



BDIZ EDI e.V. · Lipowskystr. 12 · D-81373 München · GERMANY

European Commission
Health and Consumer Protection
Health Services Consultation
B232 8/102

health-services-consultation@ec.europa.eu

European
Association
of Dental
Implantologists

B – 1049 Brussels
Belgium

30 January 2007

**Community Action on Health Services
Statement of the Bundesverband der implantologisch tätigen Zahnärzte in Europa / European Association of Dental Implantologists (BDIZ EDI)**

Ladies and Gentlemen:

Since 1989, the BDIZ EDI – European Association of Dental Implantologists has been representing the interests of currently more than 3000 German dentists in private practice and oral and maxillofacial surgeons specializing in dental implantology. Since 2002, the BDIZ EDI has been organized at EU level, counting implantological associations in other member states among its members. We are participating in the Consultation regarding Community actions of health services initiated by the cop commission bulletin of 26 September 2006 and comment on the various questions raised from the point of view of our German members.

1. Introduction

The European Union is correct in stating that high-quality health services are a priority issue for European citizens. This is also enshrined in the EU Charter of Fundamental Rights, which according to the European Court of Justice forms part of the general legal principles of the European Union (consistently ruled by the ECJ, one example being ECJ Case C-36/02, No. 33). The fundamental rights must be observed by both the Community and its Member States (ECJ, op. cit., No. 33). Article 35 (Healthcare) of the Charter of Fundamental Rights of the European Union (proclaimed in Nice on 7 December 2000, OJ C 364 of 18 December 2000, p. 1) stipulates that "everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices". In its ground-breaking decision in Kohll (Case C – 158/36), the European Court of Justice ruled as early as in 1998 that a limitation on the free selection of physicians and dentists is not compatible with fundamental European rights. (This applies equally if the national health insurance system impedes or limits the cross-border utilization of medical and dental services.) According to the ECJ, whose opinion we fully share, the demand for prior authorization constitutes an obstacle to free competition at least in the case of outpatient medical services (Decker, No. 36).

The freedom to choose an occupation and the right to engage in work provided for in Article 15 of the Charter of Fundamental Rights by necessity goes hand in

Christian Berger
President
berger@bdizedi.org

Prof. Dr. Dr. J. E. Zöller
Vice President
zoeller@bdizedi.org

Dr. Heimo Mangelsdorf
Treasurer
mangelsdorf@bdizedi.org

Dr. Detlef Hildebrand
Secretary
hildebrand@bdizedi.org

Advisors:

Dr. Dr. Bernd Kreusser
kreusser@bdizedi.org

Dr. Jörg Neugebauer
neugebauer@bdizedi.org

Dr. Renate Tischer-Richter
tischer-richter@bdizedi.org

Dr. Freimut Vizethum
vizethum@bdizedi.org

Dr. Georg Bayer
bayer@bdizedi.org

Legal Advisor:

Dr. Thomas Ratajczak
ratajczak@bdizedi.org

BDIZ EDI
Lipowskystr. 12
D-81373 München
GERMANY

Fon: +49-89-720 69 888
Fax: +49-89-720 69 023
office@bdizedi.org
www.bdizedi.org

hand with the free selection of doctors. This article states that “every citizen of the Union has the freedom to seek employment, to work, to exercise the right of establishment and to provide services in any Member State”. Finally, reference should also be made to Article 16 of the Charter of Fundamental Rights, which enshrines the freedom to conduct a business. The protection from government restrictions of the freedom to choose an occupation also applies in cases in which the doctor works on a contractual basis within a statutory health insurance system¹.

In the introduction to the paper dated 26 September 2006, which initiates the consultation process, the Commission states that the proposal introduced at the beginning of 2004 for a directive on services in the internal market primarily entailed codifying the rulings of the European Court of Justice in applying free movement principles to health services.

The German Dental Council (BZÄK) published a legal opinion on this subject prior to the conclusion of debate in the European Parliament (*Die Dienstleistungsrichtlinie und der Gesundheitsbereich, Rechtsgutachten von Prof. Dr. Siegbert Alber, Generalanwalt a.D. am Gerichtshof der Europäischen Gemeinschaften.*) In this document, Alber confirms the view that the ECJ has consistently ruled that medical activities already come within Article 50 of the EU Treaty. What is particularly important in this context is the fact that national legislation relating to social security does not exclude the application of Articles 49 and 50 of the EU Treaty.

Regrettably, this argumentation played little role in the European Parliament’s debate; instead, the political intention of declaring health services to be “services of general interest” by their very definition and excluding them from the overarching principle of undistorted competition became evident. For this purpose, reference was made to a “European model of society” as described by the Commission in its White Book on Services of General Interest (COM (2004) 374 final). Against this background, the BDIZ EDI appreciates the fact that the commission now distinguishes between, health services and services of general interest, initiating to separate consultation processes.

It is to be hoped that this approach will result in the promotion of competition in health services. If not, this would be incompatible with the EC Treaty and the rulings of the European Court of Justice. Community activities in the healthcare segment should not exclude the competition aspect and not confine the issue merely to the question of “patient mobility” and the need to safeguard and reinforce high-quality services and cross-border cooperation. The health care providers are also citizens of Europe, to whom the fundamental freedoms equally apply. Accordingly, from the vantage point of both patients and doctors (as well as other healthcare providers), it is a question of creating “clarity about their rights and entitlements when they move from one EU Member State to another” (Council Conclusions on Common Values and Principles in EU Healthcare systems, 2,733rd Employment, Social Policy, Health and Consumer Affairs Council Meeting, Luxembourg, 1-2 June 2006).

In this connection, the Commission is correct in stating that the principles already established by the European Court of Justice must be respected by all Community activities. In contrast to the Commission, the BDIZ EDI would prefer not to describe this in terms of “equality, solidarity and universality” but in terms of

¹ See Prof. Winfried Kluth, *Ärztliche Berufsfreiheit unter Wirtschaftlichkeitsvorbehalt* (MedR 2005, 65, 69)

“self-responsibility, solidarity and competition”

In this connection, it will be important to ensure that the existing discrimination of national healthcare providers within the German healthcare system is not continued but rather eliminated as a result of the new European action. Instead, recommendations should be formulated in the sectoral health services directive providing for the national healthcare systems to also be oriented to the fundamental European freedoms².

It is precisely in this respect that the planned “support for Member States in areas where European action can add value to their national action on health services” should take account of the fact that the cost reimbursement principle is more suitable for providing transparency for patients and for promoting competition than an anonymous system with entitlements to benefits in kind. Those who deplore the asymmetry of the information flow in the healthcare system should also ensure transparency in this field.

2. The need for Community action on health services

2.1 The need for legal certainty

In its paper, the Commission correctly states that “the rulings of the Court ... are clear in themselves”. The BDIZ EDI wishes to comment on the issues raised as follows:

As already stated above, the Charter of Fundamental Rights proclaims free patient access to services in this sector. It gives providers in the healthcare system the right to provide services in other European countries as well.

Common to these principles is the commitment to quality. In this connection it should be noted that the European Court of Justice ruled in Müller-Faure/van Riet (Case C-385/99) and Smits/Peerbooms (Case C-157/99) that doctors and dentists registered in other Member States must be acknowledged as being equally qualified to those registered nationally. The ECJ ruled that attempts to restrict the freedom of services by reference to the protection of health cannot be justified by questioning the quality of the medical services provided in other Member States. The ECJ, in its judgments, also refers to the former sectoral guidelines for the recognition of professional diplomas, which were consolidated in the Directive on the recognition of professional qualifications (2005/36/EC).

With respect to Member States’ scope for organizing their social (security) systems, the European Court of Justice has ruled that Member States are “permit them to exclude the public health sector, as a sector of economic activity and from the point of view of freedom to provide services, from the application of the fundamental principle of freedom of movement” (ECJ, Case C-158/96).

² (In this connection, it is difficult to understand the reasons prompting the coalition parliamentary parties in the German Bundestag to submit a motion in connection with the request for modifications to the planned Act to Amend Contractual Doctor Law and other Acts (*Vertragsarztrechtsänderungsgesetz – VÄndG*) permitting insurance holders to claim services from providers in other states of the European Union by means of cost reimbursement but preventing this in the case of the utilisation of such services in Germany (Health Committee, Committee Publication 0107 on Item 8 of the agenda on 18 October 2006).

With respect to assuring the financial sustainability of the healthcare systems, there is no risk of the greater freedom of choice in exercising individual rights leading to any disadvantages as it can be assumed that patients will not seek the same treatment more than once “just for the fun of it”. Quite to the contrary: German experience so far with the cast reimbursement provisions in § 13 of the German Social Security Code (SGB) V shows that patients exercise their greater freedom of choice in a very responsible manner. Especially in the area of dental implantology, German statutory health insurance have been reimbursing the cost of implant-supports restorations only in exceptional cases since the relevant law was changed as per 1 July 1997. The concomitant enlarged area of responsibility for patients and treatment providers alike has actually led to a substantial improvement in the availability and quality of medical care in this area. In any case, patient behaviour can be influenced by combining deductibles and reimbursements, for example.

However, there is one aspect that we cannot help acknowledging: Those who want to realize the patients’ free selection of doctors will have to utilize the instrument of cost reimbursement – as envisioned by the Services Directive – as a central instrument for control. It is the only instrument that facilitates patient mobility independently of the structure of the national healthcare systems without requiring the creation of new transnational financial and transfer bureaucracies.

Fundamental doubts are allowed as to whether there is any need for regulation concerning the identification, selection and comparison of foreign service providers as the Commission seems to think. In a system which is exposed to greater competition, the market will provide scope for comparisons of its own accord.

2.2 Different kinds of cross-border healthcare

With respect to the second alternative stated, it should be noted that the introduction of a European health insurance card on its own is of course in no way able to cover care; this is the responsibility of healthcare providers rather than a technical system, which is primarily to be used for billing purposes. Moreover, given the discussion currently being conducted in Germany about the introduction of the electronic health card it is not at all clear how such a complex system is to work on a European level. Nor does the BDIZ EDI by any means see any necessity for such a system.

2.3 The relevance of Community action to overall healthcare system objectives

At this point, the BDIZ EDI feels that the Commission is heading in the wrong direction by stating that the key to sustainability for healthcare systems is controlling costs and improving efficiency. Even though prevention and health promotion are mentioned in a single breath, this approach completely ignores the elements of **self-responsibility, quality and competition**. It is not clear why the Commission distances itself from the criteria established in the Directive on Services in the Internal Market, particularly the competitiveness of service companies in the internal market.

The goal of European-wide high-quality healthcare can only be achieved if the providers and recipients of health services take a responsible approach to allocating the limited resources available. This also concerns the question as to the extent of insurance cover which the insured person is initially required to take out. An approach based on “just distribution, equality and solidarity” is completely inadequate as it fails

to address the problems caused by demographic factors in particular in connection with financing health services in the next generation. It is particularly in light of the need for intra-generational solidarity that the European Union must aspire to promoting a sustainable financial basis for the healthcare system.

The interpretation in the Commission's paper according to which the EU research framework programs are already making a contribution to improving the efficiency and efficacy of all European healthcare systems must also be viewed critically. The BDIZ EDI is not aware of any evidence that a European system of electronic health services might help to establish safe infrastructures, systems and services for health telematics.

2.4 Nature and impact of cross-border healthcare

At this point, the BDIZ EDI would once again like to stress that the introduction of a cost reimbursement system appears to be the only practical way to ensure transparency and mobility and to give patients the power to make their own decisions. The effect on the receiving countries will reflect the principle of supply and demand as in other markets. This also offers opportunities for healthcare as a growth market in Europe.

Conclusive comments on 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?

Answer: We do not believe that cross-border healthcare in the field of dental implantology currently has any measurable influence on the accessibility, quality or financial sustainability of the German healthcare system. The reason is most probably the lowly extent to which cross-border health services are being sought. Implantological services are available both to patients from Germany and to patients from other Member States. Increased cross-border utilization of health services would, in principle, encourage competition and, thus, also enhance the quality of the services provided. The BDIZ EDI is not aware of any threats to the financial sustainability of the healthcare systems.

3. Areas of possible Community actions

3.1 Legal certainty

3.1.1 Minimum information and clarification requirements to enable cross-border healthcare

In Watts (Case C-372/04), the European Court of Justice determined in connection with hospital treatment in other Member States (at the expense of the United Kingdom National Health Service) that a medical service which is provided in a Member State and paid for by the patient does not lose its eligibility for inclusion in the freedom of movement of services as defined by the EC Treaty merely on the grounds that reimbursement of the cost of the treatment in question is applied for in accordance with the legal rules relating to the health insurance system of another Member State which primarily provides for non-cash benefits (No. 90).

It should therefore be noted that health services cannot be excluded from the scope covered by the provisions of the EC Treaty with respect to the free movement of services on account of their nature or the fact that they are provided solely in a public-sector context (cf. ECJ in Case C-372/04). The ECJ also argued that medical ser-

vices come within Article 49 et seq. of the EU Treaty, there being no need to distinguish between care provided in a hospital environment and care provided outside such an environment (No. 86; see also No. 89 and 123). Thus, a person's right to utilize health services cannot be restricted by the operation of national law, in this case, for example, membership of a national social security system. Attempts to do so would be incompatible with Article 49 of the EC Treaty.

This is not altered by the fact that the patient then seeks reimbursement of his or her costs via the national social security system. The "condition" cited by the Commission, i.e. authorization for the provision of health services abroad, is only relevant with respect to the reimbursement of the patient's costs, but not to the provision of health services as such. If such approval has been granted or unlawfully withheld, the patient is entitled to recover reimbursement of the costs which he or she has sustained even in cases in which, for example, there is no reimbursement rate in the national healthcare system in question as hospital treatment is free of charge in the country of origin (ECJ Case C-372/04, No. 127).

The European Court of Justice calls on the Member States to seek a balance between the goal of the patient's freedom of movement, on the one hand, and the national restraints with respect to planning available hospital capacity, controlling healthcare costs and safeguarding the financial balance of the social security systems (No. 145). Despite ruling that the individual Member State is responsible for organizing its own healthcare system and the provision of medical care, the European Court of Justice considers that "adjustments" to the national social security systems may be required where these are stipulated by the provisions of the EC Treaty or secondary European legislation. Article 22 of Regulation (EEC) No. 1408/71, which concerns the covering of costs for medical treatment in another Member State, must be amended in connection with treatment received outside a hospital to abolish the need for any prior authorization for such outpatient treatment.

This recital (No. 54), which had originally been included in the Commission's Directive on Services in the Internal Market, should be given greater attention once more in connection with the current consultations and the planned action in the health sector. Anything else would be a regressive step and fall far short of the principles established by the European Court of Justice on questions relating to the utilization of health services.

Conclusive comments on 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?

Answer: The BDIZ EDI doubts whether it is necessary for health-related data to be transferred between the different healthcare systems for treating patients; the same thing applies to the European health card and the electronic patient file.

If patients decide to undergo treatment in another European country, it is in their own interests to make sure that the medical files of their prior consulting doctors or dentists are made available prior to the commencement of treatment; alternatively, it would be possible for the treating doctor or dentist to request these documents in accordance with current practice. With respect to legal clarification, the BDIZ EDI considers it crucial to distinguish between legal questions arising from the insurance relationship and those arising from the treatment contract. Safe, high-quality and efficient cross-border healthcare should concentrate on the

treatment contract and the direct relationship of trust between patients and healthcare providers and supply answers to questions relating to the insurance relationship on the basis of private law.

In addition, the BDIZ EDI believes it would be desirable to create the prerequisites for a situation in which service providers wishing to provide health service in another Member State to obtain information about the legal framework in a form that is comprehensible to them. These include not only the pertinent regulations affecting the practicing of a profession (professional statutes, accounting and billing rules etc.), but also patient rights and liability issues as applicable to the respective Member State.

From the ECJ decision in the Watts case follows the need to introduce common European criteria for an objective assessment of whether a given inpatient treatment is required more quickly than the respective national healthcare system can provide it. In the absence of such common criteria, it must be feared that any deficiencies of a given healthcare system might be denied, at the expense of the patients.

3.1.2 Identifying the competent authorities and their responsibilities

The BDIZ EDI fundamentally agrees that for the internal market rules to be applied it is important to create clarity as to which authorities in the individual Member States have regulatory responsibility (professional and otherwise). With respect to litigation and compensation issues, the law of the country in which the services is provided should apply.

“Continuity of care” is ensured by virtue of professional rules, which place on healthcare providers, e.g. in the dental area, the duty to ensure that they are able provide their patients with the appropriate care, § 9 (2) Sample Rules of Professional Conduct of the BZÄK, the state associations (Chambers of the Dentists) are responsible for monitoring compliance with the rules of professional conduct. For this purpose, it is necessary for care providers who supply services outside the state in which they are registered to register with the responsible regulatory authority in the state or country in which they provide the services. In turn, these authorities should be obliged to provide comprehensive information about the determinants and legal framework according to which the services are to be provided.

Conclusive comments on question 3: Which issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of what countries? Are these different for the different kinds of cross-border healthcare described in section 2.2?

Answer: As far as the BDIZ EDI is concerned, there is no difference in the responsibilities. The treatment contract should be subject to the law of the country in which treatment is provided.

3.1.3 Responsibility for harm caused by healthcare and compensation arising from cross-border healthcare

As far as the BDIZ EDI is concerned, no additional action on the part of the European Union is necessary. The treatment contract is subject to the law of the Member State in which the treatment is provided. Legal recourse must be given according to the law of that Member State, something for which the existing European legal standards

provide sufficient legal protection per se as well as sufficient enforcement protection. However, both patients and service providers should be able to obtain information, in a form that is comprehensible to them, as to what measures the Member State in question has undertaken. If this information is lacking, a patient might not be able to decide freely to obtain health services in another Member State for fear of relinquishing legal rights. Each patient, therefore, would need to know beforehand whether the respective Member State has installed mechanisms for asserting any legal claims that appear satisfactory to the patient.

Conclusive comments on 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?

Answer: The national legal systems as well as the voluntary out-of-court arbitration arrangements installed by the associations already provide sufficient mechanisms for patients seeking redress in the event of any harm sustained in the utilization of a health service. In EU countries in which this is not yet the case, efforts should be made to ensure that the healthcare provider has sufficient liability insurance cover prior to providing the health service.

3.1.4 Ensuring a balanced healthcare accessible to all

The BDIZ EDI doubts whether action on the part of the European Union or legislative intervention in the Member States is able to influence the utilization of health services by citizens of the European Union in such a way that a “balanced availability of healthcare for everyone” or “overall sustainability of the healthcare system in the Member State concerned” can be achieved. This would be in contradiction of the principles of the freedom of services and constitute an unlawful restriction of such freedom. Public-sector regulation would also run counter to the EU’s Lisbon strategy of strengthening service companies’ competitiveness.

Conclusive comments on question 5: What action is needed to ensure that treating patients from other Member States is compatible with the provision of balanced medical and hospital services accessible to all (e.g. by means of financial compensation for their treatment in “receiving” countries)?

Answer: The BDIZ EDI assumes that in line with the draft Directive on Services in the Internal Market (Article 23) all further action will be based on the cost reimbursement principle. The BDIZ EDI takes the view that this controlling element can ensure that sufficient capacities for balanced healthcare are provided.

3.1.5 Other issues

The insured persons rather than the Member States must be able to make decisions on what health services they individually consider to be reasonable and wish to utilize. The “nanny state” approach still being adopted by social security and national healthcare systems towards European citizens is incompatible with the principle of politically mature Union citizens assuming responsibility for their own fates. From this point of view, in particular, it is important to reinforce self-responsibility by, for example, including health tuition in national education systems.

At most, the government's duty is to provide basic services (*ad curam vitae*) by ensuring that sufficient financial resources are available. Only to this extent should there be compulsory health insurance if and to the extent that the national healthcare system is not tax-financed.

Conclusive comments on 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?

Answer: The BDIZ EDI feels that it is necessary for health-related issues to be integrated in national education plans to a greater extent in the interests of encouraging a greater sense of self-responsibility on the part of citizens. A uniform base catalogue of necessary medical services financed by the social security system either on a contribution or tax basis should be drawn up in a dialog in which all elements of society participate.

Conclusive comments on question 7: Are there any 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?

Answer: The BDIZ EDI thinks that the healthcare systems should be opened up to competition to a greater extent. Only free competition ensures that Union citizens receive high-quality medical care. As already stated, it is also necessary to draw a strict line of distinction between patients' insurance relationship and the treatment contract between the provider and recipient of services.

3.2 Support to Member States

In principle, BDIZ EDI appreciates any support for assured highly specialized medical care within the European Union. A European network of reference centres as envisioned by the Commission will certainly contribute toward this goal; however, there are still a number of open questions to be answered before taking further steps in the direction of designing such a network. These questions are related to the definitions of responsibilities and objectives, to quality-related criteria within these centres and the responsibility for defining these criteria, to responsibilities and procedures for the selection of these centres, to the financial support for these centres and to patients' access to them.

The BDIZ EDI therefore proposes to continue pursuing the idea of creating a European network of reference centres, but to do so independently of any measures aimed at improving the provision of health services to avoid unnecessary delays in implementing the required measures. With regard to the realization of innovative potentials, the BDIZ EDI in principle supports the Commission's goal of promoting co-operation between Member States. It is especially in this area that medical professional associations organized a European level can serve as liaisons and supported accordingly. It should be noted, however, that the legal frameworks of the various healthcare systems within the EU are very different, meaning that innovations would always have to be evaluated against the background of the respective system. This also means that the results of any evaluations can usually only be applied to medical

aspects, but not to cost or social aspects.

Conclusive comments on question 8: In what ways should European action contribute to furthering the healthcare systems of the Member States and the various stakeholders within these systems? Are there any areas which have not been mentioned above?

Answer: The BDIZ EDI considers an end to “nanny state” approach to healthcare to be crucial. Instead, incentive systems must be developed with the aim of encouraging greater health protection, e.g. in the prevention area or by introducing bonus/penalty systems. Generally speaking, the healthcare system must be oriented more firmly to the self-responsibility of all healthcare stakeholders (providers and recipients of services), self-administration and competition to enable innovations in this sector in the future as well.

4. Tools and instruments for Community action

4.1 Options for instruments

In the view of the BDIZ EDI, the method of open coordination has proved itself, especially in those areas in which the European legislator has only subsidiary powers. Any binding legislation to which thought is additionally being given, e.g. in the form of a regulation or directive, should codify the rulings of the European Court of Justice on health services. In particular, the BDIZ EDI supports efforts to strengthen practical cooperation between healthcare system stakeholders. Dentists' associations can make a key contribution in this respect, e.g. as part of European professional law for dentists.

Conclusive comments on 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?

Answer: The BDIZ EDI supports a directive on health services in the internal market if it codifies the rulings of the European Court of Justice. Other than this, it is not in favour of legislation, particularly in view of the excessive bureaucracy which could be expected as a result of ratification as national law.

Munich, 30th of January 2007

Christian Berger
President

BDIZ EDI
Lipowskystr. 12
D-81373 München
GERMANY

Fon: +49-89-720 69 888
Fax: +49-89-720 69 023
office@bdizedi.org
www.bdizedi.org

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.