

JUDGMENT OF THE COURT (Fourth Chamber)

11 September 2008^{*}

In Case C-141/07,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 9 March 2007,

Commission of the European Communities, represented by B. Schima, acting as Agent, with an address for service in Luxembourg,

applicant,

v

Federal Republic of Germany, represented by M. Lumma and C. Schulze-Bahr, acting as Agents,

defendant,

^{*} Language of the case: German.

THE COURT (Fourth Chamber),

composed of K. Lenaerts, President of the Chamber, R. Silva de Lapuerta, E. Juhász, J. Malenovský (Rapporteur) and T. von Danwitz, Judges,

Advocate General: Y. Bot,
Registrar: R. Grass,

after hearing the Opinion of the Advocate General at the sitting on 10 April 2008,

gives the following

Judgment

- ¹ By its application the Commission of the European Communities seeks a declaration from the Court that, by providing in Paragraph 14(5) and (6) of the Law on Pharmacies (Apothekengesetz) in the version applicable from 21 June 2005 (the ‘ApoG’) that the conclusion of a contract for the supply of medicinal products is subject to cumulative conditions whose effect is to make it impossible in practice for a hospital in the Federal Republic of Germany to be supplied on a regular basis by pharmacies established in other Member States, the Federal Republic of Germany has failed to fulfil its obligations under Articles 28 EC and 30 EC.

National law

- ² The provisions on the supply to hospitals of medicinal products are contained in Paragraph 14(1) to (6) of the ApoG.
- ³ 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 within the premises of the hospital concerned and in general not accessible to the public, or from the pharmacy of another hospital, or from a pharmacy situated outwith hospital premises (an ‘external pharmacy’). Where a hospital decides to obtain its supplies from the pharmacy of another hospital or from an external pharmacy, it must enter into a contract with that pharmacy which is subject to the conditions laid down in Paragraph 14(4) to (6) of the ApoG (‘the contested provisions’).
- ⁴ Paragraph 14(1) to (6) of the ApoG provides:
- ‘(1) A licence to operate a hospital pharmacy must be granted on request to the body responsible for a hospital if:
1. it demonstrates that it has recruited a pharmacist who satisfies the conditions laid down in Paragraph 2(1), points 1 to 4, 7 and 8, and (3), in conjunction with (2) or (2a), and
 2. it demonstrates that it has the premises prescribed for hospital pharmacies by the Apothekenbetriebsordnung [Regulations on the Operation of Pharmacies].

The manager of the hospital pharmacy or a pharmacist authorised by him must give information and advice to the medical staff of the hospital on the medicinal products, in particular for the purposes of effective and economical pharmacotherapy; the same applies in relation to out-patient treatment.

(2) The licence must be withdrawn if it is subsequently discovered that, at the time of issue, one of the necessary conditions under the first sentence of subparagraph (1) was not satisfied. It must be revoked if one of the necessary conditions under subparagraph (1) is no longer satisfied or if the conduct of the licence holder or a person authorised by him grossly or persistently infringes the provisions of this Law, the regulation adopted on the basis of Paragraph 21 or the provisions relating to the manufacture or marketing of medicinal products. The same action must be taken, as regards the approval issued in accordance with the first and third sentences of subparagraph (5), if the conditions laid down in the second sentence of subparagraph (5) were not satisfied or are no longer satisfied.

(3) A holder of a licence to operate a hospital pharmacy, under subparagraph (1), who intends to supply medicinal products to another hospital for which he is not responsible must for that purpose conclude a contract in writing with the body responsible for that hospital.

(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 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 ensured; the pharmacy must, in particular, possess the premises, equipment and staff required under the Regulations 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 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 economical 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. ...'

The pre-litigation procedure

- 5 Until 20 June 2005 the original version of the ApoG contained rules, known as the 'regional principle', which imposed the restriction that contracts for the supply of medicinal products by external pharmacies could be entered into only with those pharmacies which were established in the same town, city or district as the hospital to be supplied. By letter of formal notice dated 11 July 2003, and then by reasoned opinion dated 19 December 2003, the Commission challenged the compatibility of that principle with Community law; in particular, with the provisions of the EC Treaty on the free movement of goods.

- 6 On 4 November 2004 the German Government approved a draft law amending Paragraph 14 of the ApoG, the purpose of which was to ensure that hospitals could also enter into separate supply contracts with a number of pharmacies. However, the Bundesrat (Upper Chamber of the Federal Parliament) did not approve that draft law. The German Government therefore made changes to the draft law, with the result that on 21 June 2005 Paragraph 14 of the ApoG, in the form set out in paragraph 4 of this judgment, was adopted.
- 7 On 18 October 2005, since it considered that, notwithstanding the amendments made to Paragraph 14, the Federal Republic of Germany had not yet brought to an end its failure to comply with the obligations in question, the Commission sent to that Member State an additional letter of formal notice. In that letter it stated that the cumulative conditions imposed on the conclusion of a contract for the supply of medicinal products, in accordance with Paragraph 14 of the ApoG, were equivalent to maintaining a disguised 'regional principle', which was incompatible with the provisions of the Treaty on the free movement of goods as laid down in Article 28 EC.
- 8 In its reply of 14 December 2005 to that letter of formal notice, the Federal Republic of Germany questioned whether Article 28 EC applied and expressed the view that, in any event, the domestic legislation was justified in the light of Article 30 EC. On 10 April 2006 the Commission sent that Member State a reasoned opinion in which it adhered to the analysis set out in the letter of formal notice.
- 9 On 2 June 2006 the Federal Republic of Germany informed the Commission that it also adhered to its views as regards Paragraph 14 of the ApoG.
- 10 The Commission accordingly decided to bring this action.

The action

Arguments of the parties

- 11 In support of its action, the Commission claims that the cumulative conditions laid down by the contested provisions relating to contracts for the supply of medicinal products constitute a selling arrangement within the meaning of Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097 but none the less fall within the scope of Article 28 EC, given that the effect of those conditions is that access to the market is more difficult for goods from Member States other than the Federal Republic of Germany than it is for domestic products.
- 12 Under the contested provisions the contracting pharmacy is responsible for the provision of all of the services associated with the supply of medicinal products. Since some of those services, such as provision of emergency supplies, can only be provided by a pharmacist who has his dispensary in the vicinity of the hospital to be supplied, the choice of such a pharmacy is necessarily restricted to those situated near to that hospital, which amounts to the introduction of an ‘unwritten’ regional principle. In this way, goods from other Member States have access to the market which is more restricted than that of domestic products.
- 13 Those provisions are therefore a measure having equivalent effect to a quantitative restriction, which is prohibited by Article 28 EC.
- 14 Those cumulative conditions are moreover not justified on grounds of the protection of public health. On that point, the Commission explains that it does not challenge the requirement that only one pharmacist should supply a hospital with medicinal

products, but solely the fact that only a local pharmacist can enter into a supply contract with a German hospital.

- 15 As regards the need to enter into a comprehensive supply contract, the Commission claims that to separate the provision of standard supplies from the provision of emergency supplies does not adversely affect the quality of the supply of products to the hospital concerned. In addition, while it cannot be denied that a hospital needs, in order to select its medicinal products, the advice of a pharmacist who is familiar with the needs of the hospital, such advice need not necessarily be given by the pharmacist who is subsequently to provide supplies to that hospital. Similarly, if a second pharmacist were responsible for the monitoring of stocks of medicinal products, that would not affect the quality of the supply of products. On the contrary, it is advisable to separate the responsibility for monitoring from the responsibility for providing supplies in order to guarantee optimal quality in both respects. Lastly, given the communication technology now available, it is not necessary for advice to be given in situ in order to ensure a high level quality of supply. The Commission observes, in that context, that the Court, in Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 113, accepted that medicinal products might be sold to patients on the internet.
- 16 The Federal Republic of Germany does not accept that the contested provisions are a measure having equivalent effect to a quantitative restriction on imports. In its opinion, those provisions satisfy the conditions stated by the Court in *Keck and Mithouard* and therefore fall outside the scope of Article 28 EC.
- 17 The Federal Republic of Germany contends first that, in general, medicinal products authorised in Germany are not available in a pharmacy established in another Member State. Consequently, the fact that a lesser quantity of medicinal products from other Member States is supplied to German hospitals is not due to the contested provisions. Moreover, pharmacies established in other Member States have the opportunity to supply medicinal products to a hospital's internal pharmacy or to an external pharmacy which satisfies the conditions laid down by the contested provisions, and are not obliged to conclude a supply contract for that purpose. Article 28 EC does not require that it should be possible for medicinal products to be supplied to hospitals situated in one Member State by pharmacies established in

other Member States. The Federal Republic of Germany also contends that the sale of medicinal products from other Member States is no more affected than the sale of medicinal products from regions of Germany which are remote from the hospital to be supplied. Furthermore, a pharmacy established outside German territory is able to enter into a supply contract with a German hospital provided that it satisfies the conditions.

18 In addition, according to the Federal Republic of Germany, the specification of arrangements for the provision of supplies to hospitals, which is a fundamental decision of the national legislature, falls exclusively within the powers of the Member States, in accordance with Article 152(5) EC. The Commission's action seeking a declaration that the contested provisions are contrary to Article 28 EC is a way of circumventing the limits on Community action in the field of public health.

19 Alternatively, the Federal Republic of Germany contends that those provisions are justified on grounds of protection of public health within the meaning of Article 30 EC and do not undermine the principle of proportionality. Indeed they are such as to guarantee that the supply of products is reliable and of high quality, since everything relating to the provision of medicinal products to a hospital is the responsibility of one pharmacist.

20 The Federal Republic of Germany contends in particular that the separation of the standard provision of supplies from the emergency provision of supplies is a measure which is impracticable and lacking in any objectivity. Further, to separate the standard provision of supplies from the selection of medicinal products is neither truly suited to the overall needs of the hospital nor economically viable. Similarly, the separation of tasks associated with the standard provision of supplies from those associated with the quality and proper storage of stocks of medicinal products does not guarantee optimal provision of supplies. Personal contact between the pharmacist who is supplying the medicinal products and the hospital staff also contributes to improving the reliability of the supply. Lastly, the principle that the products should be provided by one single supplier makes possible an optimal synergy between the supply of medicinal products, advice and monitoring.

Findings of the Court

Preliminary observations

- ²¹ First, it is necessary to address the argument of the Federal Republic of Germany that the Commission's action seeking a declaration that the contested provisions are contrary to Article 28 EC is a way of circumventing the limits on Community action in the field of public health.
- ²² It is certainly clear, both from the case-law of the Court and from Article 152(5) EC, that Community law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their healthcare insurance schemes and the organisation and delivery of health services and medical care (Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 16, and Case C-372/04 *Watts* [2006] ECR I-4325, paragraphs 92 and 146).
- ²³ However, in exercising that power, the Member States must comply with Community law, in particular the provisions of the Treaty on the free movement of goods (see Case C-120/95 *Decker* [1998] ECR I-1831, paragraphs 23 to 25). Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector (see, in relation to the freedom to provide services, *Watts*, paragraph 92).

24 Accordingly, this action brought by the Commission, as part of the performance of its tasks, which, under Article 211 EC, include ensuring that the provisions of the Treaty are applied, is restricted to determining whether the Member States have acted in compliance with the rules of that Treaty relating to the free movement of goods.

25 It should be noted that, as Community law stands at present, since there has been no harmonisation at Community level of the rules on the provision of medicinal products to hospitals, the Member States continue to be empowered to lay down rules on that subject, subject to compliance with the provisions of the Treaty, in particular the provisions on the free movement of goods (see, to that effect, Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 48).

26 It is necessary therefore to examine the compatibility of the contested provisions with Articles 28 and 30 EC.

Whether there is a restriction on intra-Community trade

27 The free movement of goods is a fundamental principle of the Treaty which is expressed in the prohibition, set out in Article 28 EC, on quantitative restrictions on imports between Member States and all measures having equivalent effect (Case C-170/04 *Rosengren and Others* [2007] ECR I-4071, paragraph 31).

28 According to settled case-law, the prohibition of measures having equivalent effect to quantitative restrictions which is set out in Article 28 EC covers all legislation of the

Member States that is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5; *Deutscher Apothekerverband*, paragraph 66; *Rosengren and Others*, paragraph 32; Case C-297/05 *Commission v Netherlands* [2007] ECR I-7467, paragraph 53; and Case C-143/06 *Ludwigs-Apotheke* [2007] ECR I-9623, paragraph 26).

29 The Court of Justice has none the less made clear that national provisions restricting or prohibiting certain selling arrangements which, first, apply to all relevant traders operating within the national territory and, second, affect in the same manner, in law and in fact, the marketing of domestic products and those from other Member States are not liable to hinder, directly or indirectly, actually or potentially, trade between Member States within the meaning of the *Dassonville* line of case-law (see, to that effect, *Keck and Mithouard*, paragraph 16).

30 In the present case, it must be recalled that Paragraph 14 of the ApoG lays down the requirements which external pharmacies must meet if they are to be eligible to supply medicinal products to hospitals in Germany.

31 However, the contested provisions do not concern the characteristics of the medicinal products, but concern solely the arrangements permitting their sale (see, to that effect, Case C-244/06 *Dynamic Medien* [2008] ECR I-505, paragraph 31). Consequently, they must be regarded as concerning selling arrangements within the meaning of *Keck and Mithouard*, which is moreover not disputed by the parties to these proceedings.

32 As is made clear in *Keck and Mithouard*, however, such a selling arrangement can fall outside the prohibition laid down in Article 28 EC only if it satisfies the two conditions stated in paragraph 29 above.

33 As regards the first of those conditions, it is clear that the contested provisions apply indiscriminately to all the operators concerned who carry out their business on German territory, since they apply to all pharmacies which wish to supply medicinal products to German hospitals, whether they are established in Germany or in another Member State.

34 As regards the second of those conditions, it is undisputed that the contested provisions lay down a series of cumulative criteria which in practice require, as the Federal Republic of Germany moreover expressly acknowledges, a degree of geographical proximity between the pharmacy supplying the medicinal products and the hospital for which those products are intended.

35 It follows that the contested provisions are such as to make the supply of medicinal products to German hospitals more difficult and more costly for pharmacies established in Member States other than the Federal Republic of Germany than for pharmacies established in the latter State. Pharmacies established in other Member States, unless they are in a border region and near to the German hospital concerned, which wish to conclude a supply contract with such a hospital must either transfer their dispensary to the vicinity of the hospital concerned or open another pharmacy near to the hospital.

36 Consequently, as regards the supply of medicinal products to German hospitals, those provisions do not affect in the same way products marketed by pharmacies established in the territory of the Federal Republic of Germany and those marketed by pharmacies situated in another Member State.

- 37 That conclusion cannot be rebutted by the circumstance, relied on by the Federal Republic of Germany, that, in relation to the sale of medicinal products to German hospitals, the contested provisions do not place pharmacies established outside that Member State at any greater disadvantage than pharmacies situated in Germany which have their dispensaries situated at some distance from the hospital for which the medicinal products are intended.
- 38 Those provisions cannot cease to be restrictive merely because in one part of the territory of the Member State concerned, namely that part that is distant from the hospital concerned, those provisions affect in the same way the marketing of medicinal products by pharmacies established in Germany and by pharmacies established in other Member States (see, to that effect, Case C-254/98 *TK-Heimdienst* [2000] ECR I-151, paragraph 28).
- 39 Nor can it be maintained that the marketing of medicinal products from other Member States is no more affected than the marketing of medicinal products from regions of Germany which are remote from the hospital to be supplied. For a national measure to be characterised as discriminatory or protective within the meaning 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 (Joined Cases C-1/90 and C-176/90 *Aragonesa de Publicidad Exterior and Publivia* [1991] ECR I-4151, paragraph 24, and *TK-Heimdienst*, paragraph 27).
- 40 Equally irrelevant is the circumstance, relied on by the Federal Republic of Germany, that a pharmacy established in another Member State has the opportunity to supply medicinal products to the hospital's internal pharmacy or to an external pharmacy which satisfies the cumulative conditions laid down in the contested provisions.

- 41 As pointed out by the Advocate General in point 81 of his Opinion, although the Community rules on the free movement of goods do not require that it should be possible for hospitals situated in Member States to obtain supplies of medicinal products from external pharmacies, when a Member State provides for such a possibility, it opens that activity to the market and is accordingly bound to comply with the Community rules.
- 42 The Court must also reject the argument of the Federal Republic of Germany that the contested provisions are not the cause of there being a lesser quantity of medicinal products supplied to German hospitals by pharmacies situated outside that Member State, because, as a general rule, adequate quantities of medicinal products authorised in Germany are not available in such pharmacies.
- 43 Since the contested provisions are liable to hinder intra-Community trade, they must be considered as a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 28 EC, without it being necessary to prove that they have had an appreciable effect on such trade (see Case C-166/03 *Commission v France* [2004] ECR I-6535, paragraph 15).
- 44 It follows from all of the foregoing that the contested provisions are liable to hinder intra-Community trade and constitute a measure having equivalent effect to a quantitative restriction on imports prohibited by Article 28 EC.

45 In those circumstances, it must be examined whether the contested provisions can be justified on grounds such as those relied on by the Federal Republic of Germany relating to the protection of public health.

Whether there is justification in the protection of public health

46 It must be recalled that the health and life of humans rank foremost among the assets or interests protected by Article 30 EC 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 public health and on the way in which that degree of protection is to be achieved (*Deutscher Apothekerverband*, paragraph 103; Case C-262/02 *Commission v France* [2004] ECR I-6569, paragraph 24; *Rosengren and Others*, paragraph 39; and *Ludwigs-Apotheke*, paragraph 27).

47 It is common ground that the contested provisions, which, according to the Federal Republic of Germany, have the objective of ensuring that the supply to hospitals of medicinal products by an external pharmacy is reliable and of good quality, reflect concerns for public health which are within the ambit of Article 30 EC and that, consequently, they are, in principle, capable of justifying a restriction on the free movement of goods.

48 However, legislation which is such as to restrict a fundamental freedom guaranteed by the Treaty, such as the free movement of goods, can be justified only if it is appropriate for securing the attainment of the objective pursued and does not go beyond what is necessary in order to attain it (Case C-14/02 *ATRAL* [2003] ECR I-4431, paragraph 64; Case C-254/05 *Commission v Belgium* [2007] ECR I-4269, paragraph 33; judgment of the Court (Third Chamber) of 13 March 2008 in Case C-227/06 *Commission v Belgium*, paragraph 61; and Case C-265/06 *Commission v Portugal* [2008] ECR I-2245, paragraph 37).

49 First, in relation to whether the contested provisions are appropriate, it must be observed that in so far as they require that all the services associated with the supply contract must be entrusted to a pharmacist in the vicinity, those provisions are such as to achieve the objective of ensuring that the supply of products to German hospitals is reliable and of good quality and therefore of protecting public health, which the Commission does not dispute.

50 Secondly, as regards the assessment of whether those provisions are necessary, it must be recalled at the outset that it follows from the case-law of the Court that since Article 30 EC is an exception, to be strictly interpreted, to the rule of free movement of goods within the Community, it is for the national authorities to demonstrate that those provisions are necessary in order to achieve the declared objective, and that this objective could not be achieved by less extensive prohibitions or restrictions of lesser extent or having less effect on intra-Community trade (see, to that effect, Case C-17/93 *van der Veldt* [1994] ECR I-3537, paragraph 15; Case C-189/95 *Franzén* [1997] ECR I-5909, paragraphs 75 and 76; Case C-434/04 *Ahokainen and Leppik* [2006] ECR I-9171, paragraph 31, and *Rosengren and Others*, paragraph 50).

51 In accordance with settled case-law of the Court, set out in paragraph 46 of this judgment, when assessing whether the principle of proportionality has been observed in the field of public health, account must be taken of the fact that a Member State has the power to determine the degree of protection which it wishes to afford to public health and the way in which that degree of protection is to be achieved. Since that degree of protection may vary from one Member State to the other, Member States must be allowed discretion (see, to that effect, Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375, paragraphs 46 and 51) and, consequently, the fact that one Member State imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate (Case C-262/02 *Commission v France*, paragraph 37, and Case C-443/02 *Schreiber* [2004] ECR I-7275, paragraph 48).

- 52 In this case, it must be recalled that, pursuant to Paragraph 14 of the ApoG, German hospitals have the choice of entrusting the provision of their supplies of medicinal products either to a pharmacy operating within the hospital premises ('internal provision of supplies'), or to the pharmacy of another hospital or to an external pharmacy ('external provision of supplies').
- 53 In the system of internal provision of supplies, the pharmacist of the hospital is responsible for all the services linked to the supply of medicinal products. Since he is based in the hospital premises, he is generally and quickly available to the hospital. The various elements of that system have not been challenged by the Commission.
- 54 When a hospital selects the system of external provision of supplies, it must conclude a contract with the pharmacy which it has chosen, a contract which is subject to the cumulative conditions laid down in Paragraph 14 of the ApoG, which also require that all of the services linked to that type of provision of supplies are provided by a contracting pharmacist who must be generally and quickly available in situ.
- 55 Accordingly, the fact of the matter is that the contested provisions transpose to the system of external provision of supplies requirements analogous to those which characterise the system of internal provision of supplies.
- 56 To the extent that conclusion of the supply contract with the pharmacy of another hospital or with an external pharmacy is subject to the contested provisions, which lay down conditions analogous to those applicable in the system of internal provision of supplies, namely the requirement that there be one pharmacist who is, firstly, responsible for the supply of medicinal products and, secondly, generally and quickly available in situ, it follows that those provisions ensure that all the elements of the

system for the supply of medicinal products to hospitals in Germany are equivalent and mutually compatible, and thereby guarantee the unity and balance of that system.

57 Accordingly, the contested provisions can be seen to be necessary to the achievement of the objective of ensuring a high level of public health protection and clearly do not go beyond what is necessary.

58 On the other hand, the approach upheld by the Commission, in that it permits the services linked to the system of external provision of supplies to be entrusted to contracting pharmacists whose dispensary is not situated in the vicinity of the hospital to be supplied, is likely to undermine the unity and balance of the system for the supply of medicinal products to hospitals in Germany and, consequently, the high level of public health protection which the Federal Republic of Germany seeks to achieve.

59 Furthermore, in practice, the approach recommended by the Commission would oblige those German hospitals which choose to obtain their supplies from external pharmacies or from pharmacies of other hospitals to employ several pharmacists in order to safeguard the various services linked to the provision of supplies, which would, as pointed out by the Advocate General in point 122 of his Opinion, generate additional costs inherent in any such employment.

60 While objectives of a purely economic nature cannot justify a restriction on the fundamental principle of free movement of goods, none the less, as regards interests of an economic nature concerning the maintenance of a balanced medical and hospital service open to all, the Court has accepted that such an objective may also fall within one of the derogations, on grounds of public health, in so far as it contributes to the attainment of a high level of health protection (see by analogy, in particular,

Case C-158/96 *Kohll* [1998] ECR I-1931, paragraph 50, and Case C-444/05 *Stamatelaki* [2007] ECR I-3185, paragraph 31).

⁶¹ It must be possible to plan the number of hospitals, their geographical distribution, their organisation and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, in a way which, first, meets, as a general rule, the objective of guaranteeing in the territory of the Member State concerned sufficient and permanent access to a balanced range of high-quality hospital treatment and, secondly, assists in ensuring the desired control of costs and prevention, as far as possible, of any wastage of financial, technical and human resources (see Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraphs 76 to 80; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraphs 77 to 80; and *Watts*, paragraphs 108 and 109).

⁶² From those two points of view, it is equally clear that the requirement that one local pharmacist should be given responsibility for all the tasks involved in the supply of medicinal products to German hospitals is not a measure which goes beyond what is necessary to achieve the objective pursued by the Federal Republic of Germany, namely to achieve a high level of public health protection.

⁶³ In the light of the foregoing, the contested provisions must be considered to be justified on grounds relating to the protection of public health.

⁶⁴ The Commission's action must therefore be dismissed.

Costs

⁶⁵ Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Federal Republic of Germany has applied for costs and the Commission has been unsuccessful, the Commission must be ordered to pay the costs.

On those grounds, the Court (Fourth Chamber) hereby:

- 1. Dismisses the action;**
- 2. Orders the Commission of the European Communities to pay the costs.**

[Signatures]