JUDGMENT OF THE COURT (Grand Chamber)

19 May 2009 *

In Case C-531/06,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 22 December 2006,

Commission of the European Communities, represented by E. Traversa and H. Krämer, acting as Agents, assisted by G. Giacomini and E. Boglione, avvocati, with an address for service in Luxembourg,

applicant,

v

Italian Republic, represented by I.M. Braguglia, acting as Agent, assisted by G. Fiengo, avvocato dello Stato, with an address for service in Luxembourg,

defendant,

* Language of the case: Italian.

supported by:

Hellenic Republic, represented by E. Skandalou, acting as Agent, with an address for service in Luxembourg,

Kingdom of Spain, represented by J. Rodríguez Cárcamo and F. Díez Moreno, acting as Agents, with an address for service in Luxembourg,

French Republic, represented by G. de Bergues and B. Messmer, acting as Agents,

Republic of Latvia, represented by E. Balode-Buraka and L. Ostrovska, acting as Agents,

Republic of Austria, represented by C. Pesendorfer and T. Kröll, acting as Agents, with an address for service in Luxembourg,

interveners,

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

gives the following

Judgment

1 In its action, the Commission of the European Communities requests the Court to 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

— by keeping in force legislative provisions which make it impossible for undertakings engaged in the distribution of pharmaceutical products ('distribution undertakings') 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 By order of the President of the Court of 22 June 2007, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria were granted leave to intervene in the present case in support of the form of order sought by the Italian Republic.

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 The national legislation lays down two regimes for the operation of pharmacies, namely a regime governing private pharmacies and a regime governing municipal pharmacies.

The regime governing private pharmacies

6 Article 4 of Law No 362 of 8 November 1991 relating to a reorganisation of the pharmaceutical sector ('Law No 362/1991') lays down, with regard to operation of pharmacies, a competition procedure organised by the regions and the provinces which is restricted to citizens of the Member States in possession of their civic rights and entered, as pharmacists, on the register of pharmacists.

7 Article 7 of Law No 362/1991 states:

'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 register and possess the qualifications prescribed in Article 12 of Law No 475 of 2 April 1968 [laying down provisions applicable to the pharmaceutical service; 'Law No 475/1968'], 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 register of pharmacists of the province in which the pharmacy has its seat.

…

9. If, following the acquisition by succession of a stake in a firm or company covered by paragraph 1, the conditions set out in the second sentence of paragraph 2 cease to be met, the successor must assign the stake within three years from acquisition. Where the successor is the spouse or the heir in the direct line up to the second degree, that time-limit is deferred until the successor reaches the age of 30 or, if later, until 10 years from the date of acquisition of the stake. That time-limit of 10 years shall apply solely if, within one year from the date of acquisition of the stake, the successor enrols as a

student at a pharmacy faculty of a State university or a university entitled to award a qualification having legal value. …

10. Paragraph 9 shall also apply where the private pharmacy is operated by successors within the meaning of Article 12(12) of [Law No 475/1968], as amended.

…'

8 Under the latter provision, if the holder dies the heirs may, within a period of one year, transfer the rights to operate the pharmacy to a pharmacist registered with the association of pharmacists who already has the status of holder of a pharmacy or who is considered suitable on the basis of a previous competition. During that period, the heirs are entitled to continue to operate the pharmacy provisionally under the responsibility of a manager.

9 Article 8 of Law No 362/1991 provides:

'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;

…'

10 Article 12(8) of Law No 475/1968 states:

'A pharmacy may be transferred to a pharmacist entered on the register of pharmacists, who has the requisite qualifications or has at least two years' professional experience certified by the competent health authority.'

The regime governing municipal pharmacies

11 Under the regime applicable to municipal pharmacies, it is municipalities which are the holders of the pharmacy (hereinafter 'municipal pharmacy'). For the management of those pharmacies, municipalities may set up, in accordance with Article 116 of Legislative Decree No 267 of 18 August 2000, companies limited by shares whose members are not necessarily pharmacists.

12 Article 116(1) of that decree provides:

'Local authorities may, for the performance of public services and for the carrying out of the works necessary for the proper operation of the service, as well as for the creation of infrastructure and the carrying out of other works in the public interest which, under the national and regional legislation in force, do not fall within the institutional powers of other authorities, set up companies limited by shares without a requirement of majority public ownership, even in derogation from specific legislative provisions. The authorities concerned shall provide for selection of the private shareholders and for any

offer of shares on the market by a tender procedure. The instrument setting up the company must impose an obligation on the public authority to appoint one or more directors and auditors. …'

13 By judgment of 24 July 2003, the Corte costituzionale (Constitutional Court) extended to those companies the prohibition laid down in Article 8 of Law No 362/1991 against simultaneously engaging in distribution activity, which until then had applied only to companies and firms operating private pharmacies.

14 Simultaneous engagement in the wholesale distribution of medicinal products and their retail sale was also declared unlawful by Article 100(2) of Legislative Decree No 219 of 24 April 2006 concerning the transposition of Directive 2001/83/EC (and subsequent amending directives) on the Community code relating to medicinal products for human use and of Directive 2003/94/EC (ordinary supplement to GURI No 142 of 21 June 2006).

Decree-Law No 223 of 4 July 2006

15 National pharmacy legislation was amended 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 (known as 'the Bersani Decree').

16 In particular, Article 5 of the Bersani Decree repealed Article 7(5) to (7) of Law No 362/1991 and Article 100(2) of Legislative Decree No 219 of 24 April 2006, and it amended Article 8(1)(a) of Law No 362/1991 by deleting from it the words 'and distribution'.

Pre-litigation procedure

17 Since the Commission took the view that the Italian system for the operation of pharmacies was not compatible with Articles 43 EC and 56 EC, it initiated the infringement procedure laid down in the first paragraph of Article 226 EC. After giving the Italian Republic formal notice on 21 March 2005 to submit its observations, the Commission delivered a reasoned opinion in accordance with that provision on 13 December 2005 calling on it to take the measures necessary to comply with its obligations arising from the EC Treaty within two months of receipt of the opinion. As the Commission was not satisfied with the Italian authorities' response to the reasoned opinion, it decided to bring the present action.

Admissibility

18 The Italian Republic has put forward three pleas of inadmissibility against the Commission's action.

19 First, restriction of the ownership of pharmacies to natural persons who have graduated in pharmacy ('pharmacists') and to operating companies and firms composed exclusively of members who are pharmacists is provided for not only in Italian law, but by the majority of the Member States. It is therefore necessary for the Commission's position to be defined in a uniform manner in relation to all Member State legislation, avoiding the drawing of distinctions between Member States or between sets of enactments.

20 The Italian Republic contends, second, that the Commission pleads primarily a breach of Articles 43 EC and 56 EC but fails to take account of the directives which have implemented freedom of establishment. These directives contain express provisions confirming the conditions for access to the pharmaceutical sector — which have not yet

been harmonised — by specifying that the rules concerned fall within Member State competence. In those circumstances, it is incumbent upon the Commission to set out the alleged breach of Community law precisely and specifically because, in regulating the role of pharmacists, the Italian Republic applied correctly those directives and the reservation of national competence which they contain.

21 The Italian Republic contends, third, that the amendment introduced by the Bersani Decree removes the prohibition preventing distribution undertakings from acquiring stakes in companies and firms which operate pharmacies but that, despite this, the Commission takes the view that such a prohibition may still be applied by the Italian courts. Thus, the alleged failure to fulfil obligations is not real and existing but arises from future hypothetical decisions of those courts.

22 These arguments must be rejected.

23 So far as concerns the first plea of inadmissibility, it is for the Commission, in performing the task conferred upon it by Article 211 EC, to ensure that the provisions of the Treaty are applied and verify whether the Member States have acted in accordance with those provisions. If the Commission considers that a Member State has infringed provisions of the Treaty, it is for it to determine whether it is expedient to take action against that State and what provisions the State has infringed, and to choose the time at which it will initiate infringement proceedings; the considerations which determine its choice of time cannot affect the admissibility of its action (see Case C-35/96 *Commission* v *Italy* [1998] ECR I-3851, paragraph 27, and Case C-33/04 *Commission* v *Luxembourg* [2005] ECR I-10629, paragraph 66).

24 Given this discretion, the Commission is free to initiate infringement proceedings against only some of the Member States which are in a comparable position from the

point of view of compliance with Community law. It may thus, in particular, decide to initiate infringement proceedings against other Member States subsequently, after becoming aware of the outcome of the earlier proceedings.

25 As regards the second and third pleas of inadmissibility put forward by the Italian Republic, first, the Commission has explained the nature of the alleged failure to fulfil obligations sufficiently precisely, both in its application and in its reply. Second, the question whether the Member State's acts should be assessed in the light of Articles 43 EC and 56 EC or of the directives which have implemented those articles falls within the substance of the case. The same is also true of whether the alleged failure to fulfil obligations existed at the material time for its assessment.

26 Therefore, the action brought by the Commission must be declared admissible.

Substance

The first complaint

Arguments of the parties

27 The Commission contends that, by laying down a rule which prevents natural persons who have not graduated in pharmacy and legal persons which are not composed exclusively of members who are pharmacists from operating a pharmacy ('the rule excluding non-pharmacists'), the national legislation infringes Articles 43 EC and 56 EC.

28 That rule constitutes a restriction within the meaning of those articles which may be justified only by overriding reasons in the general interest, in particular by the objective of protecting public health.

29 However, first, the rule excluding non-pharmacists is not appropriate for securing attainment of such an objective since it is based on an incorrect presumption that a pharmacist operating a pharmacy is less inclined than a non-pharmacist to favour his personal interest at the expense of the public interest.

30 Second, the legislation goes beyond what is necessary for attaining the objective of protecting public health, because that objective could be attained by other measures that restrict the freedoms laid down by Articles 43 EC and 56 EC less, 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.

31 The Italian Republic, supported by the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria, submits that the national legislation concerning the operation of pharmacies does not infringe Articles 43 EC and 56 EC.

32 First of all, Community law leaves the Member States the power to regulate the pharmacy sector, with the exception of questions relating to the mutual recognition of diplomas, certificates and other evidence of formal qualifications.

33 Next, the restrictions which flow from that national legislation are justified by the general interest of protection of public health. The legislation applies without discrimination and ensures that the proper provision of medicinal products to the

public takes precedence over economic considerations. It is only if operators of pharmacies, who exert influence over pharmacies' management, have knowledge and comprehensive specific experience that the interest of health protection is systematically put before economic objectives in their management.

34 Finally, the abovementioned Member States contend that other measures which are less restrictive do not attain the objectives in the general interest with the same effectiveness as the national legislation.

Findings of the Court

— Preliminary observations

35 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 and the free movement of capital. 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-1721, paragraph 29).

36 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-6935, paragraph 51; and *Hartlauer*, paragraph 30).

37 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.

38 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.

39 Since the Commission alleges that the Italian Republic has simultaneously infringed Article 43 EC and Article 56 EC, it should be examined, fourth, whether the national legislation concerned must be assessed in the light of the provisions relating to freedom of establishment or those relating to the free movement of capital.

40 It is to be recalled that, if the legislation under examination concerns a stake which gives its holder definite influence over the decisions of the company concerned and allows him to determine its activities, it is the provisions relating to freedom of establishment

which are applicable (Case C-251/98 *Baars* [2000] ECR I-2787, paragraphs 21 and 22, and Case C-436/00 *X and Y* [2002] ECR I-10829, paragraphs 37 and 66 to 68). However, if that legislation is not intended to apply only to stakes which enable the holder to have a definite influence on a company's decisions and to determine the company's activities, it should be examined in relation to both Article 43 EC and Article 56 EC (see, to this effect, Case C-446/04 *Test Claimants in the FII Group Litigation* [2006] ECR I-11753, paragraphs 36 and 38, and Case C-157/05 *Holböck* [2007] ECR I-4051, paragraphs 23 and 25).

41 Here, the Commission's action relates to two different situations to which the national legislation at issue is intended to apply. First, the Commission envisages the situation where that legislation prevents non-pharmacists from holding, in companies or firms operating pharmacies, significant stakes giving them definite influence over their decisions. Second, the Commission's complaints concern the situation where that legislation prevents investors from other Member States who are not pharmacists from acquiring in those companies or firms smaller stakes which do not confer such influence.

42 In those circumstances, the national legislation should be examined in the light of both Article 43 EC and Article 56 EC.

— Existence of restrictions on freedom of establishment and the free movement of capital

43 As regards Article 43 EC, according to settled case-law that provision 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).

44 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).

45 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.

46 As to Article 56 EC, 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 stakes in the undertakings concerned or to deter investors from other Member States from investing in their capital (see Case C-112/05 *Commission* v *Germany* [2007] ECR I-8995, paragraph 19, and Joined Cases C-463/04 and C-464/04 *Federconsumatori and Others* [2007] ECR I-10419, paragraph 21).

47 Here, the national legislation provides that the members of companies and firms operating pharmacies can only be pharmacists. That legislation thus prevents investors from other Member States who are not pharmacists from acquiring stakes in companies and firms of that kind.

48 Consequently, the national legislation imposes restrictions within the meaning of Articles 43 EC and 56(1) EC.

— Justification of the restrictions on freedom of establishment and the free movement of capital

49 Restrictions on freedom of establishment and on the free movement of capital 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 Case C-370/05 *Festersen* [2007] ECR I-1129, paragraph 26, and *Hartlauer*, paragraph 44).

50 In the present instance, first, the national legislation applies without discrimination on grounds of nationality.

51 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) and the free movement of capital.

52 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 Case C-141/07 *Commission* v *Germany*, paragraph 47).

53 Third, it must be examined whether the rule excluding non-pharmacists is appropriate for securing such an objective.

54 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 and Others* [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.

55 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).

56 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.

57 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.

58 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).

59 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.

60 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.

61 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.

62 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.

63 A Member State may therefore take the view, in the exercise of its discretion referred to in paragraph 36 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 61 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).

64 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.

65 The Commission submits in the alternative that, in the present case, the rule excluding non-pharmacists cannot be justified in the general interest because that objective is pursued in an inconsistent manner.

66 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-5785, paragraphs 39 and 40; and *Hartlauer*, paragraph 55).

67 In this context, it is to be observed that the national legislation does not exclude the operation of pharmacies by non-pharmacists absolutely.

68 Article 7(9) and (10) of Law No 362/1991 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 period of 1, 3 or 10 years, depending on the heirs' personal situation.

69 However, the Commission has not proved that that exception renders the national legislation inconsistent.

70 First of all, the 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.

71 Also, it should be noted that the effects of the exception are only temporary. The heirs must, as a general rule, transfer the rights to operate the pharmacy to a pharmacist within the period of just one year. It is only in the case of a stake in a company or firm composed of pharmacists who operate a pharmacy that the successors have a longer period to assign the stake, as the period is three years from acquisition of the stake.

72 These exceptions are thus designed to enable the successors to assign the pharmacy to a pharmacist within a period which does not prove unreasonable.

73 Finally, although Article 7(9) and (10) of Law No 362/1991 grants certain heirs a period of 10 years to assign the pharmacy, a period which might prove unreasonable, it must be stated that, in the light of its particularly restricted field of application, limited to the case where the successor is the spouse or the heir in the direct line up to the second degree of the deceased pharmacist, and of the fact that this successor must enrol as a student at a pharmacy faculty within a period of one year from the date of acquisition of the pharmacy, this provision cannot be sufficient to conclude that the national legislation concerned is inconsistent.

74 Nor has the Commission proved that the national legislation is inconsistent on the ground that it permits certain non-pharmacists to operate municipal pharmacies as it provides that municipalities may set up, for the management of those pharmacies, companies limited by shares whose members are not necessarily pharmacists.

75 First of all, there is nothing on the case file indicating that the municipalities, which are holders of public powers, might allow themselves to be guided by a particular commercial objective and operate municipal pharmacies to the detriment of public health requirements.

76 Next, the Commission has not contested the evidence adduced before the Court by the Italian Republic intended to show that municipalities have extensive supervisory powers over companies entrusted with the management of municipal pharmacies and that those powers enable them to ensure that the public interest is pursued.

77 According to these particulars, the municipality concerned continues to hold the pharmacies, it sets out the specific detailed rules for managing the pharmaceutical service in the pharmacies and it issues an invitation to tender in order to select the member of the company entrusted with managing the pharmacy, while the provisions intended to ensure that those detailed rules are complied with are included both in the invitation to tender and in the contractual documents which govern legal relations between the municipality and the company concerned.

78 It is also apparent from the uncontested particulars supplied by the Italian Republic that the municipality retains the power to appoint one or more directors and auditors of the company entrusted with managing the municipal pharmacy, and it participates in this way in the company's decision making and in the internal supervision of its activities. The persons appointed have the power to ensure that the municipal pharmacy systematically pursues the public interest and to prevent the professional independence of the employed pharmacists from being compromised.

79 Finally, according to the same particulars, the municipality concerned is not denied the possibility of changing, modifying or terminating the legal relationship with the company entrusted with managing the municipal pharmacy in order to implement a commercial policy which promotes to the utmost the pursuit of the public interest.

80 Consequently, in the absence of adequate evidence adduced by the Commission, the national legislation concerning municipal pharmacies cannot be considered inconsistent.

81 In view of all the foregoing, it must be found that the legislation to which the alleged failure to fulfil obligations relates 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.

82 Fourth, it must be examined whether the restrictions on freedom of establishment and the free movement of capital go beyond what is necessary for attaining that objective, that is to say whether there are measures restricting the freedoms guaranteed by Articles 43 EC and 56 EC less which would enable the objective to be attained just as effectively.

83 The Commission submits 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.

84 However, having regard to the discretion which the Member States are allowed, as referred to in paragraph 36 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.

85 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.

86 Nor, contrary to 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.

87 Accordingly, it has not been established that another measure that restricts the freedoms guaranteed by Articles 43 EC and 56 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.

88 Consequently, the national legislation 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.

89 This conclusion is not called into question by the judgment in Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, upon which the Commission relies, 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.

90 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.

91 In view of all the foregoing, the first complaint in the action must be rejected as unfounded.

The second complaint

Arguments of the parties

92 In the second complaint, the Commission submits that the regime governing municipal pharmacies is contrary to Articles 43 EC and 56 EC. It accepts that that regime permits non-pharmacists to operate municipal pharmacies in certain circumstances, by providing that companies limited by shares whose members are not necessarily pharmacists may be set up for the management of those pharmacies. However, the national legislation prevents distribution undertakings from acquiring stakes in those

companies and such a restriction cannot in any way be justified by objectives linked to the protection of public health.

93 First, such legislation is not appropriate for attaining those objectives. It is based on an incorrect presumption that a distribution undertaking would be more tempted, when operating a municipal pharmacy, to favour its personal interest at the expense of the public interest than persons not active in the pharmaceutical distribution sector.

94 Also, the legislation is inconsistent since it allows derogations of considerable scope. In particular, a person may become a member of a distribution undertaking and, notwithstanding that, operate a municipal pharmacy provided that he does not hold in that undertaking a position entailing decision making and control.

95 Second, the prohibition preventing distribution undertakings from acquiring a stake in municipal pharmacies is not necessary as the objective relied upon can be attained by other measures that are less restrictive, such as an obligation that a pharmacist be present in the pharmacy, an obligation to take out insurance or the establishment of a system of adequate controls and effective penalties.

96 The Italian Republic, on the other hand, submits that the second complaint is unfounded on the ground that the Bersani Decree removed the prohibition preventing distribution undertakings from acquiring stakes in municipal pharmacies.

97 In any event, such a prohibition is not contrary to Article 43 EC, since it can be justified by the general interest of protection of public health. The prohibition applies without discrimination and is indeed intended to prevent distribution undertakings from

promoting the medicinal products which they market by means of municipal pharmacies. Other measures which are less restrictive would not attain that objective in the general interest with the same effectiveness.

Findings of the Court

98 As regards, first of all, the Italian Republic's argument deriving from the adoption of the Bersani Decree, it is well established case-law that the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion and that the Court cannot take account of any subsequent changes (see, inter alia, Case C-103/00 *Commission* v *Greece* [2002] ECR I-1147, paragraph 23, and Case C-152/05 *Commission* v *Germany* [2008] ECR I-39, paragraph 15).

99 In the present case, it is common ground that, on the date on which the period laid down in the reasoned opinion expired, the national legislation did not allow distribution undertakings to acquire a stake in companies entrusted with the operation of municipal pharmacies as the Bersani Decree was not adopted until after that date.

100 Next, it must be found that the national legislation results in restrictions within the meaning of Articles 43 EC and 56 EC in the light of the case-law cited in paragraphs 43 and 46 of the present judgment. It prevents certain economic operators, namely those who are engaged in the distribution of pharmaceutical products, from concomitantly engaging in activity in municipal pharmacies. Also, such legislation prevents investors from Member States other than the Italian Republic which are distribution undertakings from acquiring stakes in certain companies, namely those entrusted with the operation of municipal pharmacies.

101 So far as concerns the possible justification of those restrictions, it is to be observed at the outset that the national legislation applies without discrimination on grounds of nationality and pursues the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality.

102 Moreover, the national legislation is appropriate for securing attainment of that objective. First, as follows from paragraphs 62 to 64 of the present judgment, a Member State may take the view that distribution undertakings are capable of exerting a certain amount of pressure on employed pharmacists with the objective of favouring the interest of making a profit.

103 Second, having regard to the considerations set out in the same paragraphs, the Member State concerned may take the view, in the exercise of its discretion, that the municipalities' supervisory powers over companies entrusted with the management of municipal pharmacies are not sufficient to prevent the influence of distribution undertakings over employed pharmacists.

104 Third, the Commission has not adduced concrete and specific evidence or arguments on whose basis the Court would be able to conclude that the legislation to which the second complaint relates is inconsistent in the light of other national rules, such as the rule which permits a person to become a member of a distribution undertaking and a member of a company entrusted with the operation of a municipal pharmacy provided that he does not hold in the distribution undertaking a position entailing decision making and control.

105 Finally, with regard to whether the national legislation is necessary, it must be found that, similarly to what is stated in paragraphs 84 to 86 of the present judgment, 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.

106 Consequently, the second complaint in the action must be also rejected as unfounded.

107 Since none of the pleas relied upon by the Commission in support of its action is founded, the action must be dismissed in its entirety.

Costs

108 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In the present case, the Italian Republic has requested the Court to declare the Commission's action inadmissible or unfounded 'with the measures which in consequence follow'. That form of order sought by it cannot be regarded as a request that the applicant should be ordered to pay the costs (see, to this effect, Case C-255/90 P *Burban* v *Parliament* [1992] ECR I-2253, paragraph 26). Consequently, it must be decided that the Commission and the Italian Republic will bear their own costs.

109 In accordance with Article 69(4) of the Rules of Procedure, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria are, as interveners, to bear their own costs.

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

1. **Dismisses the action;**

2. **Orders the Commission of the European Communities, the Italian Republic, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria to bear their own costs.**

[Signatures]