COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 2.7.2008
SEC(2008) 2163

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the application of patients' rights in cross-border healthcare

IMPACT ASSESSMENT

{COM(2008) 414 final}
{SEC(2008) 2164}

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Organisation and timing

In 2003 health ministers and other stakeholders invited the Commission to explore how legal certainty in the field of cross-border care could be improved following the Court of Justice jurisprudence concerning the right of patients to benefit from medical treatment in another Member State[1]. The Commission's proposal for a Directive on services in the internal market at the start of 2004 therefore included provisions codifying the rulings of the Court of Justice in applying free movement principles to health services. This approach, however, was not accepted by the European Parliament and Council. It was felt that specificities of health services were not sufficiently taken into account, in particular their technical complexities, sensitivity for public opinion and major support from public funds. The Commission therefore developed a policy initiative specifically targeting healthcare services as a separate issue.

This report is meant to assess the impact of the different options for such an initiative. It only commits the Commission's services involved in its preparation. The text is prepared as a basis for comment and does not prejudge the final form of any decision to be taken by the Commission.

1.2. Consultation and expertise

1.2.1. Internal expertise

An interservice group was established in the beginning of 2007. All DGs were invited to participate in the group, and COMP, EMPL, ENTR, JRC, JLS, MARKT, RTD, SG, SJ, INFSO, REGIO, TRADE, ESTAT and BEPA have attended its meetings. The interservice group met for the first time in January 2007 to discuss the general concept of the initiative and to discuss involvement of different DGs in the process. The second meeting took place in April. During that meeting the outcome of the public consultation was discussed, as well as the scope of the Commission proposal. During the third meeting in May, a first draft of the problem definition chapter of this impact assessment was discussed, as well as the draft stocktaking exercise carried out by the European Observatory on Health Systems and Policies (see also paragraph 1.2.3.2). A fourth meeting was organised in the end of July, to discuss the Impact Assessment as a whole.

1.2.2. Impact assessment board

A draft of this impact assessment report was sent to the impact assessment board on 8 August. On 29 August DG Sanco representatives had a meeting with the board, which sent its written opinion concerning the draft report to DG Sanco on 6

[1] See the Report of the High Level Process of Reflection on patient mobility and healthcare developments in the European Union and the Commission Communication on the follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union, COM (2004) 301 final, 20 April 2004.

September[2]. On the basis of this opinion this report has been strengthened and expanded on several points. In chapter two the consideration of subsidiarity has been further strengthened. In chapter four more clarity has been created concerning the differences between option 3A and 3B. In chapter five the analyses of aggregate and longer-term impacts have been expanded. The opinion of the board is one of the accompanying documents to this report. It will be made public once the proposal is adopted by the College.

1.2.3. Stakeholder consultation

The Commission's minimum standards concerning stakeholder consultation have been met. Stakeholders have been extensively involved in Commission activities regarding patient mobility and health care over many years, in particular through the High Level Reflection Process, the Open Forum[3] and the High Level Group on Health Services and Medical care[4].

Consultation on the specific initiative described in this report started formally in September 2006 with the publication of a Communication[5], inviting all relevant stakeholders to contribute to a consultation process regarding Community action on health services. The objective of the consultation was to clearly identify the problem(s) and to get input concerning objectives and policy options. The Communication as well as the full summary report of the responses[6] is attached to this document as an accompanying document.

The Commission received 280 responses to this consultation from a wide range of stakeholders. From individual EU citizens, health professional organisations, healthcare providers, national and regional governments, insurers, individual citizens, the industry etcetera. A wide range of issues related to (cross-border) healthcare in Europe was raised. These are included where appropriate elsewhere in the impact assessment. All contributions have been published on the Commission website[7]

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2 Impact Assessment Board Opinion, Impact Assessment on: Directive on safe, high-quality and efficient healthcare in the European Union, D(2007)7744, 5 September 2007.

3 The last Open Health Forum attracted around 380 participants from a wide range of health organisations. The Forum recommended during its conference in November 2005 that the Commission should address the potential of targeted healthcare legislation, because subsidiarity is not a sufficient guarantee of meeting the promise of universal access to high quality healthcare. The Forum also confirmed the need for strong and fully implemented safeguards of patient safety at EU level whilst respecting for the capacity of national rules guaranteeing quality and safety. The Forum also recommended to establish an internet portal for the free exchange of data, evidence and practice to foster continuous learning and innovation, Final Report of the Open Health Forum, Health challenges and future strategy, European Public Health Alliance (2005).

4 All EU Member States are represented in the High Level Group on Health Services and Medical Care, observers from the EEA/EFTA states as well as representatives from civil society have also been involved in the work of this group; Report on the work of the High Level Group on Health Services and Medical Care in 2006, European Commission (2006).

5 Commission Communication, Consultation regarding Community action on health services, SEC (2006) 1195/4, 26 September 2006.

6 Commission document, Summary report of the responses to the consultation regarding "Community action on health services" (2007)

7 http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm

Contributors to the consultation see a need for more and clearer information to patients with regard to cross-border care, and made a range of practical suggestions for achieving this. Greater clarity was also sought over instruments to control patient flows in cross-border care and in particular over the conditions under which prior authorisation for cross-border care is justified and can be refused. Suggestions by contributors for improvements include clear information for patients; effective and transparent decision procedures; a patient-centred approach; evidence-based standards; the right to appeal against refusals of authorisation; and exceptions for border regions. Greater clarity was also sought over pricing for cross-border care, and the definition of 'health services' within the scope of any Community action.

There is broad consensus among contributors that responsibility for clinical oversight should be with the country of treatment. However, cooperation with the relevant authorities in the patient's home country is important, and particular cases highlighted include managed cross-border care and international patient transport. There are also particular cases where any division of responsibilities leaves difficulties in practice, such as with control of hospital-acquired infections. Many contributors also saw value in European support to national authorities in achieving a high level of quality and safety in healthcare, such as through developing guidelines and indicators; or the introduction of a no-fault patient safety reporting system. Practical suggestions for ensuring continuity of care included systems for exchanging patient data, an EU standard discharge letter and Europe-wide prescriptions. Many contributors also argued that there should be greater clarity over patients' rights.

There is also broad consensus that the provider of treatment should be liable for harm and any redress arising. Contributors were divided, though, about the need for more legal clarity regarding liability issues for cross-border health care beyond that already provided by international private law. However, there were many practical suggestions made, such as putting in place alternative dispute resolution systems for cross-border care (perhaps building on existing networks such as SOLVIT), requiring mandatory insurance for healthcare providers, or the establishment of the Europe-wide no-fault compensation system.

Some contributors were concerned about the potential for cross-border care to undermine the provision of healthcare within their countries, in particular with regard to how to prioritise different patients and setting fair prices for cross-border care provided. On the other hand, some contributors felt that increased cross-border care could have a positive effect on domestic care provision.

Many contributors felt that there was a need for better monitoring of health professional mobility. Issues were also identified in relation to Community rules on recognition of professional qualifications, but many contributors felt that the implementation of Directive 2005/36/EC should be awaited before taking any new action. How to manage the impact of health professional mobility was also identified as an issue, in particular by contributors from the newer Member States. Greater clarity about the rules governing the establishment of healthcare providers in other Member States was also sought by a few contributors, with particular regard to pharmacies and dentists. However, most contributions were more concerned about practical issues in cross-border pharmacy services, and made suggestions such as developing ePrescriptions. Information and communication technology solutions in

general were identified as a key area for the future by many contributors, though teleradiology was seen as a priority challenge where more analysis was needed.

Some contributors identified particular issues related to the practical operation of the existing regulations on coordination of social security systems, and made a number of suggestions for improvements. Also in addition to the other suggestions for practical support contributors highlighted the scope for practical support on areas including European reference networks; an observatory for comparative data and indicators; health technology assessment; better sharing of healthcare innovations; and support for making effective use of potential investment in healthcare through the structural funds. However, many contributors argued for a rationalisation of activities and resources concerning healthcare at European level; others also argued that Community action should also involve regional authorities.

Overall, contributors welcomed the initiative of the Commission regarding Community action on health services in general. The majority of national governments and many other stakeholders expressed the wish that any proposal of the Commission on health services should be based on the "Council Conclusions on Common values and principles in EU Health Systems"[8]. Many contributions (in particular from national governments, unions and purchasers) emphasised that any Community action that affects the health systems should respect the subsidiarity principle, referring in particular to Article 152 of the Treaty establishing the European Community, although others argued that the principle of subsidiarity should not prevent the application of EU fundamental freedoms.

On the overall approach, the majority view of contributors was that a combination of both "supportive" tools (such as practical cooperation, or the 'open method of coordination') and legally binding measures would be the most efficient approach, although some contributors did not see a need for any legal measures. In terms of the preferred approach for any legal instrument there were clearly two main approaches preferred by different contributors. Some contributors preferred to include any changes within the Regulations on the coordination of social security systems, while other contributors preferred a new Directive on health services.

1.2.4. Position of European Parliament and Council

The inclusion of health services within the scope of the services directive was itself a response to the call for greater legal certainty in the field of cross-border healthcare. Both the Council and Parliament felt nevertheless that the nature of the services directive was inappropriate to the health sector, hence their exclusion. Both Council and Parliament have since again called for specific proposals on health services, considering that this is the best way forward to provide greater legal certainty whilst doing so in a way specifically adapted to and respecting the specific nature of the health sector.

The European Parliament contributed to the development of a proposal concerning cross-border healthcare with various reports. In April 2005 a report on Community

[8] 2733rd Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg, 1-2 June 2006

action on the provision of cross-border healthcare (the 'Bowis-report')[9] was adopted by the Parliament. In March 2007 the Parliament adopted a resolution on Community action on the provision of cross-border healthcare[10]. The Parliament adopted in May 2007 a report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market (the 'Vergnaud-report)[11]

The Council adopted in June 2005 conclusions on Common values and principles in EU Health Systems in which it stated that it believes there is particular value in any appropriate initiative on health services ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member State to another and in enshrining values and principles in a legal framework in order to ensure legal certainty These refer to overarching values of universality, access to good quality care, equity, and solidarity, as well as 'operating principles' of quality, safety, care that is based on evidence and ethics, patient involvement, redress, privacy and confidentiality.[12].

Linked to this, subsidiarity is a key concern for the European Parliament and the Council; the importance of the Community respecting the primary responsibility of the Member States for the organisation, financing and delivery of health services and medical care. Member States and the Parliament have expressed concerns about what the margin for manoeuvre is for national and regional authorities responsible for health systems to do so and remain in compliance with Community law – what is their 'steering capacity'. This is a concern that any proposals must take into account, and it is also part of the reason for support for proposals, both Council and Parliament considering that these issues should be set out clearly in legislation rather than be left to individual rulings by the Court on particular cases.

1.2.5. External expertise

The Commission used the expertise of external experts, both when it drew up the problem definition and to support the assessment of the policy options.

1.2.5.1. EuroBarometer

In May 2007 the Commission conducted a EuroBarometer about cross-border healthcare in the EU[13], in order to provide better insight into the actual scope of patient cross-border mobility, the willingness of patients to go abroad for medical treatment and the problems they foresee when going abroad to receive health care. The EuroBarometer is a survey instrument that reveals perceptions of EU citizens. Approximately 1000 people per member have been interviewed about possible reasons to go abroad for medical treatment (quality, timing and financial implications) and reasons which might deter them from doing so (lack of information about availability, quality or financial implications). The report summarizing the

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9 A6-0129/2005 final

10 B6-0098/2007

11 A6-0173/2007 final

12 10173/06 SAN 168 SOC 302 MI 132

13 Flash Eurobarometer Series #210, Cross-border health services in the EU, Analytical report, conducted by The Gallup Organization, Hungary upon the request of the European Commission, the Health and Consumer Protection Directorate-General (DG SANCO), 2007.

conclusions from the EuroBarometer is attached to this impact assessment. The results showed that seventy percent of the EU population believes that costs of healthcare treatment received elsewhere in the EU will be reimbursed for them by their health authority. Overall, four percent of Europeans, according to the results of the survey, received medical treatment in another EU Member State over the past 12 months. However, confirming the analysis of the consultation, this figure varies substantially - in Luxembourg, every fifth citizen sought healthcare outside the country's borders.

Slightly more than half of EU citizens are open to travel to another EU country to seek medical treatment (54%). The most prominent reason to do so would be unavailability of the necessary treatment in the domestic healthcare system. Better quality and quicker access to the necessary treatment would also be important motivating factors for patients. The 42% who are not willing to travel abroad for treatment are motivated by distinctly different reasons in the old and new Member States. Generally, the survey found that citizens in the EU15 zone would prefer to remain in their own country as they are satisfied with their domestic services, and the convenience of local treatment, while those in the new Member States are more likely to be discouraged from seeking healthcare abroad by foreseen affordability problems.

1.2.5.2. External expert support to the impact assessment

The European Observatory on Health Systems and Policies provided an independent expert analysis in support of this impact assessment taking stock of developments on health care in Europe, focussing on seven aspects of cross-border health care[14]: pre-authorization and access to healthcare; quality and safety; patient rights; cross-border collaboration; health care baskets and tariffs; past impacts of cross-border healthcare; and cross-border healthcare data. This exercise was based on existing research, examples, studies etc to provide better understanding of cross-border health care from different national health systems perspectives on the above mentioned aspects and describes how current legal and non-legal uncertainties have had an impact on cross-border health care in general and the aspects mentioned above in particular (now and in the past), who is affected, in what ways, and to what extent.

[14] Wismar M, Palm W, Figueras J, Ernst K and Van Ginneken E, Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity, European Observatory on Health Systems and Policies, 2007.

2. PROBLEM DEFINITION

2.1. Context

Patients prefer healthcare to be available as close to where they live and work as possible. For the vast majority of cases, the health systems of the European Union ensure that the healthcare that patients seek is provided within their own Member State, which meets patients' preferences. It is in general considered to be safer and more efficient to be treated within one healthcare system. However, there are situations when cross-border healthcare can be more appropriate, such as:

– for highly specialised care requiring a particular concentration of resources or expertise that is beyond the capacity of every Member State to provide, such as for rare diseases;

– for border regions, where the nearest appropriate healthcare provider may be across the border in another Member State, and where efficient provision of care may be best achieved through providers serving populations across borders throughout their local region;

– or in cases of lack of capacity, where local services are unable to provide the appropriate healthcare and there is capacity available in another Member State.

Cross-border healthcare may also simply be the preferred choice for the individual. For example, people who have moved to another Member State to work or retire may prefer to return to their country of origin for healthcare, even if the healthcare in question could also be provided in the country where they now live. Or healthcare in question may be cheaper in another Member State, which may represent a sufficient reason for a citizen to prefer to seek it abroad where they are paying some or all of the costs of that healthcare themselves (for example, as is increasingly the case for much dental care).

There is already Community legislation that helps to facilitate cross-border healthcare. The regulations on coordination of social security systems provide for persons for whom a medical treatment becomes necessary during a stay in the territory of another Member State to the same benefits as patients insured in the host Member State, using the European Health Insurance Card[15]. The regulations also provide for patients to be able to seek healthcare in another EU country, subject to prior authorisation from their own system. That authorisation must be granted if the care cannot be provided within a medically justifiable period of time, and the patient will not have to pay more if the costs of treatment in the other Member State are higher than in their own country.

In addition to those regulations, the European Court of Justice has ruled in the specific cases brought to its attention that patients can, under certain circumstances, use the free movement rights provided by the Treaties directly to have access to

[15] Council Regulation (EC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community. OJ L 149, 5.7.1971, p.2

healthcare abroad. As outlined in the Commission's communication consulting on these issues in 2006, in 1998 the Court established new principles through its rulings in two cases[16] regarding direct application of the Treaty articles on **free movement to the reimbursement** of health services provided to patients abroad. In its rulings, the Court made clear that when health services are provided for remuneration, they must be regarded as services within the meaning of Treaty and thus relevant provisions on free movement of services apply. The Court also ruled that as a result measures making reimbursement of costs incurred in another Member State subject to prior authorisation are barriers to freedom to provide services, although such barriers may be justified by overriding reasons of general interest. On the basis of these and subsequent cases[17], the Court's rulings have developed the following principles:

– Any non-hospital care to which a person is entitled in their own Member State they may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by their own system.

– Any hospital care to which they are entitled in their own Member State they may also seek in any other Member State provided they first have the authorisation of their own system. This authorisation must be given if their system cannot provide them care within a medically acceptable time limit considering their condition. They will be reimbursed at least up to the level of reimbursement provided by their own system.

2.2. The size of cross-border healthcare

2.2.1. How large is the issue?

After repeated exercises over recent years, it is clear that there is as yet no comprehensive data about cross border healthcare. However, there is sufficient data to roughly estimate its overall scale, at least for patient mobility.

Focusing on 'patient mobility', the Commission has estimated that cross-border healthcare represents around 1% of public expenditure on healthcare. This estimate was tested through the consultation exercise, and was broadly confirmed by the responses from Member States and other contributors, with similar proportions both of expenditure and numbers of patients moving.

The total GDP of the European Union is € 12,149 billion[18]. Of this, 7.6% (€ 967 billion) of GDP is being spent on public healthcare[19]. As 1% of public healthcare expenditure is spent on cross-border care, **this equals approximately € 9.7 billion**.

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16 Case C-158/96 Kohll [1998] ECR I-1931 and Case C-120/95 Decker [1998] ECR I-1831.

17 For example, Case C-368/98 Vanbraekel [2001] ECR I-5363; Case C-157/99 Smits and Peerbooms [2001] ECR I-5473; Case C-56/01 Inizan [2003] ECR I-12403; Case C-8/02 Leichtle [2004] ECR I-2641; Case C-385/99 Müller-Fauré and Van Riet [2003] ECR I-4503.

18 EU economic data pocketbook 1-2007, Eurostat (2007)

19 Europe in figures – Eurostat yearbook 2006-07, Eurostat (2007)

However, respondents to the consultation underlined that cross-border healthcare varies, and can be significantly larger in certain circumstances[20]. Factors influencing the impact of cross-border healthcare include:

– **Border regions**: The impact of cross-border healthcare is likely to be greater for European citizens living in border regions, and the associated hospitals and providers. One contributor argued that as soon as more than 5% of patients treated in a hospital are from abroad, the planning of capacities for different types of services needs to be adapted accordingly (*Euregio Maas-Rhein*). In some cross-border areas contributors indicated that this is addressed through EUREGIO projects and bilateral cross-border agreements on provider, regional or national level, but some practical problems of organising these projects remain;

– **Smaller Member States**: For smaller Member States contributors to the consultation indicated that the financial impact may be much more significant. For example, in Luxembourg, up to 7% of the healthcare budget has been spent on cross-border care in recent years. In addition, it was argued that it is not possible to provide some forms of highly specialized care in smaller Member States, with patients instead sent abroad in an organised manner to receive these treatments (*e.g. Cyprus, Malta*);

– **Individual impact**: Even though the impact may be relatively low for the systems in general, access to cross-border health services may be essential for the individuals concerned;

– **Rare diseases**: Geographical access to healthcare providers can be more difficult in smaller Member States (e.g. Luxembourg, Malta, Cyprus), which simply do not have enough patients to justify having certain institutions or technologies available in the country. In particular, patients with rare diseases may need to rely more on cross-border care to obtain appropriate treatment than patients with more common conditions.

– **Areas attracting large amounts of tourists**: Areas attracting large numbers of tourists, such as parts of southern Europe and the Mediterranean islands, face some specific impacts. If capacities are intended only for the number of residents, then in the tourist season capacities may be too limited to cope with the numbers of tourists, which could undermine access to emergency care for both residents and visitors. Tourists may also 'drain' local health systems resources, if the billing methods applied do not cover the full cost of treatment, including the necessary infrastructure. However, it could also be argued that medical services that they offer to tourists in need of healthcare also form part of the infrastructure which makes those areas an attractive tourist destination.

– **High co-payments increase cross-border care**. In many European health systems, contributors said that dental treatment is paid to a large extent or even completely by the patient. This is seen by many contributors as having an impact on cross-border care, with increased numbers of patients thus planning to receive

[20] These contributions are all published on the Commission website: http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm

less costly care abroad. Some suggested that this could concern 5-10% of all dental care, representing 60% of all cross-border care in some countries (*Swedish Government*).

2.2.2. Future trends

The extent of cross-border healthcare has grown in recent years, and is likely to continue to grow in the future; see data on cross-border healthcare collected through the regulations on social security annexed. Many contributors to the consultation also expect a noticeable increase of cross-border healthcare in the future[21]. The contribution from the *Portuguese Association of Private Hospitals* was typical of the positions of many contributions:

"There is a clear and increasing tendency for people to travel in Europe; especially new generations for whom the idea of a Europe without borders is starting to make sense. The "short break" tourism has been expanding dramatically in many European cities, in the past years, encouraged by the constantly emerging "low cost" airlines. Longer duration stays by citizens from other Member States have also increased. We only need to look at the success that the project ERASMUS is enjoying among young people. But also noticeable are the travels of northern seniors towards southern Europe, for holidays, or for seasonal stay, as a second home, or even as a permanent residence. In this context, the search for healthcare in a specific Member State by persons from another Member State is naturally increasing"(APHP).

In an EU-wide survey the majority of consumers stated that they expect that travelling long distances for healthcare services will be normal in 2020 (yes: 57%, it depends: 28%, no: 14%; do not know: 1%) (*Health Consumer Powerhouse*). The Eurobarometer underlines this potential, with most EU citizens (53%) willing in principle to go abroad to receive healthcare.

Overall, therefore, there is a rising trend for cross-border healthcare, and significant potential demand from citizens to explore cross-border healthcare when it is quicker, better, cheaper or more convenient for them. The actual extent of cross-border healthcare is likely to depend on the extent to which care abroad is actually quicker, better, cheaper and/or more convenient. As long as the home system meets the needs a patient will most likely not consider seeking healthcare abroad.

The extent of unmet need for healthcare within Member States is therefore a crucial factor in projecting likely future need. The European Statistics on Income and Living Conditions (EU-SILC) survey provides cross-sectional and longitudinal multidimensional microdata on income, poverty, social exclusion and living conditions. This includes data on unmet healthcare need, which is set out in annex 1. As this shows, most healthcare need is met in most countries, but there are some significant elements of unmet need. The average percentage of people per Member State with unmet need, each Member State weighted on the basis of the amount of inhabitants, is 8.5%. However, experience to date shows that even amongst patients

[21] These contributions are all published on the Commission website: http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm

who have a clear unmet need, and are aware of the possibility to go abroad for treatment, fewer than 10% of them actually go abroad to receive care.

This proportion may be higher in some circumstances, of course, as outlined above. For example, one particular likely reason to prompt people to consider healthcare abroad is where the care is cheaper, and they are paying some or all of its cost. One common example is dental treatment, as identified above. And indeed, the percentage of people identified through the EU-SILC survey as having an unmet need for dental examination and treatment because it was too expensive is higher than for medical treatment in general.

2.3. The issues to address

The first issue to address, concerns how the free movement rights recognised by the Court for citizens to have access to healthcare abroad can be applied in practice. The second concerns how to ensure that when cross-border healthcare is provided, it is safe and efficient.

2.3.1. Uncertainty about general application of rights to reimbursement for healthcare provided in other Member States

Many contributors to the consultation felt that currently it is difficult for patients to identify their rights with regard to cross-border healthcare. Clear information is often felt to be missing. It was widely argued that in many Member States patients are not aware of the possibilities and their entitlement to receive treatment abroad and to get reimbursed. For example, a study conducted by the *Health Consumer Powerhouse* in France, Poland, United Kingdom, Spain and Germany showed that 25% of citizens believe that they do not have the right for treatment abroad and 30% are unsure[22]. This was confirmed by the Eurobarometer survey[23] mentioned above, which showed that 30% of the citizens in the European Union are not aware of the possibility to receive healthcare outside their country of affiliation.

The Court's rulings on the individual cases outlined above are clear in themselves, and no pre-condition may be required for the exercise of the rights of patients recognised by the Court. However, it is necessary to improve clarity to ensure a more general and effective application of these rights in practice, and to ensure that they can be exercised in a way which is compatible with overall health system objectives of accessibility, quality and financial sustainability.

In practical terms, this degree of uncertainty and confusion about the general application of rights to reimbursement for healthcare provided in other Member States among the authorities responsible for cross-border care and the representatives of providers is likely to make it more difficult for patients to use their rights in practice, as those responsible will be reluctant to wholeheartedly implement rules and procedures when they are not clear about what they are. And if patients wish to contest the interpretations that are given or the rules being applied, it is difficult for

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22 http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co147.pdf

23 Flash Eurobarometer Series #210, Cross-border health services in the EU, Analytical report, conducted by The Gallup Organization, Hungary upon the request of the European Commission, the Health and Consumer Protection Directorate-General (DG SANCO), 2007.

them to do so in the absence of clarity about what their rights are and how they should exercise them.

This analysis is corroborated by the significant difference between the 1% of total health expenditure estimated by the Commission and confirmed through the consultation, and the practical experience of patients, who report an average figure of 4% using healthcare abroad in the previous year[24]. This is likely to be the case because the volume of cross-border healthcare is greater than estimated so far. And patients are making up the difference through their own expenditure or through other routes, such as private health or travel insurance, rather than claiming back reimbursements to which they should be entitled.

Patient mobility is only one of the four possible types of cross-border healthcare, which are:

– Cross-border provision of services (delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;

– Use of services abroad (ie: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';

– Permanent presence of a service provider (ie: establishment of a healthcare provider in another Member State), such as local clinics of larger providers; and,

– Temporary presence of persons (ie: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).

In this section the lack of clarity about the authorization and reimbursement of healthcare abroad has been described. This problem is only related to the use of services abroad (referred to as 'patient mobility'). It has no direct links with the other three modes of cross-border healthcare.

2.3.2. Uncertainty over how the necessary frameworks for safe and effective healthcare should be ensured for cross-border healthcare

Linked to the problem described in the previous section but broader is uncertainty over how the necessary frameworks for safe and effective cross-border healthcare work in general. Whenever healthcare is provided, it is vital for patients to ensure:

– clear information that enables people to make informed choices about their healthcare;

– mechanisms for ensuring the quality and safety of the healthcare that is provided;

– continuity of care between different treating professionals and organisations;

– and mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.

[24] See the Eurobarometer results referred to above.

Within Member States, different structures have been put in place to ensure these elements at local, regional or national level, or through non-regulatory structures such as professional organisations, or through standards linked to financing mechanisms. However, there are no clear rules at Community level about how these requirements should be met for cross-border healthcare, or who is responsible for ensuring that they are. This is the case no matter how the care is paid for – whether it is paid for publicly or privately, whether it is undertaken through the regulations on coordination of social security systems or whether it is in application of the additional free movement rights described above.

Without such clarity, there is the risk of confusion leading to a reduction of quality and safety of healthcare in cross-border cases. Even in cases where there is long term experience of cooperation between countries, it turns out to be difficult to ensure the quality and safety of cross-border care. An important explanation of these difficulties is the different approaches in the different Member States to ensuring quality and safety. For example, countries have different treatment protocols, different divisions of responsibilities and different quality control systems. Quality and safety control is often integrated into financing and planning mechanisms. As cross-border care often takes place outside of those mechanisms, quality and safety control is at risk in the cross-border context.

Several reports highlight problems with continuity of care in cross-border settings. One study analysed in detail the weaknesses in the care chain of Dutch patients treated in Belgian hospitals[25]. Other studies point mainly to the lack of information transfer from the Belgian treating doctors to the Dutch GPs and to the providers responsible for the aftercare. Several reports also mention problems with the availability at home of drugs and medical devices that were prescribed abroad[26]. This may not just be a question of quality and safety structures being lacking, but problems with overlapping and potentially conflicting systems being applied from both the country where care is provided and the patients' country of residence. This may be well-intentioned, but given the very different approaches to ensuring quality and safety in the different countries, attempting to have domestic standards accompany patients seeking healthcare in other countries may create additional risks rather than helping to ensure quality and safety.

Ensuring quality and safety in healthcare depends not just on the skills and qualifications of an individual professional. Rather, it depends on the functioning of an entire system: the individual professional; the team of professionals dealing with the particular patient; the overall providing organisation; and the applicable regulatory framework. It is precisely at the borders between each of these elements that risks increase, and thus cross-border healthcare (as healthcare involving borders between all of the systemic elements responsible for ensuring healthcare) raises greater risks than healthcare within a single Member State.

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25 Engels EL, Grenzeloos geketend? Explorerend onderzoek naar de transnationale zorgketen tussen Nederland en België, Maastricht, Universiteit Maastricht, Faculteit der Gezondheidswetenschappen (2003).

26 Grunewald CA, Smit R, Grensoverschrijdende zorg – Zorg op maat in de Euregio Maas-Rijn; evaluatie van een experiment, Utrecht, NZI (research institute) (1999). and Boffin N, Baeten R, Dutch patients evaluate contracted care in Belgian hospitals: results of a patient survey, Brussels, Observatoire Social Européen (2005)

There is also a lack of information to allow patients or their physicians to make informed choices about the possibilities and appropriateness of cross-border healthcare. There is no simple mechanism for seeking information in the language of the patient about different treatment or provision options, their cost and availability in practice, or their outcomes and success rates for healthcare in other Member States. Even when such information can be found, the lack of comparability makes informed decision-making difficult at best, and thus hinders making appropriate choices.

In terms of modes of supply of healthcare, the issues described in this paragraph mainly concerns patient mobility (ie: use of services abroad), but has some implications for the other modes of supply as well:

– Cross-border provision of services: this initiative does not address where the provider is established nor the conditions for doing so. However, it must also be clear for a provider providing services across borders what the applicable frameworks for safe and efficient healthcare are that apply. For example, through which country's error reporting systems should they report mistakes or issues arising, and in what language should they do so?

– Use of services abroad: a patient treated in another country is the main issue on which this section focuses, with the issues outlined above. For example, if a patient from one country is referred to another country for specialist treatment, should their home country check the quality of the treatment being provided?

– Permanent presence of a service provider: again, this initiative does not address where the provider is established nor the conditions for doing so, but simply what rules and procedures they should follow, and which authorities are responsible for oversight and monitoring. For example, if one country monitors standards through professional reporting structures but another country where they are present monitors standards through a specific inspectorate, whose reporting structures should monitor them?

– Temporary presence of persons: again, this initiative does not address where the professional is registered nor the conditions for being registered (which is already addressed separately through the directive on the mutual recognition of professional qualifications, 2005/36/EC), but the rules and procedures for safety and quality of care that they should follow in the case of providing services temporarily in another Member State. For example, if their home country uses red armbands to indicate patients who are allergic to aspirin but the country where they are temporarily providing services uses blue armbands for the same indication, which colour should they use?

The reason for focusing on 'patient mobility' with regard to uncertainty about the general application of rights to reimbursement for healthcare provided in other Member States is that this is the mode of supply where the problems arise. On the basis of the analysis set out - there do not appear to be equivalent problems in the other modes of supply of health services, and thus no need to address them.

However, it is important to be clear that the uncertainty over the necessary frameworks for safe and effective healthcare is not limited to use of services abroad.

This initiative focuses on the issues which have been identified as a significant problem - the main concerns having been identified as being related to use of services abroad. For the other main mode of cross-border healthcare provision (temporary presence of persons), the bulk of issues raised are already covered by the directive on mutual recognition of professional qualifications. However, the initiative will have an impact for health professionals temporarily providing healthcare abroad, by clarifying the rules and procedures for safety and quality of care that they should follow while doing so, and similarly with cross-border provision of services, and permanent presence of a service provider.

2.4. Subsidiarity

As described above, there are significant problems with cross-border healthcare, both in terms of uncertainty over the general application of rights to reimbursement for healthcare provided in another Member State, and over the necessary frameworks for safe and efficient healthcare provision.

2.4.1. The necessity test

It is primarily the responsibility of the individual Member States to organize their healthcare systems in the way that best suits their country and citizens. Nevertheless, sometimes the healthcare that citizens need can best be provided in another Member State, due to its proximity, its specialised nature, or the lack of capacity to provide that care in their own country. In accordance with the principle of subsidiarity, the Community should only act in this area if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

Community law already provides rights in principle for cross-border movement of goods, services and people in general and health products, services and patients in particular. But there are questions and uncertainties over what this means in practice; for citizens and for all other stakeholders involved. The European Court of Justice has interpreted Community rules in a different way compared to interpretation by national governments. But, as emphasised by several Member States during the consultation, also after the Court came with its interpretation, Member States still lack certainty about how these individual cases should be interpreted in general. Due to this uncertainty it is difficult for Member States to manage their healthcare systems properly. Cooperation on Community level, for example by the development of secondary legislation based on the Treaty, would bring the requested clarity, which could not be realised on national level alone.

In the second place there are concerns about how to ensure that cross-border healthcare is as safe and efficient as possible. Cross-border healthcare has, as the name already predicts, many Community-wide transnational aspects. For both patients and professionals, there is a crucial difference between having some confidence in the applicable rules for cross-border care, and being certain. The potentially very serious consequences of any legal uncertainty concerning responsibilities in cross-border healthcare settings are an important reason to act on this issue. When citizens cross borders to receive healthcare, it is important that it is clear which country is responsible for what. Currently that clarity is lacking. It is not

possible for individual Member States to define their own responsibility without agreeing on these responsibilities with other involved countries. Therefore also to solve this issue, agreement concerning responsibilities is needed on Community level.

2.4.2. Link with the Treaties

The European Court of Justice has confirmed that even though Member States are primarily responsible for the organisation and delivery of health services and medical care, health systems must comply with the provisions of Community law, including internal market rules. Both the European Parliament and the Council of Health Ministers have asked the European Commission to come up with a proposal which, taking account of the Court judgements, sets a clear framework for cross-border care. Such a framework would provide sufficient clarity about patient's rights to be reimbursed for healthcare provided in other Member States and other aspects of cross-border healthcare so that those rights could be realised in practice. On the other hand this framework should also support Member States in their efforts to secure a healthcare system of high quality, sustainable for the future. The Treaty establishing European Communities gives the Community the possibility to contribute to Member States' efforts and to support their national policies to improve public health and consumer protection (art 152 par. 1 and art 153 par. 1).

As confirmed by the Court of Justice on several occasions, health services fall within the scope of the EC Treaty, and in particular art. 49 on the free movement of services, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment. Article 95 of the Treaty foresees adoption of measures the object of which is the establishment and functioning of the internal market. This provision would therefore serve as a legal basis for establishing a general framework for provision of safe, high quality and efficient health services in the European Union and to ensure free movement of health services and high level of protection of health, whilst fully respecting the responsibilities of the Member States for the organisation and delivery of health services and medical care.

However, this does not alter the fact that health systems are primarily the responsibility of Member States and Community action shall respect Member States' responsibilities for the organisation and delivery of health services and medical care in accordance with Article 152 TEC. Moreover, health services are indispensable part of services of general interest and as such, they contribute to the quality of life of European citizens and are one of the essential pillars of the European model of society. Article 16 of the EC Treaty requires the Community and the Member States to ensure that services of general economic interest operate on the basis of principles and conditions which enable them to fulfil their missions. In addition, Article 86(2) of the EC Treaty allows reconciling the rules of Community law, including rules on competition and internal market, with the fulfilment of the mission of general economic interest by making undertakings entrusted with the operation of services of general economic interest subject to the rules contained in the EC Treaty in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them.

Article 95(3) of the Treaty further stipulates that the Commission, in its proposals for the establishment and functioning of the internal market concerning health, shall take as a basis high level of protection of health, taking account in particular of any new development based on scientific facts. The framework for cross-border healthcare in the EU would therefore need to ensure that the necessary requirements for high-quality, safe and efficient healthcare are also ensured for cross-border healthcare.

Citizens would also, alternatively to the new framework for cross-border healthcare created under article 95 of the Treaty, continue to have the rights arising from rules based on article 42 of the Treaty and in particular the regulation on the application of social security schemes to employed persons and their families moving within the Community (1408/71). In particular, where appropriate care for the patient's condition cannot be provided in their own country without undue delay, then they should be authorised to go abroad, with any additional financial costs being borne by their social security scheme in accordance with the provisions of that Regulation.

3. OBJECTIVES

3.1. Overall objective: A clear framework for cross-border healthcare within the EU

The overall objective of this initiative is to ensure that there is a clear framework for cross-border healthcare within the EU. Addressing the issues identified above, this should:

– provide sufficient clarity about rights to be reimbursed for healthcare provided in other Member States for those rights to be realised in practice;

– and ensure that the necessary requirements for high-quality, safe and efficient healthcare are also ensured for cross-border care;

whilst ensuring that such cross-border healthcare is compatible with the overall objectives of the Member States of ensuring accessibility, quality and safety of the healthcare that their health systems provide.

3.2. Specific objectives

3.2.1. Ensure that rights to reimbursement for healthcare abroad can be used in practice

This specific objective should be therefore to ensure that there is a clear framework that will enable patients to exercise their rights to reimbursement for healthcare abroad in practice. This should not amend the existing regulations coordinating social security systems, nor the mechanisms that they provide for emergency care whilst abroad or prior authorisation for healthcare abroad. Rather, it should ensure a clear framework for the additional free movement rights provided by the Treaties to have access to healthcare abroad, the principles of which have been established by the Court, in particular that the patient can only be reimbursed for costs of healthcare abroad up to the amount to which they would have been entitled had they had the care in their own country.

3.2.2. Ensure high-quality, safe and efficient cross-border healthcare

It is the objective of this initiative to ensure that the necessary requirements for high-quality, safe and efficient healthcare are also respected for cross-border care. This initiative should stipulate the general common principles and obligations without either harmonising the organisation or the structure of healthcare provision. Member States will, in compliance with Article 152, paragraph 5 EC, continue to have the freedom to organise their health systems as they wish in order to achieve these common principles. The aim of this initiative is simply to make clear which Member State is responsible in any given situation. This would avoid gaps or overlaps in responsibilities and would clarify what those responsibilities mean in practice.

3.3. Operational objectives

3.3.1. For reimbursement for healthcare abroad:

For the additional free movement rights provided by the Treaties to have access to healthcare abroad, the principles of which have been established by the Court, the

operational objectives under this heading are to ensure common, clear and enforceable Community rules with regard to:

– the entitlements of patients to have healthcare in another Member State, the limits that Member States can place on such healthcare abroad and the information to be provided to enable patients to be aware of the option of cross-border healthcare;

– the level of financial coverage that is provided for cross-border healthcare;

– the processes for decisions about such healthcare, including the criteria for assessment and mechanisms for appeal;

– and what happens with regard to harm and compensation arising from cross-border healthcare.

3.3.2. For high-quality, safe and efficient cross-border healthcare

The operational objectives under this heading are to ensure that the essential requirements for high-quality, safe and efficient healthcare are also guaranteed for cross-border healthcare, in particular:

– that people can have access to information that enables them to make informed choices about cross-border healthcare;

– that cross-border healthcare is also covered by the mechanisms for ensuring the quality and safety of healthcare of the country where treatment is provided;

– that the necessary transfer of information to ensure continuity of care between different treating professionals and organisations is ensured for cross-border healthcare;

– and that mechanisms are in place to ensure appropriate remedies and compensation for harm arising from cross-border healthcare.

3.4. Contribution to wider objectives

In addition to the direct objectives of ensuring a clear framework for cross-border healthcare, this initiative will also contribute to the overall goals of the health systems of the Member States, and to the growth, competitiveness and cohesion of the Union as a whole.

3.4.1. Contribution to the overall goals of the health systems of the Member States

In addition to the direct objectives outlined above, putting in place a clear framework for cross-border healthcare will also contribute to the overall shared goals of health systems throughout the EU of accessibility, quality and financial sustainability:

– **accessibility**: although healthcare is normally best provided within the patients' own Member States, sometimes the healthcare that patients seek can best be provided in another Member State. Putting in place a clear framework for cross-border healthcare will therefore help to ensure accessibility also for patients for whom that is the most appropriate choice. This is particularly the case for

situations where the most effective form of provision is provided in cooperation across more than one Member State (eg: in border regions, or for particularly rare conditions or specialised treatments);

– **quality**: the outcomes produced by healthcare vary significantly throughout the Union[27]. This is shown for example by the variations in the mortality amenable to healthcare throughout the Union[28]. This is not a simple correlation with resources invested – rather, there are significant issues with inappropriate use of procedures, under-use of generally accepted and widely known treatment standards, and medical errors, linked to overall systemic causes[29]. In addition to facilitating access to high-quality care where this can best be provided in another Member State, a framework for cross-border healthcare will also help to facilitate cooperation and comparison between Member States, and thus can help to disseminate best practices and improve quality of healthcare throughout the Union for everyone, whether they seek healthcare abroad or not;

– **financial sustainability**: as outlined above, sometimes the most efficient and effective means of healthcare provision can be provided in cooperation across more than one Member State, either because of the geographical proximity, or because of the concentration of specialist resources and patient volumes necessary cannot be provided as efficiently and safely within the patients' own Member State. The cost of healthcare systems to public funds has risen significantly faster than inflation in recent years, and is projected to rise by one to two percent of GDP in most Member States between now and 2050 as a direct result of ageing populations[30]. However, these projections of future costs are very sensitive to changes in costs of providing a given package of care. The key to sustainability for healthcare systems is therefore controlling costs and improving efficiency, alongside prevention and health promotion measures to maximise the number of years of life spent in good health (as measured by the Healthy Life Years indicator). A framework for cross-border healthcare can therefore help to maximise the overall efficiency of healthcare provision and thus help to ensure the financial sustainability of health systems as a whole.

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27 See http://ec.europa.eu/health/ph_information/dissemination/hsis/hsis_14_en.htm and references provided for additional information.

28 Take the example of bladder cancer; although survival rates are improving in general, there are substantial differences in survival among countries in Europe, with five-year survival rates ranging from highs of 78% in Austria to 47% in Poland and Estonia. Another example is breast cancer, where the age standardised 5-year relative survival rate ranged from 60% in Slovakia to 82.6% in Sweden – see Coleman M.P. et al., EUROCARE-3 summary: cancer survival in Europe at the end of the 20th century in Annals of Oncology 14 (supplement5):v128-v149, 2003.

29 For more information, see "Towards High-Performing Health Systems", the final report of the OECD Health Project, OECD 2004, ISBN 92-64-01555-8.

30 The impact of ageing on public expenditure: projections for the EU25 Member States on pensions, health care, long-term care, education and unemployment transfers (2004-2050), European Economy Special Report 1/2006, produced by DG ECFIN.

3.4.2. Contribution to general EU objectives of economic growth and sustainable development

Healthcare systems also have a specific impact on the economy, irrespective of the ways in which the system affects health[31]. As one of the largest service industries, the health sector represents one of the most important economic sectors in the EU. Currently its output is estimated to account for about 7.7 % of GDP in the EU, larger than the roughly 5 % accounted for by the financial services sector or the retail trade sector. And around 9 % of all workers in the EU-25 are employed in the health and social work sector. Trends in productivity and efficiency in the health sector therefore have a large impact on these performance measures in economies as a whole.

Moreover, the performance of the health sector will affect the competitiveness of the overall economy via its effect on labour costs, labour market flexibility and the allocation of resources at the macroeconomic level. Inequalities in healthcare are also a key dimension of regional disparities, both in terms of the inputs provided to them and the outcomes they produce. Improving the efficiency and effectiveness of health systems is therefore a vital contribution to improving the overall economic growth, competitiveness and cohesion of the Union as a whole.

[31] For more information, see "The contribution of health to the economy in the European Union", OPOCE 2005, ISBN 92-894-9829-3.

4. POLICY OPTIONS

This section sets out four main policy options, with two specific variations of option three (a general legal framework). These are broad groups of options – different elements could be combined, and in particular 'soft action' (option two) could also be included in support of options three or four, where appropriate.

4.1. Option 1: No further action, the baseline scenario

This option would mean not taking any further Community action on health services. There would be no additional legal measures at Community level beyond the rulings of the European Court of Justice and existing rules, in particular the regulations on the coordination of social security systems. This could be considered to be the baseline-scenario. It would be for Member States to address issues of legal uncertainty through their own measures, and for the European Court of Justice to continue to develop principles at Community level through rulings at Community level.

Regarding non-legal measures, there would be no additional coordination or support action at Community level beyond those already taken (including the Commission communication on patient mobility and healthcare developments in the European Union of 2004, and information provided to citizens about the existing systems[32]).

Under this option, the current status quo would continue to exist, subject to individual initiatives by the Member States on an individual or inter-governmental basis.

4.2. Option 2: Soft action

Under this scenario, the Commission would, in addition to existing mechanisms, provide guidance on cross-border healthcare issues, but would not propose additional binding legal measures. This option would envisage the following set of actions:

– Guidance on cross-border healthcare issues would be set out through a more detailed statement of the Commission's interpretation of the implication of the Court of Justice's rulings for cross-border healthcare and application of existing rules on harm and liability in a Commission communication. This communication would also include recommendations on information to enable informed choices, plus principles or recommendations on ensuring quality and safety of healthcare.

– The Commission would also recommend to the Member States to amend their national legislation and to incorporate the principles of the case-law of the Court of Justice into their national legal system and to make the national procedures related to the cross-border healthcare more transparent and objective. The Commission would also provide technical advice and assistance to the Member States to facilitate their efforts to implement these principles. This would be further re-enforced by initiating infringement proceedings against individual

[32] See http://ec.europa.eu/health-eu/care_for_me/mobility_in_europe/index_en.htm.

Member States that do not effectively comply with the principles established by the Court of Justice.

– Another action under this option would include establishing a mechanism to bring Member States together to share ideas and best practice, building on the work of the High Level Group on health services and medical care, which is currently working on issues such as European reference networks, patient safety, cross-border healthcare purchasing and provision, health systems impact assessment or wider issues related to mobility of health professionals. This would not, however, include any further legal commitment from the Member States to implement the outcomes of this work in practice.

– In parallel the European Commission would further strengthen the existing activities aiming at developing common data and indicators as an evidence base for policymaking on health services. Activities in this field are currently being carried out by both SANCO and Eurostat supported by EC funded research. The Statistical Office of the European Communities gathers and analyses figures from the different European statistics offices in order to provide comparable and harmonised data in the field of public health and healthcare. The European Commission has established a Working Party on Health Indicators which also deals with indicators and their implementation.

– The European Commission would also continue its current financial support to the projects aiming at cooperation between Member States and networking in the area of healthcare systems from the current and future Public Health Programme and for research cooperation on delivery of care and health systems under the current7th Research Framework Programmes. Under the future health programme 2007-2013, funding is likely to be made available for € 5 million per year to support such activities.

– The outcomes of all the previous action points would be widely disseminated through a dedicated European website. This would help to make patients aware of their rights and obligations, especially with regard to the cross-border healthcare. The existing EU Health Portal could be used for this purpose.

4.3. Option 3: General legal framework on health services

– This option would mean the establishment of a general legal framework for health services in the EU through a specific legislative measure (a directive on health services). This option could be combined with some of the soft action described under option 2. Action would be taken in the following areas: Common principles underpinning health systems in the EU: The directive would establish the general principle that Member States are responsible for ensuring that the healthcare provided on their territory is safe and of high quality (i.e. provided according to clear standards for quality and safety, to be defined by each individual Member State); quality and safety is regularly monitored; patient's right to complain and right to redress and compensation is guaranteed; privacy and data protection are respected; and the requirement that these principles set by Member States are guaranteed also for patients from other Member States, in order to ensure that safe and efficient healthcare is guaranteed in each member state, also for citizens receiving cross-border care.; This does not mean establishing minimum European

standards for healthcare. It remains up to Member States to decide on the standards for healthcare in their country. The aim of this option would simply be to make clear which Member State is responsible in any given situation, to avoid gaps or overlap, and to clarify what those responsibilities mean in practice.

– Providing sufficient clarity about rights to be reimbursed for healthcare provided in other Member States for those rights to be realised in practice: the directive would establish clearly the entitlements of patients to have healthcare in another Member State, the limits that Member States can place on such healthcare abroad and the information to be provided to enable patients to be aware of the option of cross-border healthcare; the level of financial coverage that is provided for cross-border healthcare, based on the principle that patients are entitled to obtain reimbursement up to the amount that would have been paid had they obtained that treatment at home; the processes for decisions about such healthcare, including the criteria for assessment and mechanisms for appeal; and what happens with regard to harm and compensation arising from cross-border healthcare. Specific issues to be addressed include the following:

– The directive would also put in place a general requirement that Member States must provide information to their own citizens about their rights to healthcare abroad (what their entitlements are and how to access them), and that patienst should have access to relevant information from providers to allow them to make informed choices (e.g. on availability, prices, outcomes), where this information is available domestically. These general requirements would be accompanied by additional measures, including establishing of national points of contact on cross-border healthcare; comprehensive information on cross-border healthcare being made available at the EU Health Portal; raising awareness about the existing EU framework on data protection and sharing of confidential data;

– Instruments to manage patient flows: the directive would provide legal clarity over key terms and procedures related to access to cross-border healthcare (such as prior authorisation criteria and appeals procedures), through setting out criteria for processes through which Member States would make reasonable definitions at national level. These processes should not limit the existing rights of patients provided by the European Court of Justice, but still leave flexibility for the Member States. More details regarding the specific issue of reimbursement for cross-border healthcare, including two alternative sub-options, are described below. This means that Member States have the freedom to define what appropriate care is and when for example delay is undue.

– Harm and compensation arising from cross-border healthcare: the provider of health services should be liable for any harm arising through cross-border healthcare, including when treating patients from other Member States. However, this would not prevent Member States from covering patients referred abroad with their normal domestic compensation system (as some already do, such as Sweden).

– Practical cooperation on healthcare systems: With the directive a framework would be established to support further cooperation in the areas including European reference networks, health technology assessment, data collection and quality and safety, in order to enable the potential contribution of such

cooperation to be realised effectively and on a sustained basis, and to agree on overall directions for difficult issues (ie: data standards, handling of new technologies or techniques) to promote effective long-term practical synergies.

As indicated above, this option would have two alternative sub-options for dealing with the issue of legal uncertainty regarding financial entitlements and prior authorisation for cross-border healthcare. Under both options a comitology committee would be created which would adopt any technical measures necessary for effective implementation of the general principles set out by the Directive.

4.3.1. Sub-Option 3A – Two parallel systems for financial aspects of cross-border healthcare (both hospital care and non-hospital care)

As set out above, there are currently two different routes for financial aspects of cross-border healthcare: the regulations on coordination of social security systems. and direct application of the free movement rights provided by the Treaties on the basis of the recent jurisprudence of the Court. These routes are summarised in the following table.

	PLANNED CARE		EMERGENCY CARE
	Regulation 1408/71 (and later 883/04)	**ECJ case law applying Article 49**	**Regulation 1408/71 (and later 883/04) only**
Legal basis	Article 42 (free movement of workers)	Article 49 (free movement of services)	Article 42 (free movement of workers)
Prior authorisation for "hospital care"	Obligatory	May be required by the Member States	No prior authorisation
Prior authorisation for "non-hospital care"	Obligatory	Not needed	No prior authorisation
Means of payment	Benefits in kind provided according to the legislation of the Member State of treatment (i.e. in some countries free of charge, in some countries out-of-pocket payment may be required). Settlement of costs between the social security institutions of the two countries concerned.	Out-of-pocket payment with subsequent reimbursement from the social security institution of the patient's home Member State.	Benefits in kind provided according to the legislation of the Member State of treatment. Settlement of costs between the social security institutions of the two countries concerned.
Level of reimbursement	According to the rules of the MS of treatment. If this is less than what a patient would receive in his home MS, the additional reimbursement covering that difference must be granted.[33]	According to the rules of the patient's home MS. In any event, only actual costs of the treatment are reimbursed (i.e. a patient cannot make profit)	According to the rules of the MS of treatment.

There are two key differences about these systems from the perspective of the patient. The first is about the process for going abroad: under the existing regulations, the prior authorisation requirements are stricter, but the patient does not have to pay up-front. The second is about the financial outcome and specifically, who bears the risk that healthcare in another Member State will cost more than at home: under the Court judgements, the patient bears that risk – they only get reimbursed up to the amount that would have been paid had they obtained that treatment at home. Under the social security regulations, that financial risk is borne by public funds.

[33] Although the current wording of 883/04 is "the insured person may ask the competent institution to pay the additional amount", the ECJ ruled in the *Vanbraekel* case that this additional reimbursement must be granted where in the first place the authorisation was refused and it was subsequently established that the refusal was unfounded(see also point 130 watts)

Also as set out earlier in this impact assessment, most patients want to be treated as near to home as possible. So why would they wish to use either of these routes? There are two main reasons why they might prefer healthcare abroad:

– the healthcare that they need is just not available in their own system – or at least, not available within a reasonable time; or because they live or work abroad, and rely on the system there'

– or that healthcare is available at home, but it's more convenient for them to have it abroad – because it's closer, or quicker, or better.

However, these are quite different reasons; one is a matter of need, one is a matter of personal preference, and it seems reasonable they should be treated differently. If a patient has to go abroad to get the healthcare they need because they cannot have it domestically, they should not lose out financially by doing so. But if they could stay at home and they just prefer to have the healthcare abroad, there's no reason why public funds should have to pay any additional costs as a result.

So this option follows that distinction. If the care for the patients' condition cannot be provided in their own country without undue delay, then they are allowed to go abroad, and any additional costs of treatment will be covered by public funds; the mechanism for this is already in place through the regulations on coordination of social security systems. But if they could have stayed at home and the treatment in question is among the benefits provided in the Member State of affiliation to which the insured person is entitled they can go abroad if they wish, to receive the treatment – but they would have to pay for any additional costs above what would have been covered at home.

In practical legal terms, this means that under this sub-option, the existing framework for coordination of social security schemes would remain in place in its current form (or with the modifications proposed in the regulation 883/04) with all the general principles on which the regulations on coordination of social security schemes are based, including putting the patient receiving healthcare in another Member State on the equal footing with the residents of that Member State, and with all healthcare abroad requiring prior authorisation, with that prior authorisation being granted where the care cannot be provided domestically within a reasonable time.

In parallel to this existing structure, the new directive on health services would put in place an alternative mechanism based on the principles of free movement and building on the principles underlining decisions of the Court of Justice. This would allow patients to seek any healthcare abroad that they would have been provided at home without any prior authorisation and be reimbursed not more than the amount that would have been paid had they obtained that treatment at home. The patient bears the financial risk of any additional costs arising.

Also consistent with the Court's jurisprudence, the directive would stipulate that Member States would still be able to impose on a patient seeking health services in another Member State the same conditions and formalities, such as the requirement to consult a general practitioner before consulting a specialist, to which receipt of the same health services is made subject also on their territory. So if Member States have

restrictions on authorisation for hospital care within their territory, those would also still apply to hospital care abroad.

This ensures that for cross-border healthcare under the directive, Member States are still able to apply any conditions that they consider necessary to plan and manage their health systems domestically. For example, if a country requires access to hospital care within the Member State to have the prior agreement of a general practitioner, this would still be the case under the directive for hospital care abroad. However, where a country does not have restrictions on access to or choice of hospitals within that country, they would not be able to add additional conditions any such appropriate care abroad.

By way of derogation, Member States would be able to provide for a system of prior authorisation for assumption by their social security system of the costs of hospital care provided in another Member State. The Member State would be able to do so where the outflow of patients has such an impact on the planning and rationalisation carried out in the hospital sector in order to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage as to undermine the financial balance of their social security system, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on their national territory. Such a prior authorisation system should then be limited to what is necessary and proportionate in order to ensure these objectives and shall not constitute a means of arbitrary discrimination.

	PLANNED CARE	
	Option 3A	**Option 3B**
Legal basis	Article 95 (internal market) and ECJ case law	Non hospital care: Article 95 (internal market) and ECJ case law Hospital care: Article 42 (free movement of workers), regulation 1408/71
Prior authorisation for "hospital care"	No prior authorisation, Member States may require prior authorisation by way of derogation.	Obligatory, in accordance with regulation 1408/71
Prior authorisation for "non-hospital care"	No prior authorisation	No prior authorisation
Means of payment	Out-of pocket payment with subsequent reimbursement from the social security institution of the patient's home Member State.	**Non-hospital care:** Out-of pocket payment with subsequent reimbursement from the social security institution of the patient's home Member State. **Hospital care:** Benefits in kind provided according to the legislation of the Member State of treatment (i.e. in some countries free of charge, in some countries out-of-pocket payment may be required). Settlement of costs between the social security institutions of the two countries concerned.
Level of reimbursement	According to the rules of the patient's home Member State. In any event, only actual costs of the treatment are reimbursed (i.e. the patient can not make a profit if treatment abroad is cheaper)	**Non hospital care:** According to the rules of the patient's home Member State. In any event, only actual costs of the treatment are reimbursed (i.e. the patient can not make a profit if treatment abroad is cheaper) **Hospital care:** According to the rules of the MS of treatment. If this is less than what a patient would receive in his home MS, the additional reimbursement covering that difference must be granted.

4.3.2. Sub-Option 3B – Two parallel systems for financial aspects of non-hospital cross-border healthcare, hospital care through the social security regulations

This sub-option takes the same approach as for option 3 overall and sub-option 3A in all areas except for the financial entitlements and prior authorisation for cross-border hospital care. As set out above, in its direct application of Article 49, the Court has also considered that prior authorisation requirements may be justified for hospital care. One way of interpreting this is to equate the prior authorisation that may thus be

required for hospital care abroad on the basis of Article 49 with the prior authorisation required for any cross-border healthcare under the regulations on social security, and this has been the interpretation generally taken hitherto.

Under this option, therefore, the directive envisaged under option three would only deal with the direct application of Article 49 for financial aspects of non-hospital cross-border healthcare. For hospital care, patients would follow the existing mechanism for coordination of social security schemes, with the conditions and requirements stipulated therein.

In practical terms, this would mean that for cross-border hospital care, prior authorisation would be required for only have to be granted for hospital care abroad when such treatment cannot be provided within a reasonable time within the patients' own country, regardless of whether or not a similar restriction is applied in choosing between hospitals domestically. However, it would also mean that all such hospital care would be provided on the terms of the regulations on coordination of social security, with care provided according to the legislation of the Member State of treatment, with settlement of costs between the social security institutions of the two countries concerned according to the rules of the country of treatment (and if this is less than what a patient would receive in their home Member State, an additional reimbursement covering that difference).

In legal terms, as with sub-option 3A this again would require no changes to the existing framework for coordination of social security schemes would remain in place in its current form (or with the modifications proposed in the regulation 883/04). As with sub-option 3A, the new directive on health services would put in place an alternative mechanism based on the principles of free movement and building on the principles underlining decisions of the Court of Justice, but whereas for sub-option 3A this directive would apply to the financial aspects of all cross-border healthcare, under sub-option 3B for financial aspects this directive would only apply to non-hospital cross-border care.

4.4. Option 4: Detailed legal rules at European level

Under this scenario, the Commission would not propose to put in place a package of binding and non-binding measures, but rather a detailed framework of harmonising legal measures under Community law for all cross-border healthcare issues outlined above – information to enable informed choices, financial issues and limits to healthcare abroad, quality and safety of healthcare, and issues concerning harm arising from healthcare and compensation. Such a detailed legal framework could be set out in a detailed regulation and also include a legally binding 'Charter of patient rights'.

These binding measures would provide:

– Detailed rules on which data about cross-border healthcare should be collected and on how and how often these data should be collected by each individual Member States;

– detailed requirements on improved information provision to citizens with detailed description of the information to be given to the citizens and its format;

– explicit criteria for authorization and the authorization procedure, the maximum waiting time during the procedure etc., without leaving the possibility for Member States to adapt it to their national circumstances;

– explicit standards for quality and safety defined at the European level, and detailed description of minimum requirements for Member States and individual healthcare providers concerning those standards, how compliance should be monitored and in which situations which corrective action should be taken.

– a legally binding 'Statement on patient rights' prescribing rights to preventive measures, to access care, to information, to consent, to free choice of care, to privacy and confidentiality etcetera. Patients would have legal entitlements to compliance with those rights and all those rights would be enforceable.

– concerning compensation for harm arising from cross-border healthcare, explicit measures would be adopted specifying the applicable law and jurisprudence of the courts for decisions on cross-border healthcare, adapting existing provisions of the international private law to the specificities of the cross-border healthcare. Detailed level and requirement for compensation for harm would be also defined. These detailed legislative provisions would provide greater certainty over the specific issues arising from the Court's recent jurisprudence, but also over all wider issues as raised in the consultation. This would, however, represent a significant degree of harmonisation of healthcare issues in Community law, which with regard to certain aspects can not be justified given the remits of the EC treaty in the field of organisation and delivery of health services and in any case difficult to justify in the light of the subsidiarity principle.

5. ANALYSIS OF IMPACTS

5.1. General comments and analytical approach

The aim of impact assessments in general is to give insight in the economic/financial, social, environmental impacts of the Commission proposal, compared to other options or no further action. This assessment of impacts for framework directives will necessarily be preliminary and will not provide detailed quantitative data. As outlined in chapter four, these options represent broad approaches, of which different specific elements could be combined. The impacts described therefore are also broad descriptions, but are sufficient to evaluate the overall costs and benefits of the different approaches. Overall cross-border healthcare has significant economic and social impact. The impacts described in this impact assessment will nevertheless be smaller, as this chapter will only focus on the impact of the in the previous chapter presented options for community action. This impact assessment does not describe the impact of cross-border care as a whole.

This first section describes the overall analytical approach taken for the main economic, environmental and social impacts of the different options.

5.1.1. Analysis of economic impacts

The main economic impacts of this proposal come in the areas of:

– additional costs of cross-border healthcare treatment for public funds;

– additional benefits from cross-border healthcare

– overall cost of compliance

– specific administrative burden

There are also wider macro-economic impacts to be considered. Through enabling cooperation and comparison, action in the field of cross-border healthcare will lead to more efficient provision of healthcare and will improve the overall quality and resource usage of healthcare systems as whole. As the healthcare sector is in important provider of employment and of innovation, its contribution to overall macro-economic development is substantial, and thus these improvements can be expected to help contribute to the sustainability of health systems and overall economic growth and development. However, these impacts have not been quantified for this impact assessment.

5.1.1.1. Additional costs from cross-border care

The first economic impact is the additional costs to Member States of cross-border healthcare and in particular, the additional costs arising from treatment being provided in another Member State.

However, in its rulings on the application of free movement rights under the Treaties in order to have access to healthcare abroad, the Court has made clear that that the patient can only be reimbursed for costs of healthcare abroad up to the amount to

which they would have been entitled had they had the care in their own country. So in fact, the additional cost of treatment being provided in another Member State in application of these rights could be said to be zero, as these are costs that the patients' Member State would have paid in any case. If the treatment abroad was not care to which the patient would have been entitled at home, then patients are still not entitled to have it paid for through application of internal market freedoms if they have that care in another Member State, so in principle there should be no additional costs arising for patients who are treated through this route.

Nevertheless, the cost of such treatment to public funds is still not quite zero. As set out in earlier chapters, the main reasons why a patient might wish to seek healthcare abroad are that it is quicker, or cheaper, or more convenient. Of these reasons, the main economic impact under this heading will come if the patient is reimbursed for healthcare abroad more quickly than they would have obtained that care domestically, then there is still the impact for the Member State of having to spend the funds in question more quickly than would otherwise have been the case.

In economic terms, this cost of the difference between spending funds at an earlier or later point in time can be represented by the interest applicable to the funds in question. To get a general impression of these costs, we therefore use a simple model combining:

– the estimated number of people for whom it is potentially quicker to seek treatment abroad,

– the likely average cost if they do so,

– an estimated average time difference in comparison to domestic treatment

– and thus the additional cost represented by the discount rate applied to the amounts and times in question.

To estimate the number of people for whom it is potentially quicker to seek treatment abroad, we can use the estimates of unmet medical need due to waiting for treatment provided by the SILC survey data (see tables in annex). From these tables, an average percentage of people having unmet medical needs due to waiting lists is calculated, weighted for the amount of inhabitants in the respective countries[34]. On that basis, it can be roughly estimated that on average 1.6 percent of the European population is currently on a waiting list, which is equivalent to approximately 7.8 million EU citizens. However, evidence about take-up of cross-border healthcare suggests that in practice, most people will still prefer to have healthcare at home. For example, when the Health Insurance Institute of Slovenia (HIIS) offered patients on the national waiting list for cardiac surgery the opportunity to receive treatment abroad, less than 10% decided to take up the offer[35]. We therefore assume that at

[34] For the countries for which no reliable data exist, we assume that on average they have the same percentage of citizens waiting for care as the average percentage for the other countries for which data are available.

[35] *Cross-border care in the south: Slovenia, Austria and Italy* in Rosenmöller, M., McKee, M. Baeten, R., Patient Mobility in the European Union, Learning from experience, World Health Organisation (2006). This study is part of the project Europe for Patients, an EC FP6 funded research project.

most 10% of people waiting will seek cross-border care in practice on this basis. Although data about comparisons of costs between Member States and patterns of cross-border healthcare are largely lacking, in order to estimate average costs for treatment abroad, we can use recent research comparisons of costs for different forms of treatment across the European Union[36]. For hospital care, taking as an example treatment a hip operation, as a common elective procedure, we take an estimate of average cost of treatment abroad of €7000. For non-hospital care, we take as an example eye surgery (cataracts), with thus an estimate of average cost of treatment abroad of €800[37].

Regarding estimated time differences in treatment, we can assume that maximum waiting times will be no longer than a few months, as otherwise the delay in treatment will be sufficient to justify access to cross-border healthcare not under the direct application of free movement rights being assessed in this proposal, but under the existing regulations on the coordination of social security, the costs of which fall outside the scope of this impact assessment. Estimates within the framework of the OECD Health Project[38] are that on average, a waiting time of more than six months worsens outcomes of elective surgery. Taking this as an outer limit of waiting times, we therefore assume an average waiting time of three months for domestic treatment, and take that as the average time difference between domestic treatment and treatment in another Member State.

To calculate the opportunity costs of earlier treatment, we use a discount rate of 4%[39]. If a patient receives treatment abroad immediately instead of receiving it in three months time in their own country, the additional costs will therefore be approximately 1% of the total cost of the treatment. Thus for hospital care, taking our estimated average treatment cost of €7000, the additional cost to the patient's home system would be €70. For non-hospital care, taking our estimated average treatment cost of €800, the additional cost to the patient's home system would be €8.

Of course, this assumes that the treatment abroad is at least as expensive as the treatment would have been at home – if it is cheaper, the net cost to the patient's home system is also reduced correspondingly. If it is more expensive, then there is no additional cost to public funds, as Member States are only required under the Court's jurisprudence to reimburse the amount that they would have paid in any case, but the patient would have to bear the additional costs.

The different options involve different assumptions about how many people are likely to seek such cross-border healthcare in practice, and the consequent estimated costs under the model are given under the analysis of impacts for each option.

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36 Based on research on health baskets and tariffs in different member states, Observatory mapping exercise and *Health*BASKET(www.ehma.org/projects/healthbasket.asp). *Health*BASKET – Health Benefits and Service Costs in Europe – is a project funded by the European Commission within the Sixth Framework Research Programme.

37 Based on data provided through *Health*BASKET, where this can be broken down to give an approximation of hospital and non-hospital care; these examples are likely to be a slight over-estimate.

38 The OECD Health Project, Towards High-Performing Health Systems, OECD (2004)

39 In the Annexes to Impact Assessment Guidelines, European Commission (2005) a discount rate of 4% is required.. This rate broadly corresponds to the average real yield on longer-term government debt in the EU over a period since the early 1980s.

5.1.1.2. Additional benefits from cross-border care

Of course, being treated more quickly abroad does not simply bring costs, but also benefits through treatment being provided more quickly.

In order to put a quantified value on such benefits for cost–utility analysis, health improvements are typically measured in quality-adjusted life-years (QALYs). The quality adjustment is based on a set of references or weights called utilities, one for each possible health state. These utilities reflect the relative desirability of the health state and are measured on an interval scale, where 1 refers to full health (otherwise described as perfect or excellent health) and 0 refers to death. An example of an instrument that has produced a series of health utilities is the EQ-5D[40].

Research shows that in case a patient has problems with walking, utility of life is reduced by at least 10 percentage points. Taking our example intervention of a hip replacement, we therefore assume that the consequent benefit to them can be represented by a 0.1 increase in quality-adjusted life years (for example from 0.9 to 1.0 QALYs)[41] For eye surgery to treat cataract, we use a QALY increase of 5 percent points[42].

The amount of time spent in a health state is weighted by the utility score given to that health state. If a patient is treated quicker abroad, he/she will be able to get to a healthier status more quickly. In our model we assume that a cross-border patient is treated three months earlier than at home.

The remaining element is how much a QALY is worth. Estimates vary widely, and of course any such average figure cannot fully reflect the variations in development and cost of living throughout the European Union. We have therefore opted to take a relatively conservative estimate of €40,000[43], but this is only an indicative figure to enable some rough modelling of the potential benefits of cross-border healthcare.

Extending the model set out in the previous section, we can therefore represent the benefits for hospital care of quicker treatment as being that the average patient is 0.1 QALYs healthier for a period of three months (0.25 years), leading in total to 0.025 extra QALYs. Assuming that a QALY is worth €40,000, this increase in quality-adjusted life years can thus be said to be worth € 1000 (0.025* €40,000). For non-hospital care, the treatment adds 0.05 QALYs for a same period of time, worth € 500 (0.0125* €40.000).

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40 What is a QALY?, Hayward Medical Communications, Hayward Group plc. (2003)

41 L. M. Lamers, J. McDonnell, P. F. M. Stalmeier, P. F. M. Krabbe and J. J. V. Busschbach; The Dutch tariff: results and arguments for an effective design for national EQ-5D valuation studies, in Health Econ (2006) and A. O'Hagan, J.E. Brazier, S.A. Kharroubi; A comparison of United States and United Kingdom EQ-5D health states valuations using a nonparametric Bayesian method; Health Economics and Decision Science Discussion Paper Series, University of Sheffield (2007))

42 For the specific example of eye surgery the QALY increase might be slightly higher. However, as this is an example case intended to represent the general case of non-hospital care for which the QALY impact will generally be lower, we have used a more representative figure for this general case.

43 In comparison, for example in 2006 the Dutch Council for Public Health and Health Care (an independent body which advises the Dutch government on public health and care) published a report to support debate about costs of healthcare and stated that not more than € 80.000 should be spent on healthcare to save one QALY.

Again, the different options involve different assumptions about how many people are likely to seek such cross-border healthcare in practice, and the consequent estimated benefits under this model are given under the analysis of impacts for each option.

5.1.1.3. Cost of compliance

Apart from the direct costs and benefits of treatment provided in another Member State, there are also the associated costs for administrations in implementing the necessary systems to administer such cross-border care, such as additional systems for paying for such care, estimating how much the care in question would have cost had it been provided domestically, and ensuring appropriate monitoring of care and continuity between domestic providers and providers in other Member States.

Regardless of whether there is any new legislative proposal by the Commission or other action, Member States are still required to take such steps, in order to comply with the existing jurisprudence of the European Court of Justice on the application of free movement rights in order to have access to healthcare abroad. All of the policy options therefore involve some such costs for Member States, including the option of no further action.

As in other areas, data about the size and nature of such compliance costs for health systems is largely lacking. Moreover, the size and nature of costs will vary according to the different organisations of health system used within the different Member States. Any estimation of such compliance costs is thus necessarily approximate. Subject to these qualifications, however, and based on the experience of existing cross-border cooperation projects, we estimate that the total additional compliance cost due to health care being obtained in a different EU country is 5% of the total cost of the care involved[44].

From this, we can make a baseline estimate for compliance costs related to cross-border care as it stands now. As stated earlier in this report, total public expenditure on healthcare in the European Union is approximately € 1000 billion. Taking the estimate set out in chapter two that cross-border care currently accounts for about 1% of that total amount, the total amount of money spend on cross-border care is therefore roughly € 10 billion per year. On the basis of the estimate that compliance costs equate to 5% of the total cost of cross-border healthcare, the total current compliance burden is therefore approximately 5% of €10 billion, or € 500 million per year.

In the assessment of the different options, we therefore take this amount as a baseline. For the different options for action we estimate in what direction this compliance cost might alter, and assume example percentages to thus give an impression of how much the consequent compliance cost would also change.

[44] Grunwald CA, Smit R. Grensoverschrijdende zorg – Zorg op Maat in de Euregio Maas-Rijn; evaluatie van een experiment. Utrecht, NZI (research institute), 1999.

5.1.1.4. Administrative burden

In the context of impact assessment, administrative burden has a specific definition, being the costs incurred in meeting legal obligations to provide information. As with overall compliance costs, data about the size and nature of this administrative burden for health systems is largely lacking; and again, the size and nature of these costs will vary according to the different organisations of health system used within the different Member States. The standard cost model has been used to calculate the administrative burden although, due to lack of robust data, in a simplified manner.

In order to provide some approximation of these costs, we have taken a model of how Member States could develop information mechanisms such as websites, brochures and information centres to inform citizens about cross-border care, drawing on comparisons with existing initiatives and projects providing information to citizens under the public health programme. We also need some estimate of the likely scale of enquiry from citizens for information; for this, we take the results of the Eurobarometer in terms of the number of citizens receiving cross-border healthcare, and assume that at least twice as many people will make information enquiries as actually go abroad, giving a total of 8% of the population as the likely scale of people seeking information. If for example we assume that these 8% of the population (40 million citizens) seek further information, requiring a transaction time of approximately 8 minutes of staff time to answer, costing approximately € 20 per hour, the total costs for the Union as a whole will be around € 100 million per year.

This is of course a highly theoretical and simplified model, simply intended to give some kind of impression of the overall scale of the administrative burden of Community action in this area, and the directions of change under each option. It is not intended to imply that any given health system would use the specific mechanisms outlined in the model; each system would of course use different mechanisms as appropriate to its circumstances.

As with compliance costs overall, for each option we then estimate in what direction such information provision activities would change, and assume example figures in order to give an impression of how much the consequent administrative burden would also change.

5.1.1.5. Wider economic impacts

As set out in chapter 3, in addition to these direct impacts related to the direct objectives of the initiative, Community action on cross-border healthcare would also have a wider impact on the overall goals of the health systems of the Member States, and to the growth, competitiveness and cohesion of the Union as a whole. Although it is not possible to quantify this contribution, the types of impacts and the likely relative magnitude of impact between the different options is briefly indicated.

5.1.2. Analysis of environmental impacts

The analysis of the environmental impacts of the different options is brief, as we do not expect the changes brought about by the different options to have any major environmental impacts. We briefly indicate however the likely direction of change for two groups of environmental impacts: efficient use of natural resources (as part of

efficient use of resources in general), and use of transport linked to travelling across borders for care.

5.1.3. Analysis of social impacts

The main social impacts to be assessed for the different options are:

– different impacts for different social groups;

– longer-term consequences for health systems as a whole, both for sending and receiving countries;

– and the impact on existing inequalities within and between Member States.

5.1.3.1. Analysis by socio-economic groups

Direct application of free movement rights in the Treaty to obtain reimbursement for cross-border healthcare provides additional choices to patients in particular. However, this choice is clearly not without its problems, as set out in chapter 2 above. Moreover, even when this route for cross-border healthcare works well, concerns have still been expressed by several stakeholders about the potential impact of this additional choice on equity within health systems as a whole, and how the impact of the different options might affect different socio-economic groups.

Inequality in healthcare can come from a variety of sources[45], including in particular:

– lower expectations of good health or the potential benefit of treatment by people in lower socio-economic groups, leading to lower healthcare usage;

– unequal skills in understanding and navigating often complex healthcare pathways;

– unequal levels of knowledge about a patient's own health needs and the options available to address them; and,

– unequal resources to meet direct and indirect costs of care.

Socio-economic inequalities in health care use have been identified in practice. A 2004 OECD study looking at "Income-related inequality in the use of medical care in 21 OECD countries", conducted by van Doorslaer, Masseria and the OECD Health Equity Research Group Members[46] finds significant income-biased inequality in doctor use: the rich or more educated are significantly more likely to see a specialist and a dentist than the poor or less educated are, and also more frequently. However, this is not necessarily the case for the specific issue of patients exercising choice between providers. An evaluation of a patient choice scheme in London showed no significant difference in the numbers of patients exercising choice by socioeconomic

45 See in particular "Is greater patient choice consistent with equity? The case of the English NHS", Anna Dixon and Julian Le Grand, Journal of Health Services Research & Policy Vol 11 No 3, 2006: 162–166.

46 For more information see http://www.oecd.org/dataoecd/14/0/31743034.pdf

status.[47] In fact, by providing a mechanism that can be used by all socio-economic groups, increasing the choice to go elsewhere may help to compensate for the greater 'health literacy' of people in higher socio-economic groups, and thus help to improve equity overall. However, this clearly depends on how easily such a choice mechanism can be exercised, and the issues of uncertainty set out in chapter 2. The current framework for cross-border healthcare is sufficiently complex and unclear for many patients that they decide to cover the costs related to the cross-border healthcare from their own funds instead[48]. However, unequal levels of knowledge about the options available cross-border care has been clearly identified as key issue by stakeholders, and is likely to be a major factor in determining the impact on equity of different options. By increasing the legal clarity and availability of information concerning the possibilities of cross-border healthcare to a wider public, these inequalities would be reduced.

Likewise, the resources necessary to obtain cross-border care will clearly have an impact on equal access, in particular as the direct application of free movement principles will normally involve the patient paying for care initially and being reimbursed. The extent to which people will be able to do so will depend on the resources they have available. Also the degree of certainty they have about whether they will get their money reimbursed afterwards will influence their possibilities to obtain healthcare abroad.

These two elements will therefore be the focus of analysis of the impact of the different options by socio-economic group. However, as has been described above with regard to economic impacts, citizens will be able to use the free movement rights to have access to healthcare abroad that have been established through the existing jurisprudence of the European Court of Justice in any event, regardless of whether there is any new legislative proposal by the Commission or other action, All of the policy options therefore involve some such impacts on equity for different socio-economic groups, including the option of no further action.

It is also important to bear in mind that in any case, the regulations on coordination of social security systems still exist for cases where care to which such citizens are entitled cannot be provided within a medically acceptable delay. The impact on different socio-economic groups is thus not a question of patients not having access to cross-border healthcare that cannot be provided domestically (or at least not within a reasonable time), but rather an issue of differential impacts of the additional option of direct application of free movement rights.

5.1.3.2. Analysis by long-term impact of cross-border healthcare on health system as a whole

Some contributors to the public consultation were concerned about the potential longer-term impact of cross-border healthcare on health systems as a whole, raising four types of concern in particular:

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47 See Dawson D, Jacobs R, Martin S, Smith P. Is patient choice an effective mechanism to reduce waiting times? Appl Health Econ Health Policy, 2004;3: 195–203; cited by Dixon and Le Grand, *ibid*.

48 Techniker Krankenkasse (TK), Medizin in Europa: Ergebnisse der TK-Mitglieder-Befragung 2003 (2003)

– would pressures from cross-border healthcare force restructuring of the health system more generally, to change demand-control measures? No; the quantitative analysis of cross-border healthcare in this impact assessment (in particular in paragraph 5.5.1.3) shows that the costs of any such restructuring would be vastly higher than any likely additional costs from cross-border healthcare, even in the long term, and thus the pressures of cross-border care would not justify any such wider restructuring;

– would cross-border healthcare create inefficiencies in healthcare provision which would undermine overall planning and provision? On the contrary, the evidence available, described in this section, suggests that a clear framework for cross-border care will improve efficiency in healthcare, both for the healthcare provided abroad and through transferring best practice into domestic care;

– would there be unsustainable additional costs for the health system of the 'sending' Member State? No; this impact assessment sets out clearly (in particular in paragraph 5.4.1.2) that the additional costs from cross-border healthcare will be marginal and are projected to remain at low levels, given that Member States retain control of the unit cost of such treatment, and the vast majority of patients will continue to prefer to have domestic care in any case;

– would there be additional pressures for 'receiving' Member State? No. The small overall volumes of patients have not created unsustainable pressures from existing cross-border care and will not be enough to create them in the future; and in any case, Member States can address this issue by taking steps to ensure that patients from other countries are integrated into domestic provision on an equitable basis.

The broadly positive long-term impact of cross-border healthcare is confirmed by experience to date, as shown by case studies of countries for which cross-border healthcare systems with many of the features of the preferred option have been in place for some time. These examples show that the experience of cross-border healthcare can complement domestic provision and may help to spread best practice, but has not had an overall impact that would undermine the planning or organisation of health systems in the longer term for the reasons set out above, nor is it considered to restrain Member States to develop or maintain health care services in less densely populated areas. Also without using the possibilities that cross-border care could give, Member States are now already able to withhold regions from healthcare facilities by only allocating healthcare facilities to the more densely populated areas. There is no indication that an increase of possibilities concerning cross-border healthcare would lead to a growth of inequality between regions.

- **Denmark** has had a system of 'extended free choice' for hospital care since 2002. This allows patients free choice of hospitals if they cannot be treated within eight weeks, and puts hospitals and clinics outside Denmark on an equal footing with those inside Denmark in providing such treatment. On the basis of the use made of this system up to 2006, however, the impact for the system as a whole has remained low; only 1.5% of patients have made use of their extended free choice,

and only 0.02% received that treatment abroad[49]. However, even with this low take-up of 'extended free choice', the SILC data on unmet medical need in table 8.1 show that over 98% of the Danish population considers that their health needs are met, and thus there is no reason to think that this pattern is not sustainable for the future;

- **Malta**: the smallest Member State faces some of the greatest challenges in terms of providing specialised care in particular, and has had an arrangement for referring some patients for specialist treatment to the United Kingdom for 30 years[50]. This is used for specialised treatments such as bone marrow transplants, complex major spinal surgery, and specialist paediatric cases, for which it is neither clinically nor economically appropriate to develop services in Malta, with the investment cost being too high, there being too few patients and full-time professional staff providing such services would quickly become deskilled. The number of patients referred through the system is stable at around 300 a year (or around 0.06% of the Maltese population). Again, the combination of this referral system and domestic provision appears to meet the health needs of Malta, as shown by the SILC data on unmet medical need - over 96% of the Maltese population considers that their health needs are met, and estimates of people seeking treatment abroad outside the formal referral system are low. There is again therefore no reason to think that this pattern is not sustainable for the future;

- **Belgium** has had larger patient flows for planned care than most other Member States, in particular with Dutch patients being treated in Flanders through contracts between Dutch health insurers and Belgian providers[51]. In this case study, the researchers consider that as well as being convenient for patients, this is more efficient for both the Dutch insurers (providing care that is faster and cheaper, as well as being perceived as being technologically advanced and of high quality) and the Belgian providers (helping to overcome overcapacity in the acute hospital sector by treating patients from abroad), and there was no indication of increased waiting times for Belgian patients as a result of Dutch patients also being treated in Belgian hospitals.

Regarding efficiency, it is clear that there are very large variations in efficiency of supply within Member States. The HealthBasket project[52] compared costs for some typical treatments between nine different systems, and the overall cost and variations for the specific case of hip replacement are shown below[53]

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49 See consultation response R-039 from the Danish Regions; additional data on overall hospital usage from Eurostat (comparison year 2003, as the most recent available).

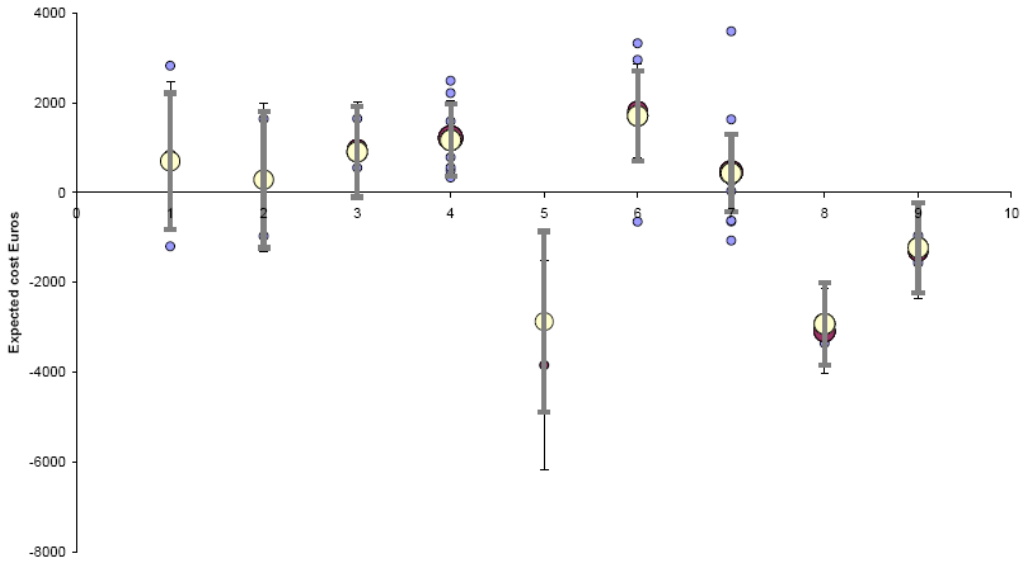
50 This example draws in particular on the case study presented in Chapter 8 of the "Patient Mobility in the European Union – Learning from experience" of the Europe 4 Patients research project, published 2006, ISBN 92 890 2287 6.

51 *Ibid*, Chapter 7.

52 For more information and the full reports of the project, see http://www.ehma.org/projects/default.asp?NCID=112&NID=91.

53 The small dots show the unexplained difference in cost of each hospital from the overall mean (hospital-level residuals). The coloured circles show different calculations of the overall mean and the country mean. The bars show 95% confidence limits (+/- 2 x standard errors) for the different models. Costs in a country are said to differ from the overall mean at the 5% significance level if the confidence

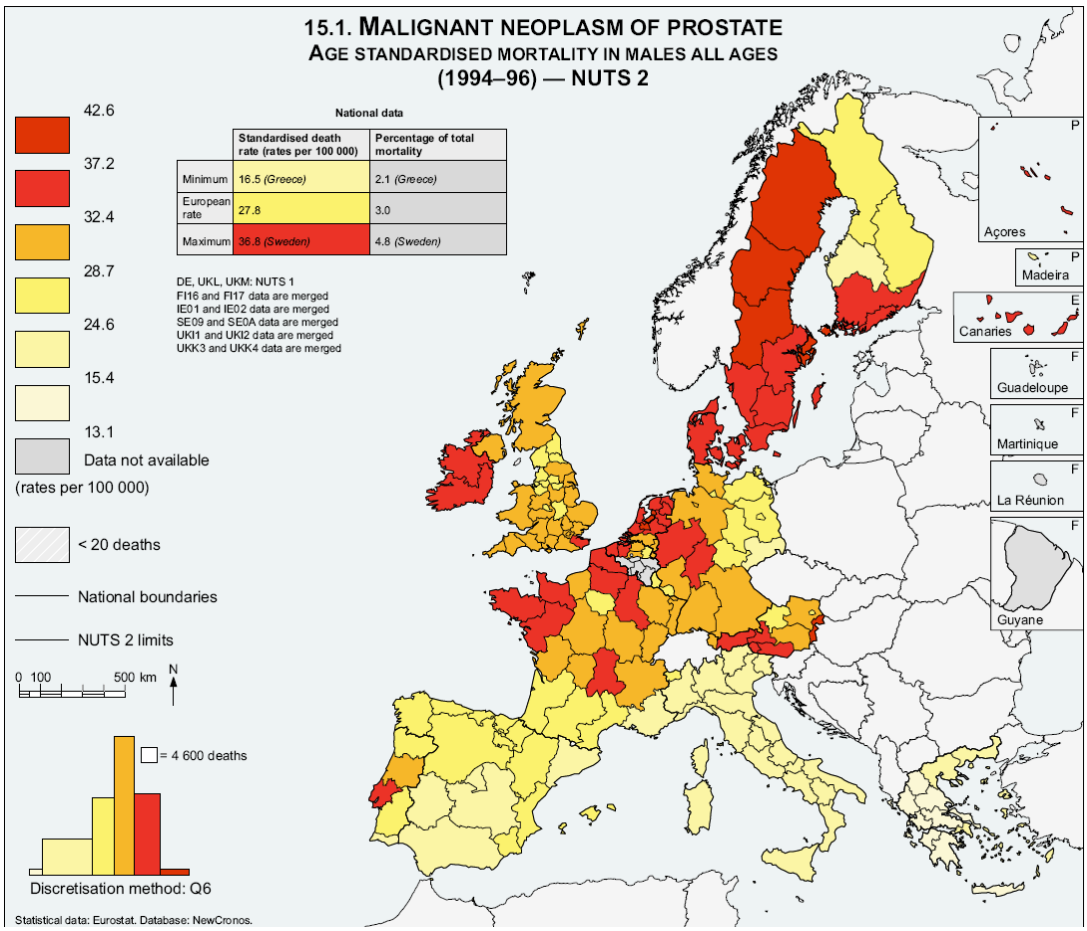
Key:	1	2	3	4	5	6	7	8	9
	Denmark	England	France	Germany	Hungary	Italy	Netherlands	Poland	Spain



Without going into the detail of the analysis, this illustrates the overall finding of the project, that while differences in average costs were significant between countries, within-country variation was also unexpectedly large – in some cases, larger than between-country variation. These differences are partly due to different accountancy standards, but also due to prices per input unit and, most importantly, due to large and apparently real differences in practice (and therefore differences in actual coverage of services).

This is confirmed by data on variations in outcomes which can be at least largely attributed to the performance of health systems, as shown by the chart below for prostate cancer. As this clearly shows, the variations in mortality within countries are often as large as the variations between countries, as can be seen by the differences between minimum and maximum levels of mortality within countries being as large as the differences between countries.

bar does not cross the horizontal axis. For more explanations, see http://www.ehma.org/_fileupload/File/Projects/WP10%20REPORT_31_Jan-07_revised.pdf



This suggests two conclusions:

– first, that the variations in efficiency and management that already exist within health systems are much more significant for overall planning and efficiency than the impact of cross-border healthcare, and thus there is no basis to consider that the additional element of cross-border healthcare will have a major additional effect on those systems;

– second, that given the variations within Member States (where resources levels are approximately equal), variations cannot only be explained by resources but also substantially by the efficiency in the use made of resources. The potential for cross-border healthcare to help improve efficiency including by comparisons between providers will provide significant added-value to health systems overall, including for domestic provision.

Far from undermining national provision, in the long term cross-border healthcare can therefore provide concrete comparisons and demonstration of better practices that help to improve domestic care, not reduce it. Having the alternative of contracting abroad not only means that demand for health care is better satisfied as supply is increased, it also serves as a strategy to warn national providers that they could lose patients and contracts as purchasers turn to providers in other countries. The very possibility of going cross-border puts pressure on national providers to improve their performance and/or lower their prices. In the English NHS, cross-border contracting aimed, for instance, at putting pressure on the domestic private sector to lower their prices for contracts with the NHS; cross-border care reduced

sharply once appropriate domestic capacity was restored. In the Belgian case study referred to above, the researchers report that one Dutch insurer gave the example of a Dutch hospital, situated very close to several major Belgian hospitals where the waiting times for heart surgery had decreased significantly (to a few weeks) compared to another hospital located in the middle of the Netherlands where people were waiting six months. Another Dutch sickness fund had clear indications that the local hospital was performing much better in terms of waiting lists, while also striving to become more patient-oriented, and was attributing this to the risk of significant outflow of patients to Belgium if the local hospital did not offer improved services to the local population.

Turning to the potentially different social impacts for countries 'sending' and 'receiving' patients through cross-border care, for sending countries, there is a potential social impact through differential take-up of this possibility for cross-border care, as outlined in the previous section. But as also outlined above, cross-border care can provide an additional choice that allows all citizens to 'exit', which for cross-border care will be particularly relevant for specialised services that otherwise have low domestic contestability. By doing so, this can provide an additional signal of patient dissatisfaction, which may bring about improvements in quality of the care concerned that would also benefit patients who do not move. There is also potentially the issue of 'supplier-induced' demand, where the possibility of additional supply from outside the country could bring about additional demand beyond that already identified within the country itself. However, this is unlikely to have a large impact on the health system as a whole, given the relatively low elasticity of demand for healthcare, and the already-identified preference of patients to be treated domestically in any case.

For receiving countries, there are potentially both advantages and disadvantages. If providing cross-border care undermined domestic planning and prioritisation, this could have a negative effect on the equity and accessibility of health services overall. For example, patients from other countries seeking cheaper care could create an additional demand that would result in an increase in prices or waiting times for those services overall, including for domestic patients. However, as described in the examples above, there is no evidence of such effects in practice, even for systems which have had significant volumes of cross-border healthcare for many years.

There are also potential advantages: healthcare provision requires a critical mass of patients to enable high-quality services and to justify investments, and if providing cross-border care can help to generate such a critical mass, it can also help to support more developed services which will also benefit domestic patients. The balance of these impacts for receiving countries will therefore depend on how well cross-border care is integrated into overall health service planning and provision on an equitable basis. And in any event, as outlined above, the extent of cross-border healthcare is always likely to remain limited, as the vast majority of patients are satisfied by their domestic provision and therefore are unlikely to seek healthcare abroad.

The impact of cross-border healthcare is therefore not likely to bring about major changes to health systems overall, given that the size of cross-border healthcare will remain marginal, despite its importance to the individuals concerned.

5.1.3.3. Analysis by inequalities between Member States

As set out above, additional choice through cross-border care can act as a signal to focus attention on improving quality, safety and efficiency of services, in particular for specialised services with little domestic contestability. Increased clarity about possibilities to receive healthcare abroad, but also more insight in differences in quality of care between healthcare providers, will make citizens better able to make informed choices about their healthcare. It is clear that there are significant inequalities within and between countries in outcomes amenable to healthcare. This combined with greater awareness of standards elsewhere may help to improve the quality of health services overall, both for patients who cross borders and those who do not.

The impact of free movement rights to obtain reimbursement for cross-border healthcare will not be equally spread throughout the Union. As set out above, this route involves greater financial risk for patients than cross-border care through the mechanisms provided through the regulations on coordination of social security systems. Quite apart from questions of risk and certainty outlined above, it is therefore also likely that this route will be less used by patients from poorer Member States, for whom care in better-off Member States will involve a significant additional financial cost.

This represents more fundamental regional disparities in healthcare overall. The Community is acting to address these, in particular through investment through structural funds, including specifically for health infrastructure, though this is outside the scope of this initiative and this impact assessment. However, as has been described above, citizens will be able to use the free movement rights to have access to healthcare abroad in any event. All of the policy options therefore involve some degree of inequality in their impact between Member States, including the option of no further action.

5.2. Option 1: No further action, the baseline scenario

The key issue with this option is that it would leave the problems set out in chapter 2, and would not provide a Commission response to the clear requests for action from the Parliament, the Council and other stakeholders. It would provide flexibility to Member States to address cross-border healthcare issues according to their healthcare systems and national circumstances. However, this is unlikely to effectively resolve the outstanding issues and problems outlined in the previous chapters.

With regard to uncertainty over general application of rights to reimbursement, the responses to the consultation regarding Community action on health services show a variety of interpretations and understandings of the current position, which are therefore likely to persist under this option. It is clearly difficult for individual Member States to address uncertainty over interpretation of Community law on their own, with the consequence of the continued problems identified in chapter 2. Moreover, continued uncertainty over who is responsible for ensuring the necessary requirements for safe and efficient healthcare in the case of cross-border care will compound reluctance to implement rights to reimbursement in practice.

The European Commission develops and backs many initiatives to improve cross-border care and to strengthen European cooperation. Important examples are the further improvement of the legislation on the coordination of social security in Europe and the legislation on the recognition of professional qualifications, as well as many projects to improve the use of eHealth. However, although all these initiatives facilitate cross-border healthcare in general, they are not sufficient to solve the challenges identified in chapter two. In particular, the updating of the social security coordination regulations covers only publicly-funded healthcare through statutory social security schemes, not other types of healthcare; it does not cover the direct application of free movement rights under the Treaty as clarified by the Court[54]; and it does not address issues of quality and safety, continuity of care or redress and compensation. And although the directives on mutual recognition of professional qualifications ensure a common standard of initial professional training for health professionals, they do not address subsequent continued professional development; and do not ensure quality and safety for the wider issues of the teams of professionals dealing with a particular patient, the providing organisation overall, and the applicable regulatory framework, nor do they ensure clarity over which authority is responsible for ensuring monitoring and oversight of the overall system for different cases of cross-border care.

5.2.1. Economic impact

Overall, no further action does not mean no cross-border care. Rather, it means continuation of current trends, but accompanied by costs of managing the uncertainties identified in chapter 2 in practice.

5.2.1.1. Additional treatment costs due to cross-border care

To assess the additional treatment costs due to cross-border care under this option, we apply the model set out in section 0 above. For this particular option, we therefore only need to assess the additional treatment costs due to non-hospital care, as (assuming that Member States apply the Commission's current interpretation of the Court's rulings) hospital care will be dealt with through the regulations on coordination of social security. We therefore assume that of those people waiting for care overall, only half will be waiting for non-hospital care; 5% of the total population waiting for non-hospital care equates to roughly 195,000 patients having cross-border care. Taking our example of eye surgery, our model suggests that the total costs under this option would be approximately € 1.6 million (195,000 people multiplied by an additional cost of € 8 per person).

5.2.1.2. Breaking this down by country according to the estimated numbers of people waiting suggested by the SILC data, this would mean for example for Germany that total additional costs of increasing cross-border hospital care would be roughly € 290,000; for Poland € 175,000; for Hungary € 15,000; and for Ireland roughly € 5,000. In these examples differences between Member States in terms of costs of an individual treatment and possibility for citizens to afford treatment abroad is not taken into account. When patients use the possibilities of cross-border care created on the basis

[54] Although the regulations could be considered to address this issue for hospital care, depending on the interpretation taken of the Court's jurisprudence, as set out for option 3 in chapter 4 above.

of the free movement principle, they will only have the costs reimbursed up to the level of the costs of the treatment in their country of affiliation. Additional treatment benefits due to cross-border care

On the basis of the same assumptions, we also apply our model estimating the additional benefits from being treated more quickly abroad.

On the basis of our assumptions that under this option 195,000 extra patients are treated through cross-border care, the total benefit estimated through the corresponding increase in quality-adjusted life years can be equated to a monetary value of approximately € 98 million.

5.2.1.3. Cost of compliance

As stated earlier, the total compliance burden of no further action is estimated to be approximately € 500 million per year.

Without any action to make the authorization procedure easier, and without bringing any additional clarity concerning quality control mechanisms for cross-border care and costs related to clinical oversight, responsibility for harm and redress, the total cost of compliance of current cross-border care is likely to remain at this level.

5.2.1.4. Administrative burden

Under this option, Member States will still need to provide information about the principles set out by the Court, and how they can be exercised in practice, although without additional Community guidance about how to do so. Uncertainty over cross-border healthcare combined with the high levels of potential interest from citizens shown above will result both in a high demand for information and difficulty in supplying it.

Using the model described in section 5.1.1.4 above, this option would involve our baseline estimate of the total administrative burden for the Union as a whole of around € 100 million per year. However, as emphasised above, this is of course a highly theoretical and simplified model, simply intended to give some kind of impression of the overall scale of the administrative burden of Community action in this area, and the directions of change under each option. It is not intended to imply that any given health system would use the specific mechanisms outlined in the model; each system would of course use different mechanisms as appropriate to its circumstances.

5.2.1.5. Wider economic impacts

With no further action at Community level, the potential contribution of cross-border healthcare to national and European objectives is unlikely to be realised in practice. This means that for example the potential economies of scale of European cooperation on areas such as European reference networks will lack a consistent framework of minimum requirements for safe and efficient healthcare, and are thus unlikely to realise their potential in practice.

5.2.2. Environmental impact

This option does not entail any significant environmental impacts, as it would mean only continuation of the existing system. There would be some additional transport use for cross-border healthcare (although this might in some cases represent less distance travelled, where the nearest provider is in another Member State). However, as outlined above, this option is unlikely to realise the potential for economies of scale through European cooperation due to lack of a clear framework for safe and efficient cross-border care, and thus will not enable the most efficient use of natural resources.

5.2.3. Social impact

As already underlined for economic impacts, the option of no further action does not mean no cross-border care. Rather, it means continuation of current trends, but accompanied by the social consequences of cross-border care without a clear framework at Community level.

5.2.3.1. Impact on socio-economic groups

Under this option, there would be no additional clarity or information about cross-border care provided at Community level. The lack of such information has been clearly identified as a major concern through the consultation. If this lack of information persists, this is likely to have a negative impact on equity. Likewise, lack of certainty about how procedures work in practice and whether money advanced for treatment for reimbursed is likely to have a regressive impact on use of this mechanism by different socio-economic groups, as less well-off patients will be less willing to take the financial risk involved. As outlined above, the current framework for cross-border healthcare is sufficiently complex and unclear for many patients that they decide to cover the costs related to the cross-border healthcare from their own funds instead, and this is particularly the case for patients from lower socio-economic groups[55].

5.2.3.2. Impact on health system as a whole

As outlined above, cross-border care can provide an additional choice for patients that can provide an additional signal to help bring about improvement of services. Given the likely inequalities in use of cross-border healthcare described above, however, this option is correspondingly less likely to bring about such changes in practice for 'sending' countries.

For receiving countries, the lack of any additional clarity about the tools that Member States can use to manage their own systems and integrate cross-border care risks undermining domestic planning and prioritisation, with a corresponding negative effect on the equity and accessibility of health services overall.

[55] Techniker Krankenkasse (TK), Medizin in Europa: Ergebnisse der TK-Mitglieder-Befragung 2003 (2003); and Eurobarometer; and Eurobarometer

5.2.3.3. Impact on inequalities between Member States

As set out above, additional choice through cross-border care can act as a signal to focus attention on improving services, in particular for specialised services with little domestic contestability. The lack of additional Community action to enable the potential of this approach to be realised in practice will also mean that its potential contribution to improving the quality of health services overall through greater comparison and collaboration will also not be realised

5.3. Option 2: Soft action

Under this option each challenge could be tackled by further Commission guidance and support, providing a further interpretation from the Commission about how these issues should be addressed in practice.

However, by its nature, such guidance can provide therefore only limited additional certainty for national authorities, patients, providers and other stakeholders, and is thus unlikely to be sufficient to achieve the objectives set out above. This is underlined by continued uncertainty on the specific issue of rights to reimbursement for cross-border care, despite these principles already being set out by the Commission in COM(2004)301 on the follow-up to the patient mobility reflection process. Although not formally titled as an 'interpretative' communication, that communication specifically included as part of its aims to provide citizens with a clear statement of their rights to healthcare under Community law, and stated following general principles for patients in particular:

– Any non-hospital care to which you are entitled in your own Member State you may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by your own system.

– Any hospital care to which you are entitled in your own Member State you may also seek in any other Member State provided you first have the authorisation of your own system. This authorisation must be given if your system cannot provide your care within a medically acceptable time limit, considering your condition. Again, you will be reimbursed up to at least the level of reimbursement provided by your own system.

– If you wish to seek treatment abroad, your health authorities can provide you with information on how you can seek authorisation for care in another Member State, the reimbursement levels that will apply and how you can appeal against decisions if you wish to.

Yet despite this clear statement from the Commission in 2004, there is a clear consensus from Council, Parliament and stakeholders that these issues are not clear in practice, and thus this rights provided in principle are not able to be realised in reality. The limited data available also suggests that this is the case, indicating that far fewer citizens having cross-border healthcare are not exercising the rights to reimbursement which Community law should provide them.

This reluctance to rely on guidance alone is logical, and unlikely to change. For both patients and professionals, it is not enough to be only reasonably sure about who will

ensure minimum standards for safe and efficient cross-border care. Given the potentially very serious consequences if there are problems, the additional risk represented by any degree of uncertainty over who is responsible and for what will act as a serious obstacle to cross-border care. Likewise, for the specific issue of reimbursement for cross-border healthcare, many patients will only be willing to advance funds for treatment if they can be certain of being reimbursed, on what basis and within what timetable. Simply providing guidance at Community is unlikely to provide sufficient this certainty in practice.

Feedback from all relevant stakeholders, including Council and European Parliament, suggests that after years of this 'bottom up' approach a critical mass has developed which recognises the potential of cross-border healthcare, but which requires a clear framework on which all stakeholders can rely, which soft action alone is insufficient to provide.

5.3.1. Economic impact

5.3.1.1. Additional treatment costs due to cross-border care

To assess the additional treatment costs due to cross-border care under this option, we apply the model set out in section 5.1.1.1. For this particular option, we only need to assess the additional treatment costs due to non-hospital care, as (assuming that Member States apply the Commission's current interpretation of the Court's rulings) hospital care will be dealt with through the regulations on coordination of social security. Nevertheless, we assume that providing guidance at Community level will somewhat increase the take-up of cross-border care in comparison to option one, and we equate this to a 7% take-up.

We therefore assume that of those people waiting for care overall, only half will be waiting for non-hospital care; 7% of the population on the waiting list equates to roughly 270,000 patients having cross-border care. Taking the example of eye surgery, our model suggests that the total costs under this option would be approximately € 2.2 million (270,000 people multiplied by an additional cost of € 8 per person).

Breaking this down by country according to the estimated numbers of people waiting suggested by the SILC data, this would mean for example for Germany that total additional costs of increasing cross-border hospital care would be roughly € 402,000; for Poland € 245,000; for Hungary € 20,000; and for Ireland roughly € 7,100.

5.3.1.2. Additional treatment benefits due to cross-border care

As stated in paragraph 5.1.1.2, an important advantage of cross-border care over care within the country of insurance is that it can at some occasions be used as a way to avoid waiting lists. Higher quality of life is then (re-)gained at an earlier stage. Analogous to the model presented in paragraph 5.1.1.2, a rough estimation can be made of the additional treatment benefits which would occur when this option would be implemented.

If we continue to assume that this option will lead to 270,000 extra patients to be treated outside their country of affiliation, total benefit due to earlier treatment would according to this model be approximately € 135 million.

5.3.1.3. Cost of compliance

Cooperation between Member States would be a way to slightly reduce the compliance costs related to the authorisation procedure and quality control mechanisms for cross-border care. Member States would be able to exchange good practices and learn from each other to reduce the compliance costs. We assume that the total administrative burden of the actual cross-border mobility will be reduced slightly from 5% of the total budget spent on cross-border care (see also paragraph 5.1.1.3) to 4%. In financial terms this could be equated to a reduction of approximately € 100 million.

5.3.1.4. Administrative burden

Some coordination and cooperation on Community level concerning information provision might be a slightly more efficient and lead to more appropriate results, it is assumed that this option would therefore lead to a minor decrease of the administrative burden due to the legal obligation to provide information. It is assumed that the administrative burden will decrease, similar as the decrease in compliance cost.

Using the theoretical model described in section 5.1.1.4, this option would therefore also involve our baseline estimate of the total administrative burden for the Union as a whole of around € 100 million per year, reduced by 20% to € 80 million per year.

5.3.1.5. Wider economic impacts

With only soft action at Community level, the potential contribution of cross-border healthcare to national and European objectives is unlikely to be fully realised in practice. Even though some potential economies of scale of European cooperation can be reached by soft action only, they will lack a consistent framework of minimum requirements for safe and efficient healthcare, and are thus unlikely to realise their potential in practice. In particular for planning purposes, when looking years ahead to plan necessary facilities, health authorities are unlikely to be willing to rely on cross-border care even where it could be the best solution to meet their health system objectives overall, without the certainty of a clear legal framework within which they can cooperate and plan.

5.3.2. Environmental impact

This option is likely to entail marginal additional transport use for cross-border healthcare (although this might in some cases represent less distance travelled, where the nearest provider is in another Member State). However, as outlined above, this option is also unlikely to realise the potential for economies of scale through European cooperation due to lack of a clear framework for safe and efficient cross-border care, and thus will not enable the most efficient use of natural resources.

5.3.3. Social impact

5.3.3.1. Impact on socio-economic groups

This option would provide some additional information to patients about cross-border care, and would thus address one of the key factors likely to hinder equitable impact of cross-border care in practice.

However, the lack of legal certainty about reimbursement is likely to have a major negative effect on ensuring an equitable impact of this option across socio-economic groups. As outlined above, the direct application of free movement principles will normally involve the patient paying for care initially and being reimbursed. The extent to which people will be willing to do so will depend on the resources that they have to do so, and the degree of certainty that they have about whether they will get their money back. Simply providing guidance at Community level is unlikely to represent a sufficient degree of certainty for many people to risk advancing significant amounts of money. This option is therefore likely to continue the likely negative impact on socio-economic equity of the direct application of free movement principles for cross-border care.

5.3.3.2. Impact on health systems as a whole

As mentioned in paragraph 5.3.1.2, under this option only a limited extra amount of citizens will be able to find their way to healthcare abroad. The impact on health systems, in both social and financial terms, and both for countries receiving and sending patients, of additional patient mobility will therefore be limited in comparison with the current position.

Nevertheless, the existing difficulties Member States encounter concerning cross-border care will continue to exist. For receiving countries, the lack of any additional clarity about the tools that Member States can use to manage their own systems will not be addressed with the introduction of this option.

5.3.3.3. Impact on inequalities between Member States

Exchange of best practices enables Member States to improve their healthcare systems and to reduce differences in quality between Member States. The introduction of more soft action would further facilitate such processes and thus contribute to a reduction of inequalities.

As in the current situation, choice through cross-border care can act as a signal to focus attention on improving the quality and efficiency of services. Possibilities to find healthcare abroad will remain even though unchanged. However, given the low overall impact of this option, the impact on inequalities will also remain low.

5.4. Option 3: General legal framework on health services

This option is likely to have a significant impact in addressing the issues outlined in chapters two and three, by providing a clear and binding framework on which both patients and professionals can rely in practice. As outlined above, for both patients and professionals, there is a crucial difference between having some confidence in the applicable rules for cross-border care, and being certain. The potentially very

serious consequences of any problems for cross-border care means that certainty about the applicable rules is likely to make them much more effective than guidance or soft action alone. However, it should not represent a substantial additional burden for health systems, as it reflects principles to which health systems already subscribe. Moreover, such a general legal framework would leave flexibility to Member States to implement these principles in practice according to local circumstances. For reimbursement issues, this option would ensure a clear binding set of rules to help ensure that free movement rights provided in principle by the Court can be realised in practice. These rules complement the existing regulations on coordination of social security schemes by ensuring clarity for care provided through the alternative route established by the Court, which is not covered by those regulations (though see the specific issue of hospital care described in sub-options 3a and 3b below).

This option would also create clear binding rules over who is responsible for ensuring the necessary requirements for high-quality, safe and efficient healthcare and thus ensure that these are also in place for cross-border care. This should not mean creating separate quality and safety systems for cross-border healthcare. Rather, ensuring high-quality, safe and efficient cross-border healthcare can be achieved by having that healthcare properly integrated into existing systems of the Member States, based on the principle of the country responsible being the country where the treatment is provided, with any specific issues related only to cross-border healthcare addressed in a proportionate way to the relatively small size of the issue. This would again complement existing Community provisions, as there is no such framework at Community level, and would thus avoid duplication or gaps in ensuring these standards. In particular, these provisions would add value to thee existing regulations on coordination of social security schemes, which do not cover these issues; and would cover all health services irrespective of how they are financed.

In this impact assessment only direct additional costs and benefits of increased cross-border healthcare are taken into consideration. More additional costs and benefits could arise, in the short and in the long run. Costs could for instance arise due to supply induced demand and demand induced supply. In the past higher costs have been reported due to duplication of examinations. Increasing cooperation in cross-border care could result in a further decrease in costs due to an increase in efficiency and the quicker availability of appropriate care.

5.4.1.1. Economic impact

As outlined in chapter 4, within this overall option there are two sub-options which have different costs and benefits arising from cross-border healthcare. The key differences between sub-options 3A and 3B concern access to cross-border hospital care. There is no difference between these sub-options if the appropriate care for the patients' condition cannot be provided in their own country without undue delay; under both sub-options they are then allowed to go abroad, and any additional costs of treatment will be covered by public funds through the existing regulations on coordination of social security systems. However, sub-option 3A would also allow patients to use cross-border care for hospital care which their system could have provided in a reasonable time but which they just prefer to have abroad – but with the patient paying any additional costs above what would have been covered at

home. Sub-option 3A therefore has both higher costs arising from cross-border treatment than sub-option 3B, and higher benefits through greater take-up.

5.4.1.2. Additional costs of cross-border healthcare treatment for public funds

To evaluate the additional costs of cross-border healthcare treatment for public funds, we apply the model set out in section 5.1.1.1. For sub-option 3A, this means modelling take-up of both non-hospital (using the example of cataract treatment) and hospital care (using the example of hip replacement). We assume that take-up will again increase in comparison to options 1 & 2, rising to the maximum likely level on the basis of current evidence of 10%.

Assuming that take-up is divided equally between hospital and non-hospital care, the additional costs of cross-border treatment of sub-option 3A for non-hospital care would therefore be € 3.1 million (390,000 patients multiplied by an additional cost of €8 per operation through earlier reimbursement). For hospital care, the additional costs would be € 27.3 million (390,000 patients multiplied by an additional of €70 per operation through earlier reimbursement). That would mean in total for sub-option 3A (both hospital and non-hospital care) an increase in treatment costs of € 30.4 million. This would mean for example that for Germany the total additional costs of increasing cross-border hospital care would be roughly € 5.6 million, for Poland € 2,7 million; for Hungary € 285,000; and for Ireland approximately €100,000[56]

As sub-option 3B would mean providing an additional mechanism for only cross-border non-hospital care, we apply the same model as above but only for non-hospital care, taking the example of cataract treatment, the additional costs of which would be €3.1 million, as set out above. That would mean, keeping the examples of Germany, Poland, Hungary and Ireland that total additional costs of increasing cross-border non-hospital care would be roughly € 575,000; €349,000; €29,000 and € 10,000 respectively.[57]

5.4.1.3. Additional benefits from cross-border care

On the basis of the same assumptions, we also apply the model estimating the additional benefits from being treated more quickly abroad, as set out in section 5.1.1.2 above. For sub-option 3A, if we assume that, as stated above, this option will lead to 780,000 extra patients to be treated more quickly through cross-border care, the total benefit due to earlier treatment can be equated to € 585 million (390*€500 + 390*€1000, reflecting the likely difference in QALY benefit from hospital and non-hospital care). For sub-option 3B, as this would be limited to non-hospital cross-border care, the benefits would also be correspondingly lower at approximately €195 million (390*€500).

5.4.1.4. Cost of compliance

Providing a definite legal framework at Community level is likely to reduce the overall compliance cost in comparison with the current situation. By providing legal

[56] For a more detailed calculation see paragraph 5.2.1 of this report.

[57] Again, for a more detailed calculation see paragraph 5.2.1 of this report.

certainty about however reimbursement for cross-border healthcare should work, and avoiding duplication, gaps and uncertainties over who is responsible for oversight of the quality and safety of cross-border care, this option will provide a clearer and easier working environment for implementing free movement rights with regard to cross-border care. In comparison with our baseline estimate set out in section 5.1.1.3 above, we represent this as implying a reduction in compliance costs to approximately 3% of total cross-border care. In a formula this calculation would have the following shape (where T1 = compliance costs as percentage of total costs under the baseline scenario, T2 = compliance costs as percentage of total costs under option 3, P = percentage of treatments concerned and TC = total healthcare costs.

$$\sum (T2 - T1)/T1 * P * TC$$

$$\sum (0{,}03 - 0{,}05)/0{,}05 * 0{,}01 * € 1000 \text{ billion}$$

Most of the cost of compliance arises from the general management of cross-border care, having processes for reimbursing cross-border care and continuity of care, and is not linked to the different options for handling hospital care and non-hospital care. We therefore assume that the difference in compliance cost between sub-options 3A and 3B will be relatively small; we assume that for the extra money spend on cross-border hospital care, the compliance cost will be 0.5%-point higher. With 390,000 treatments of on average € 7000, these costs would approximately be € 15 million. Administrative burden

As with the overall cost of compliance, providing a clear legal framework at Community level should provide an easier environment for Member States with regard to providing information than the current situation. We therefore assume that these costs reduce by a similar proportion as with the overall costs of compliance, to a total of around € 60 million per year.

5.4.1.5. Contribution to wider objectives

By providing a solid basis for cross-border care, a clear legal framework will also contribute to the overall shared goals of health systems throughout the EU of accessibility, quality and financial sustainability. Quality requirements as described in the legal framework are aiming at increasing the trust and confidence in cross-border healthcare and healthcare in general. The additional burden on health systems of these requirements will nevertheless be limited, simply because Member States have committed themselves already to fulfil these requirements by agreeing on the Council Conclusions on Common values and principles in European Union Health Systems. The same would count for the requirement for mandatory professional insurance for healthcare providers. These should not result in significant additional costs as such requirements already exist in many Member States. But, even where insurance is not mandatory at the moment, it is generally normal business practice to take out professional indemnity insurance or to provide some kind of equivalent guarantee.

Clear legal certainty over reimbursement conditions as well as responsibility for minimum requirements for safe and high quality care will provide sufficient basis for patients and providers to take full advantage of the potential of cross-border care where this is appropriate, with consequent contribution to cooperation and

comparison between Member States that will contribute to improving access, quality and financial sustainability.

5.4.2. Environmental impact

With this option, one has to also look more closely at the potential environmental impacts, in particular related to the increased demand for transport. Establishing clear framework for cross-border healthcare is likely to increase cross-border mobility to a certain extent, which is likely to also mean increased demand for transport. However, given the fact that a large proportion of cross-border healthcare would take place in the border regions (i.e. patients travelling a shorter distance across the border rather than travelling to a major city in their Member State) would reduce the potential impact on the environment.

Regarding overall efficient use of natural resources, by providing a clear legal framework that will help to take full advantage of economies of scale from cross-border care, this option would also contribute to making more efficient use of resources overall, including natural resources.

5.4.3. Social impact

5.4.3.1. Impacts on different socio-economic groups

As set out in section 5.1.3.1 above, the different resources of different socio-economic groups will clearly be a factor in affecting their ability to take advantage of using free movement principles to have cross-border care and be subsequently reimbursed, given the initial financial outlay at stake (and this issue will be more important for more expensive care, clearly). However, the certainty of a legal framework provided under this option will go some way to compensating for this problem. Patients will be more willing to advance the necessary costs depending on how certain they can be of their rights to be reimbursed and how quickly that will happen, and that if they need to contest these formally through legal proceedings, that their legal rights are clear. By providing this legal certainty, this option will therefore help to improve the equity of cross-border care through this route in comparison with options 1 or 2.

In terms of the two sub-options 3A and 3B, given that hospital care will generally be more expensive than non-hospital care, this issue of inequality will be particularly important for sub-option 3A. However, sub-option 3A also provides a greater possibility for using cross-border care to increase contestability for specialised services for which there are few domestic alternatives, which is also likely to be particularly important for hospital care. By providing such a mechanism for all socio-economic groups, increasing choice for hospital care as well may help to compensate for the greater 'health literacy' of people in higher socio-economic groups, as also set out in section 5.1.3.1 above, and thus help to improve equity overall.

The impact of a legal framework in requiring information provision and itself helping to raise awareness of the option of cross-border care will help to address unequal levels of knowledge between different social groups.

5.4.3.2. Impact for health systems as a whole

Although this option would establish a legal framework of responsibilities for ensuring safe and efficient healthcare at European level for the first time, the impact of this on health systems as a whole would not be substantial, as these should not represent new or different obligations. By taking as a basis the 'common values and principles in EU health systems' endorsed by the Council, this legal framework should not add additional obligations, but rather simply provide clarity over which authority is responsible for ensuring what in the different possible cases of cross-border care. Rather than creating a separate specific set of obligations for cross-border care, this approach therefore ensures the minimum impact compatible with legal certainty of cross-border healthcare on health systems as a whole by ensuring that its management and oversight is integrated into existing systems within Member States.

In terms of the longer-term impacts of this option, as set out in section 5.1.3.2 above, the long-term impact will also be broadly positive.

For sub-option 3A, even if we assume that double our estimated proportion of patients use cross-border hospital care, the overall financial impact remains marginal, and certainly not enough to justify any wider restructuring of demand control mechanisms. Also as set out above, the experience of countries who already have provision for cross-border care does not suggest that it will undermine overall planning or create unsustainable pressures for 'receiving' countries; on the contrary, in the long term, it is likely to help improve efficiency both for cross-border healthcare and for domestic care as well.

In terms of planning and control of costs, there is a difference between sub-options 3A and 3B. Under option 3A, the public authorities control costs of both hospital and non-hospital care by limiting the unit costs reimbursed (the costs are reimbursed up to the level of the cost of the same treatment at home). Without an authorisation procedure, the costs are not limited by restricting patients to go abroad. Nevertheless, as explained above, total financial impact of this option will be limited. Under option 3B, the public authorities partly control the cost of hospital care by limiting the number of patients treated abroad, though not the unit cost of such treatment. The criteria for authorization procedure make it more difficult to have healthcare abroad reimbursed. On the other hand, the paying Member State does not have control of the unit cost (as the patient is treated according to the tariffs of the Member State of treatment).

Neither option provides complete control for Member States for cross-border hospital care, but as already set out above, evidence to date suggests that the total impact of cross-border hospital care will remain low in the long term. Ultimately, patients prefer to have healthcare (especially hospital care) as close to home as possible. Provided that all Member States continue meet the needs of the vast majority of their population within their own systems, the overall impact of cross-border hospital care will continue to be low, even if the absolute numbers concerned are likely to rise somewhat and despite its importance for the individuals concerned.

5.4.3.3. Impact on inequalities within and between Member States

By helping to realise the full potential of cross-border care and thus maximising access for patients for whom cross-border care is more geographically appropriate, or patients requiring particularly specialised care, this option would have a greater effect on reducing inequalities than options 1 or 2.

5.5. Option 4: Detailed legal rules at European level

This option would provide a detailed framework of harmonising legal measures under Community law for all cross-border healthcare issues.

The advantage of detailed rules, established on Community level, is that it leads to a maximum amount of clarity and uniformity. This is especially an advantage for citizens crossing borders. They know exactly what they can expect in the country where they receive medical treatment. However, this would represent a significant degree of harmonisation of healthcare issues in Community law, which would include a significant additional administrative burden and would be more difficult to justify in the light of the subsidiarity principle. It is not the role of the European Union to harmonize healthcare policy and health care systems, given the limits provided by the Treaty (art.152.5 EC). Member States have different backgrounds and different healthcare systems. This diversity makes a 'top down' approach to Community action as the case for this option potentially unfeasible and ineffective in several instances. This is especially true for harmonising healthcare systems, because of the difficulty of achieving consensus about what direction the harmonisation should take. Harmonisation would, due to current differences between Member States, mean a need for considerable change of health systems of several countries. This would require considerable financial costs and organisational change for those Member States. There is a sense that many stakeholders and national governments would simply refuse to implement European legislation. For the European Union as a whole a detailed regulation may be a good compromise, but that would not be the best remedy for the individual Member States. Especially when such reforms have to be accompanied by substantial changes in the administrative organisation and an increase in costs, necessary support from stakeholders will be difficult to obtain. It is therefore unlikely to be appropriate or desirable to oblige Member States to follow a uniform organisation of health systems, which may not be the most appropriate for that specific country.

5.5.1. Economic impacts

As regards economic impacts, this option would provide a detailed framework applicable throughout the Union, which would increase confidence of the patients also in healthcare provided in other Member States. This, together with appropriate information, would enable them to make informed choices and increase the opportunities to benefit from the cross-border healthcare. However, it would be extremely difficult to implement this detailed binding system in a short term, due to the existing great variety of organisation, financing and delivery of healthcare services among (and also within) the Member States. This option would also not allow flexibility to take into account particular regional or local needs and circumstances.

5.5.1.1. Additional treatment costs due to cross-border care

The financial impact of this option would be comparable with option 3A. By increasing clarity and certainty through the introduction of a new detailed regulation and by improving information about advantages and disadvantages of cross-border healthcare, about 10% of the people on the waiting list would possibly travel abroad to receive their care. This conservative estimate would mean that 780,000 additional people would be treated abroad. The total costs of this initiative would be € 30.4 million. That would mean, for example, that for Germany the total additional costs of increasing cross-border hospital care would be roughly € 5.6 million, whereas for Poland they would amount to roughly € 3.4 million, for Hungary € 285,000 and for Ireland to roughly € 100.000[58]

5.5.1.2. Additional treatment benefits due to cross-border care

For the additional benefits counts the same as for the additional costs; the impact of this option would be comparable with option 3A. Higher quality of life is then (re-) gained at an earlier stage for 780,000 people.

Total benefit due to earlier treatment would according to this model be approximately € 585 million (see also 5.1.1.2).

5.5.1.3. Cost of compliance

Using the model which was introduced in paragraph 5.1.1.3, we assume that these costs will be reduced from 5% in the case of no further action to approximately 1% of the amount of the cross-border transaction when detailed legal rules are implemented at European level. In financial terms this means, compared to no action, a reduction of costs of € 400 million from € 500 to € 100 million.

However, such a detailed pan-European system would undoubtedly also significantly raise the compliance costs for the Member States, due to the need for transformation of the existing healthcare systems and its compliance with detailed European rules. This would have particularly heavy effect on the poorer Member States. Given their existing limited healthcare budgets and administrative capacity, also because they need to put already much effort in bringing their healthcare systems up to date, this option would therefore have adverse effects on regional inequalities. The implementation of detailed legal rules will have to lead to changes of the total healthcare systems of each Member State. It will therefore lead to a significant increase of the compliance and implementation costs. If we assume that these costs will be approximately 2% of the total healthcare expenditure, this would mean a cost of approximately € 20 billion yearly for the Union as a whole, during a transition period of approximately 3 years.

5.5.1.4. Administrative burden

The specific administrative burden of such a harmonised system would in principle be similar to option 3, as providing a clear legal framework at Community level should provide an easier environment for Member States with regard to providing

[58] For a more detailed calculation see paragraph 5.4.4 of this report.

information than the current situation. We therefore assume that these costs reduce by a similar proportion as with the overall costs of compliance, to a total of around € 60 million per year. However, this would of course be a small fraction of the total costs to Member States of implementing such a system, as outlined above.

5.5.1.5. Wider economic impacts

This option would have a positive contribution to wider objectives by enabling the full potential of cross-border care to be realised, and thus to maximise the potential contribution from economies of scale and sharing best practice through comparison and cooperation. However, it would come at a high cost, with major expenditure and systemic change required to implement detailed harmonising requirements at European level. Given those high costs, it seems unlikely that this option would be of overall benefit to health systems as a whole or to the overall economy, the potential benefits of cross-border care being outweighed by the costs of substantial regulatory harmonisation of health systems across Europe.

5.5.2. Environmental impact

As this option would enable patients to make informed choices involving also cross-border healthcare, one may expect increased mobility of patients and health services providers and thus the increased demand for transport, as with the previous two options. However, volume of patient mobility would always be limited due to factors such as inconvenience for sick people to travel, distance from the relatives or language barrier. Moreover, a large proportion of cross-border healthcare would take place in the border regions, so patients do not travel long distances. These factors would therefore reduce the potential impact on the environment.

5.5.3. Social impacts

5.5.3.1. Impact on socio-economic groups

As regards social impacts, this option would provide guarantees to the patients about quality and safety of health services and confidence about their rights throughout the European Union. This would therefore have a positive effect on social inclusion, quality of life and improved access to high quality care to all social groups, including patients with rare diseases, chronically ill, low-income patients or patients from remote areas.

5.5.3.2. Impact on health systems as a whole

As outlined above, the impact on health systems overall would be very substantial, marking a clear shift from national and local organisation towards significant European harmonisation.

If there were a clear 'correct' model of health system organisation and there could be reasonable grounds for assuming that European harmonisation would help to make progress towards such a model, then it might be possible to envisage long-term benefits in achieving overall health system objectives of accessibility, quality and financial sustainability. However, there is no evidence to date to suggest that there is such a single 'correct' model. Many different approaches are used successfully, and some similar approaches are used successfully in one context but are less effective in

others. Moreover, as all EU health systems seek to constantly improve their efficiency and effectiveness, the variety of approaches taken within the EU provide a unique resource of comparison and mutual learning of the advantages and disadvantages of the various approaches taken toward shared goals.

Substantive regulatory harmonisation at European level would therefore lose the benefits of current comparison and mutual learning, without any guarantee of putting in place a 'better' system, but with certain undermining of the local solidarity on which all European health systems depend. This option is therefore unlikely to have a positive overall impact on health systems.

5.5.3.3. Impact on inequalities between Member States

Of all presented options, this option will contribute most to a decrease of inequalities between Member States in the long term. However, this option would require fundamental changes in the national healthcare and social security systems. Although the healthcare systems across the European Union share certain common values and principles, the practical ways in which these values and principles are implemented in the national health systems vary significantly[59] These diverse systems are based on different national traditions, geographic organisation of each Member State, different distribution of competences between central, regional and local authorities and different modes of healthcare funding. The attempt to achieve uniform application of detailed European rules among those national systems would entail enormous costs for the national social security systems (leaving aside the issue of subsidiarity mentioned in chapter 2).

Moreover, as outlined above, such regulatory harmonisation of health systems would place a particularly heavy burden on the poorer Member States. Given their existing limited healthcare budgets and administrative capacity, also because they need to put already much effort in bringing their healthcare systems up to date, this option would therefore have adverse effects on regional inequalities in the short term, at least.

[59] See the Council statement on common values and principles.

6. COMPARING THE OPTIONS

Table 6.1 Impact of each option presented in financial terms[60]

	Option 1	**Option 2**	**Option 3A**	**Option 3B**	**Option 4**
Treatment costs	€ 1.6 million	€ 2.2 million	€ 30.4 million	€ 3.1 million	€ 30.4 million
Treatment benefits	€ 98 million	€ 135 million	€ 585 million	€ 195 million	€ 585 million
Compliance costs	€ 500 million	€ 400 million	€ 315 million	€ 300 million	€ 20 billion
Administrative costs	€ 100 million	€ 80 million	€ 60 million	€ 60 million	€ 60 million
Social benefit	195,000 extra patients receive treatment	270,000 extra patients receive treatment	780,000 extra patients receive treatment	390,000 extra patients receive treatment	780,000 extra patients receive treatment

On the basis of table 6.1 it is possible to compare the different options in financial terms. The calculations and modelling on which this table is based are presented in chapter five of this report. From table 6.1 it becomes clear that an increase of possibilities to receive healthcare abroad will create an increase in treatment costs. The more patients receiving healthcare abroad, the larger the increase of treatment costs will be. Where under option 1, the baseline scenario with only a very limited increase in cross-border care, additional treatment costs due to cross-border care will increase by € 1.6 million per year, in option 3A and 4 these costs have increased by more than €30 million. These extra costs remain nevertheless marginal compared to the increased treatment benefits, which also increase with the increase of possibilities to receive healthcare abroad (from € 98 million in option 1 to €585 million per year under option 3A and 4). The compliance costs, associated costs to administer cross-border care, were also analysed. The impact assessment makes clear that with the creation of more legal certainty and clarity these compliance costs decrease. Nevertheless, the creation of a detailed legal framework (option 4) creates initially a significant increase in costs, due to the fact that each healthcare system needs to be significantly adapted to the new detailed rules. In chapter five of this report changes of administrative costs in each of the options have been analyzed. The legal obligation to provide information creates costs. By creating more clarity and legal certainty, information provision becomes cheaper and easier. By creating more clarity about possibilities for cross-border care, more people will be able to receive the treatment they need at an earlier stage. Therefore the social benefits increase with more patients being involved.

[60] All data in this table are presented in more detail chapter five of this report. These data are based on modelling and are therefore only rough estimations.

Table 6.2 Comparison of the impacts of each of the options in qualitative terms

	Advantages	**Disadvantages**
1. No further action, the baseline scenario	Flexibility for Member States to tackle identified objectives themselves. Likely costs of treatments low, and outweighed by benefits; though overall costs of administering the system outweigh the likely benefits to patients.	Difficulty for Member States to develop action on their own, because of the scope and nature of the problem. Continuation of current cost trends, accompanied by high costs of managing uncertainty. Social inequality in utilisation of this mechanism for cross-border care, with the less well-off unwilling to advance the cost of healthcare without solid legal guarantees that they will be reimbursed. Potential contribution of cross-border care to wider health system and economic goals not fully realised.
2. Soft action	Flexibility for Member States to increase legal clarity and certainty concerning cross-border healthcare, combined with some additional guidance at European level. Some improved realisation of the potential of cross-border care; likely costs of treatment remain low.	Guidance unlikely to provide sufficient certainty for either patients or professionals, given the importance of the issues at stake. Social inequality in utilisation of this mechanism for cross-border care not likely to be significantly improved. Some reduction in overall costs of administering cross-border care, but still higher than the estimated benefits to patients.

3. General legal framework	Ensures sufficient binding clarity to enable patients and professionals to take full advantage of cross-border care, whilst avoiding a significant additional burden for Member States. Does most to overcome social inequality in utilisation of cross-border care by minimising financial risk through guaranteeing reimbursement. Enables full potential of cross-border healthcare to support wider health system objectives through comparisons and cooperation to be realised. **Sub-option 3A**: only option where the additional costs of treatment and the costs of administering the system are outweighed by the benefit to patients. **Sub-option 3B**: lower additional costs of treatment than sub-option 3A.	Will set binding obligations on health services overall at European level, though these reflect already-agreed political principles. **Sub-option 3B**: lower benefits to patients, with no clear net benefit comparable to the overall costs of the system.
4. Detailed rules	Highest possible legal clarity and uniformity for all stakeholders concerning cross-border healthcare. Guarantees for patients about quality and safety of health services. Maximum reduction of disparities between Member States.	No flexibility for Member States to adopt community rules to differences in national circumstances and makes it therefore difficult for them to implement. There will be little support from stakeholders for a top-down approach. High extra initial administrative burden due to strict, and therefore not always most efficient rules concerning reimbursement rules, information provision for patients and collection of data on cross-border healthcare.

Preferred Option

Under option one the current problems identified in chapter two continue, with rights to reimbursement for cross-border healthcare through direct application of free movement principles established in theory but difficult to use in practice, and no clear framework for ensuring minimum requirements for safe and efficient cross-border healthcare. Moreover, no further action does not mean avoiding costs of cross-border healthcare. Rather, it means continuation of current trends, but accompanied by costs of managing the uncertainties identified in chapter two in practice, compounded by social inequity in how the limited benefits are likely to be distributed with the less well-off unwilling to advance the cost of healthcare without solid legal guarantees that they will be reimbursed.

With option two, there is some improvement. But the key issue here is certainty; given the potentially catastrophic consequences of problems with cross-border care, merely having guidance about cross-border care is not enough, either for patients or professionals. So the costs of cross-border care continue but without its potential benefits being fully realised.

Option three provides the best balance. It achieves the core aim of providing sufficient certainty about the key issues in cross-border to enable its potential to be fully realised in practice. By doing so it maximises the benefit of cross-border care overall, and does most to ensure social equity in its usage by providing certainty of reimbursement to compensate for differences in initial resources, whilst also allowing citizens to exercise as much choice as is compatible with overall health system accessibility, quality and financial sustainability. In contrast, although option four provides a still greater degree of certainty, it involves wholly disproportionate costs and implies a degree of change and harmonisation which is not appropriate and not consistent with the principle of subsidiarity.

Within option three, the key choice is about the handling of cross-border hospital care. As set out in chapter four, under either sub-option if the appropriate care for the patients' condition cannot be provided in their own country without undue delay, then they are allowed to go abroad, and any additional costs of treatment will be covered by public funds; the mechanism for this is already in place through the regulations on coordination of social security systems. Sub-option 3A provides an additional opportunity for patients to go abroad for hospital care if it suits them better, provided that they are willing to cover any additional costs above what would have been covered at home. By maximising the potential access to cross-border care, this sub-option is the only one where the likely value of the benefits of care to patients outweighs the overall costs of the system itself. Sub-option 3B has lower costs of treatment, but also provides lower benefits, and thus does not provide a clear net benefit over the cost of the system itself. The preferred option is therefore option 3, sub-option 3A.

7. MONITORING AND EVALUATION

7.1. Data collection

All stakeholders confirm that in the field of cross-border care many challenges exist which have to be tackled. There is a general consensus that there is a problem, and data confirm that. We lack at the moment nevertheless structured and comparable data which can exactly quantify the scope of the challenges and which would be able to give insight in the development of the problem. It is therefore important that this initiative contains a proposal to strengthen the data availability. Only with more structural data available, it will be possible to see whether the solutions implemented have the effect hoped for. Data are not only needed to quantify the development of the challenges and to monitor the impact of the policy options, but coherent and comparable data are also a tool to tackle the problem itself. Member States will have a tool to better manage their healthcare system when they know how many citizens receive healthcare abroad and for which reason. On that basis they can plan their healthcare service better and adjust the availability of healthcare services within the border of the country.

7.2. Monitoring mechanism

Parallel to that, the Commission will develop a monitoring mechanism to monitor whether this initiative is appropriately implemented in each of the Member States. Within 3 years after the date the initiative enters into force, the Commission will

carry out an assessment of the actual implementation of this initiative and the impact the initiative had on legal clarity concerning cross-border care, impact on information provision to patients and impact on cross-border patient mobility itself. The Commission will therefore, in cooperation with all Member States, collect data on the actual amount of citizens receiving healthcare abroad. It will also periodically measure the awareness of EU-citizens concerning their rights and the possibilities concerning cross-border care. The Commission will, in cooperation with the Member States, investigate how in each country citizens are informed about the possibilities concerning cross-border care, and about its limitations and risk. In cooperation will all Member States the commission will take stock of possible authorization procedure for reimbursement of healthcare received abroad and possible procedures to challenge the decision of the national authority responsible for the authorization procedure.

7.3. Comitology

The new directive will provide for a comitology committee. This committee will adopt measures necessary for the implementation of the directive. For example mechanisms will have to be developed for the collection of appropriate information and data on cross-border healthcare, as mentioned in the directive. Detailed rules will have to be agreed upon concerning requirements for Member States to send regularly appropriate data on cross-border health services to the Commission. The statistical element of this data collection system will be developed in the context of the Community Statistical Programme in general and in the context of the forthcoming EP-Council Regulation[61] on Community statistics on public health and health and safety at work in particular.

8. ANNEXES

8.1. Data about cross-border healthcare

The recently available EU-SILC[62] data for 2005 (see Table 8.1 below) provide an overview of the main reasons for unmet need for medical examination and treatment.

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61 COM(2007)46 final

62 The European Statistics on Income and Living Conditions (EU-SILC) provide cross-sectional and longitudinal multidimensional microdata on income, poverty, social exclusion and living conditions.

Table 8.1 Main reasons for unmet need for medical examination and treatment (2005)

Country	Could not afford (too expensive)	Too far too travel / no transportation	Waiting list	Other*	No unmet need
Austria	0.23%**	#	#	1.57%	98.04%
Belgium	0.68%	#	#	0.24%**	99.04%
Cyprus	2.95%	#	#	2.76%	94.13%
Czech Rep	0.32%**	0.47%**	0.40%**	5.95%	92.86%
Germany	6.69%	0.14%**	1.74%	7.93%	83.49%
Denmark	#	#	#	0.81%**	98.94%
Estonia	2.74%	0.81%	2.15%	2.55%	91.75%
Spain	0.41%	0.19%	0.70%	4.87%	93.84%
Finland	1.41%	#	0.98%	0.93%	96.62%
France	1.24%	#	0.21%**	2.10%	96.42%
Greece	3.44%	0.45%	0.62%	1.66%	93.83%
Hungary	2.44%	0.37%	0.73%	12.56%	83.90%
Ireland	1.06%	#	0.65%	0.51%	97.67%
Italy	3.14%	0.09%**	1.36%	2.11%	93.30%
Lithuania	3.65%	0.39%**	2.32%	2.89%	90.75%
Luxembourg	0.35%**	#	#	4.30%	95.23%
Latvia	17.01%	0.62%**	1.72%	10.27%	70.38%
Malta	1.01%	#	0.50%**	2.12%	96.35%
Netherlands	#	#	0.28%**	0.97%	98.57%
Poland	7.13%	0.44%	2.26%	6.32%	83.85%
Portugal	3.77%	#	0.77%	0.77%	94.56%
Sweden	0.50%**	#	2.02%	12.38%	85.00%
Slovenia	#	#	#	0.19%**	99.48%
Slovakia	2.52%	0.19%**	0.34%**	4.80%	92.15%
United Kingdom	#	#	2.14%	2.96%	94.77%

Source: EU-SILC (2007); *"Other" includes: (1) Could not make time because of work, care for children or for others; (2) Fear of doctor/hospitals/examination/ treatment; (3) Wanted to wait and see if problem got better on its own; (4) Did not know any good doctor or specialist; and (5) Other reasons. **unreliable due to small N (20<n<50); # omitted due to very small N.

Table 8.1 shows that although most need is met in most countries, there are some significant elements of unmet need. For example, 17% of Latvians state that they could not afford at least one medical examination or treatment they needed (in 2005). Other figures that stand out in this respect are in Poland (7.13%) and, remarkably, Germany (6.69%). The high figure for Germany may be related to the negative publicity and public opinion surrounding the introduction of €10 co-payments for every first visit to a physician in 2004. Polish data do not correlate with the official co-payment requirements (officially none for dental care) but may be related to expected "gratitude payments".

The table shows as well that waiting lists are still an important reason for unmet medical needs. In some cases cross-border care could be a way to meet those needs. To calculate the average percentage of people having unmet medical needs due to waiting lists, an average is calculated on the basis of reliable figures in table 8.1, adjusted for the amount of inhabitants in the respective countries. The countries for which no reliable data exist, it is assumed that on average they have the same percentage of citizens waiting for care as the average percentage for the other countries for which data do exist. On that basis, it can be roughly estimated that on average 1.6 percent of the European population is currently on a waiting list, which is equivalent to approximately 7,8 million EU citizens.

It is stated that some Member States use waiting lists as an instrument to contain costs. When legal clarity concerning cross-border care is increased and more information is provided about possibilities concerning cross-border care, citizens will more and more use cross-border care to avoid waiting lists. Some argue that Member States will in that case use other instruments to contain healthcare costs. One of such examples is co-payment. In table 8.2 the main reasons for unmet need for dental examination and treatment are shown. Dental treatment is a healthcare field subjected to many cost sharing policies already. The percentage of Europeans that had an unmet need for dental examination and treatment because it was too expensive is therefore higher than for medical treatment in general (see table 8.2). It is an important incentive for patients to look for cheaper dental care abroad. Therefore both the existence of waiting lists and introduction of co-payment are reasons for increased cross-border mobility of patients. This increase of cross-border healthcare, a specific from of health tourism, is not linked to the discussion about clarity and legal certainty aspects of authorization and reimbursement of cross-border care, nevertheless the quality and safety aspects of this type of cross-border care need to be stressed.

Table 8.2 Main reasons for unmet need for dental examination and treatment in 2005

Country	Hurdle 3: Could not afford (too expensive)	Hurdle 4: Too far too travel / no means of transportation	Hurdle 6: Waiting list	Other*	No unmet need
Austria	0.85%	#	0.23%**	1.38%	97.48%
Belgium	1.56%	#	#	1.14%	97.20%
Cyprus	5.92%	#	#	6.99%	86.84%
Czech Rep	0.51%**	#	#	4.34%	94.84%
Germany	6.13%	0.12%**	0.54%	5.47%	87.75%
Denmark	1.76%	#	#	2.54%	95.48%
Estonia	11.63%	0.32%**	0.29%**	1.28%	86.48%
Spain	4.07%	0.11%**	#	4.59%	91.20%
Finland	2.82%	#	1.39%	2.30%	93.42%
France	3.24%	#	0.14%**	2.76%	93.77%
Greece	5.00%	#	0.17%**	1.83%	92.84%
Hungary	6.51%	#	0.38%	7.83%	85.18%
Ireland	1.64%	#	0.25%**	1.48%	96.58%
Italy	6.03%	#	0.75%	3.43%	89.71%
Lithuania	8.85%	#	1.00%	1.49%	88.53%
Luxembourg	0.69%	#	#	3.55%	95.71%
Latvia	22.60%	#	0.57%**	5.78%	70.85%
Malta	1.19%	#	#	2.73%	95.93%
Netherlands	1.25%	#	#	5.24%	93.28%
Poland	9.77%	0.15%	1.52%	5.05%	83.51%
Portugal	7.85%	#	0.27%**	2.21%	89.58%
Sweden	6.16%	#	0.39%**	5.95%	87.44%
Slovenia	#	#	#	#	99.37%
Slovakia	4.03%	#	0.26%**	3.23%	92.43%
United Kingdom	0.73%	#	4.09%	1.35%	93.75%

Source: EU-SILC (2007); *"Other" includes: (1) Could not make time because of work, care for children or for others; (2) Fear of doctor/hospitals/examination/ treatment; (3) Wanted to wait and see if problem got better on its own; (4) Did not know any good doctor or specialist; and (5) Other reasons. **unreliable due to small N (20<n<50); # omitted due to very small N.

There is some data available about cross-border healthcare undertaken through the regulations on coordination of social security. These data are presented in table 8.3.

Table 8.3 Claims for/on countries under Council Regulation (EEC) No.1408/71 in €, % of total and € per capita for 2004

Country	Claims from other countries (debt)			Claims on other countries (credit)		
	€ (1000)	%	€ / capita	€ (1000)	%	€/ capita
Austria	24.321	1.99	2.96	72.255	5.92	8.80
Belgium	112.084	9.19	10.73	66.564	5.46	6.37
Switzerland	12.321	1.01	1.66	73.514	6.02	9.91
Cyprus	0	0	0	0	0	0
Czech Republic	174	0.01	0.02	0	0	0
Denmark	6.440	0.53	1.19	1.634	0.13	0.30
Estonia	1	0	0	0	0	0
Finland	9.802	0.80	1.87	3.173	0.26	0.61
France	103.927	8.52	1.72	346.235	28.38	5.72
Germany	295.232	24.20	3.58	154.068	12.63	1.87
Greece	63.067	5.17	5.69	8.693	0.71	0.78
Hungary	14	0	0	0	0	0
Iceland	569	0.05	1.94	750	0.06	2.55
Ireland	6.303	0.52	1.53	0	0	0
Italy	157.961	12.95	2.70	130.452	10.69	2.23
Lithuania	5	0	0	0	0	0
Luxembourg	73.537	6.03	161.62	58.48	4.81	128.90
Latvia	2	0	0	0	0	0
Malta	0	0	0	15	0	0
Netherlands	74.006	6.07	4.54	42.651	3.50	2.62
Norway	11.161	0.91	2.42	1.191	0.10	0.26
Poland	131	0.01	0	218	0.02	0.01
Portugal	58.552	4.80	5.56	40.182	3.29	3.82
Sweden	9.483	0.78	1.05	17.179	1.41	1.91
Spain	37.349	3.06	0.87	155.772	12.77	3.62
Slovenia	281	0.02	0.14	1.989	0.16	1.00
Slovakia	52	0	0.01	0	0	0
United Kingdom	163.001	13.36	2.72	45.011	3.69	0.75
Total	1.220.194	100	2.59	1.220.194	100	2.59

Source: Administrative Commission 2005[63]

The data in this table give only a very limited picture of the use of cross-border healthcare. The table shows the outstanding claims under the regulation on coordination of social security at the end of 2004. These figures represent only a part of total cross-border healthcare. There are several reasons why the figures in the above mentioned table are an underestimation of the actual dimensions of cross-border healthcare:

[63] In: Commission consultation contribution Mutualités Belges, see http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co83.pdf

– The data may (often) exclude those patients for which healthcare abroad is financed through monetary transfers on a lump-sum basis (especially pensioners living abroad who get an E121);

– Waiver agreements between many countries lead to a situation that the countries do not calculate and therefore report utilisation and cost data;

– Several public payers, maintain cross-border collaborations outside the scope of Council Regulation No1408/71;

– Providers may accept the EHIC but – due to not receiving any extra payments for such treatment – do not bother to report utilisation;

– Patients may purchase care in another Member State completely privately, and can easily do so if they have bought 'travel insurance' for their holiday; or

– Patients may deliberately choose (under the "Kohll/Decker procedure") or are – due to forgetting the EHIC or through non-acceptance of it by providers – forced to initially pay out-of pocket for cross-border services/goods and then ask for (partial) reimbursement.

A survey among insured members of the German TK sickness fund showed that a relatively low percentage of patients has been able to use their E111-form (now EHIC), when they were in need of medical care abroad[64]. In for example the Netherlands 52%, Austria 66% and in Spain 84% of the insured Germans had to pay the treatment upfront, instead of having the bill settled between the healthcare provider and their sickness fund. So for 2003, this would mean that rather than Austrian having treated the 85,535 cases they provided bills for to Germany, the likely figure for patients treated is three times that.

8.2. Accompanying documents

– Commission Communication, Consultation regarding Community action on health services, SEC (2006) 1195/4, 26 September 2006.

– Commission document, Summary report of the responses to the consultation regarding "Community action on health services" (2007)

– Flash Eurobarometer, Cross-border health services in the EU, Analytical report results

– Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity, European Observatory on Health Systems and Policies (2007)

– Relevant articles of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community

[64] Techniker Krankenkasse (TK), Medizin in Europa: Ergebnisse der TK-Mtiglieder-Befragung 2003 (2003)

– Impact Assessment Board Opinion, Impact Assessment on: Directive on safe, high-quality and efficient healthcare in the European Union, D(2007)7744, 5 September 2007.