Health and Consumer Protection Directorate-General, European Commission

Summary report of the responses to the consultation regarding

"Community action on health services"

(SEC (2006) 1195/4 of 26 September 2006)

SUMMARY

This report summarises the responses received to the Commission's public consultation launched on 26 September 2006 regarding Community action on health services. Given that replies were received from a wide range of stakeholders, the report does not aim to provide a statistically representative survey of opinions. The views of respondents described in this report do not necessarily present in all cases the opinions held by the majority of stakeholders of a certain sector of the society or of a certain group of the population. It is important to stress that this report only attempts to give an accurate summary account of the responses as they were presented to the Commission's services. It does not take position on the comments received and does not seek to correct any of the misunderstandings or factual inaccuracies, which occasionally seem to underlie the views expressed by some respondents. Therefore, the report does not express the views of the Commission services, nor do the Commission services necessarily agree with all the views expressed therein.

Despite some additional examples, there is a clear lack of up-to-date and complete data on cross-border care. Many contributors concurred with the estimate in the Commission consultation communication that about 1% of total healthcare expenses was spent on cross-border care and is expected to increase. This phenomenon can be significantly larger in certain circumstances, in particular for border regions, smaller Member States, rare diseases, and areas with high numbers of visitors from abroad. The mechanism used for cross border care (through the regulations on coordination of social security systems, or through internal market rules) has different financial impacts for public funds and citizens depending in particular on the relative levels of the cost of care in the patients' home country and the cost abroad. And of course, though overall numbers of citizens using cross-border care remain relatively low, its importance for individuals can be high.

Contributors 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; 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 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 will also be particular cases where any division of responsibilities will leave 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 dentist. 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.

In addition to the issues identified elsewhere in the report, some contributors identified some 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 covered elsewhere in the report, contributors highlighted the scope for practical support on areas including European networks of centres of reference; 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*"[1]. 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.

INTRODUCTION

As the Commission has set out, high-quality health services are a priority issue for European citizens[2]. European citizens value health as a key element in a good quality of life. Rights to healthcare are also recognised in the Charter of Fundamental Rights of the EU[3]. The European Court of Justice has made clear that Treaty provisions on free movement of services apply to the health systems, regardless of how they are organised or financed at national level. It has further clarified that patients are entitled, subject to some conditions, to reimbursement of treatment received in another Member State. However, many healthcare stakeholders have asked for greater clarity over what Community law means in general terms for health services.

The Commission launched on the 26 September 2006 a public consultation regarding Community action on health services[4]. In this Communication, the Commission outlined the development of proposals, legislation and rulings of the European Court of Justice related to health services and the meeting of their costs on the European level. The Commission sought contributions from all stakeholders structured around nine questions on the nature and size of the phenomenon and impact of cross-border healthcare on

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

[2] See Eurobarometer 63 at http://ec.europa.eu/public_opinion/archives/eb/eb63/eb63_en.htm.

[3] See Article 35 on health care.

[4] SEC(2006) 1195 of 26 September 2006.

health systems, identification of areas of legal uncertainty, identification of areas to support to the Member States on a European level and proposals for instruments to deal with the possible problems.

Responses were invited by 31 January 2007. A total of 276 responses have so far been registered from national governments, regional authorities, international and national umbrella organisations, social security institutions, universities, industry and individual citizens.

Given that replies were received from a wide range of stakeholders, the report does not aim to provide a statistically representative survey of opinions. The views of respondents described in this report do not necessarily present in all cases the opinions held by the majority of stakeholders of a certain sector of the economy or of a certain group of the population.

It is important to stress that this report only attempts to give an accurate summary account of the responses as they were presented to the Commission's services. It does not take position on the comments received and does not seek to correct any of the misunderstandings or factual inaccuracies, which occasionally seem to underlie the views expressed by some respondents. Therefore, the report does not express the views of the Commission services, nor do the Commission services necessarily agree with all the views expressed therein.

Given the wide range of topics the public consultation raised, it is impossible to do full justice to the richness of the replies in a summary report. Those interested in reading more are invited to consult the individual responses to the consultation. The full list of contributors and their responses received may be consulted directly on the Commission's website[5].

1. IMPACT

Question 1: What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

Lack of consistent information – particular examples only

There was consensus among contributions addressing this issue that there is a serious lack of up-to-date and complete data on all types of cross-border provision of health services. Only a few, incomplete and often outdated concrete data sets were identified by contributors. These include for example data from individual or groups of hospitals; particular regional areas; or data from prior authorisation processes.

Examples of data provided by contributors include:

[5] See http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm.

– In Belgium 0.58% of hospitalised patients overall were from abroad, but with significant variations - in a particular hospital 9.3% of surgery patients were from abroad; (*Belgian Government*)

– In Cyprus the Cypriot government indicated that in 2006 the short term visitor influx was 1894, permanent visitors numbered around 7000 and the efflux around 800;

– In Denmark between 2002-2005 47,108 patients from abroad were registered, mostly from high income groups; (*Danish Confederation of Trade Unions*)

– In Poland from May 2004 to October 2006, 38,000 Polish citizens received medical treatment abroad, while around 18,000 patients from abroad were treated in Poland (*Polish Government*);

– 25,000 patients from other EU countries were treated in Sweden in 2005. This represents 0.15% of County Councils health costs (*Swedish Association of Local Authorities*);

– In the United Kingdom 281 requests for authorization of treatment abroad (through the E112 procedure) were approved in 2005. However, 917 orthopedic patients from the UK have been treated in France, Germany and Belgium in 2005 through pilot schemes. (*NHS Confederation*).

Best available estimates

Despite this lack of information, a large majority of contributors answering to the question described the current impact on their health systems as small. Many contributors concurred with the estimate in the Commission consultation communication that about 1% of total healthcare spending was spent on cross-border care. However, some stakeholders also pointed out that even with low overall percentages, the impact should not be underestimated. Even an estimated average of only 1% of health services mobility should be considered as a considerable economic and social factor. For example, one contribution stated that in Germany alone 4.2 million citizens worked in the health care sector.

Increasing impact

Many contributors mentioned that they expect a **noticeable increase of cross-border healthcare in the future**. 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).

For example, a study conducted in the UK showed that 45% of UK consumers were generally positive about treatment in a different EU Member State and 27% were quite likely to accept treatment abroad if it was paid for by the NHS and meant that they could be treated sooner (*Which?*). In another 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*).

On the other hand there were contacts between the German sickness funds in Brandenburg and Polish dentists according to which German patients were offered the possibility to be treated in Poland. Few patients took advantage of this possibility (*Council of European Dentists*)

Examples of data provided on this topic include:

– In Austria, the number of patients from abroad treated in acute settings in Austrian hospitals was 36,977 in 2001 and 42,933 in 2005 (*Gesundheit Östereich GmbH*);

– Reimbursable cross-border care costs is still limited in Estonia (0,08% of insured persons and 0,4% of Estonian health budget), but they are forecasted to increase by 10% each year for the next four years (*Estonian Government*);

– In France, between 2004 and 2005 the cost for patients treated abroad increased by 27%, and has continued to increase since then (*L'Assurance Maladie Obligatoire française*);

– In the Netherlands, figures from insurers show that the percentage of curative treatment undergone by Dutch patients abroad can be as much as about 5% of treatments in border regions. (*Dutch Government*);

– In Sweden, the number of patients going abroad for planned treatment was increasing (147 in 2004; 954 in 2005; and 1000 in 2006) (*Swedish Government*);

– In the United Kingdom the bill for treatment abroad under E111 and E112 was in 2005 £463m[6] and will be in 2006 around £641m[7] (*NHS Confederation).*

Need for patient mobility observation

Many contributors concluded that cross-border movements of patients, individual health care professionals and institutional providers need to be monitored more closely in the future in order to have a more solid data base for action and to give those responsible for health systems the ability to respond properly to significant

6 Around €676m.

7 Around €955m.

developments. Some stakeholders concluded that the development of patient mobility indicators would thus be necessary.

Factors that influence the impact of cross-border care

Several contributors highlighted that the impact of cross-border health care varies, and is significantly higher or lower depending on particular circumstances. Factors influencing the impact of cross-border healthcare include:

- **Border regions**: The impact of cross-border healthcare is seen as being likely to be greater for the estimated 10% of European citizens that live 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 (see responses to question 2);

- **Smaller Member States**: For smaller Member States contributors 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 considered as low for the systems in general, for the individuals concerned, some contributors argued that the impact of access to cross-border health services may be essential for the individuals concerned;

- **Rare diseases**: Contributors indicated that patients with rare diseases may need to travel much further for appropriate treatment than patients with more common conditions. One study showed that around a quarter of such patients travel between regions within one country to receive medical treatment (*Eurordis*);

- **Areas attracting large amounts of tourists**: Contributions highlighted that areas attracting large numbers of tourists, such as southern Europe and the Mediterranean islands, face some specific impacts (especially health care professionals and southern member states). It was argued that 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. Second, it was argued that tourists may 'drain' local health systems resources, if the billing methods applied do not cover the full cost of treatment, including the necessary infrastructure (see responses to questions 2 and 5). However, other contributors consider that the medical services that they offer to tourists in need of health care also form part of the infrastructure which makes those areas an attractive tourist destination.

- **Incomplete or late payment for providers:** Moreover, some contributors argued that practical problems with the reimbursement procedures under national rules or the regulations on coordination of social security systems lead to incomplete or delayed reimbursement for providers and Member States (see responses to question 7).

- **Areas attracting large amounts of pensioners**: Some contributors (especially health care professionals and southern member states) considered that many pensioners reside during winter months in warmer areas of Europe, but do not transfer their rights of social security from their home country to the country where they live during the winter. According to these contributors, the country where the pensioner resides during the winter would thus receive no transfer funding for the provision of local health service infrastructure. Other contributors suggested that the main reason for people not transferring their social security rights in this way was the complicated and slow bureaucratic procedure to do so, especially if it needs doing twice a year accordingly to the summer and winter season;

- **Patient wish to be treated close to home**. Some contributions referred to national studies confirming the assumption that citizens prefer to be treated close to home. For example, in Finland, 90% of elderly citizens refuse referral within Finland even though this would mean a shorter waiting time for them (*Finnish Government*). In Denmark 75% of citizens use only local dentists and want to continue to do so in the near future (*Danish Dental Association*);

- **Travelling efforts and costs** are considered to be an obstacle by some patients, especially for some disadvantaged groups, some contributors felt;

- **Cultural and language barriers** and consequent difficulties in ensuring continuity of care were also mentioned frequently by contributors as a practical obstacle;

- **Lack of information** on cost reimbursement is considered by many contributors to be a major obstacle cross-border care and thus affects its impact (in particular unions, health care professionals, authorities). **Uncertainty about quality of care, patient safety aspects and patients' rights** were similarly mentioned.

- **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 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*).

Financial inequalities and their impact

Background: In the following paragraph reference is made to **two types of cross-border patient mobility that have a different financial impact on the individual and the health care system:**

1. Regulations (EC) 1408/71 and 574/72[8]. These are based on Article 42 of the Treaty establishing the European Community (under the chapter of free movement of workers), and entitle 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. Reimbursement between the Member State and the providers is regulated by national rules. The Regulations They also ensure assumption of costs for planned treatment in other Member States, subject to prior authorisation, and deal with the settlement of financial claims between receiving and sending Member States.

2. Direct application of internal market freedoms: In 1998 the European Court of Justice made clear through its rulings in two cases[9] that the existence of the regulations described above did not prevent the direct application of the Treaty articles on free movement of goods and services to the reimbursement of health care provided to patients abroad (otherwise known as 'patient mobility'). In its rulings, the Court stated 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[10], 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 patients are entitled in their own Member State they may also be sought in any other Member State, but the Member State of origin may subject reimbursement of this type of care to the granting of a prior authorisation. This authorisation must be given if the treatment sought, or one which is equally effective for the patient, cannot be provided within a medically acceptable time limit, taking into account the state of health of the patients and the probable course of their illness. They will be reimbursed up to at least the level of reimbursement provided by their own system. The authorisation scheme must be based on a procedural system which is easily accessible and ensures that requests are dealt with objectively and impartially within a reasonable time; refusals must be justified and be open to challenge via judicial or quail-judicial proceedings.

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8 OJ L 149, 5.7.1971, p.2, and OJ L 74, 27.3.1972, p. 1, as since amended. Modernisation and simplification of these regulations has led to the adoption of regulation 883/2004 and current negotiation of its implementing regulation.

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

10 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.

Major disparities in income and prices between some Member States and especially between the fifteen longest joined Member States (the EU15) and the twelve most recently joined Member States (the EU12) were identified as a major factor in the context of provision of cross-border health services by many contributors. Prices of health services can be 5-10 times higher in one country than in another Member State, it was suggested (*Slovak Government*). Some of the impacts of this identified by contributors include:

- **Impact on public funds when applying Regulation 1408/71:** Some contributors (in particular governments, providers and industry) argued that less economically developed Member States could be faced with spending an increasing amount on healthcare abroad. As mentioned above, the *Estonian Government* expects an increase of 10% each year over the next 4 years. *Poland* mentioned a considerable increase in costs due to Polish women increasingly using maternity services in Germany (*Polish Government*) - as this is considered to be "necessary" treatment, it can be accessed without prior authorisation. Furthermore, planned treatment under Regulation 1408/71 (in particular specialised care not available in the country of residence, such as dialysis or brain surgery) were identified by contributors as causing high financial burdens for the public funds of less economically developed Member States, and many contributors felt that this could destabilise those national health systems;

- **Impact on private funds when applying Regulation 1408/71:** Citizens that seek treatment in a country that has higher co-payments than under their country of residence (for example, patients from Germany or Luxembourg who receive treatment in Belgium) end up paying more than for treatment in their home country, in particular patients' organisations considered;

- **Impact on private funds when applying internal market rules.** Some contributors (*providers, health care professionals*) considered that the reimbursement rules established by the ECJ put at disadvantage individual citizens with lower incomes. This was seen as affecting citizens from less wealthy Member States in particular. For them, it was considered that use of planned care abroad under the rules established by the ECJ would almost always mean considerable private payments in addition to the amount that is reimbursed by their social security system.

Summary for question 1

Despite some additional examples, there is a clear lack of up-to-date and complete data on cross-border care. Many contributors concurred with the estimate in the Commission consultation communication that about 1% of total healthcare expenses was spent on cross-border care and is expected to increase. This phenomenon can be significantly larger in certain circumstances, in particular for border regions, smaller Member States, rare diseases, and areas with high numbers of visitors from abroad. The mechanism used for cross border care (through the regulations on coordination of social security systems, or through internal market rules) has different financial impacts for public funds and citizens depending in particular on the relative levels of the cost of care in the patients' home country and the cost abroad. And of course, though overall numbers of citizens using cross-border care remain relatively low, its importance for individuals can be high.

2. MINIMUM INFORMATION AND CLARIFICATIONS

Question 2: What specific legal clarification and what practical information is required by whom to enable safe, high-quality and efficient cross-border healthcare?

Definition of "health services"

Several stakeholders (in particular health care professionals, governments) argued that a clear definition of "health services" is needed as the starting point for any Community action to improve legal certainty in this area, to make sure that the areas covered and the areas not covered by any Community action are clearly laid out. Some contributors also felt that any definition should take into account the current situation where different Member States have quite different definitions of medical care, psychological care, nursing care, social care and even "necessary treatment".

Need for more and clearer information to patients

Better access to clearer information was identified by many contributors as one of the key needs to be improved in order to have better and more efficient cross-border provision of care. 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.

A wide variety of proposals were made by contributors with regard to improving access to information related to cross-border health care easier and more efficient. These include:

- **Clear and transparent information** on patients' rights on reimbursement in the context of cross border care (governments, unions, health care professionals, regulators, industry);
- **National central information point** in each country (in particular patients' organisations, health care professionals);
- **Patient's Ombudsman** that can act as an independent advocate for patients;
- **European central information point.** The EU Health Portal was mentioned in particular as a possible tool to increase patients' access to information;
- **European guidelines on patient information:** the development of European guidelines on patient information was proposed by some stakeholders, although the difficulty of doing so in practice was also recognised;
- **Provider database:** the establishment of a database of doctors, dentists, pharmacies and institutions that accept patients from abroad was seen as helpful by the whole spectrum of contributors. Several contributors saw practical difficulties with such a tool, however, such as cost and language coverage, and

ideas varied about the useful and feasible content of such a database. Some suggestions about content included the following:

- Administrative data: name, address, email, web-page of the institution;
- Acceptance status of EHIC or E112;
- Medical services provided: prices, waiting times;
- Supportive services provided: languages spoken, translation services;
- Quality and safety: certification or accreditation, quality reports, mortality data, infection rates, performance data; and,
- Complaint procedures and patients' rights in the case of undesirable outcomes.

– **Information about providers within the patients' country of residence:** Some contributors took the consultation as a opportunity to underline that such a provider database with detailed information would also desirable for citizens that seek treatment within their home Member State. It was argued that only practical and transparent information would empower citizens to make informed choices and enhance health protection (especially patients' organisations).

Instruments to control patient flows

Background: The ECJ's rulings related to reimbursement of healthcare provided in another Member State are clear in themselves, and no pre-condition may be required for the exercise of the rights of patients as recognised by the Court. The Court recognised that limits to free movement could be justified by overriding reasons in the general interest with regard to hospital care abroad and that which prior authorisation may be required. However, the Court indicated that in order to be compatible with Community Law, any authorisation system should fulfil transparency and legal certainty requirements.

Reasoning for "prior authorisation"

Contributions from some national governments and purchasers in particular view the instrument of "prior authorisation" as a key element to keep their "steering capacity". This was for example mentioned by contributors in the following contexts:

– **Limiting additional costs** in application of Regulation 1408/71 for planned treatment if the treatment abroad is more expensive (see also chapter on financial inequalities);

– **Limiting supply through "gate-keeping"**. Contributions reported that in many countries access to reimbursed specialist treatment is only possible by referral from general practitioner (who thus acts as a "gate-keeper"). This system is intended to streamline patient flows and manage it in an efficient way. Several contributors argue that these systems should be protected in order to keep the system running and control costs;

– **Limiting supply with waiting lists**. In some countries contributors consider that waiting lists are used as planning tools. Some contributors

argue that if they cannot refuse an authorisation to get hospital treatment abroad when the treatment required by the medical situation of the individual patient cannot be provided without undue delay in the Member State of registration of the patient, the balance of supply and demand would be destabilised.

Need for clarity on the conditions under which prior authorisation for cross-border care is justified

The majority of national governments and dentists' and doctors' umbrella organisations in particular saw a need for clarification on the conditions under which prior authorisation is justified to ensure legal certainty for regulators, purchasers and patients.

In this context, the majority of national governments and many organisations representing providers identified the lack of clarity over the terms **hospital and non-hospital care** in particular as needing to be addressed. This was seen as particularly problematic due to the heterogeneity of health systems throughout the EU in these terms. Contributors argued that care that is provided in one Member State in a hospital may be provided as ambulatory care in another Member State, as well as that the fast evolution of medical care and thus the appropriate and feasible modes of treatment adds to the complexity of the problem. Some also argued that a difference in authorisation regimes between hospital and non-hospital care could generate problematic incentives to carry out some healthcare on an ambulatory basis that would be better provided as hospital care.

One solution proposed was the application of the definition of "hospital care" of the "patient's country of residence". Others highlighted that even for some types of ambulatory care, extensive planning and major investments have to be made and hoped for a definition that would take this into account. On the other hand *CPME* found that the definition of "hospital care" should be as narrow as possible in order to facilitate free movement of patients. They suggest the following definition:

> *"Medical care under the supervision and responsibility of medical doctors(s) and provided in specific facilities where medical surveillance is available 24 hours a day and which normally requires accommodation in the facility."*

Other interpretations were also given. For example, the *UK Government* wrote:

> *"We were surprised to see in the Commission's Communication the statement that the European Court of Justice has ruled that people may seek any 'non-hospital care' (to which they are entitled in their own Member State) in another Member State without prior authorisation. We do not agree with what the Communication says on this point. In fact the Court has said that it has yet to see a justification for a prior authorisation system for non-hospital care."*

Some representatives of patients, doctors, hospitals and national governments identified the lack of a clear definition of "**undue delay**" as a problem. Some contributors felt that interpretation of the term 'undue delay' can be quite different depending on the perspective: what may seem reasonable to a health professional or government official may seem most unreasonable to a patient who is suffering. Most stakeholders commenting on this issue felt that judgements about undue delay should be decided on case by case basis, based on clinical judgements by a general practitioner, by a specialist or by an expert panel.

Some argued that such assessments should focus on the patients' needs and concerns (e.g. pain, quality of life, prognosis, risk of travel) and not financial aspects (in particular unions, patients' organisations, scientists). Others felt that the development of national agreed guidelines regarding unacceptable waiting times based on evidence and medical expertise for the most common diseases should be encouraged by the European Commission. However, it was argued that any definition of maximum waiting times at EU level could turn out to be a controversial and long-lasting task, and critical contributions remarked that quality of care could actually decrease in some countries as a result, if a European compromise were found around a "minimum standard". Currently, countries such as Denmark and Ireland in particular have a different approach; they have introduced a "service based" **time limit,** e.g. a specified number of weeks for all types of conditions and some shorter periods for severe diseases.

Suggestions to improve the "prior authorisation" system

Suggestions by contributors for improving the current situation include:

- **Clear information to patients**. Many contributors felt that currently it is difficult for patients to identify their rights with regard to "prior authorisation". Clear information is often felt to be missing (responses to question 2). Contributors thus argued that regulators should put in place rules that are clearly defined, proportionate, transparent and understandable for any use of prior authorisation procedures;

- **Effective decision procedures**. Further to the need of information for patients, some contributors felt that the processes of receiving an authorisation from the healthcare system for cross-border healthcare were often long and could thus aggravate the physical and psychological conditions of patients (in particular patients' organisations, a few governments). 'White' and 'black'-lists (or 'health baskets') of hospital treatment procedure with 'automatic' entitlements were suggested as a practical solution, as was the "service based" undue delay rule mentioned above. In some circumstances the speed of decision may important;

- **Patient centred approach**. With regard to countries in which waiting lists are used to limit and manage health service supply, some contributors were concerned that 'patients could bypass waiting lists' via cross-border healthcare. However, other contributors argued that patient mobility should be rather seen as a signal that patients are seeking alternatives due to

concerns over quality, cost or accessibility (in particular unions). From this perspective, patient mobility would signal that action should be taken by the responsible authorities to address patients' concerns over their own health system, rather than suppressing patient mobility through administrative barriers;

- **Evidence based standards.** One university considered that the definition of 'undue delay' should be based on the **best available scientific evidence** rather than on cultural or national preferences, and therefore should be universal within the EU;

- **Right to appeal against refusals**. Many contributors stressed the need for a system of authorisation for cross-border healthcare that allows patients to challenge decisions. Some suggested that this could take the form of an independent expert panel;

- **Exceptions for border regions**. The *Belgian Government* raised the idea of allowing free planned cross-border care for residents in border regions and for access to specialist 'centres of reference';

Price setting for patients from abroad

Several contributors saw a need for more transparent pricing (scientists, unions, industry and a few governments). The *University of Groningen*, for example, argued as follows:

> *"Many States operate complex systems in which insurance pays a price for treatment that is not in fact the true total cost, because the providing institution also receives other forms of subsidy or public assistance. The price may represent the marginal cost, or a percentage of cost, or simply a politically acceptable cost calculated more with an eye to insurance company and patient behaviour than true reimbursement. […] This makes the institution competitive in the international market, and enables them to attract migrants, who are then effectively partially paid for by the host state".*

One of the suggestions from some contributors to avoid the problem of residents cross-financing patients from abroad is "**dual pricing**", meaning that patients from abroad are allowed to be charged higher fees than residents. There seemed to be no clear line amongst the contributors: some favoured dual-pricing, whilst others argued for equal pricing and felt that any discrimination in pricing should be prohibited. Some of those concerned about any differences in prices charged between residents and non-residents argue that hospitals might be encouraged by higher revenue to prefer patients from abroad over home patients, resulting in decreased access for residents.

Another issue raised by contributors in connection with pricing is the identification or codification of diagnoses and treatments in order to **identify the appropriate reimbursement level**. It was felt that the lack of similar medical billing terminology across Europe is the key problem. For example, some health systems bill per time (hours/or days in hospital), others per frequency of visit and others based on diagnosis related groups (DRGs), an approach which is becoming more

and more frequent. Some contributors consider that a **common EU DRG system** is the easiest solution to such billing problems and should be pursued in the long term.

Private provider or public provider

Background: Under ECJ case law non-hospital health services can be accessed without prior authorisation and be reimbursed up to the level of reimbursement that is foreseen in the home country. No differentiation between private and public providers has been made by the Court. However, using Regulation 1408/71 patients can only access providers accepted by the social security system of the country of treatment. These are often only public providers.

Some contributors (in particular governments, purchasers) felt that the principles established by the ECJ lead to a paradoxical situation, where patients are often not allowed by their purchaser to access private health services in their home Member State, but are allowed to do so by seeking healthcare abroad using internal market rules.

Summary for question 2

Contributors 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; 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.

3. COMPETENT AUTHORITIES AND THEIR RESPONSIBILITIES

Question 3: Which issues should be the responsibility of the authorities of which country?

Clinical oversight

Clinical oversight should generally be by the treatment country

The majority of contributors stressed the need for clarification over which authority is responsible for the clinical oversight in the context of cross-border healthcare. Many contributors (including the majority of national governments) argued that the responsibility for the clinical oversight should be with the county of treatment. However, some purchasers argued that they should have the ability to check the quality and safety of providers to some extent no matter where they are located, as they pay for the treatment and will often have to deal with follow-up costs in case of adverse events.

Shared clinical oversight in some particular cases

Notwithstanding the general consensus that clinical oversight should be with the country of treatment, contributors described some cases and areas where the issues are more complex. These include:

– **Managed cross-border health care systems**: Many contributors made a distinction between cross-border care planned by the patient themselves as opposed to cross-border care at the instigation of their health system (managed cross-border care). Overall, several contributors felt that a managed system has some particularities, as patients and providers usually have higher expectations about the good integration any health services provided abroad within the organisation of the national health system. This covers practical areas such as arrangements for travelling, accommodation for accompanying people, translation services, and patient transport. Reflecting this, sometimes the facilities patients are sent to in other Member States are visited by authorities from their country of residence to check quality and safety standards. A form of "shared responsibility" was raised by several contributors, which could be fixed through bilateral contracts, for example. With this type of cross-border care, it was felt by many contributors that even in the case of severe adverse events, the "sending" system should take responsibility and provide any compensation for the patient concerned. It would be then be for the authorities of the sending and treating systems to find a compromise on the financial aspects relating to any such compensation;

– **International patient transport**. Some contributors (*e.g. Euregios*) felt that in border regions emergency services could often be organised more effectively in close cross-border cooperation, but this requires addressing many practical and regulatory issues. To some extent these issues can be solved through bilateral agreements, but in the case of transfer of patients over several borders this was becomes complex.

Inevitable difficulties in practice

Even though most contributors agreed that the oversight should normally stay only with the authority on whose territory the service is provided, several examples from contributors show how difficult this may be to follow in practice. The lack of common quality and safety standards in the area of infectious diseases were identified in particular by the *MRSAnet* and *Euregio Maas-Rhein*. In the Netherlands an aggressive "search and destroy" strategy almost eliminated MRSA[11] in clinics, but in Germany MRSA prevalence rates are much higher. This leads to complications in the provision of cross-border care between the two countries, as personnel and patients crossing to the Netherlands can re-infect their hospital population, but the Dutch regulators

[11] Methicillin resistant Staphylococcus aureus, a bacteria that can for example cause serious wound infections and sepsis and is particularly difficult to treat.

have no possibility to impose their "search and destroy" strategy on the German provider and professionals.

Quality of care & patient safety

Many contributors felt that one of the priority areas of Community action on health services should be patient safety. The Commission was encouraged by many contributors to support the national overseeing authorities in achieving a high level of quality and safety, such as through the following measures:

- **Development of European patient safety quality of care guidelines or minimum standards**. Contributors (in particular unions and some governments) argued that not all Member States have patient safety measures in place, so European guidelines or standards on patient safety would benefit those staying within their own health system as well as those using cross-border care. Some contributors argued for ensuring patient safety through an obligation to have national programmes on quality evaluation and risk management;

- **Development of European patient safety and quality indicators** in order to benchmark and monitor the effects of guidelines in different countries. It was argued (especially by unions and welfare organisations) that indicator development should be undertaken in conjunction with the World Health Organisation (the WHO) and the Organisation for Economic Cooperation and Development (the OECD). Some contributors felt that a European observatory to monitor outcomes would be beneficial. However, others warned that it had to be kept in mind that indicators are often contentious (especially health care professionals);

- **Development of European research on patient safety** would have the advantage of covering larger populations and pooling resources, it was argued (in particular by health care professionals);

- **Development of European guidelines for accreditation for health care providers**. Some contributors (in particular unions and some health care professional organisations) felt that one of the key points for a successful accreditation system was a **continuous improvement of quality standards and reaccreditations**, but that not all national accreditation institutes fulfilled these criteria. Critics highlighted that quality of care is often attached to the health care professionals working for the provider. These teams may change workplaces and leave a skill and knowledge "vacuum". Furthermore, it was argued that hospitals might be excellent in some areas and below average in others. These issues need to be taken into account when developing or applying any accreditation system;

- **Development of common inspection rules** at European level. Some contributors argued for harmonised quality control criteria at European level for which the *MARQuIS* research project could be a starting point. It was argued that such inspection rules vary enormously throughout the EU, which in turn would hinder the assurance of patient safety when using healthcare in other Member States. One example given was that an Irish dental lab is likely to be inspected every year whereas a German one only every 125 years (*UEAPME*);

– **Introduction of a no-fault patient safety reporting system** based on anonymity and confidentiality.[12]

Continuity of care to ensure patient safety and quality

Many contributors (scientists, unions, health care professionals) argued that continuity of care is the key to successful and safe treatment, and in turn relies upon exchange of information between all parties involved. Contributors identified as particularly difficult situations where the treatment provided abroad was not available in the home country of the patient and therefore the doctors in their country of residence lack experience in the necessary follow up care. Furthermore, some contributors said that there was anecdotal evidence that some doctors are reluctant to provide aftercare to patients who have had their care elsewhere. Some practical measures proposed by different contributors to ensure quality when transferring a patient between two health systems include the following:

– **Patient data exchange system.** It was suggested that such a system would not necessarily need to be electronic, so long as it was functional. Ensuring data protection was the major concern of contributors in this area;

– **An EU standard discharge letter** with standardised fields for personal, medical and pharmaceutical data and guidelines for timely provision of it;

– **European-wide prescriptions** would help ensure continuity of care when seeking medication that was prescribed abroad (see also responses to question 6).

Patients' rights

Many contributors (especially patients' organisations, providers) argued that a **European Charter on patients' rights** would help to ensure patients' rights. In terms of what patients' rights should exactly entail, there was a wide variety of topics suggested by contributors, most of them covered separately in other parts of this report. For example, the "**Common values and principles**" were mentioned by many contributors (*in particular governments*) as a basis. These include the overarching values of universality, access to good quality care, equity and solidarity as well as the operating principles of quality, safety, care that is based on evidence and ethics, patient involvement, redress and privacy and confidentiality. In addition rights to **transparent information**, a **functional redress system** or the ability to contest **refusal of treatment abroad** were also highlighted by contributors (in particular welfare and patients' organisations). In this context some contributors also felt that some groups of people needed special protection, for example minorities, women, the elderly, the mentally ill and low income citizens.

Some contributors also felt that **ethical issues** should be clarified. For example, some contributors raised the issue of whether treatment that is restricted in the home

[12] Such a system aims at identifying systematic errors and development of strategies to avoid them (in contrast to a system that focuses on giving responsibility to individuals)

country of patient for ethical reasons (such as abortion or genetic testing) could or should be equally restricted for these citizens in other Member States as well, and whether they would have a right of reimbursement for such treatment provided in other Member States.

Summary for question 3

There is broad consensus 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 will also be particular cases where any division of responsibilities will leave 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.

4. RESPONSIBILITY FOR HARM AND COMPENSATION

Question 4: Who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

Responsibility lies with the provider

Almost all contributors felt that the provider of treatment should be liable for harm and any redress arising. Several suggestions were made by contributors to improve patients' access to compensation, including:

- **Ensuring that simple, effective, swift and easy to understand mechanisms for redress** were in place in every Member State. Many contributors felt that systems based on mediation were more effective than systems based on penalty;

- **Requiring mandatory harm insurance** for doctors and providers, though there was no consensus about who should pay for such insurance. From responses to the consultation it appears that such liability insurance is standard in a many but not all Member States at present. In the context of cross-border provision of care, some contributors argued that the level of compensation should be not only adapted to the level of harm, but also to the living costs in the patient's country of origin. Other contributors argued that the level of compensation should be set at EU level;

- **Implementation of effective national reporting systems**. It was suggested for example that such a system should have a **single contact point** for patients or an **Ombudsman (**patients' and welfare organisations, regulatory authorities*)*.

International private law

In terms of the need for Community action to clarify liability issues for cross-border healthcare, there is a clear split between the views of contributors. Some feel that the compensation rules as set out under international private law (in particular the ROME I and II conventions) cover liability aspects related to the provision of cross-border health services sufficiently. Others consider that more clarity is needed, arguing for example that when applying the rules as set out by international private law, a patient could appeal to their home courts to judge according to foreign law, if a problem occurs after the patient returns to their home country (in the case of a mistaken diagnosis, for example). Some contributors argued that the obligation to apply the compensation rules of a different country would not practicable. Furthermore, it was felt by some stakeholders that current rules of international private law do not sufficiently take into account recent developments in telemedicine (in particular organisations representing industry).

Several contributors propose the introduction of a flexible tool on EU level, similar to **SOLVIT**, to resolve cross-border liability cases. The introduction of a European ombudsman for redress was also suggested. Mediation and solution-oriented systems were the preferred systems by many contributors over more formal legal mechanisms. It was also argued that the full range of remedies should be addressed: explanations, apologies, specific actions or treatment for the patient, changes to prevent recurrence and where appropriate financial compensation. Some contributors also felt that legal aid arrangements might be need to be adjusted to facilitate patients seeking legal redress in another Member State.

Another specific proposal from contributors was the establishment of a **European wide no-fault compensation system**. For example, the *Wiener Landesregierung* described their positive experience with the introduction of a no-fault compensation fond, which reduced the pressure to cover up mistakes on the provider side and was valued by patients that experienced adverse events. It was suggested that this could be a model for other Member States. However, it was also highlighted that patient mobility could affect the balance of national non-fault compensation funds, depending on how they are funded.

Summary for question 4

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.

5. ENSURING BALANCED HEALTHCARE ACCESSIBLE TO ALL

Question 5: What action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all?

Some contributors (in particular Member States and unions) felt that balanced provision of healthcare could be disturbed by patients from other Member States. It was stressed the need to establish the right to prioritise home patients if capacities are limited. In this context it was also suggested that the hospital should have the right to set their own priority lists and to separate waiting lists for resident patients from those from abroad. Concerns were expressed that especially access for patients in EU12 Member States could be reduced by an influx of patients from the EU15. It was felt that the usually lower prices for treatment could be a strong incentive for travelling abroad in the case of planned treatment, putting pressure on local capacities in the country of treatment. A few contributors also argued that cross-border healthcare could be misused by regulators to save money in the home health care system. For example, patients could be sent systematically for expensive or high risk treatments abroad without providing appropriate financial compensation. On the other hand, it was also mentioned that an increased demand of service from patients abroad may also have a positive effect on the quality and accessibility of services.

Summary for question 5

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.

6. HEALTH CARE PROFESSIONALS AND PROVIDER MOBILITY

Question 6: Are there further issues to be addressed in the specific context of heath services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

Mobility of health care professionals

Background: **Directive 2005/36/EC**, adopted on 7 September 2005, consolidates and modernises the rules currently regulating the recognition of professional qualifications. On 20 October 2007, at the end of the transposition period, this Directive will replace fifteen existing Directives in the field of the recognition of professional qualifications. It constitutes the first comprehensive modernisation of the Community system since it was conceived forty years ago. A number of changes have been introduced compared with the existing rules, including greater liberalisation of the provision of services, more automatic recognition of qualifications and increased flexibility in the procedures for updating the Directive. The Commission is also developing cooperation with Member States in order to keep citizens better informed about their rights and give them more help in getting their qualifications recognised.[13]

To improve the communication between national regulators on EU level, the Commission is developing together with the Member States an "**Internal Market Information system (IMI)**". This is an information technology tool that will to provide faster, more structured, more reliable, more predictable exchange of information between authorities at any level in Member States leading to better implementation of legislation. In autumn 2007 the Commission will start a pilot of the IMI project, an electronic system that will, facilitate exchange of information between the competent authorities of the different Member States with regard to the recognition of professional qualifications.

Need for better monitoring of health professional mobility

Many contributors felt that consistent information about health care professionals' mobility in the EU was important but was lacking (health care professional organisations, unions). To get a clearer picture about health care professional mobility, the effects and any need for Community action in this area, it was proposed that health professional mobility should be monitored more closely at EU level. For a few contributors (in particular unions) health professional mobility is considered to be more important and viable than mobility of patients. On the other hand, other contributors felt that health professional mobility could also be seen as a signal of problems such as difficulties to attract and retain workers in the sector, lack of investment in health care services, or insufficient infrastructures for training and career development.

Issues arising in relation to Community rules on recognition of professional qualifications

There were differing views from contributors about the need for further action on healthcare professional mobility. Especially organisations representing health care professionals and many national governments, felt that the

[13] See webpage of DG Internal Market: http://ec.europa.eu/internal_market/qualifications/future_en.htm.

implementation of **Directive 2005/36/EC** the effects should be awaited before taking new action in this area.

However, almost as many other contributors (health care professionals, regulators, scientist – mostly UK based) said that despite the new legal framework some issues should be addressed. In particular:

– **lack of communication between regulators about health professionals** – the **IMI** is seen as a welcome tool to improve the communication between regulators. Nevertheless, some contributors argued for an obligation on the relevant authorities to share information between Member States about health professionals that are subject to malpractice investigations. The *European Healthcare Fraud and Corruption Network* also argued that existing data protection rules make it impossible to exchange information about specific patients or professionals who have committed fraud. Some contributors (unions, health care professionals, *Italian government*) suggested that the development and distribution of a **Europe-wide Health Professional Card**. It was suggested that this should include a unique European professional identification number to identify the professional, and enable up-to-date information about the registration status of health care professionals should be publicly accessible. Patients' organisations also asked for a **central malpractice register** to protect patients;

– Some contributors (especially from the UK) were concerned that they could not ask for systematic **language testing** when health care professionals wish to register, arguing that only assessment of language skills in a systematic way could guarantee high quality and safe care.

– **Greater clarity about registration rules** was also sought by many contributors, with several contributors particularly concerned about ensuring accountability in respect of provision of healthcare services by professionals based in one Member State but temporarily providing services in another – several contributors felt that such health professionals should be accountable within the country of temporary practice (see responses to questions 3 and 4);

– Some contributors (in particular health care professionals and unions) argued that **mutual recognition of qualifications should be based on skills and competence criteria**, rather than duration of training as at present. It was suggested that this could be linked to development of a common core curriculum for education of health professionals.

Mechanisms to manage the impact of health professional mobility

Contributors from the newer Member States in particular raised concerns about the drain of health professionals to other EU countries to an extent that could destabilise their health systems. The *Union of Private Healthcare Employers* of Poland suggested introducing an **EU education compensation fund** which would provide funding to the states experiencing emigration of medical personnel that require long-term education. A few contributors

(representing nurses and patients) argued for a **code of conduct for recruiting health care professionals**. Some contributors also suggested the development of specific training on language, culture and local best practice for integrating health professionals from other countries. Compulsory liability insurance for health professionals temporarily providing services in another Member State was also suggested (see also the response to question 4 above).

Continuous career development

Several contributors (in particular health care professionals and unions) considered that mechanisms for quality assurance have developed beyond the issue of initial qualifications and also cover continuing medical education, and the introduction of common European requirements for the content and monitoring continuing medical education was suggested. Some contributors also argued that there should be greater European recognition of training periods to achieve a specialization after graduation, in order to overcome remaining barriers to health professional mobility.

Provider establishment

Around one quarter of the contributions from providers, doctors, dentists and national governments sought clarification on the temporary and permanent establishment of providers and services in other Member States. In particular, it was felt that the possible justifications for limiting free establishment need to be clarified.

A few contributions from organisations representing dentists stressed the need for a right of free establishment within the EU, and were in favour of the resulting competition. It was argued that quality of treatment would increase with such freedom of establishment, rather than decrease, and that analysis of the impact of freedom of establishment should focus on the quality of treatment rather than on financial sustainability. It was argued that the financial impact on public funds of such freedom of establishment would be low, as payment is largely not provided out of public funds. Furthermore, some contributors considered that help to improve overall efficiency of medical provision, and that there would be a high potential for overall cost reduction.

Contributions on this issue from regulators in particular (see responses to question 4) stressed the need for providers from other Member States to be obliged to fulfil the same quality criteria (e.g. accreditation and inspection) as resident providers.

Pharmacies and pharmaceuticals

Pharmacies

A few contributors stressed the need for clarity on the rules for free establishment of pharmacies. Some feel pharmacies should be classified as health services or as services of general interest (*e.g. Spanish Government Österreichische Apothekerkammer, FEDERACIÓN EMPRESARIAL DE FARMACÉUTICOS ESPAÑOLES*). Contributors from this perspective argued

that the subsidiarity principle and the steering capacity of regulators in the Member States should be respected.

However, most contributions referring to pharmaceutical services were concerned more about practical issues in the cross-border provision of pharmacy services. A number of practical suggestions were made, including:

– **European standards on prescriptions**. It was suggested that these could build on existing work on the subject by the WHO, to enable mutual recognition of prescriptions within the EU;

– **ePrescription**. In the medium term, many contributors felt that 'ePrescriptions' (use of information and communication technologies for prescriptions) will solve a variety of the practical problems in this area. In Finland, for example, contributors stated that ePrescription is reportedly envisaged for 2007, and suggested that this could become a pilot and possible model for the rest of Europe;

– **Pharma dossier**, ideally integrated in a "patient dossier", for each European patient could increase pharmaco-safety and efficiency in dealing with patient mobility, some contributors argued;

– **Database to check legal status of providers**. A few contributors (in particular representing patients' interests*)* highlighted that patients should be able to check the legal status of providers, doctors and pharmacists themselves. A database for this purpose was suggested. It was also suggested that such a database could be used by doctors to identify qualified colleagues for a necessary referral as well by pharmacists to control the validity of a prescription from abroad (see also the responses to question 2 above;

Pharmaceuticals

Although the consultation addressed health services, some contributors also raised issues concerning pharmaceuticals. In particular, a **Europe-wide comprehensive medicines databases and a European wide system for the traceability of medicines** were suggested. It was argued that these would help to ensure that patients would be able to have access to medication linked to cross-border care after their return to their home country. A specific concern also identified by contributors in this area is the **reporting of adverse reactions** when the product is bought in one country but used in another.

The pharmaceutical industry also argued for a shorter standardised time period for reimbursement prices to be set by national authorities.

Cross-border provision of health services and 'eHealth' issues

eHealth in general

Many contributors that eHealth could help to solve a variety of problems in the health systems of the Member States and for cross-border health care. Suggested were for example the development of ePrescriptions, ePatient records, eRadiology services, eBilling etc.

However, a few contributors argued that most of these types of systems are not yet effective in practice. Contributors from this perspective were cautious about the complexity and cost of common European eHealth solutions, and felt that these could delay necessary action on areas that could be solved more quickly with simpler measures.

Specific challenges related to teleradiology

Several contributors (in particular representing radiologists and industry) identified a specific challenge within the eHealth area of the provision of **teleradiology** services. On the one hand, contributors felt that practical and legal questions related to clinical oversight, liability, registration and data protection were complex and needed thorough exploration (including to what extent they were already covered by existing provisions, such as the e-commerce directive[14]). On the other hand, contributors stated that the provision of teleradiology services from providers both inside and outside the EU is already a reality. Contributors suggested that further specific work be undertaken to analyse these issues further and find effective solutions.

Some contributors already have quite clear ideas what requirements they feel should apply to providers of teleradiology services, and argue that such doctors should in general register with and be subject to the rules of all the Member States to whose patients they provide reports.

[14] See http://ec.europa.eu/internal_market/e-commerce/index_en.htm.

Summary for question 6

Some contributors felt that there was a need for better monitoring of health professional mobility and stressed the potential of IMI in this context. 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 some contributors, with particular regard to pharmacies and dentists. However, most contributions referring to pharmaceutical services 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.

7. OTHER ISSUES REQUIRING CLARIFICATION

Question 7: Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order facilitating cross-border healthcare?

Most of the answers given by contributors under question 7 were related to aspects already covered in the other chapters, and are thus dealt with elsewhere in this report.

Issues related to Regulation 1408/71

It was widely recognised by contributors that the existing regulations on the coordination of social security systems represent a well established tool that has ensured social protection for workers, tourists and patents travelling within the Union for decades. However, some contributors identified areas in which the system is not functioning in practice as well as could be wished. These include:

- **Difficulty to identify a provider that accepts the EHIC**. Some contributors (purchasers, doctors) felt that it was difficult to identify in practice the hospitals and doctors licensed under the social security system of the country concerned to accept the EHIC. In addition, some contributors reported anecdotal evidence suggesting that in some tourist areas ambulance services and taxi drivers intentionally steer tourists to providers not accepting the EHIC;

- **Not all providers accept the EHIC that should do** (purchasers). Contributors considered that often such treatment would have to be paid directly by the patients, with reimbursement then often refused after returning home.

- **Reimbursement procedures can be burdensome for providers.** Some contributors (regional authorities, providers, dentists, doctors) argued the providers were often unwilling to accept the EHIC because of the administrative

burden of recovering those costs, and the delays in doing so. Frequently it took **years to receive payment**, which was even then sometimes only partial payment.

A modernised system of coordination of social security systems is already being put in place, replacing Regulations 1408/71 and 574/72[15]. However, contributors suggested some ideas for improving the system in practice, including:

– Introduction of a **maximum acceptable reimbursement time of 3 months** (providers).

– **Obliging acceptance of the EHIC in practice**. For example, the *Polish Government* (and a patient organisation) proposed sanctions in the case of non acceptance;

– **Acceptance of EHIC allowed for providers not licensed under the social security system** (ie: private providers);

– **Implementation of a "label" of providers** that accept the European Health Insurance Card, to help patients have clear information about access to treatment when they are abroad (mainly purchasers); and,

– **Clearer definition of "necessary treatment"** (national authorities).

Summary for question 7

In addition to the issues identified elsewhere in the report, some contributors identified some 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.

8. SUPPORT TO MEMBER STATES

Question 8: In what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

Most of the answers given by contributors under question 8 were related to aspects already covered in the other chapters, and are thus dealt with elsewhere in this report, such as better information provision and exchange with regard to cross-border healthcare; comparative information and indicators; and development of cooperation on the quality and safety of care. Some other areas of practical support that were particularly highlighted by contributors, however, include:

– Many contributors (including most contributions from doctors and national governments) supported the idea of the establishment of **European network of**

[15] See Regulation 883/2004 and the currently negotiated COM(2006) 16 final of 31 January 2006.

centres of reference in principle, although the specifics remain to be further developed;

– The creation of an **observatory for comparative data and indicators** which would be used to develop policy and strategy was suggested;

– Many contributors saw value in European cooperation in **health technology assessment**, and welcomed the existing pilot EU network in this area;

– Means of **better sharing healthcare innovations** could help them to be better disseminated throughout the EU, it was suggested. For example, in Finland mobile services were developed that enable people to book appointments with the provider online or by mobile phone;

– **Support for making effective use of potential investment in healthcare through the structural funds** was also suggested. The establishment of a **"European Solidarity Fund"** to cover the costs for treating patients that had otherwise no access to necessary cross-border treatment because of lack of resources was also proposed.

Many contributors (in particular several national governments) were also concerned about division or duplication of work on health care between different bodies at European level, and argued for a **rationalisation of activities and resources concerning healthcare** at Community level. Particular areas of concern raised by stakeholders in this context include ensuring coherence of action relating to health and social services of general interest; and activity on e-health.

Furthermore, some contributors argued that as health systems are often organised at regional level within Member States, and that thus **Community action should also involve regional authorities**.

Summary for question 8

In addition to the other suggestions for practical support covered elsewhere in the report, contributors highlighted the scope for practical support on areas including European networks of centres of reference; 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.

9. APPROPRIATE COMMUNITY TOOLS

Question 9: What tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

Importance of issues raised

Overall, contributors to the consultation welcomed the initiative of the Commission regarding Community action on health services in general. The topic is seen as important throughout the national governments and other stakeholders. Respondents mentioned that Community activities in the area of health should not only focus on health promotion and disease prevention, but should also address the care, treatment and services provided to patients.

There was also general agreement that the health systems of the Member States face several common challenges, including the ageing of the European population; constantly innovating healthcare technology and techniques; higher public expectations; improving efficiency in provision of healthcare; and reducing healthcare inequalities. However, the conclusions drawn about the scope for Community action vary. Some responses (such as from non-private health insurers) seek only a limited increase in practical support from the Commission and see no need for legislation, where others call for a legal framework at European level to be developed.

Maintaining social values

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*"[16]. These include the overarching values of universality, access to good quality care, equity and solidarity as well as the operating principles of quality, safety, care that is based on evidence and ethics, patient involvement, redress and privacy and confidentiality. Some contributors also considered that the rights to healthcare set out in the Charter of Fundamental Rights of the EU should be taken into account in any Community action. In that context some contributors (patients' and welfare organisations and providers) argued that specific groups of people need special attention, for example minorities, women, the elderly, the mentally ill and low income citizens.

However, a few contributors (in particular organisations representing dentists) also argued that the principle of "universality" could no longer be achieved in any case due to the evolution of science and ever-increasing prices for possible treatment options. They felt that citizens should take more "responsibility" for their health instead.

Maintaining Member States' capacity to manage health systems

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. In particular, many argued that the 'steering capacity' of national or regional

[16] 2733rd Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg, 1-2 June 2006

health care regulators should be preserved. Many contributors (governments, unions, purchasers, providers) also considered that health services are 'services of general interest', and this should be reflected in considering how internal market rules should be applied in this area. Also it was stressed that health services and social services were closely interrelated as they shared the same characteristics and should thus be governed by the same principles. Some consider health services as part of social services of general interest and therefore call for a coordinated approach between the two initiatives.

Potential of free movement to improve health systems

Some contributors (especially umbrella organisations of dentists and some Member States) argued that the principle of subsidiarity does not prevent the application of EU fundamental freedoms. In their view, increased freedom of choice and movement could be positive, and could help to increase access, quality and financial sustainability, rather than endangering the balance of the health care system.

Some contributions (in particular *scientists and dentists*) highlighted in this context the potential danger of a series of measures that could be used to limit patient, professional and provider mobility against the principles of the Treaty and the rulings of the European Court of Justice. These include a reference to insufficient provision of information to patients, extensive use of prior authorisation requirements, or the general argument of 'danger of instability' to health care systems.

Appropriate type of Community action

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 felt that no legal measures were necessary. The suggestions made by contributors with regard to the content of such measures are included within this report as part of the summaries of the different specific issues outlined above.

Preferred instrument for any legally binding 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.

Summary for question 9

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*"[17]. 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.

10. CONCLUSION

This report summarises the responses to the Commission's consultation with regard to possible Community action on health services. Given the breadth of responses, this report is necessarily less detailed than the responses themselves. However, all responses are available on the web-site of the Commission, and we would encourage those interested to consult specific responses in addition to this summary.

We wish to thank all those who responded to the consultation, and will take all the responses to the consultation into account in future work. The Commission plans to bring forward specific proposals for addressing these issues later in 2007.

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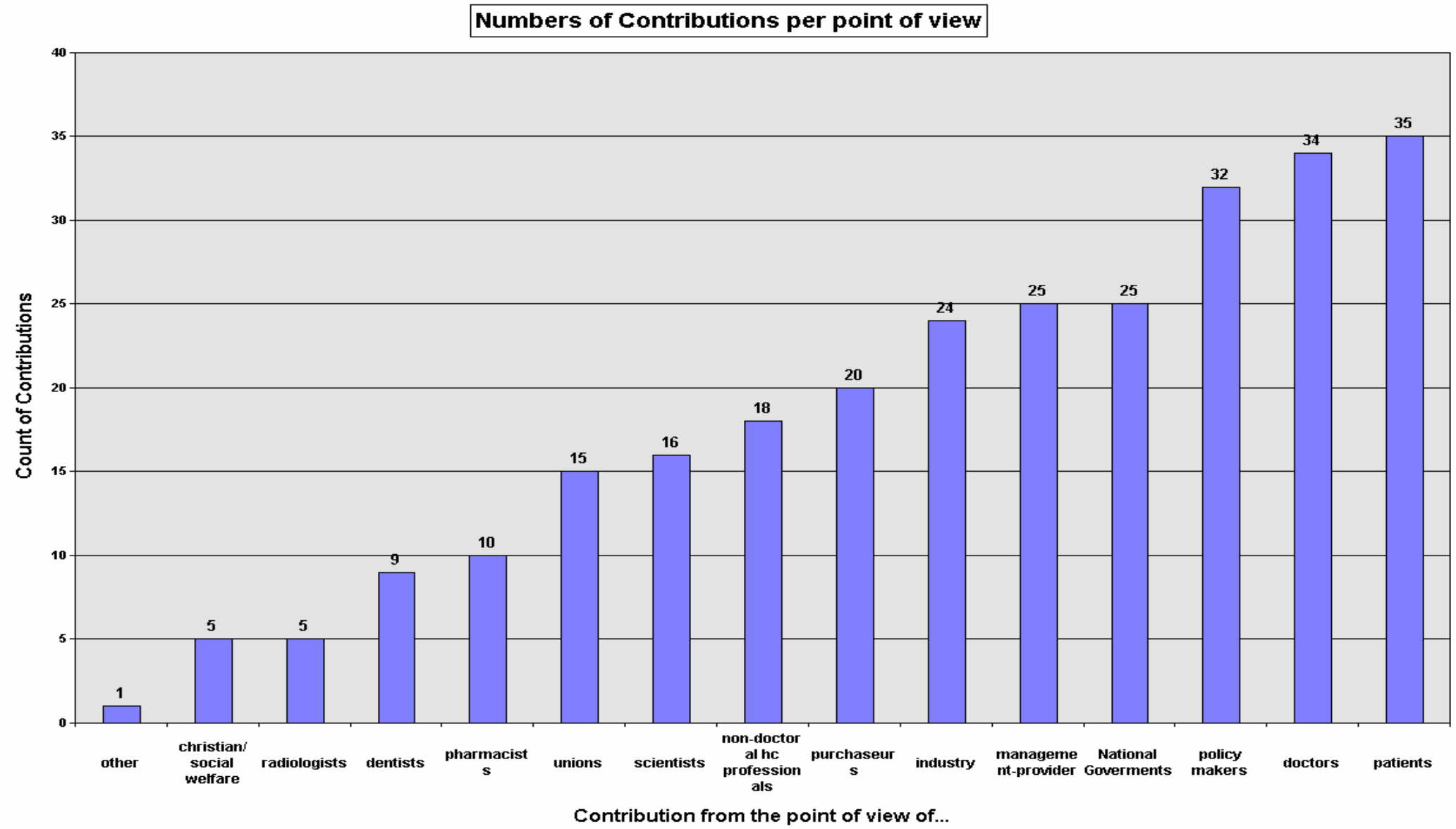
[17] 2733rd Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg, 1-2 June 2006

ANNEX

The annex gives an overview of the distribution of contributors.
The full list of contributors and their responses received may be consulted directly on the Commission's website[18].

[18] See http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm.

ANNEX I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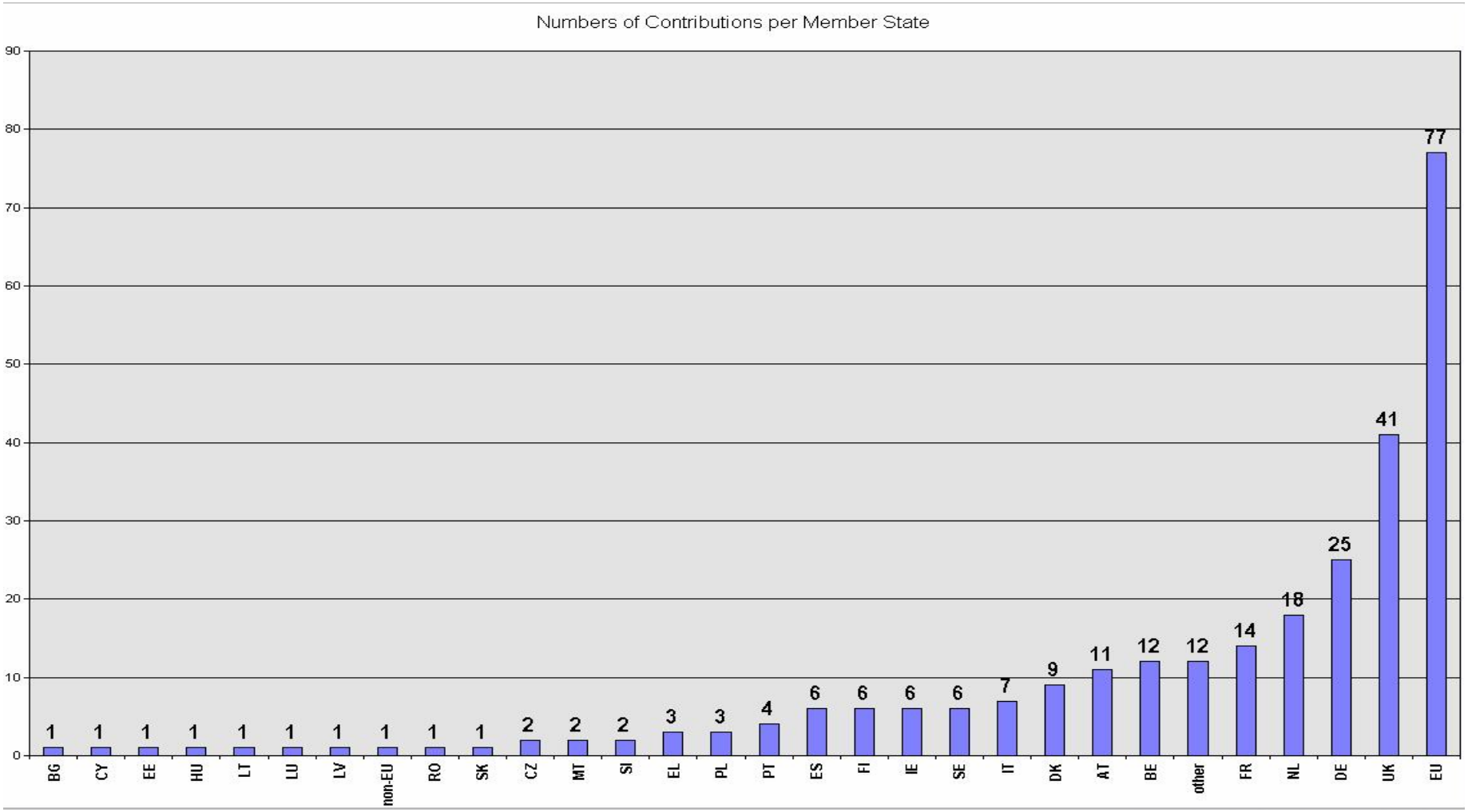
32
34
35
other
christian/ social welfare
radiologists
dentists
pharmacists
unions
scientists
non-doctoral hc professionals
purchaseurs
industry
management-provider
National Goverments
policy makers
doctors
patients
Contribution from the point of view of...

ANNEX II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SI 2
EL 3
PL 3
PT 4
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FI 6
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BE 12
other 12
FR 14
NL 18
DE 25
UK 41
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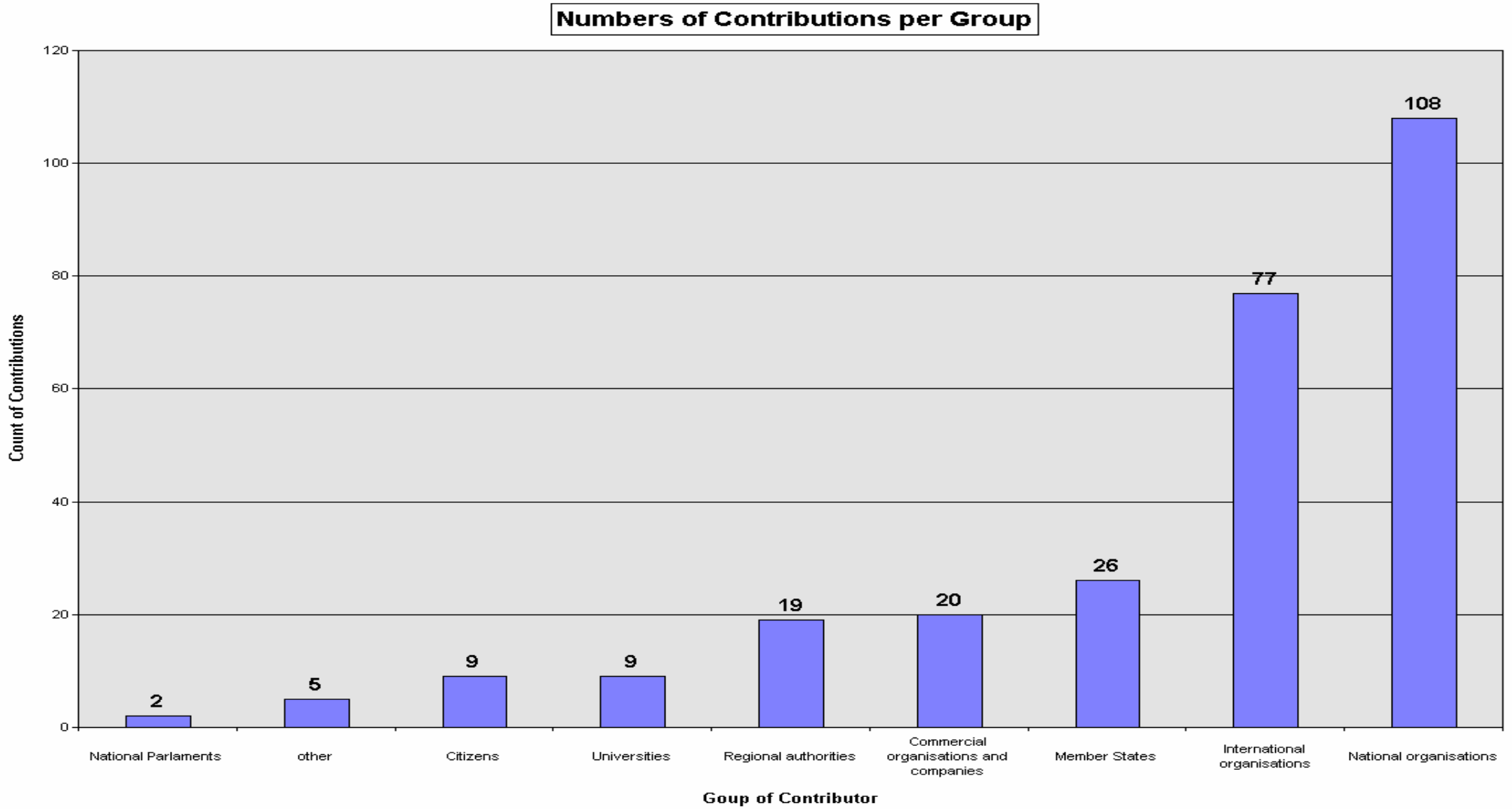
ANNEX III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National Parlaments
other
Citizens
Universities
Regional authorities
Commercial organisations and companies
Member States
International organisations
National organisations
Goup of Contributor