31 January 2007

The Norwegian Ministry of Health and Care Services

Reply to the European Commission on the Consultation regarding Community action on health services dated 26 September 2006 – general comments

Norway welcomes the opportunity to provide comments and views in response to the European Commission's consultation regarding Community action on health services. The issues addressed are highly relevant for Norway. New initiatives on health services at EU level will impact on the future formulation of legal framework with relevance for the EEA agreement.

The Norwegian Government welcomes the Commission's initiative. As the Commission indicates in its consultation document, there is uncertainty with regard to the application of Community law to health services and health care. Norway realises the need to clarify the existing legal uncertainty related to patient mobility, movement of health professional and the establishment of healthcare providers in other EEA States. However, the organisation and financing of national health and social security systems should, in accordance with the principle of subsidiarity, remain the responsibility of the Member States.

The Commission acknowledges that health services have a number of unique characteristics that need to be taken fully into account when developing any new proposal to improve the legal certainty of the application of Community law to health services. A major concern is the States' need to ensure adequate provision of such services. The overall expenditure on health services is high and has been increasing in most Member States. It is Norway's main concern that any future European legislation should not preclude the Member States from safeguarding their need to plan and control the costs of their health services.

Values and principles underpin national health services. Although Norway supports action at European level, it is of uttermost importance that any such action does not undermine national values and principles, including national principles for setting priority between patients. The quality of health services should be ensured. It is equally important to maintain a sufficient supply of health services in scarcely populated areas. Furthermore, Norway would emphasise the importance of the Member States' prerogative to make decisions regarding what constitutes appropriate and ethical treatment.

It is a challenge to make sure that developments in the area of patient mobility and health services do not lead to greater social inequality with respect to accessibility to health services. A Commission proposal must make sure to prevent a situation where only the most resourceful patients are able to enjoy rights relating to patient mobility

and wider European cooperation in the health field. Access to information and knowledge about the right to available treatment can help to reduce social inequality. Another challenge lies in women and health. It is important to ensure that women's health and female illnesses are adequately provided for in a proposal from the Commission.

European Commission Consultation – questions

Q1. 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 extent of cross-border healthcare to/from Norway is limited today. A limited increase is expected in the number of patients receiving cross-border care in the coming years.

Q2. What specific legal clarification and what practical information is required by whom (authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-boarder healthcare?

Regulation at European level is mainly needed in the area of patient mobility. In its rulings on patient mobility the European Court of Justice has balanced the EEA States' need to plan their health services with the EC provisions on the free movement of health services. In order to maintain this balance, Norway would welcome a codification of the Court's Jurisprudence limited to the following points: 1) Patients are entitled to reimbursement of non-hospital care in another State in situations where the cost would have been reimbursed if the patient received the healthcare in his/her home State. 2) EEA States shall ensure that authorisation for assumption by their social security system of the cost of hospital care provided in another EEA State is not refused where the treatment in question is among the benefits provided for by the legislation of the EEA State of affiliation and where such treatment cannot be given to the patient within a time frame which is medically acceptable in the light of the patient's current state of health and the probable course of the illness. 3) The level of assumption by their social security system of the costs of health care provided in another EEA State is not lower than that provided for by their social security system in respect of similar health care provided in their territory.

In order to ensure national needs with regard to cost control and planning of health services, the EEA States' right to limit reimbursement of expenses for travel and accompanying persons in connection with care received in another EEA State must be secured in Community law.

In Norway's view it is appropriate to clarify what is understood by hospital care, with a view to making it easy for patients, healthcare personnel and States – each according to

their needs – to decide when prior authorisation is required for assumption of the cost for healthcare incurred in another EEA State. A definition of hospital care shall only apply for this purpose. The definition must safeguard the States' need for cost control and planning of their own health systems and allow EEA States sufficient room for discretion in implementation. The definition must be robust in the sense that it allows States to uphold prior authorisation arrangements for cost-intensive and specialised treatments even if medical and technological progress/advances eventually make such treatment possible without the medical infrastructure provided by a hospital.

In Norway's opinion, regulation at a European level of patient mobility is not desirable on points other than those stated above. With reference to cost control and the need to plan health services, the responsibility for formulating national reimbursement schemes, including rates and prices for treatment is the prerogative of the states. It is not appropriate to issue detailed common rules at European level specifying which diagnoses, forms of treatment, etc. are to qualify for reimbursement. However, in order to facilitate correct handling of claims for reimbursement, there may be a need to standardise, through guidelines, the documentation health care providers are required to give patients concerning the provided treatment.

The Commission's Communication is wide-ranging. Norway thus calls attention to the need for a clear formulation of the scope of a future Commission proposal. In particular it should be clarified whether institutional and non-institutional long-term care as well as other social welfare services are covered.

It is questionable whether Article 5 of Directive 2005/36/EC on the recognition of professional qualifications exhaustively lists the requirements that may be applied to a service provider who provides services on a temporary basis in another EEA State. In Norway's view, a Commission proposal should make clear that all requirements that are justified by overriding reasons in the public interest may be imposed provided they are proportionate and non-discriminatory. It should also be clarified that the service provider/patient relationship in matters relating to patient rights, such as information, consent and access to medical records, is regulated by the legislation of the State where the service is provided and that this also applies when the service is provided in the State on a temporary basis. This must be the general rule, with no exceptions.

It should be possible for other States' supervisory authorities and for the general public to be given access to data from supervisory and authorisation authorities about a person's authorisation status as a healthcare professional and possibly also to reports regarding supervision. This information may have significance for patients, healthcare professionals and health authorities in, for example, their choice of health care providers or partners. Consideration should be given to whether legal clarification is needed to ensure this. See also Q4 on supervision.

If patients are to make informed choices about treatments and providers in other EEA States, adequate information on availability, quality, documented effect, price, liability,

complaint procedures etc. is needed. Information is important for health authorities and healthcare professionals when it comes to; purchasing health services abroad, choosing partners, and other forms of interaction which contribute to a more appropriate utilisation of resources. Measures should therefore be initiated at European level in order to make relevant information accessible and comparable. Healthcare professionals should inform their patients which national rules apply to their services.

Q3. Which issues (clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-boarder healthcare described above?

In the work for patient safety it is essential that providers of health services are supervised. It should be clear who is responsible for supervising the provider in situations of cross border provision of services. There is a particular need to clarify who is responsible for supervision when the health care provider temporarily offers his or her services in another State than his or her state of establishment. Patients should in situations of temporary health care provision, be able to complain to the supervisory authorities in his/her home State when the service is provided there. A health care provider may be regulated both by the laws and other regulations of his or her State of establishment and of the State where the service is provided on a temporary basis. It would be difficult for a State's supervisory authority to apply the laws and other regulations of another state.

In Norway's view, cooperation is needed between the authorities responsible for supervising health services in the State of establishment and in the State where the service is provided on a temporary basis. An appropriate division of tasks could be that the State where the health care is provided is responsible for any factual checks and investigations, while the State whose laws and other regulations apply to the care provider and provision of care is responsible for assessing the case. Any measures relating to authorisation as a health professional must be the responsibility of the authorities in the State(s) where the service provider is authorised. It is Norway's opinion that a legal instrument may be appropriate to ensure an obligation for supervisory authorities to cooperate.

Q4. 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?

Patient safety and prevention of harm is an area where European cooperation can be useful. The risk of harm to patients can be reduced by evaluating treatment methods and technology, developing safer routines, improving the design of medical equipment etc. Cooperation in these areas is considered helpful because duplication of work may be avoided by collaboration between the states and because greater similarity in routines etc. will be advantageous in cases where healthcare professionals, patients or services cross borders.

It is important to ensure that patients who suffer harm are guaranteed financial compensation in cases where the conditions for such compensation are fulfilled. In Norway's view the ideal solution would be for every EEA State to have a system for compensation to patients whereby patients are entitled to compensation even if the healthcare professionals are not to blame for the error in healthcare that led to injury. This is hardly a realistic prospect in the short term. However, Norway believes there now is a basis for proposing a legally binding instrument at European level, not with regard to conditions for compensation, jurisdiction or choice of law, but with regard to professional liability insurance. Everyone who provides health services in the EEA should be required to hold liability insurance (or some other adequate form for financial guarantee for claims for compensation) which covers harm to patients both when providing services in the State of establishment and for all types of cross-border services. It is Norway's view that a provision should be included in a Commission proposal obliging the Member States to implement appropriate regulations to this effect for service providers established in their State.

Patients who have suffered harm, incurred a loss or in other manner received unsatisfactory healthcare in another EEA State should also be guaranteed assistance after they have returned home. An obligation for the EEA States to establish contact points should be enacted. Such contact points should provide patients with information and guidance on patient rights, complaints and compensation systems and contact points for dispute settlement bodies, appeal bodies, patient ombudsmen and organisations which assist patients. In the light of the patients' relatively weak position as consumers vis-à-vis service providers it should be considered to impose on the States an obligation to ensure that patients are given more comprehensive assistance than other recipients of services.

Q5. 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? (By means of financial compensation for their treatment in 'receiving' countries)

It should be clarified that it is justifiable to give higher priority to patients belonging to its own social security system than to patients belonging to other social security systems when this is necessary to ensure that they receive treatment within a medically justifiable time limit.

Q6. 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?

It should be made clear that neither the freedom to provide services nor the right of establishment does entail a right to access public funding of health services. In particular it should be made clear that the right to provide cross-border services does not include a right to reimbursement from the social security system in the state where the service is provided nor does include a right to be awarded a contract to provide

services on behalf of the social security system in the state where the service is provided. A right to reimbursement or a contract to provide services must be arranged in accordance with the rules that apply for the social security system in the State where the service is provided.

A greater degree of electronic interaction between different health care providers in the EEA States could increase the efficiency of cross-border healthcare. Norway welcomes the Commission's ongoing study entitled "Legally eHealth" and would like to inform the Commission that the Nordic Council of Ministers has appointed a Working Group to identify concrete barriers to efficient cross-border cooperation on eHealth and to propose solutions to these problems. The Working Group's recommendations may be useful when considering whether a similar project should be initiated at European level. Development of codes of conduct for electronic interaction in the health sector at European level would help to facilitate electronic interaction.

Q7. 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-boarder healthcare?

Q8. In what ways should European action help support the health system of the Member States and the different actors within them? Are there areas not identified above?

Efforts should be made to strengthen the quality of the national health systems in EEA States and cooperation should be initiated at European level to promote such a development. One possible initiative at European level to ensure quality and to elicit quality indicators would be to draw up joint professional standards for groups of healthcare professionals. Cooperative measures offering the possibility of broader access to the specialist skills of health professionals and better utilisation of resources would be welcome. These could be, for example, centres of reference for rare diseases and conditions, and joint schemes for method and technology evaluation.

It is important to ensure that patients receive the necessary follow-up at home after treatment abroad. This necessitates the transfer of patient data. This can be facilitated by joint guidelines for how, when and to whom the information is to be given. A standard discharge report form, for example, would make this information more easily accessible. Member States should also cooperate across borders on risk evaluation and control of reimbursements of treatment costs.

Various forms of cooperation will be useful in these areas, while a legally binding instrument does not appear to be necessary or desirable.

Q9. 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?

Norway believes that a directive should be enacted to regulate certain issues arising in relation to patient mobility. A "soft law" approach, in the form of recommendations from the Commission etc., could be a useful supplement to a directive, but is not an adequate approach to ensure legal certainty. Patients' right to assumptions of costs of healthcare incurred in other EEA States as specified under question 2, including the need for a definition of hospital care, the obligation to hold professional liability insurance as well as the obligation to give patients assistance in their home State (see Q4) should be enacted in legally binding instrument. A directive would be most appropriate as transposition provides States with an opportunity to adapt the provisions stemming from Community law into its existing national law.

In Norway's view it is appropriate to establish the right of Member States to make temporary provision of health care in their state subject to requirements that are justified by overriding reasons in the public interest as mentioned under question 2, and to establish an obligation for supervisory authorities to cooperate and to clarify the division of tasks between them in a legally binding instrument. Again a directive is the most suitable instrument. This also applies to the clarification that the right to provide cross border services does not include a right to reimbursement from the social security system in the state where the service is provided nor does include a right to be awarded a contract to provide services on behalf of the social security system in the state where the service is provided as described under question 6.

In Norway's opinion other issues should not be tackled in legally binding instruments. Norway wishes to participate as fully as possible in European cooperation on health services.