JUDGMENT OF THE COURT (Fourth Chamber)

11 June 2009 *

In Case C-300/07,

REFERENCE for a preliminary ruling under Article 234 EC from the Oberlandesgericht Düsseldorf (Germany), made by decision of 23 May 2007, received at the Court on 27 June 2007, in the proceedings

Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik,

v

AOK Rheinland/Hamburg,

THE COURT (Fourth Chamber),

composed of K. Lenaerts, Presidents of Chamber, T. von Danwitz, R. Silva de Lapuerta, E. Juhász (Rapporteur) and G. Arestis, Judges,

* Language of the case: German.

Advocate General: J. Mazák,
Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 19 June 2008,

after considering the observations submitted on behalf of:

— Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik, by H. Glahs, and U. Karpenstein, Rechtsanwälte,

— AOK Rheinland/Hamburg, by A. Neun, Rechtsanwalt,

— the Commission of the European Communities, by G. Wilms and D. Kukovec, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 16 December 2008,

gives the following

Judgment

1 This reference for a preliminary ruling relates to the interpretation of Article 1(2)(c) and (d), Article 1(4), Article 1(5) and the first and second alternatives of letter (c) of the second subparagraph of Article 1(9) of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts (OJ 2004 L 134, p. 114).

2 The reference has been made in the course of proceedings between Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik and AOK Rheinland/Hamburg relating to, first, whether the German statutory sickness insurance funds constitute contracting authorities for the purposes of the application of the rules in Directive 2004/18, secondly, whether the supply of orthopaedic shoes, made and tailored individually in accordance with the patient's needs by specialist shoe manufacturers under an agreement with the statutory sickness insurance fund, together with detailed advice given to the patients before and after such supply is to be regarded as a supply contract or a service contract and, thirdly, if the supply of orthopaedic shoes is to be regarded as a service, whether, in the present case, it is to be regarded as a 'service concession' or a 'framework agreement' within the meaning of the provisions of Directive 2004/18.

Legal context

Community rules

3 Article 1 of Directive 2004/18, entitled 'Definitions', provides:

'…

2. (a) "Public contracts" are contracts for pecuniary interest concluded in writing between one or more economic operators and one or more contracting authorities and having as their object the execution of works, the supply of products or the provision of services within the meaning of this Directive.

…

(c) "Public supply contracts" are public contracts other than those referred to in (b) having as their object the purchase, lease, rental or hire purchase, with or without option to buy, of products.

…

(d) "Public service contracts" are public contracts other than public works or supply contracts having as their object the provision of services referred to in Annex II.

A public contract having as its object both products and services within the meaning of Annex II shall be considered to be a "public service contract" if the value of the services in question exceeds that of the products covered by the contract.

A public contract having as its object services within the meaning of Annex II and including activities within the meaning of Annex I that are only incidental to the principal object of the contract shall be considered to be a public service contract.

4. "Service concession" is a contract of the same type as a public service contract except for the fact that the consideration for the provision of services consists either solely in the right to exploit the service or in this right together with payment.

5. A "framework agreement" is an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged.

…'

4 Article 1(9) of Directive 2004/18 provides as follows:

'"Contracting authorities" means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law.

A "body governed by public law" means any body:

(a) established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character;

(b) having legal personality; and

(c) financed, for the most part, by the State, regional or local authorities, or other bodies governed by public law; or subject to management supervision by those bodies; or having an administrative, managerial or supervisory board, more than half of whose members are appointed by the State, regional or local authorities, or by other bodies governed by public law.

Non-exhaustive lists of bodies and categories of bodies governed by public law which fulfil the criteria referred to in (a), (b) and (c) of the second subparagraph are set out in Annex III. Member States shall periodically notify the Commission of any changes to their lists of bodies and categories of bodies.'

5 Chapter III of Annex III to the directive, entitled 'Germany', paragraph 1, 'Categories', point 1.1 'Authorities', fourth indent, mentions 'Sozialversicherungen (Krankenkassen, Unfall- und Rentenversicherungsträger)/[social security institutions: health, accident and pension insurance funds]'.

6 Article 21 of the directive provides:

'Contracts which have as their object services listed in Annex II B shall be subject solely to Article 23 and Article 35(4).'

7 The subject of Annex II B, Category 25, is 'Health and social services'.

8 In accordance with Article 22 of Directive 2004/18:

'Contracts which have as their object services listed both in Annex II A and in Annex II B shall be awarded in accordance with Articles 23 to 55 where the value of the services listed in Annex II A is greater than the value of the services listed in Annex II B. In other cases, contracts shall be awarded in accordance with Article 23 and Article 35(4).'

9 According to Article 32(2) of the Directive:

‘For the purpose of concluding a framework agreement, contracting authorities shall follow the rules of procedure referred to in this Directive …’

10 Article 79 of the Directive, entitled ‘Amendments’ provides as follows:

‘In accordance with the procedure referred to in Article 77(2), the Commission may amend:

…

(d) the lists of bodies and categories of bodies governed by public law in Annex III, when, on the basis of the notifications from the Member States, these prove necessary;

…’

11 Finally, Article 1(4) of Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (OJ 1999 L 171, p. 12) provides:

'Contracts for the supply of consumer goods to be manufactured or produced shall also be deemed contracts of sale for the purpose of this Directive.'

National legislation

12 The following summary of the relevant national rules is taken from the files lodged with the Court in the present proceedings and, in particular, the order for reference.

13 The public health system in Germany and the organisation and financing of statutory sickness insurance funds are governed by Books Four and Five ('SGB IV' and 'SGB V', respectively) of the Social Code (Sozialgesetzbuch). The task which the legislature has given to the statutory sickness insurance funds is defined as follows in Paragraph 1(1) of SGB V:

'As a community founded on the basis of the principle of solidarity, the task of the sickness insurance scheme is to maintain, restore or improve the state of health of the insured.'

14 It can be seen from Paragraph 4(1) of SGB V that the statutory sickness insurance funds are corporations governed by public law and have legal personality as well as a right of self-management. They were created pursuant to Paragraphs 1 and 3 of SGB V. According to the order for reference the vast majority of the population in Germany (around 90%) is compulsorily insured by law with a statutory sickness insurance fund. While persons insured under the compulsory scheme may select the particular statutory sickness insurance fund with which the wish to be insured, they may not choose between a public and a private sickness insurance fund.

15 The rules on the financing of statutory sickness insurance funds are contained in Paragraphs 20 to 28 of SGB IV and Paragraphs 3, and 220 et seq. of SGB V. That financing is provided by way of compulsory contributions from insured persons, direct payments from the Federal State and compensatory payments from the financial compensation system between statutory funds and from the risk structure compensation mechanism between them.

16 According to the order for reference, the contributions paid by those who are compulsorily insured and by their employers constitute the major part of the financing of the statutory insurance funds. The amount of contributions depends solely on the income of the insured, that is to say, his capacity to contribute. Other factors, such as age, previous illnesses or the number of co-insured persons, are irrelevant. In practice, the insured's part of the contributions is withheld from his salary by his employer and paid to the statutory sickness insurance fund along with the employer's part of the contributions. Those are public law obligations and contributions are compulsorily recovered on the basis of the provisions of public law.

17 The contribution rate is set, not by the State, but by the statutory sickness insurance funds. As is provided in the relevant rules, these funds have to calculate the contributions in such a way as to cover, when combined with other resources, the

expenses stipulated by law and to guarantee that the means of operating and statutory reserves are available. The setting of the contribution rate requires the approval of each fund's supervisory authority. According to the order for reference, the amount of the contributions is, to some extent, laid down by law, because it must be set in such a way that the revenue accrued is no lower and no higher than expenditure. Since, under the German sickness insurance scheme, the vast majority of the benefits to be provided are laid down by law, the amount of expenditure to a great extent cannot be directly influenced by the statutory sickness insurance fund in question.

18 In order to maintain the contribution rate for insured persons at the same level, Paragraphs 266 to 268 of SGB V provide for annual compensatory payments between all the statutory sickness insurance funds resulting from the risk structure compensation mechanism. According to the national court's observations, there is a mutual solidarity obligation between the funds, with each being entitled to compensation or being required to provide compensation up to a certain amount.

19 According to Paragraph 4(1) of SGB V, the statutory sickness insurance funds have self-management powers but are subject to State supervision. According to the order for reference, that supervision is not limited to a mere review of legality after the event.

20 Certain measures adopted by the statutory sickness insurance funds, such as amendments to the statutes of the sickness insurance funds, setting the contribution rates, building and property transactions and the acquisition of software, require an authorisation by the supervisory authorities, as can be seen from Paragraphs 195(1), 220(2) and 241 of SGB V. The supervisory authorities must carry out, at least every five years, a commercial, accounting and operational management review of the statutory

sickness insurance funds under their control. That supervision, which covers, inter alia, the economic efficiency of the activity of the fund in question, may be more frequent (Paragraph 69(2) and 88(1) of SGB IV and Paragraph 274(1) of SGB V). In the framework of that supervision, Paragraph 88(2) of SGB IV provides that the funds are required to transmit all necessary documents and information to the supervisory authorities. In addition, according to Paragraphs 37 and 89(3) of SGB IV, if the self-management organs of the funds refuse to perform the tasks they are required to carry out, those tasks will be taken over by the supervisory authority itself.

21 Finally, the provisional budget of each statutory sickness insurance fund must be submitted to the competent supervisory authority in good time (Paragraph 70(5) of SGB IV) and the latter may merge unviable funds with other funds or close them (Paragraph 146a, subparagraph 3 of the first sentence of Paragraph 153, Paragraph 156, subparagraph 3 of the first sentence of Paragraph 163, second sentence of Paragraph 167, and Paragraph 170 of SGB V).

22 Given that, in the context of the system at issue, the insured has a right as against the statutory sickness insurance fund, not to reimbursement of costs, but to free access to the corresponding services (Paragraph 2(2) of SGB V), in accordance with the principle of benefits in kind, the sickness insurance funds are encouraged to conclude with different suppliers provision schemes which are multi-sectoral or interdisciplinary. These 'integrated provision schemes', provided for in Paragraphs 140a to 140e of SGB V, are concluded between the statutory sickness insurance funds and different suppliers eligible to provide treatment to the insured. They define the remuneration for different formulae of the integrated provision scheme which are intended to pay for the totality of benefits that the insured can call on in the context of the scheme. It is the statutory sickness insurance fund that is party to the integrated provision scheme contract and is

to pay the remuneration of the provider. The participation of those insured in the different formulae of the scheme is optional, but once the insured opts for such a formula, he is required to call on the services of the provider with whom the relevant sickness insurance fund has concluded such a contract.

23 During the procedure before the Court, two judgments of the Bundesverfassungsgericht were also mentioned in connection with the mission of the sickness insurance funds in Germany.

24 In its order of 9 June 2004 (2 BvR 1248/03 and 2 BvR 1249/03), the Bundesverfassungsgericht held:

'Social law is one the most important instruments of the State's social policy. In the social State order established by the Constitution (Grundgesetz), protection in the case of illness is one of the fundamental tasks of the State. The legislature has performed that task by ensuring the protection of the major part of the population by the introduction of statutory sickness insurance, a compulsory, public law, insurance scheme, and by making detailed rules for the implementation of that protection. The principal task of the sickness insurance funds under the statutory scheme is the implementation of detailed social legislation enacted to perform that fundamental task of the State.'

25 Finally, in its order of 31 January 2008 (1 BvR 2156/02), the Bundesverfassungsgericht held that the sickness insurance funds are bodies governed by public law integrated into the State and which, in fact, carry out, indirectly, missions of public administration.

The dispute in the main proceedings and the questions referred for a preliminary ruling

26 By public notice published in June 2006 in a specialised periodical, AOK Rheinland/Hamburg, a statutory sickness insurance fund, invited orthopaedic footwear makers to submit tenders for the manufacture and supply of footwear for the integrated provision scheme within the meaning of Paragraph 140a et seq. of SGB V for the period from 1 September 2006 to 31 December 2006. The services to be provided were classified according to cost into different groups for which the tenderer had to enter prices.

27 The quantity of shoes to be supplied was not fixed. It was provided that patients suffering from diabetic foot syndrome holding a sickness insurance card and an appropriate medical prescription were to contact the orthopaedic footwear makers directly. The footwear maker's task was to manufacture and check individually tailored orthopaedic footwear, whilst detailed advice had to be given prior to, and after, supply of the footwear. Apart from contributions by patients, payments were to be made by the statutory sickness insurance fund.

28 Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik, an orthopaedic footwear company, submitted a tender and, two days later, lodged complaints relating to infringements of Community and national procurement law. Those complaints were rejected by the statutory sickness insurance fund on the ground that the rules of procurement law were not applicable in the present case. Since the footwear company's action against that decision was dismissed at first instance, the company appealed to the Procurement Division of the Oberlandesgericht Düsseldorf.

29 The national court observes that it is disputed in German legal literature and case-law whether, despite being mentioned in Annex III to Directive 2004/18, statutory sickness insurance funds are to be regarded as 'bodies governed by public law', and therefore, as 'contracting authorities', within the meaning of the directive. It therefore set out the problem it has with the different conditions laid down in the second subparagraph of Article 1(9) of that directive.

30 The national court considers that the conditions laid down in points (a) and (b) of that provision, are fulfilled inasmuch as the statutory sickness insurance funds are legal persons governed by public law, established for the specific purpose of maintaining, restoring or improving the health of the insured, that is to say, meeting needs in the general interest. In addition, those needs are not of an industrial or commercial character since the statutory sickness insurance funds do not operate commercially and provide their services on a non-profit-making basis.

31 The discussion should therefore deal with the conditions set out in letter (c) of the second subparagraph of Article 1(9) of Directive 2004/18.

32 With regard to the first of those conditions, namely that such bodies should be financed, for the most part, by the State, the national court refers to the characteristics of the national system in question, as set out in paragraphs 13 to 18 of the present judgment.

33 With regard to the condition concerning management supervision by the public authorities, the national court refers to the relevant aspects of the system, as set out in paragraphs 19 and 20 of the present judgment.

34 If it is concluded that the statutory sickness insurance funds are contracting authorities, a second question arises, namely whether the contract at issue is a supply contract or a service contract. The national court observes that the second indent of Article 1(2)(d) of Directive 2004/18 lays down the value of the services or products in question as the criterion for making that assessment. On the basis of that criterion, the national court considers it essential to know what place manufacture of the shoes at issue in the main proceedings occupies in the whole service, which covers the purchase of materials and the manufacture as well as the advice and information provided to patients.

35 If the individualised manufacture of the footwear at issue were to be regarded as part of the supply, the national court considers that the value of the supply of the footwear would be higher than the value of the services. If, on the other hand, the value of the supply consisted only in the raw materials, the value of the services would be greater than the value of the supply. It points out that Article 1(4) of Directive 1999/44, which deems 'contracts for the supply of consumer goods to be manufactured or produced' to be contracts of sale, seems to favour the first approach irrespective of whether they relate to standardised items or items individually tailored to the specific order, namely non-fungible goods. However, it may possibly be inferred from the case-law of the Court that qualitative aspects also play a role (Case C-220/05 *Auroux* [2007] ECR I-385, paragraph 46). In that connection, it must be borne in mind that the advice to be given to patients is not limited to the selection and use of the product.

36 The national court regards that distinction as important since the classification of the contract at issue in the main proceedings as a supply contract means that the provisions of Directive 2004/18 are fully applicable.

37 If the contract at issue in the main proceedings is not to be regarded as a supply contract, the national court asks whether that contract is to be regarded as a service contract or a service concession. In the latter case, it is clear from Article 17 thereof that Directive 2004/18 is not applicable. The court before which proceedings were brought at first instance considered that that possibility is precluded by the fact that the statutory sickness insurance fund, and not the patient, is responsible for paying the provider. However, the court making the reference considers that the criterion of who bears the operating risk must also be taken into account. It must be borne in mind, on the one hand, that because the statutory sickness insurance fund, and not the patient, is liable to pay the provider, the latter is relieved of the risk connected with debt collection and debtor insolvency. On the other hand, however, the provider bears the risk that patients will not avail themselves of its products and services. That is the factor which distinguishes this case from a normal framework contract. In the view of the court making the reference, the crucial point for the purpose of classifying the contract at issue in the main proceedings as a service concession is the fact that the provider does not have to set up and maintain any costly structures, such as the construction of premises, and the cost of personnel or equipment, which would have to be amortised later by means of 'the right to exploit for payment its own service' (Case C-324/98 *Telaustria and Telefonadress* [2000] ECR I-10745, point 30).

38 Finally, the national court points out that if the contract at issue in the main proceedings is regarded as a service contract, that would result, by reason of its character as a health service under Article 21 and Annex II B, Category 25, of Directive 2004/18, in the application only of Article 23 and Article 35(4) of the directive and an infringement of those provisions is not at issue in the present case. However, such a classification would result in certain provisions of national law being applicable, provisions which employ the same concept of 'service contract' and on the basis of which the applicant in the main proceedings would be partly successful.

39 Having regard to the foregoing considerations, the Oberlandesgericht Düsseldorf decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

‘1. (a) Is the requirement of “financing by the State” as referred to in the first alternative of letter (c) of the second subparagraph of Article 1(9) of [Directive 2004/18] to be interpreted as including a situation where the State prescribes membership of a sickness insurance fund and the duty to pay contributions — whose amount is dependent on income — to the relevant sickness insurance fund, which sets the contribution rate, but the sickness insurance funds are linked to one another by a system of solidarity-based financing described in greater detail in the grounds hereof and the satisfaction of the liabilities of each individual sickness insurance fund is guaranteed?

(b) Is the requirement referred to in the second alternative of letter (c) of the second subparagraph of Article 1(9) [of Directive 2004/18] that the body be “subject to management supervision by those bodies” to be interpreted to the effect that State legal supervision which concerns current or future transactions — with other possible means of State intervention described in the grounds hereof — is sufficient to satisfy that requirement?

2. If the first question — in part (a) or (b) — is answered in the affirmative, are letters (c) and (d) of Article 1(2) of [Directive 2004/18] to be interpreted as meaning that the provision of goods which are individually manufactured and tailored, in terms of their form, to meet the needs of the particular customer, and on whose use the individual customer is to be advised, are to be classified as “supply contracts” or as “service contracts”? Is only the value of the particular services to be taken into consideration?

3. If the provision referred to in the second question is to be or could be classified as a “service”, is Article 1(4) of [Directive 2004/18] — as distinct from a “framework

agreement" within the meaning of Article 1(5) of the directive — to be interpreted as meaning that a "service concession" also includes the award of a contract in the form where:

— the decision on whether and in what cases the contractor is awarded specific contracts is taken not by the contracting authority, but by third parties,

— the contractor is paid by the contracting authority because by law only that authority is liable to pay remuneration and is required to provide the service to third parties, and

— the contractor does not have to provide, or offer as available, services of any kind prior to their use by the third parties?'

The questions referred to the Court

The first question

40 By its first question, the national court asks, essentially, whether statutory sickness insurance funds, such as those at issue in the main proceedings, having regard to their characteristics set out in the order for reference, should be regarded as contracting authorities for the purposes of the application of the provisions of Directive 2004/18.

41 In order to answer that question, an underlying preliminary question, which is apparent from the grounds for the reference for a preliminary ruling and the problem set out therein by the national court, must first be considered, namely, whether the fact that the

statutory sickness insurance funds at issue in the main proceedings are expressly mentioned in Annex III to Directive 2004/18 is sufficient for them to be regarded, on that ground alone, as bodies governed by public law and therefore, as contracting authorities.

42 The applicant in the main proceedings and the Commission of the European Communities argue that the mere inclusion of a body in Annex III to Directive 2004/18 is a sufficient condition for considering that body to be governed by public law. Inclusion in the list raises an irrebuttable presumption that the body may be so classified, which makes any additional consideration of the nature and characteristics of the body at issue superfluous.

43 That argument cannot be accepted.

44 It can be seen from letter (b) of the first paragraph of Article 234 EC, that a national court may, at any time, request the Court to rule on the validity of an act of the institutions of the European Community if it considers that a decision by the Court on the question is necessary to enable it to give judgment.

45 In that regard, it should be pointed out that the Community rules at issue, namely Directive 2004/18, contain both substantive rules, such as those in the second subparagraph of Article 1(9) of that Directive, which lays down the conditions which a body must fulfil if it is to be regarded as a contracting authority within the meaning of the Directive, and measures implementing those substantive rules, such as the inclusion in Annex III to the same directive of a non-exhaustive list of public bodies deemed to fulfil those conditions. In such a context, the Community judicature, when a reasoned request to that effect is referred to by a national court, must make sure that the Community measure in question is internally consistent by verifying whether the inclusion of a given body in the said list constitutes a correct application of the substantive criteria laid down in the abovementioned provision. The Court's intervention in that regard is a requirement of legal certainty, which is a general principle of Community law.

46 In the present case, the national court raises, although not expressly, a question concerning the validity of the inclusion in the list in Annex III of Directive 2004/18 of the statutory sickness insurance fund at issue in the main proceedings. It refers to differences between the case-law and legal literature in Germany on the question whether such inclusion constitutes a sufficient and exclusive condition for the purpose of classifying such funds as bodies governed by public law and even makes clear its own doubts in that regard. For those reasons, it frames its first question in terms of the substantive conditions laid down in letter (c) of the second subparagraph of Article 1(9) of Directive 2004/18.

47 Consequently, the national court wishes to ask the Court for a ruling on the validity of the inclusion of the body at issue in the main proceedings in Annex III to Directive 2004/18 in the light of the substantive conditions laid down in that provision.

48 In order to answer that question, it must be noted that, according to the settled case-law of the Court, the three conditions laid down in letters (a), (b) and (c) of the second subparagraph of Article 1(9) of Directive 2004/18 which must be fulfilled if a body is to be regarded as governed by public law are cumulative (Case C-393/06 *Ing. Aigner* [2008] ECR I-2339, paragraph 36 and the case-law cited therein).

49 As is clear from the order for reference, the conditions laid down in letters (a) and (b) of the second subparagraph of Article 1(9) of Directive 2004/18 are fulfilled in the present case. The statutory sickness insurance funds at issue are legal persons governed by public law, they were established for the specific purpose of meeting needs relating to public health, which are needs in the general interest, and those needs do not have an industrial or commercial character inasmuch as the benefits are provided on a non-profit-making basis. It remains to be considered, therefore, whether at least one of the alternative conditions laid down in the three alternatives set out in letter (c) of the

second subparagraph of Article 1(9) has been fulfilled in the present case and, first, the condition concerning their being financed, for the most part, by the State.

50 It must be recalled first with regard to that condition that, as is apparent from the national system in question and from the orders of the Bundesverfassungsgericht cited in paragraphs 24 and 25 of the present judgment, the protection of public health is a fundamental task of the State and the statutory public insurance funds are integrated into the State and, in fact, perform indirectly missions of public administration.

51 Furthermore, in accordance with the Court's case-law, the first alternative in letter (c) of second subparagraph of Article 1(9) of Directive 2004/18 contains no details as to the procedures for delivering the financing to which that provision relates. Thus, in particular, there is no requirement that the activity of the bodies in question should be directly financed by the State or by another public body failing which the condition attaching to that point is not satisfied. A method of indirect financing is therefore sufficient (see, to that effect, Case C-337/06 *Bayerischer Rundfunk and Others* [2007] ECR I-11173, paragraphs 34 and 49).

52 It must first be observed, that the statutory sickness insurance funds at issue in the main proceedings are financed, in accordance with the relevant national rules, by contributions from members, including the contributions paid on their behalf by their employers, by direct payments from the Federal authorities and by compensatory payments between the funds resulting from the risk structure compensation mechanism between them. The sickness funds in question are financed, for the most part, by compulsory contributions from members.

53 Secondly, it is also apparent from the order for reference that the members' contributions are paid without any specific consideration in return within the meaning of the Court's case-law (see, to that effect, Case C-380/98 *University of Cambridge* [2000] ECR I-8035, paragraphs 23 to 25). No contractual consideration is

linked to those payments, since neither the liability to pay contributions nor their amount is the result of any agreement between the statutory sickness insurance funds and their members, since membership of the funds, and payment of contributions, are both required by law (see, to that effect, *Bayerischer Rundfunk and Others*, cited above, paragraph 45). In addition, the amount of contributions is based solely on the capacity to contribute of each member and other factors, such as the age of the insured person, his state of health or the number of co-insured persons are irrelevant in that regard.

54 Thirdly, the national court points out that, unlike the licence fee at issue in *Bayerischer Rundfunk and Others*, the contribution rate is fixed in the present case not by the public authorities but by the statutory sickness insurance funds themselves. However, it points out, correctly, that the funds have a very limited discretion in that regard inasmuch as their mission is to provide the benefits laid down in the social security legislation. Since the benefits, and the expenditure connected with them, are imposed by law and the funds perform their functions on a non-profit-making basis, the contribution rate must be set in such a way that the revenue accrued is no lower and no higher than expenditure.

55 Fourthly, it must be pointed out that the setting of the contribution rate by the statutory sickness insurance funds requires, in any event, the approval of the public body which supervises each fund. Thus, the amount of the contributions is, as the national court put it, to some extent, laid down by law. Finally, with regard to the funds' other sources of revenue, the direct payments by the federal authorities, although of a smaller amount, are unquestionably direct financing by the State.

56 Lastly, with regard to the arrangements for the collection of contributions, it is clear from the order for reference that, in practice, the insured person's part of the contributions is withheld from his salary and paid by his employer to the relevant statutory sickness insurance fund, along with the employer's part of the contributions.

Contributions are therefore collected without any possibility of intervention on the part of the insured person. The national court points out in that regard that contributions are compulsorily recovered on the basis of the provisions of public law.

57 It must therefore be considered, as the Court held in paragraph 48 of *Bayerischer Rundfunk and Others*, that financing of a statutory sickness insurance scheme such as that at issue in the main proceedings, which is brought into being by a measure of the State, is, in practice, guaranteed by the public authorities and is secured by methods of collection which fall under the provisions of public law, satisfies the condition of being financed, for the most part, by the State for the purposes of the application of the Community rules on the awarding of public contracts.

58 In view of that conclusion and having regard to the alternative nature of the conditions laid down in letter (c) of the second subparagraph of Article 1(9) of Directive 2004/18, there is no need to consider whether the condition concerning supervision of the management of the statutory sickness insurance funds by the public authorities is fulfilled in the present case.

59 The answer to be given to the first question referred is therefore that the first alternative of letter (c) of the second subparagraph of Article 1(9) of Directive 2004/18 must be interpreted as meaning that there is financing, for the most part, by the State when the activities of statutory sickness insurance funds are chiefly financed by contributions payable by members, which are imposed, calculated and collected according to rules of public law such as those in the main proceedings. Such sickness insurance funds are to be regarded as bodies governed by public law and therefore as contracting authorities for the purposes of the application of the rules in that directive.

The second question

60 By this question, the national court asks essentially what criterion must be applied in order to determine whether a mixed public contract both for the supply of goods and for the provision of services must be regarded as a supply contract or a service contract and whether the criterion to be applied in that regard is solely the value of the various parts which make up the mixed contract at issue. It is apparent from the order for reference, however, that the national court also asks whether, in the case of the supply of products which are manufactured and tailored individually according to the needs of each customer and on the use of which each customer receives individual advice, the manufacture of those products must be classified in the 'supply' part or the 'services' part of the contract for the purposes of calculating the value of each part thereof.

61 In order to answer that question, it must first be noted that when a contract concerns both the supply of products and the provision of services, the second indent of Article 1(2)(d) of Directive 2004/18 contains a specific rule fixing a criterion for classifying contracts, so that the contract can be regarded as either a contract for products or a contract for services, namely, the respective value of the products and services covered by the contract. That criterion is quantitative in nature, that is to say, it refers to the consideration due by way of payment for the 'products' part and the 'services' part of the contract in question.

62 On the other hand, in the case of a public contract for the provision of services and the carrying out of works, the third indent of Article 1(2)(d) of Directive 2004/18 employs another criterion for classification, namely, the principal object of the contract in question. That criterion was applied in *Auroux and Others* (paragraphs 37 and 46), which concerned, precisely, a contract for works and services.

63 It does not appear either from the applicable Community rules or from the relevant case-law of the Court that that criterion must also be taken into account in the case of a mixed contract concerning products and services.

64 It must also be stated that, in accordance with the definition of the concept of 'public supply contracts' contained in the first indent of Article 1(2)(c) of Directive 2004/18, that concept covers transactions such as, for example, the purchase or rental of 'products', without being more specific and without making a distinction according to whether the product in question was manufactured in a standardised manner or in an individualised manner, that is to say, in accordance with the actual preferences and needs of the customer. Consequently, the concept of 'product' to which that provision makes general reference also includes the manufacturing process, irrespective of whether the product under consideration is supplied to consumers ready-made or after being manufactured in accordance with consumers' requirements.

65 That approach is confirmed by Article 1(4) of Directive 1999/44, which classifies as 'contracts of sale', in general terms and without distinction, 'contracts for the supply of consumer goods to be manufactured or produced'.

66 The answer to be given to the second question referred is therefore that when a mixed public contract concerns both products and services, the criterion to be applied in order to determine whether the contract in question is a supply contract or a service contract is the respective value of the products and services covered by the contract. Where the products supplied are individually manufactured and tailored to the needs of each customer and where each customer must receive individual advice on the use of the products, the manufacture of those products must be classified in the 'supply' part of the said contract for the purposes of calculating the value of each part thereof.

The third question

67 The third question must be understood as asking, essentially, whether, if the provision of services is regarded as being more important than the supply of products in the contract at issue in the main proceedings and having regard to the characteristics set out in the order for reference, the conclusion of a contract between a statutory sickness insurance fund and a manufacturer of orthopaedic shoes is to be regarded as a 'service

concession' within the meaning of Article 1(4) of Directive 2004/18 or a 'framework agreement' within the meaning of Article 1(5) of that directive.

68 In accordance with the definition contained in Article 1(4) of Directive 2004/18, a service concession is a contract of the same type as a public service contract except for the fact that the consideration for the provision of services consists either solely in the right to exploit the service or in this right together with payment.

69 For its part, a framework agreement is defined in Article 1(5) of Directive 2004/18 as an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged.

70 It is apparent from those definitions that the concepts considered have fairly similar characteristics, with the effect that it is not easy to draw a clear distinction between them in advance. The legal classification of a contract therefore depends on the specific factors which distinguish the particular case.

71 In any event, it flows from the abovementioned definition of a service concession that such a concession is distinguished by a situation in which a right to operate a particular service is transferred by the contracting authority to the concessionaire and that the latter enjoys, in the framework of the contract which has been concluded, a certain economic freedom to determine the conditions under which that right is exercised since, in parallel, the concessionary is, to a large extent, exposed to the risks involved in the operation of the service. On the other hand, the distinguishing characteristic of a framework agreement is that the activity of the trader who has concluded the agreement is restricted in the sense that all contracts concluded by that trader during a given period must comply with the conditions laid down in the agreement.

72 That distinguishing factor is confirmed by the Court's case-law, according to which a service concession exists where the agreed method of remuneration consists in the right of the service provider to exploit for payment his own service and means that he assumes the risk connected with operating the services in question (Case C-382/05 *Commission* v *Italy* [2007] ECR I-6657, paragraph 34 and the case-law cited therein).

73 In the present case, the contract at issue in the main proceedings is an 'integrated provision scheme', provided for in Paragraphs 140a to 140e of SGB V, concluded between a statutory sickness insurance fund and a trader. According to that contract, the trader undertakes the obligation to serve the insured persons who come to him. At the same time, the prices for the different formulae are fixed in the contract, as is its duration. The quantities of the various services are not fixed, but a provision on that point is not required by the concept of service concession. The statutory sickness insurance fund alone pays the remuneration of the provider. It seems therefore that the conditions under which the trader carries on its activity are laid down in the contract at issue in the main proceedings, with the effect that the trader in question does not enjoy the degree of economic freedom which would distinguish a concession nor is it exposed to a significant risk connected with the services it provides.

74 It could certainly be remarked that the trader in such a case is exposed to a certain risk inasmuch as insured persons may not avail themselves of its products and services. However, that risk is limited. The trader is spared the risk connected with recovery of payment and the insolvency of the other party to the individual contract since, in law, the statutory sickness insurance fund alone is responsible for paying the trader. In addition, although the trader must be sufficiently equipped to provide its services, it does not have to incur considerable advance expenditure before an individual contract with an insured person is concluded. Finally, the number of insured persons suffering from diabetic foot syndrome, who are likely to seek out the trader in question, is known in advance, with the result that a reasonable forecast can be made as to the number of customers.

75 Consequently, the trader in the present case does not bear the principal burden of the risk connected with the carrying on of the activities in question, which is the factor which distinguishes the situation of a concessionaire in the context of a service concession.

76 The answer to be given to the third question referred is therefore that, if the provision of services is regarded as being more important than the supply of products in the contract in question, an agreement such as the one at issue in the main proceedings, concluded between a statutory sickness insurance fund and a trader, in which payment for the various types of service to be provided by the trader and the duration of the agreement are determined, with the trader undertaking an obligation to implement the agreement in regard to insured persons who ask him to do so and the abovementioned fund alone paying that trader for its services, must be regarded as a framework agreement within the meaning of Article 1(5) of Directive 2004/18.

Costs

77 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 (Fourth Chamber) hereby rules:

1. **The first alternative of letter (c) of the second subparagraph of Article 1(9) of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts must be interpreted as meaning that there is financing, for the most part, by the State**

when the activities of statutory sickness insurance funds are chiefly financed by contributions payable by members, which are imposed, calculated and collected according to rules of public law such as those in the main proceedings. Such sickness insurance funds are to be regarded as bodies governed by public law and therefore as contracting authorities for the purposes of the application the rules in that directive.

2. **When a mixed public contract concerns both products and services, the criterion to be applied in order to determine whether the contract in question is a supply contract or a service contract is the respective value of the products and services covered by the contract. Where the products supplied are individually manufactured and tailored to the needs of each customer and where each customer must receive individual advice on the use of the products, the manufacture of those products must be classified in the 'supply' part of the said contract for the purposes of calculating the value of each part thereof.**

3. **If the provision of services is regarded as being more important than the supply of products in the contract in question, an agreement such as the one at issue in the main proceedings, concluded between a statutory sickness insurance fund and a trader, in which payment for the various types of service to be provided by the trader and the duration of the agreement are determined, with the trader undertaking an obligation to implement the agreement in regard to insured persons who ask him to do so and the abovementioned fund alone paying that trader for its services, must be regarded as a framework agreement within the meaning of Article 1(5) of Directive 2004/18.**

[Signatures]