Joined Cases C-171/07 and C-172/07

Apothekerkammer des Saarlandes and Others

v

Saarland and Ministerium für Justiz, Gesundheit und Soziales

(References for a preliminary ruling from the Verwaltungsgericht des Saarlandes)

(Freedom of establishment – Article 43 EC – Public health – Pharmacies – Provisions restricting the right to operate a pharmacy to pharmacists alone – Justification – Reliability and quality of the provision of medicinal products to the public – Professional independence of pharmacists)

Summary of the Judgment

Freedom of movement for persons – Freedom of establishment – Restrictions (Arts 43 EC and 48 EC)

Articles 43 EC and 48 EC do not preclude national legislation which prevents persons not having the status of pharmacist from owning and operating pharmacies.

It is true that such a rule excluding non-pharmacists constitutes a restriction within the meaning of Article 43 EC because it allows only pharmacists to operate pharmacies, denying other economic operators access to this self-employed activity in the Member State concerned. However, that restriction may be justified by the protection of public health, more specifically by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality.

In that regard, the therapeutic effects of medicinal products, which distinguish them substantially from other goods, have the consequence that, if they are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered. Overconsumption or incorrect use of medicinal products leads, moreover, to a waste of financial resources which is all the more damaging because the pharmaceutical 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. There is thus a direct link between those financial resources and the profits of businesses operating in the pharmaceutical sector because in most Member States the prescription of medicinal products is borne financially by the health insurance bodies concerned.

In the light of those risks to public health and to the financial balance of social security systems, the Member States may make persons entrusted with the retail supply of medicinal products subject to strict requirements, including as regards the way in which the products are marketed and the pursuit of profit. In particular, the Member States may restrict the retail sale of medicinal products, in principle, to pharmacists alone, because of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to consumers.

In this connection, given the power accorded to the Member States to determine the level of protection of public health, Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence. They may also take measures which are capable of eliminating or reducing a risk that that independence will be prejudiced because such prejudice would be liable to affect the degree to which the provision of medicinal products to the public is reliable and of good quality.

Since non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists and consequently do not provide the same safeguards as pharmacists, it follows that a Member State may take the view, in the exercise of its discretion, that, unlike the case of a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level, because the pursuit of profit in the course of such operation does not involve moderating factors, such as training, professional experience and the responsibility that pharmacists owe, which characterise the activity of pharmacists.

As it has not been established that another measure that restricts the freedom guaranteed by Article 43 EC less than the rule excluding non-pharmacists would make it possible to ensure just as effectively the level of reliability and quality in the provision of medicinal products to the public that results from the application of that rule, the national legislation at issue in the main actions proves appropriate for securing attainment of the objective pursued by it and does not go beyond what is necessary for attaining that objective.

In particular, a Member State may take the view that there is a risk that legislative rules protecting the professional independence of pharmacists will not be observed or will be circumvented in practice. Nor can the risks to the reliability and quality of the provision of medicinal products to the public be excluded with the same effectiveness by an obligation to take out insurance, because such a means would not necessarily prevent the operator concerned from exerting influence over the employed pharmacists.

(see paras 24, 27-28, 31-35, 37-39, 54, 57-58, operative part)

JUDGMENT OF THE COURT (Grand Chamber)

19 May 2009 (<u>*</u>)

(Freedom of establishment – Article 43 EC – Public health – Pharmacies – Provisions restricting the right to operate a pharmacy to pharmacists alone – Justification – Reliability and quality of the provision of medicinal products to the public – Professional independence of pharmacists)

In Joined Cases C-171/07 and C-172/07,

REFERENCES for a preliminary ruling under Article 234 EC from the Verwaltungsgericht des Saarlandes (Germany), made by decisions of 20 March and 21 March 2007 respectively, received at the Court on 30 March 2007, in the proceedings

Apothekerkammer des Saarlandes,

Marion Schneider,

Michael Holzapfel,

Fritz Trennheuser,

Deutscher Apothekerverband eV (C-171/07),

Helga Neumann-Seiwert (C-172/07)

v

Saarland,

Ministerium für Justiz, Gesundheit und Soziales,

joined party:

DocMorris NV,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, C.W.A. Timmermans, K. Lenaerts, J.-C. Bonichot and T. von Danwitz, Presidents of Chambers, J. Makarczyk, P. Kūris, E. Juhász, G. Arestis, J. Malenovský (Rapporteur), L. Bay Larsen and P. Lindh, Judges,

Advocate General: Y. Bot,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 3 September 2008,

after considering the observations submitted on behalf of:

- the Apothekerkammer des Saarlandes, Ms Schneider, Mr Holzapfel, Mr Trennheuser and Deutscher Apothekerverband eV, by J. Schwarze, assisted by C. Dechamps, Rechtsanwalt,
- Ms Neumann-Seiwert, by H.-U. Dettling, Rechtsanwalt,
- Saarland and the Ministerium f
 ür Justiz, Gesundheit und Soziales, by W. Schild, acting as Agent, assisted by H. Kr
 öninger, Rechtsanwalt,
- DocMorris NV, by C. König, assisted by F. Diekmann, Rechtsanwältin,
- the German Government, by M. Lumma and C. Schulze-Bar, acting as Agents,
- the Greek Government, by E. Skandalou, acting as Agent,
- the French Government, by G. de Bergues and B. Messmer, acting as Agents,
- Ireland, by D. O'Hagan, acting as Agent, assisted by A. Collins SC and N. Travers BL,
- the Italian Government, by I.M. Braguglia, acting as Agent, assisted by G. Fiengo, avvocato dello Stato,
- the Netherlands Government, by Y. de Vries, acting as Agent,
- the Austrian Government, by C. Pesendorfer and T. Kröll, acting as Agents,

- the Polish Government, by E. Ośniecka-Tamecka and M. Kapko, acting as Agents,
- the Finnish Government, by J. Himmanen and A. Guimaraes-Purokoski, acting as Agents,
- the Commission of the European Communities, by E. Traversa and H. Krämer, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 16 December 2008,

gives the following

Judgment

- 1 These references for a preliminary ruling relate to the interpretation of Articles 43 EC and 48 EC and the principles of Community law.
- 2 The references were made in two actions, brought by the Apothekerkammer des Saarlandes (Saarland Pharmacists' Association), Ms Schneider, Mr Holzapfel, Mr Trennheuser and Deutscher Apothekerverband eV (German Pharmacists' Association) (C-171/07) and Ms Neumann-Seiwert (C-172/07) against Saarland and the Ministerium für Justiz, Gesundheit und Soziales (Ministry for Justice, Health and Social Affairs; 'the Ministry'), concerning national legislation which allows only persons who have the status of pharmacist to own and operate pharmacies.

Legal context

Community legislation

3 Recital 26 in the preamble to 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) 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.'

4 That recital repeats, in essence, the 2nd recital in the preamble to 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 (OJ 1985 L 253, p. 34) and the 10th recital in the preamble to 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 (OJ 1985 L 253, p. 37). Those two directives were repealed with effect from 20 October 2007 and replaced by Directive 2005/36.

National legislation

5 Paragraph 1 of the Law on Pharmacies (Gesetz über das Apothekenwesen) in the version published in BGBI. 1980 I, p. 1993, as amended by the regulation of 31 October 2006 (BGBI. 2006 I, p. 2407) ('the ApoG'), provides as follows:

(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.'
- 6 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;

•••

- (4) A licence to operate several public pharmacies is to be granted, on application, if:
- 1. the applicant fulfils the conditions under subparagraphs 1 to 3 above in respect of each of the pharmacies applied for;
- 2. the pharmacy and branch pharmacies to be operated by him are in the same district ("Kreis") or town or in neighbouring districts or towns.

(5) The provisions of this Law shall apply mutatis mutandis to the operation of several public pharmacies, subject to the following requirements:

- 1. the operator is required to manage one of the pharmacies (main pharmacy) personally;
- for each further pharmacy (branch pharmacy), the operator is required to designate in writing a pharmacist as the responsible person who must fulfil the obligations as laid down in this Law and in the pharmacy operation rules applicable to pharmacy managers.

...'

7 Paragraph 7 of the ApoG states:

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

8 Paragraph 8 of the ApoG 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. ...'

9 Paragraph 13(1) of the ApoG states:

'Following the death of the licence holder, his heirs may entrust the running of the pharmacy to a pharmacist for a maximum of 12 months.'

10 Under Paragraph 14 of the ApoG, hospitals have the choice of obtaining their supplies of medicinal products from an internal pharmacy, that is to say, a pharmacy on the premises of the hospital concerned, from the pharmacy of another hospital or from a pharmacy outside hospital premises. A licence to operate an internal pharmacy is granted if the hospital demonstrates inter alia that it has recruited a pharmacist who fulfils the conditions laid down in subparagraphs 1 to 4, 7 and 8 of Paragraph 2(1) of the ApoG.

The main actions and the questions referred for a preliminary ruling

- 11 DocMorris NV ('DocMorris') is a public limited company established in the Netherlands whose business includes the selling of medicinal products by mail order. 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 (Germany), subject to a condition requiring it to recruit a pharmacist who would be entrusted with managing the pharmacy in question personally and on his own responsibility ('the decision of 29 June 2006').
- 12 On 2 and 18 August 2006, the claimants in the main proceedings brought actions before the Verwaltungsgericht des Saarlandes (Administrative Court, Saarland) for annulment of the decision of 29 June 2006.
- 13 In those actions, they submitted that the decision of 29 June 2006 is contrary to the ApoG because it infringes the 'Fremdbesitzverbot', that is to say the principle, as resulting from subparagraph 3 of Paragraph 2(1) in conjunction with Paragraphs 7 and 8 of the ApoG, under which the right to own and operate a pharmacy is restricted to pharmacists alone ('the rule excluding non-pharmacists').
- 14 The Ministry, supported by DocMorris, contended that the decision of 29 June 2006 is valid because the Ministry was obliged to disapply the abovementioned provisions of the ApoG on the ground that they infringe Article 43 EC which guarantees freedom of establishment. In their submission, a capital company lawfully operating a pharmacy in a Member State does not have access to the German pharmacy market and such a restriction is not necessary for achieving the legitimate objective of protection of public health.
- 15 In those circumstances, the Verwaltungsgericht des Saarlandes decided to stay proceedings and to refer to the Court for a preliminary ruling the following questions, which are drafted in identical terms in both Case C-171/07 and Case C-172/07:
 - (1) Are the provisions concerning freedom of establishment for capital companies (Articles 43 EC and 48 EC) to be interpreted as precluding [the rule excluding non-pharmacists], 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 of Justice ... that the relevant provisions are incompatible with Community law?'

16 By order of the President of the Court of 1 June 2007, Cases C-171/07 and C-172/07 were joined for the purposes of the

written and oral procedure and the judgment.

Consideration of the questions

Question 1

17 By its first question, the national court asks whether Articles 43 EC and 48 EC preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies.

Preliminary observations

- First, it is clear, both from the case-law of the Court and from Article 152(5) EC and recital 26 in the preamble to Directive 2005/36, 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 organisation of health services such as pharmacies. In exercising that power, however, the Member States must comply with Community law, in particular the provisions of the Treaty on the freedoms of movement, including freedom of establishment. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the healthcare sector (see, to this effect, Case C-372/04 *Watts* [2006] ECR I-4325, paragraphs 92 and 146, and Case C-169/07 *Hartlauer* [2009] ECR I-0000, paragraph 29).
- 19 When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States must be allowed discretion (see, to this effect, Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 103; Case C-141/07 *Commission* v *Germany* [2008] ECR I-0000, paragraph 51; and *Hartlauer*, paragraph 30).
- 20 Second, neither Directive 2005/36 nor any other measure implementing the freedoms of movement guaranteed by the Treaty lays down conditions governing access to activities in the pharmacy field that specify the category of persons who are entitled to operate a pharmacy. Consequently, the national legislation must be examined in the light of the provisions of the Treaty alone.
- 21 Third, the regime applicable to persons entrusted with the retail supply of medicinal products varies from one Member State to another. Whereas, in certain Member States, only self-employed pharmacists can own and operate pharmacies, other Member States accept that persons not having the status of self-employed pharmacist may own a pharmacy while entrusting its management to employed pharmacists.

Existence of a restriction on freedom of establishment

- According to settled case-law, Article 43 EC precludes any national measure which, even though it is applicable without discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by Community nationals of the freedom of establishment that is guaranteed by the Treaty (see, in particular, Case C-19/92 *Kraus* [1993] ECR I-1663, paragraph 32, and Case C-299/02 *Commission* v *Netherlands* [2004] ECR I-9761, paragraph 15).
- 23 Legislation which makes the establishment in the host Member State of an economic operator from another Member State subject to the issue of a prior authorisation and allows self-employed activity to be pursued only by certain economic operators who satisfy predetermined requirements, compliance with which is a condition for the issue of that authorisation, constitutes a restriction within the meaning of Article 43 EC. Such legislation deters or even prevents economic operators from other Member States from pursuing their activities in the host Member State through a fixed place of business (see, to this effect, *Hartlauer*, paragraphs 34, 35 and 38).
- 24 The rule excluding non-pharmacists constitutes such a restriction because it allows only pharmacists to operate pharmacies, denying other economic operators access to this self-employed activity in the Member State concerned.

Justification of the restriction on freedom of establishment

- 25 Restrictions on freedom of establishment which are applicable without discrimination on grounds of nationality may be justified by overriding reasons in the general interest, provided that the restrictions are appropriate for securing attainment of the objective pursued and do not go beyond what is necessary for attaining that objective (see *Hartlauer*, paragraph 44).
- 26 In the main actions, first, the national legislation at issue applies without discrimination on grounds of nationality.
- 27 Second, the protection of public health is one of the overriding reasons in the general interest which can justify restrictions on the freedoms of movement guaranteed by the Treaty such as the freedom of establishment (see, inter alia, *Hartlauer*, paragraph 46).
- 28 More specifically, restrictions on those freedoms of movement may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality (see, to this effect, *Deutscher Apothekerverband*, paragraph 106, and *Commission* v *Germany*, paragraph 47).
- 29 Third, it must be examined whether the rule excluding non-pharmacists is appropriate for securing such an objective.
- 30 It is important that, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures that reduce, as far as possible, a public-health risk (see, to this effect, Case C-170/04 Rosengren andOthers [2007] ECR I-4071, paragraph 49), including, more specifically, a risk to the reliability and quality of the

provision of medicinal products to the public.

- 31 In this context, attention is to be drawn to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods (see, to this effect, Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 54).
- 32 Those therapeutic effects have the consequence that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered.
- Overconsumption or incorrect use of medicinal products leads, moreover, to a waste of financial resources which is all the more damaging because the pharmaceutical 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 (see by analogy, with regard to hospital treatment, Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraph 80, and *Watts*, paragraph 109). There is a direct link between those financial resources and the profits of businesses operating in the pharmaceutical sector because in most Member States the prescription of medicinal products is borne financially by the health insurance bodies concerned.
- In the light of those risks to public health and to the financial balance of social security systems, the Member States may make persons entrusted with the retail supply of medicinal products subject to strict requirements, including as regards the way in which the products are marketed and the pursuit of profit. In particular, the Member States may restrict the retail sale of medicinal products, in principle, to pharmacists alone, because of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to consumers (see, to this effect, *Delattre*, paragraph 56).
- In this connection, given the power accorded to the Member States to determine the level of protection of public health, it must be accepted that Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence. They may also take measures which are capable of eliminating or reducing a risk that that independence will be prejudiced because such prejudice would be liable to affect the degree to which the provision of medicinal products to the public is reliable and of good quality.
- 36 In this context, three categories of potential pharmacy operators must be distinguished, namely natural persons having the status of pharmacist, persons operating in the pharmaceutical products sector as manufacturers or wholesalers, and persons neither having the status of pharmacist nor operating in that sector.
- 37 It is undeniable that an operator having the status of pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.
- 38 Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.
- 39 A Member State may therefore take the view, in the exercise of its discretion referred to in paragraph 19 of the present judgment, that, unlike the case of a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level, because the pursuit of profit in the course of such operation does not involve moderating factors such as those, noted in paragraph 37 of the present judgment, which characterise the activity of pharmacists (see by analogy, with regard to the provision of social welfare services, Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 32).
- 40 It is therefore permissible for a Member State inter alia to assess, in the exercise of that discretion, whether such a risk exists in the case of manufacturers and wholesalers of pharmaceutical products on the ground that they might compromise the independence of employed pharmacists by encouraging them to promote the medicinal products which they produce or market themselves. Likewise, a Member State may determine whether operators lacking the status of pharmacist are liable to compromise the independence of employed pharmacists by encouraging them to sell off medicinal products which it is no longer profitable to keep in stock or whether those operators are liable to make reductions in operating costs which may affect the manner in which medicinal products are supplied at retail level.
- 41 In their observations lodged before the Court, DocMorris and the Commission of the European Communities also submitted that in the main actions the rule excluding non-pharmacists cannot be justified in the general interest because that objective is pursued in an inconsistent manner.
- 42 As to those submissions, it is apparent from the Court's case-law that national legislation is appropriate for securing attainment of the objective relied upon only if it genuinely reflects a concern to attain that objective in a consistent and systematic manner (see Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraphs 53 and 58; Case C-500/06 *Corporación Dermoestética* [2008] ECR I-0000, paragraphs 39 and 40; and *Hartlauer*, paragraph 55).
- 43 In this context, it is to be observed that the national legislation does not exclude the operation of pharmacies by non-pharmacists absolutely.
- 44 First of all, Paragraph 13(1) of the ApoG provides, by way of exception, that the heirs of a pharmacist who do not themselves have the status of pharmacist may operate the pharmacy which they have inherited for a maximum of 12 months.
- 45 However, this exception proves justified having regard to protection of the legitimate property rights and interests of the members of the deceased pharmacist's family. It must be found that the Member States may take the view that the interests of a pharmacist's heirs are not such as to jeopardise the requirements and guarantees flowing from their respective legal systems

which operators who have the status of pharmacist must meet. In this context, account is to be taken especially of the fact that throughout the transitional period a qualified pharmacist must be responsible for operating the inherited pharmacy. Therefore, the heirs cannot, in this specific context, be equated with other operators who do not have the status of pharmacist.

- 46 It should also be noted that the effects of this exception are only temporary since the heirs must transfer the rights to operate the pharmacy to a pharmacist within 12 months.
- 47 This exception is thus designed to enable the heirs to assign the pharmacy to a pharmacist within a period which does not prove unreasonable and it may thus be regarded as not presenting a risk to the reliability and quality of the provision of medicinal products to the public.
- 48 Next, nor can such a risk result from the fact that hospitals may operate internal pharmacies. The latter are intended to provide medicinal products not to persons outside those hospitals but to the hospitals in which they are established. Thus, hospitals which operate such pharmacies are not, in principle, capable of affecting the general level of reliability and quality in the provision of medicinal products to the public as a whole. Furthermore, having regard to the fact that those hospitals provide medical care, there are no grounds for assuming that they would have an interest in making a profit to the detriment of the patients for whom the medicinal products of the pharmacies which they house are intended.
- Finally, although the national legislation allows pharmacists to operate up to three branches of a single pharmacy, such a possibility is subject to a number of conditions which are intended to safeguard public health requirements. First of all, the pharmacist concerned is himself responsible for the branches' operation and he therefore determines their general commercial policy. Those branches are thus also presumed to be operated from a professional viewpoint, the private interest connected with the making of a profit being tempered to the same extent as in the case of the operation of pharmacies which are not branches. Next, those branches must be located within a specified geographical radius in order to ensure a sufficient presence in the branches of the pharmacist operating them and actual supervision by him. Last, the pharmacist operating the branches must designate, for each branch, a responsible pharmacist, who must ensure that legal obligations are complied with and that the management of the branch concerned conforms to the general commercial policy determined by the pharmacist operating the branches.
- 50 Since the operation of the branches is subject to those conditions, the legislation at issue in the main actions cannot be regarded as inconsistent.
- 51 In view of all the foregoing, it must be found that the legislation at issue in the main actions is appropriate for securing attainment of the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality and, therefore, that public health is protected.
- 52 Fourth, it must be examined whether the restriction on freedom of establishment goes beyond what is necessary for attaining that objective, that is to say whether there are measures restricting the freedom guaranteed by Article 43 EC less which would enable the objective to be attained just as effectively.
- 53 DocMorris and the Commission have submitted before the Court that that objective could be attained by less restrictive measures, such as an obligation that a pharmacist be present in the pharmacy, an obligation to take out insurance or a system of adequate controls and effective penalties.
- 54 However, having regard to the discretion which the Member States are allowed, as referred to in paragraph 19 of the present judgment, a Member State may take the view that there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator could make it difficult for them to oppose instructions given by him.
- 55 The Commission has not put forward, apart from general considerations, anything to show what the specific system would be that would be capable of ensuring – with the same effectiveness as the rule excluding non-pharmacists – that those legislative rules are observed in practice notwithstanding the considerations set out in the previous paragraph of the present judgment.
- 56 Nor, contrary to DocMorris's and the Commission's submissions, can the risks to the independence of the profession of pharmacist be excluded with the same effectiveness by the means consisting in the imposition of an obligation to take out insurance, such as insurance for vicarious civil liability. While that measure might enable the patient to obtain financial reparation for any harm suffered by him, it operates after the event and would be less effective than the rule excluding non-pharmacists in that it would not in any way prevent the operator concerned from exerting influence over the employed pharmacists.
- 57 Accordingly, it has not been established that another measure that restricts the freedom guaranteed by Article 43 EC less than the rule excluding non-pharmacists would make it possible to ensure just as effectively the level of reliability and quality in the provision of medicinal products to the public that results from the application of that rule.
- 58 Consequently, the national legislation at issue in the main actions proves appropriate for securing attainment of the objective pursued by it and does not go beyond what is necessary for attaining that objective. It must therefore be accepted that the restrictions flowing from the national legislation may be justified by that objective.
- 59 This conclusion is not called into question by the judgment in Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, upon which Saarland, the Ministry, DocMorris and the Commission rely, where the Court ruled that the Hellenic Republic had failed to fulfil its obligations under Articles 43 EC and 48 EC by enacting and maintaining in force national provisions under which the establishment by a legal person of an optician's shop was subject inter alia to the condition that authorisation for the establishment and operation of that shop had to have been granted to a recognised optician who was a natural person and the person holding the authorisation to operate the shop had to hold at least 50% of the company's share capital and participate at

least to that extent in the profits and losses of the company.

- 60 Given the particular nature of medicinal products and of the medicinal-product market, and as Community law currently stands, the Court's findings in *Commission* v *Greece* cannot be transposed to the field of the retail supply of medicinal products. Unlike optical products, medicinal products prescribed or used for therapeutic reasons may none the less prove seriously harmful to health if they are consumed unnecessarily or incorrectly, without the consumer being in a position to realise that when they are administered. Furthermore, a medically unjustified sale of medicinal products leads to a waste of public financial resources which is not comparable to that resulting from unjustified sales of optical products.
- 61 In view of all the foregoing, the answer to the first question is that Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies.

Question 2

62 Given the reply to the first question, there is no need to answer the second question.

Costs

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

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

Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies.

[Signatures]

* Language of the case: German.