Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

2 June 2016*

(Reference for a preliminary ruling — Public contracts — Directive 2004/18/EC — Article 1(2)(a) — Concept of 'public contract' — Scheme for acquiring goods consisting of the authorisation as a supplier of any economic operator who meets the predetermined criteria — Supply of medicinal products that are refundable under a general social security scheme — Contracts concluded between a statutory health insurance fund and all the suppliers of medicinal products based on a given active ingredient who consent to a rebate on the sale price at a predetermined rate — Legislation providing, in principle, for the substitution of a refundable medicinal product marketed by an operator not having concluded such a contract by a medicinal product of the same type marketed by an operator having concluded such a contract)

In Case C-410/14

REQUEST for a preliminary ruling under Article 267 TFEU from the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany), made by decision of 13 August 2014, received at the Court on 29 August 2014, in the proceedings

Dr. Falk Pharma GmbH

v

DAK-Gesundheit,

intervener:

Kohlpharma GmbH,

THE COURT (Fifth Chamber),

composed of T. von Danwitz, President of the Fourth Chamber, acting as President of the Fifth Chamber, D. Šváby (Rapporteur), A. Rosas, E. Juhász and C. Vajda, Judges,

Advocate General: P. Cruz Villalón,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Dr. Falk Pharma GmbH, by M. Ulshöfer, Rechtsanwalt,

* Language of the case: German.

— DAK-Gesundheit, by A. Csaki, Rechtsanwalt,

— Kohlpharma GmbH, by C. Stumpf, Rechtsanwalt,

— the German Government, by T. Henze and A. Lippstreu, acting as Agents,

— the Greek Government, by K. Nasopoulou and S. Lekkou, acting as Agents,

— the Swedish Government, by A. Falk, C. Meyer-Seitz, U. Persson, N. Otte Widgren and by E. Karlsson, L. Swedenborg and F. Sjövall, acting as Agents,

— the European Commission, by C. Hermes and A. Tokár, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 1(2)(a) 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, and corrigendum in OJ 2004 L 351, p. 44).

2 The reference has been made in proceedings between Dr. Falk Pharma GmbH ('Falk') and DAK-Gesundheit ('DAK') a statutory health insurance fund, with Kohlpharma GmbH as a joined party, concerning a procedure carried out by DAK in order to conclude rebate contracts with undertakings marketing a medicinal product whose active ingredient is mesalazine and which led to such an agreement being reached with Kohlpharma.

Legal context

EU law

3 Recitals 2 and 3 of Directive 2004/18 state as follows:

'(2) The award of contracts concluded in the Member States on behalf of the State, regional or local authorities and other bodies governed by public law entities, is subject to the respect of the principles of the Treaty and in particular to the principle of freedom of movement of goods, the principle of freedom of establishment and the principle of freedom to provide services and to the principles deriving therefrom, such as the principle of equal treatment, the principle of non-discrimination, the principle of mutual recognition, the principle of proportionality and the principle of transparency. However, for public contracts above a certain value, it is advisable to draw up provisions of Community coordination of national procedures for the award of such contracts which are based on these principles so as to ensure the effects of them and to guarantee the opening-up of public procurement to competition. These coordinating provisions should therefore be interpreted in accordance with both the aforementioned rules and principles and other rules of the Treaty.

(3) Such coordinating provisions should comply as far as possible with current procedures and practices in each of the Member States.'

4 Recital 11 of that directive states:

‘A Community definition of framework agreements, together with specific rules on framework agreements concluded for contracts falling within the scope of this Directive, should be provided. Under these rules, when a contracting authority enters into a framework agreement in accordance with the provisions of this Directive relating, in particular, to advertising, time limits and conditions for the submission of tenders, it may enter into contracts based on such a framework agreement during its term of validity either by applying the terms set forth in the framework agreement or, if all terms have not been fixed in advance in the framework agreement, by reopening competition between the parties to the framework agreement in relation to those terms. ...’

5 Article 1(2)(a) of the Directive provides that ‘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 [that] Directive’.

6 Article 1(5) defines ‘framework agreement’ in the following terms:

‘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.’

7 Article 2 of that directive is worded as follows:

‘Contracting authorities shall treat economic operators equally and non-discriminatorily and shall act in a transparent way.’

8 Article 32 of Directive 2004/18 provides:

‘...

2. For the purpose of concluding a framework agreement, contracting authorities shall follow the rules of procedure referred to in this Directive for all phases up to the award of contracts based on that framework agreement. The parties to the framework agreement shall be chosen by applying the award criteria set in accordance with Article 53.

Contracts based on a framework agreement shall be awarded in accordance with the procedures laid down in paragraphs 3 and 4. Those procedures may be applied only between the contracting authorities and the economic operators originally party to the framework agreement.

...

4. Where a framework agreement is concluded with several economic operators, the latter must be at least three in number, insofar as there is a sufficient number of economic operators to satisfy the selection criteria and/or of admissible tenders which meet the award criteria.

Contracts based on framework agreements concluded with several economic operators may be awarded either:

— by application of the terms laid down in the framework agreement without reopening competition, or,

— where not all the terms are laid down in the framework agreement, when the parties are again in competition on the basis of the same and, if necessary, more precisely formulated terms, and, where appropriate, other terms referred to in the specifications of the framework agreement, in accordance with the following procedure:

...'

9 Under the first paragraph of Article 43 of that directive:

'For every contract, framework agreement, and every establishment of a dynamic purchasing system, the contracting authorities shall draw up a written report which shall include at least the following:

...

(e) the name of the successful tenderer and the reasons why his tender was selected and, if known, the share of the contract or framework agreement which the successful tenderer intends to subcontract to third parties;

...'

10 Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18 (OJ 2014 L 94, p. 65), the implementing measures for which must, in accordance with Article 90(1) of that directive, come into force by 18 April 2016, defines procurement in the following terms in Article 1(2):

'Procurement within the meaning of this Directive is the acquisition by means of a public contract of works, supplies or services by one or more contracting authorities from economic operators chosen by those contracting authorities, whether or not the works, supplies or services are intended for a public purpose.'

National law

11 Under Paragraph 129(1) of the Sozialgesetzbuch, Fünftes Buch — Gesetzliche Krankenversicherung (Social Security Code, Fifth Book — Statutory Health Insurance) ('SGB V'), in the case of the supply of a medicinal product which has been prescribed by indicating its active ingredient and whose replacement by a medicinal product with an equivalent active ingredient is not excluded by the prescribing doctor, pharmacists must replace the medicinal product prescribed with another medicinal product with an equivalent active ingredient in respect of which a rebate contract has been concluded, within the meaning of Paragraph 130a(8) of the SGB V.

12 In accordance with that provision, the health insurance funds or their associations may enter into two-year agreements with pharmaceutical undertakings discounting the sale price of medicinal products which are issued and chargeable by those funds.

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

13 On 28 August 2013, DAK published in the supplement to the *Official Journal of the European Union* a notice concerning an 'authorisation procedure' for the conclusion of rebate contracts, in accordance with Paragraph 130a(8) of the SGB V, concerning medicinal products whose active ingredient is mesalazine. The rebate rate was fixed at 15% of the 'ex-factory' price and the period covered ran from 1 October 2013 to 30 September 2015.

14 That procedure provided for the authorisation of all interested undertakings meeting the authorisation criteria and for the conclusion with each of those undertakings of identical contracts whose terms were fixed and non-negotiable. Furthermore, any other undertaking fulfilling those criteria also had the opportunity of acceding on the same terms to the rebate contract scheme during the contract period.

15 The notice of 28 August 2013 indicated that that procedure was not subject to public procurement law.

16 Kohlpharma was the only undertaking which expressed its interest in response to that notice. A contract was concluded with that undertaking on 5 December 2013. The substitution mechanism provided for in Paragraph 129(1) of the SGB V was implemented from 1 January 2014 in the computer system used by pharmacies. The conclusion of that contract was the subject of a notice in the *Official Journal* on 22 February 2014.

17 On 17 January 2014, Falk brought proceedings before the Vergabekammer des Bundes (Federal Public Procurement Board, Germany) seeking a declaration that the authorisation procedure initiated by DAK and the only contract award which resulted from that procedure were incompatible with public procurement law. The Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany) is hearing that case on appeal.

18 In those proceedings, Falk maintains that public procurement law applies where a body classified as a contracting authority procures goods on the market and that law requires that there be a call for tenders, which implies the conclusion of exclusive contracts.

19 Conversely, DAK considers that in order to acquire the goods and services which it requires a contracting authority can have recourse not only to public procurement but also to other models and is, therefore, free to award the contract on an exclusive basis following a selection decision but also to conclude contracts with all the interested undertakings without a selection process. The existence of a selection decision is a constituent element of the concept of 'public contract' within the meaning of Directive 2004/18 and of EU law on the subject, with the result that, in the absence of selection, a contract, such as that at issue in the main proceedings, would not be a public contract.

20 Kohlpharma takes the view that a contracting authority's freedom of choice concerning the type of contract necessary to fulfil a public service obligation is contained in the Court's case-law concerning the award of service contracts.

21 The referring court states that the admissibility of the action brought by Falk depends on whether a standard rebate contract, within the meaning of Paragraph 130a(8) of the SGB V, concluded in an authorisation procedure with all interested economic operators, without a selection decision, constitutes a public contract within the meaning of Article 1(2)(a) of Directive 2004/18. In other words, the issue is whether a public contract is characterised by a selection made by the contracting authority which implies that the operator selected has exclusivity. If that were the case, an authorisation procedure for the conclusion of contracts with all interested economic operators would not constitute a procedure for the award of a public contract.

22 That court notes that the national case-law is divided on this question. For certain courts a public contract is a contract which gives the chosen operator exclusivity, so that a contract which is concluded with all the operators who wish to conclude such a contract does not constitute a public contract. Other courts take the view that all contracts concluded by a contracting authority are public contracts and that the choice of one of the tenderers, and therefore the grant of exclusivity, is an obligation of a contracting authority.

23 The referring court is inclined to the view that rebate contracts such as those at issue in the main proceedings are not public contracts. On account of the award of those contracts to all operators who fulfil the fixed terms and who ask to be included, there is no selection, no award of an economic advantage to an operator and, therefore, no risk of discrimination. As is apparent from recital 2 and Article 2 of Directive 2004/18, the law of public procurement has as its specific objective the avoidance of the abuses linked to those sort of risks.

24 That court refers in support of those considerations, first, to the judgment of 10 September 2009 in *Eurawasser* (C-206/08, EU:C:2009:540) from which it infers that a contract must not necessarily be awarded in the form of a public service contract where there is a legal alternative, which, in the case in the main proceedings giving rise to that judgment, was recourse to the use of a service concession. Neither primary law nor secondary legislation seems to imply, to the national court, that any acquisition must be the subject of a public procurement contract. It considers that although a distinction exists between public contract and service concession because of the nature of the consideration provided for in the contract, nothing precludes the existence or not of a choice between the interested economic operators being based on another distinction. That court takes the view that the judgment of 15 July 2010 in *Commission* v *Germany* (C-271/08, EU:C:2010:426) could indirectly confirm that conclusion in that the Court held, in paragraph 73, that public procurement directives have the objective of excluding the risk that a preference might be given to national tenderers or candidates in any procurement carried out by contracting authorities.

25 Secondly, the national court refers to Directive 2014/24, especially the definition of the concept of 'public procurement' introduced in that directive, which expressly refers to the choice of economic operators and the second paragraph of recital 4 of that directive, which excludes from the concept of public contract cases in which all operators fulfilling certain conditions are entitled to perform a given task without any selectivity, one of the examples given appearing to refer to a scheme comparable to that at issue in the main proceedings. The national court considers that, although in this case Directive 2014/24 does not apply *ratione temporis*, the definition of the concept of 'public procurement' which it contains, where Directive 2004/18 does not define that concept, does not introduce any change. EU law on public contracts has always been characterised by an element of competition.

26 If selection is a characteristic of a public contract and, therefore, an authorisation procedure for a rebate contract scheme, such as that at issue in the main proceedings, is not, in principle, a public procurement procedure, the national court is of the view that it is necessary to specify the conditions governing such an authorisation procedure which must be met in order for a contracting authority to be able to forgo a procurement procedure implying the selection of one or more operators.

27 That court states that the principles of non-discrimination and equality of treatment and the requirement of transparency, which are to be inferred above all from primary law, impose procedural and substantive requirements which also apply to that authorisation procedure, so as to guarantee that that procedure is in fact exempt from all selectivity, not giving any competitive advantage to any operator. However, the way in which an authorisation procedure is organised may give rise to discrimination and unequal treatment.

28 The requirements of such a procedure could be EU-wide publication of the opening of that procedure and of the contracts concluded in that procedure, clarity of the rules governing authorisation, the fixing a priori of the standard-form rebate contracts and the possibility of acceding to the contract at any time.

29 That possibility of acceding at any time distinguishes an authorisation procedure, such as that at issue in the main proceedings, from a procedure for the award of a framework agreement governed by Article 32 of Directive 2004/18. The requirement imposed by Article 32(2), second subparagraph, that contracts based on a framework agreement can only be concluded between economic operators who are parties to that framework agreement, stems from the selective nature of that type of agreement.

According to the referring court, to impose such a restriction on an authorisation procedure by fixing a time limit beyond which an operator can no longer accede to a rebate contract scheme would have a discriminatory effect since it would give a competitive advantage to operators who had acceded to that scheme.

30 That court takes the view that the mechanism for substituting a medicinal product laid down in Paragraph 129 of the SGB V does not give such a competitive advantage in the case of accession to a rebate contract scheme within the meaning of Paragraph 130a(8) of the SGB V. The situation is different where such a rebate contract is concluded in a procedure for the award of a public contract. In that situation, the exclusivity from which the successful tenderer benefits has the consequence that that tenderer enjoys a special competitive position, the award of the contract having a decisive effect on competition. By contrast, where such contracts are concluded with all interested operators, the substitution of a medicinal product takes place on the basis of a choice made not by the contracting authority but by the pharmacist or the patient depending on the sale conditions proposed by the operators who have acceded to the rebate contract scheme. Accordingly, it is possible that some of the contracting operators may see their product sold only rarely. It is the same if, as in the present case, a single operator has contracted. In granting the right to contract at any moment to any interested operator, the contracting authority refrains from exercising an influence on the competitive situation, which depends not on the possibility of substituting the contracting operator's medicinal products but on the decision taken by each operator who is potentially interested in participating or not in the rebate contract scheme.

31 In those circumstances, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Does the concept of a "public contract" under Article 1(2)(a) of Directive 2004/18/EC no longer apply if a contracting authority carries out an authorisation procedure in which it awards the contract without selecting one or more economic operators?

(2) If the answer to question 1 is that the selection of one or more economic operators is a characteristic of a public contract, ... must the characteristic of the selection of economic operators [which would imply in that situation the concept of "public contract"] within the meaning of Article 1(2)(a) of Directive 2004/18/EC be interpreted, in the light of Article 2 of that directive, as meaning that contracting authorities may refrain from selecting one or more economic operators by way of an authorisation procedure only if the following conditions are satisfied:

— the carrying out of an authorisation procedure is published at European level,

— clear rules concerning the conclusion of the contract and acceding to the contract are set,

— the terms of the contract are set in advance in such a way that no economic operator is able to influence the content of the contract,

— economic operators are granted the right to accede to the contract at any time;

— the contracts concluded are published at European level?'

Consideration of the questions referred

The first question

32 By its first question the referring court asks, in essence, whether Article 1(2)(a) of Directive 2004/18 must be interpreted as meaning that a contract scheme, such as that at issue in the main proceedings, through which a public entity intends to acquire goods on the market by contracting throughout the period of validity of that scheme with any economic operator who undertakes to provide the goods concerned on fixed terms, without choosing between the interested operators, and allows those operators to accede to that scheme throughout its period of validity, must be classified as a public contract within the meaning of that directive.

33 Admittedly, as certain interested parties who presented their written observations to the Court note, such a scheme leads to the conclusion of contracts for a pecuniary interest between a public entity, which could be a contracting authority within the meaning of Directive 2004/18, and economic operators whose objective is to supply goods, which corresponds to the definition of 'public contracts' laid down in Article 1(2)(a) of that directive.

34 However, it should be noted, first, according to recital 2 of that directive, the coordinating provisions which it establishes must be interpreted in accordance with the principles of the FEU Treaty, in particular the principles of the free movement of goods, freedom of establishment and freedom to provide services and the principles that derive therefrom, such as equality of treatment, non-discrimination, mutual recognition, proportionality and transparency to which the award of public contracts in Member States are subject.

35 Secondly, the coordination at EU level of the procedures for the award of public service contracts being, therefore, to protect the interests of economic operators established in a Member State who wish to offer goods or services to contracting authorities established in another Member State, the purpose of Directive 2004/18 is to avoid the risk of preference being given to national tenderers or applicants whenever a contract is awarded by the contracting authorities (see to that effect, concerning the directive relating to public service contracts previously in force, judgment of 10 November 1998 in *BFI Holding*, C-360/96, EU:C:1998:525, paragraphs 41 and 42 and the case-law cited).

36 Essentially, the risk of favouring national economic operators which that directive seeks to preclude is closely connected to the selection which the contracting authority intends to make from the admissible tenders and to the exclusivity which will result from the award of the contract concerned to the operator whose tender has been accepted or to the economic operators whose tenders have been accepted, in the case of a framework agreement, that constituting the objective of a public procurement procedure.

37 Consequently, where a public entity seeks to conclude supply contracts with all the economic operators wishing to supply the goods concerned in accordance with the conditions specified by that entity, the fact that the contracting authority does not designate an economic operator to whom contractual exclusivity is to be awarded means that there is no need to control, through the detailed rules of Directive 2004/18, the action of that contracting authority so as to prevent it from awarding a contract in favour of national operators.

38 It is therefore apparent that the choice of a tender and, thus, of a successful tenderer, is intrinsically linked to the regulation of public contracts by that directive and, consequently, to the concept of 'public contract' within the meaning of Article 1(2) of that directive.

39 That finding is supported by Article 43, first paragraph, (e) of Directive 2004/18, which provides that for every contract, framework agreement, and every establishment of a dynamic purchasing system, the contracting authorities are to draw up a written report which is to include the name of the successful tenderer and the reasons why his tender was selected.

40 It must, moreover, be pointed out that that principle is expressly set out in the definition of the concept of 'procurement', now set out in Article 1(2) of Directive 2014/24, in respect of which one aspect is the choice by the contracting authority of the economic operator from whom it will acquire by means of a public contract the works, supplies or services which are the subject matter of that contract.

41 Lastly, it should be noted that the special feature of a contractual scheme, such as that at issue in the main proceedings, namely its permanent availability for the duration of its validity to interested operators and, therefore, its not being limited to a preliminary period in the course of which undertakings are invited to express their interest to the public entity concerned, suffices to distinguish that scheme from a framework agreement. In accordance with Article 32(2), second subparagraph, of Directive 2004/18, contracts based on a framework agreement can only be awarded to economic operators who are originally parties to that framework agreement.

42 The answer to the first question, therefore, is that Article 1(2)(a) of Directive 2004/18 must be interpreted as meaning that a contract scheme, such as that in the main proceedings, through which a public entity intends to acquire goods on the market by contracting throughout the period of validity of that scheme with any economic operator who undertakes to provide the goods concerned in accordance with predetermined conditions, without choosing between the interested operators, and allows them to accede to that scheme throughout its validity, does not constitute a public contract within the meaning of that directive.

The second question

43 By its second question, the referring court asks, in essence, what conditions under EU law govern the validity of an authorisation procedure for a contract scheme, such as that at issue in the main proceedings.

44 It should be noted that such a procedure, in so far as its subject matter is of certain cross-border interest, is subject to the fundamental rules of the FEU Treaty, in particular the principles of equal treatment and of non-discrimination between economic operators and the consequent obligation of transparency, that obligation requiring that there be adequate publicity. In that regard, Member States have some latitude in a situation such as that at issue in the main proceedings for the purpose of adopting measures intended to ensure observance of the principles of equal treatment and the obligation of transparency.

45 However, the requirement of transparency implies publicity which allows potentially interested economic operators to apprise themselves properly of the conduct and the essential characteristics of an authorisation procedure such as that at issue in the main proceedings.

46 It is for the referring court to assess whether the authorisation procedure at issue in the main proceedings satisfies those requirements.

47 The answer to the second question is therefore that in so far as the subject matter of an authorisation procedure, such as that at issue in the main proceedings, is of certain cross-border interest, that procedure must be conceived and organised in accordance with the fundamental rules of the FEU Treaty, in particular, the principles of non-discrimination and equal treatment between economic operators and the consequent obligation of transparency.

Costs

48 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 (Fifth Chamber), hereby rules:

1. **Article 1(2)(a) 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 a contract scheme, such as that in the main proceedings, through which a public entity intends to acquire goods on the market by contracting throughout the period of validity of that scheme with any economic operator who undertakes to provide the goods concerned in accordance with predetermined conditions, without choosing between the interested operators and, allows them to accede to that scheme throughout its validity, does not constitute a public contract within the meaning of that directive.**

2. **In so far as the subject matter of an authorisation procedure, such as that at issue in the main proceedings, is of certain cross-border interest, that procedure must be conceived and organised in accordance with the fundamental rules of the FEU Treaty, in particular, the principles of non-discrimination and equal treatment between economic operators and the consequent obligation of transparency.**

[Signatures]