JUDGMENT OF THE COURT (Sixth Chamber)
11 March 2004 *

In Case C-496/01,

Commission of the European Communities, represented by M. Patakia, acting as Agent, with an address for service in Luxembourg,

applicant,

v

French Republic, represented by G. de Bergues and C. Bergeot-Nunes, acting as Agents,

defendant,

APPLICATION for a declaration that,

— by requiring that bio-medical analysis laboratories established in other Member States have their place of business in France in order to obtain the requisite operating authorisation;

* Language of the case: French.

— by precluding any reimbursement of the costs of bio-medical analyses carried out by a bio-medical analysis laboratory established in another Member State,

the French Republic has failed to fulfil its obligations under Articles 43 EC and 49 EC,

THE COURT (Sixth Chamber),

composed of: V. Skouris, acting for the President of the Sixth Chamber, C. Gulmann, J.-P. Puissochet, R. Schintgen and N. Colneric (Rapporteur), Judges,

Advocate General: J. Mischo,
Registrar: R. Grass,

having regard to the Report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 26 June 2003,

gives the following

Judgment

1 By application lodged at the Court Registry on 21 December 2001, the Commission of the European Communities brought an action under Article 226 EC for a declaration that,

— by requiring that bio-medical analysis laboratories established in other Member States have their place of business in France in order to obtain the requisite operating authorisation;

— by precluding any reimbursement of the costs of bio-medical analyses carried out by a bio-medical analysis laboratory established in another Member State,

the French Republic has failed to fulfil its obligations under Articles 43 EC and 49 EC.

Legal background

National public health rules

2 The French rules on public health are contained in the Code de la santé publique (Public Health Code). The legislative part of that code was revised by Order No 2000-548 of 15 June 2000 concerning the legislative part of the Code de la santé publique (JORF, 22 June 2000, p. 9340) and published as an annex to that order. The essential purpose of that revision was to arrange the applicable texts on a rational basis and to renumber the former articles of the Code.

3 Article L. 6211-1 of that code provides that bio-medical analyses are biological examinations which assist in the diagnosis, treatment or prevention of human diseases or which reveal any other physiological change, with the exception of pathoanatomical and pathocytological procedures carried out by specialist doctors. Laboratories may exercise their activities only on the responsibility of their directors or deputy directors.

4 Under Article L. 6221-1 of the Code de la santé publique, laboratory directors and deputy directors must hold one of the qualifications entitling the holder to practise medicine, pharmacy or veterinary medicine, be on the roll of the relevant professional association and have received specialised training, which may be evidenced by certificates in specialised studies, exemptions or equivalent qualifications or diplomas in specialised bio-medical studies.

5 Under Article L. 6211-2 of the Code de la santé publique:

'No bio-medical analysis laboratory may operate without administrative authorisation.

Without prejudice to the provisions of Article L. 6122-1 on heavy equipment, authorisation shall be granted where the conditions laid down in this Book and in the decree provided for in Article L. 6211-9 and determining the number and qualifications of technical staff and the standards applicable to laboratory fittings and equipment are satisfied.

That decree may lay down specific conditions applicable to laboratories whose activities are confined to certain procedures specified in that decree. The authorisation granted to those laboratories shall state that the activities covered are limited.

...

Authorisation shall be withdrawn where the requirements laid down by law or regulation are no longer satisfied.'

6 The procedure for obtaining such authorisation is laid down in Articles 15 to 17 of Decree No 76-1004 of 4 November 1976 laying down the requirements for authorisation of bio-medical analysis laboratories (JORF, 6 November 1976, p. 6449).

7 Article 15 of that decree provides:

'The application for authorisation provided for in Article L. 757 [now Article L. 6211-2] of the Code de la santé publique shall be sent by registered letter to the Prefect of the *département* in which the laboratory is to be operated.

The application shall state the operating conditions and the volume of activity envisaged during the first year and be accompanied by supporting documents, including, in particular:

a description and plan of the premises;

a complete list of equipment;

a list of the directors, deputy directors and technicians, including their qualifications and diplomas;

where appropriate, the company statutes.

...

The applicant shall, where appropriate, specify the category or categories of analysis in respect of which authorisation is sought.'

8 Where the requisite conditions are satisfied, the operating authorisation is granted to the applicant as of right under Article L. 6211-1 of the Code de la santé publique. Moreover, provision is made for an on-the-spot inspection by a public health inspector who is a doctor or pharmacist.

9 Article L. 6211-3 of the Code de la santé publique provides that only duly authorised laboratories may use the designation bio-medical analysis laboratory.

10 As regards withdrawal of authorisation, Article 24 of Decree No 76-1004 provides:

'Without prejudice to the provisions of the final paragraph of Article L. 757 (now Article L. 6211-2) of the Code de la santé publique and those of Article 9 of the abovementioned Decree of 15 February 1983, authorisation may be withdrawn by the Prefect where he has established, following an inspection by a public health inspector who is a doctor or pharmacist, that the laboratory is operating under conditions which represent a danger to public health.

A decision to withdraw authorisation may be adopted only after the person responsible for the laboratory has been given formal notice to submit, within one month, his observations on the facts apt to justify that decision.

In an emergency, the Prefect may suspend authorisation for a period of not more than one month without any preliminary procedure.

A decision to withdraw or suspend authorisation shall be notified by registered letter.'

11 As regards the operation of a bio-medical analysis laboratory, the French rules include precise rules applicable to certain analyses, such as the detection of anti-HIV antibodies and immunohaematological analyses.

12 Moreover, laboratories must be operated in compliance with the rules laid down in the Guide to correct conduct of bio-medical analyses ('the GBEA'), which is annexed to the decree of 26 November 1999 on the proper conduct of bio-medical analyses (JORF, 11 December 1999, p. 18441). The guide consists of a series of technical rules which define all the stages of the relevant procedure, from the taking of samples to the return of validated results.

13 The GBEA is in the nature of a regulation and, consequently, is binding on laboratories. It is therefore applicable to biologists. Failure to comply with its provisions may thus lead to withdrawal of operating authorisation.

14 The French rules also lay down constraints as regards the drafting of the reports of the results. In the case of a number of analyses, the report must contain an interpretation of the results by a biologist in order to assist the prescribing doctor in making a diagnosis.

15 As regards the control of bio-medical analysis laboratories, compliance with the French rules on the setting up and operation of such laboratories is monitored by the authorities in order to ensure the protection of public health. There are two types of controls: inspections and quality control of analyses.

16 As regards inspections within bio-medical analysis laboratories, Article L. 6213-1 of the Code de la santé publique provides that laboratories are to be monitored by public health inspectors who are doctors or pharmacists and by the General Inspectorate of Social Affairs.

17 The purpose of the inspections carried out by public health inspectors who are doctors or pharmacists is essentially to establish that laboratories are complying with the operating conditions: premises, equipment, the number of directors and assistant directors, the qualifications and number of technicians, the organisation of the laboratory, the conduct of the analyses, quality assurance; and, generally, that they are complying with all the provisions laid down by law and regulation, in particular the GBEA.

18 The inspections are also designed to ensure that corrective measures have been taken where the results of the quality control of a laboratory have revealed repeated or significant anomalies as regards their medical use. Article 9 of Decree No 94-1049 of 2 December 1994 on the quality control of bio-medical analyses provided for in Article L. 761-14 (now Article L. 6213-3) of the Code de la santé publique (JORF, 8 December 1994, p. 17382) states:

'Where the results of the quality control of a laboratory show repeated or significant anomalies as regards their medical use, the case of that laboratory shall

be submitted anonymously to the Commission du contrôle de qualité (Quality Assurance Commission), which shall make a determination on the serious nature of those anomalies. Where they are deemed to be serious, the laboratory shall be reported by the Director-General of the Agence du médicament (Medicinal Products Agency) to the Minister responsible for health, to whom the Director-General shall communicate the results for the purposes of a control pursuant to Article L. 761-13 [now Article L. 6213-1] of the Code de la santé publique designed, in particular, to ascertain the measures taken by the laboratory to improve the quality of its analyses.'

19 As regards quality control of analyses, Article L. 6213-3 of the Code de la santé publique provides that such controls are to be carried out by the Agence française de sécurité sanitaire des produits de santé (French Agency for Health Product Safety) in accordance with the procedure determined by decree.

20 Those controls are designed to guarantee the quality of the results of the analyses carried out by each laboratory. As stated in Decree No 94-1049, they are intended to ensure the reliability and improved performance of bio-medical analyses and to allow each laboratory to establish that it is using the proper techniques and employing the correct procedures.

National social security rules

21 The conditions governing the reimbursement by sickness insurance funds of the cost of laboratory services are governed by the social security rules.

22 Article L. 162-13 of the Code de la sécurité sociale (Social Security Code) provides:

'As regards laboratory analyses and examinations, insured persons may, for each category of analysis, choose freely between approved laboratories, irrespective of the status of the operator. The conditions for approval shall be laid down in an inter-ministerial decree.'

23 Under Article L. 162-14 of the Code de la sécurité sociale, the total cost of laboratory analyses and examinations to be reimbursed by sickness insurance funds and the insured person's contribution are to be fixed by a national agreement between, on the one hand, the Caisse nationale de l'assurance maladie de travailleurs salariés (National Workers' Sickness Insurance Fund) and at least one other national sickness insurance fund and, on the other, the bio-medical laboratory directors' trade unions which are recognised as the most representative at national level. The national agreement was signed on 26 July 1994 and approved by inter-ministerial decree of 30 September 1994 (JORF, 14 October 1994, p. 14552).

24 Under Article 2 of the National Agreement of 26 July 1994, sickness insurance funds may not derogate from the principle of freedom to choose the laboratory as laid down in Article L. 162-13 of the Code de la sécurité sociale. They may only refuse to reimburse any additional costs arising from the choice of a laboratory other than one of those in the area in which the insured party lives or, where there is no laboratory in that area, in the nearest area.

25 Unless the director of a laboratory gives express notification that he does not wish to be placed under the scheme set up under the agreement in force, French laboratories satisfying the conditions laid down by the rules on public health are deemed to be governed by the agreement and the costs of the analyses carried out by them are reimbursed on the basis of the tariffs fixed by the agreement and of the classification in the nomenclature of bio-medical procedures.

26 However, Article L. 332-3 of the Code de la sécurité sociale prohibits payment of sickness and maternity insurance benefits where the insured party and his dependants receive treatment outside France.

27 Article R. 332-2 of that Code makes provision for a number of derogations from that principle. It does not permit agreements between sickness funds and laboratories established outside France. As regards medical services provided abroad, the final paragraph of Article R. 332-2 of that code provides:

'exceptionally, and subject to a favourable opinion from the medical supervisory body, sickness insurance funds may reimburse, at a flat rate, the cost of treatment provided outside France to an insured person or his dependants, where the person concerned establishes that he was unable to receive the treatment appropriate to his condition in France.'

Pre-litigation procedure

28 Following a complaint by a German laboratory regarding the French rules on biomedical analysis laboratories, the Commission services, by letter of 18 March 1999, requested information from the French authorities, who replied on 21 September 1999.

29 By letter giving formal notice of 1 February 2000, the Commission informed the French Government that, in its view, certain provisions of the French rules in question raised problems of compatibility with the right of establishment and the freedom to provide services provided for in Articles 43 EC and 49 EC.

30 The French authorities failed to reply to that letter and the Commission sent the French Republic a reasoned opinion on 24 January 2001, requesting it to take the measures necessary to comply therewith within two months of its notification.

31 The French authorities replied to the reasoned opinion by letter of 6 June 2001, rejecting the complaints raised by the Commission. As it was not satisfied with that reply, the Commission brought the present action.

The action

32 According to the Commission, there are, in the present case, two types of obstacle to the exercise of the right of establishment and the freedom to provide services:

(a) the obstacle created by the requirement of a place of business in France under Article 15 of Decree No 76-1004, and

(b) the obstacle created by the refusal to reimburse the costs of analyses carried out by a foreign laboratory pursuant to Articles L. 332-3 and R. 332-2 of the Code de la sécurité sociale.

The complaint regarding the requirement of a place of business in France

Arguments of the parties

33 The Commission complains that the French Republic deprives laboratories which have their place of business in another Member State of the possibility of setting up a secondary establishment in France, as provided for in the second paragraph of Article 43 EC, or of responding to requests from persons covered by the French insurance scheme from its place of business abroad.

34 The Commission does not dispute that a Member State may lay down rules on the authorisation of laboratory activities, but maintains that such rules must nevertheless take account of the requirements and guarantees already satisfied in the Member State of establishment. If that were not the case, the failure to take account of the guarantees already satisfied in another Member State would run counter to the principle of proportionality, which requires that the objectives pursued must be achieved by less restrictive measures (see, to that effect, Case 279/80 *Webb* [1981] ECR 3305, paragraph 20, and Case C-106/91 *Ramrath* [1992] ECR I-3351, paragraph 31).

35 The Commission submits that that double set of requirements may discourage undertakings from exercising not only their right to set up a secondary establishment but also their freedom to provide services. The fact that providers of services are made subject to the same requirements as those applicable to an establishment constitutes a disproportionate additional burden, given that the services are provided on a purely temporary basis (see, to that effect, Case C-76/90 *Säger* [1991] ECR I-4221, paragraph 13).

36 According to the Commission, the French public health rules are also discriminatory in so far as services provided outside France are not authorised.

37 In its submission, the requirement that the place of business be in France is not justified.

38 The obstacle in question can be justified only on grounds of public policy, public safety and public health, referred to in Article 46(1) EC, in conjunction with Article 55 EC as regards freedom to provide services in so far as it gives rise to discriminatory restrictions. However, Article 46(1) EC does not permit the exclusion of an entire economic sector, such as the one concerned, from the application of the principles of the right of establishment and freedom to provide services (see, to that effect, Case C-158/96 *Kohll* [1998] ECR I-1931 and Case C-114/97 *Commission* v *Spain* [1998] ECR I-6717).

39 Non-discriminatory restrictions may be justified by overriding reasons in the public interest, provided that those restrictions are apt to ensure the attainment of the objective they pursue and that they do not go beyond what is necessary to attain it.

40 The Commission rejects all the reasons put forward by the French authorities.

41 The Commission points out that the quality of medical services is assured under a number of directives on coordination and recognition concerning the conditions for access to and the exercise of the professions of doctor, pharmacist and

veterinary surgeon. The conditions governing access and exercise relating to specialised qualifications not covered by those directives may fall directly within the scope of Articles 43 EC and 49 EC, according to the judgments in Case C-340/89 *Vlassopoulou* [1991] ECR I-2357, paragraph 13, and Case C-238/98 *Hocsman* [2000] ECR I-6623, paragraphs 21 to 24 and 36, and of the general schemes for the recognition of professional qualifications, namely Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three years' duration (OJ 1989 L 19, p. 16) and Council Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC (OJ 1992 L 209, p. 25).

42 Citing Joined Cases C-369/96 and C-376/96 *Arblade and Others* [1999] ECR I-8453, paragraph 34, the Commission submits that the various directives on mutual recognition facilitate some of the controls to be carried out. That proves that the need for controls does not constitute sufficient reason to justify the requirement as to the place of business.

43 In so far as the controls are concerned, the requirement of a permanent establishment can, in the Commission's view, be justified only in very exceptional cases, where the authorities show that they could not otherwise exercise their supervisory function, which is not so in the present case. The requirement of a place of business in France would not be essential if the grant of an administrative operating authorisation were made subject to the requirement that a laboratory established outside France should accept that all the controls necessary for completion of the French authorities' task should be carried out on its premises. Moreover, the aims of the controls could be achieved in full if appropriate measures of organisation were adopted at the stage of the examination of the files and of the granting of an operating authorisation, in particular by granting temporary authorisation.

44 In order for analyses carried out outside France to be assessed in accordance with French standards, laboratories established in other Member States could agree voluntarily to comply with French standards at the time of applying for authorisation. Moreover, the French inspectors could visit them in order to carry out their controls and their travel expenses could be borne by the laboratories providing the services, provided that they freely consent to those controls.

45 The Commission states that the provisions of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ 1998 L 331, p. 1) are an effective basis for assessment and may be used as an example of measures which are more proportionate to the aim pursued (see, to that effect, Case C-350/97 *Monsees* [1999] ECR I-2921, paragraph 30).

46 The Commission complains that the French Republic has failed to explain whether and why its own system ensures a higher level of quality control or why it is not possible to carry out blind testing of samples from laboratories in other Member States, or why controls carried out in other Member States are immediately deemed incapable of ensuring the level of protection sought in France.

47 The Commission submits that the effectiveness of the penalties imposed on laboratories may also be ensured by less restrictive measures than the requirement that their place of business be in France. The French Republic could, by way of a penalty, exclude a laboratory in another Member State from the French reimbursement scheme by withdrawing or refusing to renew authorisation. The French authorities could also inform the authorities of the Member State of establishment to enable them to take appropriate measures. Moreover, it would be possible to secure payment of fines imposed on laboratory directors by making

the grant of operating authorisation conditional on payment of an appropriate security.

48 As regards the maintenance of a treatment facility on national territory, the Commission claims that it has not been proven, in accordance with paragraph 51 of the judgment in *Kohll*, cited above, that a balanced medical service open to all cannot be guaranteed unless the place of business is in France.

49 The French Government concedes that the requirement of a place of business in France may be regarded as an obstacle to the freedom to provide services. However, that obstacle is justified by an overriding reason in the public interest, namely the protection of public health, and one which is proportionate to the aim pursued.

50 It notes that there are no harmonisation rules applicable to the operation of bio-medical analysis laboratories. In the absence of Community harmonisation, the French authorities are entitled to impose on bio-medical analysis laboratories the strict national rules laid down in the French rules, in particular the GBEA, in order to ensure a high level of public health protection.

51 The French Government contends that the directives on mutual recognition of medical, pharmacy and veterinary diplomas concern only the level of qualifications of the laboratory directors. Consequently, the existence of those directives does not in any event support the contention that the activities of bio-medical analysis laboratories are harmonised.

52 The French Government claims that it is unable to assess the levels of control existing in other Member States. It is for the Commission to show that the quality criteria and the supervision procedures are equivalent to those applicable in France. It also submits that it is impossible to compare the rules on in vitro diagnostic medical devices, as defined in Directive 98/79, with the situation of bio-medical analysis laboratories.

53 As regards compliance with the principle of proportionality, the French Government does not deny that its rules on the operation of bio-medical analysis laboratories preclude the provision of any service by a laboratory in another Member State. However, it claims that, in accordance with paragraph 52 of the judgment in Case 205/84 *Commission* v *Germany* [1986] ECR 3755, and paragraph 27 of the judgment in Case C-355/98 *Commission* v *Belgium* [2000] ECR I-1221, the conditions of the requirement for a permanent establishment in France are satisfied. The Commission has not explained how the French authorities' supervisory task could be carried out in a more proportionate way in that sector of activity. In the absence of Community harmonisation or bilateral agreements, it is impossible for its inspectors to carry out checks in bio-medical laboratories in other Member States. Moreover, given the lack of harmonisation in the Community of quality criteria and control procedures, the other Member States cannot carry out those checks instead of the French authorities, which cannot recognise checks carried out in other Member States as a priori equivalent.

54 The French Government describes in detail the scope of the controls carried out by its authorities and the relevant procedures and points out that those controls are closely linked to the restrictions on exercise imposed by the French rules with a view to protecting public health. For certain analyses, specific methods and an interpretation of the results have been imposed. If analyses were carried out in another Member State, there would be a greater risk of the results being misinterpreted, which would entail a real risk to patients' health.

Findings of the Court

55 First of all, in the absence of harmonisation of a profession, Member States remain, in principle, competent to define the exercise of that profession but must, when exercising their powers in this area, respect the basic freedoms guaranteed by the Treaty (see, in particular, Case C-58/98 *Corsten* [2000] ECR I-7919, paragraph 31; Case C-108/96 *Mac Quen and Others* [2001] ECR I-837, paragraph 24; and Case C-294/00 *Gräbner* [2002] ECR I-6515, paragraph 26).

56 In the present case, it is undisputed that, although harmonisation measures on the mutual recognition of qualifications of doctors, pharmacists and veterinary surgeons exist, no harmonisation measures have been adopted specifically in order to govern the exercise of the activities of bio-medical analysis laboratories.

57 Activities such as those exercised by those laboratories are therefore governed by Articles 43 EC and 49 EC.

— Freedom of establishment

58 With respect to the complaint concerning the requirement for a place of business in France, it should be noted, first of all, that the freedom of establishment conferred by Article 43 EC on Community nationals comprises the right of those nationals to take up and pursue activities as self-employed persons and the right to set up and manage undertakings under the same conditions as those laid down for

its own nationals by the law of the Member State where such establishment is effected. In addition, Article 48 EC treats companies or firms formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the Community in the same way as natural persons who are nationals of Member States.

59 It is not apparent from the French rules, nor has it been shown by the Commission, that a national of a Member State other than the French Republic or a company formed in accordance with the law of a Member State and having its registered office, central administration or principal place of business in a Member State other than the French Republic could not manage a laboratory in France as a branch or subsidiary of a laboratory which he or it also manages in another Member State.

60 In particular, nationals of another Member State are not precluded from exercising the functions of laboratory director where they satisfy the requirements imposed by the French rules, even if only through recognition of qualifications obtained by them in another Member State.

61 Nor does the Commission show that the French rules would require a laboratory established in another Member State to transfer all of its activities to France, so that the place of business in France would no longer be a secondary establishment but would become the only place of business of the company in question.

62 Moreover, the Commission has neither provided any other examples of situations which, in the light of the French rules, might constitute a breach of freedom of establishment nor explained how that freedom might otherwise be affected.

63 Accordingly, the first complaint must be rejected in so far as the French Republic is alleged to have failed to fulfil its obligations under Article 43 EC by requiring that bio-medical analysis laboratories have a place of business in France.

— Freedom to provide services

64 Article 49 EC requires that all restrictions on the freedom to provide services be removed. Any measure prohibiting, impeding or rendering less attractive the exercise of that freedom is to be considered such a restriction (see Case C-205/99 *Analir and Others* [2001] ECR I-1271, paragraph 21, and *Gräbner*, cited above, paragraph 38). Article 49 EC precludes the application of any national legislation which, without objective justification, impedes a provider of services from actually exercising that freedom (see, in particular, Case C-381/93 *Commission* v *France* [1994] ECR I-5145, paragraph 16, and Case C-451/99 *Cura Anlagen* [2002] ECR I-3193, paragraph 29).

65 The French Government does not deny that rules under which authorisation to operate a bio-medical analysis laboratory can be granted only to a laboratory with a place of business in France constitutes such a restriction on the exercise of freedom to provide services. It is clear that the requirement for a place of business in France makes it impossible for laboratories which have their place of business in another Member State to offer services in France.

66 As regards the reasons which may justify a restriction on the freedom to provide services in the sector of bio-medical analysis laboratories, the aim of maintaining the quality of medical services may be covered by one of the derogations provided

for in Article 46 EC, in so far as it contributes to the attainment of a high level of health protection (see, to that effect, Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4509, paragraph 67).

67 In particular, it is permissible under Article 46 EC to maintain the quality of medical services not only by ensuring that the directors and staff of bio-medical analysis laboratories hold the necessary qualifications but also by checking, by periodic inspections, that analyses are at all times carried out in accordance with the rules laid down by the French legislature and the French authorities and, in particular, with the requisite authorisation.

68 However, according to settled case-law, where measures taken are justified on the basis of an exception provided for in the Treaty, it must be established that those measures do not go beyond what is objectively necessary for the aim to be achieved (see, to that effect, Case C-100/01 *Oteiza Olazabal* [2002] ECR I-10981, paragraph 43, and Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 45).

69 The requirement that bio-medical analysis laboratories have a place of business in France goes beyond what is necessary to achieve the aim of protecting public health.

70 Instead of requiring that bio-medical analysis laboratories have a place of business in France and thus precluding any cross-border provision of services, the French Republic may require that, in order to provide services to persons residing in France, should they wish to do so, bio-medical analysis laboratories which have their place of business in another Member State comply, in accordance with the French rules, with the requirement to obtain authorisation.

71 However, the conditions to be satisfied in order to obtain such authorisation may not duplicate the equivalent statutory conditions which have already been satisfied in the State of establishment (see, to that effect, *Commission* v *Germany*, cited above, paragraph 47).

72 The rules on authorisation could, in particular, impose a requirement that laboratories with their place of business in another Member State ensure that their analysis reports can be understood by doctors practising in France. This applies in particular to the interpretation of the results by the biologist, who, in certain cases, is required by the French rules to assist the prescribing doctor in making his diagnosis.

73 As regards the need for effective controls, the French Government has failed to show that, even within the framework of an approval scheme, the competent authorities could not fulfil their supervisory function effectively unless bio-medical analysis laboratories had a permanent establishment in that Member State (see, to that effect, *Commission* v *Germany*, cited above, paragraph 54).

74 Even though the competent French authorities cannot be expected to carry out on-the-spot checks in other Member States, particularly inspections designed to ensure compliance with the operating conditions by the laboratories, it is nevertheless possible to require laboratories established in another Member State to prove to the satisfaction of the French authorities that the controls carried out by the competent authorities of the Member State in which they have their place of business are no less strict than those applicable in France and monitor compliance with provisions which safeguard at least the same level of health protection as the French rules.

75 The French Government's argument that it cannot assess the level of supervision in other Member States because it is not aware of the quality criteria or control procedures imposed on bio-medical analysis laboratories in those States cannot be upheld. By, in particular, requesting laboratories established in another Member State and wishing to offer their services to customers established in France, at the time of granting administrative authorisation, to provide the appropriate information, the French authorities would be in a position to know the criteria and conditions laid down in the rules of the Member State or States in which the laboratories in question have their place of business.

76 Similarly, where the conditions imposed by the French rules are not met, there is nothing to prevent the French authorities from taking measures against a laboratory which has its place of business in another Member State by withdrawing or suspending its authorisation.

77 It follows from the foregoing considerations that, by imposing on bio-medical analysis laboratories established in other Member States the requirement that they have a place of business in France in order to obtain the requisite operating authorisation, the French Republic has failed to fulfil its obligations under Article 49 EC.

The complaint concerning the refusal to reimburse the costs of bio-medical analyses carried out in another Member State

Arguments of the parties

78 The Commission complains that, in practice, the French Republic precludes reimbursement of the costs of medical analyses carried out in a laboratory

established in another Member State. That preclusion is an indirect consequence of Article R. 332-2 of the Code de la sécurité sociale, as there are no analyses which cannot be carried out by French laboratories. That constitutes an obstacle both to the freedom to provide services, in the case of a laboratory which has no establishment in France, and to the right to set up secondary establishments, in the case of a laboratory which has such an establishment in which analyses are not carried out.

79 The French rules on social security are also discriminatory in so far as they preclude reimbursement of any service provided outside France.

80 The Commission rejects the French Republic's argument that the social security rules do not have a restrictive effect on the right of establishment or freedom to provide services because, while laboratory directors must have been granted authorisation in order to be able to be accepted, a laboratory which has been granted authorisation need not have entered into an agreement with the social security. The Commission takes the view that a laboratory established in another Member State and wishing to provide services in France can do so in practice only if it complies with the national agreement of 26 July 1994.

81 Relying on paragraph 41 of the judgment in *Kohll*, the Commission submits that the risk of seriously undermining the financial balance of the social security system is the only justification for restrictions of the principles relating to the freedom to provide services. It has not been established that reimbursement of the costs of bio-medical analyses carried out in another Member State in accordance with the French social security tariffs would have a significant impact on the financing of the social security system. In that context, the Commission points out, in particular, that sickness insurance funds are permitted to refuse to

reimburse the additional costs arising from the choice of a laboratory other than one of those in the area in which the insured person resides. If that rule were also applied in relation to laboratories established in another Member State, that measure would at any rate be less restrictive than the present rules.

82 The French Government contends that the refusal to reimburse the costs charged by a laboratory established in another Member State is justified by the fact that the French rules taken together guarantee a high level of protection of public health by imposing strict quality requirements on laboratories established in France.

83 The French Government submits that the conclusion reached by the Court in *Kohll* is based on the fact that the conditions for taking up and exercising the professions of doctor and dentist have been the subject of a number of coordinating and harmonising directives. It regards the absence of harmonisation in relation to bio-medical analysis laboratories as conclusively distinguishing this case from that judgment.

84 The Commission replies that, in that judgment, the Court referred to harmonisation in the field of medical and dentistry qualifications in order to exclude the justification, put forward with respect to an authorisation, based on the protection of public health. It maintains that if, in the present case, the absence of harmonisation can justify a system of authorisation on the grounds of protection of public health, the preclusion of any possibility of granting such authorisation for laboratory analyses based on the criterion that the laboratory is established outside France is disproportionate because it goes beyond the scope of any concerns relating to the protection of public health.

85 Taking the view that, by that line of argument, the Commission is not rejecting outright the system established by the French rules, the French Republic requests the Court, in the alternative, to determine the criteria on which reimbursement without prior authorisation of certain analyses carried out by a laboratory may be made.

Findings of the Court

— Freedom of establishment

86 The complaint relating to the refusal by sickness insurance funds to reimburse the costs of bio-medical analyses carried out in another Member State cannot be upheld in so far as it alleges failure to fulfil the obligations arising under the principle of freedom of establishment.

87 The Commission does not contest the fact that, in so far as the service is provided by a laboratory with, even as a secondary establishment of a laboratory established in another Member State, a place of business in France, that laboratory is wholly subject to the French rules and may thus be affiliated to the system for reimbursement of the costs of medical analyses.

88 As regards laboratories with a secondary establishment in France in which analyses are not carried out, the Commission has not explained in sufficient detail on what grounds it might be concluded that there has been a breach of the principle of freedom of establishment.

89 Accordingly, the second complaint must be rejected in so far as the French Republic is alleged to have failed to fulfil its obligations under Article 43 EC by refusing to reimburse the costs of bio-medical analyses carried out by a laboratory with its place of business in another Member State.

— Freedom to provide services

90 First of all, it should be noted that Article L. 332-3 of the Code de la sécurité sociale prohibits payment of sickness and maternity insurance benefits where the insured person and his dependants receive treatment outside France but that, where medical services are provided abroad, the final paragraph of Article R. 332-2 of that code provides that, 'exceptionally, and subject to a favourable opinion from the medical supervisory body, sickness insurance funds may reimburse, at a flat rate, the cost of treatment provided outside France to an insured person or his dependants, where the person concerned establishes that he was unable to receive the treatment appropriate to his condition in France'.

91 Since in those circumstances the French rules prohibit sickness insurance funds from reimbursing the costs of analyses carried out by bio-medical analysis laboratories with their place of business in another Member State without prior authorisation granted by way of exception where the insured person cannot receive appropriate treatment in France, it de facto precludes laboratories established in another Member State from being able to provide services to insured persons established in France. It therefore constitutes a restriction of the freedom to provide services.

92 As regards the reasons which may be relied upon to justify that restriction, such rules may, in principle, be justified by one of the derogations provided for in Article 46 EC in so far as they are designed to contribute to ensuring a high level of public health protection. However, the refusal by sickness insurance funds to reimburse the costs of analyses carried out by laboratories with their place of business in another Member State goes beyond what is objectively necessary for that purpose.

93 In the absence of harmonisation measures, Community law, as may be seen from paragraphs 69 to 75 of this judgment, does not preclude the French Republic from imposing, in the context of an authorisation scheme, its level of public health protection on laboratories established in another Member State which wish to offer services to members of one of the French sickness insurance schemes.

94 Accordingly, it cannot be held that the refusal by sickness insurance funds to reimburse the costs of analyses carried out by laboratories with their place of business in another Member State is necessary in order to maintain the high level of public health protection.

95 Consequently, it must be held that, by precluding any reimbursement of the costs of bio-medical analyses carried out by a bio-medical analysis laboratory established in another Member State, the French Republic has failed to fulfil its obligations under Article 49 EC.

Costs

96 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. However, under Article 69(3) of those Rules, the Court may order that the costs be shared or that the parties bear their own costs where each party succeeds on some and fails on other heads. In this case, since the parties have each been partially unsuccessful, each must be ordered to bear its own costs.

On those grounds,

THE COURT (Sixth Chamber)

hereby:

1. — Declares that, by imposing on bio-medical analysis laboratories established in other Member States, a requirement that they have a place of business in France in order to obtain the necessary operating authorisation and

— by precluding any reimbursement of the costs of bio-medical analyses carried out by a bio-medical analysis laboratory established in another Member State,

the French Republic has failed to fulfil its obligations under Article 49 EC;

2. Dismisses the remainder of the application;

3. Orders each party to bear its own costs.

Skouris Gulmann Puissochet

Schintgen Colneric

Delivered in open court in Luxembourg on 11 March 2004.

R. Grass V. Skouris

Registrar President