

Consultation regarding Community Action on Health Services

Response of the Veneto Region to the Consultation

Response of the Veneto Region to the EC Communication

"Consultation regarding Community action on health services" (SEC 1195/4 of 26 September 2006)

<u>Summary</u>

The Veneto Region has expressed much interest in the Communication of the European Commission of 26th September 2006 in which a public consultation was launched on the hypothesis of EU action being taken to make "reliable, efficient and high quality health services available through an intensification of co-operation between Member States, with a definite move towards applying Community law to the provision of health services and health treatment".

Following repetitive sentences of the European Court of Justice, and the decision of the European Parliament of February 2006 to remove health-related services from the Directive proposal on goods and services, it has been decided that the directives in the EC Treaty on the free movement of goods and services in Europe has also to be applied to health services. Many national health care administrations – concerned about the possible knock-on effects on the economic sustainability of their respective health care systems – and numerous other interested parties seem to have become somewhat disoriented as far as procedures are concerned when applying the principle to the free movement of health services, and considering the possible impact on safety levels, quality and accessibility to cross-border health care services.

The Veneto Region has, among its priorities, the provision of high quality, accessible health services to those who request them, while at the same time adhering to strict rules of financial equilibrium, sustainability and competitivity of the health system. The Veneto Region foresees the need to give health care stakeholders and European citizens intending to make use of health services in another MS legal certainty, and to intensify co-operation among the various health care systems in the European Union. Consequently, the EC asks itself whether, in order to attain this objective, a Community action needs to be taken in the health services sector and if so, which would be the best tools used for this purpose.

The Veneto Region believes that it is necessary that all health care Administrations within the EU guarantee the full application of the principle of free movement, also of health care services and health protection systems, in the full understanding that the organization and provision of such services falls within the exclusive competence of the MS in accordance with art. 152 of the EC Treaty. The Veneto Region also believes that this principle should be applied and interpreted uniformly throughout the EU, and that citizens be informed fully of the existence and extensions of their rights and duties.

Consequently, the Veneto Region supports the idea that the European Commission should propose a community legislative and regulatory framework with the aim of providing safe, high quality and efficient health services, but also believes this should take place through an intensification of co-operation among regional and national health systems, rather than through the introduction of new EU rules.

In this respect, the Veneto Region believes that if a legal and regulatory framework should prove necessary to guarantee the application of the principle of free movement to health services, the most suitable tool could be the integration of regulation 883/2004 which already sets out the coordination of health protection systems among MS. This solution could, on the one hand, enable a coherent treatment of different community laws regarding cross-border health care provision, whereas on the other, all underlying practical and administrative questions (reimbursement procedures, quality levels of care, *malpractice*, etc.) which should be regulated within each health care system and clearly defined by an administrative body such as the CASSTM in which all MS – even at the regional level – are represented by experts in the field.

It is nonetheless clear that cross-border co-operation is a real laboratory of European construction, with all its challenges, risks and pitfalls.

Introduction

Up until a few years ago one of the fundamental principles of health care organization was that of territoriality, on the basis of which States regulate access to health care services exclusively for the people residing in the territory. For this reason, also in the EU, the various national health systems have each operated alone in a relative state of isolation.

Nevertheless, in the past few years, particularly in the EU, even the organization of health services is undergoing the effects of internationalization of the internal market. This depends on a series of clearly identifiable factors:

- an increase in the mobility of persons for reasons of work, study or simply for tourism, generated by an enlarged EU;
- the mobility of patients and health workers who are respectively looking for or offering health services within the framework of the free provision of services in the internal Market. Repetitive sentences of the European Court of Justice have acknowledged that the costs of medical treatment received in another MS must, under certain conditions, be borne by the health care system of the patient's country of origin¹;
- the multiplying effect generated by new information technologies which facilitate the communication and dissemination of data, as well as the new opportunities to work and receive care at a distance, thanks to telemedicine.

Clearly, the mobility factors outlined above must not be confused with the reasons which motivate individuals to look for health services abroad. The most recent studies conducted at the European level point us towards the following hypotheses:

- Mobility determined by waiting lists and by the need to get around waiting times;
- Mobility determined by a search for highly specialized treatment and/or high quality care which is normally not available in the territory of the MS of origin;
- Purchasing of health services in another MS by the health system (central and/or peripheral) of another MS in order to improve performance (with the resulting transfer of patients to health care facilities abroad)²

We can already deduce from the above how the theme of patient and health worker mobility is raising a number of problematic questions in health care policy-making, both at the national and European levels. This clearly emerges from the report by the High Level Group on the mobility of patients in the EU which places particular emphasis on questions of quality and accessibility of health services, as well as on safety; on information; on the rights and duties of patients who receive these services; on the

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¹ The sentences of the EU Court of Justice can be seen to come one after the other with surprising regularity in the last few years, in particular the cases of: Luisi & Carbone of 1984 which for the first time put forward the principle of the free movement of health services; Kohll & Decker of 1998; Vanbraekel of 2001, Muller-Faure' & Van Riet of 2003; Inizan of 2003 and the sentences Keller of 12th April 2005 and of 26 May 2006.

² The reasons for this mobility coincide only partly with the waiting lists and highly specialized treatment. The other reasons are the better management and planning of services attainable through the use of providers in another MS. This is the case of Malta, or more recently of a series of German hospitals which stipulated contracts to provide laboratory services to hospital facilities in the Czech Republic and in Poland.

bringing into line of national health policies with European policies; and last but not least, on the financial sustainability of health systems.

In its responsibility for managing and organizing its health system³ the Veneto Regional Government is deeply involved in meeting challenges represented by the accessibility of care and the scope and coverage of regional health services.

Over the past five years the regional Health Ministry has had to face the increasing effects of the impact of the free movement of people on the regional health system. This can be defined at 3 different levels:

- Health care requested for whom medical treatment becomes necessary during a temporary stay abroad (eg. for tourism, travel, or work) according to EC Regulations 1408/71 and 572/74;
 - Health co-operation and health care shared between cross-border regions;
- Health care purchased/provided as a service in another Member State (by a specialist, a hospital, or a centre of reference).

This scenario has raised many health policy issues in the Veneto Region, including quality and access in cross-border care, patient safety, information requirements for citizens, health professionals and policy-makers, as well as make it necessary to reconcile regional policies with European strategies.

With the aim of broadening its knowledge on these new phenomenon and to cope with the underlying administrative and organizational problems, the Veneto region has, since 2003, set itself a special task force with the aims of:

- 1 Collecting and providing data on the magnitude of the phenomenon of patient mobility between the Veneto region and other Regions or Member States;
- 2 –Analyzing the impact of cross-border health demand and the related health issues at the regional level to collect information and service provision re-orientation;

In the Veneto region the health care system is made up of:

- 22 Local Health Authorities (LHA) (including 1 Oncological Institute)
- 2 Public Hospital Trusts (Padova and Verona)
- 82 General hospitals
- 56 Public hospitals (owned by the LHAs)
- 9 Private hospitals administrated by the Local Health Units
- 3 National Institutes for Scientific Research (IRCS)
- 7 Private hospitals
- 18 Residential care homes operating (and not) under the NHS, (for approx. 20,000 hospital beds and 900,000 hospital admissions a year).
- 250 Residential homes for the elderly (for approx. 22.000 patient beds, both for self-sufficient and non-self-sufficient). The number of hospital beds in the public system is 19,429 (85.85% of the regional total) with 3,470 private hospital beds, (15,15%) [2002 data] .
- 1076 Specialist health care service providers (for approx. 65 million euros service provisions a year);
- 1307 Territorial Pharmacies
- 4059 General Practitioners (including pediatricians)

³ In the Veneto region the health care system is made up of:

- 3 Mapping and classifying the needs and concerns of EU citizens who require medical assistance when abroad. In particular, information on the patient–system interface; the different aspects of the system arrangements, especially on topics such as demands, patient orientation, access to and quality of care, patient rights and duties and financial arrangements;
- 4 Establishing a detailed framework of the ongoing practices of EU patients receiving care from health care providers in Veneto Region, with a special focus on: a) Tourist flows; b) Patients asking authorization to access the health care system in another European country (using the E112 form); c) Long term residents (such as retired persons) coming from an other MS and living in Veneto for a greater part of the year.

The opinion expressed on the EC Consultation has been widely based on the results of this survey (still ongoing)4.

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?

The current level of impact which cross-border health care is having in the Veneto Region does not differ greatly from the European average of 1% of total public health expenditure. Nevertheless, this figure differs according to the type of cross-border health service being provided. Furthermore, in the particular case of the Veneto Region, the phenomenon of health care provision to those citizens – especially tourists⁵ – who find themselves in the Regional territory for a temporary period cannot be treated separately. This group of citizens represent the clearest example of mobility, both in terms of the numbers involved and in terms of the economic and organizational impact they have on health services provided in the Region.

Actually, a highly restricted view of the problem tends to prevail. The studies lead so far only consider planned care mobility, i.e. based on preventive authorization, without taking into consideration outpatient treatment and/or specialist treatment in another MS. The latter are obviously difficult if not impossible to monitor systematically, especially when the patient for various reasons does not request reimbursement for the treatment received from his/her own national health service.⁶

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⁴ The Veneto Region has also contributed as a partner of the EU research project "Europe for Patients".

⁵ Regarding EU15 citizens arriving in Italy, Veneto represents the top in terms of overall tourist numbers with 54.5 million visits (16% of visits into Italy) and 11.6 million arrivals (14.3% of tourist arrivals in Italy). For foreign tourism: (30.5 million tourist visits equal to 56% of the total number, 6.9 million arrivals equal to 59% of the total).

⁶ The latter phenomenon is more frequent than would be normally expected. The reimbursement procedures tend to be somewhat fragmentary in a number of European countries, especially when the level of expenses incurred is relatively high.

A study carried out by the University of Berlin ⁷ on the German case is symptomatic of this phenomenon. In fact, more than 50% of medical expenses which the interviewees admitted to having sustained during a period of temporary stay abroad were paid directly out-of-pocket, and most of these people did not ask for a reimbursement on their return to their own country for fear of probable delays in administrative procedures, or simply because they had forgotten to do so.

Moreover, we believe that a real evaluation of the financial impact of cross-border health care mobility can only be obtained taking into account the phenomenon as a whole, in its various guises and therefore considering medical costs incurred during temporary stays abroad, and cross-border co-operation. This is particularly valid in the Veneto case. In this Region, the balance between passive and active mobility is positive, thanks to the revenue from health services invoiced according to EC Law 1408/71. In other words, as clearly shown in the table below, in the period 2000/2004⁸ the health care system of the Veneto Region has managed to cover the expenses incurred by its own Citizens who travelled abroad, even obtaining a surplus which it has invested towards improving services in its territory to tourists and/or visitors in general.

- VENETO REGION: Balance of international financial mobility - 2000/2004

Type of expenditure	Costs	Revenue	Balance
Health services provided based on the E-111 form and the EHIC	- 8.057.307,00	12.572.028,00	+ 4.514.721,00
Total balance of the period (costs deducted for health care received abroad by Veneto citizens)			+ 2.358.125,00

A similar situation has emerged on the Spanish coast resorts and in other European tourist hotspots. On the other hand, the countries of origin of the tourists, particular the countries of Northern Europe, found themselves having to cover the costs borne by their own nationals during periods of temporary stay abroad (even longer periods of stay as in the Spanish case).

Summing up, on the basis of the Veneto experience it goes without saying that to understand more clearly the phenomenon of cross-border mobility, an in-depth study and updated European statistics are vital. To obtain a complete picture of the phenomenon in terms of financial sustainability, we cannot exclude health services provided during temporary periods of stay, bound by EC Laws 1408/71 and 574/72.

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⁷ R. Busse, PPT Presentation on *Patient mobility and financial sustainability of health systems* Conference on "*Impact analysis and perspectives of the European Health Insurance Card*", Brussels, 28-29 June 2005.

⁸ A similar positive trend emerged in the financial framework for the years 1995/1999.

- Health care shared between cross-border regions

Cross-border co-operation in border regions has increased during the last twenty years, following a trend other sectors were experiencing. In the health sector, the interest for this aspect of the European construction by the actors on the field has of course been dramatically increased in the legal context created by the Kohll and the Decker rulings (1998). But in those two cases this was carried out in the wider context of patient mobility and not within a co-operation perspective. Patient mobility, being placed on the front line, has reduced the importance of the specific questions and topics of the so-called cross-border co-operation in bordering regions. Co-operation in bordering regions might even be in contradiction with other types of patient mobility: such co-operation highlights the fact that patients want to receive care close to their home and family.

It is nonetheless clear that cross-border co-operation is a real laboratory of European construction, with all its challenges, risks and pitfalls.

As far as the Veneto Region case is concerned, social and health care collaboration in bordering areas is a phenomenon of ever greater importance. Following a series of actions carried out at the experimental level within the framework of the Interreg III programme, the institutional, economic and social relationships forged between the bordering Regions of the Veneto, Friuli Venezia Giulia, Carinthia, Slovenia and Croatia have highlighted a need to strengthen further this collaboration on a political and administrative level, through the institution of a new Euroregio. This would enable a complex programme of international political-administrative collaboration to take place, especially in the area of health emergencies, the sharing of hospital facilities, and joint training programmes for medical and health personnel.

The major advantage of this form of co-operation is the local care approach which can be tailored to different regional needs, thus benefiting patients both in terms of access and quality. Moreover, co-operation in the Euregios has already shown that there is no negative impact on the financial stability of the healthcare systems involved since co-operation entails individual agreements between those concerned, and any higher care costs incurred in the neighbouring country may be compensated for by savings made by combining resources.

The Veneto Regional Government strongly supports this approach and also considers that the European Commission should continue to support it politically and financially.

- Health care provided in an other Member State by a specialist, a hospital, or a centre of reference;

Currently, the regional balance of patients going abroad to receive medical treatment on the basis of Law 1408/71 (and therefore after E-112 authorization) or on the basis of art. 49 of the EC Treaty is predominantly an outflow. In fact in 2003, a total of 328 patients from the Veneto went abroad for treatment for various pathologies. This has shown a stable trend in the last 10 years (in fact it has gone down slightly), with a flow towards the USA on the one hand, and to the EU to health providing centres in Germany, Austria, France and Belgium.

In the future, thanks to the application of the principle of free access to health services in the EU, the relationship between patient inflows and outflows seems to be inverting. The regional Administration is currently negotiating with a number of German health insurance companies in a series of bilateral agreements, to afford complete accessibility and high levels of quality of health services by the regional System to German citizens in the Veneto Region.

Question 2: what specific legal clarification and what practical information is required by whom (eg; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

The experience of the Veneto Region shows that this type of information can be either very difficult to obtain, or appear somewhat ambiguous especially where there is a cross-border element involved. There is no single answer to this question, or in no way can there be an exhaustive solution. In fact, whoever asks for or provides a service, especially health-related, has rights towards demanding the necessary legal clarifications, as well as the vital information to guarantee the safety, efficiency and high quality of the services provided.

The subjects who need to be informed are as follows:

- 1. Public Authorities which administer health need to have a clear vision of the phenomenon of mobility, both passive and active. They need to define uniform models of information, possibly coordinated at the European level, and implement suitable information campaigns to the citizen through decentralized offices, family doctors and specialists. The information to be provide would entail:
- the extension of and limits towards requesting health services in another MS in conformity with the principles set out by the EC Treaty and those interpreted by the European Court of Justice (in this realm there is a clear distinction to be made between ambulatory services and hospital services, as well as a need to indicate health care denied for ethical reasons, or because it is not allowed by law of the State of origin);
- the procedures to be followed to obtain preventive or even successive authorizations where necessary;
- the procedures, and instructions for obtaining reimbursements;
- the administrative and legal action channels to be followed in case of disagreement.
- 2. The purchasers and providers of health care services must safeguard their own rights except where fraud or malpractice are involved– through contractual clauses. Being as situations need to be tackled on a case by case basis, it doesn't make much sense to establish in this context a series of rights and duties applicable to all situations.

Rather, it would be more sound to specify that also the public administrations fall into this category, especially when they negotiate a bilateral co-operation agreement in the health sector, or else authorize the access of citizens to health services in another MS. Considering the high level of responsibility they have towards the patient requesting health care, public administrations must demand a high level of information. This

information should respond to the public's need for transparency and clarity of administrative procedures, as well as to protecting the weakest link in the chain, i.e. the patient.

- 3. As regards the patient, it is clear that of all the elements present in cross-border health care, he or she needs clearly, timely and appropriate information about:
- the extension of and limits to the right to request health services in another MS, in conformity with the principles set out by the EC Treaty, and interpreted by the Court of Justice;
- procedures to be followed to obtain preventive authorizations, or even subsequent authorizations where necessary;
- procedures and instructions to obtain reimbursements;
- ways of taking legal and administrative action in case of disagreement, or due to damages sustained;
- the safety and quality of the service requested.

We would like to stress that the right to safety and quality care are essential elements for all patients, together with the rights to privacy protection and to information. On the other hand, each patient has to have a clear idea of his/her duty and his/her responsibility.

Already the EU has set some standards on patients' rights in specific health care sectors such as on blood and blood products, or on tissues and cells, but other fields need to be covered to guarantee the quality of health care to European citizens as consumers of medical services. With a view to regulating this field, policy makers have to explore ways of satisfying the interests of the patient in the realm of the quality of and accessibility to health care.

A lot of questions still remain unanswered, however: how can patients be kept fully informed about their treatment and their state of health? How can they continue the treatment and in what ways can they take action against malpractice in another member state? Answers have to be found through the comparison among national and regional health systems.

On the other hand, patients have to take their responsibility and have to respect some duties: they need to be aware that overall, cross-border healthcare should not become an automatic activity, but rather should be delivered only where necessary, or provided in the event of temporary unacceptable delays in treatment in their own region.

In conclusion, it is necessary to promote a homogenous system of information flows at the European level. Such flows need to be compatible and suitable for each national or regional health system in which the information is given. Information on the health care professional involved is also vital, and this can be made available through the development and interoperability of intelligent health cards (here we can refer here to the NetC@rds or Ten4Health projects, for example).

Question 3: which issues (e.g.: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Is there a difference between the various types of cross-border services mentioned in the previous point 2.2?

In principle, specialist medical supervision, as well as the safe provision of quality-assured medical care, must be provided in accordance with national regulations by competent authorities and institutions of the country in which the service is provided. In particular, it is unrealistic and impracticable to expect prosecution of any conduct on the part of service-providers in one Member State which may be at fault by authorities or facilities of another Member State. The corresponding facilities of each Member State are also competent for ensuring that patients from other EU countries are treated without discrimination.

The following should be the responsibility of individual national systems which coordinate with other MS:

- the kind of entitlements that patients have regarding access to care such as type of care, and time period of access to care;
- quality and accessibility of the services, costs per type of care and the right of patients to information (e.g. adverse incidents concerning professional deontology, etc.)
- the legal framework which should obviously include: privacy and ethical issues in order to defend patient rights, that are, above all, human rights (such as the right to physical and mental integrity and security, and the right to respect his/her moral, cultural and religious values).

To achieve the above-mentioned goals is necessary to develop a health information system at the EU level by taking appropriate action in order to prevent the economic consequences of adverse health effects of other policies from shifting to the health sector: for instance by developing an equity monitoring system, introducing an equity audit as a systematic activity in all health-related activities. This system should enable:

- the linking of different existing national systems and the collection of varied information needs from the perspective of policy-makers, patients and professionals;
- the dissemination of information on available healthcare, existing supply of care, procedures, costs, quality of cares, adverse incidents, nomenclature of conditions, surveys on professional activities, etc.

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?

The Health Authorities of the Country or Region where the service is provided have the responsibility to supervise health service-providers and then should be directly responsible for ensuring safety.

Concerning the legal actions available to the patient he will refer to the respective national administrative and social law, as well as to International Private Law.

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?

There are two issues that need to be tackled here:

- equality of treatment among patients belonging to different systems, and the ironing out of possible inequalities;
- the difficulties encountered by health systems which have to sustain heavy flows of people during critical times of the year.
- a) Reducing inequalities in access to health care abroad could be reach through:
- a set of rules addressed to both patients and health care professionals;
- a clear distribution of responsibilities;
- stimulating co-operation between organizations at all levels;
- building up a network for an exchange of information between member States on: patient rights; the role of lay persons in promoting health in their own environment; the exclusion of certain groups of patients, particularly the chronically–ill and people with disabilities from society;
- promoting the right of citizens and patients to participate in the decision-making process affecting health care;
- annual assessment of equality in access to health care services performed by third parties (groups of experts, NGOs, citizens/patients associations, etc.).

b) – *Mass flows accessing local health care systems*

Some European regions in border areas or tourist districts have to face health problems due to recurring mass flows that must be solved by the local health organization to guarantee the health of both residents and non-resident people.

The vast tourist flows of some Regions has, on the other hand, anticipate the collaboration among the European health systems because tourist districts have had to tackle the problem of incoming European citizens from different countries having different health systems, different organizations, but also different languages and cultures.

Special attention has been afforded to the consequences of the mobility of citizens in terms of public health for the potential spreading of communicable diseases. But similar attention has not been given to the services dealing with situations in which tourists need medical treatment due to an accident or acute disease during their stay, or to the impact on the health infrastructure of the region. It is generally acknowledged that health services in tourist districts must not only deal with acute diseases or with the results of accidental events of healthy people, but also with the demand of health services by tourists with "special needs" to ensure continuous cost-effective healthcare services to European travellers with chronic diseases, or disabilities.

The high concentrations of people in tourist districts during the summer created by mass tourism need flexible health services. On the grounds that the local health organisation must be strengthened, medical treatment in the hospital or in the surgery must be reinforced and made more successful by increasing the range of its activities and the amount of work it does.

This particular purpose is possible only with specific investments in human resources, for example, and appropriations of funds with a view to providing tourists with effective health services.

For this reason the Veneto Region has provided an specific annual financial contribution (in 2005 more than 9 million Euro) for enabling the Local Health Authorities (LHA) with massive tourism flows to afford the increase in demand of health services.

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

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 to facilitate cross-border healthcare?

It is essential that each Member State has the right to regulate the nature and features of the healthcare delivered to be the same for both residents and non resident and foreign patients.

Moreover, the MS have the right to exclude services from the list of social insurance services, or to completely prohibit their provision on their sovereign territory in accordance with their national values and standards.

Question 8: in what ways should European action help support the health systems of the Member States and the different actors within them?

It is quite clear that there are huge differences in the judicial and administrative bases on which hypotheses on mobility are based and regulated, as well as among the different national health systems. Moreover, recognising that cross-border healthcare is not only an issue at an individual patient level, but that the phenomenon has been institutionalised, the EC would have to provide the means for debate and to enable policy makers and stakeholders (mainly social insurers, health professionals, and patients) to share views and experiences, but also discuss effective strategies to cope with the

consequences of medical treatment received or provided abroad, allowing national and regional health systems to put forward the possible solutions.

The Veneto Region believes, for example, that the following could be useful and valid tools:

- 1.to draw up a <u>common European "Glossary"</u> able to clearly define issues such as "without undue delay", "standard practices", "comparable cost", "hospital care", "major out-patient care" and "minor out-patient care", and to ensure maximum uniformity between Member States on prior authorisation requirements and on the interpretation of "a medically justifiable time-limit";
- 2. to explore whether it is possible to draw up clear, transparent and non-binding *guidelines for healthcare purchasing* which competent bodies in Member States could use when entering into agreements with each other, and then implement legislation through the European Court of Justice on the right of patients to benefit from medical treatment in another Member State;
- 3. to call on the Member States, coordinated by the Commission (where appropriate i.e. according to art. 293 ECTr), to strength the co-operation and <u>establish the framework</u> which, in its aim to avoid health inequalities among patients, should include procedures to obtain treatment, uniform mechanisms for paying for care, arrangements for travel and linguistic support, arrangements for continuing care, follow up, convalescence and rehabilitation prior to and/or after return, complaints and other related procedures;
- 4. to explore further the possibility of participation of <u>Regions and local health care</u> <u>systems</u> to the debate using the positive results of bordering regions and euroregios and health regios.

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?

The Veneto Region believes that in its current state the applicability of the principle of free movement on the basis of art. 49 of the EC Treaty, not only of goods (equipment, pharmaceuticals, etc.) and of health workers, but also of health services and medical services is a reality which prevails in all health systems of the European Union.

The dissemination of information on decisions reached by the European Court of Justice, the Communications of the Commission, the work being carried out by the High Level Group, the co-financing of projects on mobility, and the work of researchers and experts is such that no national public health administration can afford to ignore the phenomenon.

Moreover, being as we are dealing with the application of one of the fundamental principles of the EC Treaty, this has in itself direct applicability, as the Court reminds us on numerous occasions. An application can be found, even independently of the existence of a secondary norm of application.

Considering the fact we are dealing with an application of a principle of community law to an area which falls within the exclusive competence of the Member States (on the basis of the often quoted art. 152 of the EC Tr.), it is up to the MS to modify national legislation accordingly. If, however, the MS fails to adapt its system, the Commission could take legal action against the MS for infringement (ex art. 226 EC Tr.).

The Veneto Region doesn't think legal action is necessary in order to impose the above-cited principle, but for reasons of coherence it could be useful to focus on the principle to create a future community reference frame based on the availability of safe, high level and efficient health services.

To this purpose, we believe this principle could be contained either within a Directive proposal dedicated to the health care services sector and based on art. 95 of the EC Treaty, or better still in a specific chapter inserted into EC Law 883/2004 (which will subsequently need to be amended) and in the relative Law in its negotiation phase currently being enforced at the Council of Ministers of the EU.

This approach would have two major advantages:

- On the one hand an organic and systematic treatment would be obtained of the question of cross-border health care services, whether they be unplanned (ex art. 22, 1 Reg. 1408/71) or planned (ex art. 22, 2 Reg. 1408/71) or voluntary (ex art. 49 EC Tr.), combining them all in a single, legal document. This is especially important if the citizen is to have a thorough understanding of the information being provided on his behalf.
- On the other hand, all the practical and administrative questions relating to cross-border health care services (for instance procedures and methods of reimbursement, levels of quality of care provided, legal action procedures in case of *malpractice*, standards of application, continuity of care, etc.) which necessarily need to be regulated within each health care system according to its organization, can be negotiated and defined by an administrative body such as the CASSTM in which all MS even in their regional enumeration of facts– are represented by experts in the field.

Naturally, the same results can be obtained through an ad hoc Directive, but this would have the effect of separating the regulation of unplanned care (ex Reg. 1408/71) from voluntary, planned care which the Region, for reasons explained above (see for example Question 1) does not agree with.

In conclusion, the Veneto Region:

Supports the initiative of the Commission to implement a community legal and regulatory framework aimed at highlighting the availability of safe, high level and efficient health care services;

Believes it is necessary, to this end, that certain aspects of cross-border health care provision need to be tackled using legislative means;

Believes that the result of a coordination among national and regional health care systems to guarantee health care services which are compatible with the principle of free movement and with the principle of sound administration and financial equilibrium can be obtained. This can be achieved through recommendations, communication or by drafting guidelines on the one hand, and on the other by boosting concrete co-operation

initiatives between health care systems (for example, by increasing the creation of Networks of Centres of Reference) to guarantee facilities able to promote the practical day to day functioning of the co-operation.

It is nonetheless clear that cross-border co-operation is a real laboratory of European construction, with all its challenges, risks and pitfalls.

This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.