OPINION OF ADVOCATE GENERAL

BOT

delivered on 16 December 2008 [1]

1. By the present action, the Commission of the European Communities seeks a declaration that, by keeping in force:

— legislation which restricts the right to operate a private retail pharmacy to natural persons who have graduated in pharmacy and to operating companies and firms composed exclusively of members who are pharmacists; and

— legislative provisions which make it impossible for undertakings engaged in the distribution of pharmaceutical products to acquire stakes in companies which operate municipal pharmacies,

the Italian Republic has failed to fulfil its obligations under Articles 43 EC and 56 EC.

2. It should be mentioned at the outset that the Commission's first complaint is closely related to the first question referred for a preliminary ruling by the Verwaltungsgericht des Saarlandes (Administrative Court, Saarland) (Germany) in Joined Cases C-171/07 *Apothekerkammer des Saarlandes and Others* and C-172/07 *Neumann-Seiwert*, pending before the Court, in which I am also delivering the Opinion. This first complaint concerns, in essence, whether Article 43 EC and/or Article 56 EC preclude a national provision under which only pharmacists may own and operate a pharmacy.

3. For the same reasons as those given in my Opinion in Joined Cases C-171/07 and C-172/07, I shall propose that the Court hold the Commission's first complaint to be unfounded. I consider that Articles 43 EC and 48 EC do not preclude 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.

1 — Original language: French.

4. I shall also propose that the Court declare the second complaint unfounded.

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 have acknowledged that the direct effect of Articles 43 EC and 49 EC, recognised in *Reyners* [2] and *van Binsbergen* [3] respectively with effect from 1 January 1970 when the transitional period ended, also applies to health care professions. [4]

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 [5] 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. [6]

2 — Case 2/74 [1974] ECR 631.

3 — Case 33/74 [1974] ECR 1299.

4 — 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.

5 — OJ 1985 L 253, p. 34.

6 — 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. [7] 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. Furthermore, Article 56(1) EC provides that, within the framework of the provisions set out in Chapter 4 ('Capital and payments') of Title III of the EC Treaty, all restrictions on the movement of capital between Member States and between Member States and third countries are to be prohibited.

12. 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*

13. In Italy, Law No 833 of 23 December 1978 established the Servizio Sanitario Nazionale (national health service). Article 25(1) of that Law provides that medical care includes the services of general practitioners, specialists, nurses, hospitals and pharmacies.

14. Two types of pharmacy coexist in Italy, namely private pharmacies and municipal pharmacies. [8]

7 — OJ 2005 L 255, p. 22.

8 — According to the Italian Republic, there are approximately 1 600 municipal pharmacies and 16 000 private pharmacies.

1. The rules governing private pharmacies

15. Article 4 of Law No 362 of 8 November 1991 relating to a reorganisation of the pharmaceutical sector ('Law No 362/1991') lays down, for ownership of a pharmacy, a competition procedure organised by the regions and the provinces which is restricted to citizens of the Member States who are in possession of their civic and political rights and are entered on the professional register of pharmacists.

16. Article 7 of Law No 362/1991 provides:

'1. The operation of private pharmacies shall be restricted to natural persons, in accordance with the provisions in force, to partnerships and to cooperative societies with limited liability.

2. The sole object of the firms and companies covered by paragraph 1 shall be to operate a pharmacy. Their members shall be pharmacists who are entered on the [professional] register and possess the qualifications prescribed in Article 12 of Law No 475 of 2 April 1968, as subsequently amended.

3. The running of the pharmacy operated by the firm or company shall be entrusted to one of the members, who shall be responsible for it.

…

5. Each of the firms and companies covered by paragraph 1 may operate a single pharmacy and obtain the corresponding licence provided that the pharmacy is situated in the province in which the firm or company has its statutory office.

6. Each pharmacist may have a stake in only one firm or company covered by paragraph 1.

7. The operation of private pharmacies shall be restricted to pharmacists entered on the [professional] register of pharmacists of the province in which the pharmacy has its seat.'

17. Under Article 8 of Law No 362/1991:

‘1. Holding a stake in a firm or company covered by Article 7 … shall be incompatible:

(a) with any other activity in the sector of manufacture and distribution of medicinal products and dissemination of scientific information about medicinal products.

…’.

2. The rules governing municipal pharmacies

18. Under Article 12 of Law No 498 of 23 December 1992, replaced by Article 116 of Legislative Decree No 267 of 18 August 2000, municipalities may, for the purpose of managing municipal pharmacies, set up companies limited by shares whose shareholders are not necessarily pharmacists. In the case of municipal pharmacies, the split between ownership of the pharmacy, which remains with the local authority, and its management, entrusted to a company in majority private ownership that is not composed solely of pharmacists, is therefore authorised.

19. By judgment of 24 July 2003, the Corte costituzionale (Constitutional Court) (Italy) extended to companies that operate municipal pharmacies the prohibition, laid down in Article 8(1)(a) of Law No 362/1991, against engaging in that activity in conjunction with distribution activity, which until then had applied only to companies and firms operating private pharmacies.

20. Simultaneous engagement in the wholesale distribution of medicinal products and sale to the public of medicines in a pharmacy was also prohibited by Article 100(2) of Decree No 219 of 24 April 2006.

21. In addition, Italian law requires, for both private and public pharmacies, that medicinal products be sold only by pharmacists. Article 122 of the consolidated health legislation thus provides:

‘Sale to the public of medicinal substances in doses or in the form of medicines may be carried out only by pharmacists and must be effected in the pharmacy under the responsibility of its operator.’

3. Decree-Law No 223 of 4 July 2006

22. Several amendments were made to the Italian legislation by Decree-Law No 223 of 4 July 2006 laying down urgently required provisions for economic and social revival and the control and rationalisation of public expenditure, and providing for action in respect of tax revenue and the combating of tax evasion ('the Bersani Decree').

23. In particular, Article 5 of the Bersani Decree repealed several of the aforementioned provisions. These were Article 7(5) to (7) of Law No 362/1991 and Article 100(2) of Decree No 219 of 24 April 2006. It also amended Article 8(1) of Law No 362/1991 by removing the term 'distribution' from that provision.

II — Pre-litigation procedure

24. The Commission considered that the aforementioned legislation was incompatible with Articles 43 EC and 56 EC and, on 21 March 2005, it sent a letter of formal notice to the Italian Republic. Since it was not convinced by the explanations provided by that Member State, on 19 December 2005 the Commission then sent it a reasoned opinion, to which the Italian authorities replied on 17 February 2006. On 6 July 2006, those authorities sent the Commission the text of the Bersani Decree, pointing out that certain provisions in that decree-law, in particular Article 5 thereof, were designed to put an end to the pre-litigation procedure.

25. Taking the view that the amendments made by the Bersani Decree to the contested legislation did not alter its view regarding the incompatibility of the Italian legislation with Community law, the Commission decided to institute the present proceedings before the Court pursuant to Article 226 EC.

III — The action

26. By its application the Commission claims that the Court should:

— declare that, by keeping in force:

— legislation which restricts the right to operate a private retail pharmacy to natural persons who have graduated in pharmacy and to operating companies and firms composed exclusively of members who are pharmacists; and

— legislative provisions which make it impossible for undertakings engaged in the distribution of pharmaceutical products to acquire stakes in companies which operate municipal pharmacies,

the Italian Republic has failed to fulfil its obligations under Articles 43 EC and 56 EC;

— order the Italian Republic to pay the costs.

27. The Italian Republic claims that the Court should:

— declare the action inadmissible;

— alternatively, declare it unfounded, with the consequences arising therefrom.

28. The Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria intervened in support of the Italian Republic.

IV — Arguments of the parties

A — *Admissibility of the action*

29. The Italian Republic maintains, first of all, that the action is inadmissible. Since it is common knowledge that in most of the Member States it is provided that only pharmacists or companies or firms controlled by pharmacists may own pharmacies, the Commission's position should be defined uniformly in relation to that legislation, avoiding distinctions between one country and another or one set of enactments and another.

30. Next, the Italian Republic observes that the Commission pleads primarily infringement of Articles 43 EC and 56 EC, but that it fails to take account of the directives which have implemented the freedom of establishment. These directives contain express provisions confirming that the conditions governing access to the sector are not yet harmonised and stating that that sphere falls within the competence of the Member States. In those circumstances, it is incumbent upon

the Commission to specify the alleged infringement in more precise and concrete terms since, in regulating the role of pharmacists, the Italian Republic correctly applied those directives and the reservation of national competence which they contain.

31. Finally, the Italian Republic states that, in spite of the amendment introduced by the Bersani Decree, which removes the prohibition on distribution undertakings acquiring stakes in companies and firms which operate pharmacies, the Commission continues to believe that such a prohibition may still be applied by the Italian courts. Therefore, the alleged failure to fulfil obligations is not real and existing but arises from future hypothetical decisions of those courts.

B — *The first complaint*

32. The Commission maintains that, by prohibiting persons who have not graduated in pharmacy and companies and firms which are not composed exclusively of pharmacists from operating a pharmacy, the Italian Republic has infringed Articles 43 EC and 56 EC. Such a prohibition makes it not only difficult but completely impossible for those categories of person to exercise two fundamental freedoms guaranteed by the Treaty, freedom of establishment and free movement of capital.

33. It is true that the objective of protection of public health constitutes an overriding reason in the general interest capable of justifying restrictions on freedom of establishment and free movement of capital. However, the Italian legislative provisions at issue in these proceedings are neither appropriate for securing such an objective nor necessary for attaining it.

34. First, the prohibition preventing persons who have not graduated in pharmacy and companies and firms which are not composed exclusively of pharmacists from operating a pharmacy is not appropriate for securing the objective of protection of public health. In that regard, a distinction must be drawn between aspects concerning 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 aspect of pharmacy relating to contact with third parties and, more specifically, with suppliers and patients. Moreover, the Commission considers that, far from undermining the objective of protection of public health, separation of the purely entrepreneurial role of the owner of the pharmacy and the professional function of the pharmacy could in fact make a positive contribution to that objective, by enabling the pharmacist to concentrate on the functions and activities more immediately linked to the pharmaceutical activity of attending directly to users.

35. In addition, the prohibition imposed by the Italian legislation is based on an unproven presumption that a pharmacist who is an operator does his job more competently than an employed pharmacist and that he is less tempted to give priority to his personal interest at the expense of the general interest. In that regard, the Commission states that since an employed pharmacist does not pursue personal interests of an economic nature but assumes specific professional responsibilities, he ought to be more inclined than the owner of the pharmacy (irrespective of whether or not the owner has graduated in pharmacy) to discharge his duties in compliance with the law and the rules of professional conduct. The Commission also states that the independence enjoyed by a pharmacist when supplying medicinal products to patients is extremely limited. He is required inter alia to supply the medicine prescribed and cannot substitute it, except in cases strictly defined by law.

36. Secondly, the Italian legal provisions at issue go beyond what is necessary to attain the objective of protection of health, since this objective could be secured with the help of measures which restrict freedom of establishment and the free movement of capital less. In particular, the requirement that a pharmacist be present in the pharmacy is enough to ensure that the customer receives a professional service. Furthermore, a system of appropriate controls and effective penalties could be applied with respect to operators of pharmacies. Such a system would make it possible to verify and ensure that those pharmacies are working properly with a view to protecting patient health. Similarly, it would be possible to include joint liability clauses in the contract of employment between the owner of the pharmacy and the pharmacist responsible for operating it. Such joint and several liability would ensure that they are both encouraged to fulfil the public service objectives and obligations connected with operating the pharmacy.

37. The Commission also observes that the opportunity afforded by the Italian legislation to companies limited by shares which are not in majority public ownership to operate municipal pharmacies indicates that the Italian legislature considered that it is not essential for the operators of pharmacies to be pharmacists in order to guarantee the quality of the pharmaceutical service and proper protection of public health, provided that a pharmacist is present in the pharmacy and responsible for the activities related to medicinal products. The same considerations apply to the provisions under which the heirs to a private pharmacy have the right to operate it for a certain period without having the necessary qualification.

38. The Commission states, moreover, that a pharmacist is subject to similar rules of professional conduct, whether he carries out his duties as owner or employee.

39. Finally, it considers that the reasoning of the Court in its judgment in *Commission* v *Greece*, [9] in respect of opticians' shops, can be applied to the commercial activity of retail sales of medicinal products.

40. Faced with these arguments, the Italian Republic, supported by the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria, maintains that the legislation concerned, in restricting the ownership and operation of private pharmacies to natural persons who have graduated in pharmacy and to companies and firms composed exclusively of members who are pharmacists, does not infringe Articles 43 EC and 56 EC. That legislation applies without discrimination on grounds of nationality and the restrictions which stem from it may be justified by the objective of protection of public health as they are appropriate and proportionate for safeguarding that objective.

41. The Italian Republic points out that both primary and secondary Community legislation preserve the competence of the Member States to define the rules governing ownership of pharmacies at issue in these proceedings. In the absence of harmonisation at Community level, their task is inter alia to determine the level of protection of public health which must be safeguarded when medicinal products are supplied by pharmacies.

42. The Italian Republic states that the correlation between the ownership/operation of private pharmacies and entry of the owners and operators in the professional register of pharmacists is a fundamental element for guaranteeing the quality of the pharmaceutical service in Italy.

43. The potentially harmful nature of medicinal products requires their use to be controlled and rationalised. There is in a pharmacy an objective conflict between the private interest — which is to ensure that the pharmacy is financially profitable — and the objectives of general interest. To ensure that the regular and appropriate supply of medicinal products to the public has priority over economic considerations, pharmacies must actually belong to persons who have the required professional capacity and specialisation. It is only if the owners of pharmacies, who have an influence on pharmacies' management, have full specialised knowledge and experience that the protection of health is systematically put before economic objectives in their management. If non-pharmacists operated pharmacies, there would be a risk that they would be guided by criteria which are irrelevant from the pharmaceutical point of view.

9 — Case C-140/03 [2005] ECR I-3177.

44. Moreover, restricting the operation of pharmacies to pharmacists makes it possible to prevent pharmaceutical manufacturers or wholesalers from owning pharmacies. Those undertakings might be induced to market, in preference, the products which they manufacture or distribute to the detriment of actual treatment requirements and patients' freedom of choice. In addition, the commercial logic of large-scale undertakings tends to lead to a reduction in distribution and storage costs and, therefore, to the concentration of sales points in more densely populated areas. Also, the unregulated opening of new pharmacies might trigger an increase in pharmaceutical costs.

45. Such risks are apparent from several studies relating to the countries or regions that have brought about full liberalisation of access to the pharmaceutical sector — such as the Republic of Estonia, the Kingdom of Norway or Navarre — which have revealed a serious decline in the quality of pharmaceutical services.

46. The effective performance of the duty of pharmacies to meet needs in the general interest cannot be ensured through less restrictive measures. Admittedly, a Member State is entitled to provide that employed pharmacists may prepare and sell medicinal products. However, such an employed pharmacist is not able to pursue his profession with total independence, since he is subject to the orders of his non-pharmacist employer.

47. Moreover, the primary nature of health means that compensation of equivalent value cannot enable reparation in full for harm. Therefore, professional indemnity insurance cover, or forms of compensation in respect of vicarious liability, do not enable the objective of protection of public health to be secured just as effectively. Also, the decision to make both the ownership of the pharmacy and the responsibility for operating it lie with a professional businessman who is a pharmacist makes it possible to add to all his responsibilities under civil and criminal law the responsibilities which arise from the code of professional conduct and are subject to the supervision of the pharmacists' association.

48. Finally, with regard to the different rules applying to private pharmacies and municipal pharmacies, the Italian Republic explains that it was necessary to insert, for private pharmacies, an additional element to safeguard health, which distinguishes their model of management from that of municipal pharmacies, since the latter are by their nature subject to supervision and control by the local authorities. The Italian Republic states in that regard that, under the model of a partly private company with the object of supplying local public services, even if the company is in majority private ownership the local authority retains powers of guidance, control and supervision as co-manager and member of the company. Similarly, where operation is entrusted to a third party, the fact that ownership of the pharmacy remains with the local authority ensures that the public interest is pursued.

C — *The second complaint*

49. By its second complaint, the Commission submits that, by keeping in force legislative provisions which make it impossible for undertakings engaged in the distribution of pharmaceutical products to acquire stakes in companies which operate municipal pharmacies, the Italian Republic has failed to fulfil its obligations under Articles 43 EC and 56 EC.

50. In its submission, such a restriction on freedom of movement of capital and freedom of establishment is not justified by the objective of protection of public health. The Commission states, in this connection, that the regime under which the activities of distribution and retail sale of medicinal products are generally incompatible is incoherent because it allows for derogations of considerable scope.

51. In particular, a person may operate a pharmacy and simultaneously be a shareholder in a distribution company provided that he does not hold, in that company, a position entailing decision making and control. Such a person might have an interest in favouring the sale on the market of products distributed by the company of which he is a shareholder. Also, there are other situations in which a pharmacist who is a shareholder in a distribution company has the opportunity to exercise, directly or indirectly, a power of actual control over that company. The incompatibility rules are therefore very flexible for natural persons and companies and firms operating private pharmacies.

52. In contrast, those rules are very restrictive for multinational companies wishing to acquire stakes in municipal pharmacies. The Commission considers that, in the latter case, the risk of conflicts of interest may be lower or, in any event, less serious, because the municipality retains ownership of the municipal pharmacy and, under a contract for services concluded with the private management company, exerts direct and specific control over that pharmacy.

53. According to the Italian Republic, the principles set out in connection with the first complaint are equally applicable to municipal pharmacies. Moreover, the Bersani Decree removed the prohibition on the acquisition of stakes in municipal pharmacies by undertakings engaged in the distribution of pharmaceutical products.

V — Assessment

A — *Admissibility of the action*

54. It is settled case-law that, in the context of an action for failure to fulfil obligations which calls into question the compatibility of national legislation with Community law, amendments to that legislation are irrelevant for the purposes of giving judgment on the subject-matter of the action if they have not been implemented before the expiry of the period set by the reasoned opinion. [10]

55. Accordingly, it is in the light of the legislation in force on 19 February 2006, the date on which the two-month period prescribed in the reasoned opinion notified to the Italian Republic on 19 December 2005 expired, that it must be decided whether the Italian Republic has committed the infringement alleged. As at that date, the Bersani Decree had not yet been adopted.

56. It follows that all the arguments which the Commission and the Italian Republic have put forward regarding the impact of the Bersani Decree on these proceedings cannot be taken into consideration. In particular, it is unnecessary to ascertain, in the course of examining the second complaint, whether the prohibition preventing undertakings engaged in the distribution of pharmaceutical products from acquiring stakes in companies which manage municipal pharmacies is still in force in the Italian legal system in spite of the Bersani Decree, whether owing to the survival of certain legislative provisions or to case-law retaining such a prohibition.

57. Accordingly, the Italian Republic is not justified in maintaining that the failure to fulfil obligations of which it is accused is not real and existing because it arises from future hypothetical decisions of the national courts.

58. The other arguments raised by that Member State in support of its claim that this action is inadmissible must also be rejected. It is in fact irrelevant with regard to the admissibility of an action for failure to fulfil obligations that the Commission has chosen to take its action against one Member State and not against those which have similar legislation. In addition, the Commission indicated precisely the Community provisions in respect of which it asks the Court to declare that the Italian Republic has failed to fulfil its obligations, namely Articles 43 EC and 56 EC.

10 — See, inter alia, Case C-392/96 *Commission* v *Ireland* [1999] ECR I-5901, paragraph 86; Case C-177/03 *Commission* v *France* [2004] ECR I-11671, paragraph 19; and Case C-412/04 *Commission* v *Italy* [2008] ECR I-619, paragraph 42.

B — *The first complaint*

59. By the first complaint, the Commission calls into question, in the light of Articles 43 EC and 56 EC, one of the conditions necessary for owning and operating a private pharmacy in Italy, namely to have graduated in pharmacy. It considers that, at the level purely of the rules governing ownership of the pharmacy, possession of a qualification as a pharmacist cannot be required. On the other hand, that condition, in its view, is necessary and must be fulfilled in order to perform the role of manager responsible for the pharmacy and, more generally, in order to carry out any task concerning contact with the users of the pharmacy.

60. Since the Commission complains that the Italian Republic has failed to fulfil its obligations arising under both Article 43 EC and Article 56 EC, it is necessary, first of all, to determine whether the national legislation at issue is to be assessed in the light of freedom of establishment and the free movement of capital or in the light of only one of those freedoms of movement.

61. According to the Court, in order to ascertain whether national legislation falls within the scope of one or other of the freedoms of movement, the purpose of the legislation concerned must be taken into consideration. [11]

62. It is clear that the main purpose of the provisions of Italian legislation at issue in the first complaint is to establish a condition for pursuing an activity as a self-employed person, here, pharmaceutical activity as owner of a pharmacy. Those provisions restrict the right to own and operate a private pharmacy to natural persons who have graduated in pharmacy and to partnerships and cooperative societies with limited liability composed exclusively of pharmacists. I consider that the Italian legislation, by regulating in this way the opening of private pharmacies in Italy, and therefore the conditions for the establishment of natural and legal persons in the pharmacy sector, primarily affects freedom of establishment. It therefore falls, first and foremost, within the scope of the Treaty provisions concerning that freedom.

63. Accordingly, if it were to be accepted that such a national measure may have restrictive effects on the free movement of capital, such effects would have to be seen as an unavoidable consequence of any restriction on freedom of establishment and do not justify an independent examination of that measure in the light of Article 56 EC. [12]

11 — Judgment of 17 July 2008 in Case C-207/07 *Commission* v *Spain*, paragraph 35.

12 — See, in particular, Case C-464/05 *Geurts and Vogten* [2007] ECR I-9325, paragraph 16 and the case-law cited therein.

64. I shall therefore examine the first complaint only from the point of view of freedom of establishment and, more specifically, in the light of Articles 43 EC and 48 EC. [13]

65. 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

66. 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.

67. 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]

68. 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'.

69. 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.

13 — I would also point out that, in the action for failure to fulfil obligations giving rise to the judgment in *Commission* v *Greece*, the Commission addressed the same type of issue — in connection with the opening of opticians' shops — only in the light of freedom of establishment. I do not consider it necessary to extend the issue now to the free movement of capital.

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.

70. Overall, the provisions of Article 152 EC contain the bases of an unintegrated public health policy and also define a sphere of protected national competence.

71. The Court must in my view take due account of the choice thus made by the drafters of the 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]

72. 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]

73. 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]

74. 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.

75. 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]

76. Having made these points, it must first be determined whether the Italian 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

77. 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.

78. 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]

79. Under Italian law, the operation of a private pharmacy is restricted to natural persons who have graduated in pharmacy and to partnerships and cooperative societies with limited liability whose sole object is to operate a pharmacy and whose members are pharmacists entered on the professional register of pharmacists.

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; *Commission* v *Greece*, paragraph 27; and Case C-500/06 *Corporación Dermoestética* [2008] ECR I-5785, paragraph 32 and the case-law cited therein.

80. The effect of these conditions is to prevent nationals of the Member States who are not pharmacists from owning and operating a private pharmacy in Italy. The conditions can be classified as restrictions on freedom of establishment by reason of the effects which they have on market access for natural or legal persons wishing to open a private pharmacy in Italy. By hindering access of new operators to the market in question, they objectively constitute barriers to the freedoms of movement which economic operators are, in principle, entitled to enjoy.

81. 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

82. A restriction such as that imposed by the Italian 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]

83. 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 Italy, irrespective of their Member State of origin.

84. 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] The Italian legislation must therefore be examined in the light of that objective, and more specifically the objective of ensuring proper provision of medicinal products to the public.

85. 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.

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.

86. I consider that this is indeed the case. More specifically, I consider that that rule ensures a provision of medicinal products to the public which is such as to give adequate guarantees regarding quality and variety.

87. In this regard, I am not persuaded by the Commission's 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 Italian 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.

88. 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.

89. 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.

90. 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.

91. 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.

92. In deciding to allow only pharmacists to own and operate pharmacies, the Italian 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 Italian 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.

93. 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.

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

95. 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.

96. It is to be recalled, in this regard, 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]

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

97. In laying down the rule that only a pharmacist may own and operate a pharmacy, the Italian 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.

98. Following the example of other Member States, the Italian legislature could also have adopted another system and chosen to protect public health by other means, for example by making just 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 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.

99. 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.

100. When establishing whether national measures, such as the one at issue in the present action, 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.

101. I consider that, in providing that only a pharmacist may own and operate a pharmacy, the Italian Republic 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.

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

103. 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]

104. 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.

105. 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.

106. 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.

24 — The arguments raised in this regard by the Commission in support of its 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.

107. The Italian 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.

108. 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.

109. Finally, 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.

110. In the light of the foregoing, I consider that the Italian 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.

111. 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 the Commission maintains, by the fact that in certain circumstances operation of a pharmacy by a non-pharmacist is allowed under Italian law. The situations referred to are the following.

112. First, there is the right afforded to the heirs of the owner of a private pharmacy to operate it for a maximum of 10 years from the date of death of the pharmacist, even though they do not have the required qualification. The Italian legislature sought in that way 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. I do not think that this exception undermines the coherence of the Italian legislation, since it is limited in time and does not compromise the essential aim of that legislation, namely to prevent the risks of conflicts of interest which might be linked to vertical integration of the pharmaceutical sector.

113. Secondly, there is the specific situation of municipal pharmacies. I would recall, in that regard, that Article 116 of Legislative Decree No 267 of 18 August 2000 provides that municipalities may, for the purpose of managing municipal pharmacies, set up companies limited by shares whose shareholders are not necessarily pharmacists. For this type of pharmacy, the split between ownership of the pharmacy, which remains with the local authority, and its management, entrusted to a company in majority private ownership that is not composed solely of pharmacists, is therefore authorised.

114. This bending of the rule that ownership and management of a pharmacy are indivisible cannot, in my view, compromise the coherence of the Italian legislation. As the Italian Republic has demonstrated, a local authority which entrusts the management of a pharmacy to a private company has a certain number of powers enabling it to guide and supervise the way in which that pharmacy assumes its role of providing the public with medicinal products.

115. The municipality's control over the management of the pharmacy is exercised, first, by laying down requirements which are inserted, case by case, in the call for tenders, in the statutes of the company providing the services and in the contract for services. Those requirements concern the specific manner in which the pharmacy is to be managed and, in particular, matters relating to the supervision exercised by the municipality and to the penalties incurred by the service provider if the management is not in accordance with the objective of protection of public health. In addition to the fact that the local authority retains ownership of the pharmacy and that it may terminate the contractual relationship between it and the company entrusted with the service, it should also be pointed out that that authority has the power to appoint one or more directors and auditors.

116. In my view, this set of factors makes it possible to ensure that in their operation municipal pharmacies actually give priority to the general interest and, more specifically, offer proper provision of medicinal products

to the public. I therefore do not think that the coherence of the Italian legislation is affected.

117. 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.

118. 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.

119. 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.

120. 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]

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

121. 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.

122. 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]

123. 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.

124. 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.

125. For all those reasons, I propose that the Court declare the Commission's first complaint unfounded.

C — *The second complaint*

126. By its second complaint, the Commission requests the Court to declare that, by keeping in force legislative provisions which make it impossible for undertakings engaged

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

28 — Ibidem, paragraph 13.

in the distribution of pharmaceutical products to acquire stakes in companies which manage municipal pharmacies, the Italian Republic has failed to fulfil its obligations under Articles 43 EC and 56 EC.

127. I would point out, first, that, on expiry of the period fixed in the reasoned opinion sent to that Member State, the Bersani Decree, which abolishes that prohibition, had not yet been adopted. It therefore cannot be taken into consideration by the Court when ruling on whether the infringement alleged under this complaint has been committed.

128. As regards, secondly, the scope of this complaint, it should be noted that, contrary to what the Commission suggests in certain passages in its pleadings, [29] the complaint cannot be extended to private pharmacies, because its wording, since the pre-litigation stage, has referred only to the case of municipal pharmacies.

129. The Court should therefore limit its assessment to the issue of whether Articles 43 EC and 56 EC preclude a prohibition preventing an undertaking engaged in the distribution of medicinal products from having a stake in a company which manages a municipal pharmacy.

130. Contrary to the situation in the first complaint, it is not a question here of assessing whether a condition for pursuing pharmaceutical activity as owner of a pharmacy is in accordance with Community law. Under the system for operating municipal pharmacies, the municipalities continue to own the pharmacy and they assign only the management to a company whose capital may be in majority private ownership. Therefore, the question here is to determine whether or not Community law precludes an undertaking engaged in the distribution of medicinal products being prevented from participating in the management of a municipal pharmacy by acquiring a stake in the private management company.

131. Since that prohibition is not intended to apply only to stakes giving the shareholder definite influence over the decisions of the company which manages the municipal pharmacy and permitting him to determine its activities, I consider that the prohibition can

29 — See, in particular, paragraph 5 of the Commission's reply.

fall within the scope of both Article 43 EC and Article 56 EC. [30]

1. The existence of restrictions on the freedoms of movement

132. The Court has stated that national measures must be regarded as 'restrictions' within the meaning of Article 56(1) EC if they are liable to prevent or limit the acquisition of shares in the companies concerned or to deter investors from other Member States from investing in their capital. [31]

133. Since the Italian legislation may have the effect of deterring persons established in other Member States who are active in the pharmaceutical distribution sector from acquiring financial stakes in companies whose object is the management of a municipal pharmacy in Italy, it constitutes a restriction on the free movement of capital.

134. As regards freedom of establishment, it is apparent from settled case-law that national provisions that apply to holdings of nationals of the Member State concerned in the capital of a company established in another Member State which give such persons definite influence over the company's decisions and permit them to determine its activities come within the substantive scope of the provisions of the Treaty on freedom of establishment. [32]

135. Since the national provisions at issue here have, at least in part, the effect of preventing undertakings engaged in pharmaceutical distribution from acquiring, in companies which manage municipal pharmacies, stakes giving them definite influence over the decisions of those companies and permitting them to determine their activities, it must also be considered that the provisions involve restrictions on freedom of establishment.

2. Justification for the restrictions found to exist

136. Similarly to freedom of establishment, the free movement of capital may be restricted by national measures justified either on the grounds set out in Article 58 EC or by overriding reasons in the general interest to the extent that there are no Community

30 — See, by analogy, *Commission* v *Spain*, paragraphs 36 and 37.

31 — Ibidem, paragraph 34 and the case-law cited therein.

32 — Ibidem, paragraph 60 and the case-law cited therein.

harmonising measures providing for measures necessary to ensure the protection of those interests. [33]

137. I consider that a measure making it impossible for undertakings engaged in the distribution of pharmaceutical products to acquire stakes in the companies which manage municipal pharmacies is justified in the light of the objective of ensuring a high level of public health protection.

138. It is to be remembered that, under Italian law, municipalities may, for the purpose of managing municipal pharmacies, set up companies limited by shares whose shareholders are not necessarily pharmacists.

139. I have explained that this bending of the rule that ownership and management of a pharmacy are indivisible cannot, in my view, compromise the coherence of the Italian legislation owing to a certain number of guarantees which make it possible to ensure that in their operation municipal pharmacies actually give priority to the general interest and, more specifically, offer proper provision of medicinal products to the public. In particular, the municipality's powers of guidance and supervision in respect of the company which manages the municipal pharmacy help to prevent the risks of conflicts of interest linked to the participation of non-pharmacists in the management of this kind of pharmacy.

140. In my view, the fact that it is impossible for undertakings engaged in the distribution of pharmaceutical products to acquire stakes in companies which manage municipal pharmacies provides an additional guarantee, conferring enhanced protection against the risks of conflicts of interest which might arise from the participation of this category of economic operator in the management of municipal pharmacies.

141. I therefore consider that the Italian Republic was able, without infringing the principle of proportionality, to retain the prohibition preventing undertakings engaged in the distribution of pharmaceutical products from acquiring stakes in companies which manage municipal pharmacies.

142. Consequently, the second complaint should in my view be declared unfounded.

33 — Ibidem, paragraph 41.

VI — Conclusion

In view of the foregoing considerations, I propose that the Court should:

— dismiss the present action for failure to fulfil obligations as unfounded, and

— order the Commission of the European Communities to pay the costs and the interveners to bear their own costs.