REGERINGSKANSLIET

Memorandum

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Ministry of Health and Social Affairs

European Commission
Health and Consumer Protection
Directorate-General
Health services consultation
B232 8/102
B-1049 Brussels
Belgium

Response to the Commission's Communication

General comments

The Swedish Government is very positive to the Commission's initiative to discuss the Community's future action on health services together with Member States.

It is important that the financing and organisation of health care remain a national responsibility in the future. The Swedish Government considers that it is important that the development of the EU in the area of health services is based on the fundamental values and principles of health care, but with respect for Treaty provisions and the principle of free movement of services and persons as they have been developed though the case-law of the Court of Justice. The Swedish Government considers that it is important to develop a common system that guarantees good access to high-quality health care both for people seeking care in their home country and those seeking care in some other Member State.

The Swedish Government welcomes both the consultation process and a binding legal instrument in the area. The Swedish Government considers that certain matters should be regulated and not solely be the subject of cooperation or interpretative communications.

The Swedish Government considers that in a future system the Commission should focus on the issues that are common to Member States and where there is a clear need for and added value from common rules.

The Swedish Government considers that the aim of future Community action should be to provide clarity about what rules apply to people seeking care or working in health services in another Member State and also to stipulate good safety for patients.

In order to anticipate any case law and to clarify the existing legal framework the Swedish Government welcomes measures that can facilitate business activities in the area of the health services. Many Member States already export advanced services in this sector and with a clear regulatory framework in place there should be potential for increased exports leading to greater growth and employment.

The Swedish Government considers that Member States are responsible for working towards the best possible quality and accessibility of health services in their own country. The Swedish Government understands that other Member States may to some extent have other problems or challenges in connection with cross-border health care, but in the case of Sweden cross-border health care is still on a relatively small scale.

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?

Cross-border mobility among patients to seek care abroad is still on a limited scale in Sweden. At the same time, the number of people seeking planned treatment in another EU or EEA country has increased in recent years. In 2004, 147 people were granted reimbursement for planned care, in 2005 the corresponding figure was 954 and in the first six months of 2006 almost 1000 people were granted reimbursement. The most common treatment that is reimbursed, over 60 per cent of applications, is dental care. So far, the reasons that it has been possible to see for people seeking dental care in another EU country are personal tries to the country, a lower treatment cost for the patient and, in some cases, the avoidance of long waiting times for care. The most common reasons among those seeking health care in another Member State are personal ties, waiting times for treatment and the fact that the treatment is not available in the patient's own county council or in Sweden. Cross-border health care is most widespread in the regions that border on another country. There is not any great inflow of patients to Sweden either. So far the cross-borders flows of patients have been on a limited scale. Even if the number of patients receiving care outside Sweden has increased, until now this has not had any great impact on the national system or for the county councils, which are responsible in Sweden for organising, funding and providing health care.

As regards health care professionals working in some country other than their home country, this is a much more frequent occurrence. For instance, a high proportion of professionals working in health care in Sweden have been trained abroad. As regards health care professionals leaving Sweden to work in their profession in another Member State, the most common example is Swedish dentists moving to other EU countries to work there after completing their degree, with few of them returning to Sweden. A

further dimension of cross-border health care is telemedicine and other heath care services provided at a distance with the aid of IT support. These are methods that are being used with good results in Swedish health care today and it is thought that their use will increase substantially over time.

The Swedish government makes the assessment that in the long term cross-border care may have a greater impact on our system and that this impact will mainly be positive. Having free mobility and competition in the health care sector is positive for both the system and individuals. The Swedish Government makes the assessment that the positive effects of patients receiving treatment abroad largely outweigh the negative consequences. Similarly, the Swedish Government welcomes health care professionals and companies in this sector being given the opportunity of working and operating in another country.

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?

Despite the extensive case-law of the Court of Justice on cross-border health care there is not sufficient clarity as to how Community law is to be applied in this respect, and what it means for both the individual and care providers. The case-law of the Court of Justice has resulted in the establishment of rules, alongside the provisions of regulation 1408/71, on the right of individuals to receive treatment in another Member State and be reimbursed for the costs of the care that follow directly from fundamental Treaty rules. This means that current regulations are to be found in two places, which is hard for the individual to grasp. The Swedish Government considers that it is difficult to weave together the rules on the right to reimbursement of costs of health care in another Member State that follow from the interpretation of the Treaty made by the Court of Justice and Regulation 1408/71 in a single legal instrument. Instead the Swedish Government welcomes binding legislation at Community level alongside Regulation 1408/71 that is so comprehensive and consistent with Community law that no further source of regulations can arise parallel to the legislation that is in force. Such legislation would provide greater legal clarity and certainty throughout the Union and increase transparency for Union citizens in this matter.

The matters that need to be regulated in order to clarify the right to reimbursement pursuant to the EU Treaty are: who are covered by the right to reimbursement; the conditions for receiving reimbursement from a Member State for planned and emergency care; the possibility for a Member State to introduce a prior authorisation requirement; the duty to treat patients equally; what costs will be reimbursed; what county is responsible for patient safety and for supervision; the obligation of the home country to provide pre-treatment and after-care, and the administrative law principles set out by the Court of Justice such as the opportunity for the individual to

appeal decisions, the requirement for objectivity and impartiality in decision-making, etc.

The Swedish Government considers that one pre-condition for reimbursement must be that the care costs will only be reimbursed by the paying country if treatments for corresponding diseases or conditions are reimbursed in that country. The main aim of having a future Community system leave it to Member States to decide what diseases or conditions will be reimbursed is that a Member State will not be required to reimburse treatments or conditions that a Member State has decided, within its own competence, cannot be regarded as medically or ethically defensible, such as cosmetic treatments or euthanasia. As regards what treatment methods will be reimbursed by the paying country, the Swedish Government considers that it follows from the case-law of the Court of Justice that, as a minimum, the treatment method that has been used in the Member State or is sufficiently proved and recognized by international medical science gives an entitlement to reimbursement for planned health care. The Swedish Government considers that the above should be incorporated into future Community legislation and that this legislation should deal with reimbursement for both planned and emergency care.

Member States should be given the possibility of providing their patients with care of good quality within a normal period of time in their country. The Swedish Government therefore considers it necessary for future Community legislation to contain a possibility for Member States to introduce or retain a prior authorisation requirement for planned health care, if justified on the basis of Community law. What is justified can be seen to some extent from the case-law of the Court of Justice and this should be clarified in a legal instrument. The Swedish Government takes the view that the current definitions of hospital care and non-hospital care are not satisfactory and that the future legal instrument will have to define in more detail in what situations a prior authorisation is justified and what it entails, and also set up general guidelines. The meaning of the concept “undue delay” has been clarified by the Court of Justice and the same definition should be used in a common legal instrument. A future legal instrument should clarify under what country's costs/rates the patient shall be reimbursed, either according to their home country’s costs/rates or according to the costs in the country where the health care is delivered. Moreover, the Swedish Government welcomes clarification of the special conditions that should apply to where the medical assessment, in which the individual's health care needs are defined, shall be conducted in order for care delivered in another Member State to be reimbursed.

The Swedish Government considers that it is of great importance that a future system is coherent with Regulation 1408/71, where possible. Above all, the rules on responsibility for health care and on patient safety should cover both emergency and planned care according to both regulatory sources. The Swedish Government considers that Regulation 1408/71 and the future regulation 883/04 are functional and should be retained.

The Swedish Government considers that safety for the patient must be at the focus of a future system, irrespective of whether it is the patient, the practitioner or the service that moves across borders. It is necessary to decide what country is responsible for the health care, patient information, the handling of medical records and the transfer of patient information between states, etc.. As regards the handling of medical records and the transfer of patient information between Member States, it is important to secure the patient's need of confidentiality and the patient's possibility of giving consent to information processing. The Swedish Government welcomes clarifications so as to facilitate the exchange of patient information and of medical records. In order to enable patients to feel secure in health care abroad, both the payer country, the country providing health care and the providers should be responsible for giving the necessary information to patients. However, in the view of the Swedish Government it should be left to Member States to decide how information is to be given and what it has to cover.

The Swedish Government also welcomes clarifications in areas that regulate professional practice and establishment in the health care area. Current regulations, such as the directive on the recognition of professional qualifications in health care, are already well-established and a reference to this directive should be included in a future system for cross-border health care. At present there is no common system concerning non-regulated professions and the Swedish Government considers that no legislation is needed either. However, clarifications may be needed in another form in order to establish that it is the country where health care is delivered that is entitled to make demands on professional practice in order to establish good quality and safety for patients. The purpose of a clarification in the area should also be to facilitate professional practice, temporary and permanent movement and the establishment of health care services.

In order to clarify the division of responsibility between different actors the Swedish Government considers that it is of great importance that service like care and treatment provided at a distance using telemedicine are also covered by a future common system in the area.

Intensified cooperation to enhance quality in health care throughout the Union, as well as to spread evidence-based methods, are a pre-condition for the development of the sector, even though no legally binding regulation is being considered at present.

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?

The Swedish Government welcomes clarifications that firmly state that it is the country where the care is given and delivered that has full responsibility for the quality and planning of the health care as well as for the system for handling any cases of patient injuries. In the same way, the responsibility for supervision of health care and practitioners is a responsibility that rests on the Member State in which the health care is delivered. The payer

country is not, unless otherwise agreed, responsible for the content of the health care and any harm to patients. Considering the health of the population, it is justified to make special demands on practitioners of health care services, irrespective of whether or not the service is provided in a regulated or a non-regulated profession. It should be the Member State in which the service is delivered that decides what these special demands are. The Swedish Government welcomes intensified cooperation in this area in order to avoid differences in regulations that will prevent free movement. Even though it rests on the country where the healthcare is given to be responsible for the care, the Swedish Government nevertheless considers that there is a need to clarify what possibilities the payer country has of calling attention to any deficiencies in quality and delivery. The purpose being to provide some feedback to the practitioner who delivered the service.

When telemedicine services are used, the division of responsibility is somewhat more complicated, but clarifications are also desirable here. The Swedish Government considers that the country where the health care is delivered is also responsible for these services. As care and treatment using telemedicine are also growing globally, an effective system should be implemented. A patient receiving treatment must not be placed in a worse situation that if the service had been solely national.

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 Swedish Government considers that questions concerning patient safety are one of the most important components of a legal instrument intended to clarify what applies to patients seeking care in another Member State. The Swedish Government considers that the Member State where the medical measures have been taken or the health care has been delivered shall be responsible for patient security, irrespective of whether or not the care provided is cross-border and irrespective of where the professionals or the patient come from. There is a somewhat unclear division of responsibility for other cross-borders services, such as directly procured healthcare, cooperation on highly specialised healthcare, telemedicine and medicinal products prescribed in one Member State but collected in another. It is important in these cases that the patient does not come to harm, so responsibility needs to be clarified in future Community action.

The Swedish Government recommends that a common legal instrument also set out that each Member State must have a patient-friendly system for handling any injuries to patients. However, there should be no common legal instrument setting out how such a system shall or should be designed. Greater cooperation on patient safety issues is of the utmost importance. The Swedish Government considers that there is a great need for

cooperation to prevent spread of infections, which may increase when cross-border health care increases.

5. 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)?

The Swedish Government considers that it is important that all Member States work jointly and individually for compliance with and the full implementation of the common values and principles for health care adopted as Council conclusions in June 2006. The Swedish Government considers that all EU citizens shall be treated equally irrespective of where they seek care and that the principle of non-discrimination in Article 12 of the EU Treaty also applies in the context of health care. This should be set out in any future Community action. This shall also state that, in the first place, care shall be given to the patient in the greatest need. There should be no common legal framework for other national priorities for the provision of health care, costs of care and what diseases should be given priority, etc.

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?

The Swedish Government welcomes some form of clarification in order to facilitate cross-border professional practice on a temporary or permanent basis, but also in order to establish good safety for patients. Regulated professions, both within and outside the area of health care, are covered by Community legislation in the 15 directives now in force. In a year they will be replaced by a single directive (Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. The Directive must be implemented by Member States no later than 20 October 2007.) Member States decide by themselves what professions are to be regulated. The Swedish Government therefore considers that there is satisfactory and sufficient regulation for regulated professions.

In the case of non-regulated professions in the area of health care, the Swedish Government considers that it is important that future Community legislation makes clear that it shall be the law of the country where the health care is given that will be fully applicable concerning supervision and responsibility for professional activity and training in broad terms. There is also a possibility of regulating a profession that was previously non-regulated if there is deemed to such a need.

At present the Swedish Government sees no clear need to incorporate rules and conditions for establishment in legislation at Community level. If clarification is still required, interpretative communications or common guidelines from the Commission can be suitable instruments.

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?

No comment.

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?

The Swedish Government considers that there is a need for Community-level action to provide support in the area of health care. There is every reason to work for accessible, high-quality health care throughout the Union. The Swedish Government considers that it is important to have a joint discussion of standards and indicators for quality as well as of what methods are effective, i.e. "evidence-based methods". To achieve this the Swedish Government welcomes measures concerning an enhanced exchange of information and the collection of statistics on cross-border health care. The enhanced collection of statistics makes it possible to follow the costs of EU health care, patient flows, what groups are seeking health care in another country and the reasons for the care. Cooperation on an Internal Market Information System is welcomed. It is important to continue the discussion on what information the patient should have access to in order to be able to seek care in another EU country, as well as to discuss the need to further develop an Internet health portal for the Union. There is a need to investigate what information is needed and how it can best be provided. A similar discussion should also be conducted on information to practitioners in the health care sector who want to work or establish themselves in another Member State.

Cooperation in the patient safety area should be intensified and also include cooperation on quality, quality indicators and evidence-based health care, as well as the need for reporting systems in health care. Directly procured health care, referrals of patients to health care services in other countries and cooperation on networks and centres of reference at European level have been common and will probably be even more so in the future. It is important to cooperate at European level on highly specialised care and on rare diseases. There is clear added value in involving more people in work on how best to procure health care and writing agreements that protect patients and clarify the division of responsibility. One future area that the Swedish Government is supporting actively is eHealth. More efficient

information systems will be needed in order to organise and fund health care in the long term, and they will have to be able to work with systems across national borders. The Swedish Government therefore welcomes deeper international cooperation in this area, for instance through the international terminology and concept system SNOMED-CT. Similarly, the Commission can have an important role in work to produce an electronic patent identity card, the "eEHIC". One important issue for the Swedish Government is to discuss and cooperate on how patient records and other essential information about patients can follow the patient beyond national borders and how information to patients can be handled in a safe and secure way.

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 Swedish Government welcomes legislation in the form of a directive for issues related to cases where patients seek care in another Member State. The questions that the Swedish Government proposes be regulated in a new directive are: What/who are covered, when a right to reimbursement exists, what is reimbursed, who is responsible for supervision, responsibility for malpractice and information, responsibility for pre-treatment and after-care, and certain administrative law principles established by the Court of Justice. In this context there should be a clear statement of what is a national competence, such as decisions on what treatments for diseases or conditions are reimbursable and when a Member State assesses that it is justified in the light of Community law to require prior authorisation, etc. The Swedish Government is of the view that the current definitions of hospital care and non-hospital care are not satisfactory. Today a large part of the healthcare provided outside of Sweden is given as out-patient care, such as dental care. Moreover, advanced and highly specialised health care is increasingly performed as out-patient care instead of as in-patient care. Depending on costs and scope, prior authorisation may eventually also be required for such care (see also the response to question 2).

As a complement to this legal instrument the Swedish Government welcomes intensified cooperation to facilitate cross-border health care. This involves cooperation on information to the patient and about the patient, cooperation on quality and quality indicators, the exchange of information and statistics on flows of patients and practitioners and cooperation on the drafting of international agreements in the area of health care. It is important not to focus future work solely on a binding legal instrument but to instead combine this with more practical and concrete cooperation that can add value for providers and patients.

For other parts of cross-border health care, such as regulatory frameworks for the practice of regulated and non-regulated professions, as well as for establishment, the Government considers that certain clarifications may be needed. However, it considers that most of this can be done through interpretative communications and not necessarily through legislation.

Heléne Dahl Fransson
(Ministry of Health and Social Affairs)