MINISTRY OF HEALTH
AND CONSUMER AFFAIRS

Response from the Spanish Ministry of Health and Consumer Affairs to the European Commission's consultation on Community action on health services

(Communication from the Commission of 26 September 2006)

Madrid, 31 January 2007

1. GENERAL CONSIDERATIONS

1.1. The need to tackle health services from a European perspective based on universality, quality, equality and solidarity

It is now a fact that there is considerable interaction between health policies and health protection systems in the European Union; increasing mobility amongst patients, professionals and providers throughout Europe can also be observed, allied with rapid dissemination of information and of medical advances via information technologies, the impact of other Community policies and the EU's own activities (Commission, Council, Parliament and Court of Justice) in the health sector. Finally, in connection with the above, the existence of common risks to health makes it necessary to coordinate mechanisms so that the way the Member States' health services operate takes on an increasingly European dimension. This is also underpinned by the positive fact that European citizens are steadily becoming better informed and are aware of their rights.

Recent rulings by the European Court of Justice (ECJ), establishing that the principles of free movement are applicable to health services, irrespective of the way in which they are organised or funded at national level, have launched a debate on the best way to continue developing the European dimension of the Member States' health systems, which must be firmly based on the common values and principles adopted in June 2006, whilst abiding by the principles of legal certainty and subsidiarity.

In 2006, the Parliament and the Council took the view that incorporating specific articles on health services in the internal market services directive was not the best way of achieving this and asked the Commission to explore the best ways of drafting specific proposals to this end.

In June 2006, as mentioned above, the Council approved a document on conclusions on "Common values and principles in the Member States' health systems" which Spain fully endorses. These values are universality, access to high-quality care, equality and solidarity. The document also includes a series of operational principles endorsed throughout Europe, namely: quality, security, evidence and ethics-based care, patient involvement and respect for privacy and confidentiality.

For some of these principles, the document specifies areas where European citizens are entitled to expect the Member States' authorities to intervene to guarantee the provision of accessible and high-quality health care. In the case of quality, for example, the document says that this is achieved "in particular by training healthcare staff based on clearly defined national standards and ensuring that staff have access to advice about good practice in quality, stimulating innovation and spreading good practice, developing systems for good clinical governance, and through monitoring quality in the health system". The same is true of "safety", "evidence and ethics-based care" and "patient involvement".

In September, the Commission presented a Communication in order to launch a public consultation on the aspects of health services which Community action should address and on the right tools to be used in each of these fields. The consultation is intended to elicit contributions from the Member States, the European Parliament and other players in the health sector including citizens, patients' associations, health professionals, providers and national and regional health authorities.

The Communication from the Commission includes an introduction, justification of the action by the EU in the health services sector, a breakdown of possible areas for Community action and a description of the instruments to carry out this action. The operational part is made up of nine questions. The first seven refer to patient, professional or provider mobility. The eighth opens the doors to topics other than that mobility and the ninth refers to the instruments of Community action (legislative or non-legislative) considered appropriate to tackle these issues.

1.2. Spain's position

Spain has already expressed its view in various fora that that some of the issues stemming from both the challenges facing the Member States' health systems and the ECJ's rulings need to be addressed by means of specific European legislation. It also has held that this legal framework must be based on the common principles and values and the operating principles included in the Council's conclusions, which constitute essential guidance for the exercising of citizens' rights with regard to health.

Spain believes that the consultation process opens up an opportunity to plan a development in the EU health's policies which is informed by citizenship and progress and that the debate should therefore not be restricted to questions stemming from "patient mobility", although this topic forms an essential part of it.

Spain therefore believes that the European legal framework on health services should also address issues such as health information systems, coordination in the event of health alerts and emergencies, specific elements of policies to promote health and public health (such as vaccinations), general conditions for authorising and accrediting health centres and establishments (including European reference centres), classification of pharmacies as health services due to their specific involvement in the Spanish National Health System, since, apart from storing, safekeeping and dispensing medicinal products, they also participate in the management of the procedure for the public financing of health medicines and products included in the pharmaceutical care provided by the National Health System.

General joint criteria could likewise be included for preparing programmes for training health professionals (in particular post-graduate and continuing training), for preparing national healthcare quality and safety programmes with some minimum common elements and for developing active national policies designed to prevent discrimination with regard to citizens' access to healthcare on the grounds of gender, ethnic background, culture or level of income.

All the above has a bearing on quality, and ultimately equality, in healthcare. It is all guaranteed in one way or another for virtually all the citizens of the Member States, in many of which there are – sometimes long-standing - action programmes or Community initiatives. In most of these, it would be enough to include one or several general definitions, establish areas for action and to lay down common criteria to which Member States could be held by citizens and/or Community institutions.

1.3. Patient mobility

European citizens are entitled to high-quality healthcare and the benefits provided by the various EU health systems are determined by the Member States themselves.

Patients wish to benefit from high-quality healthcare as close to where they live and as quickly as possible. They will tend to go to other Member States if they believe that they can obtain better or cheaper health services and/or quicker.

Access to healthcare may depend on having the right information on the quality, availability and suitability of various services and the clarity and predictability of the procedures to be followed.

The term "patient mobility" or "cross-border healthcare" covers a number of different situations from both the patients' and the funders', insurers' and providers' point of view. The most common situations are: a temporary move to another Member State for various reasons (work or tourism), long-term residence (permanent or interrupted) in another Member State, patients who are referred officially by insurers or providers to another Member State and patients who are seeking treatment on their own account.

The vast majority of these situations have been and still are resolved on the basis of bilateral agreements or conventions between the Member States. In general, these do not cover reimbursement of costs in the case of patients who seek treatment on their own account, although they do so in the case of emergency treatment if certain conditions are met.

Until 1998, the only Community mechanism enabling patients to receive treatment abroad (except when the treatment was paid for by the patients themselves) was Regulation 1408/71, which entitled patients who needed to be treated whilst staying in another Member State to the same benefit as the patients insured in the host Member State. It also made provision for the possibility of treatment in other Member States subject to prior authorisation.

In 1998, the European Court of Justice ruled that the provisions on free movement of services applied to health services and that the measures which subjected reimbursement of the costs incurred in other Member States to prior authorisation were obstacles to freedom to provide services, although they might be justified on exceptional grounds of general interest (such as, say, the risk of seriously undermining the financial equilibrium of the social security systems).

The additional principles established by the ECJ are: a) any outpatient care to which persons are entitled in their own Member State can also be applied for in any other Member State without the need for prior authorisation and will be reimbursed to the level provided for by the system in the patient's own country; b) any inpatient care to which persons are entitled in their own Member State can also be applied for in another Member State, as long as prior authorisation is obtained in the country of residence. This authorisation must be granted if the clinical situation is such that the system cannot provide the care in a medically acceptable time. Such treatment will be reimbursed at least to the level of reimbursement provided by the system in the patient's own country.

The legal instrument which Spain proposes for "patient mobility" should therefore include the general principles which inform Regulation 1408/71 and the additional principles established by the ECJ. In the case of a), with due caution to the increasing scale of outpatient care, this legal instrument should serve as a reference for the process of revising the Regulation to update its context to the new situation in European health services 36 years after it was adopted.

2. RESPONSE TO THE QUESTIONS RAISED BY THE COMMISSION

Question 1

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

The precise impact in terms of numbers of persons affected and the financial impact are not known. Official data from the forms sent to CASSTM (which do not necessarily correspond to the number of patients) are available but there is no information on patients who, instead of using public health services, use travel insurance (Europassistance or similar) or purely private patients, who, although they do not have any effect on the National Health System, do have an impact on the health system in general.

By the same token, the number of “fake tourists” (permanent or semi-permanent residents, mainly retired, who request services as tourists) is not known either.

Moreover, the difficulties in providing quality cross-border healthcare in a different language should not be underestimated.

Finally, the uncertainty generated by the possibility of future rulings by the ECJ on cross-border healthcare is also problematic.

Future developments will depend on new rulings and the outcome of this consultation.

Question 2

What specific legal clarification and what practical information is required by whom (e.g. authorities, purchasers, providers, patients) to enable safe high-quality and efficient cross-border healthcare?

The health services or health benefits European citizens travelling from other Member State are entitled to would have to be defined.

To request a given health service in another Member State, the health system of the sending Member State must make the referral to the host Member State in order to discuss and establish certain conditions for referrals between Member States which would be applied equally by all of them.

This means that consideration must be given to the need not only for prior authorisation by the referring Member States but also for acceptance by those States receiving patients.

These services should be defined in a *Joint catalogue of EU health services*, at least for care "which is necessary in the event of temporary movement". In the case of scheduled care, the catalogue is defined by the country of origin. In any event, here too it must be made clear that the principle of subsidiarity applies, that organisational responsibility lies with the Member States and that there is no question of harmonising health services in the EU treaties at present.

The Member States should publish the services which they offer and include additional information on the competent authorities, how these services operate, selection procedures, quality standards, cost of the services, whether patients have to make a contribution to the costs, conditions for reimbursement, etc. An indication may be given as whether all the information is universally accessible or whether types of information and channels and levels of access for various types of players such as citizens, health professionals, authorities, insurers, etc. have to be identified. The language in which health professionals provide services should also be indicated.

This might be useful, at least in an initial phase for information about cost, procedures and formalities, times (waiting list), notifiable and other diseases.

Providers will need to know if they can recover the costs of care, who will bear the costs of interpretation where necessary, who is responsible for patients after their discharge, what happens if undesirable secondary effects arise after discharge, if preference is given to patients from abroad over local patients or the reverse, what is covered for cross-border patients, where are they put on the waiting lists and what benefits are not available in the country of destination or which are but cannot be requested because they are not available in the country of origin. The interaction between outpatient and inpatient care, care at home and emergency care has to be clarified properly in each Member State.

It is important for the majority (if not all) information on European health services to be accessible. Such information might therefore be disseminated through the Commission's website and by the contact points in the Member States.

Question 3

Which issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

Issues such as the organisation of the health system, laying down the entire range of benefits for citizens in the country, health cover, quality standards and working conditions for health professionals must be the responsibility of the authorities of each country.

In any case, it must be made clear that the principle of subsidiary applies, that organisational responsibility lies with the Member States and that there is no question of harmonising health services.

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 for the safety of cross-border healthcare should lie with the country of origin when patients are referred officially because there are waiting lists or a lack of capacity. The country of destination should be responsible for the care provided on its own territory.

If any harm comes to patients, compensation must be arranged and established in accordance with the standards of the host country. For patients referred officially, the country of origin may want to secure additional "assurances". Deciding what happens if the problem arises some time after the treatment and it is not clear whether it can be attributed to the treatment or the illness itself is a delicate matter, although patients will probably take the matter to the courts in their country of residence and the court will decide who is to pay. It would also be necessary to establish European rates or charges so as to ensure that there is a reciprocal system with the country of origin.

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 service accessible to all (for example, by means of financial compensation for their treatment in "receiving" countries)?

The countries which provide the service should be reimbursed at cost and no more, otherwise there would be an incentive for providers to treat more foreign patients who would be more profitable. Citizens in transit should not have better conditions of access to services or receive additional benefits which might divert funds away from resident patients (for example, money spent on interpreters could be used for more and better benefits for nationals). A European compensation fund also ought to be set up in such cases to ensure that requirements for adequate care (such as interpreters etc.) can be funded.

Patients should not obtain any economic advantage from care in another country by, for example, avoiding patients' contributions, which would be an incentive to seek healthcare from other countries' 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?

For the purposes of establishing health professionals and centres from other Member States or third countries in the territory of an Member State, it will have to be made clear that the requirements for opening and operating private services in a country must comply with the standards of that country (for example, if a citizen from X goes to Y to receive outpatient healthcare without prior authorisation and has to be reimbursed as advocated by the ECJ, what happens if the same doctor who treats them decides to hold a doctor's surgery in X three days a week? What would happen if, instead of this, he established a medical advice line (by telephone) to treat patients from X or Z without moving from Y? Would this be cross-border healthcare or private healthcare?)

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?

Thought should be given to setting up a high-level political body like the Social Protection Committee, where these issues can be discussed, and a specific discussion forum bringing together the authorities responsible for social security and health.

Clear and precise conditions must be laid down so that the Member States know what they can regulate as a national area of responsibility and what will be subject to the standards of the internal market.

As a rule, patients should not go to other Member States on their own initiative to request a specific health service but it should be the health service of the sending Member State which makes the referral to the receiving Member State.

Specific conditions for referral between Member States should be discussed and established which would be applied equally by all of them. The need for both prior authorisation by the sending States and acceptance by the receiving States should therefore be considered.

The possibility of establishing special agreements for the care of border populations should also be included.

A mechanism for maintaining the continuity of the health care process in the event of health services being provided in other Member State should be examined.

The cost of health services provided in Member States other than the country of origin raises a series of questions which need to be clarified.

The need to move towards harmonising charges for services between various Member State merits some consideration. As an initial steps, measures will be taken to ensure that these are known to citizens, professionals and financers.

A mechanism is also needed to prevent any Member States from making referrals in order to avoid healthcare which is more costly in their own countries and claims for damage (for example in the case of serious, complex or high-risk diseases or procedures).

Question 8

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

As stated in the general section, a legal instrument such as we propose could include more than patient mobility. *Inter alia*: health information systems, coordination in the event of health alerts and emergencies, specific elements of policies to promote health and public health (such as vaccinations), general conditions for authorising and accrediting health centres and establishments (including European reference centres), classification of pharmacies as health services due to their specific involvement in the Spanish National Health System, since, apart from storing, safekeeping and dispensing

medicinal products, they also participate in the management of the procedure for the public financing of health medicines and products included in the pharmaceutical care provided by the National Health System.

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Question 9

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

A legal instrument such as we propose would constitute basic common rules and would enable other procedures (in particular the method of open coordination) to continue to be used on a number of issues, in order to, say, refine information systems, identify and disseminate good practice, define criteria for determining European reference centres and services which enable high-quality services to be offered to citizens with strict quality and efficiency parameters, and to organise health cooperation trials between border areas, etc. Many of these issues are already dealt with in the high-level group and other Commission and Council working groups.