JUDGMENT OF THE COURT (Grand Chamber)

10 March 2009 *

In Case C-169/07,

REFERENCE for a preliminary ruling under Article 234 EC from the Verwaltungsgerichtshof (Austria), made by decision of 22 February 2007, received at the Court on 30 March 2007, in the proceedings

Hartlauer Handelsgesellschaft mbH

v

Wiener Landesregierung,

Oberösterreichische Landesregierung,

* Language of the case: German.

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, A. Rosas, K. Lenaerts, T. von Danwitz, Presidents of Chambers, A. Tizzano, J.N. Cunha Rodrigues, R. Silva de Lapuerta, K. Schiemann, J. Malenovský (Rapporteur), A. Arabadjiev, C. Toader and J.-J. Kasel, Judges,

Advocate General: Y. Bot,
Registrar: K. Sztranc-Sławiczek, Administrator,

having regard to the written procedure and further to the hearing on 26 February 2008,

after considering the observations submitted on behalf of:

— Hartlauer Handelsgesellschaft mbH, by W. Graziani-Weiss, Rechtsanwalt,

— the Oberösterreichische Landesregierung, by G. Hörmanseder, acting as Agent,

— the Austrian Government, by C. Pesendorfer, F. Felix, G. Aigner and G. Endel, acting as Agents,

— the Netherlands Government, by C. Wissels, M. de Grave and Y. de Vries, acting as Agents,

— the Norwegian Government, by K.B. Moen and J.A. Dalbakk, acting as Agents,

— the Commission of the European Communities, by G. Braun, E. Traversa and V. Kreuschitz, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 9 September 2008,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 43 EC and 48 EC.

2 The reference was made in the course of proceedings between Hartlauer Handelsgesellschaft mbH ('Hartlauer') and the Wiener Landesregierung (Government of the Province of Vienna) and between Hartlauer and the Oberösterreichische

Landesregierung (Government of the Province of Upper Austria) concerning those governments' decisions to refuse Hartlauer authorisation to set up and operate independent outpatient dental clinics.

National legal context

3 The conditions for setting up and operating health institutions are laid down at Federal level by the Krankenanstaltengesetz (Law on hospitals, BGBl. 1/1957), as amended by the law published at BGBl. I, 5/2001 ('the KAG'), subsequently retitled the Krankenanstalten- und Kuranstaltengesetz (Law on hospitals and sanatoria), as amended by the law published at BGBl. I, 122/2006 ('the KAKuG').

4 In accordance with Paragraph 2(1) of the KAG and Paragraph 2(1) of the KAKuG, 'health institutions' (Krankenanstalten) within the meaning of those laws are inter alia 'independent outpatient clinics (selbständige Ambulatorien) (radiology institutions, outpatient dental clinics and similar establishments), that is, organisationally independent establishments for the examination or treatment of persons who do not require admission to an institution.'

5 Paragraph 3 of the KAG provides:

'(1) Health institutions require authorisation from the provincial government both for setting them up and for their operation. …

(2) Authorisation to establish a health institution within the meaning of subparagraph 1 may be granted only if, in particular,

(a) according to the stated purpose of the health institution and the services proposed to be offered, having regard to the already existing care offered by public, private non-profit-making, and other health institutions with contracts with sickness funds, and, in the case of the setting up of a health institution in the operational form of an independent outpatient clinic, having regard also to the care offered by established doctors contracted to sickness funds, establishments owned by sickness funds and establishments contracted to sickness funds, and, in the case of outpatient dental clinics, having regard also to established dentists (Dentisten) contracted to sickness funds, there is a need;

…'

6 Paragraph 3(1) and (2) of the KAKuG repeats Paragraph 3(1) and (2) of the KAG in similar terms, but provides that the application for authorisation is also to be examined from the point of view of the health institutions plan of the province concerned and, in the case of setting up a health institution in the form of an independent outpatient clinic, having regard also to the care offered by the outpatient departments of public, private non-profit-making, and other health institutions contracted to sickness funds, and by dental practitioners.

7 In accordance with Article 12(1)(1) of the Bundes-Verfassungsgesetz (Federal Constitutional Law), it is for the provinces to adopt implementing laws and to enforce the federal legislation concerning health institutions.

8 At the material time for resolution of the dispute between Hartlauer and the Wiener Landesregierung, the applicable law was the KAG. That law was implemented by the Wiener Krankenanstaltengesetz 1987 (Viennese Law on health institutions of 1987, LGBl. 23/1987), as amended by the law published at LGBl. 48/2001 ('the Wr. KAG').

9 Paragraph 4(2) of the Wr. KAG provides:

'Authorisation to set up a health institution [such as an independent outpatient clinic] may … be granted only subject to the conditions and obligations necessary in accordance with the state of knowledge of medical science and with the requirements for the correct operation of a health institution, and only if

(a) in accordance with the stated purpose of the institution and the services proposed to be offered, having regard to the already existing care offered by public, private non-profit-making, and other health institutions with contracts with sickness funds, and, in the case of the setting up of a health institution in the operational form of an independent outpatient clinic, having regard also to the care offered by established doctors contracted to sickness funds, establishments owned by sickness funds and establishments contracted to sickness funds, and, in the case of outpatient dental clinics, having regard also to established dentists (Dentisten) contracted to sickness funds, there is a need;

…'

10 At the material time for resolution of the dispute between Hartlauer and the Oberösterreichische Landesregierung, the applicable law was the KAKuG. That law

was implemented by the Oberösterreichisches Krankenanstaltengesetz 1997 (Law of Upper Austria on health institutions of 1997, LGBl. 132/1997), as amended by the law published at LGBl. 99/2005 ('the Oö. KAG').

11 Paragraph 5 of the Oö. KAG provides:

'(1) Authorisation to set up an institution is to be granted … if

1. there is a need within the meaning of subparagraph 2,

…

(2) The need for a health institution with the stated purpose and the services proposed to be offered is to be assessed, taking into account the maximum number of beds classified under the health institutions plan of Upper Austria …, having regard to the already existing care offered within a reasonable distance by public, private non-profit-making, and other health institutions with contracts with sickness funds, and, in the case of the setting up of a health institution in the operational form of an independent outpatient clinic, having regard also to the care offered by outpatient clinics of those health institutions and by established doctors contracted to sickness funds, establishments owned by sickness funds and establishments contracted to sickness funds, and, in the case of outpatient dental clinics, having regard also to established dentists (Dentisten) contracted to sickness funds. …'

12 Paragraph 3(1) of the Ärztegesetz 1998 (Law on doctors of 1998, BGBl. I, 169/1998), as amended by the law published at BGBl. I, 110/2001, provides that the independent practice of the profession of doctor is reserved exclusively to general practitioners, licensed doctors and specialist doctors.

13 Under Paragraph 52a of that law, doctors can practise together in the form of a group practice with an independent entitlement to practise ('group practice'). A group practice's entitlement to practise derives from the entitlement to practise of the doctors and dentists who are involved in the practice as personally liable partners. The practice must take the legal form of a partnership. Only doctors and dentists who are entitled to practise independently can be personally liable partners in a group practice.

14 Paragraph 26(1) of the Zahnärztegesetz (Law on dental practitioners, BGBl. I, 126/2005), which entered into force on 1 January 2006, as amended by the law published at BGBl. 1, 80/2006, provides:

'Independently practising members of the dental profession within the meaning of Paragraph 24(1) can also practise together as a group practice with an independent entitlement to practise, to be set up in the legal form of a partnership within the meaning of Paragraph 1 of the Erwerbsgesellschaftengesetz (Law on partnerships) … Only members of the dental profession and doctors entitled to practise independently may belong to a group practice as personally liable partners. Other persons may not belong to the group practice as partners and may not therefore share in the turnover or profits.'

15 The establishment of a group practice is not subject to any examination of need as defined in the legislation cited above.

16 As to the provision of medical care by the social security system, it is stated in the order for reference that the current system is primarily a system of benefits in kind (Sachleistungssytem). Under that system the social security institutions are obliged to set up arrangements by which insured persons can obtain medical services without having to pay fees to the provider of the services. That means that those services are provided either by establishments belonging to the social security institutions or by establishments or independent practitioners who are under contract to those institutions and provide the services on their own account ('contractual practitioners').

17 In addition to the system of benefits in kind, there is a system of reimbursement of costs paid by the insured person (Kostenerstattungssytem). Under this system the social security institutions are obliged to reimburse the medical costs paid by insured persons where such a person, instead of consulting a contractual practitioner, has had recourse to a doctor who is not a contractual practitioner and has entered into an agreement to pay him fees. The insured person then enjoys the right to reimbursement by the social security institution of the costs he has paid, up to a ceiling which is generally 80% of the sum which would have been charged if the treatment had been entrusted to a contractual practitioner.

The main proceedings and the order for reference

18 By decision of 29 August 2001 the Wiener Landesregierung rejected the application by Hartlauer, a company established in Germany, for authorisation to set up a private health institution in the form of a outpatient dental clinic in the 21st District of Vienna. The Wiener Landesregierung based its decision on Paragraph 4 of the Wr. KAG and a report produced by an official medical expert. According to the report, dental care was adequately ensured in Vienna by public and private non-profit-making health institutions and other contractual practitioners offering comparable services. That assessment had been carried out on the basis of the ratio of the number of inhabitants to the number of dental practitioners, which was 2 207 inhabitants per practitioner. On the basis of the expert's findings, the Wiener Landesregierung concluded that the health institution whose establishment was sought would not have the effect of substantially

accelerating, intensifying or improving the provision of dental medical care for patients resident in Vienna, so that there was no need for the institution.

19 On similar grounds, the Oberösterreichische Landesregierung by decision of 20 September 2006 rejected Hartlauer's application for authorisation to set up a outpatient dental clinic in Wels. The application was examined on the basis of the waiting time for appointments with the providers of services mentioned in Paragraph 5(2) of the Oö. KAG, including the outpatient departments of the health institutions concerned.

20 Hartlauer brought proceedings against those decisions before the Verwaltungsgerichtshof (Administrative Court), which joined the two cases.

21 The Verwaltungsgerichtshof is uncertain as to the compatibility with Article 43 EC of the national legislation on the definition of needs in connection with the setting up of health institutions, and the effect on that compatibility of the fact that, when assessing those needs, Paragraph 5(2) of the Oö. KAG now requires account also to be taken of the care offered by the outpatient departments of certain health institutions, with the consequence of making access to the market in question by a new candidate even more difficult.

22 In those circumstances the Verwaltungsgerichtshof decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'1. Does Article 43 EC (in conjunction with Article 48 EC) preclude the application of national legislation under which authorisation is required to set up a private health institution in the operational form of an independent outpatient clinic for dental medicine (outpatient dental clinic) and authorisation is to be refused if, according

to the stated purpose of the institution and the services proposed to be offered, having regard to the existing provision of care by established doctors contracted to sickness funds, establishments owned by sickness funds and establishments contracted to sickness funds and by established dentists (Dentisten) contracted to sickness funds, there is no need for the planned outpatient dental clinic?

2. Is the answer to Question 1 any different if the existing provision of care by outpatient departments of public, private non-profit-making and other health institutions contracted to sickness funds is also to be included in the examination as to need?'

The questions referred for a preliminary ruling

Admissibility

23 At the hearing the Austrian Government expressed doubt as to the admissibility of the reference for a preliminary ruling, claiming that Hartlauer is abusing the Community rules. It submitted that, in the present case, the cross-border connection was established artificially, since Hartlauer is the subsidiary of an Austrian company which intends to re-establish itself in Austria and which set up the subsidiary with the sole aim of bringing its situation within the scope of Community law.

24 In that regard, it must be recalled that it is solely for the national court before which the dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine in the light of the particular circumstances of the case both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the

questions submitted concern the interpretation of Community law, the Court is in principle bound to give a ruling (see, inter alia, Case C-379/98 *PreussenElektra* [2001] ECR I-2099, paragraph 38, and Case C-476/01 *Kapper* [2004] ECR I-5205, paragraph 24).

25 The Court can refuse to give a preliminary ruling on a question submitted by a national court only where, in particular, it is quite obvious that the ruling sought by that court on the interpretation or validity of Community law bears no relation to the actual facts of the main action or its purpose or where the problem is hypothetical (Case C-308/06 *Intertanko and Others* [2008] ECR I-4057, paragraph 32 and the case-law cited).

26 In the present case, it is not obvious that the interpretation sought bears no relation to the actual facts or purpose of the main actions or that the problem is hypothetical.

27 In those circumstances, the request for a preliminary ruling must be held to be admissible.

Question 1

28 By this question the national court asks essentially whether Articles 43 EC and 48 EC preclude national legislation such as that at issue in the main proceedings under which authorisation is necessary for setting up a private health institution in the form of an independent outpatient dental clinic, and authorisation must be refused if there is no need for that outpatient clinic, having regard to the care already offered by contractual practitioners.

Preliminary observations

29 First, it should be recalled that it is clear, both from the case-law of the Court and from Article 152(5) EC, that Community law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the organisation and delivery of health services and medical care. In exercising that power, however, the Member States must comply with Community law, in particular the provisions of the Treaty on the freedoms of movement, including freedom of establishment. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the healthcare sector (see, to that effect, Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 16; Case C-372/04 *Watts* [2006] ECR I-4325, paragraphs 92 and 146; and Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraphs 22 and 23).

30 In accordance with settled case-law, when assessing whether that obligation has been complied with, account must be taken of the fact that a Member State has the power to determine the level of protection which it wishes to afford to public health and the way in which that level is to be achieved. Since the level of protection may vary from one Member State to the other, Member States must be allowed discretion (*Commission* v *Germany*, paragraph 51 and the case-law cited).

31 Second, it must be pointed out that the main proceedings relate to the rule that an authorisation based on the criterion of the needs of the population is required simply to set up an independent outpatient dental clinic, regardless of whether that institution is likely subsequently to conclude a contract with a social security institution which would enable it to provide medical services in the context of the system of benefits in kind. In this respect, Hartlauer asserts that it intends to provide care services within the system of reimbursement of the costs paid by the person insured, and does not wish to obtain the status of a contractual establishment.

32 It must therefore be examined whether that requirement constitutes a restriction within the meaning of Article 43 EC and, if so, whether such a restriction may be justified.

Existence of a restriction of freedom of establishment

33 According to settled case-law, Article 43 EC precludes any national measure which, even though it is applicable without discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by Community nationals of the freedom of establishment that is guaranteed by the Treaty (see, inter alia, Case C-299/02 *Commission* v *Netherlands* [2004] ECR I-9761, paragraph 15, and Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, paragraph 27).

34 A national rule under which the establishment of an undertaking from another Member State is subject to the issue of a prior authorisation constitutes a restriction within the meaning of Article 43 EC, since it is capable of hindering the exercise by that undertaking of freedom of establishment by preventing it from freely carrying on its activities through a fixed place of business.

35 First, that undertaking may have to bear the additional administrative and financial costs involved in any grant of such an authorisation. Second, the national legislation reserves the pursuit of self-employed activity to certain economic operators who satisfy predetermined requirements, compliance with which is a condition for the issue of that authorisation (see, in relation to the freedom to provide services, Case C-76/90 *Säger* [1991] ECR I-4221, paragraph 14, and Case C-168/04 *Commission* v *Austria* [2006] ECR I-9041, paragraph 40).

36 Moreover, the Court has already held that national legislation under which the pursuit of an activity is subject to a condition linked to the economic or social need for that

activity constitutes a restriction in that it tends to limit the number of providers of services (see, to that effect, Case C-63/99 *Gloszczuk* [2001] ECR I-6369, paragraph 59, and Case C-255/04 *Commission* v *France* [2006] ECR I-5251, paragraph 29).

37 In the main proceedings, the national legislation makes the setting up of a health institution such as an independent outpatient dental clinic subject to the issue of a prior administrative authorisation. It further provides that authorisation can be granted only if 'there is a need' to set up a new institution, having regard to the care already available, inter alia from contractual practitioners.

38 That legislation deters or even prevents undertakings from other Member States from pursuing their activities on the territory of the Republic of Austria through a health institution designed as a fixed place of business. In the present case, its application had the effect of depriving Hartlauer altogether of access to the market in dental care in Austria.

39 Consequently, the legislation constitutes a restriction of freedom of establishment within the meaning of Article 43 EC, notwithstanding the alleged absence of discrimination on grounds of the nationality of the persons concerned.

40 In those circumstances, it must be examined whether the provisions at issue can be objectively justified.

Justification of the restriction of freedom of establishment

41 The Oberösterreichische Landesregierung and the Austrian and Norwegian Governments submit that the requirement of a prior authorisation for the setting up of an independent outpatient dental clinic is justified on grounds of the protection of public health. The system ensures a medical service of high quality, balanced and accessible to all, and ensures the financial balance of the social security system in that in enables social security institutions to control expenditure by adapting it to planned needs.

42 They submit that such a requirement is indispensable for maintaining the bases of the medical system established by the Austrian legislature, which chose to give priority to a system of benefits in kind and to the provision of medical care for the population by establishments financed from public funds. Care was thus to be provided primarily by contractual practitioners. An uncontrolled expansion of services on offer by the establishment of new independent outpatient dental clinics would have harmful consequences for the economic situation of those practitioners, and therefore also for the access of patients to the medical services provided by them throughout national territory, since such clinics would to some extent displace them from the market.

43 The Austrian Government further submits that those restrictions are necessary because, in the public health sector, the ordinary laws of the market apply only to a very limited extent and failures of the market are frequent. In particular, the sector is not governed by the law of supply and demand. Demand is induced by supply, so that an increase in supply does not produce a fall in prices or a division of the same volume of services among several providers of services, but an increase in the volume of supplies at constant prices. Uncontrolled growth in the number of providers of medical services would thus impose uncontrollable burdens on the social security institutions. They would not have any possibility of taking corrective action by means of a policy on contracts, since even if they did not offer contracts to the new service providers they would be obliged, in the context of the system of reimbursement of costs paid by the

person insured, to spend sums substantially the same as those spent in the context of the system of benefits in kind. The result would be an immediate endangering of the financial capacities of the social security system.

44 On this point, it must be recalled that a restriction of freedom of establishment, applicable without discrimination on grounds of nationality, may be justified by overriding reasons in the general interest, provided that it is appropriate for ensuring attainment of the objective pursued and does not go beyond what is necessary for attaining that objective (*Commission* v *Greece*, paragraph 34 and the case-law cited).

45 In the present case, it is common ground that the system of prior authorisation at issue in the main proceedings applies without discrimination on grounds of nationality.

46 Moreover, the protection of public health is one of the overriding reasons in the general interest which can, under Article 46(1) EC, justify restrictions of freedom of establishment.

47 It follows from the case-law that two objectives may, more precisely, be covered by that derogation in so far as they contribute to achieving a high level of protection of health, namely the objective of maintaining a balanced high-quality medical or hospital service open to all and the objective of preventing the risk of serious harm to the financial balance of the social security system (see, to that effect, *Watts*, paragraphs 103 and 104 and the case-law cited).

48 As regards the first of those objectives, Article 46 EC allows the Member States, in particular, to restrict the freedom to provide medical and hospital services in so far as

the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival, of the population (see, to that effect, Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraph 67, and *Watts*, paragraph 105).

49 As regards the second of those objectives, it should be noted that the planning of medical services, of which the requirement that authorisation is needed for the setting up of a new health institution is a corollary, is intended to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources, since the medical care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied (see, with regard to hospital care in the context of the freedom to provide services, *Müller-Fauré and van Riet*, paragraph 80, and *Watts*, paragraph 109).

50 Consequently, it must be ascertained whether the restrictions at issue in the main proceedings are appropriate for ensuring attainment of the objectives of maintaining a balanced high-quality medical service open to all and preventing the risk of serious harm to the financial balance of the social security system.

51 It cannot be excluded from the outset that, as the Court has already ruled with respect to hospitals (Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraphs 76 to 80, and *Watts*, paragraphs 108 to 110), establishments providing outpatient care such as doctors' surgeries and outpatient clinics may also be the subject of planning.

52 Planning which requires prior authorisation for setting up new providers of services may prove indispensable for filling in possible gaps in access to outpatient care and for avoiding the duplication of structures, so as to ensure medical care which is adapted to the needs of the population, covers the entire territory and takes account of geographically isolated or otherwise disadvantaged regions.

53 From that point of view, it is permissible for a Member State to organise medical care in such a way that it gives priority to a system of benefits in kind, so that all patients have easy access, throughout national territory, to the services of contractual practitioners.

54 In the present case, however, two series of considerations prevent the legislation in question from being accepted as appropriate for ensuring attainment of the above objectives.

55 First, it must be recalled that national legislation is appropriate for ensuring attainment of the objective pursued only if it genuinely reflects a concern to attain it in a consistent and systematic manner (see, to that effect, Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraphs 53 and 58, and Case C-500/06 *Corporación Dermoestética* [2008] ECR I-5785, paragraphs 39 and 40).

56 However, it follows from Paragraph 3(1) and (2) of the KAG and Paragraph 3(1) and (2) of the KAKuG, which were implemented by Paragraph 4 of the Wr. KAG and Paragraph 5 of the Oö. KAG, that a prior authorisation based on an assessment of the needs of the market is required for setting up and operating new independent outpatient dental clinics, whatever their size, and that the setting up of new group practices, by contrast, is not subject to any system of authorisation, regardless of their size.

57 Yet it appears from the order for reference that the premises and equipment of group practices and those of outpatient dental clinics may have comparable features and that in many cases the patient will not notice any difference between them.

58 Moreover, group practices generally offer the same medical services as outpatient dental clinics and are subject to the same market conditions.

59 Similarly, group practices and outpatient dental clinics may have comparable numbers of practitioners. It is true that the practitioners who provide medical services within group practices have the status of personally liable partner and are authorised to practice independently as dental practitioners, whereas the practitioners in an outpatient clinic have the status of employee. However, the documents before the Court do not show that that circumstance has any definite effect on the nature or volume of the services provided.

60 Since those two categories of providers of services may have comparable features and a comparable number of practitioners and provide medical services of equivalent volume, they may therefore have a similar impact on the market in medical services, and are thus liable to affect in an equivalent manner the economic situation of contractual practitioners in certain geographical areas and, in consequence, the attainment of the planning objectives pursued by the competent authorities.

61 That inconsistency also affects the attainment of the objective of preventing a risk of serious harm to the financial balance of the national social security system. Even supposing that the uncontrolled establishment of independent outpatient dental clinics may lead to a considerable increase in the volume of medical services at constant prices to be paid for by that system, the Austrian Government has not put forward anything capable of explaining why the establishment of those clinics but not of group practices could have such an effect.

62 Moreover, the provision of dental care in those independent outpatient clinics is liable to prove more rational, in view of the way they are organised, the fact of having several practitioners, and the use in common of medical installations and equipment, which

enable them to reduce their operating costs. They will thus be able to provide medical services in conditions that are less costly than those, in particular, of independent practitioners who do not have such opportunities. The provision of care services by those institutions may have the consequence of more efficient use of the public funds allocated to the statutory health insurance system.

63 In those circumstances, it must be concluded that the national legislation at issue in the main proceedings does not pursue the stated objectives in a consistent and systematic manner, since it does not make the setting up of group practices subject to a system of prior authorisation, as is the case with new outpatient dental clinics.

64 Second, it follows from settled case-law that a prior administrative authorisation scheme cannot render legitimate discretionary conduct on the part of the national authorities which is liable to negate the effectiveness of provisions of Community law, in particular those relating to a fundamental freedom such as that at issue in the main proceedings. Therefore, if a prior administrative authorisation scheme is to be justified even though it derogates from a fundamental freedom, it must be based on objective, non-discriminatory criteria known in advance, in such a way as adequately to circumscribe the exercise of the national authorities' discretion (see, to that effect, inter alia, Case C-205/99 *Analir and Others* [2001] ECR I-1271, paragraphs 37 and 38, and *Müller-Fauré and van Riet*, paragraphs 84 and 85).

65 In the main proceedings, the provisions concerned make the issue of authorisation to set up a new outpatient dental clinic subject to a single condition, namely the existence of a need for the services offered by the new institution. That condition follows from Paragraph 3(2) of the KAG and Paragraph 3(2) of the KAKuG and was take up by the legislation of the provinces concerned, in Paragraph 4 of the Wr. KAG and Paragraph 5 of the Oö. KAG.

66 It is apparent from the documents submitted to the Court that in practice different criteria are used, depending on the province, to ascertain whether that condition is satisfied.

67 Thus in the province of Vienna, the existence of a need is assessed on the basis of the number of patients per dental practitioner in the area covered. In the province of Upper Austria, the assessment is based on the waiting time for an appointment with a dental practitioner.

68 However, as regards the province of Vienna, it is clear that the number of patients in question is not fixed or brought in advance to the notice of the persons concerned in any way.

69 In the province of Upper Austria, the relevant assessment is made on the basis of the answers given by practitioners practising in the catchment area of the independent outpatient dental clinic intended to be set up, even though they are potential direct competitors of that clinic. Such a method is liable to affect the objectivity and impartiality of the treatment of the application for authorisation.

70 In those circumstances, it must be concluded that the system of prior administrative authorisation at issue in the main proceedings is not based on a condition capable of adequately circumscribing the exercise by the national authorities of their discretion.

71 It follows from all the foregoing that the national legislation at issue in the main proceedings is not appropriate for ensuring attainment of the objectives of maintaining a balanced high-quality medical service open to all and preventing the risk of serious harm to the financial balance of the social security system.

72 Consequently, the answer to Question 1 is that Articles 43 EC and 48 EC preclude national legislation such as that at issue in the main proceedings under which authorisation is necessary for the setting up of a private health institution in the form of an independent outpatient dental clinic, and authorisation must be refused if there is no need for that outpatient clinic, having regard to the care already offered by contractual practitioners, where that legislation does not also subject group practices to such a system and is not based on a condition capable of adequately circumscribing the exercise by the national authorities of their discretion.

Question 2

73 In view of the answer to Question 1, there is no need to answer Question 2.

Costs

74 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

Articles 43 EC and 48 EC preclude national legislation such as that at issue in the main proceedings under which authorisation is necessary for the setting up of a

private health institution in the form of an independent outpatient dental clinic, and authorisation must be refused if there is no need for that outpatient clinic, having regard to the care already offered by contractual practitioners, where that legislation does not also subject group practices to such a system and is not based on a condition capable of adequately circumscribing the exercise by the national authorities of their discretion.

[Signatures]