Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

8 June 2017*

(Reference for a preliminary ruling — Public procurement — Medicinal products for human use — Directive 2004/18/EC — Article 2 and Article 23(2) and (8) — Articles 34 and 36 TFEU — Public contract for supplying a hospital — National legislation requiring that hospitals are to be supplied as a matter of priority with medicinal products obtained from national plasma — Principle of equal treatment)

In Case C-296/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal, Slovenia), made by decision of 14 May 2015, received at the Court on 18 June 2015, in the proceedings

Medisanus d.o.o.

v

Splošna Bolnišnica Murska Sobota

THE COURT (Third Chamber),

composed of L. Bay Larsen, President of the Chamber, M. Vilaras, J. Malenovský, M. Safjan and D. Šváby (Rapporteur), Judges,

Advocate General: H. Saugmandsgaard Øe,

Registrar: I. Illéssy, Administrator,

having regard to the written procedure and further to the hearing on 22 September 2016,

after considering the observations submitted on behalf of:

— Medisanus d.o.o., by A. Godec, odvetnik, G. Backmann and M. Žlebnik,

— the Slovenian Government, by A. Grum, acting as Agent,

— the Spanish Government, by A. Gavela Llopis, acting as Agent,

— the European Commission, by G. Braga da Cruz, A. Sipos and B. Rous Demiri, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 1 December 2016,

* Language of the case: Slovenian.

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 2 and Article 23(2) and (8) 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, OJ 2004 L 351, p. 44), read in conjunction with Article 83 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) as amended by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 (OJ 2003 L 33, p. 30) ('Directive 2001/83'), with Article 4(2) of Directive 2002/98 and with Article 18 TFEU.

2 The request has been made in proceedings between Medisanus d.o.o. and Splošna Bolnišnica Murska Sobota (Murska Sobota General Hospital, Slovenia) ('the hospital') concerning the legality of a clause in the tender specifications relating to a public procurement procedure launched by that hospital for the supply of medicinal products.

Legal context

EU law

Directive 2004/18

3 Directive 2004/18, which applies *ratione temporis* to the dispute in the main proceedings, was repealed as from 18 April 2016 by Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement (OJ 2014 L 94, p. 65). Article 1(2)(a) of Directive 2004/18 defined public contracts as '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'.

4 Article 2 of the directive, headed 'Principles of awarding contracts', provided that contracting authorities were to treat economic operators equally and non-discriminatorily and act in a transparent way.

5 Under Article 23 of the directive:

'…

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

…

8. Unless justified by the subject matter of the contract, technical specifications shall not refer to a specific make or source, or a particular process, 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 paragraphs 3 and 4 is not possible; such reference shall be accompanied by the words "or equivalent".'

6 The meaning of 'technical specification' was defined in paragraph 1 of Annex VI to the directive. With regard in particular to public supply and public service contracts, paragraph 1(b) of that annex defined such a specification as one set out 'in a document defining the required characteristics of a product or a service, such as quality levels, environmental 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 and conformity assessment procedures'.

Rules of EU law concerning human blood

7 According to recitals 2, 4, 23 and 32 of Directive 2002/98, which governs various operations in relation to human blood:

'(2) The availability of blood and blood components used for therapeutic purposes is dependent largely on Community citizens who are prepared to donate. …

…

(4) ... Furthermore, Member States should take measures to promote Community self-sufficiency in human blood or blood components and to encourage voluntary unpaid donations of blood and blood components.

…

(23) Voluntary and unpaid blood donations are a factor which can contribute to high safety standards for blood and blood components and therefore to the protection of human health. The efforts of the Council of Europe in this area should be supported and all necessary measures should be taken to encourage voluntary and unpaid donations through appropriate measures and initiatives and through ensuring that donors gain greater public recognition, thereby also increasing self-sufficiency. …

…

(32) ... The objectives of this directive, namely to contribute to general confidence both in the quality of donated blood and blood components and in the health protection of donors, to attain self-sufficiency at a Community level and to enhance confidence in the safety of the transfusion chain among the Member States ...'

8 Article 2(1) of Directive 2002/98 defines the scope of that directive as follows:

'This Directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion.'

9 Article 4(2) of the directive provides as follows:

‘This directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary and unpaid donations, which include the prohibition or restriction of imports of blood and blood components, to ensure a high level of health protection and to achieve the objective set out in Article 20(1), provided that the conditions of the Treaty are met.’

10 Under Article 20(1) of the directive:

‘Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.’

11 Recital 19 of Directive 2001/83, a directive which concerns, essentially, industrially manufactured medicinal products for human use, states:

‘The Community entirely supports the efforts of the Council of Europe to promote voluntary unpaid blood and plasma donation to attain self-sufficiency throughout the Community in the supply of blood products, and to ensure respect for ethical principles in trade in therapeutic substances of human origin.’

12 Article 1 of that directive contains, inter alia, the following definitions:

‘10. Medicinal products derived from human blood or human plasma:

Medicinal products based on blood constituents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin;

…

17. Wholesale distribution of medicinal products:

All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned;

…’

13 Article 83 of Directive 2001/83, which is part of Title VII on the wholesale distribution and brokering of medicinal products, provides:

‘The provisions of this Title shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:

…

— medicinal products derived from blood,

…’

14 In Title X of Directive 2001/83, which concerns specific provisions on medicinal products derived from human blood and human plasma, Article 109 provides:

'For the collection and testing of human blood and human plasma, Directive [2002/98] shall apply.'

15 Under Article 110 of Directive 2001/83:

'Member States shall take the necessary measures to promote Community self-sufficiency in human blood or human plasma. For this purpose, they shall encourage the voluntary unpaid donation of blood and plasma and shall take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations. They shall notify the Commission of such measures.'

Slovenian law

Law on medicinal products

16 Concerning the definition of the principle of priority supply of medicinal products manufactured industrially from plasma collected in Slovenia, Article 6(71) of the Zakon o zdravilih (Law on medicinal products) (Uradni list RS, No 17/14) provides:

'The priority supply of medicinal products industrially manufactured from Slovenian plasma (that is to say, from frozen fresh plasma for processing, collected in the Republic of Slovenia) constitutes a principle whereby medicinal products obtained from foreign plasma which originate in the European Union are to be supplied on the basis of a marketing authorisation, in the event that medicinal products prepared from Slovenian plasma fail to cover the total demand for such products in the Republic of Slovenia, except where the introduction or importation of a specific medicinal product obtained from foreign plasma is justified on scientific or strategic grounds, as defined by the Strateški svet za zdravila [(Strategic Council for pharmaceutical products, Slovenia)] and by the Strokovni svet za preskrbo s krvjo in z zdravili iz plazme [(Scientific Council for the supply of blood and medicinal products obtained from plasma, Slovenia)].'

17 Article 6(106) of the Law on medicinal products defines 'medicinal products obtained from blood or plasma' as follows:

'Medicinal products obtained from blood or plasma are industrially manufactured medicinal products, such as, for example, medicinal products containing, in particular, albumin … and immunoglobulin of human origin, which are manufactured by specialist operators using blood components collected in accordance with the rules governing the supply of blood and blood products and the rules governing medicinal products.'

18 Article 11(6) of the Law on medicinal products defines the scope of that law as follows:

'The provisions of the present law shall not apply to … blood, plasma or blood cells which are subject to the legislation on the supply of blood, with the exception of plasma which is prepared using a method involving an industrial process and used in the manufacture of medicinal products.'

The Law on the supply of blood

19 Article 2 of the Zakon o preskrbi s krvjo (Law on the supply of blood) (Uradni list RS, No 104/06) provides as follows:

‘1. The supply of blood under this Law forms part of transfusion activities, which include planning, collection, processing, testing, storage, distribution and medical treatment as well as the regular and sufficient supply of blood and blood products to the population and the marketing of such products.

2. The activities referred to in the previous paragraph shall be carried out in accordance with the principles of national self-sufficiency and of voluntary unpaid blood donation, in order to guarantee a sufficient number of donors and the safety of blood transfusions.

…’

20 In Article 3(11), (12), (13), (18) and (27) of that law, the following terms are defined as follows:

— ‘blood’ is defined as ‘whole human blood’;

— ‘blood component’ is defined as ‘an active component of blood (... plasma), which may be prepared from blood by various methods’;

— ‘blood product’ is defined as ‘any therapeutic product (component or agent) which is derived from human blood or human plasma’;

— ‘self-sufficiency’ is defined as ‘the principle relating to the supply of blood and blood products under which the State is to meet its demand for blood and blood products using its own resources’; and

— ‘blood-based medicinal product’ is defined as ‘any medicinal product obtained from human blood or human plasma’.

21 Article 5(1) of that law, which concerns, in particular, blood collection, provides:

‘The activity of collecting and testing blood and blood components, whatever their intended purpose, and their processing, storage and distribution, when intended for transfusion, shall constitute a public service. The service shall be performed by the institute of transfusion or by the transfusion centre designated and licensed by the Agency.’

22 Article 10(1) and (2) of that law determines the function of the Zavod Republike Slovenije za transfuzisko medecino (Institute of Transfusion Medicine of the Republic of Slovenia) (‘the Institute’) in the following terms:

‘1. The [Institute] is … responsible at national level for the supply of blood and blood products to professional bodies, and for the integration of transfusion medicine in hospital practice.

2. The [Institute] shall coordinate all activities concerning donor selection, the collection, testing, processing, storage and distribution of blood and blood products, the clinical use of blood …’

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

23 By decision of 14 January 2015, the hospital launched a public procurement procedure for the purchase of two types of medicinal products derived from plasma, namely human albumin, 200 mg/ml infusion solution, and human immunoglobulin for intravenous administration, 50 mg/ml or 100 mg/ml.

24 It was specified in the tender specifications that the medicinal products that were the subject matter of the contract were to be 'obtained from Slovenian plasma'. On enquiry from an economic operator, that requirement was justified by reference to the principle that supplies must come as a matter of priority from medicinal products manufactured industrially from plasma collected in Slovenia, as set out in Article 6(71) of the Law on medicinal products.

25 Disputing that national origin requirement for medicinal products derived from plasma, Medisanus requested the hospital to withdraw the requirement and amend the tender specifications accordingly. Indeed, since the Institute enjoys a monopoly for blood collection in Slovenia, by definition it is the only body that is able to supply medicinal products obtained from plasma collected in Slovenia and thus satisfy the national origin requirement for the plasma as prescribed in the tender specifications. However, according to Medisanus, such a requirement infringes EU law.

26 The hospital rejected Medisanus's request on the ground that the requirements stemmed from national legislation, that they were justified from a scientific point of view and that, in addition, they were consistent with an objective of EU self-sufficiency set out in Article 110 of Directive 2001/83. The contracting authority also pointed out that medicinal products derived from Slovenian plasma failed to meet the total demand of the Slovenian population for medicinal products derived from plasma. Part of that demand would therefore be covered by a call for tenders relating to the purchase of medicinal products obtained from blood originating in various Member States.

27 Medisanus then challenged the decision to reject its request before the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal, Slovenia).

28 That body is a special national authority governed by the Zakon o pravnem varstvu v postopkih javnega naročanja (Law on appeals in public procurement procedures) (Uradni list RS, No 43/11), with exclusive jurisdiction to rule on the legality of decisions adopted by contracting authorities in the context of public procurement procedures.

29 In the context of the application for review pending before it, the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal) has doubts whether the Slovenian origin requirement for the plasma used to manufacture the medicinal products covered by the public procurement at issue in the main proceedings is compatible with Articles 2 and 23 of Directive 2004/18, in so far as that requirement might infringe the principle of equal treatment and respect for competition between economic operators.

30 The referring tribunal observes, however, that that requirement is based on Slovenian law. In the first place, Article 6(71) of the Law on medicinal products requires that supplies must come as a matter of priority from medicinal products manufactured industrially from plasma collected in Slovenia. In the second place, the Law on the supply of blood lays down the principle of self-sufficiency, pursuant to which the Republic of Slovenia has decided to meet its demand for blood and medicinal preparations obtained from human blood and plasma by using its own resources. In the third place, that law entrusts the Institute with carrying out the public service relating to the activity of collecting and testing blood and blood components, whatever their intended purpose, and to their processing, storage and distribution, when intended for transfusion.

31 In that context, the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal) decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Must Directive [2004/18], in particular Article 23(2), Article 23(8) and Article 2 thereof, read in conjunction with

— Directive [2001/83], in particular Article 83 thereof;

— Directive [2002/98], in particular Article 4(2) thereof; and

— the FEU Treaty, in particular Article 18 thereof,

be interpreted as precluding a specification that industrially manufactured medicinal products must be obtained from "Slovenian plasma" (a requirement based on the domestic legislation ...)?'

Consideration of the question referred

Admissibility

32 At the outset, consideration should be given to whether the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal) meets the criteria for being regarded as a 'national court or tribunal' for the purposes of Article 267 TFEU.

33 Whether a body making a reference is a 'court or tribunal' within the meaning of Article 267 TFEU depends on a number of factors, such as whether the body is established by law, whether it is permanent, whether its jurisdiction is compulsory, whether its procedure is *inter partes*, whether it applies rules of law and whether it is independent (see, to that effect, judgment of 6 October 2015, *Consorci Sanitari del Maresme*, C-203/14, EU:C:2015:664, paragraph 17 and the case-law cited).

34 In the present case, on the basis of the information provided by the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal) in the annex to the order for reference, it is clear that that body has no connection with the public authorities whose decisions it reviews. Furthermore, its members enjoy the safeguards laid down in the Zakon o sodniški službi (Law on the duties of a judge) concerning their appointment, their term of office and the grounds for removal from office, so that their independence is guaranteed.

35 Moreover, the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal) is provided for by the Law on appeals in public procurement procedures, which makes it permanent and its jurisdiction mandatory.

36 Also, not only does that body rule on the basis of that law, but it also applies the *Zakon o pravdnem postopku* (Law on Civil Procedure) and its own rules of procedure, which were published in the *Uradni list Republike Slovenije* (*Official Gazette of the Republic of Slovenia*). In addition, referrals to that body are made by appeals and its decisions have the force of *res judicata*.

37 Lastly, the parties and, as the case may be, the tenderer whose bid is accepted are entitled to present their views in the course of the proceedings and to comment on the evidence and arguments presented by the other parties and by the representative of the public interest. The procedure before the referring body is therefore *inter partes*.

38 It follows that the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (State Public Procurement Tribunal) meets the criteria for being regarded as a 'national court or tribunal' for the purposes of Article 267 TFEU and that the question referred by it to the Court is admissible.

Substance

Preliminary observations

39 The purpose of the question referred is, in essence, to determine whether the requirement to manufacture medicinal products from plasma collected in Slovenia is compatible, first, with Article 2 and Article 23(2) and (8) of Directive 2004/18, read in conjunction with Article 83 of Directive 2001/83 and Article 4(2) of Directive 2002/98 and, secondly, with Article 18 TFEU.

40 It is apparent from the order for reference that, with regard to medicinal products manufactured industrially from human plasma, the Slovenian legislature established a system based on the following elements.

41 In the first place, Article 3(18) of the Law on the supply of blood lays down a principle of self-sufficiency in human blood and in components and medicinal products obtained from human blood or human plasma, under which the Slovenian State is to meet by using its own resources the demand for blood, and for medicinal products obtained from blood or plasma, of patients being treated in its territory ('the national self-sufficiency principle').

42 Under Article 2 of that law, the national self-sufficiency principle must be observed in all transfusion activities, namely, inter alia, the collection, processing, distribution and supply to the population of blood and of components or medicinal products obtained from blood and plasma as well as the marketing of such components and medicinal products.

43 Article 2 of that law also lays down the principle of voluntary unpaid blood donation. It states that the combined application of the national self-sufficiency principle and the principle of voluntary unpaid donation is aimed at guaranteeing both a sufficient number of donors and the safety of blood transfusions.

44 In the second place, Article 10 of the Law on the supply of blood provides that the Institute, a public body, is, inter alia, responsible at national level for the supply of blood and of components and medicinal products obtained from blood and plasma. It also coordinates activities concerning, inter alia, the collection, processing and distribution of such components and medicinal products.

45 In the third place, Article 6(71) of the Law on medicinal products lays down the principle that supplies must come as a matter of priority from medicinal products manufactured industrially from plasma collected in Slovenia ('Slovenian plasma'). Accordingly, the marketing of medicinal products derived from plasma collected outside Slovenia is authorised, as a matter of principle, only in the event that the medicinal products derived from Slovenian plasma do not meet the total demand ('the priority supply principle').

46 Therefore, it follows from that principle that the demand of Slovenian hospitals for medicinal products derived from plasma is to be met as a matter of priority by medicinal products obtained from Slovenian plasma ('the national origin requirement') and, where medicinal products of Slovenian origin are not sufficient, if necessary by using medicinal products obtained from plasma collected in other Member States.

47 In practice, the Institute allocates the quantities of Slovenian plasma that are not used for transfusion purposes to the manufacture of medicinal products. To this end, the Institute organises procedures for public service contracts with a view to selecting the economic operator that will undertake the manufacturing process, while the Institute will continue to own the plasma and become the owner of the medicinal products obtained from that plasma. The Institute then supplies those medicinal products to hospitals against payment of an amount equivalent to their production costs.

48 In addition, in order to meet the demand for medicinal products obtained from plasma that is not satisfied by the medicinal products derived from Slovenian plasma, the Institute, jointly with Slovenian hospitals, organises procedures for public supply contracts.

49 It is in that context that the public procurement procedure at issue in the main proceedings takes place, by which the hospital seeks to purchase medicinal products obtained from plasma that, under the priority supply principle, must be of Slovenian origin and for which the Institute is the only possible supplier.

The categorisation of human blood and components thereof

50 Both in its written observations and at the hearing the Slovenian Government relied on Article 168(7) TFEU to argue that human blood and components thereof are 'resources' and not goods for the purpose of Article 34 TFEU.

51 Under Article 168(7) TFEU, admittedly, the allocation of resources is included in the Member States' responsibilities regarding the definition of their health policy, as are the organisation and delivery of health services and medical care.

52 However, the wording of Article 168(7) TFEU provides no ground for inferring that the drafters of the Treaties intended the generic term 'resources' to specifically cover blood or components thereof.

53 In addition, nothing precludes medicinal products derived from human blood or human plasma from coming under the definition of 'goods' for the purposes of the provisions of the FEU Treaty on the free movement of goods, given the particularly broad interpretation of that term in the Court's case-law on, inter alia, medicinal products and blood and blood components (see, to that effect, judgments of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraphs 27 to 32, and of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraphs 27 and 30). It follows that medicinal products derived from human blood or human plasma are 'goods' for the purpose of Article 34 TFEU.

54 Moreover, as the Advocate General has pointed out in points 62 to 66 of his Opinion, the medicinal products at issue in the main proceedings are 'products' within the meaning of Article 1(2)(a) and (c) of Directive 2004/18 that can be valued in money and thus be the subject of commercial transactions.

The applicable provisions

55 It should be recalled that a question referred for a preliminary ruling must be examined in the light of all the provisions of the Treaties and of secondary legislation which may be relevant to the issue raised (see, to that effect, judgment of 11 July 1985, *Mutsch*, 137/84, EU:C:1985:335, paragraph 10). The fact that a national court's question refers to certain provisions of EU law does not mean therefore that the Court of Justice may not provide the national court with all the guidance on points of interpretation that may be of assistance in adjudicating on the case pending before it, whether or not that court has referred to those points in its question (see, to that effect, judgment of 12 December 1990, *SARPP*, C-241/89, EU:C:1990:459, paragraph 8).

56 With regard to the provisions of EU law that the referring tribunal has asked the Court of Justice to interpret, consideration should be given, as a preliminary point, to whether Article 83 of Directive 2001/83, Article 4(2) of Directive 2002/98 and Article 18 TFEU apply to a situation such as that at issue in the main proceedings.

57 In the first place, Article 83 of Directive 2001/83 authorises Member States to apply more stringent requirements in respect of the wholesale distribution of medicinal products derived from blood than those which govern, on the one hand, the wholesale distribution of other medicinal products and, on the other hand, other distribution methods for medicinal products not covered by that provision.

58 'Wholesale distribution of medicinal products' is defined in Article 1(17) of Directive 2001/83 as 'all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned'.

59 The substance of the hospital's activities is clearly different. It follows that Article 83 of Directive 2001/83 does not apply in circumstances such as those of the dispute in the main proceedings.

60 In the second place, under Article 4(2) of Directive 2002/98 a Member States may prohibit or restrict imports of blood and blood components with a view to encouraging the voluntary unpaid donation of blood and blood components.

61 In that respect, the Court notes that Article 2(1) of Directive 2002/98 governs the distribution of human blood and blood components only 'when intended for transfusion'. Since medicinal products derived from plasma have a different purpose, Article 4(2) of Directive 2002/98 does not apply in circumstances such as those of the dispute in the main proceedings.

62 In the third place, and as the Advocate General has explained in points 37 and 38 of his Opinion, it should be borne in mind that Article 18 TFEU is to apply independently only to situations governed by EU law in regard to which the Treaty lays down no specific prohibition of discrimination (see, inter alia, to that effect, judgments of 21 June 1974, *Reyners*, 2/74, EU:C:1974:68, paragraphs 15 and 16; of 30 May 1989, *Commission* v *Greece*, 305/87, EU:C:1989:218, paragraphs 12 and 13; and of 18 December 2014, *Generali-Providencia Biztosító*, C-470/13, EU:C:2014:2469, paragraph 31).

63 In the circumstances of the main proceedings and to the extent that the free movement of goods is concerned, the Court finds that the national origin requirement falls within the scope of Article 34 TFEU, which prohibits obstacles to the free movement of goods.

64 In that regard, it must be borne in mind that the Court has consistently held that the prohibition, laid down in Article 34 TFEU, of measures having equivalent effect to quantitative restrictions covers any measure of the Member States that is capable of hindering, directly or indirectly, actually or potentially, imports between Member States (judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 22 and the case-law cited).

65 Read in conjunction with Article 36 TFEU, Article 34 thereof prohibits, inter alia, all discriminatory obstacles to the free movement of goods and thus provides for a specific prohibition of discrimination as against Article 18 TFEU.

66 It follows that, in circumstances such as those at issue in the main proceedings, Article 83 of Directive 2001/83, Article 4(2) of Directive 2002/98 and Article 18 TFEU do not apply to the main proceedings.

Whether a national origin requirement for medicinal products derived from plasma such as the requirement at issue in the main proceedings is compatible with Articles 2 and 23 of Directive 2004/18 and Article 34 TFEU

67 In the light of the above, the question referred should be understood as seeking to ascertain whether Article 2 and Article 23(2) and (8) of Directive 2004/18, and Article 34 TFEU read in conjunction with Article 36 TFEU, must be interpreted as precluding a clause in the tender specifications for a public contract which, in accordance with the law of the Member State to which the contracting authority belongs, requires medicinal products derived from plasma, which are the subject matter of the public contract at issue, to be manufactured from plasma collected in that Member State.

68 In the present case, clearly, the national origin requirement is inherently discriminatory. Indeed, the requirement that supplies must be obtained as a matter of priority from medicinal products derived from Slovenian plasma precludes any undertaking with medicinal products derived from plasma collected in another Member State of the European Union from tendering effectively in response to calls for tenders such as that issued by the hospital.

69 In that respect, the Court notes, as the Advocate General has observed in point 94 of his Opinion, that Directive 2004/18 does not bring about exhaustive harmonisation of the aspects relating to the free movement of goods. That finding follows in particular from the wording of Article 23(8) of the directive, in that it accepts that technical specifications may be justified by the subject matter of the contract.

70 Moreover, on the one hand, the contracting authority in the main proceedings is subject to the requirements for the award of public contracts, namely those under Article 2 and Article 23(2) and (8) of Directive 2004/18; on the other hand, it must bear in mind Article 110 of Directive 2001/83, pursuant to which Member States are to take the necessary measures to promote EU self-sufficiency in human blood and human plasma. The latter provision states that, for this purpose, the Member States are to encourage the voluntary unpaid donation of blood and plasma and take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations.

71 With regard to the Member States' powers and responsibilities under Article 168(7) TFEU in respect, inter alia, of blood donations, in the field of health policy, of the management of health services and medical care and of the allocation of the resources assigned to them, it must be noted that in exercising those powers, especially in the context of public procurement, Member States must comply with EU law, in particular the provisions on the free movement of goods (see, to that effect, judgment of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraphs 22 to 25 and the case-law cited).

72 It follows that, with regard to both the discriminatory obstacles to the free movement of goods and the grounds for their justification, examination of the national origin requirement at issue in the main proceedings, according to which medicinal products derived from plasma must be obtained from plasma collected in Slovenia, cannot be limited to an assessment under Directive 2004/18; it must also take the provisions of primary law into account.

73 With regard to Directive 2004/18, the finding in paragraph 68 of the present judgment is sufficient to establish non-compliance with Article 2 of the directive, which requires that the contracting authority is, inter alia, to treat economic operators equally and non-discriminatorily.

74 It should be noted, moreover, that under Article 23(2) of Directive 2004/18 technical specifications that are set out in the public contract documentation should afford equal access for tenderers and not have the effect of creating unjustified obstacles to the opening up of public procurement to competition.

75 It is apparent, however, that the conditions laid down in Article 23(8) of Directive 2004/18 are not satisfied in circumstances such as those at issue in the main proceedings.

76 It is clear from the wording of Article 23(8) of Directive 2004/18 that a technical specification may not refer to a specific source unless this is justified by the subject matter of the public contract, and that this is permitted on an exceptional basis only. In any event, any reference to a technical specification, such as a specific source or origin, must be accompanied by the words 'or equivalent' (see, to that effect, judgment of 22 September 1988, *Commission* v *Ireland*, 45/87, EU:C:1988:435, paragraph 22).

77 With regard to the main proceedings, by not adding the words 'or equivalent' after imposing the national origin requirement, the hospital may not only have deterred economic operators with analogous medicinal products from taking part in the tendering procedure, but also have impeded the flow of imports in trade between Member States by reserving the contract for medicinal products derived from Slovenian plasma exclusively to the Institute. In so doing, the hospital has failed to comply with Article 2 of Directive 2004/18, Article 23(2) and (8) thereof and Article 34 TFEU (see, by analogy, judgment of 24 January 1995, *Commission* v *Netherlands*, C-359/93, EU:C:1995:14, paragraph 27).

The justification for the obstacle to the free movement of goods

78 In order to determine whether a clause in the tender specifications for a public contract that imposes a national origin requirement for medicinal products derived from plasma, such as that at issue in the main proceedings, constitutes a restriction that is prohibited under Article 34 TFEU, the Court must examine whether it can be justified on grounds of public health protection, as the Slovenian Government and the Commission in particular have submitted (see, by analogy, judgment of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 31).

79 As a preliminary point, the Court notes that in the main proceedings the contracting authority is subject to two potentially conflicting requirements, as mentioned in paragraph 70 of the present judgment. Indeed, the contracting authority must comply with Article 6 of the Law on medicinal products, which lays down the principles of priority supply and national self-sufficiency, the latter stemming from Article 2 of the Law on the supply of blood. At the same time, the contracting authority must, pursuant to Article 2 of Directive 2004/18, afford equal access to public procurement and, accordingly, ensure non-discriminatory treatment of economic operators that have medicinal products derived from plasma.

80 In the present case, since the national origin requirement is discriminatory, as established in paragraph 68 of the present judgment, the Slovenian legislation can be justified only on one of the grounds listed in Article 36 TFEU (see, inter alia, by analogy, judgments of 17 June 1981, *Commission* v *Ireland*, 113/80, EU:C:1981:139, paragraphs 7, 8, 10 and 11, and of 30 November 1995, *Gebhard*, C-55/94, EU:C:1995:411, paragraph 37).

81 In that regard, the Slovenian Government takes the view that the system for the collection of human blood and human plasma at issue in the main proceedings is justified on grounds of public health.

82 The Court has consistently held that, in order to assess whether a Member State has observed the principle of proportionality in the field 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 FEU Treaty 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 the degree of protection may vary from one Member State to another, Member States must be allowed a measure of discretion (see, inter alia, judgments of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 51; of 19 May 2009, *Apothekerkammer des Saarlandes and Others*,

C-171/07 and C-172/07, EU:C:2009:316, paragraph 19; of 21 June 2012, *Susisalo and Others*, C-84/11, EU:C:2012:374, paragraph 28; of 5 December 2013, *Venturini and Others*, C-159/12 to C-161/12, EU:C:2013:791, paragraph 59; and of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 30).

83 However, it is apparent also from the Court's case-law that legislation that is capable of restricting a fundamental freedom guaranteed by the FEU Treaty, such as the free movement of goods, can be properly justified only if it is appropriate for securing the attainment of the legitimate objective pursued and does not go beyond what is necessary in order to attain it (see, to that effect, in the context of human health, judgments of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 48, and of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 34).

84 As a first step, it is therefore necessary to examine whether the national origin requirement at issue in the main proceedings pursues a legitimate objective.

85 According to the Slovenian Government, the national origin requirement is intended (a) to encourage voluntary unpaid blood donations and (b) to ensure observance of the principle of national self-sufficiency. The Slovenian Government, which underlines the overlapping nature of the two objectives, draws attention to the fact that the strict conditions surrounding voluntary unpaid blood donations have a considerable impact on the quantities of human blood and blood components collected, which has an effect on self-sufficiency in blood supplies and, therefore, on the supply of blood components.

86 The Court notes, as a preliminary point, that the fact that the two objectives put forward by the Slovenian Government overlap follows from the very wording of Article 110 of Directive 2001/83. As provided in that article, 'Member States shall take the necessary measures to promote Community self-sufficiency in human blood or human plasma. For this purpose, they shall encourage the voluntary unpaid donation of blood and plasma ...'.

87 Encouraging voluntary unpaid blood donations is a way of addressing public health concerns such as those referred to in Article 36 TFEU. Therefore, that objective is, in principle, capable of justifying a restriction on the free movement of goods (see, to that effect, judgment of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 33).

88 Since the second objective put forward by the Slovenian Government consists in ensuring compliance with the principle of national self-sufficiency, it is necessary to examine whether national legislation, such as that at issue in the main proceedings, which pursues that objective contributes to the promotion of EU self-sufficiency in human blood and human plasma, referred to in Article 110 of Directive 2001/83.

89 In the first place, since the EU legislature did not set out detailed rules on how to attain EU self-sufficiency in human blood and human plasma, it may be accepted, as the Commission has, that as EU law currently stands EU self-sufficiency is achieved through the pursuit by each Member State of a national objective of self-sufficiency.

90 In the second place, the Court notes that the EU legislature uses various terms to define the scope of EU self-sufficiency. Whereas Article 110 of Directive 2001/83 mentions only human blood and human plasma, Article 20(1) of Directive 2002/98, read in the light of recital 4 thereof, requests Member States to take the necessary measures to encourage voluntary unpaid donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.

91 The scope of the principle of EU self-sufficiency is made even broader in recital 19 of Directive 2001/83, which refers to 'self-sufficiency throughout the Community in the supply of blood products'.

92 Since the intended objective of ensuring EU self-sufficiency in the supply of blood products is to protect public health, its scope must be interpreted broadly.

93 Consequently, national legislation such as that at issue in the main proceedings pursues legitimate objectives of public health protection.

94 As a second step, it is necessary to assess whether such legislation is proportionate in achieving the objective of public health protection.

95 Since Article 36 TFEU is an exception, to be interpreted strictly, to the free movement of goods within the European Union, any national legislation must be necessary to achieve the declared objective and it must not be possible to achieve that objective by prohibitions or restrictions that are less extensive or have less effect on trade within the European Union (see, to that effect, judgment of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 50).

96 In that regard, the material before the Court clearly does not lead to the conclusion that the priority supply principle for medicinal products manufactured industrially from Slovenian plasma collected from Slovenian hospitals contributes decisively to encouraging the Slovenian population to make voluntary unpaid blood donations.

97 It is true that recital 19 and Article 110 of Directive 2001/83 are both in line with the concept of solidarity. Since they are not paid, all blood donors act in the interest of all individuals with whom they share the same interests, by making it possible, together, inter alia, to guard against risks of insufficient quantities of medicinal products derived from blood or plasma. However, the priority supply principle at issue in the main proceedings, in that it excludes economic operators wishing to import into Slovenia medicinal products derived from plasma coming also from voluntary unpaid blood donations, collected in other Member States, is in clear contradiction to that concept underlying the objective of EU self-sufficiency. Accordingly, inasmuch as (a) the blood donors' motivation is the same in other Member States as in Slovenia and (b) all donors in the Member States have objectively concurring interests with regard to the manufacture and use of products derived from human blood and human plasma coming from such voluntary unpaid donations, there is no reason to consider, as the Slovenian Government claims, that conditions based on a purely national concept of solidarity are the only ones liable to have a major impact, in Slovenia, on the quantities of human blood and blood components collected and, thus, on the quantities of blood products derived from such donations.

98 It is not therefore evident that the objective of encouraging and maintaining a high level of voluntary unpaid blood donations necessarily requires recourse to the national origin requirement at issue in the main proceedings. In those circumstances, the Court finds that the priority supply principle is disproportionate.

99 That finding cannot be called into question by the argument that a system of priority supply, such as that described in paragraphs 41 to 48 of the present judgment, may be regarded as the least detrimental solution to the free movement of goods, having regard in particular to the fact that the medicinal products are supplied to hospitals against payment of an amount corresponding exclusively to their production costs.

100 It is true that a system of plasma collection such as that at issue in the main proceedings has been established in a global context characterised by a prolonged and undeniable shortage of quality blood and plasma and by a highly concentrated sector for industrial processing of blood and plasma into medicinal products. Moreover, as the Commission has pointed out in its written observations, that continuing tendency induces the few undertakings working in that field to prefer selling medicinal

products derived from plasma in countries that can pay a higher price or buy them on a larger scale, and smaller States are thus facing a significantly higher price for medicinal products derived from plasma.

101 Admittedly, interests of an economic nature that aim at maintaining a quality hospital service that is safe and accessible to all may come within the derogation on grounds of public health set out in Article 36 TFEU, to the extent that they contribute to the attainment of a high level of health protection (see, to that effect, judgment of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 60).

102 However, a system of priority supply of medicinal products manufactured industrially from Slovenian plasma, such as that at issue in the main proceedings, cannot be considered to be necessary to avoid higher costs for medicinal products derived from plasma, since the price of all medicinal products manufactured industrially from plasma, whether in Slovenia or in another Member State, is set on the same basis, namely voluntary unpaid blood donations.

103 Having regard to all of the foregoing considerations, the Court finds that a restriction such as that stemming from the national legislation at issue in the main proceedings has not been shown to be an appropriate means of attaining the objectives invoked and cannot therefore be regarded as justified by the achievement of those objectives.

104 Consequently, the answer to the question referred is that Article 2 and Article 23(2) and (8) of Directive 2004/18, and Article 34 TFEU read in conjunction with Article 36 TFEU, must be interpreted as precluding a clause in the tender specifications for a public contract which, in accordance with the law of the Member State to which the contracting authority belongs, requires medicinal products derived from plasma, which are the subject matter of the public procurement at issue, to be obtained from plasma collected in that Member State.

Costs

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

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

Article 2 and Article 23(2) and (8) 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, and Article 34 TFEU read in conjunction with Article 36 TFEU, must be interpreted as precluding a clause in the tender specifications for a public contract which, in accordance with the law of the Member State to which the contracting authority belongs, requires medicinal products derived from plasma, which are the subject matter of the public procurement at issue, to be obtained from plasma collected in that Member State.

[Signatures]