OPINION OF ADVOCATE GENERAL
SAUGMANDSGAARD ØE
delivered on 1 December 2016 (1)

Case C-296/15

Medisanus d.o.o.
v
Splošna Bolnišnica Murska Sobota

(Request for a preliminary ruling from the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (National Commission for the review of awards of public procurement procedures, Slovenia))

(Reference for a preliminary ruling — Article 267 TFEU — Status of a 'court or tribunal' — Directive 2004/18/EC — Public procurement — Articles 2 and 23 — Equal treatment and non-discrimination — Directive 2001/83/EC– Medicinal products for human use — Medicinal products derived from industrially prepared plasma — Directive 2002/98/EC — Human blood and blood components — National rules requiring supplies to be obtained as a matter of priority from medicinal products manufactured on the basis of plasma collected in the territory of the Member State concerned — Article 34 TFEU — Free movement of goods — Discrimination between imports — Article 36 TFEU — Justification — Promotion of blood donations — National self-sufficiency — Autarky)

I – Introduction

1. By decision of 14 May 2015, received at the Court on 18 June 2015, the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (National Commission for the review of awards of public procurement procedures, Slovenia) requested the Court to give a preliminary ruling on the interpretation of Article 2 and Article 23(2) and (8) of Directive 2004/18/EC, (2) Article 83 of Directive 2001/83/EC, (3) Article 4(2) of Directive 2002/98/EC (4) and Article 18 TFEU.

2. That request was submitted in the context of an action brought by Medisanus d.o.o. against the Splošna Bolnišnica Murska Sobota (Murska Sobota general hospital, Murska Sobota, Slovenia) concerning the legality of a clause in the tender specifications relating to a public procurement procedure for the supply of medicinal products launched by that hospital. Under that clause, the medicinal products forming the subject matter of that procedure had to be manufactured on the basis of Slovenian plasma ('the national origin requirement').

3. That clause was introduced by the Murska Sobota general hospital in order to comply with national rules under which imports of medicinal products manufactured on the basis of plasma collected in another Member State may be authorised only if the medicinal products manufactured on the basis of plasma collected in the national territory are not sufficient to cover the needs of the national population ('the priority supply principle').

4. For the reasons which I shall set out below, I consider that Directive 2004/18 and Articles 34 and 36 TFEU must be interpreted as meaning that they preclude both the priority supply principle and the national origin requirement.

II – Legal framework

A – *EU law*

1. Directive 2004/18

5. Article 1(2)(a) Directive 2004/18 defines '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'.

6. Article 2 of that directive, entitled 'Principles of awarding contracts', states that contracting authorities are to treat economic operators equally and non-discriminatorily and are to act in a transparent way.

7. Article 23 of that directive concerns technical specifications.

8. That concept of 'tender specifications' is defined in point 1 of Annex VI to that directive. As regards, in particular, public supply and public service contracts, point 1(b) contains the following definition:

'… a specification in a document defining the required characteristics of a product or service, such as quality and environmental performance levels, design for all requirements (including accessibility for people with disabilities), and conformity-assessment, performance, use of the product, its 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 methods and procedures, as well as conformity assessment procedures'.

9. In the words of Article 23 of that 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. …'

2. Directive 2002/98

10. 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.'

11. Article 4(2) of that directive provides:

'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.'

12. In the words of Article 20(1) of that 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.'

3. Directive 2001/83

13. Article 1 of Directive 2001/83 contains, in particular, the following definitions:

'2. Medicinal product:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings, or;

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

…

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.'

14. According to Article 2(1) of Directive 2001/83, that directive is to apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

15. Article 83 of Directive 2001/83, which is part of Title VII, on 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,

…'

16. Article 109 of Directive 2001/83, under Title X on special provisions on medicinal products derived from human blood and plasma, states that Directive 2002/98 is to apply for the collection and testing of human blood and human plasma.

17. In the words of 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.’

B – *Slovenian law*

1. The Law on medicinal products

18. Concerning the definition of the priority supply principle in medicinal products industrially manufactured from plasma collected in Slovenia, Article 6(71) of the Zakon o zdravilih (Law on medicinal products) of 4 March 2014 (Uradni list RS, No 17/2014) provides:

‘The priority supply of medicinal products industrially manufactured from Slovenian plasma (that is to say, from frozen fresh plasma for processing, collected in Slovenia) constitutes a principle whereby medicinal products obtained from foreign plasma originating 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 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) 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)’.

19. Paragraph 106 of that article defines ‘medicinal products obtained from blood or plasma’ as follows:

‘Medicinal products obtained from blood or plasma are industrially manufactured pharmaceutical products, such as, for example, medicinal products containing, in particular, human albumin and human immunoglobulin, which are produced for that purpose by specialist operators using blood compounds which are obtained in accordance with the rules governing the supply of blood and blood products and the rules governing medicinal products.’

20. 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 is used in the manufacture of medicinal products’.

2. The Law on the supply of blood

21. The Zakon o preskrbi s krvjo (Law on the supply of blood) of 5 October 2006 (Uradni list RS, No 104/2006) contains the following definitions in Article 3(11) to (13), (18) and (27), respectively:

‘11. Blood: whole human blood; …

12. blood component: active component of blood (… plasma), which may be prepared from blood by various methods;

13. blood product: any therapeutic product (component or agent) which is derived from human blood or human plasma;

…

18. self-sufficiency: 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;

…

27. blood-based medicinal product: any medicinal product prepared from human blood or human plasma.'

22. Article 2 of that Law, relating to the supply of blood, is worded as follows:

'The supply of blood forms part of transfusion activities, including the planning, collection, processing, testing, storage, distribution, treatment and regular, adequate supply of blood and blood products to the population, and the marketing of blood and such products. Those activities shall be carried out in accordance with the principles of national self-sufficiency and the voluntary unpaid donation of blood, in order to guarantee an adequate number of donors and the safety of blood transfusions.'

23. Article 5(1) of that Law, which concerns, in particular, the collection of blood, provides:

'The activity of collecting and testing human 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 Medicine] or by the transfusion centre designated and licensed by the Agency.'

24. 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 ZTM') as follows:

'1. The [ZTM] is a transfusion institute 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 [ZTM] shall coordinate all activities concerning donor selection, the collection, testing, processing, storage and distribution of blood and blood products, and the clinical use of blood.'

III – The main proceedings and the question for a preliminary ruling

25. On 14 January 2015, Murska Sobota general hospital decided to launch a tendering procedure for the supply of medicinal products.

26. It is apparent from the tender specifications for the call for tenders that that public contract concerned medicinal products having the following characteristics:

– 'human blood albumin 200 mg/ml infusion solution, obtained from Slovenian plasma',

– 'human immunoglobulin for intravenous administration, 50 mg/ml or 100 mg/ml, obtained from Slovenian plasma'.

27. In answer to an economic operator which had objected to the national origin requirement, Murska Sobota general hospital claimed that that requirement was consistent with the priority supply principle in medicinal products manufactured industrially on the basis of Slovenian plasma, as provided for in Article 6(71) of the Law on medicinal products. It stated, moreover, that another call for tenders had been published jointly with the Ministry of Health concerning human albumin and human immunoglobulin obtained from foreign plasma.

28. On 25 February 2015, Medisanus, a company having its seat in Ljubljana (Slovenia), requested the contracting authority to review the tender specifications. In support of its request, Medisanus claimed that only the ZTM was in a position to satisfy the national origin requirement as it had an exclusive right in respect of blood collected in Slovenia, from which it followed that the ZTM was the only operator able to supply medicinal products obtained from plasma collected in Slovenia. Medisanus was therefore of the view that such a requirement was incompatible with EU law, as regards industrially-manufactured medicinal products.

29. On 23 March 2015, Murska Sobota general hospital rejected that request for review as unfounded, for the following reasons. First of all, the national origin requirement followed from domestic law. Next, that requirement was scientifically justified. Last, the requirement was consistent with an objective of self-sufficiency promoted within the European Union. In the latter regard, the hospital in question referred to Article 83 of Directive 2001/83 and stated that the objective pursued was to ensure not absolute territorial self-sufficiency but the adequate use, limited to certain medicinal products, of the proportion of plasma collected in Slovenia that is available for the production of medicinal products derived from blood. It further stated that a certain percentage of its needs was covered by a call for tenders relating to the acquisition of medicinal products derived on blood from other Member States.

30. Following the rejection of its request, Medisanus submitted a request for revision to the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (National Commission for the review of awards of public procurement procedures). That commission has doubts as to the compatibility of the national origin requirement with Articles 2 and 23 of Directive 2004/18, in that it might give rise to a breach of the principle of equal treatment and respect for competition between economic operators.

31. That commission observes, however, that that requirement is based on Slovenian law. Article 6(71) of the Law on medicinal products imposes a priority supply of medicinal products produced industrially from plasma collected in Slovenia. Furthermore, the Law on the supply of blood establishes the principle of self-sufficiency, under which the Republic of Slovenia is to cover its needs for blood by its own resources. That law entrusts the ZTM with carrying out the public service relating to the activity of collecting and testing blood and blood components, independently of their intended use, and also with their preparation, storage and distribution when they are intended for transfusion.

32. In that context, the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (National Commission for the review of awards of public procurement procedures) decided to stay 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 with

– the TFEU, 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 …)?’

IV – Procedure before the Court

33. The request for a preliminary ruling was lodged at the Court Registry on 18 June 2015.

34. Written observations have been submitted by Medisanus, the Slovenian and Spanish Governments and the European Commission.

35. The representatives of Medisanus, the Slovenian Government and the Commission appeared at the hearing on 22 September 2016 and presented oral argument.

V – Analysis of the question for a preliminary ruling

36. I consider that the question for a preliminary ruling referred by the referring body should be reformulated, for the following reasons.

37. First of all, the question submitted to the Court refers to the principle of non-discrimination as provided for in Article 18 TFEU. However, it follows from its wording that that provision is to apply without prejudice to any special provisions contained in the Treaties. Consequently, and as the Court

has explained on numerous occasions, that article is to apply independently only to situations governed by EU law in regard to which the Treaty lays down no specific prohibition of discrimination. (5)

38. In fact, it has consistently been held that Article 34 TFEU reflects, inter alia, the obligation to comply with the principle of non-discrimination. (6) Since the priority supply principle and the national origin requirement come under Article 34 TFEU, (7) I shall examine them in the light of that article, as the Commission has suggested.

39. Next, the question refers to Article 4(2) of Directive 2002/98 and Article 83 of Directive 2001/83. For the reasons which I shall set out in points 155 to 164 of this Opinion, I consider that those provisions are not relevant in the circumstances of the main proceedings.

40. Last, it is necessary to take account of the respective scope of Directive 2004/18 and of Article 34 TFEU and also of the existence of two national measures at issue in the main proceedings:

– the priority supply principle and

– the national origin requirement.

41. The priority supply principle cannot be appraised, as such, by reference to Directive 2004/18, which applies only in the context of public contracts. Conversely, that principle must be appraised by reference to Article 34 TFEU, which guarantees the free movement of goods. (8)

42. On the other hand, the national origin requirement comes within the scope of both Directive 2004/18 and Article 34 TFEU. (9)

43. In the light of the foregoing, I propose that the question for a preliminary ruling should be reformulated as follows. By its question, the referring body asks the Court:

– whether Articles 34 and 36 TFEU must be interpreted as meaning that they preclude the priority supply principle; and

– whether Article 2 and Article 23(2) and (8) of Directive 2004/18 and Articles 34 and 36 TFEU must be interpreted as meaning that they preclude the national origin requirement.

44. For the reasons which I shall set out below, I consider that the abovementioned provisions must be interpreted as meaning that they preclude both the priority supply principle and the national origin requirement.

45. Before addressing those questions, however, I must ascertain whether the Court has jurisdiction to answer the question referred, by examining the status as a ‘court or tribunal’ within the meaning of Article 267 TFEU of the referring body. I shall then set out a number of considerations on the factual and legal context of the main proceedings.

A – *The jurisdiction of the Court*

46. It follows from Article 267 TFEU that the Court has jurisdiction only to answer questions referred by ‘courts or tribunals’.

47. In accordance with settled case-law, in order to determine whether a body making a reference is a ‘court or tribunal’ for the purposes of Article 267 TFEU, which is a question governed by EU law alone, the Court takes account of 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. (10)

48. I consider that it follows from the following factors, communicated by the referring body, that the latter does indeed have the status of a ‘court or tribunal’ for the purposes of Article 267 TFEU:

– it was set up by the national legislation on public contracts;

– it is permanent;

– its jurisdiction is compulsory, since its competence does not depend on the parties' agreement and its decisions are binding; (11)

– the procedure before it is *inter partes*;

– it applies rules of law; and

– the guarantees of its independence and the independence of its members are analogous to those applicable to the ordinary courts and tribunals.

49. In addition, it should be borne in mind that, when appraising the legal status of national non-judicial bodies referred to in Article 2(9) of Directive 89/665/EEC (12) responsible for public procurement review procedures, the Court has already confirmed that several other national bodies essentially comparable to the referring body in the present case were 'courts or tribunals'. (13)

50. Consequently, I consider that the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (National Commission for the review of awards of public procurement procedures) has the status of a 'court or tribunal' for the purposes of Article 267 TFEU and that the Court therefore has jurisdiction to answer the question referred by that body.

B – *Considerations concerning the factual and legal context of the main proceedings*

51. Before answering the question submitted by the referring body, it seems to me to be important to provide certain information, derived from the observations submitted to the Court, concerning the legal and factual context of the main proceedings.

52. I recall that the call for tenders at issue in the main proceedings related to the acquisition not of blood or blood components but rather of medicinal products manufactured industrially on the basis of plasma. The national origin requirement was imposed by the awarding authority in order to comply with the priority supply principle provided for in Article 6(71) of the Zakon o zdravilih (Law on medicinal products).

53. Within the system established by the Law on the supply of blood, and in particular by Article 10 thereof, the ZTM is responsible at national level for the supply of blood and blood products to bodies and for the integration of transfusion medicine in hospital practice.

54. According to the observations submitted by Medisanus, the Slovenian Government and the Commission, that law confers exclusive competence on the ZTM for the collection of blood and blood products in the territory of the Republic of Slovenia. It follows from that exclusive competence that only the ZTM is authorised to supply medicinal products based on Slovenian plasma, in such a way that the ZTM was in practice the only operator capable of supplying medicinal products in conformity with the national origin requirement.

55. The Slovenian Government has explained that the blood collected by the ZTM is primarily intended to be used for transfusion purposes. Only the surplus amounts of blood collected are intended to be processed into medicinal products such as human albumin or human immunoglobulin, which form the subject matter of the call for tenders at issue in the main proceedings.

56. It also follows from the observations submitted by the Slovenian Government that the ZTM does not itself process the blood collected in Slovenian territory into medicinal products, but sends that blood to a private operator which manufacturers the medicinal products by means of an industrial process. The ZTM selects that operator within the framework of an open procurement procedure in accordance with Directive 2004/18.

57. The medicinal products thus obtained are intended exclusively for the Slovenian market. The ZTM distributes those medicinal products to other public health services in Slovenia, and in particular

to the hospitals. By way of consideration, the ZTM receives only the costs of manufacturing the medicinal products and does not make a profit.

58. Furthermore, it is only if and in so far as the quantity of medicinal products manufactured on the basis of Slovenian plasma is not sufficient to satisfy the needs of the Slovenian population that medicinal products manufactured on the basis of foreign plasma are bought, within the framework of an open public procurement procedure in accordance with Directive 2004/18.

C – *The infringement of Directive 2004/18*

59. In this section, I shall consider whether Article 2 and Article 23(2) and (8) of Directive 2004/18 must be interpreted as meaning that they preclude the national origin requirement.

60. In order to do so, it is necessary to assess (i) the applicability of Directive 2004/18 in the circumstances of the main proceedings and (ii) the existence of an infringement of the abovementioned provisions.

1. The applicability of Directive 2004/18

61. In the first place, it is clear from the Slovenian Government's observations that Murska Sobota general hospital is a public body created by the Republic of Slovenia. On that basis, it must be regarded as a 'contracting authority' within the meaning of Article 1(9) of Directive 2004/18; moreover, that capacity has not been disputed by any of the parties which have submitted observations to the Court.

62. Nor, in the second place, to my mind, can it be disputed that the medicinal products at issue in the main proceedings constitute 'products' within the meaning of Article 1(2)(a) and (c) of Directive 2004/18.

63. Admittedly, the Slovenian Government has claimed that those medicinal products were not 'products' within the meaning of that directive or 'goods' for the purposes of Article 34 TFEU, on the ground that the ZTM and the Slovenian hospitals together provided a public service of general interest consisting in the supply of medicinal products manufactured on the basis of plasma.

64. In that regard, I would emphasise that the Court established long ago a particularly broad definition of 'goods' for the purposes of the FEU Treaty provisions on the free movement of goods, as referring to any product that can be valued in money and thus be the subject of commercial transactions. (14) In the absence of a different definition within Directive 2004/18, that definition seems to me to be capable of being transposed to the concept of 'product' within the meaning of that directive.

65. To my mind, there is scarcely any doubt that the medicinal products at issue in the main proceedings are products that can be valued in money and as such be the subject of commercial transactions. The fact that the supply of such medicinal products pursues an objective of general interest is not in my view capable of calling in question the quality of 'products' or 'goods' of the medicinal products at issue, but may, if appropriate, be taken into consideration at the justification stage.

66. My conviction in that respect is borne out by the Court's case-law on the free movement of goods. The Court has considered on numerous occasions that medicinal products came within the scope of Articles 34 and 36 TFEU. (15) Furthermore, the Court held in the judgment in *Humanplasma* that a prohibition on the importation and marketing of blood and blood components obtained from paid blood donations constituted a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 34 TFEU. (16)

67. In the third place, the Slovenian Government has disputed the pecuniary nature, for the purposes of Article 1(2)(a) of Directive 2004/18, of the supply of medicinal products manufactured on the basis of Slovenian plasma, relying on the fact that the ZTM was prohibited from making a profit on that supply. (17)

68. I recall, in that regard, that a contract cannot fall outside the definition of 'public contract' merely because the remuneration remains limited to reimbursement of the expenditure incurred in providing the agreed good or service. (18) In the present case it is apparent from the observations submitted by the Slovenian Government, that the ZTM requests, by way of consideration for the supply of the medicinal products manufactured on the basis of Slovenian plasma, reimbursement of the costs of manufacturing the medicinal products. In doing so, it passes on to the purchasers the expenditure incurred in the processing, by a third operator, of the surplus blood collected in Slovenian territory. Accordingly, the supply of medicinal products manufactured on the basis of Slovenian plasma must, in those circumstances, be characterised as a 'contract for pecuniary interest'.

69. In the fourth place, under the first indent of Article 7(b), the applicability of Directive 2004/18 is also subject to the condition that the estimated value, exclusive of value added tax (VAT), of the public contract must be equal to or greater than a threshold of EUR 207 000, that being the threshold applicable in the case of public supply contracts awarded by contracting authorities other than those referred to in Annex IV, such as Murska Sobota general hospital.

70. In answer to a question for clarification addressed to it by the Court, the referring body stated that the estimated value, exclusive of VAT, of the public contract at issue in the main proceedings was EUR 791 476. That contract is therefore above the threshold provided for in the first indent of Article 7(b) of Directive 2004/18.

71. In the fifth place, the Slovenian Government has also relied on the exception established by the Court in the judgment of 9 June 2009, *Commission* v *Germany*, (19) in support of its contention that Directive 2004/18 is not applicable. To my mind, however, that exception does not seem to be applicable to the circumstances of the main proceedings.

72. That judgment concerned a contract concluded for a period of 20 years between the City of Hamburg (Germany) and four Landkreise, for the purpose of establishing long-term cooperation between those local authorities for reciprocal treatment of waste. Thus, that contract, which had been concluded without launching a call for tenders, formed both the basis and the legal framework for the future construction and operation of facility intended to perform a public service, namely thermal incineration of waste. The Court held that such a contract was not required to be the subject matter of a prior call for tenders. (20)

73. Admittedly, the circumstances of the main proceedings bear certain resemblances to those of the judgment in *Commission* v *Germany*, and in particular the public nature of the contracting parties, namely Murska Sobota general hospital and the ZTM. However, in that judgment it was not the Court's intention to exclude all contracts between public entities (21) from the rules applicable to public contracts, but only those forming both the basis and the legal framework for long-term co-operation with the intention of carrying out a public service. That is not the case of the contract at issue in the main proceedings, the object of which is limited to the occasional supply of medicinal products manufactured on the basis of human plasma.

74. Consequently, I consider that the contract at issue in the main proceedings does not come within the exception established by the Court in the judgment in *Commission* v *Germany*.

75. It follows from the foregoing that Directive 2004/18 is applicable in circumstances such as those of the main proceedings.

2. The existence of an infringement of Article 2 of Directive 2004/18

76. Under Article 2 of Directive 2004/18, the contracting authorities are required to treat economic operators equally and non-discriminatorily.

77. According to the Court's case-law, in application of the principle of equal treatment as between tenderers, the aim of which is to promote the development of healthy and effective competition between undertakings taking part in a public procurement procedure, all tenderers must be afforded equality of opportunity when formulating their tenders, which therefore implies that the tenders of all competitors must be subject to the same conditions. (22)

78. Strictly speaking, the national origin requirement distinguishes not between economic operators but between products, by excluding medicinal products not manufactured on the basis of Slovenian plasma.

79. Nonetheless, it has consistently been held that the principle of equal treatment, of which Article 2 of that directive is a particular expression, prohibits not only overt discrimination based on nationality but also all covert forms of discrimination which, by applying other distinguishing criteria, in fact achieve the same result. (23)

80. A clause requiring that a medicinal product be manufactured on the basis of plasma collected in the national territory is liable to operate mainly to the detriment of economic operators of other Member States, since they will find it more difficult to have access to plasma collected in the national territory than the economic operators of the Member State concerned. (24)

81. In the circumstances of the main proceedings, the discriminatory effects of that national origin requirement are all the more apparent because the ZTM, a Slovenian body, is in practice the only economic operator capable of supplying medicinal products manufactured on the basis of Slovenian plasma, which precludes all operators in other Member States.

82. I conclude from the foregoing that Article 2 of Directive 2004/18 of Directive 2004/18 must be interpreted as meaning that it precludes the national origin requirement. (25)

3. The existence of an infringement of Article 23(2) and (8) of Directive 2004/18

83. Article 23 of Directive 2004/18 imposes a number of obligations in relation to technical specifications. According to the definition provided in point 1(b) of Annex VI to that directive, 'technical specification' covers, in particular, any specification defining 'the required characteristics of a product or service', including requirements relevant to the product as regards 'production processes and methods'.

84. In the light of that definition, it seems indisputable — and, moreover, it has not been disputed by the parties which have submitted observations to the Court — that the national origin requirement is a technical specification for the purposes of Article 23 of Directive 2004/18.

85. According to Article 23(2) of that directive, technical specifications are to afford equal access for tenderers and are not to have the effect of creating unjustified obstacles to the opening up of public procurement to competition. For the reasons set out in points 79 to 81 of this Opinion, I consider that the national origin requirement does not permit equal access for tenderers within the meaning of that provision.

86. In addition, that requirement is contrary to Article 23(8) of Directive 2004/18, in that it refers to a specific source or origin, which has the effect of eliminating medicinal products manufactured on the basis of plasma of foreign origin.

87. I conclude from the foregoing that Article 2 and Article 23(2) and (8) of Directive 2004/18 must be interpreted as meaning that they preclude the national origin requirement. (26)

D – *The infringement of Article 34 TFEU*

88. In the context of this section, I shall consider whether Article 34 TFEU must be interpreted as meaning that it precludes the priority supply principle and the national origin requirement. (27)

89. In order to do so, it is necessary to assess (i) the applicability of Article 34 TFEU in the circumstances of the main proceedings and (ii) the existence of an infringement of that article.

1. The applicability of Article 34 TFEU

90. A number of questions must be examined before it can be concluded that Article 34 TFEU is applicable.

91. In the first place, it is necessary to assess whether Article 34 TFEU is still applicable in the circumstances of the main proceedings when it has just been established that there has been an infringement of Article 2 and Article 23(2) and (8) of Directive 2004/18.

92. I would emphasise in that regard that the scope of the priority supply principle, as provided for in Article 6(71) of the Law on medicinal products, is not limited to the sphere of public contracts. It is therefore necessary to determine whether that principle is compatible with Article 34 TFEU in all situations not coming under Directive 2004/18.

93. Furthermore, as regards the situations that do come within the scope of Directive 2004/18, it is necessary to determine whether that directive brings about exhaustive harmonisation, which would mean that the national measures in question could not be assessed in the light of the provisions of primary law. (28)

94. I consider that Directive 2004/18 does not bring about exhaustive harmonisation of the aspects relating to the free movement of goods, (29) in such a way that the national origin requirement may be assessed in the light of Article 34 TFEU. (30) The Commission has rightly claimed, in that regard, that that requirement was imposed by a public body, namely Murska Sobota general hospital, (31) which as such is subject to the obligations arising under the free movement of goods. (32)

95. In the second place, the Slovenian Government has claimed that the priority supply principle comes within an exclusive power afforded to the Member States by Article 168(7) TFEU in connection with the allocation, use, processing and distribution of human blood.

96. In that regard, the Court has already had occasion to rule that, in accordance with Article 168(7) TFEU, EU law does not affect the power of the Member States to adopt provisions intended to organise health services. In exercising that power, however, the Member States must respect EU law, in particular the FEU Treaty provisions on freedoms of movement. (33)

97. Contrary to what the Slovenian Government's apparent contention, therefore, Article 168(7) TFEU does not confer on the Member States any exemption from the obligations imposed on them by Article 34 TFEU or other provisions of EU law.

98. In the third place, I would observe that, for the reasons set out in points 62 to 66 of this Opinion, medicinal products manufactured on the basis of blood or blood components are 'goods' within the meaning of Article 34 TFEU.

99. Consequently, it is necessary to consider whether the priority supply principle and the national origin requirement establish a difference in treatment prohibited by Article 34 TFEU.

2. The existence of an infringement of Article 34 TFEU

100. It is apparent from the observations submitted by the Slovenian Government and from those submitted by the Commission that the medicinal products manufactured on the basis of Slovenian plasma are prepared not in Slovenian territory, but in another Member State. As the Republic of Slovenia does not have plasma fractionation facilities in its territory, the ZTM has the surplus blood collected processed by a private operator established in another Member State. (34)

101. Accordingly, the priority supply principle does not distinguish between medicinal products manufactured in the Republic of Slovenia and those imported from other Member States, but, rather, distinguishes between medicinal products imported from other Member States. Among the latter medicinal products, only those manufactured on the basis of Slovenian plasma at the request of the ZTM can be freely imported, whereas other medicinal products, manufactured on the basis of foreign plasma, can be imported only if the former do not permit the needs of the Slovenian population to be covered.

102. Such a difference in treatment, which leads to the channelling of imports in the sense that only certain economic operators can import the products concerned while others are precluded from doing

so, constitutes a measure having equivalent effect to a quantitative restriction on imports, as the Commission has claimed. (35)

103. For the same reasons, the national origin requirement also constitutes a measure having equivalent effect to a quantitative restriction on imports, since only suppliers of medicinal products manufactured on the basis of Slovenian plasma are authorised to participate in the public procurement procedure at issue in the main proceedings.

104. I conclude from the foregoing that Article 34 TFEU must be interpreted as meaning that it precludes the priority supply principle and the national origin requirement.

E – *The existence of justification on the basis of Article 36 TFEU*

105. After having established that Article 2 and Article 23(2) and (8) of Directive 2004/18 and Article 34 TFEU must be interpreted as meaning that they preclude the priority supply principle and the national origin requirement, it remains to be ascertained whether those measures may be justified by an objective recognised as legitimate by EU law.

106. As regards the differences in treatment prohibited by the provisions of Directive 2004/18, I would observe that that directive does not effect an exhaustive harmonisation of the aspects relating to the grounds of justification, in such a way that those differences may be assessed, in that regard, in the light of the relevant provisions of primary law and the relevant case-law of the Court. (36)

107. In the judgment in *Humanplasma*, (37) the Court set out the principles applicable to the grounds of justification based on the protection of health and life of humans referred to in Article 36 TFEU.

108. First of all, public health ranks foremost among the assets or interests protected by Article 36 TFEU and it is for the Member States, within the limits imposed by the Treaty, to decide on the degree of protection which they wish to afford to human health and on the way in which that protection is to be achieved. Since the level may vary from one Member State to another, Member States should be allowed some measure of discretion. (38)

109. Next, it follows from the case-law that a provision which is capable of restricting a fundamental freedom guaranteed by the 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. (39)

110. Last, as regards, more specifically, the assessment of the proportionate nature of the provision at issue, it follows from the Court's case-law that since Article 36 TFEU constitutes an exception, which is to be strictly interpreted, to the rule of free movement of goods within the European Union, it is for the national authorities to demonstrate that that provision is necessary in order to achieve the declared purpose and that that objective could not be achieved by less extensive prohibitions or restrictions, or by prohibitions or restrictions having less effect on trade between Member States. (40)

111. In application of that case-law, it is appropriate to examine the legitimacy of the objectives put forward by the Slovenian Government and also the appropriateness and necessity, in the light of those objectives, of the priority supply principle and the national origin requirement imposed in the call for tenders at issue in the main proceedings.

112. The Slovenian Government has invoked the objective of encouraging voluntary unpaid blood donations in the national territory and also the objective of national self-sufficiency in blood and in blood products, including medicinal products manufactured on the basis of blood. The Commission has, in essence, examined the same grounds of justification under the more general objective of protection of the health and life of humans referred to in Article 36 TFEU.

113. I would emphasise that the Slovenian Government has not claimed, as a ground of justification, that medicinal products manufactured on the basis of non-Slovenian plasma might be dangerous. I also note, in that regard, that the competent authorities import such medicinal products when the medicinal products manufactured on the basis of Slovenian plasma are exhausted. (41)

114. I shall examine separately the two objectives invoked by the Slovenian Government, in the light of the case-law cited above.

1. The objective of encouraging voluntary unpaid blood donations

115. In the first place, to my mind there is scarcely any doubt that encouraging voluntary unpaid blood donations is a legitimate objective forming part of the more general objective of protecting the health and life of humans.

116. I would emphasise that that objective has been supported on many occasions by the Parliament, the Council and the Commission since the 1990s, (42) following, in particular, the 'contaminated blood' affair in France. (43)

117. Encouraging blood donations is a legitimate objective having regard to the considerable therapeutic importance of blood and blood products. In a communication of 21 December 1994, the Commission wrote in that respect:

'Blood and the products derived from it have become an indispensable facet of modern medicine. Their use has brought about dramatic advances in therapy and surgery, saved countless lives, and improved significantly the longevity as well as the quality of life for those who suffer from long-term blood disorders such as haemophilia. Ensuring the safety and the supply of blood and blood products, therefore, is of vital importance. …' (44)

118. As emphasised in recital 2 of Directive 2002/98, the availability of blood and blood components used for therapeutic purposes is dependent largely on Community citizens who are prepared to donate.

119. In addition, the voluntary and unpaid nature of these donations is the consequence of ethical and sanitary considerations put forward by the Slovenian Government. First of all, the principle of inalienability and non-commercialisation of the human body operates against the purchase and sale of blood. (45) Next, the fact that no payment is made for donations makes it possible to preserve the health of donors by ensuring that they are not exploited, in particular those among the most vulnerable categories of the population. (46) Last, the fact that no payment is made makes it possible to protect the health of recipients, by eliminating the risk that a donor may conceal certain relevant medical information in order to receive payment. (47)

120. That political will was implemented by a legal obligation which is now found in Article 20 of Directive 2002/98 and Article 110 of Directive 2001/83, which require Member States to take the necessary measures to encourage voluntary and unpaid blood donations. (48)

121. Having regard to the foregoing, encouraging voluntary and unpaid blood donations constitutes a legitimate objective with regard to Article 36 TFEU.

122. As regards, in the second place, the appropriateness of the measures at issue in the main proceedings, it must be ascertained whether the priority supply principle and the national origin requirement are capable of achieving that legitimate objective of encouraging voluntary and unpaid blood donations.

123. I must confess to having serious doubts in that regard. I see no obvious relationship between those measures, which seek to steer national *demand* towards products manufactured on the basis of national plasma, and the objective of promoting voluntary and unpaid donations, which seeks to increase the *supply* of blood and blood components in the national territory.

124. More specifically, how can the fact that Murska Sobota general hospital is required to obtain its supplies from medicinal products manufactured on the basis of national plasma, as is the case in the main proceedings, encourage potential donors to make voluntary and unpaid donations of blood or blood components?

125. The Slovenian Government has claimed, in that regard, that it is important to prohibit the commercial exploitation of the blood and blood components collected, in order to preserve the

motivation of potential donors.

126. From that viewpoint, the priority supply principle and the national origin requirement again seem to me to be incapable of achieving the objective ascribed to them, since those measures do not directly or indirectly prohibit the commercial exploitation of the blood collected in the national territory. Furthermore, those measures fail the necessity test, since it is sufficient in that regard to impose a ban on commercial exploitation on the ZTM and on any other person involved in the collection, processing or distribution of the blood collected.

127. Having regard to the foregoing, I consider that the priority supply principle and the national origin requirement cannot be justified by the objective of encouraging voluntary and unpaid donations of blood.

2. The objective of national self-sufficiency (or sufficiency)

128. The Slovenian Government has also relied on the objective of national self-sufficiency in blood and blood products in order to justify the priority supply principle and the national origin requirement.

129. Like the promotion of voluntary and unpaid donations, the objective of self-sufficiency in blood and in blood products has been supported on many occasions by the Parliament, the Council and the Commission. (49)

130. That political will has also been implemented by a legal obligation, now provided for in Article 110 of Directive 2001/83, (50) which provides that Member States are to take the necessary measures to promote EU self-sufficiency in human blood or in human plasma.

131. However, the concept of 'self-sufficiency' contains two ambiguities that affect its ability to justify the priority supply principle and the national origin requirement. It should be emphasised in that regard that that concept has not been defined by the EU legislature, in particular not in either Directive 2001/83 or Directive 2002/98.

132. The first ambiguity concerns the territorial scale of the objective of self-sufficiency in blood and blood products. Must that objective be pursued at EU level or may it be pursued at national level? I note that that question is not novel within the EU. (51)

133. None of the parties which have submitted observations to the Court has disputed the fact that self-sufficiency in blood and blood products is a legitimate objective at EU level. (52) However, although the objective of self-sufficiency at EU level may justify restrictions on products imported from third countries, (53) it cannot readily justify a restriction on imports between Member States, such as those at issue in the main proceedings.

134. Therefore, the question that arises in the context of the present case is that of the legitimacy of the objective of self-sufficiency pursued *at national level*. I consider that that objective of national self-sufficiency is legitimate for the following reasons.

135. First, I recall the considerable therapeutic importance assumed by the use of blood and blood products. (54) In the light of the objective of protecting the health and life of humans referred to in Article 36 TFEU, it is therefore legitimate for a State to ensure that the health services in its territory have sufficient quantities of blood and blood products, without being dependent in that regard on any imports from other Member States.

136. Second, it is apparent from the Commission's observations that lightly populated States, such as the Republic of Slovenia, may encounter difficulties in obtaining supplies on the international markets. According to the Commission, the tendency on those markets, on which the demand for medicinal products derived from blood exceeds the supply of plasma, should encourage undertakings to sell the final product, out of preference, in countries that can pay a higher price or that buy larger quantities. Accordingly, it is legitimate for a lightly populated State to adopt measures to ensure that it is self-sufficient in blood and blood products.

137. Third, and as the Commission has claimed, in the absence of harmonisation at EU level, the objective of self-sufficiency pursued at the level of each State contributes indirectly to the self-sufficiency of the European Union in blood and blood products, an objective the legitimacy of which is not disputed.

138. Fourth, I note that a number of documents issued by the EU institutions approve of the objective of self-sufficiency in blood and in blood products pursued at Member State level. (55)

139. Having regard to the foregoing, I consider that national self-sufficiency in blood and in blood products constitutes a legitimate objective in the light of Article 36 TFEU.

140. A second ambiguity concerns the material scope of the concept of 'self-sufficiency', which may be interpreted in two appreciably different ways. According to a first, more moderate, approach, the objective of national self-sufficiency consists in promoting the capacity of the population of a Member State to satisfy its needs, whether by means of its own resources or by means of imports.

141. According to a second, more radical, approach, that objective means that the needs of the population of a Member State are satisfied solely by means of its own resources, to the exclusion of any imports. This second approach to national self-sufficiency thus promotes an objective of autarky, namely satisfaction, in a closed circuit, of national demand by national supply. (56)

142. I would emphasise that, in a recent working document of the Commission's services, (57) these two approaches were designated respectively by the expressions 'national sufficiency' (58) and 'national self-sufficiency' (59) and, in the interest of clarity, I shall use those terms.

143. It should be strongly emphasised that the objective of national self-sufficiency, based on the idea of autarky, represents the simple negation of the freedoms of movement and the internal market. Since exceptions to the free movement of goods must be interpreted strictly, (60) it does not seem to me to be possible to describe that objective as 'legitimate' in the light of Article 36 TFEU.

144. Admittedly, I cannot rule out the possibility that the second sentence of Article 4(2) of Directive 2002/98 allows Member States to pursue such an objective by prohibiting imports of blood. However, that provision refers to blood and blood products *to the exclusion* of medicinal products manufactured industrially on the basis of plasma, such as those at issue in the main proceedings. (61)

145. I recall, moreover, that such medicinal products come under Directive 2001/83 and, accordingly, under the rules of free movement based on mutual recognition of marketing authorisations as provided for in Articles 28 to 39 of that directive. (62) The fact that those medicinal products are included in those rules on free movement shows that the EU legislature did not intend to allow Member States to pursue an objective of autarky with respect to those products.

146. To my mind, therefore, it must be precluded that the objective of national self-sufficiency, based on the idea of autarky, may constitute a legitimate objective in the case of medicinal products manufactured industrially on the basis of plasma, such as those at issue in the main proceedings.

147. On the other hand, I consider that the objective of national sufficiency, conceived as the promotion of the capacity of the population of a Member State to satisfy its needs, whether by means of its own resources or by means of imports, represents such a legitimate objective, for the reasons set out in points 135 to 138 of this Opinion.

148. In addition, that approach seems to me to be consistent with the ultimate objective of the blood policy conducted by the EU and the Member States, which is to ensure the availability of blood products. The fact of authorising imports of blood products makes it possible to counteract, to a certain degree, the risks affecting the collection of blood in the national territory. In other words, the availability of blood and blood products seems to me to be better ensured where there are two supply channels, the national offer and imports from other Member States. (63)

149. It nonetheless remains to be ascertained whether that objective of national sufficiency, conceived as promoting the ability of the population of a Member State to satisfy its needs, whether by means of

its own resources or by means of imports, may justify the priority supply principle and the national origin requirement.

150. To my mind, those measures are not appropriate for the pursuit of that objective.

151. The priority supply principle and the national origin requirement have the effect of restricting imports of medicinal products manufactured on the basis of plasma collected in another Member State. By limiting the potential of that first channel of the supply of blood products, those measures reduce the ability of the national population to satisfy its needs.

152. Furthermore, the priority supply principle and the national origin requirement do not have a positive impact on the second channel of supply of blood products, namely the national offer. I have already set out the reasons why those measures, which seek to steer national demand towards products manufactured on the basis of national plasma, are not in my view capable of promoting the collection of blood in the national territory. (64)

153. Consequently, I consider that the priority supply principle and the national origin requirement cannot be justified by the objective of national self-sufficiency in blood products.

154. Having regard to the foregoing, I consider that the infringements of Article 2 and Article 23(2) and (8) of Directive 2004/18 and of Article 34 TFEU, which result from those measures, are not justified in the light of the objective of protection of the health and life of humans referred to in Article 36 TFEU.

3. The irrelevance of Article 4(2) of Directive 2002/98 and Article 83 of Directive 2001/83

155. The question for a preliminary ruling expressly mentions Article 4(2) of Directive 2002/98 and Article 83 of Directive 2001/83. Both of those provisions permit the Member States to introduce more stringent requirements or measures than those laid down in those directives.

156. In the interest of completeness, I wish to set out briefly the reasons why those provisions are not relevant in the circumstances of the main proceedings.

157. As regards Directive 2002/98, it follows from Article 2(1) thereof that the distribution of medicinal products manufactured industrially on the basis of plasma, such as those at issue in the main proceedings, does not fall within the scope of that directive.

158. As the Court explained in the judgment in *Octapharma France*, (65) the collection and testing of plasma fall within the scope of Directive 2002/98 even where an industrial process is involved, as confirmed by Article 109 of Directive 2001/83. On the other hand, the intervention of an industrial process removes the processing, storage and distribution of plasma from the scope of Directive 2002/98.

159. Consequently, Article 4(2) of Directive 2002/98 is not applicable in the circumstances of the main proceedings, as Medisanus, the Spanish Government and the Commission have claimed. I find confirmation of that interpretation in the wording of the second sentence of Article 4(2) of Directive 2002/98, which provides that a Member State may prohibit or restrict ‘imports of blood and blood components’. That provision cannot be interpreted as referring to the import of medicinal products manufactured industrially on the basis of plasma, such as those at issue in the main proceedings.

160. As regards Directive 2001/83, it cannot be disputed that the medicinal products at issue in the main proceedings fall within its scope, since they constitute medicinal products based on blood components and prepared industrially. That solution follows from Article 2(1) of that directive, which defines its scope, and also from the definitions in Article 1(1) and (10) of that directive. (66)

161. Article 83 of Directive 2001/83 comes under Title VII of that directive, which lays down certain requirements that must be met when carrying out the activities of wholesale distribution and brokerage of medicinal products. In particular, Article 77 requires Member States to ensure that wholesale

distribution is subject to the requirement of an authorisation, while the conditions on which such authorisation may be granted are defined in Articles 79 and 80.

162. It is in that context that Article 83 of Directive 2001/83, which allows Member States to impose more stringent requirements in respect of the wholesale distribution of certain medicinal products, including medicinal products derived from blood, must be interpreted. In fact, that article refers only to the conditions of the exercise of the activity of wholesale distribution, as defined in the provisions of Title VII of that directive, and which may be supplemented by other obligations determined by the Member States, as confirmed in recital 38 of that directive.

163. The priority supply principle and the national origin requirement relate not to the conditions of the activity of wholesale distribution of medicinal products derived from blood, but to the conditions in which such medicinal products may be imported from another Member State. Consequently, Article 83 of Directive 2001/83 is not relevant in the circumstances of the main proceedings, as Medisanus, the Slovenian and Spanish Governments and the Commission have correctly maintained.

164. It follows from the foregoing that neither Article 4(2) of Directive 2002/98 nor Article 83 of Directive 2001/83 is relevant in the circumstances of the main proceedings.

VI – Conclusion

165. Having regard to the foregoing, I propose that the Court should answer the question for a preliminary ruling referred by the Državna revizijska komisija za revizijo postopkov oddaje javnih naročil (National Commission for the review of awards of public procurement procedures, Slovenia) as follows:

– Articles 34 and 36 TFEU must be interpreted as meaning that they preclude national rules authorising the import of medicinal products manufactured on the basis of plasma collected in another Member State only if the medicinal products manufactured on the basis of plasma collected in the national territory are not sufficient to cover the needs of the national population, and

– 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 work contracts, public supply contracts and public service contracts must be interpreted as meaning that they preclude a clause requiring, in accordance with those national rules, medicinal products forming the subject matter of a public supply contract procedure to be manufactured on the basis of plasma collected in the national territory.

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1 – Original language: French.

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2 – 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), as most recently amended by Commission Regulation (EU) No 1336/2013 of 13 December 2013 (OJ 2013 L 335, p. 17) (‘Directive 2004/18’).

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3 – 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 most recently amended by Directive 2012/26/EU of 25 October 2012 (OJ 2012 L 299, p. 1) (‘Directive 2001/83’).

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4 – Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ 2003 L 33, p. 30), as most recently amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ 2009 L 188, p. 14) (‘Directive 2002/98’).

5 – See, in particular, judgments of 14 July 1994, *Peralta* (C-379/92, EU:C:1994:296, paragraph 18); of 18 December 2007, *Laval un Partneri* (C-341/05, EU:C:2007:809, paragraphs 54 and 55); and of 16 December 2010, *Josemans* (C-137/09, EU:C:2010:774, paragraphs 51 and 52 and the case-law cited).

6 – See, to that effect, judgments of 7 May 1997, *Pistre and Others* (C-321/94 to C-324/94, EU:C:1997:229, paragraphs 49 and 54); of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725, paragraph 48); and of 26 April 2012, *ANETT* (C-456/10, EU:C:2012:241, paragraph 33).

7 – See points 90 to 99 of this Opinion.

8 – See points 91 and 92 of this Opinion.

9 – See points 93 and 94 of this Opinion.

10 – Judgments of 6 October 2015, *Consorci Sanitari del Maresme* (C-203/14, EU:C:2015:664, paragraph 17 and the case-law cited), and of 24 May 2016, *MTHøjgaard and Züblin* (C-396/14, EU:C:2016:347, paragraph 23).

11 – See in that regard judgment of 6 October 2015, *Consorci Sanitari del Maresme* (C-203/14, EU:C:2015:664, paragraph 23 and the case-law cited).

12 – Council Directive of 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts (OJ 1989 L 395, p. 33), as most recently amended by Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 (OJ 2014 L 94, p. 1).

13 – See, in particular, judgments of 17 September 1997, *Dorsch Consult* (C-54/96, EU:C:1997:413, paragraphs 22 to 38); of 4 February 1999, *Köllensperger and Atzwanger* (C-103/97, EU:C:1999:52, paragraphs 16 to 25); of 18 September 2014, *Bundesdruckerei* (C-549/13, EU:C:2014:2235, paragraphs 20 to 23); and of 6 October 2015, *Consorci Sanitari del Maresme* (C-203/14, EU:C:2015:664, paragraphs 17 to 27).

14 – Judgment of 10 December 1968, *Commission* v *Italy* (7/68, EU:C:1968:51, p. 626). This judgment concerned a tax imposed by the Italian Republic on exports of objects of artistic or historic interest.

15 – See, in particular, judgments of 20 May 1976, *de Peijper* (104/75, EU:C:1976:67); of 28 February 1984, *Commission* v *Germany* (247/81, EU:C:1984:79); of 1 June 1994, *Commission* v *Germany* (C-317/92, EU:C:1994:212); and of 11 September 2008, *Commission* v *Germany* (C-141/07, EU:C:2008:492).

16 – Judgment of 9 December 2010, *Humanplasma* (C-421/09, EU:C:2010:760, paragraphs 24 and 30).

17 – It will be recalled that, in practice, the ZTM is the only operator able to supply medicinal products that conform to the national origin requirement and therefore to participate in the call for tenders at issue in the main proceedings. See point 54 of this Opinion.

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18 – See, in particular, judgments of 19 December 2012, *Ordine degli Ingegneri della Provincia di Lecce and Others* (C-159/11, EU:C:2012:817, paragraph 29), and of 11 December 2014, *Azienda sanitaria locale n. 5 'Spezzino' and Others* (C-113/13, EU:C:2014:2440, paragraph 37).

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19 – C-480/06, EU:C:2009:357.

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20 – Judgment of 9 June 2009, *Commission* v *Germany* (C-480/06, EU:C:2009:357, paragraphs 5, 6, 31, 37, 44 and 49).

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21 – It will be recalled that contracts between public entities are not for that reason excluded from the scope of the EU legislation on public contracts. See the definition of 'economic operator' provided for in Article 1(8) of Directive 2004/18 and also the judgment of 6 October 2015, *Consorci Sanitari del Maresme* (C-203/14, EU:C:2015:664, paragraph 34 and the case-law cited).

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22 – Judgment of 12 March 2015, *eVigilo* (C-538/13, EU:C:2015:166, paragraph 33 and the case-law cited).

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23 – See, to that effect, judgments of 5 December 1989, *Commission* v *Italy* (C-3/88, EU:C:1989:606, paragraph 8); of 26 September 2000, *Commission* v *France* (C-225/98, EU:C:2000:494, paragraph 80); of 21 February 2008, *Commission* v *Italy* (C-412/04, EU:C:2008:102, paragraph 66); and of 17 July 2008, *ASM Brescia* (C-347/06, EU:C:2008:416, paragraph 60).

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24 – See, by analogy with the criterion of residence on the national territory, judgment of 16 January 2003, *Commission* v *Italy* (C-388/01, EU:C:2003:30, paragraph 14).

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25 – As regards the existence of possible justification, see points 105 to 164 of this Opinion.

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26 – As regards the existence of possible justification, see points 105 to 164 of this Opinion.

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27 – I would point out that I have reformulated the question for a preliminary ruling, which referred to Article 18 TFEU, for the reasons set out in points 36 to 43 of this Opinion.

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28 – On the concept of 'exhaustive harmonisation', see, in particular, judgments of 14 December 2004, *Swedish Match* (C-210/03, EU:C:2004:802, paragraph 81); of 16 July 2015, UNIC *and Uni.co.pel* (C-95/14, EU:C:2015:492, paragraph 33); and of 12 November 2015, *Visnapuu* (C-198/14, EU:C:2015:751, paragraph 40).

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29 – I find confirmation of that interpretation in recital of Directive 2004/18, which states that that directive lay downs coordinating provisions which are to be interpreted in accordance with the principle of free

movement of goods

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30 – This approach was taken by the Court in the judgment of 22 June 1993, *Commission* v *Denmark* (C-243/89, EU:C:1993:257), in which it was found that there had been an infringement of both the EU legislation on public contracts and Article 34 TFEU. In the judgment of 9 December 2010, *Humanplasma* (C-421/09, EU:C:2010:760), which also concerned a call for tenders for the supply of blood products, the Court held that there had been an infringement of Article 34 EU, but was not asked whether there had been an infringement of EU law relating to public contracts.

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31 – See point 61 of this Opinion.

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32 – According to settled case-law, the obligations arising under the free movement of goods also apply to autonomous bodies established by the State. See, to that effect, judgments of 18 June 1975, IGAV (94/74, EU:C:1975:81, paragraph 11); of 13 December 1983, *Apple and Pear Development Council* (222/82, EU:C:1983:370, paragraph 17); of 12 December 1990, *Hennen Olie* (C-302/88, EU:C:1990:455, paragraphs 13 to 16); and of 5 November 2002, *Commission* v *Germany* (C-325/00, EU:C:2002:633, paragraphs 17 to 20).

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33 – See, as regards freedom of establishment, judgment of 26 September 2013, *Ottica New Line* (C-539/11, EU:C:2013:591, paragraph 24 and the case-law cited). See also judgment of 21 June 2012, *Susisalo and Others* (C-84/11, EU:C:2012:374, paragraphs 26 and 27 and the case-law cited). That broad interpretation of the scope of the freedoms of movement is not limited to the areas referred to in Article 168(7) TFEU. See, in particular, judgments of 27 January 2011, *Commission* v *Luxembourg* (C-490/09, EU:C:2011:34, paragraph 32) and of 4 February 2015, *Melchior* (C-647/13, EU:C:2015:54, paragraph 21), and order of 17 November 2015, *Plaza Bravo* (C-137/15, EU:C:2015:771, paragraph 19).

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34 – See point 56 of this Opinion.

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35 – See, in that regard, judgments of 11 July 1974, *Dassonville* (8/74, EU:C:1974:82, paragraphs 8 and 9), and of 20 May 1976, *de Peijper* (104/75, EU:C:1976:67, paragraph 13).

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36 – See the case-law on the concept of ‘exhaustive harmonisation’ cited in footnote 28. Only Article 23(8) of Directive 2004/18 refers to the possibility of justification ‘by the subject matter of the contract’, which has not been relied on as such in the observations submitted to the Court. I observe that the Court examined the grounds of justification based on the provisions of primary law, when faced with a national measure contrary to EU legislation on public service contracts, in the judgment of 29 April 2010, *Commission* v *Germany* (C-160/08, EU:C:2010:230, paragraphs 73 to 86 and 125 to 130).

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37 – Judgment of 9 December 2010, *Humanplasma* (C-421/09, EU:C:2010:760).

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38 – Judgment of 9 December 2010, *Humanplasma* (C-421/09, EU:C:2010:760, paragraphs 32 and 39 and the case-law cited). See also judgments of 11 September 2008, *Commission* v *Germany* (C-141/07, EU:C:2008:492, paragraphs 46 and 51) and of 19 October 2016, *Deutsche Parkinson Vereinigung* (C-148/15, EU:C:2016:776, paragraph 30).

39 – Judgment of 9 December 2010, *Humanplasma* (C-421/09, EU:C:2010:760, paragraph 34 and the case-law cited). See also judgment of 11 September 2008, *Commission* v *Germany* (C-141/07, EU:C:2008:492, paragraph 48).

40 – Judgment of 9 December 2010, *Humanplasma* (C-421/09, EU:C:2010:760, paragraph 38 and the case-law cited). See also judgment of 11 September 2008, *Commission* v *Germany* (C-141/07, EU:C:2008:492, paragraph 50).

41 – See point 58 of this Opinion.

42 – See, in particular, Resolution of the Parliament of 14 September 1993 on self-sufficiency in and safety of blood and its derivatives in the European Community (OJ 1993 C 268, p. 29); Resolution of the Parliament of 18 November 1993 on safe blood transfusions and use of blood derivatives (OJ 1993 C 329, p. 268); Council Conclusions of 13 December 1993 on self-sufficiency in blood in the European Community (OJ 1994 C 15, p. 6); Communication from the Commission of 25 May 1993 on blood self-sufficiency in the European Community (COM(93) 198 final); Communication from the Commission of 21 December 1994 on Blood safety and self-sufficiency in the European Community (COM(94) 652 final); Council Resolution of 2 June 1995 on blood safety and self-sufficiency in the Community (OJ 1995 C 164, p. 1); Resolution of the Parliament of 14 July 1995 on blood safety in the European Union (OJ 1995 C 249, p. 231); Resolution of the Parliament of 17 April 1996 on the communication from the Commission on blood safety and self-sufficiency in the European Community (OJ 1996 C 141, p. 131); and Council Resolution of 12 November 1996 on a strategy towards blood safety and self-sufficiency in the European Community (OJ 1996 C 374, p. 1).

43 – This affair, which concerned inoculation with the AIDS virus in the course of blood transfusions in the 1980s, was revealed by the press in the course of 1991.

44 – Communication COM(94) 652 final, p. 2. See also 2nd Report from the Commission of 23 March 2011 on Voluntary and Unpaid Donation of Blood and Blood Components (COM (2011) 138 final), p. 3.

45 – See, in particular, Resolution of the Parliament of 14 September 1993 on self-sufficiency in and safety of blood and its derivatives in the European Community, point F; Communication COM(94) 652 final, p. 8; Resolution of the Parliament of 17 April 1996 on the communication from the Commission on blood safety and self-sufficiency in the European Community, point 7.

46 – See, in particular, Communication COM(93) 198 final, p. 4, and Communication COM(94) 652 final, p. 8.

47 – See, in particular, Communication COM(93) 198 final, p. 4; Report from the Commission of 21 April 2016 on the implementation of Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for human blood and blood components (COM(2016) 224 final), p. 10.

48 – See also recital 19 of Directive 2001/83 and recital 23 of Directive 2002/98.

49 – See documents cited in footnote 42.

50 – This provision was first introduced into the EU legal order by Article 3(4) of Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma (OJ 1989 L 181, p. 44).

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51 – See written question E-146/95 submitted by José Valverde Lopez (PPE) to the Commission on 8 February 1995, on difficulties with interpretation of the concept of blood self-sufficiency (OJ 1995 C 152, p. 34).

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52 – As regards human blood and human plasma, that objective is clear from Article 110 of Directive 2001/83.

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53 – See, in particular, Resolution of the Parliament of 14 July 1995 on blood safety in the European Union, point 3.

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54 – See point 117 of this Opinion.

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55 – See, in particular, Resolution of the Parliament of 14 September 1993 on self-sufficiency in and safety of blood and its derivatives in the European Community points D and 2; Communication COM(93) 198 final, p. 8; Council conclusions of 13 December 1993 on self-sufficiency in blood in the European Community; Council Resolution of 2 June 1995 on blood safety and self-sufficiency in the Community.

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56 – The Republic of Slovenia adopted this second approach when defining the concept of self-sufficiency provided for in Article 3(18) of the Law on the supply of blood.

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57 – Commission Staff working document of 21 April 2016 on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [SWD(2016) 130 final].

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58 – Ibid., p. 4: ‘National sufficiency means fulfilling the needs of blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country and through regional/international co-operation’. See also the answer to the written question E-146/95, submitted by José Valverde Lopez (PPE) to the Commission on 8 February 1995, on difficulties with interpretation of the concept of blood self-sufficiency (OJ 1995 C 152, p. 34): ‘The concept of Community self-sufficiency implies that patients should always have access to the medicinal products they need’.

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59 – Ibid.: ‘National self-sufficiency means fulfilling the needs of human blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country’s population’. See also Communication COM(93) 198 final, p. 7: ‘Self-sufficiency — Provision of human blood and blood products from within a population to satisfy the clinical needs of that population’.

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60 – See 110 of this Opinion.

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61 – See points 157 to 159 of this Opinion.

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62 – See point 160 of this Opinion.

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63 – On the positive effect of trade between Member States on safety of supply in blood and blood products, see, in particular, Resolution of the Parliament of 14 September 1993 on self-sufficiency in and safety of blood and its derivatives in the European Community, points B and 3(i); Resolution of the Parliament of 14 July 1995 on blood safety in the European Union, point 1; and Resolution of the Parliament of 17 April 1996 on the communication from the Commission on blood safety and self-sufficiency in the European Community, point 1.

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64 – See points 122 to 127 of this Opinion.

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65 – Judgment of 13 March 2014, *Octapharma France* (C-512/12, EU:C:2014:149, paragraph 40): ‘plasma from whole blood which is prepared by a method involving an industrial process and which is intended for transfusions comes, in accordance with Article 109 of Directive 2001/83, within the scope of Directive 2002/98 with respect to its collection and testing, and within the scope of Directive 2001/83, as amended by Directive 2004/27, with respect to its processing, storage and distribution, on condition that it satisfies the definition of a medicinal product under Article 1(2) of the latter directive.’

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66 – See also judgment of 13 March 2014, Octapharma *France* (C-512/12, EU:C:2014:149, paragraphs 38 and 39).