Comments
from the German Hospital Organisation [*Deutsche Krankenhausgesellschaft e. V. (DKG)*]
on the European Commission Communication
"Consultation regarding Community action on health services"

The German Hospital Organisation [*Deutsche Krankenhausgesellschaft e.V. (DKG)*] is the umbrella organisation of hospital operators in Germany. It represents the interests of its 28 members – 16 Land associations and 12 national associations – in German policy-making, European and international affairs and performs the tasks conferred on it by law in the context of German self-regulation. It covers 2 137 hospitals and a staff of around 1.1 million, taking care of over 17.4 million patients a year. With German hospitals having an annual turnover of circa EUR 61 billion, the DKG represents a significant sector of the health service.

German hospitals are primed to be international service providers. In a society increasingly characterised by mobility and with a rising number of health services with a cross-border element, there is a growing need for information on the different healthcare systems, their financing and rules covering accidents, service providers and conditions for the use of services.

Against this background, the DKG welcomes the consultation process initiated by the European Commission on Community action on health services and affirms its intention to play a constructive part in this consultation. The DKG supports the European Commission in the efforts it is making with this Communication to create more legal certainty for service providers and recipients and to support the Member States.

The DKG also emphasises that health is a fundamental component of society and of individuals and that since he provision of high-quality healthcare is the sole responsibility of the Member States, they alone can and should regulate and manage human resources in this field along with the relevant technical and financial capacities.

Any Community action on health services should aim to balance the creation of a common market in health services and the abolition of the obstacles to the provision of cross-border health services with the recognition of the Member States' sovereignty in the area of health and their practical responsibilities. Account should also be taken of cultural differences between the Member States.

The "country-of-origin principle", which came to the fore in the debate on the services Directive has not been deemed acceptable for the health area for good reasons. Any revival of this concept in the current discussion must be rejected out of hand.

In this light, the DKG's answers to the questions from the European Commission are as follows:

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?**

At present there is only a low volume of cross-border provision or utilisation of health services. The European Commission itself assumes a negligible level. Furthermore, no increase in cross-border cases can be established at the moment, insofar as they can be reliably quantified at all. The lack of reliable figures makes a reliable impact assessment impossible at present. It is, however, imperative that one be carried out before any Community framework is created.

Against this background it is very difficult to predict the actual impact on health care. Therefore, any health measures should be modest in scope, reflecting the low incidence of cross-border healthcare. It is also evident that the market in cross-border health services is an area which can be managed by individual countries and which does not require European action. Particular importance should therefore be attached to the principle of subsidiarity.

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?**

Practical information:

As well as patients, service providers and funding bodies need clear information. Knowledge of financing rules, legal certainty and transparency are essential prerequisites for service providers and funding bodies if cross-border healthcare is to be feasible.

It is therefore vital that – as suggested by the Commission – a comprehensive base of information be created for cross-border care agreements. If they are to become operational on a cross-border basis, the competent national operators must be able to rely on this kind of clear framework for the cross-border utilisation of health services.

The DKG therefore supports the European Commission's initiatives in the area of health information, particularly the introduction of a European health portal in May 2006. In line with this information system at European level, there should be a comprehensive overview of the different health systems and services. The information currently available should be enhanced in this sense.

Regulatory framework:

Any Community action developed in the area of health services should take account of existing cooperation arrangements, such as intergovernmental agreements and cross-border projects. Experience gained in numerous projects and cooperative ventures should be incorporated into the design of a new concept and be used as a starting point for discussions.

For example, German hospitals are successfully involved in cross-border projects within the Euroregions in a variety of ways. These existing approaches to cross-border networking of supply structures and capacity sharing should be promoted and expanded further.

In the formulation of possible framework conditions, it could be clarified that service providers providing out-patient or in-patient services to foreign EU nationals are not bound by the restrictions created by membership of the domestic social insurance system in the Member State, e.g. more scope for the reimbursement of services.

ECJ case law states that patients may avail themselves of in-patient services in other EU countries under various conditions (if they cannot be provided within a period of time that is judged appropriate given the patient's overall medical condition). Clarification is needed in this context, for example, on what constitutes an appropriate period of time.

3. Which issues (e.g. clinical supervision, 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 design and organisation of the national care schemes must remain the exclusive preserve of the Member States. The Member States should therefore have as broad a range of instruments as possible for shaping and running their health systems. Consequently, the European principle of the freedom to provide services must always be subordinate to the national governing interest when it adversely affects the cost and supply management of the national system in question.

The DKG advocates an approach under which the Member State on whose territory the health service is provided is responsible for the supervision, inspection and follow-up of any misconduct.

The "country-of-origin principle" that came to the fore in the debate on the Services Directive has not been deemed acceptable for the health area for good reasons. Any revival of this concept in the current discussion must be rejected out of hand.

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?**

Redress may be based on the regulations and rules of procedure of the Member State that proved responsible under the principle outlined under question 3, failing which, the rules of international private law apply. Existing mechanisms could in principle be used. However, this is merely stating how things are and does not provide either service providers or patients with any added value.

Community action on health services could provide added value through an informal and unbureaucratic problem-solving system akin to the existing EU "SOLVIT" project. The idea of a solution-oriented mediation process might make patient mobility more attractive.

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)?**

Supply planning, particularly hospital planning, that satisfies needs (including seasonal fluctuations) should continue to be a matter for the host regions. European rules would be unnecessary and counterproductive here.

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?**

With regard to possible rules on the provision of health services in the context of the freedom of establishment, the DKG stresses that the Member States continue to enjoy exclusive sovereignty when it comes to setting up and running health systems.

Otherwise, the rules set out in the Directive on the recognition of professional qualifications apply.

7. **Are there other issues where legal certainty should also be improved in the context of each specific health and 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?**

--

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 designation of European reference centres could – regardless of their actual

form – be one approach to promoting cross-border healthcare. An informed appraisal of this approach is not possible at present as the Commission's thoughts on this subject to date leave many questions unanswered.

- There is no clear definition of the objective, target groups or spheres of competence. For example, the types of disorders to be treated are not sufficiently defined.
- There is nothing about the criteria for designating reference centres, e.g. quality criteria.
- The Commission fails to say who would designate the reference centres, or how.
- It is unclear how the reference centres would fit in with existing cross-border healthcare projects and with ongoing national and European research initiatives (e.g. European Networks of Excellence, European Rare Diseases Networks, the centres of excellence attached to the Federal Ministry of Education and Research, etc.).
- Nor is there any explanation of how patient care, research and teaching in these reference centres would be funded.

Against this background, a precise concept for European Reference Centres must be developed. This concept must satisfy the following requirements:

- The remit of European Reference Centres must be limited to rare diseases and rare types of treatment.
- The definition of an appropriate level of care for the national population must remain the sole preserve of the Member States.
- European Reference Centres must not undermine the exclusive national competence for capacity planning in medical care.
- EU activities must be confined to rulings on cases with a cross-border element. Existing cross-border initiatives must not be jeopardised in the process.
- National regulatory sovereignty over research and teaching, along with healthcare funding, the care must not be adversely affected by European Reference Centres.
- European Reference Centres must not jeopardise existing national initiatives and structures, such as the centres of excellence attached to the Federal Ministry of Education and Research.The selection of reference centres must be based on objective, transparent procedures and the principle of equal opportunity. The suitability of the selected establishments must be checked regularly.
- Questions regarding the financing of cross-border treatment, as well as research and teaching, must be fully clarified.

The DKG thinks that the development of a European HTA network for the coordination of activities and the exchange of information makes sense. This could build on existing initiatives in the framework of the EU-funded "European Collaboration for Health Technology Assessment" (ECHTA/ECAHI), in which the German Institute for Medical Documentation and Information is also involved.

In addition, the development of a HTA database at EU level, in which all HTA reports produced globally are stored, could increase data transparency and improve the exchange of information. Existing databases should be included in this, if possible.

Consideration must also be given to the fact that HTA results are to a certain extent context-dependent and thus cannot be readily transferred between different healthcare systems. The individual Member States must therefore continue to have sole competence for deciding how information from the HTA reports should influence decisions on care and funding.

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?

As pointed out in the reply to question 1, and given the low anticipated volume of cross-border health services, adopting legislation should be done with caution and be viewed as a last resort only, so that existing cross-border partnerships and cooperation are not made less effective. Priority should be given to expanding existing cooperation arrangements. This includes intergovernmental agreements such as the Franco-German framework agreement on cross-border cooperation in the area of health.

Regardless of the answer to the question of which legislative or non-legislative measures are to be taken, a Community framework for the area of health services should be introduced with a view to creating legal certainty for the provision and uptake of cross-border health services. Its measures should serve solely to support the Member States in the areas in which a European approach can provide added value in comparison to health measures taken at national level.

Whether legislative measures are helping to achieve these objectives is something that should be checked at short and regular intervals after their entry into force. The DKG is following with particular interest the introduction of the "Health Systems Impact Assessments" as part of the better legislation initiative and will take an active part in the discussion on those procedures and results.