

Judgment of the Court (Ninth Chamber) of 25 October 2018.

Proceedings brought by "Roche Lietuva" UAB.

Request for a preliminary ruling from the Lietuvos Aukščiausiasis Teismas.

Reference for a preliminary ruling — Public supply contract for medical diagnostic equipment and materials — Directive 2014/24/EU — Article 42 — Award — Margin of appreciation of the contracting authority — Detailed formulation of the technical specifications.

Case C-413/17.

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JUDGMENT OF THE COURT (Ninth Chamber)

25 October 2018 (^{*1})

(Reference for a preliminary ruling — Public supply contract for medical diagnostic equipment and materials — Directive 2014/24/EU — Article 42 — Award — Margin of appreciation of the contracting authority — Detailed formulation of the technical specifications)

In Case C-413/17,

REQUEST for a preliminary ruling under Article 267 TFEU from the Lietuvos Aukščiausiasis Teismas (Supreme Court, Lithuania), made by decision of 30 June 2017, received at the Court on 10 July 2017, in the proceedings brought by

‘Roche Lietuva’ UAB

in the presence of:

Kauno Dainavos poliklinika VšĮ,

THE COURT (Ninth Chamber),

composed of K. Jürimäe, President of the Chamber, E. Juhász (Rapporteur) and C. Vajda, Judges,

Advocate General: J. Kokott,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- ‘Roche Lietuva’ UAB, by G. Balčiūnas and K. Karpickis, advokatai,
- Kauno Dainavos poliklinika VšĮ, by K. Laurynaitė and J. Judickienė, advokatai,
- the Lithuanian Government, by D. Kriauciūnas and K. Dieninis, and by D. Stepanienė, acting as Agents,
- the Greek Government, by M. Tassopoulou and A. Magrippi, and by K. Georgiadis, acting as Agents,
- the Italian Government, by G. Palmieri, acting as Agent, assisted by S. Fiorentino, avvocato dello Stato,
- the European Commission, by A. Steiblytė and P. Ondrůšek, 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 Articles 2 and 23 and of Annex VI to 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 request has been made in proceedings brought by ‘Roche Lietuva’ UAB, an unsuccessful tenderer in a procedure for the award of a public procurement contract organised by Kauno Dainavos poliklinika VšĮ, a public polyclinic established in Kaunas (Lithuania) (‘the Polyclinic for the Dainava District of Kaunas’), regarding the technical specifications of that contract.

Legal context

European Union law

- 3 Directive 2004/18 was repealed, with effect from 18 April 2016, by 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](#)), in accordance with Article 91(1) of the latter directive.
- 4 Recital 74 of Directive 2014/24 states:

‘(74)The technical specifications drawn up by public purchasers need to allow public procurement to be open to competition as well as to achieve objectives of sustainability. To that end, it should be possible to submit tenders that reflect the diversity of technical solutions standards and technical specifications in the marketplace, including those drawn up on the basis of performance criteria linked to the life cycle and the sustainability of the production process of the works, supplies and services.

Consequently, technical specifications should be drafted in such a way as to avoid artificially narrowing down competition through requirements that favour a specific economic operator by mirroring key characteristics of the supplies, services or works habitually offered by that economic operator. Drawing up the technical specifications in terms of functional and performance requirements generally allows that objective to be achieved in the best way possible. Functional and performance-related requirements are also appropriate means to favour innovation in public procurement and should be used as widely as possible. Where reference is made to a European standard or, in the absence thereof, to a national standard, tenders based on equivalent arrangements should be considered by contracting authorities. It should be the responsibility of the economic operator to prove equivalence with the requested label.

...’

- 5 Article 18(1) of that directive, entitled ‘Principles of procurement’, provides:

‘Contracting authorities shall treat economic operators equally and without discrimination and shall act in a transparent and proportionate manner.

The design of the procurement shall not be made with the intention of excluding it from the scope of this Directive or of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators.’

- 6 Article 42 of the directive, entitled ‘Technical specifications’, provides:

‘1. The technical specifications as defined in point 1 of Annex VII shall be set out in the procurement documents. The technical specifications shall lay down the characteristics required of a works, service or supply.

Those characteristics may also refer to the specific process or method of production or provision of the requested works, supplies or services or to a specific process for another stage of its life cycle even where such factors do not form part of their material substance, provided that they are linked to the subject-matter of the contract and proportionate to its value and its objectives.

...

2. Technical specifications shall afford equal access of economic operators to the procurement procedure and shall not have the effect of creating unjustified obstacles to the opening up of public procurement to competition.

3. Without prejudice to mandatory national technical rules, to the extent that they are compatible with Union law, the technical specifications shall be formulated in one of the following ways:

- (a) in terms of performance or functional requirements, including environmental characteristics, provided that the parameters are sufficiently precise to allow tenderers to determine the subject-matter of the contract and to allow contracting authorities to award the contract;
- (b) by reference to technical specifications and, in order of preference, to national standards transposing European standards, European Technical Assessments, common technical specifications, international standards, other technical reference systems established by the European standardisation bodies or — when any of those do not exist — national standards, national technical approvals or national technical

specifications relating to the design, calculation and execution of the works and use of the supplies; each reference shall be accompanied by the words “or equivalent”;

- (c) in terms of performance or functional requirements referred to in point (a), with reference to the technical specifications referred to in point (b) as a means of presuming conformity with such performance or functional requirements;
- (d) by reference to the technical specifications referred to in point (b) for certain characteristics, and by reference to the performance or functional requirements referred to in point (a) for other characteristics.

4. Unless justified by the subject-matter of the contract, technical specifications shall not refer to a specific make or source, or a particular process which characterises the products or services provided by a specific economic operator, or to trade marks, patents, types or a specific origin or production with the effect of favouring or eliminating certain undertakings or certain products. Such reference shall be permitted on an exceptional basis, where a sufficiently precise and intelligible description of the subject-matter of the contract pursuant to paragraph 3 is not possible. Such reference shall be accompanied by the words “or equivalent”.

...’

- 7 Annex VII to Directive 2014/24, entitled ‘Definition of certain technical specifications’, provides in its first paragraph:

‘For the purpose of this Directive:

1. “technical specification” means one of the following:

- (a) ...
- (b) in the case of public supply or service contracts a specification in a document defining the required characteristics of a product or a service, such as quality levels, environmental and climate performance levels, design for all requirements (including accessibility for disabled persons) and conformity assessment, performance, use of the product, safety or dimensions, including requirements relevant to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking and labelling, user instructions, production processes and methods at any stage of the life cycle of the supply or service and conformity assessment procedures.’

Lithuanian law

- 8 Articles 2 and 23 of, and Annex VI to, Directive 2004/18 have been transposed into Lithuanian law by Articles 3 and 25 of, and Appendix 3 to, the Lietuvos Respublikos viešųjų pirkimų įstatymas (Law on Public Procurement of the Republic of Lithuania). As regards Directive 2014/24, it was transposed by law XIII-327 of 2 May 2017. That law entered into force on 1 July 2017.

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

- 9 It appears from the file before the Court that on 22 June 2016, the Polyclinic for the Dainava District of Kaunas published public procurement procedure entitled ‘Procurement of services concerning the rental of laboratory diagnostic equipment for human health care and procurement of materials and services to ensure the operation of such equipment’. That procurement was divided into 13 lots. The value of the part of the lot at issue amounts to EUR 250000.
- 10 On 4 July 2016, Roche Lietuva argued, in the context of a complaint, that the technical specifications set out in Annex 1 to the contract documents unreasonably restricted competition among suppliers due to their high specificity and in reality corresponded to the

- products of specific manufacturers of blood analysers. The Polyclinic for the Dainava District of Kaunas, by a decision of 14 July 2016, amended certain provisions of the technical specifications.
- 11 On 28 July 2016, unsatisfied with the amendments brought to the tender specifications following its complaint, Roche Lietuva brought an application before the national courts.
 - 12 The first-instance court as well as the appellate court dismissed Roche Lietuva's application, on 6 October and 14 December 2016 respectively, namely on the grounds that the Polyclinic for the Dainava District of Kaunas had correctly exercised its discretion in laying down the detailed technical specifications in the light of its requirements based on the quality of testing and the value of health care, and that the applicant in the main proceedings had failed to prove that the tender specifications at issue corresponded to specific devices or manufacturers.
 - 13 On 28 December 2016, the Polyclinic for the Dainava District of Kaunas terminated the procurement procedure concerned following a request to that effect by the Viešųjų pirkimų tarnyba (Public Procurement Office, Lithuania) that authority having found the infringement of applicable provisions other than the ones indicated in the request for a preliminary ruling.
 - 14 On 17 January, 2017, Roche Lietuva filed an appeal in cassation before the Lietuvos Aukščiausiasis Teismas (Supreme Court, Lithuania), which examined that case on 17 May 2017. By order of 19 June 2017, that court decided ex officio to re-open the case. It informed the parties of its intention to go beyond the ambit of the appeal in cassation and invited them, as well as the Public Procurement Office, to submit their observations on the provisions of the procurement specifications defining not the requirements applicable to the services (medical analyses), but to the requirements concerning the materials necessary for the provision of those services.
 - 15 The referring court raises the question of the limits to the margin of appreciation of a contracting authority, such as the defendant in the main proceedings, regarding the laying down, in the procurement documents, of specific characteristics of supplies of medical equipment to be acquired not for the independent purpose of having them at one's disposal but for the purpose of carrying out medical tests. In that regard, the referring court asks whether that contracting authority would comply with the legal requirements if the functioning of the equipment was defined as a functional requirement, regarding not the isolated functioning of the equipment or its characteristics, but rather the result of that functioning, namely as regards the speed or reliability of the tests and of the methods used.
 - 16 In those circumstances, the Lietuvos Aukščiausiasis Teismas (Supreme Court of Lithuania) decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Should Articles 2 and 23 of, and Annex VI to, Directive 2004/18 (whether together or separately, but without limitation to those provisions), be interpreted and understood as meaning that, in the case where a contracting authority — a human health care institution — intends to acquire supplies (medical diagnostic equipment and materials) or specific rights thereto by way of a public procurement procedure in order to be able to carry out tests by itself, its discretion includes the right to lay down in the technical specifications only such requirements for those supplies as do not describe in isolation the individual operational (technical) and use-related (functional) characteristics of the equipment and/or materials but instead define the qualitative parameters of the tests to be carried out as well as the performance of the testing laboratory, the content of which must be separately described in the specifications of the public procurement procedure in question?'

Preliminary observations

- 17 The referring court refers to certain provisions of Directive 2004/18 in its question. As regards the *ratione temporis* applicability of that directive, it should be noted that the

notice of procurement at issue in the main proceedings was published on 22 June 2016, that is after the date that the repeal of that directive took effect, that date having been fixed on 18 April 2016, in accordance with Article 91(1) of Directive 2014/24.

- 18 According to established case-law, the applicable directive is, as a rule, the one in force when the contracting authority chooses the type of procedure to be followed and decides definitively whether it is necessary for a prior call for tenders to be issued for the award of a public procurement contract (judgment of 14 September 2017, *Casertana Costruzioni*, [C-223/16](#), [EU:C:2017:685](#), paragraph 21 and the case-law cited).
- 19 It should be added that Articles 2 and 23 of Directive 2004/18 were substantially reproduced in, respectively, Article 18(1) and in Articles 42 to 44 of Directive 2014/24. The content of Annex VI to Directive 2004/18 was substantially reproduced in Annex VII to Directive 2014/24. The conditions applicable to the technical specifications defining the required characteristics of the works, services or supplies that are the object of a contract are more specifically governed by Article 42 of that latter directive.
- 20 It follows that the relevant provisions of Directive 2014/24 should be interpreted in order to provide a useful answer to the referring court.

Consideration of the question referred

- 21 In light of the above, it must be noted that, by its question, the referring court asks, in essence, to what extent, under Articles 18 and 42 of Directive 2014/24, and according to the principles of equal treatment and proportionality, a contracting authority must attach importance to the individual characteristics of the devices or to the result of the functioning of those devices when establishing technical specifications in a procurement procedure regarding the acquisition of medical supplies.
- 22 As a preliminary point, the European Commission wonders whether that question is admissible in the light of the fact that the tender procedure, which was the object of the dispute in the main proceedings, was terminated, so that the question is rendered hypothetical.
- 23 In that regard, it is necessary to state that in accordance with the settled case-law of the Court, in proceedings under Article 267 TFEU, it is solely for the national court before which the dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine, in the light of the particular circumstances of the case, both the need for a preliminary ruling and the relevance of the questions which it submits to the Court. Consequently, where the questions referred by national courts concern the interpretation of a provision of European Union law, the Court is, in principle, bound to give a ruling. In the context of the procedure for cooperation between the Court of Justice and national courts that is established by Article 267 TFEU, questions concerning EU law enjoy a presumption of relevance. The Court may refuse to give a ruling on a question referred by a national court under Article 267 TFEU only where, for instance, the requirements concerning the content of a request for a preliminary ruling set out in Article 94 of the Rules of Procedure of the Court of Justice are not satisfied, or where it is quite obvious that the interpretation of a provision on EU law, or the assessment of its validity, which is sought by the national court, bears no relation to the actual facts of the main action or to its purpose, or where the problem is hypothetical (judgment of 25 July 2018, *Confédération paysanne and Others*, [C-528/16](#), [EU:C:2018:583](#), paragraphs 72 and 73, and the case-law cited).
- 24 In the present case, the referring court provided in its request for a preliminary ruling several grounds indicating the reasons why, despite the termination of the procurement procedure, there remains, according to national law, a legal interest in the resolution of the dispute. In those circumstances, it should be declared that the question referred is not of hypothetical nature and must, consequently, be considered admissible.
- 25 On the substance, in accordance with Article 42(1) of Directive 2014/24, the technical specifications defined in paragraph 1 of Annex VII to that directive are set out in the

- procurement documents, and lay down the required characteristics of the works, services or supplies.
- 26 Under Article 42(3) of that directive, the technical specifications can be formulated in several ways, either in terms of performance or functional requirements, or by reference to technical specifications, and, in order of preference, to national standards transposing European standards, European Technical Assessments, common technical specifications, international standards, other technical reference systems established by the European standardisation bodies or — when any of those do not exist — national standards, national technical approvals or national technical specifications relating to the design, calculation and execution of the works and use of the supplies, or a combination of both ways.
- 27 In this regard, it should be noted that Article 42(3), which provides that the technical specifications shall be formulated in terms of performance or functional requirements that are sufficiently precise or by reference to technical specifications and to various standards, does not exclude the specification, in a procurement procedure regarding medical supplies intended to carry out medical examinations, of the individual operational and use-related characteristics of the materials.
- 28 Furthermore, the wording of Article 42(3) of Directive 2014/24 does not establish a hierarchy among the methods of formulation of technical specifications and does not prioritise either of those methods.
- 29 Moreover, it appears from that provision that the Union legislation relating to technical specifications allows broad discretion for the contracting authority in the formulation of the technical specifications of a procurement contract.
- 30 That margin of appreciation is justified by the fact that the contracting authorities are better placed to know which supplies they need and to determine the requirements necessary to achieve the desired results.
- 31 Nonetheless, Directive 2014/24 sets certain limits that the contracting authority must comply with.
- 32 In particular, Article 42(2) of Directive 2014/24 requires that the technical specifications afford equal access of economic operators to the procurement procedure and do not have the effect of creating unjustified obstacles to the opening up of public procurement to competition.
- 33 That requirement implements the principle of equality of treatment set out in the first subparagraph of Article 18(1) of that directive for the purpose of the formulation of technical specifications. According to this provision, contracting authorities are to treat economic operators equally and without discrimination and are to act in a transparent and proportionate manner.
- 34 As the Court has previously held, the principles of equality of treatment, non-discrimination and transparency are of crucial importance so far as concerns technical specifications, in the light of the risks of discrimination related either to the choice of specifications or their formulation (see, as regards Directive 2004/18, judgment of 10 May 2012, *Commission v Netherlands*, [C-368/10](#), [EU:C:2012:284](#), paragraph 62).
- 35 It is, in addition, stated in the second subparagraph of Article 18(1) of Directive 2014/24 that the design of a procurement is not to be made with the intention of excluding it from the scope of that directive or of artificially narrowing competition, and that competition is to be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators.
- 36 Similarly, recital 74 of Directive 2014/24 specifies that technical specifications should be ‘drafted in such a way as to avoid artificially narrowing down competition through requirements that favour a specific economic operator by mirroring key characteristics of the supplies, services or works habitually offered by that economic operator’. Also according to that recital, ‘it should be possible to submit tenders that reflect the diversity of technical solutions standards and technical specifications in the marketplace’.

- 37 Complying with those requirements is all the more important when, as in the present case, the technical specifications listed in the procurement documents are formulated in a particularly detailed manner. Indeed, the more detailed the technical specifications, the higher the risk of favouring the products of a given manufacturer will be.
- 38 As follows from Article 42(4) of Directive 2014/24, it is possible, on an exceptional basis and where a sufficiently precise and intelligible description of the subject matter pursuant to Article 42(3) of that directive is not possible, to refer to a specific make or source, or a particular process, which characterises the products of services provided by a specific economic operator, or to trade marks or patents, to the extent that it is justified by the subject matter and that the conditions laid out in Directive 2014/24 are complied with, in particular that such reference is accompanied, in the contract documents, by the words ‘or equivalent’. Nonetheless, since that provision constitutes a derogation, the conditions in which the contracting authority may make use of such a possibility must be strictly interpreted.
- 39 According to previous case-law on public supply contracts, the failure to add the words ‘or equivalent’ after the designation, in the contract documents, of a particular product, may not only deter economic operators using systems similar to that product from taking part in the procurement procedure, but may also impede the flow of imports in intra-Union trade, by reserving the contract exclusively to suppliers intending to use the product specifically indicated (see, to that effect, order of 3 December 2001, *Vestergaard*, [C-59/00](#), [EU:C:2001:654](#), paragraph 22 and the case-law cited).
- 40 In the light of the above factors, it is for the referring court to determine if, taking into account the contracting authority’s margin of appreciation in laying down the technical specifications according to the qualitative requirements related to the subject matter of the procurement contract at issue, the particularly detailed character of the technical specifications at issue does not indirectly favour a tenderer.
- 41 It is also necessary that the level of detail of the technical specifications complies with the principle of proportionality, which implies, in particular, an examination of the question establishing whether that level of detail is necessary to achieve the desired objectives.
- 42 That being said, it should be noted that the principle of proportionality is applied in a particular manner in the sensitive area of public health. The Court has consistently held that, in order to assess whether a Member State has observed the principle of proportionality in the area of public health, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty FEU and that it is for the Member States to determine the degree of protection which they wish to afford to public health and the way in which that degree of protection is to be achieved. Since that level may vary from one Member State to another, Member States should be allowed a measure of discretion (see judgment of 8 June 2017, *Medisanus*, [C-296/15](#), [EU:C:2017:431](#), paragraph 82 and the case-law cited).
- 43 It should also be noted in this context that, as recalled in paragraph 11 of the recommendations to national courts and tribunals in relation to the initiation of preliminary ruling proceedings ([OJ 2018 C 257](#), p. 1) although, in order to deliver its decision, the Court necessarily takes into account the legal and factual context of the dispute in the main proceedings, as defined by the referring court or tribunal in its request for a preliminary ruling, it does not itself apply EU law to that dispute. When ruling on the interpretation or validity of EU law, the Court makes every effort to give a reply which will be of assistance in resolving the dispute in the main proceedings, but it is for the referring court or tribunal to draw concrete conclusions. For those reasons, the interpretation provided by the Court is usually expressed *in abstracto*.
- 44 Here, it is for the referring court, in the light of the elements of interpretation stated above, to concretely assess the conformity of the technical specifications at issue in the main proceedings with the principles of equality of treatment and proportionality.
- 45 In the light of all the foregoing considerations, the answer to the question referred is that Articles 18 and 42 of Directive 2014/24 must be interpreted as not imposing on the

contracting authority, in establishing technical specifications in a procurement procedure concerning the acquisition of medical supplies, by principle, prioritising either the importance of the individual characteristics of the medical supplies or the importance of the result of their functioning, but requiring that the technical specifications, as a whole, comply with the principles of equality of treatment and proportionality. It is for the national court to assess whether, in the dispute before it, the technical specifications at issue comply with those requirements.

Costs

- 46 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 (Ninth Chamber) hereby rules:

Articles 18 and 42 of Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC must be interpreted as not imposing on the contracting authority, in establishing technical specifications in a procurement procedure concerning the acquisition of medical supplies, by principle, prioritising either the importance of the individual characteristics of the medical supplies or the importance of the result of their functioning, but requiring that the technical specifications, as a whole, comply with the principles of equality of treatment and proportionality. It is for the national court to assess whether, in the dispute before it, the technical specifications at issue comply with those requirements.

[Signatures]

(^{*1}) Language of the case: Lithuanian.
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