OPINION OF ADVOCATE GENERAL BOT

delivered on 16 December 2008 [1]

1. In the questions referred here for a preliminary ruling, the Verwaltungsgericht des Saarlandes (Administrative Court, Saarland), Germany, asks the Court to rule whether Articles 43 EC and 48 EC are to be interpreted as precluding national legislation under which only pharmacists may own and operate a pharmacy.

2. Under German law, any person who wishes to operate a pharmacy requires a licence from the competent authority. Among the conditions for granting that licence are that the applicant must possess a licence to practice as a pharmacist and must manage the pharmacy personally on his own responsibility.

3. The two references for a preliminary ruling that are under consideration have been made in proceedings brought by the Apothekerkammer des Saarlandes, [2] Ms Schneider, Mr Holzapfel and Mr Trennheuser [3] and Deutscher Apothekerverband eV [4] (Case C-171/07) and Ms Neumann-Seiwert (Case C-172/07) ('the claimants in the main proceedings') against Saarland, represented by its Ministerium für Justiz, Gesundheit und Soziales (Ministry for Justice, Health and Social Affairs, 'the Ministry'). Both sets of proceedings concern an application for annulment of the Ministry's decision to grant a public limited company, DocMorris NV ('DocMorris'), a licence to operate a branch pharmacy in Sarrbrücken, Germany.

4. In this Opinion, I shall set out the reasons why I consider that Articles 43 EC and 48 EC are to be interpreted as not precluding a Member State from opting to allow only pharmacists to own and operate pharmacies. [5]

1 — Original language: French.
2 — The Saarland Pharmacists' Association.
3 — All three are pharmacists.
4 — The German Pharmacists' Association.
5 — This issue is also raised in Case C-531/06 *Commission* v *Italy*, pending before the Court, in which I am also delivering the Opinion.

I — Legal framework

A — *Community legislation*

5. The first paragraph of Article 43 EC prohibits restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State. According to the second paragraph of Article 43 EC, freedom of establishment includes the right to take up and pursue activities as self-employed persons and to set up and manage undertakings.

6. Pursuant to the first paragraph of Article 48 EC, companies or firms formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the European Community are also to enjoy the rights conferred by Article 43 EC.

7. Under Article 46(1) EC, Article 43 EC is not to constitute an obstacle to restrictions justified on grounds of public health.

8. Article 47(3) EC provides that, in the case of the medical and allied and pharmaceutical professions, the progressive abolition of restrictions on the freedom of establishment is dependent upon coordination of the conditions for their exercise in the various Member States. However, the Council of the European Union and the Commission of the European Communities have acknowledged that the direct effect of Articles 43 EC and 49 EC, recognised in *Reyners* [6] and *van Binsbergen* [7] respectively with effect from 1 January 1970 when the transitional period ended, also applies to health care professions. [8]

9. Moreover, the medical and allied and pharmaceutical professions have been the subject of coordinating directives. For the field of pharmacy, they were Council Directive 85/432/EEC 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 [9] and Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy. [10]

6 — Case 2/74 [1974] ECR 631.

7 — Case 33/74 [1974] ECR 1299.

8 — Accordingly, it is stated in the first recital in the preamble to Council Directive 75/362/EEC of 16 June 1975 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in medicine, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services (OJ 1975 L 167, p. 1), that, pursuant to the EEC Treaty, all discriminatory treatment based on nationality with regard to establishment and provision of services is prohibited as from the end of the transitional period.

9 — OJ 1985 L 253, p. 34.

10 — OJ 1985 L 253, p. 37.

10. Those two directives were repealed and replaced by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. [11] Recital 26 in the preamble to Directive 2005/36 states:

'This Directive does not coordinate all the conditions for access to activities in the field of pharmacy and the pursuit of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States. This Directive leaves unchanged the legislative, regulatory and administrative provisions of the Member States forbidding companies from pursuing certain pharmacists' activities or subjecting the pursuit of such activities to certain conditions.'

11. Finally, it is appropriate to mention Article 152(5) EC, which provides:

'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. …'

B — *National legislation*

12. Paragraph 1 of the German Law on Pharmacies (Apothekengesetz), [12] as amended by the regulation of 31 October 2006 [13] ('the ApoG'), provides:

'(1) The obligation in the public interest to ensure proper provision of medicinal products to the public shall be incumbent on pharmacies.

(2) A person who wishes to operate a pharmacy and up to three branch pharmacies requires a licence from the competent authority.

(3) The licence shall cover only the pharmacist to whom it is granted and the premises identified in the licence certificate.'

11 — OJ 2005 L 255, p. 22.

12 — BGBl. 1980 I, p. 1993.
13 — BGBl. 2006 I, p. 2407.

13. Paragraph 2 of the ApoG provides:

'(1) A licence is to be granted, on application, if the applicant:

1. is German within the meaning of Article 116 of the Basic Law (Grundgesetz), a national of one of the other Member States of the European Union or of another State party to the Agreement on the European Economic Area…;

2. has full legal capacity;

3. possesses a German licence to practice as a pharmacist;

4. has the trustworthiness required to operate a pharmacy;

…

7. is not physically unfit to manage a pharmacy properly;

…'

14. Paragraph 7(1) of the ApoG states:

'The licence shall oblige the holder to manage the pharmacy personally on his own responsibility.'

15. Finally, Paragraph 8(1) of the ApoG lays down the forms in which a number of persons may operate a pharmacy together. That provision excludes participation in the capital alone and prohibits any legal structure which enables a party other than the holder of the licence to operate the pharmacy or to share in the profits from its operation. The provision is worded as follows:

'A number of persons may operate a pharmacy together only in the form of a civil law partnership or commercial partnership; in such cases, each partner requires a licence. Any holding in a pharmacy by way of a partnership with a sleeping partner and

agreements under which the return on loans granted to the holder of the licence or on assets provided to him in another way depends on the turnover or profit of the pharmacy, in particular leases under which the amount of rent depends on the turnover or profit, are unlawful…'

II — The main proceedings and the questions referred for a preliminary ruling

16. DocMorris is a public limited company established in the Netherlands which operates a mail order business for medicinal products. By decision of 29 June 2006, the Ministry granted it with effect from 1 July 2006 a licence to operate a branch pharmacy in Saarbrücken, subject to the condition that a pharmacist manage the pharmacy personally and on his own responsibility. By decision of 28 June 2006, likewise with effect from 1 July 2006, the Ministry granted DocMorris a licence for the pharmacy in Saarbrücken authorising the dispatch of prescription medicines. By further decision of 7 August 2006, the Ministry ordered the immediate implementation of the licence granted on 29 June 2006 to operate a branch pharmacy.

17. On 2 and 18 August 2006, the claimants in the main proceedings brought actions before the Verwaltungsgericht des Saarlandes for annulment of the decision of 29 June 2006 granting an operating licence.

18. In support of their actions, the claimants in the main proceedings contended that that decision is contrary to the ApoG because it infringes the 'Fremdbesitzverbot', that is to say the rule, as resulting from the third subparagraph of Paragraph 2(1) in conjunction with Paragraphs 7 and 8 of the ApoG, which restricts the right to operate pharmacies to pharmacists alone. They also submitted that the Ministry does not have power to decide whether German law is compatible with Community law as this is a matter for the Court of Justice in accordance with Article 234 EC.

19. The Ministry and DocMorris claimed that the rule excluding non-pharmacists contained in the German legislation infringes Article 43 EC, which guarantees freedom of establishment, since a pharmacy established in another Member State and operated in the form of a capital company does not have access to the German pharmacy market. Such a restriction is, in their view, not necessary for attaining the objective of protection of public health. They also maintained that the principles of primacy and effectiveness of Community law require not only national courts but also national authorities to disapply national law where it is contrary to Community law.

20. In the light of the arguments raised before it, the Verwaltungsgericht des Saarlandes decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

‘(1) Are the provisions concerning freedom of establishment for capital companies (Articles 43 EC and 48 EC) to be interpreted as precluding a prohibition on third-party ownership of pharmacies, as provided for by subparagraphs 1 to 4 and 7 of Paragraph 2(1), the first sentence of Paragraph 7 and the first sentence of Paragraph 8 of [the ApoG]?

(2) If the first question is answered in the affirmative:

Having regard in particular to Article 10 EC and to the principle of effectiveness of Community law, is a national authority entitled and obliged under Community law to disapply national provisions it regards as contrary to Community law even if there is no clear breach of Community law and it has not been established by the Court… that the relevant provisions are incompatible with Community law?’

III — Analysis

A — *The first question*

21. By its first question, the national court asks the Court, in essence, to rule whether Articles 43 EC and 48 EC are to be interpreted as precluding national legislation under which only pharmacists may own and operate a pharmacy.

22. This question has divided the parties into two camps radically opposed as regards the reply to be given to it. On the one hand, the claimants in the main proceedings and the German, Greek, French, Italian, Austrian and Finnish Governments consider that such national legislation, in so far as it may constitute a restriction on the freedom of establishment protected by Article 43 EC, is justified by the objective of protection of public health. On the other hand, Saarland, DocMorris, the Polish Government and the Commission maintain that freedom of establishment precludes the rule prohibiting non-pharmacists from owning a pharmacy, since such a rule is neither appropriate for attaining the objective of protection of public health nor necessary for securing such an objective. Since the main arguments in support of these two views are, essentially, identical to those in *Commission* v *Italy*, which are set out in my Opinion in that case, I do not think it is necessary at this stage of my argument to

recount in detail the observations which have been submitted to the Court.

23. Before I examine whether or not the rule under which only persons entitled to practise as pharmacists may own and operate a pharmacy is in accordance with Articles 43 EC and 48 EC, I shall make some preliminary observations on the nature of the respective powers of the Member States and the Community concerning public health.

1. Preliminary observations on the nature of the respective powers of the Member States and the Community concerning public health

24. Under Article 152 EC, the Community is not assigned full and absolute competence in respect of public health. Such competence is therefore shared between the Community and the Member States.

25. The rules applicable to that sharing of competence, as resulting from the wording of Article 152 EC, point to the existence of a shared, predominantly national, competence. [14]

26. The retention of national competence in respect of public health is expressly affirmed in Article 152(5) EC, which, it may be recalled, provides that 'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care'.

27. The fact that the conferring of competence in health matters on the Community does not involve removing competence from the Member States can also be inferred from the nature of the national and Community powers that results from Article 152 EC. The powers are simultaneously complementary, since Community action complements national public health policies, and coordinated, because Community action seeks to coordinate national actions in that sphere.

28. Overall, the provisions of Article 152 EC contain the bases of an unintegrated public

14 — In the words of Michel, V., 'La compétence de la Communauté en matière de santé publique', *Revue des affaires européennes,* 2003-2004/2, p. 157.

health policy and also define a sphere of protected national competence.

29. The Court must in my view take due account of the choice thus made by the drafters of the EC Treaty. In particular, where the Court is faced with a national measure relating to the organisation and supply of health services and medical care, its assessment should, I believe, always take account of what may resemble constitutional protection of the competence of the Member States in that sphere. [15]

30. Clearly, that does not mean that, in the exercise of their retained competence, the Member States should be regarded as released from their Community constraints. Indeed, we know that, in exercising such competence, the Member States must comply with Community law, in particular the provisions of the Treaty on the freedoms of movement. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of the freedoms of movement in the healthcare sector. [16]

31. It should also be noted that, as Community law stands at present, the conditions for pursuing pharmaceutical activities have not all, by any means, been the subject of coordinating measures — and even less so of harmonisation measures — at Community level, as recital 26 in the preamble to Directive 2005/36 shows. The Community legislature stated there that, for example, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States. It is also stated that the directive leaves unchanged the legislative, regulatory and administrative provisions of the Member States forbidding companies from pursuing certain pharmacists' activities or subjecting the pursuit of such activities to certain conditions. In those unharmonised spheres, the Member States continue to be empowered to lay down rules, subject to compliance with the provisions of the Treaty, including the provisions on freedom of establishment. [17]

32. In order to be maintained, a national rule providing that pharmacies may be owned and operated only by pharmacists must therefore be in accordance with Article 43 EC, even if it is the expression of a retained competence of the Member States concerning public health, and more particularly concerning the organisation and delivery of health services and medical care.

15 — See Michel, V., op. cit., p. 177.

16 — See, in particular, Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 23 and the case-law cited therein.

17 — See, to this effect, *Commission* v *Germany*, paragraph 25 and the case-law cited therein.

33. However, the fact that such a rule takes effect in a sphere of retained national competence expressly protected by Article 152(5) EC is not without consequence. When assessing the justification for that rule in the light of a requirement in the general interest such as the protection of public health, the Court will have to take account of this protection of national competence enshrined in the Treaty. It will, in that regard, be able to apply its case-law according to which, 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. [18]

34. Having made these points, it must first be determined whether the German rule prohibiting non-pharmacists from owning and operating a pharmacy constitutes a restriction on freedom of establishment.

2. The existence of a restriction on freedom of establishment

35. The freedom of establishment provided for by Articles 43 EC and 48 EC confers upon companies or firms formed in accordance with the law of a Member State the right to take up an activity in another Member State and to pursue that activity permanently there under the same conditions as companies or firms whose seat is in that State. That fundamental freedom extends to the formation and management of undertakings and the setting-up of agencies, branches or subsidiaries. Article 43 EC requires the abolition of discriminatory measures.

36. It is also apparent from settled case-law that measures which, even though they apply without distinction, prohibit, impede or render less attractive the exercise of freedom of establishment by nationals of the Member States constitute restrictions contrary to the Treaty. [19]

37. Under German law, any person who wishes to operate a pharmacy requires a licence from the competent authority. Among the conditions for granting that licence are that the applicant must possess a licence to practice as a pharmacist and must manage the pharmacy personally on his own responsibility. Furthermore, a number of persons may operate a pharmacy together only in the form of a civil-law partnership or commercial partnership; in such cases, each partner requires a licence, and must therefore be a pharmacist.

18 — See, in particular, *Commission* v *Germany*, paragraph 51.

19 — See Case C-442/02 *CaixaBank France* [2004] ECR I-8961, paragraph 11 and the case-law cited therein; Case C-299/02 *Commission* v *Netherlands* [2004] ECR I-9761, paragraph 15; Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, paragraph 27; and Case C-500/06 *Corporación Dermoestética* [2008] ECR I-5785, paragraph 32 and the case-law cited therein.

38. The effect of these conditions is to prevent a capital company such as DocMorris from obtaining a licence to operate a pharmacy in Germany. The conditions can be classified as restrictions on freedom of establishment by reason of the effects which they have on market access for this type of company. By hindering access of new operators to the market in question, they objectively constitute barriers to the freedoms of movement which companies such as DocMorris are, in principle, entitled to enjoy.

39. Having found that an obstacle to freedom of establishment exists, it must now be determined whether the prohibition against non-pharmacists owning and operating a pharmacy may be regarded as justified under Community law.

3. Justification for the restriction on freedom of establishment found to exist

40. A restriction such as that imposed by the German legislation may be regarded as in accordance with Community law if it fulfils the following four conditions. It must, first of all, be applied in a non-discriminatory manner. Next, it must be justified on legitimate grounds or by an overriding reason in the general interest. Finally, it must be suitable for securing attainment of the objective pursued and it must not go beyond what is necessary in order to attain that objective. [20]

41. First, I detect nothing discriminatory in the legislation at issue, since it applies to all entities wishing to set up and operate a pharmacy in Germany, irrespective of their Member State of origin.

42. Second, the protection of public health is one of the overriding reasons in the general interest which, under Article 46(1) EC, can justify restrictions on the freedom of establishment. [21] As Paragraph 1(1) of the ApoG shows, the German legislation prohibiting a non-pharmacist from owning and operating a pharmacy reflects public health concerns. That legislation is therefore capable of being justified in the light of the objective of protection of public health, and more specifically the objective of ensuring proper provision of medicinal products to the public.

20 — See, inter alia, Case C-170/04 *Rosengren and Others* [2007] ECR I-4071, paragraph 43, and *Corporación Dermoestética*, paragraph 35 and the case-law cited therein.

21 — *Corporación Dermoestética*, paragraph 37.

43. With regard, third, to the suitability of such legislation for securing attainment of the objective of protection of public health, it must be determined whether the prohibition on non-pharmacists owning and operating a pharmacy is appropriate for achieving that objective effectively.

44. The following arguments have been raised in support of the view that that prohibition is not appropriate for attaining the objective of protection of public health.

45. According to those who hold that view, a distinction must be drawn between aspects relating to the operation, management or administration of pharmacies and those relating to contact with third parties. The need to be a professionally-qualified pharmacist is justified in respect of the latter aspects, but not the former, because the requirement to protect public health concerns only the external aspect of pharmaceutical activity, that is to say, the aspect relating to contact with third parties and, more specifically, with suppliers and patients.

46. Furthermore, it is argued that the criterion of appropriateness may be fulfilled only if there is concrete evidence showing that, when the owner of a pharmacy is not a qualified pharmacist and only an employed pharmacist is present in it, the control or influence exerted by the owner over that pharmacist is liable to undermine the pharmacist's independence and personal responsibility and to jeopardise observance of the professional rules and rules of conduct applicable to a pharmacist's activities. In actual fact, capital companies are not, as a rule, structurally more inclined to make profits improperly. A pharmacist who is personally responsible and heavily in debt at the outset owing to the cost of setting up his pharmacy may be under much greater pressure in respect of his economic survival than an employed pharmacist.

47. Also, even if pharmacies managed in the form of a capital company actually intended to increase their profits excessively, that could not provoke health risks connected with the supply of medicinal products. The supply of most medicinal products is by prescription and is therefore authorised only on presentation of a prescription. Therefore, even if a pharmacy wished to sell more medicinal products to a patient, it could not do so without a prescription made out by a doctor. Moreover, the German legislation has placed more and more restrictions on a pharmacist's ability to substitute medicinal products, that is to say, to replace one medicinal product with another which has the same active ingredient.

48. I consider, on the contrary, that the rule under which only a pharmacist may own and operate a pharmacy is appropriate for

ensuring attainment of the objective of protection of public health. More specifically, I consider that this rule ensures a provision of medicinal products to the public which is such as to give adequate guarantees regarding quality and variety.

49. In this regard, I am not persuaded by the argument that it is necessary to draw a distinction between the internal aspects (ownership, administration and management of the pharmacy) and the external aspects (contact with third parties) of pharmaceutical activity. In my view, a person who has a pharmacy and is both owner and employer inevitably influences the policy followed within the pharmacy in respect of the dispensing of medicinal products. Therefore, the German legislature's decision to link professional competence and economic ownership of the pharmacy appears justified in the light of the objective of protection of public health.

50. We must not forget that the task carried out by pharmacists is not limited to the sale of medicinal products. The dispensing of medicinal products also requires a pharmacist to provide other services such as checking medical prescriptions, making up pharmaceutical preparations, or providing information and advice to ensure the proper use of the medicinal products. [22] I also consider that a pharmacist's duty to give advice is very important in the case of over-the-counter medicines, the number of which is constantly increasing as a result of decisions taken by States in order to maintain the balance of the welfare budget. In those circumstances, a patient can rely only on the information provided by the health professional, the pharmacist.

51. As pharmaceutical activity is characterised, as are many health professions, by an asymmetrical distribution of information, a patient must be able to have complete confidence in the advice given by a pharmacist. It is therefore important to ensure that pharmaceutical advice is neutral, that is to say competent and objective.

52. In addition, pharmacists are linked, for the above reasons, to a general public health policy which is largely incompatible with the purely commercial approach of capital companies that is directly focused on viability and profit. The specific nature of the task entrusted to pharmacists therefore requires them to be granted and guaranteed, as professional persons, the independence necessary for their role.

53. Accordingly, quality in the dispensing of medicinal products is, in my view, closely linked to the independence which pharmacists must display in the performance of their task.

22 — For a list of the various activities carried out by pharmacists, see Article 45(2) of Directive 2005/36.

54. In deciding to allow only pharmacists to own and operate pharmacies, the German legislature specifically wished to ensure the independence of pharmacists by making the economic structure of pharmacies impervious to outside influences from, for example, manufacturers of medicinal products or wholesalers. It sought, in particular, to prevent the risks of conflicts of interest which it considered might be linked to vertical integration of the pharmaceutical sector, in order, inter alia, to combat the phenomenon of overconsumption of medicinal products and to ensure the presence of a sufficient variety of medicinal products in pharmacies. The German legislature also considered it necessary for a professional person to act as a filter between manufacturers of medicinal products and the public in order to provide independent control over the proper administration of medicinal products.

55. A pharmacist who owns his own pharmacy is financially independent, which ensures his freedom to engage in his profession. Such a pharmacist has full control of his tools and can therefore pursue his profession with the independence which characterises the liberal professions. He is both the head of a business in touch with economic realities, which are linked to the management of his pharmacy, and a health professional who is concerned to balance his economic requirements with public health considerations, a fact which distinguishes him from a mere investor.

56. That is why I consider that the preventive measure taken by the German legislature is appropriate for ensuring protection of public health.

57. Lastly, it is necessary to determine whether the rule under which only a pharmacist may own and operate a pharmacy is necessary in order to attain the objective of protection of public health, and whether this objective could be achieved by prohibitions or restrictions of lesser extent or having less effect on freedom of establishment.

58. Various arguments have been put forward to support the view that the rule is disproportionate in light of the objective of protection of public health.

59. It is thus argued that it would be sufficient if only an employed pharmacist were allowed to manage the pharmacy, provide medicinal products and supply advice to customers. He would be able, just like a self-employed pharmacist, to pursue his profession in accordance with his obligations. He would, irrespective of the legal form of his employer, be subject to the same professional rules and rules of conduct as a self-employed pharmacist. An employed pharmacist is admittedly subject to the operator's instructions, but he has the obligation to disobey those which are incompatible with the professional rules and rules of conduct applicable to pharmacists.

60. Moreover, the national legislature could adopt provisions regulating legal relations between operators and employed pharmacists in order to prevent the control or influence exerted over an employed pharmacist from undermining his independence and personal responsibility, jeopardising observance of the professional rules and rules of conduct applicable to pharmacists. Similarly, it would be possible to require the employed pharmacist and the operator to take out professional indemnity insurance.

61. It is also argued that this analysis is supported by *Commission* v *Greece* as the Greek legislation at issue in that judgment is comparable to the measure at issue in the main proceedings and there is no fundamental difference between the sale of optical products and the provision of medicinal products. In each of those activities, products provided inappropriately or bad advice may entail risks to human health. The reasoning adopted by the Court in that judgment should therefore be applied to the present case.

62. I do not share that point of view.

63. It is to be recalled that the Court has held that, 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 another, Member States must be allowed discretion 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. [23]

64. In laying down the rule that only a pharmacist may own and operate a pharmacy, the German legislature has exercised that discretion by choosing a system which it believes makes it possible to ensure a high level of public health protection and, in particular, proper provision of medicinal products to the public.

65. Following the example of other Member States, the German legislature could also have adopted another system and chosen, subject to its national constitutional constraints, to protect public health by other means, for example by making the opening of new pharmacies subject to the fulfilment of conditions regarding their geographical distribution, to the existence of a certain number of inhabitants per pharmacy or to rules relating to observance of a minimum distance between two pharmacies. Among other measures designed to ensure that the objective of protection of public health takes

23 — *Commission* v *Germany*, paragraph 51 and the case-law cited therein.

priority over economic interests, a Member State might choose to keep the monopoly on the sale of medicinal products by pharmacists and/or decide to regulate the price of medicinal products.

66. In short, account should be taken of the fact that in accordance with Article 152(5) EC, and in the absence of harmonisation of all the conditions for pursuing pharmaceutical activity within the Community, the Member States have a discretion in designing the system which best meets their aspirations in terms of protection of public health.

67. When establishing whether national measures, such as the one at issue in the present proceedings, comply with the principle of proportionality, the Court must, in the end, be satisfied that Member States have not exceeded the limits of their discretion. It also determines whether other measures would not help to ensure, just as effectively, a high level of public health protection.

68. I consider that, in providing that only a pharmacist may own and operate a pharmacy, the Federal Republic of Germany has not exceeded the limits of its discretion in respect of the protection of public health and that, therefore, this rule does not go beyond what is necessary to ensure a high level of public health protection.

69. Accordingly, I am not convinced that the measures which have been described before the Court and which, according to the opponents of the German rule, ought to replace it could ensure as high a level of public health protection.

70. Generally, it should be pointed out, first, that the rule prohibiting non-pharmacists from owning and operating pharmacies constitutes a measure intended to prevent the excesses I have mentioned above, in particular the risks of conflicts of interest which might be linked to vertical integration of the pharmaceutical sector and which might have a detrimental effect on quality in the dispensing of medicinal products. This preventive dimension is particularly important where the need to protect public health is at issue. I do not consider that the introduction of a system conferring liability on both operators who are not pharmacists and employed pharmacists and of a system of penalties imposable against them is sufficient to ensure as high a level of public health protection, since they are principally measures intended to correct excesses a

posteriori where they have actually occurred. [24]

71. Furthermore, I do not believe that the mere obligation that an employed pharmacist must be present to carry out tasks involving contact with third parties can ensure, with the same strictness in terms of quality and neutrality in the dispensing of medicinal products, the proper provision of medicinal products to the public.

72. It is admittedly true that an employed pharmacist is required to observe the professional rules and rules of conduct imposed on him. However, since he does not control the commercial policy of the pharmacy and is in practice required to carry out his employer's instructions, it is not inconceivable that an employed pharmacist in a pharmacy operated by a non-pharmacist will be led to put the economic interest of the pharmacy before the requirements linked to the pursuit of pharmaceutical activity. It cannot therefore be ruled out that an operator who is not a pharmacist — who does not have sufficient professional competence to evaluate what is required by the dispensing of medicinal products — will be tempted to reduce the giving of advice to patients or to discontinue unprofitable activities, such as making up pharmaceutical preparations. This would lead to a reduction of quality in the dispensing of medicinal products which an employed pharmacist, who is required to carry out the orders given by his employer, could find it difficult to counteract.

73. More fundamentally, in my view the distinction between the internal aspects and the external aspects of pharmaceutical activity is artificial and I think it is inevitable that, since the operator controls the pharmacy, it is he who will determine its commercial policy. It is therefore difficult to make sure that an operator who is not a pharmacist will not interfere in the relationship between the pharmacist and the customers, even indirectly when he manages the stock of medicinal products in the pharmacy. The mismanagement of such stock is bound to have repercussions on quality in the dispensing of medicinal products.

74. The German rule is therefore necessary because it means that a pharmacist who owns a pharmacy is personally accountable to his peers for his decisions as regards the quality of the professional services offered in his pharmacy, that he is personally subject to all the laws, regulations and rules of professional conduct governing pursuit of the profession of pharmacist, and that he is not subject to any influence from non-pharmacist third parties in respect of the conduct of his pharmacy's business.

24 — The arguments raised in this regard by the opponents of the German rule in support of their view seem to me largely theoretical and also contradicted by the reality of the present financial crisis. A banking system involving supervisory authorities and legal systems that provide for civil, commercial or criminal liability has tragically revealed its limitations and its inability to prevent or control the excesses arising from giving priority to return on invested capital.

75. Accordingly, the link between professional competence in the pharmaceutical field and ownership of the pharmacy enables the operator to assess correctly the consequences of his commercial decisions on the performance of the task which he is required to carry out in the public interest, namely proper provision of medicinal products to the public.

76. Finally, as the German Government points out, requiring the licence for operating a pharmacy to be held by a pharmacist is an effective means of ensuring that the public will be properly provided with medicinal products, in particular because, in the event of professional misconduct, the pharmacist operating the pharmacy faces the withdrawal not only of his licence to practice, but also of his operating licence, with the resulting serious financial consequences. In addition to the consequences under disciplinary provisions, a pharmacist's professional misconduct puts his economic existence at stake, which is a further inducement for him to give priority to public health requirements in the management of his pharmacy. The rule which requires competence and professional ethics to coexist with economic responsibility for the pharmacy in one and the same person is therefore necessary to ensure that priority is given to the general interest.

77. In the light of the foregoing, I consider that the German rule under which only a pharmacist may own and operate a pharmacy does not go beyond what is necessary for securing a high level of public health protection and, in particular, for ensuring a varied and high-quality provision of medicinal products to the public. I therefore take the view that the requirement that the person who has economic control of the pharmacy and, as such, determines its commercial policy should be a pharmacist is in accordance with Article 43 EC.

78. The analysis I have just carried out in respect of the appropriateness and proportionality of the rule under which only a pharmacist may own and operate a pharmacy cannot, in my view, be called into question, contrary to what DocMorris and the Commission maintain, by the fact that in certain circumstances operation of a pharmacy by a non-pharmacist is allowed under German law. The situations referred to are the following.

79. First, in the event of the incapacity or death of the holder of the licence to operate a pharmacy, it is possible for him or his heirs to continue to operate the pharmacy for a certain length of time, under a lease or management agreement. As the Apothekerkammer des Saarlandes points out, in providing for such a possibility the German legislature sought to reconcile the rule prohibiting non-pharmacists from owning and operating a pharmacy with the need to protect the interests of the pharmacist's family, giving it time to reach a decision concerning the future of the pharmacy. I do not think that this exception undermines the coherence of the German legislation, since it is limited in time and also

the pharmacy is entrusted to a manager who must be a qualified pharmacist. In addition, it is apparent from Paragraph 9(2) of the ApoG that the lessee must hold the licence provided for in Paragraph 1 of that Law and that the leasing-management agreement must not prejudice either the lessee's professional responsibility or his freedom to take decisions.

80. Secondly, there is the system of internal provision of medicinal products in hospitals. Under Paragraph 14(1) to (6) of the ApoG, hospitals have the choice of entrusting the provision of medicinal products to an internal pharmacy, that is to say, a pharmacy operating on the premises of the hospital concerned and not accessible to the public. In that case, it is the hospital management which must obtain the licence to operate the hospital pharmacy. The issue of that licence is subject inter alia to the recruitment of a pharmacist who satisfies the conditions laid down in subparagraphs 1 to 4, 7 and 8 of Paragraph 2(1) and Paragraph 2(3), in conjunction with Paragraph 2(2) or (2a), of the ApoG.

81. It is true that, in that case, the pharmacy is not operated by a pharmacist. However, unlike public pharmacies, the task of hospital pharmacies is to supply medicinal products not to the public but only to the departments of the hospital to which they belong. Since hospital pharmacies have to cover the requirements of those hospitals for medicinal products, I consider it appropriate that they are operated by the managing bodies of the hospitals of which they form part. Moreover, the risks of conflicts of interest linked to vertical integration of pharmaceutical activity which may be noted in the case of public pharmacies are not present in the system of internal provision of medicinal products in hospitals as framed by the German legislature. I therefore consider that that system cannot affect the coherence of the rule under which only a pharmacist may own and operate a pharmacy open to the public.

82. Nor, in my view, does the fact that a pharmacist may, under Paragraph 1(2) of the ApoG, operate up to three branches of his pharmacy affect the coherence of that rule. The holder of the licence to operate the main pharmacy is still required, under Paragraph 7 of the ApoG, to manage the main pharmacy and its branches personally on his own responsibility. He therefore retains full control of all his premises which, what is more, are authorised in limited number.

83. Finally, the argument that the reasoning followed by the Court in *Commission* v *Greece* in respect of the operation of opticians' shops should be applied to pharmacies must, in my view, be rejected.

84. In the infringement proceedings which it had brought against the Hellenic Republic, the Commission asked the Court to declare that that Member State had failed to fulfil its obligations under Articles 43 EC and 48 EC. It complained, first, that that State prevented a qualified optician as a natural person from operating more than one optician's shop. Secondly, it challenged the national legislation under which the establishment by a legal person of an optician's shop was subject to the following conditions:

— authorisation for the establishment and operation of the optician's shop had to have been granted to a recognised optician who was a natural person, the person holding the authorisation to operate the shop had to hold at least 50% of the undertaking's capital and participate at least to that extent in its profits and losses, and the undertaking had to be in the form of a collective or limited partnership, and

— the optician in question could participate at most in one other partnership owning an optician's shop, subject to the condition that the authorisation for the establishment and operation of that shop was in the name of another authorised optician.

85. Having established the existence of restrictions on freedom of establishment, [25] the Court undertook a global examination of whether or not the various disputed aspects of the Greek legislation were justified by the objective of protection of public health. It considered that this was not the case, since the principle of proportionality had not been observed.

86. It thus held that 'the objective of protecting public health upon which the Hellenic Republic relie[d] [could] be achieved by measures which [were] less restrictive of the freedom of establishment both for natural and legal persons, for example by requiring the presence of qualified, salaried opticians or associates in each optician's shop, rules concerning civil liability for the actions of others, and rules requiring professional indemnity insurance'. [26]

87. In my view, the Court should take a different approach with regard to the activity of dispensing medicinal products, which, owing to the extent of its impact on public health, can be distinguished from the activity of selling optical products.

25 — *Commission* v *Greece*, paragraphs 27 to 29.
26 — Ibidem, paragraph 35.

88. Admittedly, the Court has recognised that the sale of optical products such as contact lenses cannot be regarded as a commercial activity like any other, since the vendor must be able to provide users with information on the use and care of such products. [27] That is why it has held that national legislation which prohibits the sale of contact lenses and related products in commercial establishments which are not run or managed by persons who fulfil the conditions laid down for practising as opticians is justified on grounds of the protection of public health. [28]

89. Nevertheless, since medicinal products can have a more serious impact on health than optical products and, if improperly used, may even cause the death of those who take them, I consider that their supply must be subject to specific guarantees. Accordingly, I consider it legitimate for a Member State to wish to attain a high level of public health protection by seeking to preserve the quality and neutrality of the dispensing of medicinal products.

90. Since, in respect of the protection of public health, the dispensing of medicinal products cannot be regarded in the same way as the selling of optical products, I consider that a Member State may decide, without infringing the principle of proportionality and for the reasons I have already stated, to allow only pharmacists to own and operate pharmacies.

B — *The second question*

91. By this question, the referring court asks the Court, if the reply to the first question is in the affirmative, to rule whether, having regard in particular to Article 10 EC and to the principle of the effectiveness of Community law, a national authority is entitled and obliged under Community law to disapply national provisions it regards as contrary to Community law even if there is no clear breach of Community law and it has not been established by the Court that the relevant provisions are incompatible with Community law.

92. Since I propose that the Court reply to the first question in the negative, I do not consider that it is necessary to reply to the second question.

27 — See, to this effect, Case C-271/92 *LPO* [1993] ECR I-2899, paragraph 11.

28 — Ibidem, paragraph 13.

IV — Conclusion

93. In the light of all the foregoing considerations, I propose that the Court give the following ruling:

Articles 43 EC and 48 EC are to be interpreted as not precluding national legislation under which only pharmacists may own and operate a pharmacy, since such legislation is justified by the objective of ensuring proper provision of medicinal products to the public.