Answer from the German Federal Government
in Co-operation with the Laender
on the Commission Communication on Community Action on Health Services

Against the background of the exemption of health services from the scope of the Services Directive, Germany welcomes the fact that the Commission is initiating a consultation process on how to further proceed in the field of health services. At the same time, however, care should be taken to ensure close coordination between the procedures concerning social services and health services, since there are a number of overlaps. This goes, incidentally, also for the Health Policy Strategy.

Germany takes the view that in-depth discussion of health services should be based on the **Common Values and Principles** as agreed at the EPSCO Council on 1st / 2nd June 2006. The Common Values and Principles reflect the importance of the national health care systems. They contribute to a Social Europe that meets the expectations of European citizens. In this regard, they have a far wider scope than the issues addressed in this Commission Communication. In order for this consultation process to make an active and sound contribution to the debate on the future of health services, the health sector in the broader sense must be included.

Maintaining a healthcare system that is founded on the overarching principles of universality, access to high-quality care, equality and solidarity is a most intrinsic task of each Member State. The services offered by the solidarity-based health insurance are largely determined by what is medically necessary, in line with the generally recognised state of medical knowledge, while the financial contribution to be paid by each insured is determined by their financial capacity. To protect the coherence of the solidarity-based health care systems in the Community, it is essential that **Member States' steering capacity** – exercised through different instruments such as planning, licensing systems, pricing mechanisms, competitive elements or budget-capping - is guaranteed and that fundamental principles of the health care systems - such as Germany's benefits-in-kind principle – are retained without restriction. When applying Community provisions on free movement, competition, state aid etc, the specific character of the health care system concerned must be taken into consideration. In this context, therefore, care must be taken to ensure that the subsidiarity principle and the proportionality principle apply in full.

We welcome the fact that, in respect of Community action, the Commission distinguishes between areas in which legal certainty is to be established by means of legislative acts and other areas. Member States' exclusive responsibility for organising and financing their national healthcare systems must be respected and may not be eroded.

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?

In 2004, the national health insurance law was adjusted to the ECJ's ruling on patient mobility. In Germany, the insured have been able, since then to take up health services in other Member States not only by invoking the ECJ's rulings, but also on the basis of national law. Non-hospital treatment does not require prior authorisation; however, hospital treatment must be authorised in advance. In this respect, Germany's insured now have a greater choice of service providers. At the same time, health insurance funds were granted the right to enter into contracts with service providers within the Community. Accordingly, Germany's insured already have a Community-wide choice of care providers and the German providers are already now contending with community-wide competition.

According to the data available so far, the possibility of cross-border healthcare has not led to a sizable take-up of these services by the insured in Germany. The amounts spent by statutory health insurance funds on outpatient and inpatient services abroad are clearly below 0.5% whereby this number does not even distinguish between EU countries and non-EU countries. Take-up of hospital services by patients from other EU countries who come specifically for planned inpatient treatment is also negligible. By contrast, the willingness of healthcare providers to offer their services on a cross-border basis – either temporarily or by establishment – might tend to be somewhat higher.

Instances of cross-border services are largely restricted to border regions. There, good instruments are in place for cross-border co-operation, for example in the form of the Euregios. Several projects are already in place in the hospital sector, in emergency medical services and the mutual supply with blood products. Moreover, there are projects on individual diseases and the cross-border use of electronic health services. Meanwhile, health insurance funds are making ever more use of the recently granted possibility to conclude service contracts with foreign service providers. In the border regions, numerous framework agreements have already been concluded in order to avoid, *inter alia*, problems with the billing of inpatient services. Co-operation contracts concluded locally by health insurance funds with foreign service providers that are tailored to the specific demand and situation in a certain region, are usually a suitable means of allowing people living near the border freedom of choice without jeopardising the steering capacity and affordability of the national health care system.

Cross-border cooperation arrangements concluded between hospitals are on the increase, since they are of mutual advantage for the local actors, especially in densely populated areas near the border. So far, such cooperation arrangements have mainly taken the form of the pur-

chase of services between hospitals. This means that the 'purchasing' hospital finances the service of the foreign co-operation partner within the framework of its budget. Consequently, third-party payers are only indirectly involved in such forms of cooperation.

In addition, Germany has concluded a framework agreement on cross-border co-operation in the health field (including EMS) with France that will enter into effect in spring 2007. While the implications cannot now be assessed, all parties involved are interested in a marked intensification of cross-border care.

In the longer term, cross-border care is expected to increase further. In which ways this will impact on the German health insurance system is as yet unknown. A both conceivable and meaningful approach would be, for instance, for direct neighbour states to mutually factor in the capacities available in each other's health care facilities. Already now, some health care systems are benefiting from the efficient mutual use of resources.

Question 2: What specific legal clarification and what practical information is required by whom (eg; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

Issues requiring legal clarification:

- What are **health services**? The scope of a legislative regulation must be clearly defined. In this context, it should be borne in mind that the Services Directive already includes a definition of health services. In defining health services, care must be taken to ensure that Member States' autonomy in organising their health care systems is taken into account. High quality standards, transparency of services for the service recipient, 'wall-to-wall' services and universal access to health services respecting the equal treatment principle must continue to be ensured.

- When is treatment **subject to prior authorisation**? Until now, the ECJ has distinguished between non-hospital treatment (not requiring authorisation) and hospital treatment (requiring authorisation). However, Germany takes the view that this distinction should not depend solely on the hospital versus the non-hospital criterium. Another determinant might be whether certain treatments require a costly care provision structure and the concomitant planning.

- How long a **waiting period** must the insured observe before being eligible for hospital treatment abroad without obtaining prior authorisation? In the inpatient sector, the free-

dom to provide services applies subject to the restrictive conditions which the ECJ has imposed in several rulings. These conditions – that relate to waiting periods and internationally recognised medical standards – should be worded in a more concrete manner so that those who are potentially affected can have a degree of legal certainty and know, for instance, from which date they qualify for cost reimbursement.

- How must the **right to verification** be formulated if the insured wishes to determine whether the health insurance fund was right in denying them the approval of treatment abroad? The verification procedure must be transparent, objective and swift.

- In connection with **cost reimbursement**, the following legal issues should be clarified and practical information provided:

  - What **treatment costs** does treatment abroad involve for the insured? Before accessing services, the insured must know what added cost they will have to bear since reimbursement will be limited to the amount assumed if the treatment had been provided domestically.

  - What is the relationship between uptake of health services based on the freedom to **provide services** and uptake under **Regulation 1408/71**? At present, the scope of services differs according to whether they are taken up under the freedom to provide services or under Art. 22 (1) c) of Regulation 1408/71.

  - May a national regulation **make cost reimbursement contingent on** whether treatment of the insured abroad was provided by a **care provider** who is generally entitled to provide **services** or specifically entitled to provide certain forms of treatment according to the **foreign social insurance system**? (for example in Germany: is a German hospital that is not nationally licensed to provide outpatient services, entitled to provide these services to foreign insured persons?)

  Issues relating to **cost reimbursement** as addressed in the ECJ's jurisdiction might be covered in Regulation 1408/71 or in Regulation 883/2004 on the coordination of social security systems. If the provisions required for that purpose go beyond the coordination of social security systems and Art. 42 EC consequently no longer provides the appropriate legal basis, a separate directive on the basis of Art. 95 EC should be considered. In any event, however, it must be ensured that the provisions contained therein are compatible both with the ECJ's decisions and with the Regulation on the coordination of social security systems.

Practical information:
The insured must have easy access to information on the conditions under which they are entitled to receive treatment abroad. The information can be limited to only the conditions under which treatment abroad is covered. Information on which facility in which Member State can provide the necessary treatment, should the need arise, may not be demanded. It is up to the patients themselves to obtain this information with the assistance of their attending physician or the facilities in the Member State in which they are seeking treatment. No Member State can be expected to have information available on service providers in all other Member States.

Question 3: which issues (eg: 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?

Responsibility for the foregoing issues must lie with the Member State in whose territory the service is provided. Each competent body of a Member State oversees and supervises to the extent stipulated by national law the services that fall within their (territorial and technical) remit. Consequently, possible EU provisions on health services must start from these principles, respect existing Community law (e.g. the provisions of the Recognition Directive) but not create any new bureaucratic requirements such as 'points of single contact'.

This principle will certainly require some adjustments where special cross-border services, such as telematics, are concerned. Here, it is necessary to define who is responsible for drawing up and monitoring compliance with quality and safety standards and under what conditions.

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?

Responsibility for monitoring the safety and quality of healthcare services must remain with the competent bodies of the national system of the State in which the service is used. Depending on the structure of the national system concerned, these can be either government bodies or self-administration entities.

For contractual and non-contractual liability and compensation, provisions under international private law are currently being prepared on the EU level (Draft Regulations 'Rome I' and 'Rome II'). These legal instruments should also include a compact survey of conflict-of-law provisions governing cross-border healthcare services.

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)?

At this point in time, the hospitals licensed to provide care are already equally accessible to both German and foreign patients for treatment. Treatment of patients from other Member States does not compromise care supplied to the national population. Measures that go beyond cross-border cooperation and task-sharing cooperation among care facilities including reciprocal supplementation of services provided by the care facilities are not necessary. The foregoing already has a positive record in several Euregios (North Rhine-Westphalia / Maas, Baden-Wuerttemberg / Upper Rhine).

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?

Germany considers the provisions of Directive 2005/36/EC as sufficient.

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?

Question 8: 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?

Germany takes the view that the already existing fora are sufficient. The High-Level Group on Health Services has already made major contributions to the exchange of experience on problems related to cross-border healthcare services. However, its future role should be rethought. Should legislation on patient mobility be proposed, duplication of work will need to be avoided (negotiations in the Council and the EP on the one hand and group work on the other). Moreover, we have the OMC as a forum in which to exchange experience on non-harmonised legal

fields, such as the organisation of the national health insurance systems. It can have a complementary function in this regard.

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?

Future Community initiatives in the field of health services will have to be largely in line with the 'Common Values and Principles in EU health systems (adopted at the EPSCO Council on 1st /2nd June 2006).

- **Legal certainty for the Member States** to organise and structure their healthcare systems can be secured by means of various tools. In the final analysis, the decisive criterium is that the coherence of national healthcare systems is protected. Steering instruments such as planning, licensing systems, price-setting mechanisms, competitive elements or budget-capping must continue to be ensured.

- With respect to the question of how **legal certainty for the insured and service providers** can be guaranteed, in other words, under what conditions patients are entitled to obtain treatment abroad at what cost, please refer to the answer to question 2.

- In the field of **non-legislative measures**, Germany welcomes the establishment of an EU-wide network for the benefit of **patient safety**. However, Germany suggests that Community actions be more closely coordinated with those of WHO and the Council of Europe. In the patients' interest, intensive exchange among the Member States on existing national information possibilities and entities (without each Member State being required to have detailed information on the other healthcare systems available), and the current law on complaints and liability is desirable. Owing to the profound differences which exist, closed system descriptions and comparisons would seem to be useful. This also shows in the results achieved so far by the working group on 'Cross Border Healthcare Purchasing and Provision (including rights and duties of patients)' of the High-Level Group on Health Services.