

**EUROPEAN COMMISSION** 

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

#### HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

# Document: Summary paper on Common principles of Care, from the Mapping Exercise of the High level Group on Health Care Services 2006.

Date: 3/11/2006	Reference: HLG/CBH/2006/4/4
To: Members	From: Secretariat
Action: -	

# Summary paper on Common principles of Care

# -from the Mapping Exercise of the High level Group on Health Care Services 2006.

# **1. Summary and recommendations**

This note summarises some of the key findings from the Mapping exercise issued by the High Level Group on Health Services and Medical Care (HLG), spring 2006. The working group on cross-border healthcare purchasing and provision (including rights and duties of patients) initiated the mapping exercise to increase information about the different existing structures for providing patient information on health care provider's obligations, patient's rights, responsibilities and entitlements related to cross border health care.

In total responses were received from 22 countries<sup>1</sup>. The nature of the data and the way they are collected and compiled make analysis difficult. The compiled information is not comprehensive and not necessarily comparable but still some recommendations can be made:

> Member States might consider appointing <u>a clearly defined contact point for patients that</u> seek information on access to health care across abroad.

 $\succ$  The national or regional contact points could form a network in order to share experiences and information related to cross border care. The contact details of the participants in the network could be made available through the EU Health Portal<sup>2</sup> and the Commission could provide assistance to the network by raising awareness about the EU legislation.

> To increase the knowledge about the trends concerning cross-border care it is necessary to <u>built up comparable data concerning patient mobility</u>, with regard to Regulation (EEC) 1408/71, but also with regards to block purchase and individual patient mobility. The HLG should cooperate with the Administrative Commission on Social Security for Migrant Workers on the issue of data collection.

> Further work is needed to identify existing procedures regarding the complaints processes, <u>arrangements for handling liability issues</u> and ways to get compensation in the Member States.

# 2. About the mapping exercise

Since 2004 the working group on cross-border healthcare purchasing and provision (including rights and duties of patients) has worked on cross border issues related to health care. It has become increasingly clear that the lack of knowledge among patients about the different models supplying health care, and that the subsequent uncertainty for the patients may have provided an obstacle to cross border healthcare.

To explore how and what kind of information patients get when they are considering cross border health care the working group agreed to do a mapping exercise. The mapping exercise took a practical and a detailed approach to some of the issues agreed by the Member States in

<sup>&</sup>lt;sup>1</sup> AU, BE, CY, CZ, DK, DE, EE, ES, FI, FR, HU, IE, IT, LA, LI, MT, NL, NO, PO, SL, SK, SE, UK.

<sup>&</sup>lt;sup>2</sup>One alternative is to create a page like: http://ec.europa.eu/employment\_social/missoc2001/index\_en.htm

the EPSCO Council Conclusions 2 June on "Common values and principles in EU Health Systems."  $^{3}$ 

Based on the input to the mapping exercise (see annex 1) this paper shows some examples of how Member States have chosen to solve common challenges in particular related to:

**a) Information to patients through contact points,** to increase the knowledge about the national strategies to get information to patients on getting treatment in another Member State. The paper shows that most countries have mechanisms for the provision of information to patients. There is a need however for information to patients on health care in other Member States and for increased cross-border cooperation.

**b) Principles of care** where the mapping exercise aimed establish whether there was a possible structure relating to patient rights, responsibilities, entitlements and liability issues in Member States. There are of course particular ethical issues that will vary between Member States, and these are not intended to be covered by this exercise. The purpose is to help address issues linked to cross border care. However to achieve this, it is necessary to gather information about the current provision within national systems, in order to identify existing shared principles of care throughout the EU, and areas of difference.

c) The paper has a part on **numbers and costs** related to cross border care. This was included in an attempt to get a more complete picture based on updated information from the Member States on the numbers and costs of treatments within and outside Regulation (EEC) 1408/71, within and outside EU. The data provided in this part of the paper is compared to data and adjusted to a structure previously provided by the Member States.

# a. Information to patients

From the replies it is clear that <u>most countries have structures that provide information to</u> <u>patients.</u> This is done either at a national, regional or municipality level, through the insurance companies like in Germany or through the liaisons offices for social security.

Some countries have defined explicit contact points for patient information, while others lack such clearly defined centres. It is also clear that family doctors and other physicians are an important source for information for how to get care for the citizens as in Belgium, Czech Republic, France, Italy and the United Kingdom. In Norway there is a specific contact point providing information to facilitate the use of the right to choose hospital, and another specific contact point for patients who have not received treatment within the limit set for him/her and therefore is entitled to receive the treatment immediately, if necessary from a service provider in the private sector or abroad.

The information provided to the patients range from information on the European Health Insurance Card while other focus mainly on care within the countries. It seems that insurance based systems mainly provide information about treatment within the country and the specific system. Some contact points also provide information about access restraints as in Denmark where information is provided about hospitals abroad, waiting times in domestic systems, what kinds of services that are provided abroad and what the waiting times are.

<u>The information provided</u> and the applicability for users from other countries varies. For example, it will be difficult for foreign patients to select one of the Insurance Funds in Slovakia and to assess the objectivity of the information provided.

<sup>&</sup>lt;sup>3</sup> Endorsed by the EPSCO Council 1-2 June, press release available at:

http://www.consilium.europa.eu/uedocs/cms\_Data/docs/pressdata/en/lsa/89830.pdf

The <u>routines for updating the information</u> seem to vary in the different Member States. National authorities and national administration are often the main source for information circulated and there seems to be a lack of control of the accuracy of the information finally reaching the patients. Most countries have some kind of <u>web page</u> either at the Ministry or National Insurance Fund in addition to information through phone or leaflets, brochures etc.

In most of the insurance based systems it is the responsibility of the insurance company to provide the information to the insured. However, it is unclear who has the responsibility to provide information to foreign citizens that consider receiving health care in the country. It is likely that it requires quite good knowledge about the system prior to finding the right insurer to provide the needed information. An insured person should be able to get information how to get access to cross-border care in the country where that person is insured. Providing information to insured persons from another Member State might prove extremely difficult, given for example the language barriers. Competition among different insurers may also be a challenge.

The distribution of the European Health Insurance Card (EHIC) is the responsibility of the EU Member States. They have developed information on the EHIC through leaflets, national websites etc and the Commission provide information on its website: http://ec.europa.eu/employment\_social/healthcard/index\_en.htm, which is regularly updated and improved.

# **Recommendation- Information to patients:**

> Member States might consider appointing a clearly defined contact point for patients that seek information about access to health care across borders.

> The national or regional contacts could form a network in order to share experiences and information related to cross border care. The contact details of the participants in the network could be made available through the EU Health Portal and the Commission could provide assistance to the network by raising awareness about the EU legislation.

# b. Principles of care

# 3.1 Types of legislative acts

Most countries seem to have some legal provisions that ensure the rights of patients e.g. in relation to the quality of the services through the regulations, national standards that set out the organisation of the services, the ethical codes of the professionals or the contracts from the providers of healthcare.

In some countries there are <u>separate laws/provisions on patient rights</u>, such as in Belgium, Finland, Lithuania, Norway and Spain. As examples of countries where patients are ensured through more <u>general legislation for the health services</u>, are Czech Republic, Denmark, Hungary, Latvia, and Poland. In some countries like Sweden and Finland legislation sets up a number of <u>demands on the provider organizations of public care and their personnel</u>, ensuring that the residents of that country have access to high quality healthcare.

In some insurance based models the <u>insurance contract regulates the terms of treatment</u>. In Germany the terms of treatment are regulated by social insurance law. In addition separate provisions are set out in terms of a contract that specify the terms of cooperation In the Netherlands the type of insurance policy (benefits in kind-policy or policy based on the

refunding of costs) regulates the duties of the insurance company, ranging from ensuring enough contracted health care providers to helping an insured person find a health care provider and the refunding of the costs.

Again other countries ensure the rights through <u>regulation of health professionals</u>, the Professional Code or even through the criminal code.

Finally other countries seem to have general <u>non-binding documents</u> as in France where there is a "Hospitals Patient Charter" that defines the rights of the patients. Another example is in the UK where patient entitlements are normally set out as guidelines from the Secretary of State to NHS commissioners and advisers who in turn are required to advise patients of what services are available.

# 3.2 a) Access to care,

#### - including preventive services such as cancer screening services

According to the Article 35 of the Charter of Fundamental Rights of the European Union<sup>4</sup> "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices".

Access to health care is a central principle in Most EU Member States as set out in the statement of the EPSCO Council: "The overarching values of universality, access to good quality care, equity, and solidarity have been widely accepted in the work of the different EU institutions. Together they constitute a set of values that are shared across Europe. Universality means that no-one is barred access to health care; solidarity is closely linked to the financial arrangement of our national health systems and the need to ensure accessibility to all; equity relates to equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay."

However there are differences as to whom the coverage applies e.g. if it explicitly covers foreign citizens. There are differences as to what is covered e.g. how the access to care is implemented. As an example in Latvia the Law on Medical Treatment defines who are eligible for treatment, and the Regulation of Cabinet Ministers on organisation and financing of health care defines which health care services are paid for by the State budget.

In terms of coverage it is clear that <u>preventive health care</u> is often not accessible for foreign citizens staying temporarily in a country. In the insurance based countries the provision of preventive care is mainly targeted at the insured people as in Germany, Hungary and in Belgium.

Several countries ensure access to health care through <u>compulsory health insurances</u>: as in Belgium, Estonia, Germany, Hungary, Slovenia, Slovak Republic that stipulate that all patients shall have the right to receive from health professionals high quality medical care that meet their needs, with respect for human dignity, their self discrimination and without discrimination of any grounds.

<sup>&</sup>lt;sup>4</sup> 2000 O.J. (C 364) 1 (Dec. 7, 2000).

Other countries ensure access through providing <u>benefits in kind</u> such as Czech Republic, Denmark, Finland, Norway, Spain and Sweden without apparent restrictions to the "core benefit package".

In terms of <u>implementation</u>, the level of <u>co-payments</u> by the patients may have an influence on the accessibility of the health services in all systems for both foreign and domestic patients. Access may be restricted by other factors such as <u>waiting times</u>. Some countries like Finland, Spain and Sweden there is a national guarantee for maximum waiting time for treatments.

The effects of possible access restrictions may depend on where in the system they occur. As an example in some countries the GPs serve a gatekeeper function to restrict access to specialist services, while patients in other countries can seek specialist care at their own initiative. This may influence the situation related to cross border care.

### 3.2 b) Information and consent:

While part 3.2.c) deals mainly with how personal and private information is treated, stored and passed on to others, this part considers issues such as information and consent. Do patients have to give consent to treatment? Who is exempted? How do children, mentally ill and others give consent? The information requirements prior to consent will equally be covered.

The concept of <u>informed consent</u> seems to be applicable to the majority of European Countries as Belgium, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, Poland, Slovak Republic, Slovenia, Netherlands, Norway and Spain. It is a general principle that consent is given on the basis of adequate information provided by the medical attendant. In many countries the regulations contain several exemptions, such as when the patients are minor, have permanently lost the capacity to give informed consent or situations where immediate treatment is needed.

For situations related to <u>planned cross-border care</u> where adults fully able to give consent prior to treatment are receiving health care, most EU Member States have the same provisions. There are some differences as to whether the consent need to be given explicitly for normal health care. In Belgium, Denmark, Hungary and France this is the case, while it in other countries not is a particular requirement for explicit consent.

Informed consent is required for <u>participation in research activities</u> in several countries such as Finland, France, Germany, Hungary, Latvia, Norway. Clinical trials on medicinal products for human use are regulated on EU level, and informed consent is one prerequisite for these trials. Some countries have special provisions that require consent for the storage and use of human biological material such as Norway.

Many countries have specific provisions where the <u>patients have a right to refuse information</u> as in Finland, Hungary and Spain. In other countries as Latvia and Spain <u>doctors may provide</u> <u>incomplete information to the patients</u> if the information may cause deterioration of the state of health of the patient.

Informed consent does not necessarily imply the right to <u>choice of treatment</u>, however in some countries this seem to be the practice as in France. In Norway the patient has a right to participate in choosing between available and medically sound methods of examination and

treatment. In some countries like Finland, Hungary, Latvia, Slovenia and Spain patients have the <u>right to refuse treatment</u>. However in Latvia and Spain this right is not respected if it implies a danger to the life and health of others. Latvian doctors have the obligation to inform the patients of the consequences of the non-treatment, if that is the choice of the patient. Norway has similar rules as Latvia in that the patient may refuse treatment with some exceptions, among them where it comes in a conflict with the duty of health personnel to save life. There are special rules about the right for the patient to refuse life-saving or lifeprolonging treatment in certain situations and on certain conditions.

There are some differences as to whether patients can <u>change or withdraw consent</u> that has been given at some point in time. In Hungary, Germany, Norway, and Spain patients can withdraw consent at any given time.

The information provided for patients in order to get their informed consent and the practical arrangements may be different in different countries. In Germany jurisprudence have set out what kind of information the patient should get: current health condition, the name of the physician who has to operate or who has the responsibility, the nature of the treatment, possible secondary effects and other risks of treatment, chance of success, the degree of urgency of the treatment, the costs of the treatment. In Hungary it is even specified that the information provided should take into account the age, education and mental health of the patient concerned. Similarly Norway has the requirement that the information shall be adapted to the qualifications of the individual recipient, such as age, maturity, experience and cultural and linguistic background. In addition it is required that the information shall be given in a considerate manner, and the health personnel shall as far as possible ensure that the patient has understood the contents and significance of the information. <u>Patients' right to look into medical records</u> is also ensured in some countries like Hungary, Finland, Norway and Sweden.

Some legislation specifies <u>who should provide the information</u>. In Latvia the information is supposed to be provided from a doctor.

It is a concern that <u>particular dimensions due to cross border care may hinder people to give</u> <u>informed consent</u>, e.g. due to the lack of information in understandable language, differences in common treatments that care providers do not inform about, e.g. in Germany most patients bring their own blood prior to surgery, while blood in other countries is provided from donors. Also a large part of the cross-border care is provided as emergencies.

# 3.2.c) Privacy and confidentiality

This part of the questionnaire relates to privacy and confidentiality in the process of collection, storage, communication and use of personal data in the health care sector. It also covers the link to the handling of personal information and has a clear link to point 3.2 b) on information and consent.

As a general rule, activities related to processing of data need to comply with the EU Directive  $95/46/EC^5$  on the protection of individuals with regard to the processing of personal

<sup>&</sup>lt;sup>5</sup> OJ L 281 of 23/11/1995.

data and on the free movement of such data. In general, health data may be shared where this is required for the purposes of prevention, medical diagnosis, the provision of care or treatment (including continuity of care and follow-up) or the management of health care services, and where those data are processed by a health professional who is subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy. If data are to be used for other purposes this has to follow the principles of consent set out in the legislation of the Member States.

Most EU countries have provisions in their national legislation ensuring that <u>patient data are</u> <u>confidential</u> and cannot be shared without consent. In France it is also specified that social information, personal, administrative, medical and administrative data are covered by the same rules. In Latvia it is specified that the information regarding a patient cover medical treatment, diagnosis and prognosis of a disease, as well as info on the private life and closest relatives. In Germany consent is required before data can be used for other purposes than it was collected for. However in Slovenia and Hungary the patients can ask the health workers not to transfer data on their health condition to any other person without permission.

Some countries have special provisions related to the length, the contents and keeping of medical records, including rules on corrections, deletions, and storage, and filing of the data as in Finland, Italy, Norway, and Spain.

Many countries such as Belgium, Germany, Hungary and Spain, have <u>deviations to the</u> <u>general rule of consent</u>, as set out as in the Belgian Legislation that specify that patients have the right of protection of their privacy in any medical care treatment; particularly in respect of the information about their health unless there is a <u>danger for public health or for the rights</u> and liberties of others. In Denmark there is a specific clause for exemptions <u>if treatment is</u> required (this provisions is ensured by a directive.) In Slovenia there are exemptions if the personal information is necessary for <u>scientific research</u>. Norway has provisions about confidentiality, consent to dissemination of information, and what exemptions can be made from the main rule without consent, also in relation to other personnel in the health care service. In Slovenia and Germany the court can release health professionals from their obligation to protect professional confidentiality. Some countries have exemptions if there are <u>clinical trials and research</u> if these are performed anonymously. Some countries like Norway have particular provisions related to <u>bio banks</u>.

Most European countries also have provisions ensuring that <u>patients have access to medical</u> <u>records and correspondence concerning patient information</u> as in Slovenia where patients have right to examine the information stored about their medical condition. In some countries, like Norway, the patient also has a right to get a copy or print of the medical records.

It is also clear that <u>privacy should be respected when care is provided</u> as in France where it is provided that the beliefs of the patient must be respected, while they must be ensured peace and quiet. In Sweden this is ensured through a general provision that the care shall be provided as to promote good contacts between the patient and medical personnel. In Finland the law stipulates that the care of the patient has to be arranged so that his/her human dignity is not violated and that his/her conviction and privacy is respected.

Some countries have these regulations specified in separate laws/provisions, such as in Belgium, Germany, Latvia, Netherlands Spain and Poland, where there is a particular law on data protection. While other countries like Hungary and Slovak Republic ensure this through

provisions in other legislation like (Act on Health Personnel, Specialised Health Services or Health Establishments). Norway has provisions both in the Patients' Rights Act, and in other acts, among them Act relating to Health Personnel, Act on Specialised Health Services and Act on Personal Health Data Filing Systems and the Processing of Personal Health Data.

Particularly relevant for cross-border care situations are provisions that ensure the <u>transfer of</u> <u>the information</u>. Some countries like have as Slovenia a regulation that obliges the doctors to hand over to the doctors that continue the treatment all relevant medical information. Of other relevance for cross border care could be differences in the kind of information that is registered and if the patient can request to get the information in a particular language.

# 3.2 d) Quality and safety

Linked to the question of 3.2.a) access to care is the question on "access to what?" In Belgium, Germany and Spain it is specified that patients have access to high quality health care. However, how patients and professionals know and ensure that the care is of high quality depends on the existence of a system for monitoring of quality and safety.

Most EU countries ensure the quality of the treatment through some monitoring bodies and through national legislation either related to the organisation of the health services or the responsibilities related to health professionals. This can be done at a national and a regional level and there may of course be differences in what levels that are regarded as sufficient standards.

Most EU countries have <u>quality and safety provisions in the general regulation of the health</u> <u>services</u> as in Czech Republic, Estonia, Finland, France, Hungary, Italy, Latvia, Lithuania, Norway, Netherlands, Slovak Republic, Sweden and Slovenia is in a process of developing legislation in this area. As an example in the Czech Republic there are sets of <u>national quality</u> <u>and safety standard rules</u> that providers need to comply with. In Norway, Spain, Netherlands and Hungary the legislation ensures that all health providers shall operate <u>quality management</u> <u>systems and there is an independent body that supervise</u>. In Norway there is also a system for reporting errors in treatment. In Hungary the quality management system covers guidelines for professionals, personal and material minimum conditions needed to provide certain conditions.

The issue related to patient safety has also resulted in the Hungarian government issuing guidelines concerning internal quality management, and the establishment of a patient identification system. About 260 guidelines and protocols have been developed, and they are also attempting to develop a patient identification system, in case of emergencies and in case of limited communication skills. (Sweden also has national normative work being done by the National Board of Health and Welfare in this area. They provide guidelines and recommendations with regard to different aspects of quality.)

In some countries like Belgium and Germany the quality of the services are ensured through the regulation of the <u>health professionals</u>. As an example there is a particular request for additional training from the Regional Medical Association. In Norway the health personnel are under obligation to conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general. The health personnel shall act in accordance with their professional qualifications. If the patient's needs so indicate, the profession shall be performed through co-operation and inter-action with other qualified personnel

# **3.2 e)** Choice and access to different providers - including services abroad

This section looks at the choice of providers and finds that several countries allow a free choice of GP's, specialist and hospital care. Some countries even have the possibilities to choose between health insurers. The section aims to highlight how the choice of providers is extended to cover services abroad and how that is integrated as apart of the system or and how the rulings of the ECJ are made operational.

The <u>right to choose the care provider</u> is a common element in the legislation of the EU Member States.

Some EU Member States ensure the choice of providers at levels of <u>primary and secondary</u> <u>care</u> like in Belgium, France, Germany, Hungary and Slovenia. In Denmark patients that have chosen to be covered by one kind of coverage, Group 2, are allowed to choose at the <u>primary</u> <u>care level</u>, General Practitioners both within and outside the national borders, however patients receive the compensation equivalent of the costs of a Danish GP within the public system. This is a good example of the link between the practical arrangements and the degree of choice. In Hungary the primary care providers can be chosen but in advance and normally for a longer period. In Norway the patients can choose their regular GP who will have a particular responsibility to give priority to and follow up the patients on his/her list. However, the patient is free to go to another GP when he or she so wishes. The patient also has the right to choose hospital within the country (among hospitals linked to the public health care system).

Italy, Denmark and Norway offer treatment abroad at a <u>secondary care level</u>, if there is a lack of competence or capacity in national hospitals. In Denmark there is a time limit of 2 months as a measure of the lack of competence. In Norway the patient on certain conditions has a right to receive such care within a medically justifiable time limit set for each individual patient. In Finland it is regulated that if the hospital district cannot provide medical care in Finland within maximum waiting times, it has to give a preliminary authorisation for the patient, on his/her request, to seek the treatment in the other EU/EEA countries or Switzerland.

# 3.2 f) Complaints and compensation

Unfortunately medical errors occurs. In situations that involve cross-border care the system to follow up and to file a complaint may be of influence for the choice of the country. It is therefore of relevance to identify what patients have to do in case of medical error, and if there is a system for compensation.

The mapping exercise showed that there are differences between the Member States in the way these systems are organised, and in the way these are connected to the monitoring of health professionals, e.g. if the body that monitors the adverse events is also engaged in access to information such as medical dossiers, has a direct influence over health

professionals etc. However, further work needs to be done to get more clarity on how the different systems function in this area.

# 3.2 g) others

In some countries patients have other rights and entitlements that may influence cross border care situations. As an example in Slovenia if the patients agree to be treated by a health professional, the patient is required to provide the health care worker with true data on their health condition and to behave according to the instructions of the health care worker, to actively cooperate in protection, reinforcement and restoration of his own health. If the patient does not comply the health professional may refuse to offer help.

# 3.3. Are there plans to change the legislation or policy documents mentioned above?

Based on the different responses it is not possible to draw general trends in the planned changes in policies and legislation.

### **Recommendation - Principles of care:**

 $\succ$  From the mapping exercise it is clear that most European Health care systems have common elements related to patient's rights and obligations through different provisions. The complexity of the organisation of the health services makes it difficult for patients to understand the range of services that are provided in different countries. Further work is needed to identify the existing procedures regarding complaints' processes, arrangements for handling liability issues and ways to get compensation but also on the differences in the provisions ensuring consent.

# c. Data on patient mobility

It is clear from the responses that complete comparable data do not exist. Member States supplied their data in terms of either numbers of patients or overall costs, and most of the Member States were unable to reply systematically to all the questions. Some of the difficulties may result from the legal or administrative structures (e.g. decentralisation). Based on the existing data some trends are however apparent:

Although the extent of cross border care is still low, there has been an <u>increase in cross-border</u> <u>care activities</u> during the last five years. As an example Belgian claims on other Member States for the category of persons authorised to receive treatment in Belgium under form E112, was  $\in 25.9$  million in 2000. This is almost half of the claims in 2004 of  $\in 44.5$  million. In Denmark there has been nearly a five times increase in the number of citizens from other EU States that received hospital treatment from 2001 to 2005.

There are <u>differences in the trends</u>, as to they are due to increases in numbers or on costs. For example in the UK although the numbers of patients actually declined from 2003 to 2004 from 1732 to 1183, the costs rose with nearly £9 mill from £40.1 mill £49.5 million. This increase in cost could be due to the nature of the procedures carried out.

<u>Regulation (EEC) 1408/71 remains the basic legal instrument for patient mobility</u>. Financial mechanisms set out in this Regulation also ensure transparency of the financial flows for the social security institutions involved. Some <u>cross border care outside Regulation (EEC)</u> <u>1408/71 seems to be linked to particular arrangements</u>. In some countries the arrangements are left to the local authorities or counties and without control of the national authorities. This is the case in Sweden where the county councils are free to make their own arrangements on cross-border cooperation with other countries. A relatively small number of such arrangements in border regions, where hospitals in the country of non-residence may be closer to the citizens place of residence. An example could be from Spain where it is considered to establish a French-Spanish hospital in Puigcerdá (Catalonya).

There is no <u>symmetry in the patterns of cross border care</u>. As an example in Spain the majority of foreign forms come from Germany while the majority of Spaniards seeking health care abroad go to France. Several persons insured in Austria receive care in Hungary while persons insured in Hungary seek treatment in Slovakia out of which great numbers are frontier workers.

<u>Cross border care is also a phenomenon that goes beyond the European Union</u>. There is also an increase in this activity. In 2003 France received claims form patients treated outside EU and in countries linked to France by a Social Security agreement, of  $\notin$ 40 million.

Despite the framework for the collection and presentation of data on cross border care issues, found in the Recommendation N° 17 of 12 December 1984 of the Administrative Commission on Social Security for Migrant Workers concerning the statistical data to be provided for the reports to the Administrative Commission in particular point 2,<sup>6</sup> the Administrative Commission does not have the necessary data of cross border care, required to investigate trends or financial impacts. In its meeting of October 2006 the Administrative Commission will discuss ways to improve the data collection. The data collection will, however, most likely not cover treatment outside Regulation (EEC) 1408/71.

Only limited information exists about the percentages of authorisations granted and the number of claims reimbursed without prior authorisation. In Estonia the share of authorisations granted has declined from 91% in 2000 to 69% in 2005. In Germany, the number of authorisations granted is only known to one of the 220 the respective social insurance companies, but the known trend shows that only approximately of 1% of the annual budget is used for cross border care. During 2005, 157 individuals applied at the Swedish Social Insurance Agency for authorisation beforehand for planned treatment abroad. In Latvia the number of applications was low only 34 applications however 16 were granted.

# **Recommendation – Data:**

In the absence of complete, comprehensive and comparable data concerning patient mobility, the High Level Group, taking account of the different legal and administrative structures in the Member States, suggests that:

<sup>&</sup>lt;sup>6</sup> OJEC N° C.273 of 24 October 1985

 $\succ$  Member States take the necessary measures for the compilation and registration of data allowing at least a view on the medical, financial and administrative information related to cross-border care.

> A clear and transparent common dataset (numbers of patients, amount of money involved, and preferably the treatment received abroad) is essential to get a grasp of the much discussed issue of patient mobility. This collection of data should be done in relation to regulation 1408/71, block purchasing, and individual patient mobility.

 $\succ$  there should be a close cooperation between the HLG and the Administrative Commission on Social Security for Migrant Workers on the issue of data collection.

# List of annexes:

ANNEX 1. Responses to the questionnaires. ANNEX 2. Data on cross border care

# ANNEX 1. Responses to the questionnaires

#### 1.a/b) Is there a national/regional contact point for patient information?

In **Austria**, no there is no clear contact point however insured people can get information about the treatment abroad through their insurance companies, which provide normal customers care. At the headquarters of the "voralberger" "gebietskrankenkassen" there is one person responsible for requests concerning cross-border healthcare, that work as a part of the department for "Zwischenstaatliche Sozialversicherung" the wanted knowledge. The employees at all levels are also providing information. At the "Karnter Krankenanstalten" are information material in English, Italian and Spanish and Slovenian.

In **Belgium**, the five national unions of mutual health insurance funds and the two public funds have regional agencies that provide information at the request of the patients.

**Cyprus**: The national contact point for patient information on cross border care is the Ministry of Health. There are no regional contact points. Information is provided through District State Hospitals. The Ministry of Health has delegated to the State Hospitals the authority to issue European Health Insurance Cards (EHIC), to Cypriot nationals and European citizens who are permanently residing in Cyprus. State Hospitals provide also information about EHIC.

**Czech Republic**: The national contact point for patient information on cross-boarder care for the Czech republic is the Centre for International Reimbursements, this is a cooperation between all 9 health insurance funds (currently active within the Czech health care system) as the liaison body according to Regulation EEC 1408/71. The Czech Republic is relatively small country and therefore it seems as unnecessary to create any other regional contact point. In case of a real necessity, there are regional branches of health insurance funds, which have enough relevant information or which stay in close touch to the Centre for International Reimbursements.

**Denmark** have a system where the local municipalities provide information on reimbursement on crossborder care relating to non-planned health care benefits in kind according to regulation 1408/71 and on reimbursement of costs for planned non-hospital care. Patients can also either call or visit the patient advisory units in the county.

**Estonia** Information is mainly provided through the Estonian Health Insurance Fund and their internet page: www.haigekassa.ee

**Finland** General information for patients and health care providers on European and national rules on crossborder care is available through the Ministry of Social Affairs and Health <u>www.stm.fi</u> and Social Insurance Institution (Kansaneläkelaitos) <u>www.kela.fi</u>. In the Ministry's website there is a guidebook for health care personnel concerning situations when foreign patients come to Finland (Medical care in Finland for persons residing abroad, available only in Finnish). In the SII's website there is a brochure that contains information about benefits in kind available in other countries (Brochure: If you fall ill abroad, available only in Finnish), and information on the European Health Insurance Card).

**France** has established a Centre of European International Liaisons for Social Security, which is a French public national institution, mainly funded by the French Social Security Schemes. The centre assists French Social Security organisations in the implementation of the European regulations and bilateral agreements related with coordination of social security systems. It intervenes at the request of the French and foreign organisations and of insured persons or their employers; it supplies information about procedures provided for in different international agreements and gives constructions of laws or other legal texts issued by its supervisory authorities. However it is only limited known to the public. In addition every French local social security organisations are able to inform insured persons on cross-border care.

**Germany:** The insured persons may get information about treatment abroad from their health insurance company. Most of the health insurance companies have information available via internet or brochures. At the time the opportunity to receive treatment abroad was established under German Law in 2004 as a

consequence of the judgement of the European Court of Justice, most of the health insurances informed their insured persons about this possibility.

Since the health insurances are responsible for their insured persons, they are not in charge of informing from non-insured persons from outside Germany who wish to get a treatment here. However, if foreigners wish information about the system they may ask the liaison office for Directive 1408/71 in Germany:

**Italy:** The Ministry of Health provides some information about cross border healthcare mainly trough its website www.ministerosalute.it. In addition, every region has an office for travelling patients which deals with trans-regional travel and usually also of international travel

**Ireland**: The national contact point for patient information on cross-border care and competent authority in the context of the Administrative Commission on social security for migrant workers is the Department of Health and Children, Hawkins House, Dublin 2, www.dohc.ie (as per Annex I of Regulation (EEC) 574/72). In addition, as per Annex IV of the Regulation, the Health Services Executive, Naas, Co. Kildare www.hse.ie is the designated liaison body under Article 3 of Regulation (EEC) 575/72, and is therefore also a national contact point in this context. The regional contact points for patient information are the competent institutions as listed in Annex 2 of Regulation (EEC) 574/72 for Ireland:

Health Services Executive Dublin-Mid Leinster, Tullamore, Co. Offaly;

Health Services Executive Dublin-North East, Kells, Co. Meath;

Health Services Executive South, Cork; and

Health Services Executive West, Galway.

**Latvia** Information on national level about the rules regulating treatment in another MS is provided by State Agency for Compulsory Health Insurance and five branches of Agency.

**Lithuania:** At national level the information on cross-border care for the patient in regards to the Regulation No. 1408/71/EEC can be received from the State Patient Fund under the Ministry of Health, at a regional level the information can be collected from the regional representatives the so- called Territorial Patient Fund.

**Netherlands:** There is no governmental national contact point for patient information on cross border care. However, patients can obtain information from the Federation of Patients and Consumer Organizations in the Netherlands (NPCF) which aims at enforcement of the position of patients and consumers in health care. Patients can obtain information on cross border care from the Euregios.

**Norway**: At national level there is a contact point for patients who are not treated within the time limit, for other reasons than lacking competence, and therefore are entitled to health care immediately, if necessary in private sector or abroad. The contact point is responsible for informing patients, as well as contracting providers to give the care and organise travel and care for the individual patients. The contact point does not have an internet page. However information about the relevant patient's right are found on national websites such as:

• The website for free choice of hospital in Norway <u>www.frittsykehusvalg.no</u> (including information about waiting times at different hospitals for 90 different treatments and quality indicators for each hospital, i.e. information which also might be of interest for patients from abroad who seek health care in Norway)

- The Directorate for Health and Social affairs' site <u>www.shdir.no</u>.
- The National Insurance Administration's website <u>www.nav.no</u>.

At regional level there are contact points for patients that need treatment abroad for the reason of lack of competence in Norway. The contact points are responsible for informing patients, as well as contracting providers to give the care and organise travel and care for the individual patients. In addition regional information centres for free choice of hospitals will provide patients with relevant information and refer them to the correct contact points.

**Malta:** A national contact point for patient information on cross-border care has been established in Malta. The island of Gozo, which forms part of the Maltese archipelago, is administratively managed as a region. Health care on the island is therefore regionally managed, organised and funded. However, provision of treatment to patients outside Malta is managed, funded and co-ordinated by the Department of Institutional Health within the Ministry of Health, the Elderly and Community Care, as outlined in reply to question 1a above.

**Sweden**: Information on national level about the rules regulating treatment in another MS is provided by the Swedish Social Insurance Agency or by the County Council. The Swedish social insurance agency has over 200 local offices and 21 regional offices who are responsible for providing such information. The regional county

council are also responsible of providing information about national health care and, in specific cases, international care.

**Slovakia**: No defined contact point, the main source of information on cross-border health care are physicians-specialists, clinics and health insurance funds.

**Slovenia**: Information are available through The Health Insurance Institute of Slovenia (ZZZS) – Head Office or the 10 Regional Units of the Health Insurance Institute of Slovenia.

**Spain**: Information is being provided through the Ministry of Labour and Social Affairs: <u>http://www.seg-social.es</u> or at the local level through the 489 regional centres of the National Institute of Social Security.

**UK**: No. There is some information available on the Department of Health website http://www.dh.gov.uk/Home/fs/en this generally sets out the Department's policy for handling requests for overseas treatment. Decisions about requests from patients for treatment in other member states are made by healthcare commissioners such as Primary Care Trusts or Health Boards in Scotland. These commissioners also have the role of advising patients about the services provided and entitlements.

### 1.c) How is the information made available to the patients?

In Austria, the insured get the information at either written or oral requests.

The **Belgian Health Insurance funds** often provide information on what to do when requiring health care while staying temporarily abroad in their internal information bulletins or on different web sites while information on cross border health care is mainly provided at the request of the patients.

**Cyprus**: Information is made available to patients through brochures, word of mouth, telephones, website, etc.

**Czech Republic**: The Centre for International Reimbursement, as well as the Ministry of Health and health insurance funds, provides relevant information via internet, seminars for general public and experts, brochures etc.

**Denmark**: In addition to the information provided by the Ministry of the Interior and the National Social Security Agency to the municipalities and regions, the Danish Association of Regions (Danske Regioner) arrange seminars to make sure that the regions have the most recent information. There is also a national web page that provides information on waiting times for national hospitals. <u>www.venteinfo.dk</u>. The Danish Ministry have also made leaflets on the <u>www.im.dk</u>.

Estonia: <u>www.haigekassa.ee</u>

**Finland**: Brochures are developed, and they are available on the Internet (<u>www.stm.fi</u> and <u>www.kela.fi</u>). In individual cases health care personnel gives advice to patients who are interested in cross-border care.

**France**: At a national level, social security organisations generally provide information by web sites such as <u>http://www.ameli.fr</u>, <u>http://www.canam.fr</u>, and <u>http://www.msa.fr</u>. Special leaflets about cross-border care is also issued and social security organisations generally provide information at the request of the insured persons (for example by phone, letter or directly

**Hungary**: General information on treatment abroad is available via internet. Concrete information is available both by phone or provided by leaflets, brochures etc.

**Italy**: There is a central technological structure capable for giving information which a person can thus acquire in a precautionary way. The web site provides, general information on cross border health care for Italian citizens abroad, for foreigner citizens in Italy (available in English), EU and Italian legislation related to cross border care, data and FAQ session. They DO NOT provide any kind of information about hospitals abroad, waiting times in domestic systems, what kind of services that are provided abroad and what the waiting times are

**Ireland:** Patient information on cross-border care is made available through a number of mediums including: direct communication between the patient and the different contact points; from various websites, e.g. the 'Health Information' page of the Department of Health and Children website www.dohc.ie, which also provides links to other relevant websites such as www.ehic.ie which is the dedicated website for the European Health Insurance Card providing detailed information regarding the entitlements of insured persons

to healthcare benefit-in-kind during temporary stays in other EU/EEA member states and Switzerland, etc. Extensive advertising on radio and through the print media was undertaken to coincide with the launch of the EHIC in Ireland. This medium is particularly useful for informing large number of people of changes to cross-border benefits or process by which these benefits can be obtained; The regional contact points can also provide a variety of information leaflets in connection with entitlement to cross-border benefits.

Latvia: have several web pages with patient information: <u>www.vm.gov.lv</u>, & <u>www.voava.gov.lv</u> and a hotline with information telephone +371 8001234, TV- advertisement once per week on several health issues, combined with regular information on newspapers and journals and patient brochures. The information is updated daily on the web. Regulation of Cabinet of Ministers for financing of health care gives information about possibility to receive health care abroad. About hospitals abroad, waiting times, what kind of services provided abroad we are providing information in any case individually face to face.

**Lithuania**: The State Patient Fund under the Ministry of Health make the information available to patients on the health care abroad in the following ways: on the web-site <u>www.vlk.lt</u>, answering their letters, email messages, phone calls, interviewing face to face persons, through mass media.

**Malta:** The main vehicle for communicating information to patients on cross-border care is either by phone or through personal contact with the Secretary of the Treatment Abroad Advisory Committee who is also a senior staff member within the Department of Public Health.

**Norway:** The contact point provide most of their information in direct contact with the patients and they have a telephone service. National authorities have developed general information about patients' rights that also covers information about the right to treatment abroad. This is made available on the net and in printed brochures.

**Netherlands:** The usual means of making information available is on request or via the website of the different institutions.

Poland: There is a national contact point and 16 competent regional institutions.

**Slovenia**: There is a national contact point at the National Health Insurance Institute of Slovenia and 10 regional offices that provide information to patients. <u>http://www.zzzs.si</u> Information on access to medical services during a temporary stay in the Republic of Slovenia for insured persons from other EU Member States is available on the Health Insurance Institute of Slovenia (the Institute or ZZZS) website: http://www.zzzs.si/zzzs/internet/zzzseng.nsf/o/41A664904BA3992AC1256E890048C1AB

**Sweden:** The Swedish Social Insurance Agency (SSIA) has information sheets about the rights and possibilities to cross-boarder care, both planned and unplanned. This information is available on the internet and at the local offices.

**Spain:** The information is provided directly to applicants in the local centres or via telephone and in the webpage: <u>http://www.seg-social.es/inicio/?MIval=cw\_usr\_view\_Folder&LANG=1&ID=11566</u>. There are special campaigns during summer months regarding European health card. The brochures and information regarding the European health card are also delivered at health care centres and in the offices of the regional health services and the Ministry of Health.

**United Kingdom**: NHS commissioning bodies such as PCTs (Primary Care trusts) are responsible for making decisions about patient requests for treatment outside of the United Kingdom. Except where the NHS has specifically commissioned spare capacity from other Member States to treat NHS patients (eg Belgium under the London Patient Choice Pilot arrangements), Patients are generally required to find information about overseas treatment options themselves from the internet or information offered by individual providers whom the patient may wish to have treatment from.

# 1.d) How does the contact point get the information they provide?

Austria: The concerned place of service at the "gebietskrankenkassen" gets the information over the internet.

**Belgium**: The authorities distribute circular letters when there is new information such as on the judgements of the ECJ. This is afterwards passed on to the inhabitants through information bulletins to the members of the Health Insurance Funds. If errors are detected these will be commented on and corrected.

Cyprus: Information is provided centrally by the Ministry of Health (national contact point).

**Czech Republic**: The Centre for International Reimbursement as the liaison body for informing people about providing health care works shoulder to shoulder with the Ministry of Health and health insurance funds. The Centre participates in activities within the coordination of social security and rather deals with reimbursements and rights on payments of costs to health insurance funds and payments made by health insurance funds, according to the Regulation EEC 1408/71

**Denmark**: The patient advisory units update themselves with relevant and new patient information ex on new acts on patient's rights from the County, the Ministry of the Interior and Health, Danske Regioner (Danish Regions), seminars etc. Furthermore, www.venteinfo.dk (National Board of Health) and www.sygehusvalg.dk (Danish Regions) provide information about hospitals abroad, waiting times in domestic systems, what kinds of services that are provided abroad and what the waiting times are. The Ministry of the Interior and Health together with The National Social Security Agency issues a Newsletter on International Social Security, including Health Insurance. The newsletter is sent to all municipalities and counties. The Ministry has made leaflets on the use of the European Health Insurance Card in all Member States and a leaflet on non hospital cross border care that can be subsidized by the public health care system. The leaflets are available for citizens in the municipalities and can be found on the website of the Ministry www.im.dk

**Estonia**: Department of International Relations gets information from the competent institutions of other EU countries. They do not provide information about hospitals in Estonia nor the hospitals abroad. They provide general information about health care systems in other EU and EEA countries as well as Estonia. Information about hospitals and waiting lists is provided by health services department.

**Finland:** Guidelines and brochures are drafted by different authorities and stakeholders (e.g. Ministry of Social Affairs and Health, Social Insurance Institution, Finnish Federation of Municipalities.)

**France**: The Directorate of social security, which belongs to the French Ministry of Health, provides information to the CLEISS on the basis on which this latter updates and monitors the information provided to the insured persons.

**Germany**: Patients are mainly informed by their health insurance companies. The health insurance companies are working on the basis of the Social Code – Fifth Book that provides cross border access according to the judgement of the ECJ. In case of a new judgement which has not been incorporated in the national law, the association of health insurance companies inform their members of mandatory changes for the access to cross border care as long until legislation will be changed. In addition there are regional contact points (so called "INFOBEST") especially in regions close to the border, e.g. cross border cooperation between Germany, France, Switzerland and Luxembourg called "INFOBEST Upper Rhine" or "INFOBEST Palmrain".

**Italy:** it the contact points get information from the CASSTM, from EU laws and directives, from formal and informal contacts with other ministries.

Latvia Contact points get the information from web, cooperation with other competent institutions. On website of state Agency of Compulsory health insurance you can find the addresses of web-sites of health insurance of every EU country.

**Lithuania:** The contact points get the information they provide from the competent bodies abroad: from web-sites, conferences, cooperation between colleagues etc. In regards to the Regulation No. 1408/71/EEC the information on the foreigners who get medical treatment in Lithuania is provided by the hospitals to the State Patient Fund under the Ministry of Health of the Republic of Lithuania. In regards to the Regulation No. 1408/71/EEC the information on the Lithuanian citizens, who get medical treatment abroad, is received by the State Patient Fund under the Ministry of Health from the foreign country's competent authority.

**Malta:** Due to its insularity and size, Malta has had to rely on treatment overseas schemes for a substantial number of years. These schemes have ensured that the Maltese public gets access to specialised care normally offered in tertiary centres and which care cannot realistically and cost effectively be developed or offered within an island which has a population of approximately 400,000.

**Norway:** The information provided by the contact points are developed and maintained by the contact points themselves according to their own procedures

Netherlands: From the Dutch government, the Health Insurance Board, health insurance companies, independent experts etc

**Poland:** Information is provided through internet pages: <u>www.nfz.gov.pl</u>; by phone, personal contact, leaflets and brochures. The contact points don't provide information about hospitals abroad but only about waiting times in domestic systems

**Slovenia:** Information on access to medical services during a temporary stay in the Republic of Slovenia for insured persons from other EU Member States is available on the Health Insurance Institute of Slovenia (the Institute or ZZZS) website:

http://www.zzzs.si/zzzs/internet/zzzseng.nsf/o/41A664904BA3992AC1256E890048C1AB

Within the uniform system of the Health Insurance Institute of Slovenia (the Institute), insured persons can obtain all information relating to compulsory health insurance in the Republic of Slovenia from the Institute's website. Information available includes information on rights deriving from compulsory health insurance, health services providers, waiting periods for individual providers, etc. All Institute's printed material is also available in electronic form. The Institute's website is regularly updated with all new information. The Institute does not provide information about hospitals in other countries, medical services in other countries or waiting periods in other countries.

**Slovakia: :** The patients can obtain information on getting treatment abroad at: the General Insurance Fund, the Common Insurance Fund, Apollo,health insurance fund, Dovera, health insurance fund, Sideria, health insurance fund Union health insurance co.

**Spain:** The information provided relates to the Regulation 1408/71, so mainly about rights and conditions, no waiting times. The Ministry of Health and the Ministry of Labour and Social Security update themselves and update the webpage information as well as the Centers of the Institute of Social Security.

**Sweden**: The Swedish social insurance agency (SSIA) has information sheets about the rights and possibilities to cross-boarder care, both planned and unplanned. This information is available on the internet and at the local offices

United Kingdom: Not applicable as there are no explicit contact points

# **1.e)** If there are no contact point in relation to cross border care how do the patients then obtain information?

**Belgium** a study revealed that the <u>key sources for information</u> was from the National Health Insurance Fund, followed by doctors (both specialists and GP's) friends and relatives and finally the media.

**Italy**: the Italian family doctor is the main source of information. This might be true also for information about cross border care, in particular about the specialized health care structures and about specific treatments patients can receive abroad.

**Netherlands**: Patients can also obtain information on cross border care from their health insurance company as well as from the Health Insurance Board (College voor zorgverzekeringen). The Health Insurance Board informs all the health insurance companies that operate the Dutch social health insurance of any developments concerning cross border care such as, for instance, judgements of the Court of Justice in the field of health care.

**Slovak Republic:** The main source of information on cross-border health care are: physicians-specialists, clinics and health insurance funds.

**Sweden:** In cases where the above mentioned sources for information does not meet all the needs of the patient, the patient can obtain more detailed information from the physician that handles the individual case.

**United Kingdom**: Patients get information from a variety of sources including General Practitioners, the internet, healthcare providers, health care commissioners and in some instances as a result of the fact they have second homes in the areas where they wish to be treated. The veracity of such information lies with the individual organisation providing it. Legislation is in place in relation to complaints processes, negligence schemes and the protection of information

# 3) Principles of care

# 3.1 Please list the legislative or administrative acts that regulate patient rights, responsibilities, entitlements and liability issues in the country?

**Belgium:** A Patients Rights act as of 22 August 2002 applies to all legal relations of private and public law in respect to health in general and particularly in respect of healthcare furnished by a professional to a patient. It mainly defines the rights:

- to receive high-quality medical care
- to freely choose the health care professional
- to expect information to assess the health status
- to well-informed consent
- relative to medical records
- of protection of privacy
- to lodge a complaint

The coordinated law of 14 July 2006 on the compulsory health insurance, and subsequent regulations, who is covered, the package of health care services provided, the requirements to benefit from reimbursement of health care services<sup>7</sup>.

**Cyprus:** The provision of health care services by the Government Medical Services is governed by the Government Medical Institutions and Services General Regulations of 2000 up to 2005. The scheme is tax financed, providing benefits in-kind to Cypriot and European citizens residing in Cyprus. The text of the referred regulation is available only in Greek.

**Czech Republic:** The <u>system of public health insurance</u> within the Czech Republic is built on 4 essential legal documents:

- act 48/1997 Coll. on public health insurance
- act 592/1992 Coll. on premium on public health insurance
- act 551/1991 Coll. on General health insurance fund
- act 280/1992 Coll. on resort, departmental, company and other health insurance funds.

The <u>quality of the system</u> is mainly covered by 2 following legal acts accompanied by their implementing legal documents:

- act 20/1966 Coll. on public health care,
- act 258/2000 Coll. on public health protection.

**Denmark**: From 1 January 2007 all legislation concerning patient rights, responsibilities, entitlements and liability issues are gathered in the Health Act, Act No. 546 of 24 June 2005. The act is not translated into English.

**Estonia**: Legislation covers: health insurance principals; primary care (family physician, emergency health care), hospital care, registration of health workers and licensing healthcare providers; inform consent (confidentiality). Main acts: 1) Law of Obligations Act 2) Health Insurance Act 3) Health Services Organisation Act, Others having relevance: 4) Communicable Diseases Prevention and Control Act, 5) Mental Health Act, 6) Medical Devices Act, 7) Medicinal Products Act, 8) Transplantation of Organs and Tissues Act, 9) Artificial Insemination and Embryo Protection Act.

**France**: The hospital's patient charter, which has just been updated, is the most comprehensive document, which also includes all the legal references. This charter is also available and downloadable on the ministry's website, www.sante.gouv.fr/htm/dossiers/charte\_patient/accueil.htm – in French and English. It can be obtained for free in any hospital. (is t binding?)

<sup>&</sup>lt;sup>7</sup> http://riziv.fgov.be/information/fr/wetgeving/ index.htm

#### Finland:

- Act on the Status and Rights of Patients (785/1992)
- Patient Injuries Act (585/1986)
- Primary Health Care Act (66/1972)
- Act on Specialised Health Care (1062/1989)
- Medical Research Act (488/1999)

All Acts and their updated versions are available on the Internet: www.finlex.fi in Finnish and Swedish.

**Germany**: Different codes regulate, patient rights pertaining to the national and to health care including European cross border access, the contract between patient and doctor/hospital including the civil entitlements of patients that comprise claims between patient and doctor/hospital, compensation, claims due to violation of body integrity or due to violation of duties by the doctor that is considered as an arbitrary act, the criminal liability of the doctor in case of violating the rights of patients, .

• Social Code – Fifth Book (V) – National Health Insurance regulates all patient rights pertaining to the national and to health care including European cross border access.

The Civil Code regulates to the contract between patient and doctor/hospital including the civil entitlements of patients that comprise claims between patient and doctor/hospital. The statute of limitations of such claims is between 3 to 30 years starting from the relevant date of existence or knowledge of the claim. In addition to the above mentioned contractual entitlements the Civil Code regulates compensation claims due to violation of body integrity or due to violation of duties by the doctor that is considered as an arbitrary act. The statute of limitations amount to 3 years only starting from the relevant date of knowledge of entitlement. The Criminal Code determines the criminal liability of the doctor in case of violating the rights of patients. A doctor might be sued in order to facilitate a claim for damages. The Professional Code for German Doctors regulates doctor duties and patient rights. The Model Professional Code was decided upon at the 100th German Medical Assembly in Eisenach in 1997 and last revised in 2004. The Code and its rules take on legal validity when adopted at the meetings of the Regional Medical Associations ("Landesärztekammern") and approved by the supervisory authorities. They are legally binding for doctors who are compulsory members of the Medical Association in their respective "Land". There are only marginal differences between the Model Code and the Code adopted by the association in each Land. The Model Professional Code was decided upon at the 100th German Medical Assembly in Eisenach in 1997 and last revised in 2004. The Code and its rules take on legal validity when adopted at the meetings of the Regional Medical Associations ("Landesärztekammern") and approved by the supervisory authorities. They are legally binding for doctors who are compulsory members of the Medical Association in their respective "Land". There are only marginal differences between the Model Code and the Code adopted by the association in each Land.

**Hungary**: Main legislative instruments are: Act 154 of 1997 on health, and act 83 of 1997 on the services of the compulsory health insurance.

**Ireland:** Eligibility for health services in Ireland is regulated through the Health Acts 1947 to 2004. This legislation can be accessed at www.irishstatutebook.ie

Work has commenced on a new legislative framework to provide for clear statutory provisions on eligibility and entitlement for health and personal social services. The aim is to produce a clear set of statutory provisions that ensure equity and transparency and to bring the system up to date with developments in service delivery and technology that have occurred since the Health Act 1970.

The Department is preparing legislation that will:

- define specific health and personal services more clearly
- define who should be eligible for what services
- set out clear criteria for eligibility
- establish when and in what circumstances charges may be made.
- provide for an appeals framework.

**Italy:** Mainly the art. 32 of the Constitution, Law December the 23th 1978, n. 833, institution of the National Health System (SSN), Ministerial decree November the 3 th 1989, authorization to receive planned treatments abroad, Legislative decree December the 30 th 1992, n. 502 and decree Law n. 517 of the year 1993, modification regarding SSN.

**Latvia:** Main legislative document is Law on Medical Treatment (adopted 12.06.1997, Regulation of Cabinet of Ministers on organisation and financing of Health care(adopted 21.12.2004) and 21 legal acts.

Lithuania: Law No. I-552 on the Health System of the Republic of Lithuania, adopted 19-07-1994; Law No. I-1343 on the Health Insurance of the Republic of Lithuania, adopted 21-05-1996; Law No. I-1562 on the Rights of Patients and Compensation of the Damage to their Health, adopted 03-10-1996.

**Malta:** Different codes regulate patient rights, responsibilities, entitlements and liabilities not in a specific manner but by applying general legal principles contained in:

the Civil Code (Cap. 16);

the Criminal Code (Cap. 9),

the Constitution of Malta

These general principles are interpreted by the Court as they apply to patient rights, responsibilities, entitlements and liability issues. A specific Patient Charter in Maltese and English is available for patients making use of the main acute hospital in Malta. A number of quality service charters apply to several parts of the Maltese health sector. The Social Security Act (Cap. 318) covers certain aspects of entitlement to free medicines for persons suffering from chronic diseases and for persons in low income groups. The Healthcare (Fees) Regulations (LN 201/04) stipulates who should pay for medical care received in Malta.

**Norway**: Patients' rights, liability issues and other topics covered by the questionnaire are regulated in several acts regulating the health sector. Among the most important ones are:

- The Patients' rights act, 2 July 1999 number 63
- The Act on Specialised Health Services, 2 July 1999 number 62
- The Act on Municipal Health services, 19 November 1982 number 66
- The Act on Health Personnel, 2 July 1999 number 64
- The Act on Termination of Pregnancy, 13 June 1975 number 50
- The Act on Collection and Storage of Human Biological Material, 21 February 2003 number 12

• The Act on Personal Health Data Filing Systems and the Processing of Personal Health Data, 18 May2001 number 24

- The Act on Compensation for Patient Injuries, 15 June 2001 number 53
- The Act on Psychiatric Health Care, 2 July 1999 number 62
- The Act on Communicable Diseases Control, 5 August 1994 number 55
- The Act on Application of Biotechnology in Human Medicine, 5 December 2003 number 100

All these acts establish a legal basis for enacting implementing and additional regulation. For most of the Acts substantive regulations are given in secondary legislation based on such legal basis.

#### Netherlands:

-Health Insurance Act (Zorgverzekeringswet), Law of 16 June 2005

-General Exceptional Medical Expenses Act (Algemene wet bijzondere ziektekosten), Law of 14 December 1967

Both texts are annexed to this questionnaire (in Dutch)

**Poland**: Has 13 legal acts that cover: The rules on which health care units operate (health care facilities – see point 8 of the previous section); The scope of entitlements to health services, the principles of access to them and the way it is granted is laid down in the law on health services (health care services financed from the public resources – see point 7); The rules for providing medical aid in emergencies (medical aid – partialy see point 13); Important social problems: addictions (alcohol, tobacco) and infectious diseases (see points 10 – 13); Mental health (see point 3); Transplanting tissues and organs (see point 6); Spa treatment; Vocational medicine.

**Slovak Republic:** Six acts are identified to target this. Health Insurance Act, Health Insurance Companies and Surveillance Authority Act, Health Care Providers Act, Act of Emergency Services, Health Care Act, Act on the Scope of Health Care Covered by Public Health Insurance

#### Slovenia:

Health Services Act (Official Journal RS, No. 23/2005), Medical Services Act (Official Journal RS, No. 36/2004), Health care and Health insurance Act (Official Journal RS, No. 100/2005), Healthcare Databases Act (Official Journal RS, No. 65/2000) The Rules of compulsory health insurance (Official Journal RS, No. 30/2003- consolidateted text, 84/2004, 44/2005) The Regulations on implementing of preventive health care on primary level (Official Journal RS, No.: 19/1998, 47/1998, 26/2000, 67/2001, 33/2002, 37/2003, 117/2004, 31/2005)

**Sweden**: The legislation regulating the Swedish healthcare system is not based on the principle of patients rights. Instead, the legislation sets up a number of demands on the provider organizations of public care and their personnel, ensuring that the Swedish citizens get access to high quality healthcare. The most important piece of Swedish healthcare legislation is the Health and Medical Service Act (1982:763). Responsibilities and liabilities for health care personnel are regulated in the Health and Medical services (Professional Activity) Act (1998:531).

**Spain**: In general: <u>http://www.msc.es/normativa/home.htm</u>:

National Health Act 14/1986:

http://www.060.es/canales/legislacion/servicios/disposiciones/25326-ides-idweb.jsp,

Act 41/2002 regulating patient's autonomy and rights and duties in information and clinical documentation: http://www.060.es/canales/legislacion/servicios/disposiciones/24453-ides-idweb.jsp,

Act 16/2003 of Cohesion and Quality of National Health Service:

http://www.060.es/canales/legislacion/servicios/disposiciones/26568-ides-idweb.jsp,

Royal Decree 1030/2006, of common health benefits in the National Health System and the procedure for updating: <u>http://www.msc.es/profesionales/servicios/home.htm</u>,

There are regional laws developing the rights covered in national legislation.

**United Kingdom**: In general, Healthcare legislation in the UK (what provisions) sets out the powers for the Secretary of State to deliver appropriate NHS services. Patients are made aware of rights and entitlements through other routes. Information is available both locally and nationally about NHS services but in principle NHS commissioners are responsible for setting out the range of NHS services that are available to patients within their areas. Patients are also advised by GPs about the services they may need. Patient entitlements to services are often set down in guidelines from the Secretary of State to NHS commissioners and providers who in turn are required to advise patients of what services are available.

Guidance has been given to NHS providers by DH on most of the issues listed at 3(a) -3(f). Standards for service provision both public and independent are set by the Secretary of State these set out the level of care patients should expect to find when accessing health and social care services.

# 3.2 What areas are covered by legislative or administrative provisions in Member States relating to the principles of care, and how?

# 3.2 a) Access to care - including preventive services such as cancer screening services

**Belgium:** The Patients Rights Act as of 22 August 2002, stipulates that all patients shall have the right to receive from their health professionals high-quality medical care that meets their needs, with respect for human dignity and their self-determination and without any discrimination on whatever grounds. In addition there is <u>compulsory health insurance</u>, that grants financial contributions to the costs of health care. Patients "own contribution" is normally 25% but may vary depending on the services offered (it also varies depending on the status of the beneficiary. Several programmes ensure access to preventive health care measures such as programmes for early detection of breast cancer, prostate cancer and cervical cancer. The nature of these programmes makes them not accessible to people staying temporarily in the country.

**Cyprus:** The Regulations distinguish the persons who use the Government Medical Services into the following categories: 1) Persons to whom services are provided free of-charge such as, The President of the Republic, the members of the Council of Ministers, the members of the House of Representatives, Active and retired civil servants, members of the educational service, of the police force and the armed forces, Dependants of the persons above, Members of families with 4 or more children, Students of tertiary education for recognized degree level studies, War pensioners, Persons in receipt of public assistance, Certain categories of patients with chronic diseases, Political Refugees and asylum seekers, Single persons whose annual income does not exceed  $\pounds$ 9.000 and members of families whose annual income does not exceed  $\pounds$ 18.000 increased by  $\pounds$ 1.000 for each dependent child. 2) Persons to whom services are provided at reduced fees such as single persons whose annual income is between  $\pounds$ 9.001 and  $\pounds$ 12.000, members of

families whose annual income is between £18.001 and £22.000, increased by £1.000 for each dependent child. 3) Paying Patients such as persons not coming under category 3.2 (a).1 and 2 can make use of the Government Medical Services against payment of the fees prescribed from time to time.

**Czech Republic:** Every policyholder has the same right to the free health care provided, which is compared to other countries to wide – it includes all the prevention, rehabilitation, stomatology, medicines, spas.... The system is built on principles such universality, solidarity and equity, therefore everybody is individually and obligatorily insured and has the same entitlements to free health care

**Denmark:** All citizens resident in Denmark are entitled to public health care benefits in kind. Anybody staying in Denmark is entitled to hospital care free of charge in case of accident, sudden illness, birth or sudden aggravation of a chronic disease.

Estonia: Health Insurance act.

**France:** Each patient is free to choose the health care institution he wants to take care of him, subject to the limitations of each institution. The public hospital service is accessible to everyone, in particular to the most needy persons and, in the event of emergency, to persons without social security cover. It is adapted to handicapped persons.

**Finland:** Every person who is resident in Finland is without discrimination entitled to health and medical care required by his state of health. Concerning the right to treatment of those persons who stay in Finland temporarily, what has specially been provided or what has been agreed upon between states reciprocally remains in force. Law defines the services provided by municipalities and they cover all medically necessary care and preventive care.

Patients receive immediate medical attention in emergencies. Maximum waiting times for non-urgent treatment are defined in law since 1 March 2005. People have to be able to contact their health centre immediately during weekday opening hours. If the treatment needs assessment requires that the patient visits the health centre, the appointment time has to be available within three working days of contacting the health centre. Health centre treatment is usually started with the patient's first visit. If this cannot be done, access to treatment must take place within three months. If specialised medical treatment is given at a health centre, it has to be available within six months of the treatment needs assessment. Mental healthcare treatment for children and young people has to be made available within three months. Needs assessed medical dental treatment has to be arranged within a reasonable timeframe, and at most within six months.

In addition to municipal health services, private health care providers are available. The costs of private health care are partly reimbursed by the sickness insurance system that covers all residents.

**Germany:** The prevailing health care services provided by the health insurance companies consists in first place of an entitlement for medical treatment, such as preventive services in order to avoid a disease or alleviate the consequences of a disease; sterilisation, termination of pregnancy; contraception, early diagnosis and therapy, rehabilitation and all kind of preventive services in order to avoid home care. Only in certain cases (e.g. cross border care services – see under 3.2 e) there are financial reimbursements granted.

**Hungary:** The Hungarian compulsory health insurance system covers nearly the entire population and endures access to care according to the principle of free choice of providers. Medical services, such as preventive care; general and specialist care, including basic dental care; hospitalization; maternity care; medical rehabilitation; sanatorium care; and ambulance services are provided directly to patients through the facilities of the public health services in contractual relationship with the health insurance scheme. For primary health care, patients have to register with a general practitioner of free choice (employed or contracted). There are no geographical restraints.

**Italy:** Access to care is regulated by the National Healthcare Plan that foresees the so called "Essential Levels of care" (LEA). Prevention is considered a key factor for enhancing the quality of the health services and it is practised in various branches of medicine, including oncology.

**Ireland:** Eligibility for health services in Ireland is primarily based on residency and means. Any person, regardless of nationality, who is accepted by the Health Service Executive (HSE) as being ordinarily resident

in Ireland is classified as either full eligibility (Category 1, i.e. medical card holders) or limited eligibility (Category 2) for health services.

Persons in Category 1 are medical card holders and they have a full eligibility for the following services:

- (i) general practitioner services provided under the General Medical Service scheme
- (ii) approved prescribed drugs and medicines,
- (iii) all in-patient public hospital services in public wards including consultants services,
- (iv) all out-patient public hospital services including consultants services,
- $(v) \quad \text{dental, ophthalmic and aural services and appliances}$
- (vi) maternity and infant care service.

Under the Health Act 1970, determination of eligibility for medical cards is the responsibility of the Health Service Executive (HSE), aside from people over the age of seventy years who are automatically entitled to a medical card. Medical cards are issued to persons who, in the opinion of the Executive are unable to provide general practitioner, medical and surgical services for themselves and their dependants without undue hardship. The HSE has discretion, in cases of exceptional need, to provide assistance to individuals where undue hardship would otherwise be caused.

All other persons who are 'ordinarily resident' in Ireland have limited eligibility. Those with limited eligibility are eligible for all in-patient (public ward) and out-patient public hospital services and consultant services, subject to specified charges. They must meet all of their GP costs, but those above the income guideline for full eligibility may apply for free GP services under a 'doctor only' card. Details are available on the HSE's website at <u>www.hse.ie</u> All persons with limited eligibility must meet the first  $\in$ 85 of prescribed drugs costs per month, above which the Drug Payments Scheme meets all further costs.

Dental and routine ophthalmic and aural services are not provided by the State, but this treatment is provided to children who have been referred from a child health clinic or a school health examination. A maternity and infant care service is provided during pregnancy and up to six weeks after birth. An A&E charge applies except where the patient has a GP referral note.

**Malta:** The Ministry of Health, the Elderly and Community Care is responsible for the financing and provision of publicly funded health care services. Health care in public services is generally free at the point of use. Persons living in Malta and covered by Maltese social security legislation are entitled for public health care services in accordance with entitlements as determined from time to time by the Ministry. EU citizens resident in Malta are entitled to equivalent consideration. Their entitlement has to be confirmed with and certified by the Entitlements' Unit within the Ministry of Health, the Elderly and Community Care. This official certification together with a personal identification document will be enough to receive health care in public health care services.

Latvia: Latvia: According to Law on Medical Treatment Section 6, A patient has the right to receive qualitative, considerate and respectful medical treatment and care (from 2006 08.06) Section 17. (version from 2006 08.06) The amount of medical assistance guaranteed by the State in accordance with the procedures prescribed by the Cabinet shall be provided to 1) citizens of Latvia, 2) non-citizens of Latvia, 3)Citizens of European Union, European Economic Area countries and Switzerland Confederation ,who stay in Latvia as employed or self employed person and their family members, 4) foreigners, who has authorisation for permanent residence, 5)refugees and persons with alternative status, 6) to persons detained, arrested and sentenced with deprivation of liberty, 7) children of above mentioned persons have the right to receive free of charge the medical assistance guaranteed by the State. There are listed health care services paid by State budget, including preventive services in Regulation of Cabinet of Ministers on organisation and financing of Health care

**Lithuania:** Lithuanian legislative acts as Law on the Rights of Patients and Compensation of the Damage to their Health and Law on Health System regulate access to care (including preventive services), information and consent, privacy and confidentiality, quality and safety, free choice of GP (in advance too), specialist (with referral), choice of hospital in country and access to different providers (expenses of Lithuanian citizens for the planned treatment abroad can by covered by the State Patient Fund under the Ministry of Health only in case, when they can't get the kind of treatment they need in Lithuania), complains and compensation.

**Netherlands**: -Entitlements to care are covered by the Health Insurance Act and the General Exceptional Medical Expenses Act. Health insurance companies who operate the Health Insurance Act have a care

obligation: they must make sure that the insured person has access to the insured care or that the costs of care are reimbursed.

**Norway:** The Patient's Right Act chapter 2 regulates patient's rights to health care. Patients have a right to emergency care when needed. Patients have a right to necessary primary health care (including preventive measures), and it is the municipalities' responsibility to provide the care.

Patients have a right to necessary specialised health care. Five regional health authorities owned by the state are responsible for providing specialised health care to the population in their region. The right to specialised health care includes a right to have one's state of health examined within 30 working days from referral to the specialised health service. If the patient needs specialised health care he will, pursuant to certain conditions, be granted a right to receive care. The care must be provided within the time good medical practice demands. A time limit for providing the care is set for the patient in each case. If that time limit is not met the patient is entitled to receive the care immediately, if necessary in the private sector or abroad. If the treatment can not be provided in Norway because the competence to provide the treatment is not available the patient has a right to receive the treatment abroad. The Act on Termination of Pregnancies establishes a right to have abortions provided by the regional health authorities. The Act on Communicable Diseases Control has provisions about rights and duties for patients and health authorities in relation to such diseases.

**Poland:** Access to care is regulated by the same provision, i.e. the Law of 27th August. 2004 on Health care services financed from the public resources (preventive services such as cancer screening services are regulated by the same Law as above at art. 48); (that and implies... what?)

**Slovak Republic**: Access is ensured through the following Acts Health Care Act, Act on the Scope of Health Care Covered by Public Health Insurance, Act of Emergency Services, Health Care Providers Act.

The Health Insurance Act ensures "Universal coverage, solidarity principle" The health care shall be provided to every insure according to his or her needs in the scope set by the special regulation rather than their actual solvency. Horizontal equity is defined as the equity in the treatment of people in similar situations. The principle of the horizontal equity means that people should be treated equally. Vertical equity means that people whose status is different are treated equally.

**Slovenia**: According to the Health care and Health insurance Act, Article 23, the Compulsory insurance guarantees the insured person payment of health services for:

- systematic and other preventative examinations of children, school children, students attending full time education, women in connection with childbirth and other adults in accordance with programmes, except preventative examinations which employees are guaranteed by law,

- early detection and prevention of illness in accordance with programmes,

- treatment and rehabilitation of children, schoolchildren and students in full time education, and children and young people with disturbed mental and physical development,

- health care of women in connection with advice on family planning, contraception, pregnancy and childbirth,

- prevention, detection and treatment of infection from AIDS and contagious diseases for which the law proscribes the implementation of measures for the prevention of their spread,

- compulsory injections, immunoprofilactics and chemoprofilatics in accordance with programmes,

- treatment and rehabilitation of malign illnesses, muscular and nervous muscular illnesses, paraplegia, tetraparaplegia, cerebral paralysis, epilepsy, haemophilia, mental disorders, developed forms of diabetes, multiple sclerosis and psoriasis,

- treatment and rehabilitation for professional illnesses and injury at work,

- health care in connection with the donation and exchange of tissue and organs for transplantation in other persons,

- urgent medical assistance, including urgent transport by ambulance,

- home visits, treatment and home nursing and in social care institutes,

- medicaments in accordance with the classification of medicines, orthopaedic and other aids in connection with treatment for people and conditions from paragraphs 1 10 of this point;

Reimbursement of different cost shares depending on the different kind of treatment.

Sweden: The Health and Medical Service Act (1982:763) regulates the county councils and municipalities responsibilities to offer good health and medical services to all persons living or residing within their

boundaries. The Act specifically states that the health and medical services shall be conducted to meet the requirements for healthcare and in particular that the care must be of good quality and cater to the patient's need of security in care and treatment, it shall also be readily available, be founded on respect for the self-determination and privacy of the patient and promote good contacts between the patient and health and medical personnel. The act also states that care and treatment as far as possible shall be designed and conducted in consultation with the patient and that the patients shall be given individualized information concerning their state of health and the treatment methods available; when several treatments exist which comply with science and proven experience, the county council shall give the patient the possibility of choosing the alternative which he or she prefers.

As of the 1 November 2005 there is a national guarantee for maximum waiting-time for treatment. This guarantee states that the patient should be able to get in contact with the health care service immediately, should not have to wait more than a week to se a physician, if necessary meet at specialist within 90 days and receive treatment within 90 days from the day that a decision on treatment is made.

**Spain**: Regulated by the National Health Act 14/1986, the Act 16/2003 of Cohesion and Quality of National Health Service and the Royal Decree 1030/2006, of common health benefits in the National Health System and the procedure for updating. The benefits on public health (prevention and promotion), primary health care, specialised health care, emergency care, pharmaceuticals and medical devices, health transport and other are included. The care is free at the point of delivery (a co-payment of 40% is asked to active workers for regular medicines; not for chronic treatments).

The Law guarantees access, mobility (benefits in all national territory), waiting times, information, safety, quality, and reference services.

### 3.2 b) Information and consent:

**Belgium:** The Patients Rights Act as of 22 August 2002, article 7 prescribes that patients have the right to expect from their health professionals all relevant information to assess their health status and their prognosis in a clear language. The information may be requested in writing. Health personnel may refuse to give the information only if it may cause grave harm to the patient and if the opinion of another health professional has been gathered.

Article 8, in the patients rights act prescribes that patients have the rights to consent well informed, freely and in advance to any services provided by health professionals. The consent shall be given expressively, unless health professionals may reasonably infer the patient's consent from his behaviour. Patients have the right to withdraw their consent.

**Denmark:** The principal rule is an informed consent, cf. section 6, according to which no treatment shall be initiated or continued without the patient's informed consent unless otherwise provided for in the law or in provisions set out according to the law. Except when: patients are minors, or have permanently lost the capacity to give informed consent or situations where immediate treatment are needed. This is regulated by the Act on patients' legal rights and entitlements, and through provisions in order No. 665, of 14. September 1998.

An informed consent shall mean the consent given on the basis of adequate information provided by the medical attendant. The Act on patients' legal rights and entitlements in Denmark, part 3, section 13 -18, deal with decision-making under special circumstances such as hunger strike, right to refuse to receive blood and the treatment of terminally ill patients (a terminally ill patient may refuse any treatment that will only prolong death).

Estonia: Law of Obligations Act

**France:** Information given to the patient must be accessible and reliable. The hospitalised patient can participate in the choice of treatment. He can be assisted by a trusted support person that he freely chooses. A medical procedure can only be conducted with the free and informed consent of the patient. The latter has the right to refuse all treatment. Any adult can express his wishes as to the end of his life in advance directives.

Specific consent is needed for patients participating in biomedical research, the donation and use of parts and products of the human body and for screening procedures. A patient who is asked to participate in biomedical research must be informed of the expected benefits and the foreseeable risks. His agreement must be given in writing. His refusal will not have any effect on the quality of care that he receives. The hospitalised patient can, unless otherwise provided for by the law, leave the institution at any time after having been informed of any risks incurred.

**Finland**: According to the Act on the Status and Rights of Patients, the patient has to be cared in mutual understanding with him/her. If the patient refuses a certain treatment or measure, he/she has to be cared, as far as possible, in other medically acceptable way in mutual understanding with him/her. There are specific provisions on the consent procedure in health care for minors and major persons who because of mental disturbance or mental retardation or for other reason cannot decide on the treatment given to them. In addition, consent requirements in medical research are regulated in the Medical Research Act.

A patient shall be given information about his/her state of health, the significance of the treatment, various alternative forms of treatment and their effects and about other factors related to his/her treatment that are significant when decisions are made on the treatment given to him/her. However, this information shall not be given against the will of the patient or when it is obvious that giving the information would cause serious hazard to the life or health of the patient. Health care professionals should try to give the information in such a way that the patient can understand it. If the health care professional does not know the language used by the patient or if the patient because of a sensory handicap or speech defect cannot be understood, interpretation should be provided if possible. The patient has a right to check the data concerning him/her in the patient documents (as stipulated in the Personal Data File Act (523/1999).

**Germany**: The fact of performing a medical treatment without having provided the patient of the appropriate information is considered by jurisprudence as an arbitrary act, violating the right of self-determination and dignity. Information must be provided in each specific case in a clear and comprehensive way, timely so that the patient can consider the alternative treatment options. Patients has the rights to refuse explicitly his/her right to information. Jurisprudence has set the elements on which the right to information is based:

- the present health condition and the diagnostic on which the treatment is based;
- the name of the physician who has to operate or who has the responsibility;
- the nature of the treatment;

- the possible secondary effects and the other risks related to the treatment and possible alternatives;

- the chance of success;
- the degree of urgency of the treatment;
- the costs.

In the Model Professional Code for German Doctors, article 7.1 states that in all medical treatment, human dignity must be ensured and the personality, will and rights of the patients, in particular the right of self-determination must be respected. Article 8 obligates doctors to require the consent of the patient in order to provide treatment. In principle consent must be preceded by the necessary explanation in personal discussion. The precedents of the high level Court decisions, based on the German Constitution, treatment carried out on a person against his/her will constitutes bodily injury.

**Hungary:** The Act on health lays down a fundamental right for the patient to receive information on his/her state of health. The provisions of the Act include personalized information about the outcome of the examination, and its causes, taking into account the age, education and mental health of the patient concerned. Patients are entitled to look into all their medical documentation. Right to autonomy means the right of accepting and/or refusing medical treatment. Refusal of treatment is excluded if it was a danger to the life and health of others. Consent can be given in writing or orally and be withdrawn at any time, apart for in case of invasive treatment, when consent can only be granted in writing. Life-saving or life-protecting treatment can only be refused under strict conditions, in case of incurable fatal diseases, and a special procedure applies.

**Italy:** The informed consent of the patient is another legal requirement and the person providing the treatment is responsible for complying with this

Latvia: According to Law on Medical Treatment, Section 20, Patients have the right to receive information from a doctor in a way that they can comprehend regarding the diagnosis of his or her illness, examination and medical treatment plans, as well as regarding other medical treatment methods and the prognosis. And

the

section 21. patient has the right to receive information regarding the medical treatment process from other medical practitioners at the level of their competence. Article 41 The doctor may provide incomplete information to the patient regarding the diagnosis and prognosis of the disease if he or she considers that such information may cause deterioration of the state of health of the patient.

Section 23, A patient has the right to refuse, in full or in part, examination or medical treatment offered by certifying such refusal with his or her signature. If a patient is a minor or a person who due to his or her state of health is unable to understand the consequences of his or her actions, family members, but if such do not exist, the closest relatives or lawful representatives of the patient (trustees, guardians) have such rights and liability for the decisions taken. The doctor has a duty to explain to the patient, his or her family members, closest relatives or lawful representatives (trustees, guardians) the consequences of such refusal. If a patient has accepted a treatment plan, he or she is responsible for observing all instructions of the medical practitioner related to the medical treatment and care.

Latvia has a special law on Human Genes Research Act that regulate creation and function of the Genome Database and genetic research connected with the database; and ensure the voluntary nature of gene donation and the confidentiality of the identity of gene donors and protect gene donors from misuse of their data and from discrimination based on interpretation of their DNA. A written informed consent of the gene donor shall be prepared in two copies and signed by the gene donor and main processor.

**Lithuania:** The Law on the Rights of Patients and Compensation of the Damage to their Health is the main legal document witch specifically deals with patients right to information and principles of informed consent. According the Articles 6 and 8 of the Law, a patient shall have a right to information on the condition of his health, disease diagnosis, medical examination results, treatment methods and treatment prognosis. The information must be presented to the patient in a form comprehensible to him, with an explanation of the special medical terms involved. In providing information regarding the treatment, the physician must explain to the patient the course of treatment, possible results of the treatment, possible alternative methods of treatment and other circumstances, which may have an effect upon the patient's decision to accept or refuse the proposed treatment and also the possible consequences of refusal of the proposed treatment. The information should not be provided to the patient against his will, however, his will must be clearly expressed and the history of his illness should contain a mention of this wish of his. A patient also shall have the right to obtain information concerning the services provided by the health care system and the opportunities to make use of them, he must be informed of the name, surname, position and qualifications of the doctor treating him and the nursing staff member, nursing him, of the internal regulations and procedure of the health care or nursing institution, insofar as that concerns his stay at that institution.

There are several other legal documents that deal with the issue of informed consent, namely, the Civil Code of the Republic of Lithuania (Articles 6.727-6.730), the Law on Health Care, the Law on Ethics of Biomedical Research., etc.

Malta: In accordance with the provisions of the Civil Code (Cap. 16).

**Norway:** The Patients' Right Act chapter 3 regulates patients' right to information and participation. The patient is entitled to participate in the implementation of his or her health care. This includes the patient's right to participate in choosing between available and medically sound methods of examination and treatment. The form of participation shall be adapted to the individual patient's ability to give and receive information. The patient shall have the information that is necessary to obtain an insight into his or her health condition and the content of the health care. The patient shall also be informed of possible risks and side effects. Information shall be adapted to the qualifications of the individual recipient, such as age, maturity, experience and cultural and linguistic background. The information shall be provided in a considerate manner. The patient is entitled to have access to his or her medical records. Chapter 5 of the Patient's Rights Act regulates the right to access medical records.

The Patients' Right Act Chapter 4 regulates consent to health care. The general principle is that health care may only be provided with the patient's consent, unless a legal basis exists for providing the care without the patient's consent. Issues such as competence to give consent, requirements regarding the form of consent and consent of behalf of persons without competence to give consent as well as the right to refuse health care in special situations are regulated here.

Specific provision on consent to the storage and use of human biological material is regulated in the Act Relating to "Biobanks". Likewise specific rules on consent to the filing of personal health data is given in the Personal Health Data Filing System Act

**Netherlands**: Patients can obtain information on cross border care from their health insurance company as well as from the Health Insurance Board. The insurance policy of the Health Insurance Act has world coverage for the Dutch entitlements package; insured persons can obtain medical care abroad (without consent) and receive reimbursement up to Dutch tariffs. Consent for treatment abroad under the E112 procedure has to be given by the health insurance company where the patient is insured.

**Poland:** Patient is informed by his/her general practitioner about method planned of further care but in the case of surgical procedure his is asking for the signature a text of consent on document; Law of 30th August 1991 on Health care establishments

**Slovak Republic**: In the Slovak legislation there is an obligation for physicians to receive the so called "informed consent" of the patient are covered by the Health Care Act, Health Care Providers Act, Act on the Scope of Health Care Covered by Public Health Insurance.

**Slovenia**: According to the Health Services Act 47, all persons have the rights: to be informed of the diagnosis of their illness and the extent, manner, quality and duration of treatment; to give agreement for any kind of medical intervention and to be informed from the beginning regarding all possible methods of diagnosis and treatment and their consequences and effects; to refuse a proposed medical intervention; Health Services Act, Article 48: Urgent medical interventions may only be performed without the prior consent of the patient only if the patient is unable to make the decision because of his medical condition. Health Services Act, Article 49: A patient who because of mental illness threatens his own life or the life of other people or causes great damage to himself or others, may also be directed to and accepted for treatment in a psychiatric hospital without his consent.

**Sweden:** The Health and Medical Service Act states that care and treatment as far as possible shall be designed and conducted in consultation with the patient and that the patients shall be given individualized information concerning their state of health and the treatment methods available; when several treatments exist which comply with science and proven experience, the county council shall give the patient the possibility of choosing the alternative which he or she prefers. Sweden has regulations both within the Health and Medical Services Act and the Secrecy Act that regulates information and access to information about patients.

Spain: Act 41/2002 regulating patient's autonomy and rights and duties in information and clinical documentation

Every act in providing health care requires previous consent of the patient. The patient has the right to decide, after adequate information, among all available options. The patients have the right to know every information about their health.

**UK:** Informed consent is a requirement under Common law in the UK and patients must give their consent before being treated.

# 3.2.c) Privacy and confidentiality

**Belgium:** Patients Rights Act as of 22 August 2002, article 10 Patients have the right of protection of their privacy in any medical service medical treatment, particularly in respect of the information about their health. This law may only be interfered if it is provided by law and if it is necessary for the protection of human health or for the rights and liberties of others.

**Czech Republic**: The Czech legislation follows the main stream within the personal data protection and the level of development in this field could be evaluated as above standard.

**Denmark:** The Act on patients' legal rights and entitlements in Denmark, section 23 - 32 deal make a distinction between conveyance of health data in connection with the treatment of patients and conveyance of

information etc. for other purposes. The principal rule, cf. section 24 and 25 for both situations is that the <u>patients' consent is required before the information can be passed on</u>. Exceptions are if the treatment is necessary, and information is conveyed in due consideration of the interests and needs of the patient, or if the conveyance is necessary to safeguard an obvious general interest or to safeguard the specific interest of the patient, the medical attendant or other or if the information is conveyed to the patient's general practitioner by a doctor acting as a substitute for the former.

Estonia: Law of Obligations Act

**Finland:** The care of the patient has to be arranged so that his/her conviction and privacy is respected. The information contained by patient documents is confidential. Health care professionals or other persons working in a health care unit or carrying out its tasks shall not give information contained by patient documents to outsiders without a written consent by the patient, or unless otherwise provided by the law. Section 13 of the Act on the Status and Rights of Patients' has detailed provisions on these exceptions. Breach of secrecy is punishable by law

**France:** The hospitalised patient must be treated with consideration. His beliefs must be respected. He must be ensured privacy and peace and quiet. Respect of privacy is guaranteed to every patient, as well as confidentiality of personal, administrative, medical and social information concerning him.

**Germany:** The disclosure of personal information to third parties will be sanctioned by Article 823 of the Civil Code, which governs the protection of personal rights Data protection is provided by the Federal Data Protection Act 1990, which covers the applies to the collection, processing and use of personal data by public and private bodies, insofar as they process or use data from data files for business, professional, or commercial purposes.

Processing and using personal data is only permissible to the extent that it is authorized by the Act or another legal provision, or if the data subject has consented. In general, storage, modification or use of personal data by public bodies is only permissible if it is necessary for the performance of the duties of the data controller, or if it serves the purpose for which it was collected. However, the Act provides other specified circumstances in which personal data may be stored, modified or used for purposes other than those for which it was collected.

**Hungary:** Personal data is strongly protected by law in Hungary. The limit for the personal data protection is the life and health of others.

**Italy:** the right to confidentiality of personal data is another intangible right. The Italian legislator has been particularly attentive to this aspect of human relations, and has established with specific regulations rules, ways and guarantees under which personal data can be filed and processed. In particular, for personal data concerning the state of health, eventual pathologies and the treatments received, the Italian legislation is very strict.

a) Law n. 59, 15 March 1997, know as "Legge Bassanini"

b) Republic Presidential Decree November the 10 th 1997, n. 513, "Regulation establishing criteria and methods for the creation, filing and transmission of documents by telematic and electronic means, pursuant to art. 15, paragraph 2, of the Law 15 March 1997, n.59."

c) Law n.196 of the year 2003 (Known as "Privacy Code").

Latvia: Information regarding the medical treatment of a patient, the diagnosis and prognosis of a disease (hereinafter – information regarding a patient), as well as information obtained by medical practitioners during the medical treatment process regarding the private life of a patient and his or her closest relatives, shall be confidential. Information regarding a patient may be provided to: other medical practitioners, the Medical Commission for Expert-Examination of Health and Working Ability (MCEEHWA); the Quality Control Inspection for Expert-Examination in Medical Care and Ability to Work, to a court, the Office of the Prosecutor, the police, the State Centre for the Protection of the Rights of the Child (inspectors), an Orphan's court (a parish court), as well as to investigative institutions only at the written request of such institutions if there is a permission signed by the head of the medical treatment institution. Information regarding a patient may be used in scientific research if the anonymity of the patient is guaranteed or his or her consent has been received. State military service administrations of the Ministry of Defence are entitled to request from medical treatment institutions information regarding the state of health of the conscripts, reserve soldiers and reservists in accordance with the procedures prescribed by the Cabinet.

Latvia has a particular law on data protection that states that processing of sensitive personal data is prohibited, except where the data subject have given written consent for the processing of the data, there are regulatory enactments that guarantee the protection of personal data. Personal data protection is necessary to protect the life and health of the data subject or another person, and the data subject is not legally or physically able to express his or her consent, and several other exemptions. A data subject has the right to request that his or her personal data be supplemented or rectified, as well as that their processing be suspended or that the data be destroyed if the personal data are incomplete, outdated, false, unlawfully obtained or are no longer necessary for the purposes for which they were collected.

**Lithuania:** Law on Legal Protection of Personal Data, adopted 11-06-1996, regulates privacy and confidentiality. Health professionals are bound by medical secrecy, before disclosing personal health information patient's prior consent is required.

#### Malta:

- Data Protection Act (Cap. 440);
- Official Secrets Act (Cap. 50);
- Professional Secrecy Act (Cap. 337);
- Criminal Code (Cap. 9)

**Norway:** Privacy and confidentiality is regulated in inter alia the Act Relating to Health Personnel Chapter 5, the Act on Specialised Health Services Chapter 6 and in the Act on Municipal Health services. Specific privacy and confidentiality issues are regulated in the Act Relating to Biobanks and in the Personal Health Data Filing System Act.

**Netherlands:** The use and exchange of personal data (including patient files) is regulated in the Netherlands under the Personal Data Protection Act (Wet bescherming persoonsgegevens).

**Poland:** Law of 29 August 1997 on personal data protection; Law of 30th August 1991 on Health care establishments.

Slovak Republic: The issues of privacy and confidentiality are covered by: the Health Care Act.

**Slovenia**: According to the Health Services Act 47, all persons have the right to: to examine the health documentation which relates to his condition, unless the physician is of the opinion that this would adversely effect the patient's health condition; to demand that health workers and their associates do not transfer data on their health condition to any other person without their express permission;

Article 51 Health workers and health associates are bound to protect as confidential professional information about the health condition of individuals and about the causes, circumstances and consequences of this condition.

Data from the first paragraph of this article may not be given to other people or made public and may also not be reported in such a way that enables the discovery of the individual to whom it relates. Only the person himself or a court, and the parent or guardian of young persons and persons in care, may release the health worker from the obligation to protect professional confidentiality. The physician treating the patient may only give data on the health condition of a patient to a patient's close relative or guardian.

In the case of the transfer or removal of a patient or if the patient chooses another doctor, all important health documentation regarding the patient must be handed over to the doctor who is continuing treatment.

Whenever personal data on health conditions is used for research purposes, the identity of the source must be protected and not revealed. This also applies to the promulgation of the results of research work.

**Sweden**: According to the Health and Medical Service Act, care shall be provided with respect for the selfdetermination and privacy of the patient and promote good contacts between the patient and health and medical personnel.

**Spain**: Act 41/2002 regulating patient's autonomy and rights and duties in information and clinical documentation. Dignity of human person, respect to autonomy and privacy are basic when obtaining, using,

storing, keeping and transmitting information and clinical documentation. All persons having access to clinical information and documentation are obliged to keep secrecy.

**UK:** Patient data is protected by the Data Protection Act in the UK this restricts access to personal medical information.

# 3.2 d) Quality and safety

**Belgium:** The right to access as ensured by Patients Rights Act, is a right to access to high quality health care that meet their needs.

**Czech Republic:** The Czech health care providers are supplied by sets of quality and safety standard rules, which correspond to transnational standards and the providers are obliged to follow those standards while providing health care.

**Denmark**: In 2004 a national reporting system for adverse event was launched as a result of the Act on Patient Safety in the Danish Health care system launched (June 2003) The purpose is to gather, analyze and communicate knowledge of adverse events. The Act obligates, frontline personnel to report on adverse events, the hospital owners to act on the reports and the National Board of Health to communicate learning from the reports.

Estonia: Health Services Organisation Act

**Finland:** According to the Act on the Status and Rights of Patients, the patient has a right to good quality health care and medical care. It is inherent that the health care provided for patients is safe The quality or safety of municipally produced services is not generally specified in detail. Many laws or decrees nevertheless set the bases for defining the quality and safety of services. Since 2000, there have been numerous national quality recommendations given to support the municipalities' quality management work. For example, such quality recommendations cover services for older people, mental health services, school healthcare, assistive device maintenance and substance abuser care. The law on health care professionals regulates the professional competence of healthcare personnel. Services bought from private service providers have to meet the level required by corresponding municipal services. This condition aims to ensure that all publicly funded services fulfil the same minimum quality requirements. The organisation and supervision of private services is individually regulated in legislation on private healthcare as well as in legislation on the supervision of private social services. A working group set up by the Ministry of Social Affairs and Health published in the beginning of 2006 national guidelines for the provision of pharmacotherapy in public and private social and health care units.

**France**: Health care institutions must guarantee the quality of reception, treatment and care. They must be attentive to pain relief and do everything possible to ensure everyone is treated with dignity, particularly at the end of life.

**Germany**: The basis for the quality and safety of the service is Article 4 and 5 of the (Model Professional Code for German Doctors). Article 4 states that all physicians have to undergo further vocational training. On demand they have to prove the training to their Regional Medical Association. The Medical Associations ensure the quality of the services by provisions.

**Hungary**: The act on health provides that health service providers shall operate quality management systems, supervised by the National Public Health and Medical Officers' Service. The Act includes provisions to ensure that in the provision of health care services, professional rules, such as evidence-based professional guidelines, protocols etc. are applied. Personal and material minimum conditions needed to provide health services for each health profession and activity, is enacted by Decree 60/2003 (X.20.) of the Ministry of Health, Social and Family Affairs. The existence of these minimum conditions is also controlled by the National Public Health and Medical Officers' Service.

The National Supervisory System controls the compliance with guidelines, protocols concerning the quality assurance of professional activities, provided by health services providers, as it is laid down in Decree 15/2005 (V.2.) of the Ministry of Health on professional supervision of health services.

The Ministry of Health issued guidelines (do they have a legal basis?), concerning requirements on internal quality management, development of professional guidelines and of clinical audit, health-specific guidelines for ISO 9001-2000 standards and national standards for professional and quality requirements of primary, outpatient and inpatient care. In the field of patient safety there is a particular focus on operation of patient-identification system, an identification system to be operated on case of immediate emergency and/or patients with limited communication skills. (combined with some kind of register?) In order to improve the quality of care provided to patients, professional guidelines, protocols are continuously developed. So far 260 have been issued in several specialisations.

**Italy:** The Italian Ministry of Health ahs an Office which is involved on the topic of analysing and reducing the risk of malpractice and delivers recommendations about it to the Health structures and medical doctors. A campaign is under way to make those providing treatments more aware of these aspects. There is also a study regarding reduction of risks. It should also be said that in case of errors in treatments or low quality of the same, the National legislation provides for particular safeguards in favour of the patient concerned. The safeguard is provided by virtue of the Italian civil Law that states the right of damaged persons to ask a civil Court for reimbursement, meaning that compensation would be provided to these persons, not in an automatically way, but depending on the Court rulings.

Latvia: The following regulation deals with the issues:

- Medical Treatment Law article 6,55,66, (adopted 12.06.1997)- Regulation on Clinical Trials of Drugs and Pharmaceutical Products (Nr 172, 28.02.2006- Cabinet of Ministers)

- Law on Pharmacy (adopted 10.04.1997)

- Epidemiological Safety Law (adopted 13.01.1998) Supervision or monitoring by Quality Control Inspection for Expert-Examination in Medical Care and Ability to Work (statute adopted 29.03.2005) and Drug Agency (statute adopted 07.12.2004)

**Lithuania:** The quality regulate following legal acts: Law No. X-709 on Pharmacy,, adopted 22-06-2006; Law on the Health System, adopted 24-11-1998 and the Law on Health Care Institutions, adopted 01-12-1990. Health professionals are obliged to provide high quality of care and their continuous training is required. The State Health Care Inspectorate is charged with the supervision of quality and safety questions. The accreditation/quality management system is in place.

**Malta:** Health Care Professions Act (Cap. 464);Medicines Act (Cap. 458);Medical and Kindred Professions Ordinance & its regulations (Cap. 31); Human Blood and Transplants Act (Cap. 483)

**Norway:** The individual health personnel and health service providers are under a legal obligation to provide a safe service. All health service providers must establish a system for internal quality control. Providers of specialised health services must as part of their internal control system have a quality commission. A national system is established for reporting errors and damages in treatment of patients.

**Netherlands:** Covered by the Health institutions Quality Act (Kwaliteitswet zorginstellingen): The Act stipulates that health providers must provide care aimed at creating the best possible health condition of the patient. The Health Care Inspectorate is charged with the supervision of quality questions so that can rely on the quality and safety of care and related products.

**Poland:** Law of 5th December 1996 on the profession of a physician and a dentist; Law of 5th July 1996 on the profession of a nurse and a mid-wife.

Slovak Republic: quality and safety are covered by Health Care Providers Act and Health Insurance Companies and Surveillance Authority Act.

**Slovenia:** At present quality and safety are not incorporated fully into legislation. The requirements for quality will be included into revised Health Services Act. A national body for quality and safety of healthcare is envisaged. Continuous quality improvement will be required from all healthcare providers with self-assessment and accreditation according to generic standards. Regular reports on outcomes and other quality indicators will be mandatory. Non-punitive reporting system of patient safety incidents will be introduced. National policy for Quality in health care was published at the beginning of 2006 as a guide to providers for development of quality and safety systems.

**Sweden:** It is primary the responsibility of the County Councils to provide health care services that are safe and of a high quality. At national level there are a number of government agencies that monitor and supervise healthcare services in order to guarantee that the County Councils provide the quality care that they are obliged to by law

**Spain:** Act 16/2003 of Cohesion and Quality of National Health Service. Guarantees on safety and quality applicable to all centres, public and private. The public authorities guarantee the quality of benefits. There is a National Plan for Quality in the National Health Service

http://www.msc.es/organizacion/sns/planCalidadSNS/home.htm

**UK :** The Care Standards Act 2000 and Health and Social Care Act 2003 currently provide the basis for the legal powers of the health care regulator in England the Health Care Commission. Similar legislation exists in Scotland and Wales. This legislation also sets out powers for regulations to govern service provision and to set out National Minimum Standards for the quality of services in the private sector. NHS services are covered by standards set out in guidance "Standards for Better Health Care".

### 3.2 e) Choice and access to different providers

#### - including services abroad

**Belgium**: A basic principle of Belgian health care is the right to choose provider, both at the level of primary and of specialist care and also to change that choice.

**Cyprus:** State hospitals and specialized institutions and State Health Centres, Limited use of private hospitals under contracts with the Ministry of Health, Free choice of government doctors. Patients are not obliged to register with one general practitioner, Access to specialists upon referral by their practitioner. Choice of hospital. Referral by the treating doctor is needed for specialized institutions. The patient is referred to the hospital at which the treating doctor is employed.

**Czech Republic:** Every Czech policyholder has the right to choose one of the health insurance funds, unless it is determined otherwise according to the Regulation EEC 1408/71 and Czech law. The policyholder can change his health insurance fund only once in 12 months. Validity of such change of the health insurance fund is with the period from the first day of the quarter.

**Denmark:** Patients can choose <u>GP or specialist</u> and among two schemes for insurance coverage. The reimbursement scheme differs according to the choice. Persons insured in Group 1 must choose a general practitioner (GP) affiliated to the public health care. Treatment is free of charge. Persons insured in Group 2 can choose any GP or specialist – including in other EEA countries. They receive a subsidy corresponding to the cost of similar medical help from a GP or medical specialist for persons in Group 1. Denmark has a public tourist insurance that covers acute necessary treatment from GPs, specialists and hospitals during holidays of up to 1 month in Europe.

Patients can be offered hospital treatment abroad in the following situations:

• If the waiting time is more than 2 months at the hospitals in the patients home county and there is an agreement between the counties and a specific hospital abroad.

• If the patient has been diagnosed or has received treatment at one of the most experienced hospitals in Denmark concerning the patients diagnose, and relevant treatment cannot be offered in the national health care system.

• another life threatening illness and relevant treatment cannot be offered in the national health care system.

Estonia: Health Insurance Act; Health Services Organisation Act

**Finland:** In Finland patients do not have a general right to choose their GP at their health centre or to choose their hospital, because these are predetermined by the choice of the place of residence. Nevertheless the wishes of the patient as regards e.g. changing the doctor are taken into account whenever possible. Patients can choose between private and public providers, where private services are available. Costs for using private

services (e.g. doctor's fees) are partly reimbursed from the Sickness insurance system. A person in need of urgent treatment has to be given medical care irrespective of his/her place of residence.

Since 1 March 2005 access to health care in other EU/EEA countries and in Switzerland has been regulated in the Act on Specialised Medical Care. In case the hospital district cannot provide medical care in Finland within maximum waiting times, it has to give a preliminary authorisation for the patient, on his/her request, to seek the treatment in the countries mentioned above.

**France:** Each patient is free to choose the health care institution he wants to take care of him, subject to the limitations of each institution.

**Germany:** According to Article 76 Social Code (V) the insured person has the right of free choice among the providers of ambulatory and stationary treatments. The ambulatory treatments must be accredited for public health care such as doctors, medical care centres, authorised clinicians and hospitals. For stationary treatment, the need for a treatment has to be stated by a doctor in first place. The doctor is deciding according to Article 39 Para 4 Social Code (V) together with the insured person on the hospital where the treatment shall be received. In terms of cross-border care, free choice of different providers is subject to the provider's admission under an EU-regulation or to a national admission.

**Hungary:** The insured person is entitled to choose a suitably qualified service provider and doctor professionally well-founded by his/her state of health. Family doctors providing primary care are chosen in advance, usually for a longer period. In case of planned treatment abroad, the patient generally has the possibility to choose the service provider where the treatment can be organised.

**Italy:** The principle is that if the cure can not be obtained through the structures of the National Health Service or not promptly enough in relation to the clinical case in question, the patient has the right to be treated abroad at the expense of the National Health Service.

**Latvia:** According to Law on Medical Treatment, A patient, his or her closest relatives or lawful representatives (trustees, guardians) have the right to choose a medical treatment institution located in Latvia and a medical practitioner for the diagnosis and medical treatment of illnesses and injuries, and rehabilitation of the patient.

**Malta:** Free market rules apply to private health care services for which patients pay either out-of-pocket or through private medical insurance. The Health Division regulates the private sector through regular inspections and annual licensing.

**Norway:** Patients have a right to choose their regular GP. Patients also have a right to choose the hospital or district psychiatric centre, or treatment unit in such an institution, in which the health care shall be provided. In situations where patients have a right to receive health services abroad pursuant to The Patient's Right Act § 2-1 they are not entitled to choose the service provider. Foreign providers are contracted by the regional health authority and the National Insurance Authority to treat these patients. The patient might choose to apply for an E-112 form under 1408/71 in stead.

**Netherlands:** Covered by the Health Insurance Act: Free choice of doctor and hospital, The insurance policy of the Health Insurance Act has world coverage for the Dutch entitlements package; insured persons can obtain medical care abroad (without consent) and receive reimbursement up to Dutch tariffs.

Poland: art. 26 of Law of 27th August 2004 on Health care services financed from public resources

**Slovak Republic:** Act on the Scope of Health Care Covered by Public Health Insurance Health Care Act.

**Slovenia**: Health Services Act, Article 47: All persons have the right under equal conditions and in accordance with the law: ..; to consultation with appropriate specialists whom they choose themselves, and to demand an advisory examination; Article 80 to demand transfer to another health institution. The rules of compulsory health insurance also ensures that each insured person may only have one selected personal physician from a specific field of health care at any one time.

**Sweden**: Swedish patients are free to choose any care provider they like. Swedish patients are entitled under Article 49 EC to receive medical treatment in another Member State. The expenses incurred by such medical care are reimbursed by the Swedish Social Insurance Agency.

**Spain**: Health care is provided with the norms of National health System, regionalised, and with public providers. The patient can choose his/her general practitioner in his/her health area. The right to a second opinion is guaranteed. The general practitioner is the gatekeeper of the health system. Services abroad are only covered inside the regulation of 1408/71 and derived.

**United Kingdom:** Patient Choice was established in England from January 2006 with patients being able to choose a minimum of 4 providers for elective surgery in the most common specialties from a local menu. This choice is being supplemented by a national menu of NHS Foundation Trusts and Independent Sector providers from the autumn. From 2008 Free Choice for many elective procedures will be in place in England.

## 3.2 f) Complaints and compensation

**Belgium**: Patients have the right to lodge a complaint about the exercise of the rights granted under the patient Rights Act with the competent. (how is this done?)

**Czech Republic:** In case that the person, to which health care has been provided, is not satisfied with the services received he/she can turn his/her complains towards the executives of the provider, professional organizations, health insurance funds, Ministry or municipality.

**Denmark**: The Patient Complaint Board has been established and also works to monitor if the health professionals has broken the Practice of Medicines Acts or the Act on Patients' Legal Rights and Entitlements. The Board express opinions on the thoroughness and conscientiousness as defined in the Practice of medicine Act, access to medical files, informed consent, or on decisions made by local psychiatric boards. The most important cases are made anonymous and published at the website of the board www.pkn.dk. The Board also issues an annual report where amongst other examples of the Boards decisions are published.

The Patient Insurance Act establishes an insurance scheme that covers all patients, donors, anyone being examined treated and cared for by authorised healthcare professionals, in public and private hospitals and private clinics. It covers damages that may have occurred during treatment or examination, including dental treatment. Pharmaceutical injuries are covered by the Act on Damages for Pharmaceutical Injuries.

Estonia: Health Insurance Act; Law of Obligations Act, Health Services Organisation Act

**Finland:** There are several different complaints procedures in the Finnish health care system. These procedures are applied in different situations but are not necessarily exclusionary. Often the most effective way to solve the problems is to handle them as near to the service provider as possible. Therefore, a patient who is not satisfied with the health care or medical care and the related treatment received by him/her has the right to submit an objection on the matter to the director responsible for health care in the health care unit in question. Decision on the objection has to be given in a reasonable time from the submitting it. Submitting an objection does not restrict the right of a patient to appeal to the authorities controlling health care or medical care about the care or related treatment received by him/her. If, when the objection is dealt with, it becomes obvious that the care or other treatment of the patient may e.g. cause liability for patient injury meant in the Patient Injury Act (585/1986), the patient shall be advised as to how the matter can be initiated in a competent authority or organ. Patient Insurance covers bodily injuries that patients have sustained in connection with health care in accordance with the Patient Injuries Act. The Finnish Patient Insurance Centre handles these claims. More information on the system and claims procedure can be found in English on the website: www.potilasvakuutuskeskus.fi.

**France:** The hospitalised patient can express his views on the care and reception provided. In each institution, a commission for relations with users and the quality of care given ensures that the rights of users are respected. Every patient has the right to be heard by a manager of the institution to express his grievances

and request compensation for harm to which he believes he has been subjected within the context of an amicable settlement procedure for disputes and/or before the courts.

**Germany:** In case of litigation the medical association offer a mediation procedure that examines the prospects of liability claim against its members in order to avoid legal disputes. There are no costs occurring for the patient if the case can not be settled by the medical association. The medical association may also be addressed in order to complain against violation of patient rights or doctor's duties.

Compensation can also be decided upon by the competent county court. However it is to be considered that the claim will be only successful if the patient may prove a medical error by the doctor. Only in case of a violation of the doctor's duties and patient rights (grave medical error) there is a reversal of burden of proof in favour of the patient. That means e.g. if the doctor has violated the right of information then the patient could not consent to the medical care which results in an arbitrary act.

**Hungary**: The patient can lodge a complaint in connection with the medical treatment by the service provider or by the maintaining body of the provider. The latter has to examine the complaint and inform the patient on its results in 10 days. The institution of the patient rights' representative has a determining role, he/she informs the medical employees, helps the patients to the medical documentation, initiates the examinations of the complaints etc

Latvia Patient can make complaints to Quality Control Inspection for Expert-Examination in Medical Care and Ability to Work, ,Ministry of Health or court

Malta: In accordance with the provisions of the Civil Code (Cap. 16).

**Norway:** The Patients' Rights Act Chapter 7 regulates complaints and complaints procedures. Patients can complain about breaches or non-fulfilment of most of their patient's right to the county office of the Norwegian Board of Health. A patient ombudsman is established in every county in order to assist patients among other things in this regard. Provisions about the patient ombudsman are given in the Patients' Rights Act Chapter 8.

Norway has a kind of non-fault system for compensation for damages that patients suffer while receiving health care. As a main rule there must have been some kind of error or omission in the treatment, but it is not a condition for compensation that a specific person is to blame for the injury. The system also covers damages patients suffer while receiving health care abroad when the care is provided pursuant to a contract between the provider and a regional health authority, the National Insurance Authority or a municipality. At present the system does not cover all private health service providers in Norway or foreign health service providers operating in Norway but the Ministry of Health- and Care Services is working to expand the system to also cover these providers.

**Netherlands:** -Disputes between insured persons and health care insurers can be submitted to the Health Insurances Disputes Board, and to the civil court. The Health Insurance Ombudsman hears any complaints about health insurance and deals with complaints about supplementary insurances.

Poland: the civil procedure code, physicians' insurance for civil liability

**Slovak Republic**: complaints and compensation are covered by Health Insurance Companies and Surveillance Authority Act.

**Slovenia**: Health Services Act, Article 47: All persons have the right under equal conditions and in accordance with the law: ....; to discuss circumstances with the competent supervisory body if he believes that inadequate resources are being used for his treatment or that a violation of ethical principles has occurred; to the compensation for damages related to inappropriate treatment. The rules of the compulsory health insurance (in relation about decisions on rights deriving from compulsory health insurance; it is general act of Institute). Complaints relating to the work of health institutions shall be addressed by the health institutions themselves. A special body of the health institution or its management shall decide on the complaint.

**Sweden**: Several different bodies share the task of safeguarding patients interests in receiving adequate and safe healthcare. The patient can turn to The National Board of Health and Welfare and to The Medical Responsibility Board with complaints. They can also in some cases turn directly to a court of law.

**Spain**: A new Law on Liability is being prepared. Now the compensation is made directly if agreement of via contentious-administrative jurisdiction if no agreement

**United Kingdom:** In England and Wales powers to set out complaints processes are set out in legislation under the Care Standards Act 2000 and the Health and Social Care Act 2003. Section 21 of the NHS Services and Community Care Act 1990 enables the Secretary of State to set up schemes for dealing with clinical negligence.

## 3.2 g) others

- Do patients have other rights or entitlements that may influence cross border care situations?

**Denmark**: Section 17 - 18 in the Act of patients' rights and entitlements in Denmark deal with a special patient right – a living will. Any person who has reached the age of 18 and who does not have a guardian dealing with his/her personal conditions, shall be entitled to make a living will. In a living will, the person may express his/her last wishes with a view to treatment if the person concerned should arrive in a condition in which he/she has lost the capacity to make decisions

Poland: NGO's such as Association of patients rights or "Primum non nocere"

**Slovenia:** A patient who entrusts his treatment to a health professional is required, consistent with their health condition: to provide the health worker with true data on their health condition; to behave according to the instructions of the health worker; to actively cooperate in the protection, reinforcement and restoration of his own health.

If the patient does not fulfil the conditions and responsibilities under the previous paragraph, the health professional may refuse help, except urgent medical assistance. The Health Services Act, Article 47 ensures that all persons have the right under equal conditions and in accordance with the law to be acquainted with the costs of treatment and to demand an explanation of an account for health services;

# 3.3. Are there plans to change the legislation or policy documents mentioned above?

**Denmark:** By 1 January 2007, Act on Complaints and Damages in the Health Care System (Act No. 547 of 24 June 2005) replaces the Patient Insurance Act and the Act on Damages for Pharmaceutical Injuries and the provisions about complains in Act on Central Direction of Health Care. The key change is to gather all the rules on complaints and damages in one act.

**Czech Republic:** The Czech Republic is currently only several weeks before the parliamentary elections, it is very hard to say which legislation is about to be changed. It all will depend on the result.

Estonia: There are no major changes foreseen in the near future to the legislation in place.

**Finland:** Ministry of Social Affairs and Health has drafted a proposal to amend the Act on the Status and Rights of Patients. The aim of the amendments is to strengthen patient's right to self-determination and to enhance legal obligation to follow patient's explicit wishes on his/her treatment (living will). It is expected that the proposal will be submitted to the Parliament 2007.

**Hungary:** Hungary has just gone through a general election in April 2006, a new government will be set up by early June, and consequently, a new government programme will be approved. In the course of election, one of the major issues was the modernisation and structural reform of the Hungarian health care system, therefore it is quite likely, that current legislation will be changed, but at present we are not in the position to provide information on it.

**Ireland:** Eligibility for health services in Ireland is regulated through the Health Acts 1947 to 2004. This legislation can be accessed at www.irishstatutebook.ie

Work has commenced on a new legislative framework to provide for clear statutory provisions on eligibility and entitlement for health and personal social services. The aim is to produce a clear set of statutory provisions that ensure equity and transparency and to bring the system up to date with developments in service delivery and technology that have occurred since the Health Act 1970.

The Department is preparing legislation that will:

- define specific health and personal services more clearly
- define who should be eligible for what services
- set out clear criteria for eligibility
- establish when and in what circumstances charges may be made.
- provide for an appeals framework.

**Malta:** A draft "Health Care Services Act" is currently under internal discussion within the Ministry of Health, the Elderly and Community Care. It is expected that specific reference to regulation of patient rights, responsibilities, entitlements and liability issues be included in the act itself or its subsidiary legislation.

**Slovenia:** There is a proposal to amend the Health Care Insurance Act, in order to extend it so that socially weaker citizens of the Republic of Slovenia that they be exempted from payment of voluntary health insurance and included among the categories of insured persons for whom, in accordance with Point 1 of the first paragraph of Article 23 of the Act, health care is provided wholly (100%) from compulsory health insurance. The proposal also suggests new methods for calculating the contributions to the health insurance. The draft amending statute sets lower percentages for allowances during the period of absence from work.

There is also a draft for a new Patients Rights Act: This act aims to bring together all rights of patients (now scattered over different laws) and thus make them more transparent, to standardize complaint procedures and to enhance the influence of patients in health care. A provision on patients' duties related to safety in health care is part of the law. Among the issues still to be resolved are: compensation for damages, position of liability-insurers, separate fines for violation of specific rights, appropriate ways of involving civil society.

**Sweden:** There are plans to introduce a system that will require prior authorisation for reimbursement of expenses incurred by hospital treatment in another Member State. A report, which contains proposals on compulsory authorisation for all cross border care given in hospitals, is now taken into consideration by the Ministry of Health and Social Affairs. The report is published in the Ministry Publications Series (Ds. 2006:4).

**Spain**: No. The recent Royal Decree 1030/2006 has just replaced the one from 1995. The package of benefits is in continuous updating.

# ANNEX 2. Data on cross border care

# Table 1: Number of patients who are nationals from other Member States treated in your Member State

### -a) within the Regulation 1408/71 & 574/72

## -b) others ways

Austria In 2005 did 2701 people receive treatment based on E112 forms. With a total number of treatments of 95.916, this accounts for app 2. 8% of the activities.

(no cost data available for 2005, however by September 2006  $\in$  2,359 085 is reimbursed to foreign holders of E112 forms.)

**Belgium** Data from Belgium 2004, within the Regulation 1408/71 & 574/72, Temporary stay (E.111 – EHIC – replacement form)

Compositive Study ( 12.111	Errice replacement form )	
2004	Number	Costs
Austria	186	97,867
Spain	4,681	2,984,045
Finland	0	0
France	33,775	22,901,032
UK	2,813	2,167,961
Luxemburg	3,047	1,661,056
Greece	687	383,355
Hungary (*)	31	10,204
Iceland	5	886
Liechtenstein	1	37
Malta (*)	3	1,165
Norway	0	0
Poland (*)	265	259,240
Portugal	953	804,299
Sweden	262	105,783
Switzerland	229	168,893
Italy	6,951	4,156,299
Netherlands	3,098	3,784,475
Germany	2,496	1,843,297
Slovenia (*)	18	16,769
TOTAL	59,501	41,346,664 €
) Data for the second se	master of 2004 only	

(\*) Data for the second semester of 2004 only

The expenditure in Belgium <u>on employed persons insured abroad</u> were in 2000  $\notin$ 165,672,436 but increased in 2004 to  $\notin$ 249,024,600. At the same time the expenditures related to <u>self-employed persons insured abroad</u> increased from  $\notin$ 3,118,435 in 2000 to  $\notin$ 5,344,882 in 2004.

Belgian claims on other Member States for the category of persons authorised to receive treatment in Belgium under form E-112 increased from €25,907,697 (14,061 persons) in 2000 to €44,512,463 (21,492 persons) in 2004.

**Cyprus** The number of patients, nationals of other Member States, who received medically necessary treatment in Cyprus, using their E111/EHIC, are 384 for 2004 and 1.335 for 2005.

Czech12,278 EU citizens received health care within Regulation 1408/71 & 574/72Republic(hereof 3,558 tourists, 8,708 workers, 13 others). The costs were: € 2,556,087

(hereof 1.5 mill € tourists, 510,000 workers, 546,000 others)

**Denmark** In 2005, there were 11,595 cases and 58,605 non-hospital treatments for citizens from other EU States received hospital treatment in Denmark. In 2001 the comparable figure was 2,401 persons.

Denmark has a waiver of reimbursement with many Member States and therefore has neither knowledge of the number of Danish patients treated in countries covered by waivers of reimbursements nor of patients from these countries treated in Denmark under Regulation 1408/71. Please note, that the following information concerns claims received and sent in 2005. Some of the benefits have been provided in earlier years.

In 2005 the Danish institutions issued 7,970 claims at a total amount of 12.4 mill DKK (app. 1.7 mill.  $\in$ ) on the basis of E111, E112, E128 and EHIC from other EU-Member states. Of these 16 were issued on the basis of E 112 at a total amount of 171,881.97 DKK (app. 23,000  $\in$ )

- **Estonia** In 2004 were the number of forms E 125 issued 648. However the first half of 2005 were 622 forms issued and the claims so far in 2005 are already higher than the ones in 2004 with  $\notin$  89,496 compared to  $\notin$  88,884 in 2004.
- **Finland** Claims presented by Social Insurance Institution to other EU Member States were  $\in$  3,328 million in the end of 2005. In 2004 the amount was  $\in$  3,173 million, and in 2002  $\in$  2,230 million. The underlying causes for increase in costs are e.g. the enlargement of the EU and better coordination of bills between local authorities and Social Insurance Institution.

According to the data collected by the Social Insurance Institution, costs of treatment based on E112 were  $\notin$  162.004.85 in 2005. However, this data is not comprehensive.

	Country	<b>Claims</b> based on art. 93 in 2005 ( $\in$ )
	Austria	14,750
	Estonia	146,540
	France	248,160
	Germany	469,660
	Greece	74,180
	Italy	398,230
	Ireland	55,840
	Norway	21,640
	Portugal	77,670
	Poland	29,120
	Sweden	212,010
	Spain	1,561,250
	United Kingdom	19,390
	Total	3,328,440
France	Claims presented to EU Member States in 2005 represented € 554.5 million of which € 436.0 millions were reimbursed. Claims presented to CLEISS by other Member States in 2005 250,7 million €, reimbursed 289.7 millions of euros. This level can therefore be seen to be stable if compared to the level in 2002 of €297.2 million. Number of E125 broken down by country	
	~	

Country	Number of	Costs €
	E 125	

Germany	1,160	390,000
Belgium	1,626	4,200,000
Spain	288	200,000
Italy	105	100,000
Portugal	178	10,000

Concerning the costs of the <u>patients treated abroad outside Regulation 1408/71 but</u> <u>within EU jurisprudence</u>, no precise information is up till now available. The national and local social security organisations work on the creation of a specific statistic instrument. This latter will be implemented in 2007.

Concerning the costs of the patients <u>treated abroad outside Regulation 1408/71 and outside EU</u>, but within countries linked to France by a Social Security agreement, claims reimbursed by other states in 2005:  $\notin$  11.7 million, reimbursed by to other states in 2005 were  $\notin$  77.3 millions.

Concerning the costs of the patients treated abroad outside EU and outside countries linked to France by a Social Security agreement, in 2003, the amount was evaluated about 40 millions of euros.

**Germany** The total amount of German claims on other Member States for the category of persons authorised to receive treatment in Germany under Art. 93 and 96 of Regulation No 574/72 from 2005.

Country	Costs
Austria	30,984,407
Belgium	10,828,199
Switzerland	7,254,188
Cyprus	3,719.
Czech Republic	1,070,837
Denmark	704,832
Estonia	57,115
France	15,388,152
Finland	953,786
Great Britain	7,452,083
Greece	11,138,014
Hungary	674,338
Italy	19,259,066
Ireland	135,702
Iceland	59,412
Luxembourg	34,326,207
Lithuania	390,982
Latvia	247,163
Malta	3,718
Norway	107,150
Netherlands	12,306,920
Portugal	2,254,531
Poland	14,073,220
Sweden	2,387,287
Slovakia	203,776
Slovenia	299,911
Spain	57,115
Total	€172,521,676

This data show that Germany with its geographical position in Europe have high claims on other EU Member States as a result of cross border care activities.

Country :	Number of bills	Costs (€)
Austria	7,312	696,281
Belgium	8	355
Czech Republic	16	545
Denmark	2	33
France	8	2,374
Germany	104	118,502
Italy	49	6,423
Luxemburg	37	2,002
Poland	1	2
Slovakia	69	4,900
Slovenia	200	7,074
The Netherlands	1	3
United Kingdom	no settlement	-
Total	7 806	838,490

**Hungary** Cost-settlement in the frame of the Regulation 1408/71 EEC, outgoing and incoming invoices (form E 125).

This table shows that Hungary have a relatively large part of the claims on Austria and Germany as a result of the regulation 1408/71. However it also show the difference in the nature of the claims and probably also the treatments provided.

- **Ireland** The information sought under this table, number and cost of E125 forms issued to other states in respect of benefits in kind provided in Ireland, is currently not collated on a national basis.
- Italy In 2005: Year 2004 as far as E 111 form is concerned: 23,426 invoices (€ 15,113,317) Year 2003 as far as E 112 form is concerned: 193 invoices (€ 525,671.94)

### In 1999: 1,022 persons.

**Latvia** The table underneath show accepted E125 forms total expenditure broken down by states and E form presented,  $\notin 1 \notin = 0.703$  LVL: (For patients from other countries treated in Latvia. Including amounts disbursed for E125 forms received in 2004 according to the currency conversion rates on the date of disbursement.

Country	Numbers	Disbursed in €
Czech Rep.	2	13
Denmark	2	33
Estonia	48	2,172
Finland	14	900
France	2	4122
Germany	1	10
UK	6	492
Ireland	1	1,149
Italy	2	3,963
Lithuania	35	5,782
Norway	2	28
Poland	8	670
Slovak Rep.	1	24
Spain	1	667
Sweden	10	885
Total	135	20,912

This show that in Latvia the costs related to cross border care are still relatively

low compared to the overall health care costs. Also most of the claims are on countries in a close geographical distribution.

Malta	Persons with a European	E111 who received Cases	l treatment in Malta in 2005 Cost in €
	Austria	28	9,352
	Belgium	14	1,488
	Czech Rep.	2	839
	Denmark	23	175
	Finland		1,304
	France	74	22,819
	Germany	128	59,911
	Greece	3	3,005
	Hungary	3	128
	Iceland	1	23
	Ireland	25 122	6,485
	Italy Latvia	3	60,056
	Latvia Lithuania	3 1	5,719 35
		1 2	144
	Luxembourg Netherlands	2 7	1,479
	Norway	15	13,254
	Poland	4	978
	Portugal	4	1,316
	Slovakia	6	1,310
	Slovenia	4	489
	Spain	37	3,252
	Sweden	39	24,754
	Total	527	218,274
		521	210,274
Netherlands	$1 \in = 0.4293$ Malta Liri No new figures has been provided.		
	For 2000: 3,316 persons.		
Poland	In 2004 and I-VI 2005, 5000 patients have received treatment on the basis of the		
Snain	provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 In 2004 1 826 features were delivered to other countries because of a E112. These		
Spain	In 2004 1,826 factures were delivered to other countries because of a E112. These		
	can be decomposed by country and the majority is from Germany (1023) Followed		
	by France (306) and UK (196).		
	In 2001:		
	E112: €457,821.9 corresponding to 3,156 persons		
	· · ·		
	E 111: €20,102,004.2 corresponding to 133,958 persons Total: €20,559,825 corresponding to 137,114 persons		
Slovak Rep		ases. the amounts 54	,483,428.46 SKK (app 1,469,236
	€)		
	a) Under No 1408/71 and Regulation (EEC) No 574/72 7 135 cases, the amounts		
	129,690,885.86 SKK- (app	3,497,33U€)	
Slovenia	In 2005 16,409 patients from other EU Member States took advantage of		
	health care services in the	e Republic of Slove	nia

Sweden	2005: SEK appr 93 millions reimbursed for the treatment of residents of othe		
	member states. Appr SEK 130 million paid for the treatment of residents of other		
	Nordic Countries. The Nordic countries are not requested to reimburse these		
	amounts.		

There is presently no conclusive information available on the number of patients from other EU-countries seeking care in Sweden. It is not possible to estimate the amounts of reimbursement but according to available statistics, it seems that patients from Greece are the ones that most frequently seek planned treatment in Sweden.

The Swedish authorities transmitted information expressed in financial volumes. For 2000:

SEK 33.5 millions ( $\pm \in 3,666,411$ ) reimbursed for the treatment of citizens of other Member States SEK 53.1 million ( $\pm \in 5,838,000$ ) paid for the treatment of citizens of other Nordic countries. The countries in question are not asked to reimburse these amounts

**United** The National Health Service (NHS) trusts are not required to provide statistics on the number of EEA nationals seen or treated under the provisions of the NHS care in the United Kingdom.

E112 scheme - in 2003, 963 patients were treated under E112 in the United Kingdom corresponding to a total of £1.3 million. 794 patients were from Ireland and 86 were from Italy.

In 2001, 871 patients were treated under E-112 in the United Kingdom corresponding to a total of £5.56 million ( $\pm \in 8,720,428$ ). 641 were from Ireland and 121 were from Italy.

In 2002, this figure stood at 776 corresponding to a total of £1.21 million ( $\pm$  €1,897,791), with Ireland accounting for 659 and Italy 60.

## Table 2: Number of nationals who have

- a) applied for authorisation for treatment in another Member State/abroad
- b) been treated abroad or costs related to the treatment

Austria	2.581 cases got permission from all the insurance companies to receive treatment abroad funded by the E112. No data is available on the number of applicants.
Belgium	The Belgian authorities transmitted information expressed in financial terms. For 2000: - Expenditure abroad by employed persons insured in Belgium: BEF4,213,474,790 (€ 104,449,312), down 12.50% since 1999 - Expenditure abroad by self-employed persons insured in Belgium: BEF113,149,378 (€ 2,804,890), down 23.49% since 1999
Cyprus Czech Rep.	The number of Cypriot nationals who received medically necessary treatment in other Member State, using their E111, are 29 for 2004 and 54 for 2005. In 2005 within 1408/71: <u>The numbers were:</u> - 44,887 Czech citizens received health care abroad (hereof workers 27,454, Authorized treatment: 753, Tourists 16,680
	<u>The costs were</u> : - € 7,330,938 (hereof 2,032 mill workers, 1.257 mill authorised treatment, 4,049 mill € tourists)
Denmark	Outside 1408/71 – not monitored There are no precise data on the number of applications for authorisation made or granted.
	However, according to Regulation No 1193 of 7 December 2004, which entered into force by 2005 and which makes provision for <u>maximum waiting times</u> , in 2005 210 persons received treatment in another Member State. (1.07.02 and 30.09.02, 50 persons) In 2005, 500 patients whose state of health was such that it required <u>specialist treatment</u> were treated abroad, including in the EU. (in 2000, 70 patients, in 2001 75 patients)
	There is electronic exchange between Denmark, Austria, Germany and Spain of claims on E125 concerning E111, E128 and EHIC (medical necessary benefits during a temporary stay) and E112 (planned health care). In 2005 Denmark received 671 claims from the said countries at a total amount of 236,485 $\in$ . Of these 11 claims from Germany were based on E112. The total amount for these claims was 24,376 $\in$ .
	In addition to these claims Denmark received 1019 claims on paper forms (E125) from Estonia, Latvia, Poland, Slovakia, Slovenia, Czech Republic, Hungary, Germany, Austria, Italy and Switzerland.
Estonia	In Estonia the number of applicants for treatment abroad is still low however the numbers in 2005 are almost four times higher than the ones in 2000. In $2000 - 22$ persons applied for authorisation; in $2001 - 19$ persons; in 2002 - 31 persons; in $2003 - 24$ persons; in $2004 - 37$ persons; in $2005 - 89$ persons.

**Finland** Claims based on Art. 93 sent by other Member States to the Finnish Social Insurance Institution were  $\notin$  2,358 million in the end of 2005. In 2004 the amount was  $\notin$  4,291 million and in 2002  $\notin$  1,926 million.

According to the data collected by the Social Insurance Institution, over the period 2000-2005 only 17 E112 forms were issued. The costs of treatment based on E112 were  $\in$  77,562. However, this data is not comprehensive.

Finnish hospitals purchase treatment directly from health care providers in the other Member States (outside the 1408/71-system). Data before 2000 shows that there are more of these cases than E112 issued. Updated data is not available.

Country	Claims based on art. 93 in 2005 (€)	
Austria	32,390	
France	275,740	
Germany	399,090	
Greece	42,850	
Italy	609,700	
Latvia	910	
Netherlands	40	
Portugal	20	
Slovakia	10	
Slovenia	660	
Spain	690,800	
Śweden	169,360	
Switzerland	136,790	
Total	2,358,360	

- **France** Over the period 1996-1999, 1,240 persons applied for authorisation for treatment abroad, 789 of which were granted (64%).
- **Germany** The cost underneath are provided by Germany for 2005, and are only related to invoices relying on Art. 93 of the Directive 574/72. Numbers of the accident insurances are not included. Please note furthermore that the number of application for authorisation for treatment abroad are not collected in Germany (that concerns Annex 1 Table 2 a). No information exists concerning the number of patients, although the number f forms exist.

Invoices from	No of invoices - Art. 93 Directive 574/72	Sum of invoices in €
Austria	137,264	44,373,999
Belgium	15,818	5,401,132
Switzerland	17,430	24,679,804
Cyprus	0	0
Czech Republic	13,371	1,232,945
Denmark	7,114	1,328,372
Estonia	65	3,360
Spain	58,460	15,017,081
Finland	871	632,700
France	135,553	69,435,586
Great Britain	2	22,265
Greece	21,947	4,157,951
Hungary	104	123,139

Ireland	0	0
	•	<sup>o</sup>
Iceland	31	69,610
Italy	44,529	19,475,759
Lichtenstein	160	35,249
Lithuania	37	10,105
Luxembourg	517	836,784
Latvia	0	0
Malta	119	49,849
Netherlands	11,709	9,499,489
Norway	0	0
Poland	3,646	1,537,794
Portugal	7,799	1,150,654
Sweden	3,834	2,737,851
Slovenia	2,535	1,274,461
Slovakia	285	33,672
Total	483,200	203,119,611
1 ( 1 0	. 1 1 1	111 1 X · · · 1

If compared to the figures provided under table 1.a) it is clear that Germans seeking care abroad follow a somehow different pattern than foreign citizens that seek health care in Germany.

**Hungary** In 2005, there were applications for prior authorisation for planned treatment abroad in 330 cases at the NHIF. These applicants requested treatment inside and outside the EU. According to the Hungarian legal provisions laid down in Government Decree 227/2003, granting a prior authorisation, issued by the NHIF, depends of a supporting certification of a nationwide medical institute relevant in connection with the patient's illness. In case the patient has received this certification, the NHIF finances 100% of the expenses.

<b>Bills from</b>	Bills	€
Austria	601	549,863
Belgium	31	9,930
Czech Republic	61	22,829
Denmark	5	2,446
Estonia	6	47
France	92	40,141
Germany	960	693,411
Italy	43	90,654
Luxemburg	32	8,499
Malta	6	405
Poland	45	27,612
Slovakia	10656	351,854
Slovenia	48	42,568
Spain	80	16,993
Sweden	62	101,706
The Netherlands	69	37,582
United Kingdom	No cost-settlement	-
Total	12 797	1,996,539

This table show that there are somehow more bills concerning Hungarians being treated abroad, than it is concerning foreign citizens being treated in Hungary.

It also show that there probably are differences in the nature of treatment provided for the different nationalities as the average costs differ by app 50%.

Italy As far as the E 112 form is concerned, the number of transfers of Italian patients for treatment abroad in the year 2004, 3,547 persons (unofficial estimate).

**Ireland** Information in the format and detail required in this table is currently not collated on a national basis in Ireland with the exception of E125 Forms associated with Forms E112.

#### (a) Referrals abroad under the provisions of Regulation 1408/71.

The table below provides information on the approximate number of referrals abroad for a first episode of treatment under the E112 referral system for the years 2001 to 2005. These figures do not include those patients who had been previously referred abroad and who were referred for follow-up or continuing treatment. The vast majority of these referrals were to UK treatment centres. Approximate figures for the amount paid in the years concerned in respect of E112 referrals are also shown in this table.

Year	No. of Applications	Amount €
2001	140	1,835,742
2002	200	1,025,126
2003	200	2,708,480
2004	260	4,549,487
2005	255	3,778,635

#### (b) Referrals abroad outside the scope of Regulation 1408/71

The table below provides information on the approximate number of referrals abroad for a first episode of treatment outside the scope of Regulation 1408/71. Approximate figures for the amounts paid in respect of referrals in this context are also provided.

Year	No. of Applications	Amount €
2001	22	863,289
2002	16	1,290,800
2003	23	546,231
2004	27	858,975
2005	25	1,553,352

The National Treatment Purchase Fund was established under national legislation to address waiting times in the public health system in Ireland by purchasing procedures for public patients in private hospitals in the Republic of Ireland and in the UK. While the majority of these patients are treated in private facilities in the Republic, the Fund also purchases procedures in the UK (including Northern Ireland). Of the 18,000 patient treated by the Fund in 2005, approximately 5 per cent were referred to the UK for treatment.

Latvia

Issued E125 forms total expenditure broken down by states and E form presented,  $\notin 1 \notin 0.703$  LVL- These costs relate to a total of 224 forms. The numbers are available.

Country	Numbers	Total
		Costs in €
Austria	36	14,143
Belgium	10	3,678
Czech Rep.	5	5,653
Denmark	1	82
Estonia	58	12,442
France	19	38,722
Germany	106	424,544
Lithuania	5	973
Malta	1	47
Norway	12	35,138

Poland	13	2,579
Slovak Rep.	2	30
Slovenia	3	1,703
Finland	22	17,988
Spain	28	1,761
Sweden	76	126,684
Netherlands	6	10,397
Total	403	696,564

This show that the numbers of Latvian citizens that receive health care abroad are still low although higher than the foreign citizens that receive care in Latvia.

It also show that the value per bill for foreign citizens being treated are nearly lower than the costs of Latvians being treated abroad.

Malta

Persons with a Maltese E111 who received treatment in other Member states

	Number	Costs €
Austria	14	1,639
Belgium	5	2,459
Czech Rep.	3	24
Finland	3	214
France	21	24,644
Germany	4	2,877
Italy	3	7,708
Luxembourg	3	170
Netherlands	6	1,118
Poland	2	38
Slovenia	1	240
Spain	10	4,456
Sweden	7	2,456
TOTAL	82	48,036

Within the framework of a bilateral convention between Malta and the UK, 180 patients are <u>sent to the UK</u> for specialised care every year. The financial arrangements for this agreement incorporate also waivers of 1408/71 provisions between these two Member States. An additional number of patients per year are sent for treatment to the UK (outside the bilateral convention provisions). Referral for treatment outside the EU is an extremely rare occurrence.

This can be summarized in 2005 the following activity took place, within EU 180 patients were covered by bilateral agreements. Within EU but outside bilateral arrangements were there 75 patients at a cost of  $\notin$  945,639. There were one person outside EU at the cost of  $\notin$ 9,317 1 $\notin$  = 0.4293 Malta Liri

Norway
 Costs of health services abroad under regulation 1408/71 and 574/72 are not available broken down on the different forms, only broken down on invoiced debts (actual costs, cf. art. 93; E112, E106, E111, EHIC, E128 etc.) and lumpsum debts (cf. art. 95; E121 and E109). The registered debts do not include expenses covered by waiver agreements that Norway has with other countries, i.e. Austria (by permanent residence), Belgium, Denmark, Finland, Germany, Iceland, Ireland, Luxembourg, Netherlands, Portugal, Sweden and United Kingdom.

The total number of applications for E112 in 2004 was 39, 18 were granted and 21 refused. In 2005 the number of applications was 26, 14 were granted and 12 refused. The breakdown of the granted applications for E112:

	2004	2005
Finland	-	3
France	2	1
Germany	6	1
Iceland	-	1
Netherlands	2	-
Sweden	7	6
Switzerland		1
UK		1
Other/Not known	1	

In addition to those treated under regulation 1408/71, during 2004 two patients were treated abroad, both in Sweden, to fulfil their right to specialised health care within the time good medical practice demands. In 2005 four patients in this category was treated in other EEA –states for the same reason. Three of these patients were treated in Sweden and one in Germany.

In addition to the mentioned patients there were 206 situations where patients consulted health care providers abroad in 2005 with coverage of costs from the regional health enterprises. This number only refers to the number of consultations and does not indicate the number of patients which presumably is lower.

**Poland** 7,000 persons were treated in other Member States since the 1st of may 2004 until the 30 June 2005.

**Spain** In 2004, 760 Forms were delivered to Spanish citizens for health care. Until September 2005, 569 forms were delivered. These can be decomposed by country and there are largest numbers going to France with 304 forms in 2004, followed by Germany with 146 forms.

In 2001, 651 E-112s were issued and 57,468 E-111s.

Slovak Rep in 2005: 791 cases

Slovenia In 2004: 143 patients (insured persons) were treated or examined abroad. Since some patients were treated or examined abroad more than once, the total number of referrals was 172. The cost of treatment abroad was SIT 396 million. Of those treated or examined abroad, 138 were treated or examined in EU Member States or Switzerland, while 5 were treated or examined in other countries (outside the EU).

In 2005, 166 patients (insured persons) were treated or examined abroad. Since some patients were treated or examined abroad more than once, the total number of referrals was 216. The cost of treatment abroad was SIT 373 million. Of those treated or examined abroad, 154 were treated or examined in EU Member States or Switzerland, while 12 were treated or examined in other countries (outside the EU).

Sweden In 2005 app. 20,000 Swedes received planned or unplanned care in another Member State. - 157 individuals applied at the Swedish Social Insurance Agency for

authorisation beforehand for planned treatment abroad.

- 1,050 patients claimed reimbursement for planned health care abroad.

In 2000 the Swedish authorities say that they have received few applications for treatment abroad. In 2002, 6 applications were made under E-112 and all were refused. The Swedish authorities issue around 400,000 E 111s per annum.

UnitedIn 2003, 1,732 persons applied for authorisation for treatment abroad under E112Kingdomscheme. In 2004, the figure was 1,183. In 2000, 1,100 persons applied for<br/>authorisation for treatment abroad under E-112. In 2001, this figure was 1,134.

The UK expenditure on patient mobility (excluding pensioners) between 2000 and 2005 was as follows:

Year	Expenditure in millions £ (Member States claims against the UK)
2000/01	£26.6
2001/02	£28.2
2002/03	£26.5
2003/04	£40.1
2004/05	£49.5

No data are available centrally concerning non E-112 procedures which are administered by the local authorities (Primary Care Trusts). However, the UK has set up a project offering patients awaiting treatment the possibility of being treated in another Member State. This project is run by the local authorities (Primary Care Trusts).190 patients were treated during the pilot phase, and 269 since the end of the pilot phase. The cost of the pilot phase was £1.1 million ( $\pm$  €1,725,265) and the next phase £770,000 ( $\pm$  €1,207,685)

A direct referral scheme outside the scope of the European Community arrangements was available in England. Between January and April 2002 there was a pilot scheme in south east England whereby a number of surgical procedures were commissioned directly by the NHS from healthcare providers in France and Germany. One hundred and ninety patients were treated under this pilot at a cost of £1.1 million.

This was extended for orthopaedic treatment overseas as part of two patient Choice pilot schemes, with patients drawn from five different areas. By the time the scheme ended in March 2005 a total of 890 patients were referred for treatment abroad as part of the overseas treatment programme at a cost of £5.7 million.

07/09/2006 V01.0