MINISTRY OF HEALTH OF THE REPUBLIC OF HUNGARY
SECRETARY OF STATE

757- /2007-0010EKF **” ” January 2007**

Mr. Robert Madelin
Director-General

European Commission
Health and Consumer Protection Directorate-General

B232 8/102
B-1049 Brussels
Belgium

Dear Mr Madelin,

Please find enclosed the answers of the Hungarian Government to the questions put by the Communication of the Commission on Consultation regarding Community action on health services.

Sincerely yours,

Ágnes Horváth

Position of the Hungarian Government on the European Commission's communication regarding its consultation concerning health services

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 volume of foreign patient mobility does not influence the accessibility, quality and financial sustainability of healthcare services in Hungary. In view of the expenses of the Healthcare Fund, both the number of cases and the volume of expenditures are insignificant. The patients arriving in Hungary mostly use private services and the influence is positive there. In order to develop it, it is necessary to improve the provision of information on cross-border healthcare and to examine how the possible free capacities of the publicly financed service providers could be used better, and, furthermore, it is necessary to explore the reasons of the positive effects appearing in the private sector – also in view of the structural changes currently taking place in Hungary. The mutual development of certain fields of cooperation organised along the borders and the redirection of patients may contribute to the establishment of more economical services.

When developing our position, the following points of view were taken into account:

- Motivations of the foreigners coming to Hungary: less expensive, but good healthcare, and shorter waiting time. The fact that patients looking for special expertise or equipment would individually arrive in the country cannot be considered as general.
- In Hungary, the service providers receive foreigners in the following fields: dentistry, plastic surgery, spa therapy, addictology, and care for the elderly. We consider that the degree of use is low, although exact information is not available in this respect.
- It is almost exclusively the private healthcare providers that receive foreigners in large numbers in a targeted (planned) manner.
- Those participating in public financing use healthcare in a limited number in the field of emergency services (on the basis of Community law); the number of cases submitted for financing on this basis was 3,569 in 2005. In 2005, 137 patients arrived in Hungary with E112 forms. On the basis of Decree No. 227/2003. (XII. 13.) Korm, 380 patients were authorised in Hungary to use foreign healthcare services charged to the Healthcare Fund. The target states include primarily Austria (e.g., in the area of lung transplants), Germany (e.g., in the area of liver transplants for children and in the area of treating patients with cleft palates) and Switzerland (e.g., in the area of providing special Y90 DOTATOC isotope treatment for locomotor disorders and spinal diseases.
- In the fields referred to above (concerning private service providers), the effects were positive because the services retained highly trained professionals, the instrument park was well equipped, and they promoted not only the healthcare services, but also the supplementary services (hotel services) and, because – due to their private character – they did not have a bearing on accessibility either.

- Consequently, for the time being, the effects are limited; they are related mostly to private providers and produce positive effects there.

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?

Our fundamental idea is that the questions relating to healthcare should continue to be handled under Member State authority, while a system can be developed in which a structure that serves the patients' interests and offers them greater opportunities is established. In this system, however, it is expedient to rely on the already existing legal sources, to integrate the actual legal questions into these legal sources, while it is advisable to handle the other, not necessarily legal, questions by relying on a set of tools that ensures maximum voluntary Member State activity. Hungary is to represent a position that promotes a long-term improvement in the situation of both the citizens and the services (e.g. by increasing the financial means that can be drawn in from the EU), while avoiding an exigency, which passes the regulation of the different elements of the health system into "external" hands in a way that makes later performance difficult. Therefore, our actual proposals can also be divided into two groups. One of them includes the actual legal questions that we consider adjustable, while the other one deals with questions where the emphasis is laid on networking and self-development.

The questions to be regulated are to be identified first, and this can then be followed by a discussion of the ways to seek the solutions. We consider it important that the economic, social and health impacts of cross-border healthcare on the citizens and on the health and social security systems should be thoroughly analysed. This analysis must also include the impacts on "receiving" States (including appropriate cross-border financing) and, especially, on the economically backward Member States.

I.

In our view there are questions of detail, the solution of which seems indispensable for ensuring an optimum application of the currently valid legal regulations. Essentially, two avenues may be open. On the one hand, it would be expedient to examine whether these questions of detail could be regulated under Council Regulation (EC) No 883/2004 on the coordination of social security systems and under Directive 2005/36/EC on the recognition of professional qualifications. Even today, certain provisions of, and the enforcement regulation relating to, Regulation (EC) No 883/2004 are being considered; the aim of the provisions included in the sickness and maternity chapter is to implement the legal cases of the European Court of Justice (Kohll and Decker etc.).

On the other hand, if that avenue is not feasible, or if, on the basis of some other considerations, the adoption of (a) separate legal regulation(s) would seem to be a more optimum solution, one should consider both the advantages and disadvantages of such a course. In this case, regulation by directives is worthy of consideration for the Community level handling of healthcare services. The aim of regulation by directive could be a framework regulation laying down the most fundamental rules, thereby avoiding over-regulation. As far as the technique of regulation is concerned, the

Community framework regulation could contain horizontal rules, which could be applied and made more concrete by Member States in consideration of the country-specific conditions. The regulation should pay primary consideration to the interests of patients and service providers without endangering the equilibrium of the social systems.

We consider the following as questions that are to be solved:

- The legal possibilities introduced by the European Court of Justice in the *Kohll and Decker* cases should be recorded in a legal regulation, according to which the insured may, in other Member States, resort to other than hospital treatment even without preliminary permission and – in this case – may claim reimbursements up to the actually arising costs, but within the limits of the tariffs applied at home.
- The record systems are not uniform; the forwarding of patient data raise *problems of data protection*, in respect of which authorising provisions could be put in place;
- One should regulate the exact conditions for the insured of another Member State *to get on a waiting list and to get off that list*. Since health insurance is in national competence, Member States should avoid harming the interests of their own insured (e.g., how could a situation be handled if too many people arrived in a Member State from other Member States; is the Member State in question obliged to receive all the patients). The possibility for completely separating the waiting lists for domestic patients and those for patients arriving from other Member States should also be considered because it would thereby be possible to monitor the number of registrations made by a given patient on the waiting lists of Member States open for foreigners. In addition to getting on waiting lists, separate financial compensation to the receiving country is also a question to be studied.
- Some kind of a uniform handling of *responsibility and compensation* for possible professional errors should also be considered; as an alternative, a solution could be considered whereby the providers of planned healthcare to foreign patients should satisfy more stringent liability insurance provisions, which would also cover possible compensations. According to Hungarian providers, they would not be able to pay any compensation fixed in another Member State if that compensation exceeded the amount paid in Hungary.
- Questions relating to *the protection of consumers*.
- In this respect the recognition of the liability insurance of healthcare professionals in other Member States arises.
- The Directive on the recognition of professional qualifications contains different provisions relating to certain conditions for carrying out activities in the field of cross-border services. The application of these provisions raises several further legal and procedural questions. The differences existing in Member States in the levels of competence that may be required for carrying out certain professional activities could be an example, the handling of which is necessary in the case of providing services in the territory of another Member State.
- In the field of the recognition of professional qualifications, there are no harmonised rules regarding *further training*. In some Member States, participation in compulsory further training is a precondition for practicing the profession; in others participation in further training is only a recommendation. There are no rules, however, that would ensure that participation in further training in a Member State should be recognised by other Member States, and this may impede the free movement of health professionals.

II.

There are questions that are continuously on the agenda between Member States and the European Union for whose solution there are two basic possibilities. On the one hand, the answer to these questions is conceivable under the frameworks of soft-law, that is, in the framework of more intensive cooperation. The subjects under consideration could be channelled into the activities of the European Union at a number of points. Supplementing the open mechanism of coordination already in operation, or the consideration of certain questions in the HLG working groups could be a good basis. On the other hand, however, in respect of the questions supporting mobility, one could also conceive obligatory rules; e.g., the simplification of administrative requirements (such as the elaboration of a uniform format of final hospital bulletins). This is the point where the requirement of regulating in separate legal provisions and the need for the regulation referred to under point I may connect with each other. Also in such cases, it would be worth considering the current situation first and then creating a legal regulation.

The following questions might arise:

- In a number of cases there is no appropriate *information* available on the services to foreigners; patients obtain information from other patients; thus, the use of services is often accidental. A flow of information laying down the existing legal possibilities would in itself be a step forward. It would be worth considering the idea of establishing a *source of information (homepage)* where information would be available to the patients on the places they could turn to if they had special or rare diseases or in case the treatment was not available in the Member State within a required period of time – that is to say, a website that could provide information on the service providers of Member States where foreigners are accepted. (Naturally, not every healthcare provider would be required to take part in the treatment of foreigners.);
- In the absence of uniform qualification systems, it is difficult to compare the services to each other in respect of quality and prices; data could be collected in order to establish the *system of minimum requirements* (infrastructure, instruments, professionals, communication) that is connected to a given service level in Member States. A comparison of the *licensing and control* systems existing in Member States could be connected to this, and the Member States could share their best and, in given cases, their worst practices in respect of these systems.
- In like manner, the comparison of *quality control protocols* would mean a step forward.
- It would be worth considering the *flow of knowledge*, the elaboration of mechanisms under which the technological evaluations made in certain Member States would be disclosed to other Member States, or the reinforcement of cooperation between different healthcare fields by Community programmes to be implemented in given specialities (such as oncology).
- It would be possible to start a *professional-mobility incentive* programme, in the framework of which – in fields requiring special expertise – specifically resident doctors would be sent from a Member State institution to an institution of another Member State. We consider, furthermore, that, in order to win the confidence of patients and increase their feeling of safety, it would be worth considering the sending of doctors/nurses speaking the given language on missions to, or for employment by,

the providers that provide services used in large numbers by the nationals of another Member State. We would consider it expedient to strengthen inter-institutional relations in this field and explore the possibilities that may exist at the EU level to reinforce that kind of cooperation.

- The methods of *statistical data collection* should be surveyed. Since a large part of cross-border services is provided privately, the statistical data on these services are not necessarily available, a fact that also blurs the picture of their use at a European level.
- It would be expedient to establish how long it is necessary to wait before the different services can be used in another country. A thoroughly elaborated system of indicators could make it possible to provide information to professionals and later to patients. Similar programmes have already existed at the Community level and in a form supported by the World Health Organisation.

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?

We consider that the main organising principle should be that the user (consumer) of a service is able to assert their rights in the best possible manner. We believe that the governing law in the place where the service is provided should prevail in respect of establishing professional oversight and financial responsibility. The requirement that the regulations valid at the place where the service is provided should be applicable is made expedient first of all by the interests of patients, who cannot be expected to know the legal provisions of different Member States. In view of the fact that the provision of healthcare mostly requires an extended material infrastructure, economic establishment may also be required in the Member State where the services are provided; thus, in these cases, the law of the place where the service is provided will agree with the law of the place where the service provider is established. According to Directive 2005/36/EC, the largest group of exceptions from the requirement of economic establishment consists of medical professionals moving under the framework of the free movement of persons. Also in these cases, the regulatory authorities in the Member State where the services are provided should monitor and supervise the activity in accordance with the local rules and in a manner that is applicable to the receiving State's own service providers.

- In the matter of liability for injuries caused in the course of providing cross-border healthcare and for compensation, it is expedient to establish the responsibility of the party causing the injury – that is, the healthcare provider – as is provided for by the general rules applicable to compensation. Compensation cases must be judged on the basis of the legal system of the Member State where the service is provided.
- In addition to approximating the questions of liability, it would also be expedient to work out a Community mechanism that would ensure the possibility to monitor professional errors in every Member State (regarding both the service provider and the user of the services).
- Accordingly, in view of the differences existing among the different countries in the regulation of liability for injuries and the amounts of compensation, it is expedient to link the licensing of cross-border healthcare to meeting certain conditions, such as a higher level of liability insurance and the amount of appropriate capacity.

In the case of the different kinds of cross-border healthcare listed in section 2.2 of the Communication, it is expedient to consider the following:

- In the case of delivering healthcare services valid in the territory of some Member State from the territory of another Member State (such as telemedical services, remote diagnostics, laboratory services, etc.), the observation of the regulations in force in the place from where the services are provided should be the primary organising principle; in respect of professional oversight, it is expedient to ensure opportunities for the authorities of the receiving State to oversee the provider of services even if that provider provides the services from another Member State with the help of telecommunications. Naturally, the right of the sending Member State to control and oversee would also be upheld toward its own provider; the licensing of operations would remain within the scope of its powers in the same manner as the revocation of licences to practice. In this field it is required that the two Member States involved should cooperate with each other in cases of malpractice occurring during the provision of services from abroad, when the authority of the receiving State exercising oversight informs the sending State so that the appropriate sanctions could be applied if needed.
- In the case of using healthcare abroad, in respect of the specification of quality and safety provisions and also in respect of ensuring professional oversight, it is expedient to establish the responsibility of the Member State from which the services are provided. Of the four cases listed, this one is characterised by the fact that responsibility is not established according to patient rights; that is to say, in this single case, the application of the regulations valid at the place of service provision breaks the process of adaptation to patient rights.
- In the case of the permanent presence of a service provider in a given Member State (such as the local clinics of larger providers), the issue is basically about the secondary establishment of a provider that has already established itself in another Member State, which clearly brings up the need to comply with the regulations of the receiving State and the enforcement of the law that is valid in the place where the service is provided.
- In respect of the temporary presence of persons providing healthcare in the receiving State, the obligation to report in the receiving State already exists in certain professions (doctors, dentists, nurses, midwives), while in respect of the rest of the health profession it will be a requirement for the provision of healthcare once Directive 2005/36/EC has entered into force. However, the receiving State, that is to say, the Member State according to the place where the service is provided, is also entitled to exercise oversight and control over the services carried out on the basis of the reporting obligation; professionals who provide services are also held accountable in accordance with the law of this Member State.
- In respect of delimiting the relations of responsibility, an interesting question arises if more than one Member State is involved in connection with the provision of services (e.g., a citizen of a given Member State provides healthcare in the territory of another Member State to a citizen of a third Member State). However, this case also underlines the justifiability of the starting point, which considers responsibility according to the place at which service is provided as being primary.

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?

We consider the application of the law valid in the place from where cross-border healthcare is provided as the main organising principle; this is the principle that determines the system of responsibilities, as well as the questions relating to compensation and indemnification. At the same time, we consider it important to underline the fact that these procedures must be made known and clear to the patients using the services.

- In the case of cross-border healthcare, safety can be ensured within the framework of the overseeing and control activities discharged by the Member State in accordance with the place from where the service is provided, since in the given State it is the local authorities that exercise professional oversight of healthcare and the service providers; thus they are also the ones who can guarantee the level and safety of healthcare.
- We are of the view that in respect of responsibility for injury caused during the provision of cross-border healthcare and for compensation, it is expedient to establish the responsibility of the healthcare provider. Accordingly, in view of the differences existing among the different countries in the regulation of responsibility for compensation and the amount of compensation, the licensing of cross-border healthcare should be tied to the existence of higher-level liability insurance. In cases in which there is a kind of healthcare that – according to the current state of scientific development is considered to be appropriate – is later discovered to cause harm to patients, there arises the need to indemnify the patients and establish the State's responsibility – naturally in accordance with the procedures also applied to their own nationals – since the service provider cannot be called to account for it.
- New questions are raised in respect of establishing responsibility if, for example, the treatment ends in a Member State other than the one in which it began or if examination and treatment, further home care or rehabilitation takes place in another country. In addition to the need for dividing the levels of responsibility, further problems arise in the fields of the manner and form of the flow of information, data protection and professional control over the activity. We would consider it expedient to know the practices followed in this connection by Member States.
- The elaboration of uniform professional protocols and standards for the different professions – e.g., within the framework of different European professional organisations – could provide a sound basis for guaranteeing the professional level of healthcare.
- We suggest that the different Member States should operate appropriate patient rights agencies in order protect the patients using healthcare services abroad and promote access to adequate information. In order to protect patient rights, we consider it expedient to involve the civil sphere and to support civil initiatives, such as the public foundation to promote the enforcement of patient rights operating in Hungary. We consider that the implementation of Community cooperation would be conceivable, thereby promoting a patient-centred approach to prevail and the strengthening of a feeling of safety among patients who use healthcare services abroad and are, therefore, in a more exposed position.

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 (for example, by means of financial compensation for their treatment in 'receiving' countries)?

It is expedient if, against their free capacities, Member States undertake the provision of planned healthcare. Naturally, it is expedient for the service providers established in resort areas and border settlements to consider the possibly significant cross-border demand when setting up their capacity programmes. The cases that arise beyond the possibility of using free capacities, the cases where the demand for the free use of services arising on the part of the nationals of another Member State and the obligation to provide healthcare in the given Member State are concurrently present require deeper analyses. Consequently, the most important point that emerges in the course of answering this question is how the principle of the free movement of services and the obligation of the healthcare systems in the Member States to provide their own nationals with undisturbed healthcare can be upheld at one and the same time.

- The conditions for getting on the waiting lists of different Member States require appropriate and transparent regulation in order to make sure that the treatment of patients who are nationals of other Member States and may possibly arrive in large numbers should not endanger the healthcare to be provided to domestic patients. The question of "passing over" among the waiting lists of different Member States, the conditions under which a patient can leave the waiting list of a Member State and get on the waiting list of another, requires further consultations and investigation. Although professional principles should determine the inclusion in and advancement on a waiting list, it is necessary to avoid a situation in which a patient could be included in distinguished positions in the waiting lists of several Member States at the same time, while a given Member State is not able to guarantee healthcare to its own nationals. It is also necessary to consider what kind of relationship a patient should have with a given Member State in order to be eligible for getting on that Member State's waiting list. In order to solve the problem, it is necessary to examine how the different EU Member States are currently regulating the possibility for foreign nationals to get on their own domestic waiting lists.
- The question of separate financial compensation arises in connection with the special healthcare services provided by different Member States that the providing system of the sending State is not able to deliver. The possibility of financial compensation can also arise in connection with questions where the provision of certain services is not profitable in different Member States; it is conceivable that compensation can be made to the Member State undertaking to provide services in such cases. The possibility of financial compensation in cases in which resources are needed for the development and operation of the so-called centres of reference requires further consideration.

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?

In the first part of our reply to the second question, we listed the fields that we think Community law should address. Such questions include the elevation of the relevant case law of the European Court of Justice to the level of secondary legislation; the regulation of the problems of data protection; the stipulation of conditions for getting on the waiting list of some Member State; the definition of a uniform procedure for handling responsibility and compensation; the questions relating to recognition of the liability insurance of health professionals; the harmonisation of the rules relating to further training.

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?

- The reduction and speeding up of the required administration should be examined as improvements in order to guarantee legal certainty on a continuous basis. Establishing and maintaining databases that would operate between Member States would facilitate the development of better administration.
- Furthermore, the avenues open for improving cooperation between Member State authorities should also be studied in order to develop a better possibility for monitoring the "patient life-path" of different nationals, the possibility for querying the health services used at different places and the result of the examinations performed – naturally, by observing the data protection regulations. We feel that keeping records of contagious diseases and handling those records in some form or other in a joint record system of the EU Member States are weighty questions in the field of monitoring the patient life-path of citizens.
- The use of cross-border healthcare would be facilitated if the necessary information sheets and consenting declarations were available in each of the Member States in the languages of all Member States.
- Furthermore, we consider that it would also be expedient to examine how the Internal Market Information (IMI) System now being tested in respect of the Directive on the recognition of professional qualifications and the Directive on services in the internal market could be applied to handling the questions connected to healthcare provision.
- The use of cross-border services would be greatly facilitated if the format of the different certificates and forms were made uniform, toward which different steps are in fact being taken (e.g., in respect of the conformity certificates used for the recognition of professional qualifications, the "good standing" certificate, the hospital discharge summary, etc.).

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?

- It would be expedient to maintain and possibly expand the level of assistance that could be obtained from the EU Structural Funds, since targeted resources and allocations could be obtained if the range of cooperation and coordination at the Community level expands;
- Current information of the European body of knowledge and capacities available in different professional fields of importance seems to be indispensable; it could serve as a basis for the broad and efficient operation of the European Centres of Reference; currently the European Centres of Reference focus their attention on rare diseases, but this range should be expanded.
- In questions falling under national regulation, the European Union may be of help to Member States in promoting the transparency of training programmes and in the areas of harmonising accreditation, quality control, the protection of patient rights and in the minimum definition of equal opportunity. In order to ensure an identical level of services to European citizens in different Member States, it is necessary to stipulate directives and professional criteria that would assist the Member States in regulating their own healthcare systems. In order to achieve this aim, it is important to promote the initiatives put forward by European professional organisations.

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?

First of all the questions that need to be regulated must be identified, which can then be followed by a discussion about how to find the solutions.

First, the problem of how the questions forming the subject of legislation could be fitted into Council Regulation (EC) No 883/2004 on the coordination of social security systems and in its enforcement regulation should, in our view, be examined, taking into account the provisions of the draft enforcement regulation that is currently under consideration, which intend to transpose the conclusions of the cases dealt with by the European Court of Justice into the regulation. Further investigation would be required to establish whether the questions that also touch on certain matters of providing services could be regulated in the framework of this regulation or under Directive 2005/36/EC.

If that possibility is not feasible, or if, on the basis of some other considerations, it seems to be a more optimum solution to adopt (a) separate legal regulation(s), both the advantages and disadvantages of such a course of action should be examined. In this case, regulation by directives should be considered for handling healthcare services at the Community level. The aim of regulation by a directive could be a framework regulation laying down the most fundamental rules, which would thereby avoid over-regulation.

We consider that, along with this, it would be expedient to examine the possibilities for using certain non-legal forms of cooperation, primarily the applicability of the open coordination mechanism appearing at the levels of the health system and steady care; these forms of cooperation could be expanded by new topics enjoying the intellectual and material support of the Community. Furthermore, the high-level meetings of the Council's Public Health Working Group, which are appropriate forums for discussing certain strategic questions, and the work of the High Level Group (HLG) on Health Services and Medical Care, provide good frameworks for cooperation through non-legal means. This is the group where a number of exploring documents has been prepared, such as the document comparing the principles of healthcare or the document evaluating the European Centres of Reference.[1]

[1] http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_working_groups_en.htm EU documents entitled "Summary paper on common principles of care" and "Overview of current centres of reference on rare diseases in the EU".