Letter dated: 12 February 2007

From:

Permanent Representation of Denmark to the European Union, Brussels

To:

European Commission (Secretariat General) (for the attention of DG SANCO)

Subject: Reply to the Commission's "Consultation regarding Community

action on health services"

Ref.: 400.S.1-0-0-0

Attached is Denmark's reply, in the form of a letter signed by the Danish Minister of the Interior and Health, Lars Løkke Rasmussen.

Yours faithfully,

Jeppe Tranholm-Mikkelsen Ambassador, Deputy Permanent Representative Letter dated: 12 February 2007

From: Ministry of the Interior and Health

(International Office)

To: European Commission (Secretariat General)

(for the attention of DG SANCO)

Subject: Reply from the Danish government to the Commission's

"Consultation regarding Community action on health

services"(SEC(2006)1195/4)

Ref: 2006-10333-293

The Danish Government considers it positive that the Commission, as part if its work on future Community initiatives in the health sector, has chosen to consult the Member States and other stakeholders. It has noted that the purpose of the Commission's Communication is to initiate a public consultation of both public and private sector players with a view to identifying the subjects which should be covered by any future Community action in the health sector. In its consultation the Commission raises a number of relevant points in connection with access to treatment against payment in other Member States and better cooperation between Member States' health systems.

The Communication contains a number of specific questions on how cross-border healthcare services should be regulated under EU Law and on how to improve voluntary cooperation in the health sector, where coordinated action can give added value to Member States' own initiatives. The Danish government has opted to concentrate on the question of codification of European Court of Justice rulings on citizens' access to treatment in other Member States pursuant to the Treaty's provisions on free movement of healthcare services. It would like to start by emphasising the fact that these are provisional comments and it reserves the right to add to them if necessary.

Concerning codification of ECJ rulings on citizens' access to both hospital and non-hospital care in other Member States, Denmark would first of all agree with the Commission that there is a need to increase legal certainty and clarity. It feels it would be appropriate for entitlement to treatment in another Member State to be explained in a set of clear rules that are easy for both citizens and authorities to understand. As a starting point, the Danish government would be open to the possibility of this set of rules including provisions on patients' rights to complain and obtain compensation where treatment causes them harm.

In this connection, there is one vital condition as far as the Danish government is concerned, namely that individual Member States themselves should decide which benefits are offered within the framework of the national health system and hence which benefits are covered, subject to the conditions laid down, by entitlement to treatment against payment in another Member State, cf. also Article 152(5) of the EC Treaty. It follows from this that a patient will not be able to travel to another EU country to receive healthcare there and have the cost reimbursed if the care concerned is not offered by the social security scheme in the patient's own country. Similarly it is the individual Member State which is competent to decide which conditions will apply to access for an

individual patient to specific healthcare, including the requirements concerning referral. In Denmark's opinion, this fundamental condition should be made clear in EU rules.

The Danish government also considers it important that, when the ECJ rulings are transposed into a clear and comprehensible set of rules, it should be ensured that there is a suitable balance between Member States' competence regarding organisation and delivery of healthcare / medical treatment, cf. Article 152(5) of the EC Treaty, and citizens' access to treatment in other Member States. In the government's view, entitlement to treatment against payment in another Member State should under no circumstances lead to the undermining of an individual Member State's health system to the detriment of patients receiving treatment in their own country. In Denmark's opinion, the Commission, as part of its further work in cooperation with the Member States, should review this problem thoroughly in order to ensure that each individual Member State, also in the future, can fully honour its obligation to its citizens to provide equal and easy access to healthcare services and a financially sustainable health system. In this connection the Danish government refers to the Council's conclusions and associated statement of 2 June 2006 on common values and principles in European health systems.

The Danish government also feels, in connection with the codification of ECJ rulings on patient mobility, that it is essential to take a closer look at the distinction made by the Court between hospital care and non-hospital care.

In Denmark's opinion, this distinction is based on the fact that hospital care is particularly costly and requires planning, meaning that there are good grounds for protecting Member States' spending levels, investments and planning possibilities. The requirement for prior approval is therefore accepted with regard to hospital care. However, non-hospital care can in some cases also be very costly and demanding, necessitating a high level of investment. This applies, for example, to the use of scanners.

The Danish government therefore feels that there can be objective reasons also in the case of non-hospital care which can justify a restriction on the free exchange of healthcare services - in other words it should be possible to impose prior authorisation. In other words the government thinks that EU rules on patient mobility must allow Member States, in more precisely defined situations, to impose prior authorisation for non-hospital care as a condition for the reimbursement of the cost of treatment.

Denmark will, however, also be prepared to consider other possible solutions which allow Member States to impose prior authorisation also for treatment other than hospital care.

With regard to non-hospital care, including the choice of GP (family doctor), it is the Danish government's view that the doctor's familiarity with individual patients underpins the referral system and thus helps to limit demand for specialist care in, for example, the hospital system to justified cases and also contributes to ensuring treatment continuity and completeness and hence a proper chain of treatment for patients. A registration system based on making State subsidies conditional upon patients consulting their chosen GP thus helps to optimise the use of overall health service resources and ensure a cohesive and qualified chain of treatment for patients.

Under the current Danish legislation, persons insured in Denmark may opt to be insured in either group 1 or group 2. Patients insured in Group 1 receive free treatment from their chosen GP and specialists, although, with the exception of ear, nose & throat and eye specialists, a referral from the patient's GP is needed in order to consult a specialist.

Persons insured in Denmark who do not wish to be tied to a specific GP and who want to be able to consult a specialist without a referral can be insured in group 2, allowing them to consult both GPs and specialists of their own choice both in Denmark and in other Member States and to have the cost reimbursed by their health insurance. Persons insured in Denmark have a free choice between groups 1 and 2 and can transfer from one to the other once a year.

The Danish government would like further work to take account of the Member States' possibility of maintaining a registration-based hospital and specialist access system (with the GP as the "gatekeeper"), which safeguards the patients' chain of treatment.

Danish legislation gives everyone resident in Denmark the right to free hospital care. The legislation relating to hospital treatment (both in-patient and out-patient) states that patients with an acute need for treatment should have priority where there a waiting list, on the basis of a concrete assessment of their state of health and need for treatment, and that, wherever possible, they should be offered treatment without unnecessary delay.

A two-month waiting time for treatment has been set, to be reduced to one month from 1 October 2007. Maximum waiting times have also been laid down for life-threatening illnesses, and there are specific rules for highly specialised types of treatment. These rules entitle patients, subject to precisely defined conditions, to obtain treatment abroad where the waiting time is exceeded. In addition, the competent authorities may refer patients for treatment abroad on their own initiative, also subject to certain conditions, and also for experimental or research-related treatment. In the latter case, however, there is no question of patient entitlement.

Based on its experience with Danish legislation and its administration, the Danish government feels that codification of ECJ rulings as regards hospital care should take account of the following elements:

First of all, a condition for obtaining prior approval should be that treatment in accordance with a medical assessment of the individual patient's needs cannot be provided by the competent authority in due time in the specific case, and that the treatment concerned can be provided more quickly in a hospital in another Member State.

Secondly, prior authorisation should be granted for treatment in a hospital in another Member State only if the hospital has entered into an agreement with the competent national authority or authorities. The authorities concerned should be obliged to enter into an agreement with any hospital in another Member State which so wishes (provided, of course, that a consensus can be reached between the authority or authorities and the hospital on the terms of the agreement).

In connection with such agreements, in order to ensure treatment quality and value for money, the national authorities should be able to require documentation pertaining to the treatment offered, including experience with the treatment, medical qualifications, standby duty organisation, standard of equipment, treatment principles, waiting time for treatment and observance of patients' rights.

Furthermore, Member State authorities in receipt of a request from a hospital in another Member State should have access to established agreement terms, including scales of charges, in case the prospective parties to an agreement cannot themselves reach a consensus. Furthermore, for the purposes of hospital system administration in the patient's own country, it should be possible, when an agreement is entered into, for the

hospital in the other Member State to ask for information from the competent institution in the patient's own country for the purposes of billing, statistics and research.

The Danish government also considers it important for the Member States, in accordance with ECJ rulings, not to be obliged to reimburse expenditure for treatment received abroad in excess of the amount which would have been paid if treatment had been provided in the patient's own country.

With regard to the question on health service supervision (hospitals, clinics, etc.) in the individual Member State, the Danish government has no doubt that supervision should be the task of the competent national authorities of the individual Member State. Furthermore, Denmark feels that complaints by patients who have been treated in another Member State should be dealt with through the complaints system of the country of treatment. Patients who have been treated in a Member State other than their own should not be able to complain about that treatment in their own country, whose authorities will not have the information etc. needed to be able to deal with a complaint. However, the Danish government does not wish to reject the possibility of cooperation between Member States with a view to making it easier for patients to complain about crossborder healthcare services. For example, cooperation of this kind could involve setting up one or more national contact points giving patients easy access to information on how to lodge a complaint in another Member State where they have received treatment.

The Danish government is also of the opinion that cooperation between Member States' competent health authorities should be considered with a view to ensuring the justifiable and effective exchange of information on inappropriate professional conduct. More specifically, it feels that in conjunction with cross-border healthcare services it would be useful to have a cooperation arrangement to allow the competent authorities in individual patients' own countries, in justified cases, to draw the attention of the competent authorities in the country of treatment to inappropriate professional conduct by a healthcare provider in that country. The exchange of such information would help to ensure that the competent national authorities are in a position to follow up errors committed in the national health system during the treatment of patients from other Member States.

The procedures for such cooperation should be considered in detail in order to establish conditions for the forwarding of information, also taking account of the need to protect personal data.

With regard to reimbursement, the Danish rules (patient insurance scheme) also cover patients referred for treatment to a hospital or clinic etc. abroad, in accordance with Article No 546 of 24 June 2005 (Health Act), but patients who have been treated abroad without being referred must apply for reimbursement in accordance with the general rules on reimbursement. This also applies to treatment which is paid for by the Danish state health insurance scheme in accordance with the provisions of Regulation No 1408/71. The Danish patient insurance scheme also covers patients from other countries who are treated in Denmark both under the public health system and at private clinics, etc. The Danish government considers it important for patients who receive treatment in another Member State in all cases to have the possibility of applying for reimbursement. Its view is that, as a basic minimum, individual patients should be able to apply for reimbursement according to the rules of the country of treatment.

The Danish government is also of the opinion that the links between ECJ rulings concerning patient mobility and Regulation No 1408/71 need to be precisely clarified in

order to ensure coherent and consistent rules. It would like to make the following comments in this connection:

In its individual rulings on free movement of healthcare services, the ECJ has addressed specific problems on the basis of the provisions on the coordination of public healthcare services in Regulation No 1408/71 on social security for migrant workers. In the Kohll judgment (case C-120/95), the Court held that the purpose of Article 22(1) of Regulation No 1408/71 is to allow an insured person, who has been authorised to go to another Member State for treatment, to receive that treatment there at the cost of the competent institution but in accordance with the conditions applicable to insured persons in the country of treatment.

However, the Court also considers that Article 22 does not cover the situation where insured persons apply to their insurance scheme for reimbursement of expenditure at the tariffs in force in their own country for treatment which they voluntarily obtained and paid for in another Member State without authorisation. The question here is whether the relevant provisions of national legislation are consistent with the EC Treaty's provisions on free movement of services.

The ECJ rulings in this and similar cases mean that EU law, through two Treaty provisions and secondary legislation, regulates access for insured persons to state subsidies for treatment obtained in a Member State other than that where they have their health insurance. Either subsidies according to the rates and conditions which ensue from the legislation under which the patient is insured, drafted in accordance with the EC Treaty provisions on free movement of services, cf. Article 49 ECT. Or subsidies according to the rates and conditions which ensue from the legislation of the Member State in which treatment is provided, but at the expense of the patient's own health insurance, cf. the provisions of Regulation No 1408/71, adopted on the basis of Article 42 ECT.

Clarification of insured persons' subsidy entitlements under these two sets of rules is covered by the ECJ judgment in the Vanbrækel case (C-368/98), which states that "if the reimbursement of costs incurred on hospital services provided in a Member State of stay, calculated under the rules in force in that State, is less than the amount which application of the legislation in force in the Member State of registration would afford to a person receiving hospital treatment in that State, additional reimbursement covering that difference must be granted to the insured person by the competent institution".

However, the ECJ has not had to rule on cases covering different circumstances, necessitating clarification of the question of subsidies for healthcare services under the two sets of rules. A future EU legal act should clarify the legal uncertainties here.

The Danish government is of the opinion that it will be vital for any future rules governing this overlap problem both to clarify insured persons' rights from the legal point of view and to offer a solution which duly takes account of the need for simple and economical administration by the competent authorities.

Article 19 of Regulation No 1408/71 contains provisions regulating entitlement to subsidies for state healthcare services where the person concerned is insured in one Member State but resident in another, for example a frontier worker. The Regulation ensures that the persons concerned are entitled to such benefits in both Member States under the same conditions as persons who are insured in those States. The cost of benefits in the State of residence is paid by the State of insurance. In other words, insured

persons may choose in which of the two States they wish to obtain treatment. The treatment is subsidised under the same conditions as for insured persons in the Member State where it is obtained.

Denmark feels that a future EU legal act clarifying the overlap problems as described above and containing rules which ensure access to subsidies for state healthcare services under provisions on free movement of healthcare services should be drawn up taking account of Regulation No 1408/71 and without changing the rights or financial balance established by it.

The Regulation also contains provisions which mean that a person who has health insurance in one Member State is entitled, during a stay in another Member State, to subsidised state healthcare services where a need arises during that stay. The subsidy is granted under the same conditions as for persons insured under the state scheme in the country of stay. The costs are paid by the insured person's health insurance.

Regarding a future EU legal act regulating overlap problems which can also arise in relation to this provision, Denmark feels that administrative and financial considerations dictate that it should be left to insured persons receiving treatment to choose which legislation (country of stay or country of insurance) they wish to be applied in a specific case.

However, to help citizens choose, Member States should be obliged to provide information for citizens on the general possibilities and conditions for obtaining subsidies for state healthcare services in the Member States, including information on concrete rates. This information should also include a guide to the different rules on subsidies for treatment obtained outside the insured person's country of insurance/residence.

The Danish government cannot support proposals for a "recalculation model" corresponding to Article 23(3) of the Commission's original proposal for a Directive on services in the internal market (COM(2004) 2). A model of this type would impose significant administrative burdens on the Member States. However, this does not apply where the insured person meets the "referral for treatment abroad" criteria under national legislation or Regulation No 1408/71.

As far as other areas of cooperation are concerned, it is the Danish government's view that an increased level of voluntary European cooperation would have a large added value in areas such as treatment of rare diseases, centres of expertise where knowledge about treatment is pooled to the benefit of patients, patient safety and research. The government regards the present European project on health technology assessment (EUnetHTA) as very useful and promising and therefore worthy of being pursued at European level.

Finally, the Danish government feels it would also be advantageous to step up voluntary cooperation between the Member States on the more common types of treatment. Free treatment capacity in one Member State could be used to help reduce waiting lists in another . Denmark will be pleased to contribute to any discussions on the possibility of establishing cooperation between the Member States for the mutual exchange of information on free treatment capacity.

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.