OPINION OF ADVOCATE GENERAL

BOT

delivered on 10 April 2008 [1]

1. This action for failure to fulfil obligations concerns whether the provisions of German law applying when a hospital decides to obtain its supplies of medicinal products from an external pharmacy are compatible with the EC Treaty rules on the free movement of goods.

2. Under German law, a hospital located in Germany may obtain supplies of medicinal products either from an internal pharmacy within the hospital or from a pharmacy in another hospital or from an external pharmacy. In the last two cases the hospital must enter into a contract with the pharmacy concerned, which must agree to carry out all aspects of the supply of medicinal products, that is to say, to make supplies on a regular basis and in emergencies, to give advice to hospital staff on a regular basis and in emergencies, to be involved in selecting medicinal products and to check stocks of medicinal products supplied to the hospital.

3. It is common ground that those cumulative requirements ('the contested requirements') can be met only by a pharmacy in the geographical vicinity of the hospital concerned.

4. The Commission of the European Communities contends that, by maintaining in force that law, which makes it impossible in practice for pharmacies established in other Member States to supply medicinal products to a hospital in Germany, the Federal Republic of Germany has failed to fulfil its obligations under Articles 28 EC and 30 EC.

5. In this Opinion I shall explain in what way the contested requirements, although they should be regarded as selling arrangements within the meaning of *Keck and Mithouard*, [2] constitute a measure having an equivalent effect to a quantitative restriction on imports.

1 — Original language: French.

2 — Joined Cases C-267/91 and C-268/91 [1993] ECR I-6097, paragraph 16.

6. I shall then state that, in the light of the explanations provided by the Federal Republic of Germany, that restriction appears to me to be justified in order to protect public health, so that the present action for failure to fulfil obligations should be dismissed as unfounded.

I — Legal context

7. Under Paragraph 43(1) of the German Arzneimittelgesetz (Law on Medicinal Products), in Germany medicinal products may be sold only by pharmacies, including sales to hospitals and doctors, and purchasing direct from manufacturers or wholesalers is in principle prohibited.

8. The provisions on the supply of medicinal products to hospitals are contained in Paragraph 14 of the German Apothekengesetz (Law on Pharmacies). [3]

3 — The 'ApoG'.

9. Under that paragraph, hospitals have the choice of obtaining their supplies of medicinal products either from an internal pharmacy, that is to say, a pharmacy operating within the hospital and normally not accessible to the public, or from the pharmacy at another hospital, or from an external pharmacy. Where a hospital takes the decision to obtain supplies from the pharmacy at another hospital or from an external pharmacy it must conclude a contract with that pharmacy which is subject to the contested requirements set out in Paragraph 14(4) to (6) of the ApoG.

10. Those provisions, in the version in force since 21 June 2005, read as follows:

'(4) If the body responsible for a hospital intends to obtain supplies for the hospital from the holder of a licence to operate a pharmacy under Paragraph 1(2), or under the laws of another Member State of the European Union or of another State Party to the Agreement on the European Economic Area, it must conclude a contract in writing with that licence-holder. The place of performance of the contractual supplies shall be the address of the hospital. The applicable law shall be German law.

(5) In order to be valid, a contract concluded under subparagraph 3 or 4 must be approved by the competent authority. Approval shall be given where it is established that the hospital has concluded a contract with a pharmacy under subparagraph 3 or 4, for the supply of medicinal products to the hospital, which satisfies the following requirements:

1. proper provision of supplies of medicinal products is be ensured; in particular, the pharmacy must possess the premises, equipment and staff required under the Apothekenbetriebsordnung [Regulation on the Operation of Pharmacies] or, in the case of pharmacies established in another Member State of the European Union or in another State Party to the Agreement on the European Economic Area, under the provisions in force in that State;

2. the pharmacy supplies the hospital with the medicinal products it has ordered directly or, where they are to be sent, in accordance with the requirements laid down in Paragraph 11a;

3. the pharmacy makes available to the hospital without delay and in accordance with what is needed the medicinal products it requires particularly urgently for acute medical treatment;

4. the manager of the pharmacy within the meaning of subparagraph 3 or 4, or the pharmacist of the supplying pharmacy authorised by him, personally advises the hospital staff in accordance with what is needed and, in an emergency, without delay;

5. the supplying pharmacy ensures that it provides hospital staff with advice on a continuous basis with a view to effective and economic pharmacotherapy;

6. the manager of the supplying pharmacy within the meaning of subparagraph 3 or 4, or the pharmacist authorised by him, is a member of the hospital's medicinal products committee.

Authorisation from the competent authority shall also be required for a hospital pharmacy to supply another hospital for which the same body is responsible. The provisions of the second sentence shall apply mutatis mutandis with regard to the grant of such authorisation.

(6) The manager of the hospital pharmacy within the meaning of subparagraph 1, or of a pharmacy within the meaning of subparagraph 4, or a pharmacist authorised by him, must check stocks of the medicinal products at the hospital to be supplied, in accordance with the Regulation on the Operation of Pharmacies, and must in particular in that regard ensure that the medicinal products are of faultless quality and are properly stored. …'

II — The pre-litigation procedure

11. Until it was amended in June 2005, the ApoG contained rules that were known as 'the regional principle', whereby an external pharmacy wishing to conclude a contract to supply medicinal products to a hospital had to be established in the same town or district as that hospital.

12. The Commission had challenged the conformity of that principle with Community law in a letter of formal notice dated 11 July 2003 and in a reasoned opinion dated 19 December 2003.

13. On 4 November 2004 the German Government approved a draft law amending Paragraph 14 of the ApoG in order to enable hospitals also to conclude different supply contracts for medicinal products with a number of pharmacies.

14. However, the Bundesrat (Upper Chamber of the Federal Parliament) declined to approve that draft law on the ground that the supply system for medicinal products at regional level had proved successful as regards quality and safety and that the system had not been shown to be incompatible with Community law. In addition, a majority of the *Länder* opposed the possibility of a hospital concluding separate contracts with different suppliers. That is why Paragraph 14 of the ApoG was amended with effect from 21 June 2005 to read as above.

15. On 18 October 2005 the Commission sent a further letter of formal notice to the Federal Republic of Germany, in which it stated that the contested requirements imposed on suppliers under the new version of Paragraph 14 of the ApoG were equivalent to maintaining the regional principle in a disguised form.

16. By letter of 14 December 2005 the Federal Republic of Germany argued that the contested requirements, designed to assign to a single supplier all the aspects of supplying medicinal products to a hospital, were authorised selling arrangements and, in the alternative, that they were justified in order to protect public health, in accordance with Article 30 EC.

17. The Commission sent the Federal Republic of Germany a reasoned opinion dated 10 April 2006, in which it maintained its criticisms and rebutted that Member State's arguments.

18. The Federal Republic of Germany replied to the Commission by letter of 2 June 2006, stating that its position was unchanged.

III — Procedure before the Court of Justice and forms of order sought

19. The Commission brought the matter before the Court by application of 9 March 2007. The Federal Republic of Germany lodged its defence on 21 May 2007. The Commission lodged its reply on 10 July 2007 and the Federal Republic of Germany lodged its rejoinder on 15 August 2007. The parties did not request a hearing.

20. The Commission claims that the Court should:

— declare that, by providing in Paragraph 14(5) and 14(6) of the ApoG that a contract to supply medicinal products is subject to cumulative requirements which make it impossible in practice for pharmacies in other Member States to supply medicinal products to a hospital in Germany on a regular basis, the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC and Article 30 EC;

— order the Federal Republic of Germany to pay the costs.

21. The Federal Republic of Germany contends that the Court should dismiss the application and order the Commission to pay the costs.

IV — Arguments of the parties

A — *The Commission*

1. Application of Article 28 EC

22. The Commission contends that the contested requirements fall within the scope of Article 28 EC, that they constitute a measure having an equivalent effect to a quantitative restriction on imports, and that that restriction is not justified.

23. The Commission states that, as Community law now stands, the sale of medicinal products is subject to harmonisation only in limited areas. Although Member States may therefore legislate in the other areas, they must none the less comply with the rules of the Treaty, in particular those relating to the free movement of goods, irrespective of the provisions of Article 152 EC.

24. The fact noted by the Federal Republic of Germany that in some other Member States only an internal pharmacy may supply medicinal products to a hospital does not reduce the scope of that requirement once the Federal Republic has made provision for an external pharmacy to provide such supplies.

2. A measure having an equivalent effect to a quantitative restriction on imports

25. The Commission states that the contested requirements laid down in Paragraph 14(5) and (6) of the ApoG are selling

arrangements within the meaning of *Keck and Mithouard*. It considers that those requirements none the less fall within the scope of Article 28 EC because they affect medicinal products from other Member States more severely than medicinal products of national origin.

26. Thus the Commission argues that several of the contested requirements imposed on external pharmacies, such as speedy delivery of medicinal products in accordance with what is needed, the task of advising hospital staff in an emergency, membership of the hospital's medicines committee and checking the hospital's stocks of medicinal products, require such pharmacies to be located in the close geographical vicinity of the hospital being supplied.

27. Requiring a single supplier to fulfil all these requirements therefore has the effect of excluding pharmacies from other Member States from access to the market for supplying medicinal products to German hospitals, and hence of preventing medicinal products from those other Member States from having access to that market.

28. The contested requirements imposed by the ApoG therefore constitute a measure having an equivalent effect to a quantitative restriction on imports. This view is not altered by the fact that those requirements also penalise pharmacies located in Germany a long distance from the hospital to be supplied or by the fact that a local supplier can buy the necessary medicinal products from a foreign wholesaler.

29. The Commission also rejects as irrelevant the Federal Republic of Germany's argument that pharmacies established in other Member States do not, as a rule, have sufficient stocks of medicinal products authorised in Germany.

3. No justification

30. The Commission states that the burden of proof in justifying a restriction on a ground referred to in Article 30 EC or on the ground of an overriding reason of public interest falls on the Member State which is claiming that justification.

31. It notes first of all that it convinced the Federal Republic of Germany of the need to abolish the regional principle applying up until June 2005 and that, in the draft law forwarded to it by that Member State in November 2004, the principle of concentrating all the aspects of a contract for supplying medicinal products to a hospital in a single supplier had been abandoned.

32. The Commission also states that the two grounds on which the Federal Republic of Germany maintains that the contested requirements are justified in order to protect public health are unfounded.

33. As regards, first, the need for a single pharmacy to supply medicinal products to a hospital, the Commission maintains that it does not challenge that requirement. It simply challenges the fact that only a local pharmacy can conclude a supply contract with a hospital. Hospitals should be able to decide themselves whether to assign the provision of normal supplies, the provision of emergency supplies, the checking of stocks of medicinal products and the provision of advice to hospital staff to a single pharmacy.

34. As regards, second, the need for a comprehensive supply contract for medicinal products, the Commission states that the Federal Republic of Germany's argument that the complexity of supplying medicinal products to hospitals does not allow there to be more than one person responsible for the various aspects of such provision, in particular the supplying of medicinal products and the checking of stocks of medicinal products, is unfounded. It justifies its position as follows.

35. To begin with, there would be no deterioration in the quality of the provision of such supplies if the provision of normal supplies were separated from the provision of emergency supplies. In the Commission's view, a decisive factor in the quality of the provision of emergency supplies is the speed at which the medicinal product required can be delivered, so that there is no need to link the provision of emergency supplies compulsorily with other aspects of the supply of medicinal products to hospitals.

36. Next, there would be no deterioration in the quality of the provision of such supplies if the provision of normal supplies were separated from the selection of medicinal products. The Commission accepts that a hospital needs the advice of a pharmacist in selecting its medicinal products, but it does not understand why he should be the pharmacist supplying those products. The latter

should in any event check the quality of his products.

37. Likewise, there would be no deterioration in the quality of the provision of supplies of medicinal products to a hospital if the supply of medicinal products were separated from the checks on stocks of medicinal products. The Commission considers that such separation would, on the contrary, lead to optimum quality being achieved in both activities.

38. Lastly, there would be no deterioration in the quality of the provision of such supplies were hospital staff to be given advice by telephone. The Commission contends that giving advice on the spot, as point 4 of Paragraph 14(5) of the ApoG requires, is not needed in order to achieve a high level of quality. It points out in that regard that in *Deutscher Apothekerverband* [4] the Court of Justice agreed that medicinal products could be sold to patients via the internet, thus dismissing the idea that the absence of advice given in person might endanger their safety. This view, according to the Commission, applies a fortiori in the case of specialist hospital staff, especially since responsibility for the use of medicinal products always lies with the doctor. Moreover, a pharmacist, even one located in the vicinity of the hospital, must spend most of his time in his own dispensary and not at the hospital.

B — *The Federal Republic of Germany*

39. The Federal Republic of Germany points out, first of all, that the present proceedings originate, not in a complaint from a pharmacy established in another Member State which is prevented from supplying its products in Germany, but from a company which runs several hospitals in Germany through its subsidiaries and wishes to be able to supply them all through a single pharmacy.

40. It also maintains that the purpose of the contested requirements laid down in Paragraph 14 of the ApoG is to ensure that hospitals are supplied with high-quality medicinal products and that the requirements should be assessed in the light of the fact that, in a large number of other Member States, provision of such supplies is restricted to an internal pharmacy.

4 — Case C-322/01 [2003] ECR I-14887, paragraph 113.

41. The Federal Republic of Germany contends in its defence that the contested requirements do not constitute a restriction on the free movement of goods and, in the alternative, that such a restriction is justified in order to protect public health.

1. No restriction on the free movement of goods

42. The Federal Republic of Germany states, first, that the contested requirements do not constitute a measure having an equivalent effect to a quantitative restriction on imports and, second, that it is not for the Commission to require a Member State, under cover of Article 28 EC, to amend legislation that falls within the powers of that Member State.

(a) No measure having an equivalent effect

43. The Federal Republic of Germany maintains that the two requirements laid down in *Keck and Mithouard*, whereby selling arrangements do not fall within Article 28 EC, are met.

44. On one hand, the contested requirements are applicable without distinction. On the other hand, they do not hinder access to the market for medicinal products from other Member States any more than access for domestic medicinal products, on the following grounds:

— Pharmacies established in other Member States, as a rule, do not stock medicinal products covered by a marketing authorisation for Germany, so the fact that they do not sell many medicinal products in that Member State is not attributable to Paragraph 14 of the ApoG.

— Foreign pharmacies could perfectly well deliver medicinal products to a hospital's internal pharmacy or to an external pharmacy meeting the contested requirements.

— Foreign pharmacies could conclude a supply contract with a German hospital where the contested requirements are met, which presupposes that they are located in the vicinity of that hospital.

— The sale of medicinal products from other Member States is not affected to a greater extent than the sale of medicinal products from regions of Germany that are distant from the hospital being supplied.

— Article 28 EC does not require pharmacies of other Member States to be able to supply medicinal products directly to the hospitals of a Member State. That contention is contradicted by the fact that in many Member States medicinal products may be supplied to hospitals only by internal pharmacies and by the case-law whereby a State monopoly in the sale of medicinal products can be compatible with Community law. [5]

5 — The Federal Republic of Germany cites Case C-438/02 *Hanner* [2005] ECR I-4551.

(b) Article 28 EC does not affect the powers of Member States in public health matters

45. The Federal Republic of Germany notes that, according to Article 152(5) EC, European Community action in the field of public health must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. It states that the contested requirements were laid down under a basic legislative provision, adopted in response to the difficulties experienced earlier in supplying medicinal products to hospitals.

2. Justification on the ground of protecting public health

46. The Federal Republic of Germany states that the contested requirements are designed to ensure reliable and high-quality supplies by assigning to a single pharmacy responsibility for all the tasks involved in supplying medicinal products to hospitals.

47. It contends that to separate those tasks and have them coordinated by the hospital management would not ensure such a high level of quality. It puts forward the following arguments in that regard.

(a) Separation of provision of normal supplies from provision of emergency supplies

48. The Federal Republic of Germany states that a hospital which takes the decision to obtain its supplies of medicinal products from an external pharmacy does so mainly in order to ensure effective provision of supplies with low storage costs and low stocks of medicinal products. That hospital will, therefore, order the medicinal products it needs for each patient in the quantities required, so there is not really any distinction between emergency supplies and normal supplies, which also require speedy and frequent delivery.

49. Moreover, the selection of medicinal products needed in an emergency requires knowledge of the hospital's stock and also requires a system of coordination if the hospital uses various suppliers.

50. It is also important that the pharmacist called upon to supply a medicinal product in an emergency should know what other medicinal products the patient concerned has taken in order to avoid incompatibilities.

51. Moreover, the stock of medicinal products needed to supply a hospital is different from that of a 'normal' pharmacy. The Federal Republic of Germany names several medicinal products which a hospital would need but which a 'normal' pharmacy would not keep in stock.

52. Therefore, in the view of that Member State, linking provision of normal supplies to provision of emergency supplies ensures that the necessary medicinal products are available and that hospitals have more effective and better targeted provision of supplies of medicinal products.

(b) Separation of the provision of normal supplies from the selection of medicinal products

53. The Federal Republic of Germany states that the pharmacist responsible for supplying a hospital with the medicinal

products chosen by its medicines committee may negotiate prices and thus ensure better financial management if he is also in charge of selecting them on the market.

(c) Separation of the provision of normal supplies from the checking of a hospital's stocks of medicinal products

54. Assigning the checking of stocks of medicinal products to the pharmacist who supplies such products to the hospital ensures better stock control, because that pharmacist knows precisely which products he has supplied.

55. In connection with such checking, that pharmacist is also better informed by the hospital staff about any issues relating to obtaining supplies of medicinal products and to the use, selection and dosage of such products.

(d) The need to advise hospital staff

56. Practice shows that even doctors need advice on pharmaceutical matters. Personal contact between a pharmacist and hospital teams enables the pharmacist to be a member of the treatment team and to improve the safety of medicinal products while optimising the success of the treatment provided. This personal contact cannot be replaced by giving advice over the telephone in individual cases. Moreover, the presence of the pharmacist in person is particularly essential in emergency cases.

(e) The synergy between supplying medicinal products, advising hospital staff and checking stocks of medicinal products

57. The principle of a single supplier providing supplies of medicinal products to a hospital also gives optimum synergy between the supply of medicinal products, advice to hospital staff and the checking of stocks of medicinal products. This principle has proved its effectiveness, and has resolved the problems in connection with supplying medicinal products to hospitals which existed up to 1980.

V — Analysis

A — *Application of Article 28 EC*

58. As the Commission states first of all, the compatibility with Community law of the contested requirements laid down in Paragraph 14 of the ApoG must be assessed against the yardstick of the Treaty provisions relating to the free movement of goods.

59. First, the supplying of medicinal products to hospitals has not been the subject of legislation or even harmonisation within the Union. [6] Those conditions should therefore be considered in the light of the freedoms of movement provided by the Treaty. [7]

60. Second, the contested requirements may affect whether it is possible for a German hospital to purchase medicinal products from a pharmacy located in another Member State. Moreover, even though those requirements apply to the service of selling between a pharmacy and a German hospital and impose a number of service obligations on the pharmacy, the requirements mainly determine the way in which medicinal products may be supplied to a hospital by an external pharmacy. The contested requirements are therefore likely to affect mainly the free movement of goods. [8]

B — *The existence of a restriction*

61. I share the Commission's view that the contested requirements constitute a measure having an equivalent effect to a quantitative restriction on imports prohibited by Article 28 EC.

6 — The movement of medicinal products within the Union was facilitated by the adoption of a number of directives which harmonised the conditions for issuing a national marketing authorisation and the rules applying to wholesale distribution, classification of medicinal products, labelling and advertising. The content of those directives was combined in 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). The Community legislature also instituted a Community marketing authorisation, valid in all Member States, which is currently governed by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1). Lastly, the free movement of medicinal products was also facilitated by the adoption in 1985 of directives laying down the minimum level of training for pharmacists and the range of occupational activities they may pursue. Those directives were replaced by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22).

7 — See, to that effect, *Deutscher Apothekerverband*, paragraph 102.

8 — See, to that effect, Case C-36/02 *Omega* [2004] ECR I-9609, paragraph 26 and case-law cited.

62. First, those requirements should be regarded as selling arrangements which affect the marketing of medicinal products from other Member States more than the marketing of domestic medicinal products. Second, that view, in my opinion, does not have the effect of undermining the powers of the Federal Republic of Germany in public health matters and the provisions of Article 152 EC. I will deal with these two points in turn.

1. The existence of a measure having an equivalent effect to a quantitative restriction on imports

63. The free movement of goods is a fundamental principle guaranteed by the Treaty, which is expressed in the prohibition, laid down in Article 28 EC, on quantitative restrictions on imports between Member States and all measures having an equivalent effect. [9] That prohibition of measures having an equivalent effect to quantitative restrictions is very broad since, according to case-law, it applies to all legislation of the Member States that is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade. [10]

64. Of course, in *Keck and Mithouard* the Court limited the scope of that case-law by excluding from the scope of Article 28 EC measures that relate not to the properties of the product concerned but to the selling arrangements, so long as those measures apply irrespective of the product concerned and affect in the same manner, in law and in fact, the marketing of domestic products and that of products from other Member States. [11]

65. Like both parties in the case, I am of the view that the contested requirements should be regarded as selling arrangements within the meaning of that judgment. Those requirements do not concern the properties of medicinal products but the requirements that an external pharmacy must comply with under a contract for the supply of medicinal products concluded with a hospital. Those requirements therefore lay down the procedure under which medicinal products may be sold. [12]

9 — Case C-147/04 *De Groot en Slot Allium and Bejo Zaden* [2006] ECR I-245, paragraph 70.

10 — Case C-170/04 *Rosengren and Others* [2007] ECR I-4071, paragraphs 31 and 32.

11 — *Keck and Mithouard*, paragraph 16.

12 — See, to that effect, Case C-254/98 *TK-Heimdienst* [2000] ECR I-151, paragraph 24.

66. It is also common ground that the contested requirements apply indiscriminately, since they make no distinction between pharmacies according to the Member State in which they are located.

67. However, those requirements hinder the marketing of medicinal products from other Member States more than the marketing of domestic medicinal products, for the following reasons.

68. As the Commission has shown, and as the Federal Republic of Germany has expressly acknowledged, the requirement that an external pharmacy should undertake, using its own resources, all aspects of supplying medicinal products can be met only by operators who are located in the vicinity of the hospital being supplied.

69. The contested requirements therefore oblige a pharmacist operating a pharmacy in another Member State who seeks to conclude a contract for the supply of medicinal products with a German hospital to relocate his dispensary and set it up in the vicinity of that hospital or to open another pharmacy in the area. Such measures, therefore, require foreign pharmacies to bear costs and overcome difficulties which are not encountered by operators that are already located in the vicinity of that hospital. It can therefore be deduced from this that the effect of the contested requirements is to hinder more seriously the marketing of medicinal products from other Member States.

70. The Federal Republic of Germany raises a number of arguments against this position, which to my mind do not alter it.

71. That Member State thus contends, first, that a foreign pharmacy can conclude a contract for the supply of medicinal products with a German hospital if it meets the contested requirements and, second, that the sale of medicinal products from other Member States is not affected to a greater extent than the sale of medicinal products from other parts of Germany that are distant from the hospital being supplied.

72. These arguments do not affect the existence of the barrier resulting from the contested requirements. In *TK-Heimdienst*,

the Court was faced with similar arguments concerning legislation of a Member State which created the same geographical partitioning as those requirements.[13] It noted that, for a national measure to be categorised as discriminatory or protective for the purposes of the rules on the free movement of goods, it is not necessary for it to have the effect of favouring national products as a whole or of placing only imported products at a disadvantage and not national products.[14]

73. In other words, the contested requirements, like the legislation at issue in *TK-Heimdienst*, constitute a restriction within the meaning of Article 28 EC because they have the effect of partitioning the market concerned, which is, by nature, contrary to the common market, that is to say, an internal market characterised in particular by the abolition, as between Member States, of obstacles to the free movement of goods.[15]

74. The Federal Republic of Germany also disputes the existence of a barrier to the marketing of medicinal products from other Member States, on the ground that the pharmacies of those States, as a rule, do not stock medicinal products covered by a marketing authorisation for Germany.

75. That argument does not seem to me to be acceptable either. Certainly, at the present state of Community law no industrially produced medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State or by the European Medicines Agency (formerly the European Agency for the Evaluation of Medicinal Products).[16] In order for a pharmacy located in another Member State to be able to supply medicinal products to a German hospital, that pharmacy must, therefore, stock a sufficient quantity of medicinal products authorised in Germany.

76. However, the fact that foreign pharmacies do not, as a rule, stock a sufficient quantity of such medicinal products does not remove the restriction in question.

13 — The legislation provided that bakers, butchers and grocers could make sales on rounds in a given administrative district only if they also traded from a permanent establishment where they offered for sale the same goods as they did on rounds, located in that administrative district or an adjacent municipality or, in some circumstances, in another Member State.

14 — *TK-Heimdienst*, paragraph 27. That interpretation of the scope of Article 28 EC had already been given in Joined Cases C-1/90 and C-176/90 *Aragonesa de Publicidad Exterior and Publivía* [1991] ECR I-4151, paragraph 24.

15 — Article 3(1)(c) EC.

16 — Articles 2 and 6(1) of Directive 2001/83.

77. It is settled case-law that Article 28 EC applies to measures that are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade. [17] Classification of a measure as a measure having an equivalent effect to a quantitative restriction on imports does not therefore require verification that a foreign undertaking has actually been prevented from exporting its products to the Member State concerned. It is sufficient that the contested measure is capable of hindering intra-Community trade without it being necessary to prove that it has had an appreciable effect on trade within the Union. [18]

78. That case-law is relevant in the present case because, although medicinal products are not ordinary products in view of their effects on human health, they none the less constitute goods for the purposes of Article 28 EC, that is to say, products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions. [19] The scope of that article, in so far as they are concerned, is no less than with regard to any other goods within the meaning of that article.

17 — See, in particular, *Deutscher Apothekerverband*, paragraph 66 and case-law cited.

18 — Case C-166/03 *Commission* v *France* [2004] ECR I-6535, paragraph 15.

19 — Case 7/68 *Commission* v *Italy* [1968] ECR 423, 428.

79. Lastly, the Federal Republic of Germany denies the existence of a barrier to the intra-Community trade in medicinal products on the ground that a foreign pharmacy could perfectly well deliver medicinal products to a hospital's internal pharmacy or to an external pharmacy meeting the contested requirements. According to that Member State, Article 28 EC does not require that pharmacies of other Member States should be able to deliver medicinal products directly to the hospitals of another Member State. That view, it says, is in contradiction to the fact that in many Member States only an internal pharmacy is allowed to supply a hospital with medicinal products and to the case-law whereby a State monopoly in the trade in medicinal products may be compatible with Community law.

80. Those arguments do not seem to me to be well founded. Certainly, Article 28 EC does not in my view preclude the hospitals of Member States being supplied with medicinal products exclusively by an internal pharmacy. It does not in itself require Member States to provide that their hospitals should also be able to obtain supplies of medicinal products directly from pharmacies located in other Member States. However, the situation is different when a Member State provides in its legislation that its hospitals may also obtain such supplies from an external pharmacy, that is to say, from a pharmacy that is a third party in relation to the hospital.

81. From the time that a Member State, in the exercise of its sovereign powers, decides that supplies of medicinal products for hospitals may be obtained under a contract with a person who is a third party in relation to a hospital, it opens up that activity to the market. It is therefore required to comply with the Community rules relating to the common market and, in particular, the fundamental freedoms of movement.

82. That does not mean, however, that that Member State is deprived of its regulatory powers and that any restriction on the exercise of those fundamental freedoms is necessarily contrary to the Treaty. In other words, the Member State is not left in an all or nothing situation where either medicinal products must be supplied by an internal pharmacy or they may be supplied from a source left to the discretion of each hospital.

83. The rules surrounding the exercise of its reserved powers mean that if its legislation causes a restriction of one of the fundamental freedoms of movement it must be in a position to provide a legitimate reason, given in the Treaty or recognised as an overriding reason of public interest, to justify this. A Member State which provides that supplies of medicinal products for hospitals may also be obtained from an external pharmacy, and which imposes requirements in this regard that have the effect of partitioning the market, must therefore be able to justify the need for such partitioning.

84. This view also conforms to settled case-law.

85. According to that case-law, since harmonisation of national laws with regard to the distribution of medicinal products remains incomplete, Member States are entitled to adopt measures in this field designed to protect public health. However, the Court has consistently held that national rules or practices liable to have a restrictive effect, or having such an effect, on imports of medicinal products are compatible with the Treaty only to the extent to which they are necessary for the effective protection of human health and life. [20]

20 — Case 215/87 *Schumacher* [1989] ECR 617, paragraph 18, and *Deutscher Apothekerverband*, paragraph 104.

86. Lastly, this view does not conflict with the exercise by Member States of their reserved powers in public health matters and the provisions of Article 152 EC.

2. No effect on the reserved powers of the Member States in public health matters and the provisions of Article 152 EC

87. I cannot agree with the Federal Republic of Germany when it argues that the Commission's action seeking a declaration that the contested requirements are contrary to Article 28 EC is a way of circumventing the limits of Community action in the field of public health laid down in Article 152 EC.

88. That article determines the legislative powers of the Community in public health matters. As the Community only has the powers that have been conferred on it, the High Contracting Parties limited its powers in that field by providing in that article that it may only complement the Member States' action and that its action must fully respect the responsibilities of the Member States for the delivery of health services and medical care.

89. However, that limitation on the Community's legislative powers in the field of public health does not affect the Member States' obligation, confirmed by settled case-law, to comply with the Treaty rules, in particular the freedoms of movement, when they exercise their reserved powers. [21] In other words, Article 152 EC cannot have the effect of excluding public health from the scope of the Treaty rules on freedom of movement.

90. The Commission, which has the task under Article 211 EC of ensuring that the provisions of the Treaty are applied, is therefore acting quite correctly if it brings proceedings against a Member State for failure to fulfil its obligations, where it considers that the legislation of that State concerning the

21 — See, in particular, with regard to direct taxation, Case C-196/04 *Cadbury Schweppes and Cadbury Schweppes Overseas* [2006] ECR I-7995, paragraph 40; with regard to criminal matters, Case 186/87 *Cowan* [1989] ECR 195, paragraph 19; and with regard to public security, Case C-285/98 *Kreil* [2000] ECR I-69, paragraphs 15 and 16.

provision of supplies of medicinal products to hospitals is affecting the free movement of goods.

91. Such action does not constitute misuse of Article 152 EC because it does not allow the Commission or the Court to take the place of the Member State concerned and impose one outcome rather than another on the latter. It cannot therefore be compared to the exercise of a legislative power. It merely has the effect of circumscribing the exercise by that State of its reserved powers in public health matters by specifying the limits which stem from the freedoms of movement which all the Member States have undertaken to respect by entering into and then ratifying the Treaty. [22]

92. It is in the context of examining the justification for the contested requirements that the powers of the Federal Republic of Germany in public health matters will be taken into account, in particular under the case-law whereby, in the absence of common or harmonised rules, it is for each Member State to decide on the degree of protection which it wishes to afford to public health and on the way in which that protection is to be achieved, while observing the principle of proportionality. [23] In particular, it is in that context that the Federal Republic of Germany's argument that in a number of Member States medicinal products are supplied to hospitals exclusively by internal pharmacies will be taken into consideration. [24]

93. Therefore, as the Commission contends, since the contested requirements constitute a restriction on the free movement of goods within the meaning of Article 28 EC they should be declared incompatible with Community law if that restriction is not justified on one of the grounds laid down in Article 30 EC or by an overriding reason of public interest. I shall now demonstrate why that restriction is justified.

22 — Case 6/64 *Costa* [1964] ECR 585, 593 and 594.

23 — See, to that effect, *Aragonesa de Publicidad Exterior and Publivía*, paragraph 16.

24 — This way of reasoning applies with regard to all the freedoms of movement and all economic activities. For example, in the field of betting the Court accepted that moral, religious or cultural factors, as well as the morally and financially harmful consequences for the individual and for society associated with betting and gaming, might serve to justify a margin of discretion for the national authorities, sufficient to enable them to determine what is required in order to ensure consumer protection and the preservation of public order. However, it was in the context of considering justification of the restriction on freedom of establishment and freedom to provide services caused by the national legislation in question that the Court took into consideration that discretion of the Member States (Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraphs 47 and 48).

C — *Justification for the restriction*

94. The Federal Republic of Germany contends that the restriction on intra-Community trade in medicinal products caused by the contested requirements is justified in order to protect public health. Those requirements are designed to ensure that the provision of supplies of medicinal products to hospitals from external pharmacies is reliable and of high quality.

95. I consider that justification to be acceptable in the light of the arguments put forward by the parties.

96. According to case-law, a restriction on the free movement of goods may be justified on one of the grounds referred to in Article 30 EC or by an overriding reason of public interest, provided that the measure concerned is appropriate for securing the attainment of the objective pursued and does not go beyond what is necessary in order to attain it. [25]

97. The first of these requirements does not raise any difficulties. The protection of public health ranks foremost among the interests protected by Article 30 EC. [26] Moreover, the Commission does not dispute that the contested requirements, which are designed to assign to a single supplier all aspects of supplying medicinal products to hospitals, are appropriate for ensuring reliable and high-quality supplies and hence for protecting public health.

98. The second requirement is the one at the centre of this dispute.

99. A restriction on intra-Community trade in medicinal products can be justified in order to protect public health only if the measure in question observes the principle of proportionality. Under that principle, in order for the ground of justification to apply, it is necessary that the protection of human health and life cannot be achieved by less extensive prohibitions or restrictions, or by prohibitions or restrictions having less effect on intra-Community trade. [27] Moreover, as the Commission quite rightly points out, it

25 — Case C-254/05 *Commission* v *Belgium* [2007] ECR I-4269, paragraph 33 and case-law cited.

26 — *Deutscher Apothekerverband*, paragraph 103.

27 — *Rosengren and Others*, paragraph 43.

is for the Member State whose legislation is at issue to demonstrate that that principle is observed. [28]

100. Unlike the Commission, I think that the explanations provided by the Federal Republic of Germany in that regard are convincing. I base my view on the following three considerations.

101. First, it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection of public health they wish to ensure. [29]

102. The Federal Republic of Germany is therefore entitled to make provision that in any hospital a pharmacist must assist in the distribution of medicinal products to hospital patients, within the context of providing advice on a regular basis to hospital staff and, where appropriate, when medical treatment must be administered in an emergency.

103. It should be noted in that regard that the work of a pharmacist does not consist solely in distributing medicinal products. Under the provisions of Article 45 of Directive 2005/36, which repeated Article 2 of Council Directive 85/432/EEC, [30] it also includes the provision of information and advice on medicinal products.

104. Therefore, even though, as the Commission observes, it is the doctor who assumes responsibility in individual cases for the use of the medicinal products he has prescribed, it is still the case that the pharmacist has a competence of his own, namely to give information and advice. On that basis he is required to provide appropriate advice for the proper use of those medicinal products and must, where necessary, point out any error in the prescription. That particular competence of pharmacists provides justification for the monopoly in the distribution of medicinal products to the public which they enjoy in several Member States.

28 — Ibid., paragraph 50.

29 — *Deutscher Apothekerverband*, paragraph 103 and case-law cited.

30 — Directive of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (OJ 1985 L 253, p. 34).

105. A Member State is entitled, in the exercise of its sovereign powers in the field of public health, to decide that such advice and supervision on the part of a pharmacist must also be assured for all hospital patients, irrespective of the type of hospital and its specialisations.

106. The way in which this assurance is provided clearly varies according to the size of each hospital and its specialisations. It may be assumed that it is provided to a lesser extent in a hospital specialising in geriatric medicine, caring for elderly people whose needs for medicinal products are stable and well known to the medical staff, than in a hospital specialising in cardiovascular surgery or dealing with medical emergencies.

107. However, in all situations I am of the view that the effective way of carrying out this duty of giving advice and supervising the proper use of medicinal products requires the pharmacist to go to the hospital in person on a regular basis and according to a schedule worked out for each hospital.

108. Unlike the Commission, I consider that the situation is not comparable to that of distributing medicinal products to the public. In the latter situation, a patient who has been prescribed treatment by his doctor and who then goes to his pharmacist is in a position to understand and put into practice the advice the pharmacist gives him. On the other hand, in a hospital, medicinal products are administered by the nursing staff and the patient is most often in a completely passive situation.

109. Consequently, in order for the pharmacist to carry out this duty to give advice and supervise the proper use of medicinal products in a hospital environment effectively, he must be able to familiarise himself with each patient's situation. The pharmacist, as the Federal Republic of Germany contends, must form an integral part of the treatment team. Otherwise, if intervention by the pharmacist were to be limited to providing advice over the telephone, his role would be restricted merely to cases in which a hospital doctor or a member of the nursing team had doubts about the use of a medicinal product.

110. If an external pharmacist is to carry out this duty of providing advice and supervision, he must therefore be present at the hospital

in person on a regular basis and be available in an emergency. The logical assumption therefore is that he carries on his business in the vicinity of the hospital, since, as the Commission points out, he must also be present in his dispensary in order to be able to attend to the public.

111. Second, the Federal Republic of Germany is correct, in my view, in arguing that it is difficult to separate the selection of medicinal products from the provision of advice to hospital staff.

112. The list of medicinal products authorised in a Member State is much more extensive than the list of medicinal products that a hospital actually needs. A hospital's needs are limited to the diseases it is called upon to treat. Moreover, a large number of medicinal products have identical or comparable properties. Consequently, any hospital, for the sake of good management, must select the medicinal products needed for its areas of specialisation and avoid unnecessary ordering of a number of medicinal products having the same properties.

113. The Commission does not dispute that in order to select its medicinal products a hospital needs the help of a pharmacist with a detailed knowledge of what that hospital requires. It is therefore the pharmacist whose job it is to provide advice on the use of medicinal products within the hospital who would appear to be the best person to be aware of precisely what the hospital's needs are and to take part in the process of selecting medicinal products.

114. Third, I share the Republic of Germany's opinion that the functions of supplying medicinal products and checking a hospital's stocks of medicinal products, on the one hand, and those of advising hospital staff and selecting medicinal products, on the other hand, cannot be separated either. I base my view on two complementary reasons, the first functional and the second economic.

115. At the functional level, I share the view of the Federal Republic of Germany that the pharmacist who would appear to be the best placed to provide advice in order to ensure the proper use of medicinal products and supervise that use is the one who has supplied or dispensed them.

116. Similarly, the external pharmacist who would appear to be the best placed to supply a hospital with all the necessary medicinal products and to keep in his dispensary adequate stocks to meet the hospital's needs in all circumstances would appear to be the person who provides advice to the medical staff and takes part in the process of selecting medicinal products, since he is well acquainted with the needs of the hospital to be supplied.

117. Like the Federal Republic of Germany, I am of the view that those different functions are complementary and that, from the functional point of view, it is more rational to assign them to the same professional.

118. This view also applies as regards the function of checking a hospital's stocks of medicinal products. As the Federal Republic of Germany explains, a hospital which takes the decision to obtain its supplies from an external pharmacy does so primarily in order to free itself of the burden of having to stock large quantities of medicinal products on its own premises. It is therefore the external pharmacy which has to have sufficient stocks of medicinal products to be able to meet the needs of that hospital in all circumstances. Consequently, it is that pharmacy which is best placed to carry out regular checks on the quality and storage of such products.

119. As the Federal Republic of Germany states, there is a synergy between supplying medicinal products, advising hospital staff and checking stocks.

120. At the economic level, it is important to take into consideration the fact that the activity of providing advice forms an integral part of the pharmacist's job when he issues a medicinal product to a patient. It does not involve additional payment.

121. Where a hospital takes the decision to obtain all its supplies of medicinal products from an external pharmacy, the staff of that pharmacy must undertake the task of providing advice within that hospital, including in emergencies, with the availability constraints which that involves, and the other tasks of selecting medicinal products and checking stocks of medicinal products within the dispensary and at the hospital, because those tasks may be regarded as forming an integral part of the service of supplying medicinal products. The cost

of those additional tasks is included in the selling price of the medicinal products. They should not therefore give rise to any special payment. However, it is difficult to see how this could be done if the external pharmacist responsible for carrying out those additional tasks were not the one supplying the hospital with all its medicinal products.

122. In reality the hospital concerned would be forced to employ a pharmacist to carry out these tasks specially, which, because of the additional charges inherent in such recruitment, would offset to a great extent the advantage of using an external pharmacist.

123. Of course, in principle, aims of a purely economic nature cannot justify a barrier to the fundamental principle of the free movement of goods. [31] However, in the field of public health the Court has accepted that derogations from that principle may be allowed where interests of an economic nature concern maintaining a balanced medical and hospital service open to all, [32] in particular the maintenance of treatment capacity or medical competence on national territory. [33]

124. It has acknowledged in that regard that a Member State must be able to plan the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are equipped, and also the nature of the medical services which they are able to offer. Such planning, as a general rule, ensures that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. It also assists in controlling costs and preventing, as far as possible, any wastage of financial, technical and human resources. [34]

125. Such wastage, in the view of the Court, would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied. [35]

126. I am of the view that those considerations may be applied to the present case and that the Federal Republic of Germany was right to state that supplying a hospital with medicinal products could not be separated

31 — Case C-120/95 *Decker* [1998] ECR I-1831, paragraph 39.

32 — Case C-444/05 *Stamatelaki* [2007] ECR I-3185, paragraph 31 and case-law cited.

33 — Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraph 67 and case-law cited.

34 — Ibid., paragraphs 77 to 80.

35 — Ibid., paragraph 80.

from the other tasks of advising hospital staff, selecting medicinal products and checking the hospital's stocks of medicinal products in order to ensure a high level of protection for public health while maintaining a rational supply of healthcare.

127. Moreover, I find nothing in the documents before the Court to suggest that the contested requirements constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States, within the meaning of the second sentence of Article 30 EC, as interpreted in *Henn and Darby*.[36] It does not appear that the public health ground relied on to justify the contested requirements has been diverted from its purpose and used in such a way as to discriminate against goods originating in other Member States or indirectly to protect certain national products.

128. Hence, the requirement for a single supplier to take on all the aspects of supplying medicinal products to a hospital and the requirement of geographical proximity stemming from this are, in my view, justified on the ground of protection of public health. It also seems to me that the fact that in a number of Member States medicinal products are supplied to hospitals exclusively by internal pharmacies confirms this view.

129. Against this, the Commission also argues that it does not object to a hospital being able to make such requirements. It considers, however, that hospitals should be able to decide themselves whether to assign to a single pharmacy provision of normal supplies, provision of emergency supplies, checks on stocks of medicinal products and provision of advice for hospital staff.

130. I do not share that point of view. As I said above, a Member State is entitled to determine the level of health protection it intends to provide in its territory. The Federal Republic of Germany is therefore entitled to require that the same level of protection is ensured in all hospitals.

131. I therefore propose that the Court should dismiss the Commission's action for failure to fulfil obligations as unfounded and order the Commission to pay the costs, under Article 69(2) of the Rules of Procedure.

36 — Case 34/79 [1979] ECR 3795, paragraph 21.

VI — Conclusion

132. In view of the foregoing considerations, I propose that the Court should dismiss the present action for failure to fulfil obligations as unfounded and order the Commission of the European Communities to pay the costs.