibility to supervise that regulated profession follow professional rules when they offer information society services (Art. 8.1.).

Established CPME Policy

CPME has adopted ethical guidelines for telemedicine (CPME 97/033).

Proposed CPME policy

National medical associations should adopt the " Ethical guidelines in telemedicine", (CPME 97/033).

4. IDENTIFICATION OF THE DOCTOR AND THE PATIENT

Description of the topic

Medical treatment is based on a doctor-patient relationship. Thus it is essential that both parties can identify each other. Identification is necessary also for many other practical and legal aspects of health care, like continuity of care, and in some instances identification is important to in order to solve questions related to responsibility and indemnity.

We studied:
- whether anonymous use of telemedicine was possible for doctors and patients.
- whether identification of doctors/patients was regulated.

Results of the study

Anonymous provision of medical services
Anonymous provision of telemedicial services was not possible for doctors in 8 countries out of 13: Finland, France, Germany, Greece, Italy, Norway, and Sweden. Anonymity was possible in Belgium, Iceland (probably), Netherlands, Portugal , Spain and the UK the reason being lack of mechanisms such as legislation to prevent anonymity (Netherlands, Portugal).

Anonymous use of services
Anonymous use of telemedicine was not possible for patients in only two countries, Finland and Italy. Anonymity was possible in 10 countries out of 12: Belgium, France, Germany, Greece, Netherlands, Norway, Portugal, Spain, Sweden and the UK and probably in Iceland.

All together, anonymous use of telemedicine was possible for both the doctors and patients in 5 countries: Belgium, Netherlands, Portugal, Spain and the UK.

Measures for identification of doctors
Identification of doctors was regulated by legislation in 9 countries out of 15: Belgium, Denmark, Finland, France, Iceland, Germany, Greece, Norway, Spain and Sweden. Recommendations were used in 5 countries, Belgium, Finland, Greece, Italy and Sweden.

Measures for identification of patients
Identification of patient was regulated by legislation in 6 countries: Denmark, Finland, Germany Italy, Norway and Sweden and also by recommendations in Finland, Germany and Sweden.

Notice: Finland and Germany answered to these questions only in respect of telemedicine and the aspect of the countries answering 'no legislation/no recommendations' (Belgium, France, Greece, Netherlands, Portugal and Slovenia) is not known.

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets sets the minimum for the information the service provider has to offer to the service receiver about him/herself (Article 5): name, geographical address of establishment, other contact information, the registrative body, supervising authority, possible identification number for value added tax. In addition, regulated professions, such as doctors, also have to indicate their professional title and the body and the member state which registered their authority. Access to Professional rules in that state must be displayed.

Thus, in European Community anonymity of the service provider in e-commerce is not recommended.

Directive 1997/7/EC on the protection of consumers in respect of distance contracts, applies to contracts concluded by means of distance communication such as telephone, telefax, videotext with keyboard and e-mail. According to this Directive, the supplier has to offer the consumer his/her identity and also address in a case of a payment in advance prior to the contract (Article 4).

Established CPME Policy

CPME Ethical guidelines in telemedicine (CPME 1997/033) require that the doctor and the patient can reliably identify each other in a telemedicine consultation.

Proposed CPME policy

Anonymous use of telemedicine should be allowed neither for doctors nor for patients regardless of the status (commercial or non-commercial) of the service.

5. SUPERVISION OF THE PRACTISE OF TELEMEDICINE

Description of the topic

Supervision of medicine is usually performed nationally, where the doctor is located or service provider established. However, telemedicine brings new aspects to the supervision as it can and it is practised across the borders. International co-operation is needed to offer safety for practise of telemedicine and to ensure that there are commonly accepted rules when measures are needed. The study sought the various mechanisms of the national countries in this area.

A. Supervision of telemedicine

We studied:
- which authorities (medical associations/ministries/others) supervise doctors practising telemedically
- which authorities investigate cases of malpractise in telemedicine if doctor and the patient were in the same/different country
- where a possible trial took place if a case of malpractise was taken into a court if the doctor and the patient were in different countries.

Results of the study

Supervision of telemedicine
Supervision of telemedicine was performed by:
-Medical association in 5 countries: Belgium, France, Germany, Greece and Portugal.
-Ministry in 6 countries: Finland, France, Greece, Norway, Slovenia and Sweden.
-Other: institution/body in 6 countries: Denmark (Danish National Board of Health), Finland (provincial governments), Germany public health care service), Iceland (Directorate of Health) Portugal (Health Department (General Inspectorate for Health, Courts, National Commission for Data Protection)),Sweden (National Board of Health and Welfare)

Investigation and measures for malpractise

In a case when a supervising authority receives information about malpractise in telemedicine performed by a doctor, and

- *both the patient and the doctor are within the same country:*
  - authorities will investigate the case in 14 countries (Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden and the UK). The only exception was Italy stating that no authority would perform investigation.
  - Conventional consequences of the misconduct were applicable in 10 countries (Belgium, Finland, France, Greece, Iceland, Netherlands, Norway, Portugal, Spain, Sweden and the UK).
  - Only in one country of the 14 one case of malpractise in telemedical contact was observed: This was a case of misfault diagnosis in Norway (in the question undefined skin malignoma was mistaken to solar keratosis, a pre-carsinoma of the skin).

- *doctor is in the country of complaint and the patient is abroad:*
  - authorities would study the case in 12 countries (Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden) and would not investigate the case in two countries (Italy and the UK).
  - Normal consequences were the case in 8 countries (Finland, France, Germany, Greece, Iceland, Norway, Spain and the UK) i.e., in all the countries that answered to this question.
  - In Germany there had existed a case of malpractise, which was not specified.

- *doctor is abroad and the patient is in the country of complaint:*
  - authorities of the country of the complaint would investigate the case 6 countries (Austria, Belgium, France, Greece, Portugal and Spain) and would not investigate the case in 7 countries (Finland, Germany, Iceland, Italy, Norway, Sweden and the UK). Denmark and Slovenia did not know acts in such cases.
  - Eight countries would contact the supervising authority in that country (Austria, Belgium, Finland (quite likely), Germany, Greece, Iceland, Netherlands, Portugal and Slovenia). Italian authorities would not contact the respective authority.

Place of the trial

In a case where a patient from abroad sues a doctor for malpractise, the trial could take place in:

- the country of the patient: 3 countries (Greece, Netherlands, Slovenia)
- the country of the doctor: 9 countries (Belgium, France, Greece, Iceland, Netherlands, Portugal, Slovenia, Spain and Sweden)
- was thought to be possible in both the countries in 6 countries: Greece, Iceland, Netherlands, Portugal, Slovenia and Sweden

In a case where the doctor is abroad, and the patient turn to the supervising authority, the trial could take place in:

- the country of the patient: 5 countries (Greece, Netherlands, Portugal, Slovenia and Spain)
- the country of the doctor: 5 countries (Austria, Belgium, France, Greece and Slovenia)
- was thought to be possible in both: 5 countries (Greece, Iceland, Netherlands, Portugal and Slovenia)

Relevant EU regulations

Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications (Medical Directive) establishes the process for recognition of doctor's profession, the process being in theory automatic in many cases. Practise of telemedicine would require the recognition of the doctor in the country where the service is given. Thus the country may be other than the country of establishment and recognition by the national authority concerned may be necessary. However, in telemedicine the service is transferred instead of the professional moving which was the actual scope of this directive. It is however not clear weather the Medical Directive really gives the authority to practise telemedicine over national borders.

Council Regulation (EC) No 2001/44 on jurisdiction and recognition and enforcement of judgements in civil and commercial matters states that jurisdiction in consumer contracts the consumer may bring proceedings against the other party of the contract in the domicile of the consumer or in the domicile of the defendant when the contract has been made in the domicile of the consumer and the defendant has performed commercial or professional activities in that country. The Regulation also states that other member state (of the EU) have to recognise the accordingly given judgement and enforce the judgement if it has been recognised in that country due to the application of the interest party.

The Regulation means that in the case of trial due to a harmful effect in telemedicine the consumer(patient) could choose the country for the trial. Thus, it should be possible for the consumer to start the procedure and make the complaint of the service accordingly to the authority system of the chosen country.

B. Recognised problems of telemedicine

We studied:

- whether illegal practise in telemedicine had been recognised
- whether there existed recognised problems in telemedical practise (quality of service/liability/other)

Results of the study

None of the countries acknowledged any illegal practise of telemedicine (14/14). Some problems in the practise of telemedicine were however, recognised, such as:

-quality of service (1 country)
Germany listed such problems as technical aspects of 3-dimentional images; time lacks, reliability of networks, qualifications of participants.

- liability (3 countries)
Belgium stated that a clinical anamnesis and examination is missing in telemedical services.

Germany said that basic questions were still unsolved. Norway mentioned that there existed a case of a false diagnosis.

-other (8 countries)
Lack of standardisation and legislation, security, authenticity, identification etc.

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets establish a legislative framework for the practise of information society services. Member states are required to establish means for supervision of the implementation of the Directive and shall co-operate with other member states when necessary.

EU has taken measures to promote safer use of the Internet. Decision no 276/1999/EC adopted a multi-annual community action plan on promoting safer use of Internet by combating illegal and harmful content on global networks. It is based much on non-legislative measures to regulate Internet.

Established CPME Policy

In "Ethical guidelines in telemedicine" (CPME 97/033) it is stated:
"Physicians practicing telemedicine must be authorised to practise medicine in the country or state in which they are located…"
"When practising telemedicine directly with the patient, the doctor must be authorised to practise medicine in the state where the patient is normally resident or the service must be internationally approved."
Hence the body giving the authorisation is also the body responsible for the supervision of the practise.

Proposed CPME policy

The aim of the directive 93/16/EEC is to make it possible for doctors who are authorised to practise medicine in one country, to practise their profession also in other member countries. As specific regulations for telemedicine do not exist, the directive must be understood so that doctors who are authorised to practise medicine in one EU country, can provide telemedical services over national borders within the EU without further authorisation.
Appropriate mechanisms for international supervision of telemedicine should be investigated by the CPME together with the CIO. International agreements of the supervision should be developed and the possible need for international registration of doctors practising telemedicine internationally shall be evaluated.

6. REGULATIONS ON THE PROTECTION OF CONFIDENTIALITY

Description of the topic

Confidentiality of patient data has always been essential for the practise of medicine and it has been recognised by both the law and by ethical norms. Use of electronic means for the transfer and processing of patient data has brought new problems that have not been faced in traditional medicine. Fear for breaches of medical confidentiality has inhibited the development of telemedicine. European Union has harmonised legislation on data protection and also made arrangements to ensure sufficient confidentiality of the data transferred between the EU and the USA. This is particularly important when telemedicine is practised with countries outside the EU. For example, in Greece some private hospitals consult experts in the USA.

We studied:
- whether the existing legislation is sufficient and relevant for data protection in telemedicine.
- whether existing guidelines and recommendations are sufficient and relevant for data protection in telemedicine.
- which are the mechanisms used for the protection of such data (encryption/other).
- whether the patient is allowed by law/regulations to access his/her data

Results of the study

Legislation
Seven countries, Finland, Greece, Iceland, Italy, Netherlands, Portugal, Slovenia and Sweden, replied that special legislation did not exist on security and confidentiality in telemedicine, but general legislation on health care or data protection was relevant also for telemedicine. Seven countries, Belgium, Denmark, France, Germany, Norway and Spain, stated that there existed special legislation on telemedicine, such as legislation on e-signatures.

Recommendations
Recommendations on security and confidentiality in telemedicine existed in Belgium, introduced by Ordre des Medicins and in Germany. Italy reported to use generally applied practises.

Regulated or recommended mechanisms for the protection of data
Encryption was used in 8 countries out of 11 (Belgium, Finland, Germany, Greece, Italy, Norway, Sweden and the UK). Other methods were either/also used in Germany (digital signature, firewalls etc.), Denmark (closed networks) and Spain. Netherlands data protection authority was preparing guidelines for the issue.

Patient's access to his/her information was guaranteed by legislation in 12 countries out of 13: Belgium, Finland, France, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden and the UK and also by recommendations in 3 countries, Greece, Italy and Sweden.

Relevant EU regulations

Directive 1995/46/EC on protection of individuals when processing personal data and on free movement of such data aims to protect the fundamental rights and freedoms of individuals and their right to privacy when their personal data is processed. The Directive establishes that personal data has to be processed for a specified and legitimate purposes at adequate extent and updated when necessary (Art.6). The data subject has to give a consent to the processing of his/her individual data as well as information about the data collector and the purposes the data is collected. According to the Directive the data subject has the right to access the registered data and in some circumstances demand to update or delete the data (Art. 7, 10, 12). Processing of certain individual data (such as health or sexual orientation related issues) is forbidden unless for medical purposes and even then processed by a health professional (Art.8). The Directive demands the Member States to ensure that the keeper of the register carries out the data processing by confidential and secure means within Europe and to third countries.

Member states have adopted divergent interpretations of this Directive when applied on deceased persons.

'Safe Harbour' agreement between the US and the EU was approved by the EU in year 2000 as a consequence of the demand stated in Directive 95/46 EC on personal data protection when (electronically) transferred to third states. The Directive forbids the transfer of personal data outside the EU unless confidential processing of data has been ensured in the destination. The US companies can voluntarily participate the Safe Harbour agreement, but it is a necessity if they want to continue co-operation with their European partners.

Directive 1997/66/EC on processing of personal data and protection on privacy in telecommunications sector establishes responsibilities to the service providers on telecommunication networks and the Member States to ensure confidentiality of the service in telecommunication networks.

Established CPME Policy

'Normal rules of confidentiality and security of medical data also apply to telemedicine documentation. Storing or transmission methods may be used only where confidentiality and security can be guaranteed'.

'All doctors practising telemedicine must keep adequate patient records and all case have to be properly documented. The manner of patient identification shall be recorded, as well as the quantity and quality of data and other information received. Findings, recommendations and telemedical services delivered shall be adequately documented'.

Ethical guidelines in telemedicine (CPME 97/033).

Proposed CPME policy:

Instructions given in the Ethical Guidelines on Telemedicine (CPME 97/033) shall be followed.
The CPME should study whether the European legislation is sufficient and applicable for telemedicine. The CPME shall evaluate weather new recommendations ensuring the confidentiality and secrecy in telemedicine should be given.

7. LIABILITY AND PATIENT INSURANCE

Definitions

Liability insurance protects the doctor from financial losses if sued or condemned for liability.

Patient insurance compensates the patient in a case of an unexpected adverse outcome in a health
care service irrespective of liability.

Description of the topic

We studied:
- whether liability insurance is valid for telemedicine practised within the country/abroad
- whether additional liability insurance can be obtained for telemedicine practised within the country/abroad
- whether patient insurance is valid for telemedicine practised within the country/abroad
- whether additional patient insurance can be obtained for telemedicine practised within the country/abroad

Results of the study

Liability insurance in telemedicine
Liability insurance covered a doctor's liability in the practise of telemedicine within the same country in most of the countries (9/13) that replied: France, Germany, Iceland, Netherlands, Norway, Slovenia, Spain, Sweden and the UK. However, liability insurance covered doctor's liability to abroad only in 3 countries: France, Germany and Spain. In both cases, liability within the same country and to abroad could be extended if acquired, in Germany.

In those countries i.e., Belgium, Greece and Italy, where liability insurance did not cover the practise of telemedicine within the country nor to abroad, as well as in Iceland additional coverage could be obtained in Belgium and Greece.

Patient insurance
Patient insurance covers accidents also in telemedicine in Finland, Iceland, Sweden and UK, if the patient is within that country and not abroad. In Finland, Iceland and the UK patient insurance covered accidents if the patient from that country was temporarily abroad and the treating doctor in Finland, Iceland and in the UK respectively.

Relevant EU regulations

According to the EC Treaties EU does not have the competence to govern health care systems and social security systems of the Member States as they are matter of subsidiary.

However, citizens have the right to get services from another country. This also applies to medical services. Recent European Court of Justice rulings indicate that in some cases, national countries are obliged to reimburse a medical treatment abroad. What are the rights of the patients when the service provider is abroad and a harmful effect is occurs? In telemedicine the place of establishment is the place where the service is given, ie, where the patient is. Nationally, doctor has to be insured in the country he/she practises.

Established CPME Policy

To facilitate the practise of medicine over the borders in Europe and to increase patient safety, the CPME advocates patient insurance in all European countries and has drafted a proposal for a European Directive on patient insurance in medicine.

Proposed CPME policy

(1) Liability/patient insurance should cover telemedical practise as any other form of practise of medicine.
(2) Doctors should ensure that they have adequate insurance coverage when they practise telemedicine within a country and/or to abroad.

8. REIMBURSEMENT OF TELEMEDICINE

Description of the topic

Most citizens in the EU member countries are covered by public health care insurance or they have access to publicly arranged health care. Private health care insurance can be taken to cover the gap between total expenses and reimbursed costs or additional services which are not covered by public health care.

Reimbursement and health care systems differ from one country to another in Europe s well as the services they offer.

We studied:
- whether telemedical services were reimbursed by public insurance systems.
- whether telemedical services were reimbursed by private insurance.

Results of the study

Public sickness insurance
Telemedicine was reimbursed by neither public nor private sickness insurance in 8 respective 7 countries. National sickness insurance reimburses telemedical service in 4 (5) countries: Germany (in appropriate cases), Greece, Norway (limited by a special tariff) and Finland, which stated that telemedicine was reimbursed in some cases such as in a case of medical imaging.

Private health care insurance
Private insurance reimbursed telemedical service only in Germany and Greece.

Relevant EU regulations

EU does not have the competence to govern health care systems and social security systems of the Member States; instead, they are matters of subsidiary. The European Court of Justice has however ruled that pointed health care services belong to commercial services, which can be freely sold and bought in the internal market. In the cases of Kohl and Decker[2] and the recent cases of Peerbooms and Geraets[2] it ruled that in principle, with some limitations, a patient can seek out-patient care as well as hospital care from another EU-country and be reimbursed without prior permission by his/her sickness fund. Specific cases concerning telemedicine are not available.

Proposed CPME policy

(1) Telemedical service should be reimbursed by the national social security system in the same way as any other form of medical service.
(2) Reimbursement of telemedical services across national borders should be made possible with agreements between national social security systems and/or private insurance companies.

9. ADVERTISING OF HEALTH CARE SERVICES

Description of the topic

Rational regulations for advertising medical services are divergent in Europe, Scandinavia perhaps leading the most liberal policy. Advertising in Internet bring new dimension for the promotion of medical services. The CPME and Conference Internationale des Ordres are in co-operation preparing European guidelines for advertising of medical services in internet. These Guidelines shall be available in Spring 2002, and they will be published as a part of the CPME Telemedicine guidebook.

[2] The European Court of Justice rulings can be found from the web site of the Court: http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en.

We studied:
- whether advertising of medical services, conventional/telemedical, was possible by conventional means/via internet.
- whether advertising of medical services was regulated by legislative or non-legislative measures.

Results of the study

Advertising of health care services
Advertising of *conventional* health care services was possible by conventional means in 11 countries (Denmark, Finland, Germany, Greece, Iceland, Italy, Norway, Slovenia, Spain, Sweden and the UK; not possible in Belgium, France, Netherlands and Portugal)) and via internet in 10 countries (all of the previously mentioned expect for Spain). Advertising was often strictly restricted.

Advertising of *telemedical* services was possible by conventional means in 7 countries (Denmark, Finland, Greece, Italy, Norway, Sweden and the UK) and in the Internet in the same 7 countries.

Legislative/Non-legislative measures for advertising
Advertising of health care services was regulated by legislative measures in 11 countries (Austria, Belgium, Finland, Germany, Iceland, Norway, Portugal, Slovenia, Spain, Sweden and the UK) and by (recommendations) in 6 countries (Belgium, Finland, Germany, Italy, Norway and Sweden).

Advertising telemedical services were regulated by legislative measures in 4 countries (Denmark, Norway and Portugal. In Sweden general legislation applied also to telemedical advertising) and by non-legislative measures (recommendations) in 4 countries (Belgium, Finland, Italy and Sweden).

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets promotes the regulated profession associations and bodies, thus also the doctors, to establish Community level codes of conduct for commercial communication (as a part of information society service) and to determine what type of information can be given to such communication.

Proposed CPME policy

CPME should adopt guidelines for internet advertising of medical services, which then should be by adopted by the national medical associations in compliance to their national regulations.

10. E-MAIL IN DOCTOR-PATIENT RELATIONSHIP

Definitions

E-mail is mail in electronic form; the sender composes a message on his/her computer and transmits it via a communications network to the receiver's computer (European Commission: Telemedical Glossary 2001).

E-mail correspondence between a doctor and a patient means in this context professional communication to assist the doctor to fulfil his/her professional obligations and to assist the patient to communicate with the doctor in the treatment or a follow-up of his/her condition.
(CPME Guidelines for e-mail correspondence in health care, CPME 2001/112 Final)

A. Volume for e-mail correspondence in doctor-patient relationship

We studied:
- volume for e-mail correspondence between a doctor and a patient (less than 10%/10-50%/more than 50%/No information)

Results of the study

The results of the study could not give accurate estimates of the volume of the use of e-mail correspondence between a doctor and a patient. Seven of the countries that answered to e-mail part of the study did not gave any estimates. Seven of the countries estimated that e-mail was used by doctors to correspond with their patients less than 10 %. These countries were: Belgium, Denmark, France, Italy, Netherlands, Norway and Spain. Sweden seemed to use most e-mail in doctor-patient relationship by estimating that 10-50 % of the doctors used e-mail for this purpose.

B. Statutory framework for e-mail correspondence between a doctor and a patient

We studied:
- whether legislation existed on e-mail correspondence between a doctor and a patient (general/specific)
- whether there existed guidelines on e-mail correspondence between a doctor and a patient
- whether there is a need for such guidelines and what these guidelines should contain (time scale for answering time/documentation of the e-mail/privacy matters/style of e-mail/definition for suitable topics/liability issues/other)

Results of the study

<u>Legislation</u>
Most countries (13/15) stated that they did not have legislation on e-mail correspondence between a doctor and a patient. Finland and Iceland stated that general legislation apply to e-mail correspondence in doctor-patient relationship. Germany and Italy stated that there were legislation on this issue; which was general for health care. This would probably be the case in those countries that stated e-mail was not regulated by legislation.

Guidelines
Six countries out of 15 stated that there were recommendations concerning e-mail correspondence between a doctor and a patient. They were introduced by health authorities or professionals organisations. These countries were: Belgium, Finland, France, Italy, Norway and the UK. In Finland there was the reference to the CPME/WMA guidelines on telemedicine, but at least in the UK there exist a guideline also concerning the exact e-mail correspondence between a doctor and a patient, introduced by the General Medical Council. Iceland stated that a committee was preparing guidelines.

Special guidelines for e-mail correspondence
Most of the countries considered that a guideline for e-mail correspondence between a doctor and a patient should be provided. It should cover issues such as definitions for suitable topics, liability of e-correspondence, privacy matters, documentation of e-mail and turnaround time.

Proposed CPME policy

CPME member associations should adopt the CPME guidelines for e-mail correspondence in health care (CPME 2001/112 Final).

C. Charging and reimbursing of e-mail correspondence

We studied:
- whether charging of e-mail correspondence was possible.
- whether reimbursement of e-mail correspondence was done.

Results of the study

Charging
Charging for email correspondence was possible in 3 countries (out of 13): Netherlands and Norway, where also recommendations on the email consultation fee were set). The Social Insurance Institution of Finland assumed that email correspondence was charged, but no tariffs for reimbursement were given. However, reference to telephone consultation was made. In Norway law based tariffs for charges of e-mail correspondence were used.

Reimbursement
Email consultations were reimbursed in all the three countries where the services was charged, Finland, Norway and Netherlands.

Relevant EU regulations

EU does not have the competence to govern health care systems and social security systems of the Member States; instead, they are matters of subsidiary.

CPME policy

Adopted guidelines on e-correspondence between a doctor and his/her patient (CPME 2001/112 Final). These guidelines state that doctors should be able to charge for professional e-correspondence in the same way as for any other professional services and that patients should likewise be entitled to reimbursement.

11. ELECTRONIC PRESCRIPTIONS

Description of the topic

Some EU-countries, such as Denmark, already use electronic prescriptions of drugs. Many other countries are currently developing and testing systems for electronic prescribing. So far, electronic prescribing is aimed to happen within one country, but in principle, electronic networks offer possibilities for cross-border prescribing, an action which is not legally clear.

A. Identification of the doctor

We studied:

- identification of doctors by a prescription (number/code issued by health insurance/other).

Results of the study

Generally, doctor's signature and in most case, accompanied by a code was the main means to certify a prescription. The code number is issued either by a ministry of health, medical association, sickness fund or other relevant authority or body. Eight countries had an approved system for electronic signature: Austria, Denmark, France, Germany, Iceland, Portugal, Spain and Sweden. Four other countries stated that legislation on e-electronic signature was being developed: Belgium, Finland, Netherlands, the UK.

Finland stated that one possibility to check an e-prescriptions, at least used with telephone and -fax was to make a check call to the doctor.

Relevant EU regulations

Directive 1999/93/EC on a Community framework for electronic signature defines advances e-signature as: 'uniquely linked to the signatory, capable of identifying the signatory, created using means that the signatory can maintain under his sole control and linked to the data to which it relates in such a manner that any subsequent change of the data is detectable' (Art.2 2).
The directive offers electronic signature the same legal position as a hand-written signature has: 'the Member States shall ensure that electronic signatures satisfy the legal requirements of a signature in relation to data in electronic form in the same manner as a hand-written signature satisfies those requirements in relation to paper-based data and that they are admissible as evidence in legal proceedings '(Art. 5.1.)

The Directive gives the Member Sates states the possibility to require additional accreditation in public sector: 'Member States may make the use of electronic signatures in the public sector subject to possible additional requirements. Such requirements shall be objective, transparent, proportionate and non-discriminatory and shall relate only to the specific characteristics of the application concerned. Such requirements may not constitute an obstacle to cross-border services for citizens' (Art 3.7.)

Directive 1999/93 has become into force in the Member States by July 19, 2001.

B. Accepted forms of e-prescriptions

We studied:
- which were the used means for e-prescriptions (telephone/fax/e-mail/other).
- whether any legislation/guidelines for e-prescriptions existed

Results of the study

Used means
Some form of e-prescriptions was practised in 9 countries. Different forms were:

- Telephone prescriptions: Finland, Greece, Iceland, Norway, Portugal and Sweden
- Telefax prescriptions: Finland, Iceland, Norway, Sweden and Netherlands
- E-mail prescriptions: Norway, Sweden and Spain
- Other forms of e-prescriptions: Denmark (closed networks), Finland (Internet server between the pharmacy and the prescribing doctor in a hospital or health centre; e-mail prescriptions were under development), Iceland (a communication set up by an EDI programme), Sweden (no specification) and the UK (no specification).

Legislation/Guidelines
Of those countries where electronic prescriptions were possible, either general legislation and guidelines applied to electronic prescriptions or special ones were applicable (Finland: Order issued by the National Agency for Medicines; Iceland: General legislation; UK: Guidelines by General Medical Council).

E-prescribing was not allowed in Austria, Belgium, France, Greece, Italy and Slovenia.

Proposed CPME policy

Electronic prescriptions should be made possible as soon as a reliable system for the identification of the doctor and for the assessment of his/her prescription right has been established.

C. Prescription issued by a foreign doctor

We studied:
- whether a an ordinary/electronic prescription issued by a foreign doctor was accepted if not licensed in the country of delivery.

Results of the study

A prescription issued by a foreign doctor who had no licence in the country in concern, is accepted
only in Greece and in the Nordic countries, which accept a prescription issued by a Nordic doctor (though some limitations regarding the prescriptions exist). Iceland stated that it accepts prescriptions from any EEA country beside the Nordic ones. Denmark stated that it also a prescription issued by a doctor who has a licence in any other EU-country. Respectively, a telemedical non-national prescription is accepted in Norway (and France?)

Relevant EU regulations

Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications in principle refers the certificate of basic medical studies equal in all the Member State. License to practise within a country has to be applied from the competent authority in order to practise in that country.

Council Resolution 95/C 350/04 on mutual recognition of the validity of medical prescriptions in the Member States calls the Commission in co-operation with member states to study the present situation of mutual recognition of medical prescriptions within the European Internal Market area. The Resolution marks that discrimination based on nationality of establishment and provision of (doctor's) services is prohibited in medical practise. The resolution does not apply to financing and reimbursement of medical products nor the prescriptions classified narcotic of psychotrophic drugs in the UN conventions.

The Commissioner of DG Industry, Mr. Bangemann, and the Commissioner of DG Internal Market, Mr. Monti have in their replies to written questions of the Members of European Parliament supported mutual recognition of prescriptions within the Internal market area.

Proposed CPME policy

A prescription of a doctor who is authorised to prescribe in one EU country, should be valid in all EU countries.
Possible problems related to the recognition of the doctor and to the recognition and the proper use of medical product purchased from a foreign country, and to the reimbursement of the drug shall first be solved.