JUDGMENT OF THE COURT (Grand Chamber)

1 June 2010 *

In Joined Cases C-570/07 and C-571/07,

REFERENCES for a preliminary ruling under Article 234 EC, from the Tribunal Superior de Justicia de Asturias (Spain), made by decisions of 26 October and 22 October 2007, received at the Court on 24 December and 27 December 2007, in the proceedings

José Manuel Blanco Pérez,

María del Pilar Chao Gómez

v

Consejería de Salud y Servicios Sanitarios (C-570/07)**,**

Principado de Asturias (C-571/07)**,**

* Language of the case: Spanish.

intervening parties:

Federación Empresarial de Farmacéuticos Españoles (C-570/07),

Plataforma para la Libre Apertura de Farmacias (C-570/07),

Celso Fernández Gómez (C-571/07),

Consejo General de Colegios Oficiales de Farmacéuticos de España,

Plataforma para la Defensa del Modelo Mediterráneo de Farmacias,

Muy Ilustre Colegio Oficial de Farmacéuticos de Valencia,

Asociación Nacional de Grandes Empresas de Distribución (ANGED)

THE COURT (Grand Chamber),

composed of V. Skouris, President, K. Lenaerts and E. Levits, Presidents of Chambers, C.W.A. Timmermans, A. Rosas, E. Juhász, G. Arestis, A. Borg Barthet, M. Ilešič, J. Malenovský (Rapporteur), U. Lõhmus, A. Ó Caoimh and L. Bay Larsen, Judges,

Advocate General: M. Poiares Maduro,
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 19 May 2009,

after considering the observations submitted on behalf of:

— Mr Blanco Pérez, Ms Chao Gómez and the Plataforma para la Libre Apertura de Farmacias, by D. Cueva Díaz, abogado,

— the Consejería de Salud y Servicios Sanitarios and the Principado de Asturias, by R. Paredes Ojanguren, abogado,

— the Federación Empresarial de Farmacéuticos Españoles, by R. Ariño Sánchez, abogado,

— the Consejo General de Colegios Oficiales de Farmacéuticos de España, by A. García Castillo, C. Ruixo Claramunt, M. Troncoso Ferrer and I. Igartua Arregui, abogados,

— the Plataforma para la Defensa del Modelo Mediterráneo de Farmacias and the Muy Ilustre Colegio Oficial de Farmacéuticos de Valencia, by E. Navarro Varona and E. García Aguado, abogados,

— the Asociación Nacional de Grandes Empresas de Distribución (ANGED), by J. Pérez-Bustamante Köster, abogado,

— the Spanish Government, by J.M. Rodríguez Cárcamo, acting as Agent,

— the Belgian Government, by L. Van den Broeck, acting as Agent,

— the Greek Government, by K. Georgiadis, S. Alexandridou and V. Karra, acting as Agents,

— the French Government, by G. de Bergues and B. Messmer, acting as Agents,

— the Italian Government, by G. Palmieri, acting as Agent, and G. Fiengo, avvocato dello Stato,

— the Austrian Government, by C. Pesendorfer and T. Kröll, acting as Agents,

— the Portuguese Government, by L. Inez Fernandes and A.P. Antunes, acting as Agents,

— the Slovak Government, by J. Čorba, acting as Agent,

— the European Commission, by E. Traversa, R. Vidal Puig and G. Luengo, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 30 September 2009,

gives the following

Judgment

1 These references for a preliminary ruling concern the interpretation of Article 49 TFEU.

2 The references were submitted in the course of proceedings brought by Mr Blanco Pérez and Ms Chao Gómez against, on the one hand, the Consejería de Salud y Servicios Sanitarios (Ministry of Health and Public Health Services) (C-570/07) and, on the other, the Principado de Asturias (C-571/07), concerning a call for applications in connection with the issue of licences to open new pharmacies in the Autonomous Community of Asturias.

Legal context

European Union 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), the terms of which are essentially the same as those of the second 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), 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 Article 1 of Directive 2005/36 states:

'This Directive establishes rules according to which a Member State which makes access to or pursuit of a regulated profession in its territory contingent upon possession of specific professional qualifications … shall recognise professional qualifications

obtained in one or more other Member States … and which allow the holder of the said qualifications to pursue the same profession there, for access to and pursuit of that profession.'

5 Article 45 of Directive 2005/36, which is entitled 'Pursuit of the professional activities of a pharmacist', provides:

'1. For the purposes of this Directive, the activities of a pharmacist are those, access to which and pursuit of which are contingent, in one or more Member States, upon professional qualifications and which are open to holders of evidence of formal qualifications of the types listed in Annex V, point 5.6.2.

2. The Member States shall ensure that the holders of evidence of formal qualifications in pharmacy at university level or a level deemed to be equivalent, which satisfies the provisions of Article 44, are able to gain access to and pursue at least the following activities, subject to the requirement, where appropriate, of supplementary professional experience:

(a) preparation of the pharmaceutical form of medicinal products;

(b) manufacture and testing of medicinal products;

(c) testing of medicinal products in a laboratory for the testing of medicinal products;

(d) storage, preservation and distribution of medicinal products at the wholesale stage;

(e) preparation, testing, storage and supply of medicinal products in pharmacies open to the public;

(f) preparation, testing, storage and dispensing of medicinal products in hospitals;

(g) provision of information and advice on medicinal products.

…

5. If, on 16 September 1985, a Member State had a competitive examination in place designed to select from among the holders referred to in paragraph 2, those who are to be authorised to become owners of new pharmacies whose creation has been decided on as part of a national system of geographical division, that Member State may, by way of derogation from paragraph 1, proceed with that examination and require nationals of Member States who possess evidence of formal qualifications as a pharmacist referred to in Annex V, point 5.6.2 or who benefit from the provisions of Article 23 [relating to acquired rights] to take part in it.'

6 Paragraphs 2 and 5 of Article 45 of Directive 2005/36 reproduce in substance the terms of paragraphs 1, 2 and 3 of Article 1 of Directive 85/432.

National legislation

7 Under Article 103(3) of General Law 14/1986 on Health (Ley General de Sanidad 14/1986) of 25 April 1986 (BOE No 102 of 29 April 1986, p. 15207), pharmacies are to be subject to public health planning in accordance with the special legislation on medicinal products and pharmacies.

8 Article 2 of Law 16/1997 on the regulation of pharmacies (Ley de Regulación de los Servicios de las Oficinas de Farmacia 16/1997) of 26 April 1997 (BOE No 100, p. 13450) ('Law 16/1997') provides:

'1. … [F]or the purposes of organising pharmaceutical services for the general public, the Autonomous Communities, which are responsible for ensuring such services, shall establish specific planning criteria for the licensing of pharmacies.

…

2. In establishing planning policy for pharmacies, account shall be taken of population density, geographical characteristics and the distribution of inhabitants, with a view to ensuring accessibility and quality of service, as well as the satisfactory supply of medicinal products, in accordance with the public health needs in each territory.

The territorial distribution of pharmacies shall be established by unit of population and distance between pharmacies, as determined by the Autonomous Communities in accordance with the general criteria referred to above. In any event, the rules for territorial distribution must ensure adequate pharmaceutical services for all members of the public.

3. The minimum unit of population required for the opening of a pharmacy shall be, as a general rule, 2 800 inhabitants per establishment. Depending on the concentration of the population, the Autonomous Communities may establish higher minimum units of population up to a maximum of 4 000 inhabitants per pharmacy. In any event, once those thresholds have been exceeded, a new pharmacy may be opened per fraction above 2 000 inhabitants.

Notwithstanding the provision made in the preceding subparagraph, the Autonomous Communities may establish smaller units of population for rural, mountainous or tourist areas, or for areas where, by reason of their geographical, demographic or public health characteristics, pharmaceutical services would not be possible if the general criteria were applied.

4. As a general rule, the minimum distance between pharmacies, account being taken of geographical criteria and the distribution of inhabitants, shall be 250 metres. Depending on the concentration of the population, the Autonomous Communities may authorise shorter distances between pharmacies. In addition, the Autonomous Communities may set limits on the establishment of pharmacies in the proximity of public health centres.'

9 Pursuant to that legislation, the Autonomous Community of Asturias adopted Decree 72/2001 regulating pharmacies and dispensaries in the Principality of Asturias (Decreto 72/2001 regulador de las oficinas de farmacia y botiquines en el Principado de Asturias) of 19 July 2001 (BOPA No 175 of 28 July 2001, p. 10135) ('Decree 72/2001').

10 The first subparagraph of Article 1(1) of Decree 72/2001 provides:

'The territory of the Autonomous Community is divided into pharmaceutical areas which coincide, as a general rule, with the basic health areas established under the public health planning policy of the Principality of Asturias.'

11 According to the information provided by the Consejería de Salud y Servicios Sanitarios and by the Principado de Asturias, the Autonomous Community of Asturias is divided into 68 basic health areas which coincide, as a general rule, with the pharmaceutical areas.

12 Article 2 of Decree 72/2001 provides:

'1. In each pharmaceutical area, the number of pharmacies shall be based on a unit of population of 2 800 inhabitants per pharmacy. Once that number has been exceeded, a new pharmacy may be established for the fraction above 2 000 inhabitants.

2. In all the basic health areas and in all municipalities there may be at least one pharmacy.'

13 Article 3 of Decree 72/2001 provides:

'For the purposes of this Decree, the number of inhabitants shall be calculated on the basis of the data derived from the most recent municipal census.'

14 Article 4 of Decree 72/2001 provides:

‘1. As a general rule, the minimum distance between pharmacies shall be 250 metres, irrespective of the pharmaceutical area in which they are located.

2. That minimum distance of 250 metres must also be observed in relation to health centres in any of the pharmaceutical areas, whether public or private, which are under contract to provide hospital care or care outside hospital, offering external consultation or providing emergency services, and irrespective of whether they are already in operation or under construction.

That distance requirement for health centres shall not apply in pharmaceutical areas in which there is only one pharmacy or in towns or villages which currently have only one pharmacy and in which it is not foreseeable, in the light of the characteristics, that new pharmacies will be opened.

…’

15 The procedure for obtaining a licence to open a pharmacy is governed by Articles 6 to 17 of Decree 72/2001.

16 As one of its obligations under those provisions, the Autonomous Community of Asturias is required, as a matter of course, to launch a licensing procedure at least once a year for the opening of new pharmacies to take into account changes in population density.

17 The notification of the competitive examination indicates the pharmaceutical area and, where appropriate, the administrative area and the locality in which the new pharmacy is to be opened. Following publication of that notification, pharmacists who are interested must submit their applications, together with documentary evidence of their qualifications. Next, a board whose members are drawn from the administration, the register of pharmacists and the various professional associations meets in order to assess the candidates' qualifications.

18 After being granted the licence, the successful pharmacist is required to specify the premises in which he will pursue his activities. The competent authorities are to check whether the territorial planning criteria imposed by the legislation have been observed.

19 Decree 72/2001 subsequently provides, in an annex, a scale of qualifications setting out the criteria on the basis of which, in the context of the above procedure, applicants for licences to open a new pharmacy are to be evaluated.

20 The scale of qualifications assesses the applicants inter alia according to their training, postgraduate and professional experience, and their academic record.

21 Decree 72/2001 also states in points 4 to 7 of that annex:

'4. Neither professional experience as a pharmacy licence-holder or joint licence-holder nor any other type of qualification shall be taken into consideration if one or the other has previously been used to obtain a licence to set up a pharmacy.

…

6. Points for professional qualifications shall be increased by 20% for professional experience within the Principality of Asturias.

7. In the event that several applicants score an equal number of points on the scale, licences shall be granted in accordance with the following order of priority:

(a) pharmacists who have never held a licence to operate a pharmacy;

(b) pharmacists who have held a licence to operate a pharmacy in pharmaceutical areas or towns with a population of fewer than 2 800 inhabitants.

(c) pharmacists who have pursued their professional activities within the Principality of Asturias;

…'

The disputes in the main proceedings and the questions referred for a preliminary ruling

22 In 2002, the Autonomous Community of Asturias decided to launch a procedure, in accordance with Articles 6 to 17 of Decree 72/2001, for the grant of licences to open new pharmacies.

23 By decision of 14 June 2002, the Consejería de Salud y Servicios Sanitarios launched a call for applications, with a view to the granting of licences to open new pharmacies in the Autonomous Community of Asturias (BOPA No 145 of 24 June 2002, p. 8145; 'the decision of 14 June 2002').

24 The rules of the call for applications envisaged the opening of 24 new pharmacies, on the basis of such criteria as population density, the distribution of inhabitants, the distance between pharmacies, and very small population units.

25 Mr Blanco Pérez and Ms Chao Gómez, who are both qualified pharmacists, wished to open a new pharmacy in the Autonomous Community of Asturias, but without having to comply with the territorial planning rules flowing from Decree 72/2001.

26 Consequently, in the first case before the referring court, they brought an action against the decision of 14 June 2002, and against the decision of the Consejo de Gobierno del Principado de Asturias of 10 October 2002, confirming the earlier decision.

27 In the second case before the referring court, Mr Blanco Pérez and Ms Chao Gómez brought an action before the Tribunal Superior de Justicia de Asturias challenging the implied decision relating to the objection lodged against Decree 72/2001 and, specifically, against Articles 2, 4, 6 and 10 thereof and against the Annex thereto relating to the scale of qualifications.

28 In both of those cases, Mr Blanco Pérez and Ms Chao Gómez disputed the legality of the abovementioned decisions and of Decree 72/2001, inter alia on the ground that they had the effect of preventing pharmacists from gaining access to new pharmacies in the Autonomous Community of Asturias. Moreover, they claimed, Decree 72/2001 sets out improper criteria for the selection of licensees for new pharmacies.

29 In that context, the referring court inquires whether the body of rules laid down in Decree 72/2001 constitutes a restriction on the freedom of establishment which is incompatible with Article 49 TFEU.

30 Accordingly, in Case C-570/07, the Tribunal Superior de Justicia de Asturias decided to stay the proceedings and to refer to the Court the following question for a preliminary ruling:

'Should Articles 2, 3 and 4 of [Decree 72/2001] and Sections 4, 6 and 7 of the Annex thereto be considered to be in breach of Article [49 TFEU]?'

31 In Case C-571/07, the Tribunal Superior de Justicia de Asturias decided to stay the proceedings and to refer to the Court the following question for a preliminary ruling:

'Does Article [49 TFEU] preclude the legislation of the Autonomous Community of the Principality of Asturias concerning authorisation for the establishment of pharmacies?'

32 By order of the President of the Court of 28 February 2008, Cases C-570/07 and C-571/07 were joined for the purposes of the written and oral procedure and the judgment.

Admissibility

33 The Consejo General de Colegios Oficiales de Farmacéuticos de España and the Spanish, Greek, French and Italian Governments dispute the admissibility of the references for a preliminary ruling.

34 First of all, they argue, the referring court does not provide any information on the factual situation of Mr Blanco Pérez and Ms Chao Gómez. Secondly, it does not clearly indicate the provisions of national law concerned and does not sufficiently set out the reasons which led it to inquire as to the compatibility of those provisions with Article 49 TFEU. Lastly, the questions referred are hypothetical since the disputes in the main proceedings concern two Spanish nationals. In the absence of any cross-border element, those questions are unrelated to European Union law ('EU law').

35 In that regard, it should be borne in mind that it is solely for the national court before which the dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine in the light of the particular circumstances of the case both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted concern the interpretation of EU law, the Court is in principle bound to give a ruling (see, to that effect, Case C-379/98 *PreussenElektra* [2001] ECR I-2099, paragraph 38, and Case C-169/07 *Hartlauer* [2009] ECR I-1721, paragraph 24).

36 It follows that questions concerning EU law enjoy a presumption of relevance. Thus, the Court may refuse to rule on a question referred by a national court only where it is quite obvious that the interpretation of EU law that is sought is unrelated to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (see, to that effect, Joined Cases C-94/04 and C-202/04 *Cipolla and Others* [2006] ECR I-11421, paragraph 25, and Joined Cases C-222/05 to C-225/05 *van der Weerd and Others* [2007] ECR I-4233, paragraph 22).

37 Having regard to that case-law, it should be observed, first, that the national court states in the orders for reference, as the reason why it considers it necessary to refer the questions for a preliminary ruling, that the lawfulness of the legislation at issue in the main proceedings depends on the interpretation by the Court of Article 49 TFEU.

38 Secondly, it is not obvious that the interpretation sought is unrelated to the actual facts of the main actions or their purpose, or that the problem is hypothetical.

39 Admittedly, it is common ground that Mr Blanco Pérez and Ms Chao Gómez are of Spanish nationality and that all aspects of the main proceedings are confined within one Member State. However, as is apparent from the case-law, the Court's answer may be useful to the referring court even in such circumstances, in particular if its national law were to require it to grant a Spanish national the same rights as those which a national of another Member State would derive from EU law in the same situation (see, inter alia, Case C-451/03 *Servizi Ausiliari Dottori Commercialisti* [2006] ECR I-2941, paragraph 29, and *Cipolla and Others*, paragraph 30).

40 Furthermore, while national legislation such as that at issue in the main proceedings – which applies to Spanish nationals and to nationals of other Member States alike – is, generally, capable of falling within the scope of the provisions relating to the fundamental freedoms established by the Treaty only to the extent that it applies to situations connected with trade between the Member States, it is far from inconceivable that nationals established in Member States other than the Kingdom of Spain have been or are interested in operating pharmacies in the Autonomous Community of Asturias (see, to that effect, Case C-384/08 *Attanasio Group* [2010] ECR I-2055, paragraphs 23 and 24 and the case-law cited).

41 Thirdly, the orders for reference adequately describe the legal and factual background to the disputes in the main proceedings and the information provided by the referring court allows the scope of the questions referred to be determined. Thus, the orders for reference have given interested parties a genuine opportunity to submit observations in accordance with Article 23 of the Statute of the Court of Justice of the European Union, as is indeed shown by the content of the observations submitted in these proceedings.

42 In those circumstances, the questions referred for a preliminary ruling must be held to be admissible.

Substance

Preliminary observations

43 It should first be noted that, pursuant to Article 168(7) TFEU, as clarified by the case-law of the Court and by recital 26 in the preamble to Directive 2005/36, EU law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions to govern the organisation of health services such as pharmacies. In exercising that power, however, Member States must comply with EU law and, in particular, with the Treaty provisions on the fundamental freedoms, since those provisions prohibit Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the healthcare sector (see, to that effect, *Hartlauer*, paragraph 29; Case C-531/06 *Commission* v *Italy* [2009] ECR I-4103, paragraph 35; and Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, paragraph 18).

44 That being so, 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 should be allowed a measure of discretion (see, to that effect, Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 51, and *Apothekerkammer des Saarlandes and Others*, paragraph 19).

45 Secondly, neither Directive 2005/36 nor any other measure implementing the fundamental freedoms lays down rules, concerning access to activities in the pharmacy field, which seek to set the conditions for opening new pharmacies in Member States.

46 Admittedly, Article 45(5) of Directive 2005/36 provides that, if, on 16 September 1985, a Member State had a competitive examination in place designed to select the pharmacists to be authorised to become owners of new pharmacies whose creation has been decided on as part of a national system of geographical division, that Member State may proceed with that examination and also require nationals of other Member States to take part in it.

47 As it is, it is common ground in that connection that, on 16 September 1985, such an examination was in place in Spain and that the procedure at issue in the main proceedings corresponds to that examination. Consequently, the Member State concerned may maintain that procedure and may require all pharmacists to take part in it, provided that the rules relating to it are in conformity with EU law.

48 That being so, it does not follow that, as regards the requirements relating to the territorial distribution of pharmacies, the rules governing the procedure concerned escape application of the Treaty by virtue of the fact that that aspect remains outside the scope of Directive 2005/36.

49 The aim of Directive 2005/36, in accordance with Article 1 thereof, is to establish rules on the recognition of professional qualifications in order to allow holders of those qualifications to pursue a regulated profession on a self-employed or employed basis. On the other hand, the directive does not contain any rules governing the establishment of pharmacies, or the conditions of their operation, or, more specifically, their territorial distribution.

50 That finding is supported, furthermore, by recital 26 in the preamble to Directive 2005/36, pursuant to which the directive does not coordinate all the conditions for access to activities in the field of pharmacy, so that the territorial distribution of pharmacies, in particular, remains a matter for the Member States.

51 In those circumstances, the rules of national law concerned, relating to territorial distribution, must be examined in the light of the provisions of the Treaty and, specifically, in the light of Article 49 thereof.

The first part of the questions referred for a preliminary ruling, Erelating to the main conditions linked to population density and the minimum distance between pharmacies

52 By the first part of its questions, the referring court essentially inquires whether Article 49 TFEU precludes national legislation, such as that at issue in the cases before it, which imposes restrictions on the issue of licences for the opening of new pharmacies, by providing that:

— in each pharmaceutical area, a single pharmacy may be opened, as a general rule, per unit of 2 800 inhabitants;

— a supplementary pharmacy may not be opened until that threshold has been exceeded, that pharmacy being established for the fraction above 2 000 inhabitants; and

— each pharmacy must be a minimum distance away from existing pharmacies, that distance being, as a general rule, 250 metres.

The existence of a restriction on the freedom of establishment

53 It is settled case-law that any national measure which, albeit applicable without discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by EU nationals of the freedom of establishment guaranteed by the Treaty constitutes a restriction within the meaning of Article 49 TFEU (see, to that effect, Case C-299/02 *Commission* v *Netherlands* [2004] ECR I-9761, paragraph 15, and Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, paragraph 27).

54 A national rule which makes the establishment of an undertaking from another Member State conditional upon the issue of prior authorisation falls within that category, since it is capable of hindering the exercise by that undertaking of freedom of establishment by preventing it from freely pursuing its activities through a fixed place of business. First, the undertaking may have to bear the additional administrative and financial costs which any such grant of authorisation entails. Secondly, the system of prior authorisation acts as a bar to self-employed activity for economic operators who do not satisfy predetermined requirements, compliance with which is a condition for the issue of that authorisation (see, to that effect, *Hartlauer*, paragraphs 34 and 35).

55 Moreover, national legislation constitutes a restriction where it makes the pursuit of an activity subject to a condition which is linked to the economic or social needs for that activity, since it tends to limit the number of service providers (see, to that effect, *Hartlauer*, paragraph 36).

56 It should be noted first that, in the disputes before the referring court, the national legislation makes the setting up of a new pharmacy conditional upon prior administrative authorisation which is granted, moreover, only upon success in a competitive assessment.

57 Secondly, that legislation allows, in each pharmaceutical area, only one pharmacy to be set up per unit of population of 2 800, the opening of a supplementary pharmacy not being permitted until that threshold has been exceeded, when a new pharmacy can be set up for the fraction over 2 000 inhabitants.

58 Thirdly, that legislation precludes pharmacists from being able to pursue an independent economic activity in the premises of their choice, since they are required, in general, to observe a minimum distance of 250 metres in relation to existing pharmacies.

59 The effect of such rules is to hinder and render less attractive the exercise by pharmacists from other Member States of their activities on Spanish territory through a fixed place of business.

60 Consequently, national legislation such as that at issue in the cases before the referring court constitutes a restriction on the freedom of establishment within the meaning of Article 49 TFEU.

The justification for the restriction on the freedom of establishment

61 It is settled case-law that restrictions on freedom of establishment which are applicable without discrimination on grounds of nationality may be justified by overriding reasons relating to 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 (*Hartlauer*, paragraph 44, and *Apothekerkammer des Saarlandes and Others*, paragraph 25).

62 It should be noted, in the first place, as regards the cases before the referring court, that the rules at issue apply without discrimination on grounds of nationality.

63 In the second place, it is apparent from Article 52(1) TFEU that the protection of public health can justify restrictions on the fundamental freedoms guaranteed by the Treaty, such as the freedom of establishment (see, inter alia, *Hartlauer*, paragraph 46, and *Apothekerkammer des Saarlandes and Others*, paragraph 27).

64 More specifically, restrictions on the freedom of establishment may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality (*Commission* v *Italy*, paragraph 52, and *Apothekerkammer des Saarlandes and Others*, paragraph 28).

65 The importance of that objective is confirmed by Article 168(1) TFEU and Article 35 of the Charter of Fundamental Rights of the European Union, under which, inter alia, a high level of protection for human health is to be ensured in the definition and implementation of all policies and activities of the European Union.

66 It follows that the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality is such as to justify national legislation like that at issue in the cases before the referring court.

67 In the third place, it is necessary to determine whether such legislation is appropriate to the attainment of that objective.

68 In that connection, it should first be noted that, in view of the discretion referred to in paragraph 44 above, the fact that one Member State imposes more stringent rules than another in relation to the protection of public health does not mean that those rules are incompatible with the Treaty provisions on the fundamental freedoms (see, to that effect, Case C-110/05 *Commission* v *Italy* [2009] ECR I-519, paragraph 65 and the case-law cited).

69 Consequently, the fact that the rules laid down in that connection vary from one Member State to another and, specifically, the fact that some Member States do not restrict the number of pharmacies which may be established on the national territory, whereas others limit the number of new pharmacies by making them subject to geographical planning rules, is not decisive for the outcome of the cases before the referring court.

70 Secondly, it should be borne in mind that, according to the case-law of the Court, public health establishments and infrastructures may be subject to planning. That may include prior authorisation for the establishment of new service providers, where this proves indispensable for filling in possible gaps in access to public health services and for avoiding the duplication of structures, so as to ensure the provision of public health care which is adapted to the needs of the population, which covers the entire territory and which takes account of geographically isolated or otherwise disadvantaged regions (see, by analogy, Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraphs 76 to 80; Case C-372/04 *Watts* [2006] ECR I-4325, paragraphs 108 to 110; and *Hartlauer*, paragraphs 51 and 52).

71 That finding is fully transposable to the provision of public health services in the field of pharmacy.

72 Thirdly, it should be observed that there are certain densely populated areas which might be perceived by many pharmacists as very profitable, and consequently more attractive, such as those in urban areas. By contrast, other parts of the national territory might be considered to be less attractive, such as rural, geographically isolated or otherwise disadvantaged areas.

73 In those circumstances, it is not inconceivable that, if this field were wholly unregulated, pharmacists would become concentrated in the areas considered to be attractive, so that certain other less attractive areas would suffer from a shortfall in the number of pharmacists needed to ensure a pharmaceutical service which is reliable and of good quality.

74 Fourthly, it should be borne in mind that, where there is uncertainty as to the existence or extent of risks for public health, a Member State can take protective measures without having to wait until the reality of those risks becomes fully apparent (*Apothekerkammer des Saarlandes and Others*, paragraph 30).

75 Thus, a Member State might see a risk that some parts of its territory will be left with too few pharmacies and that, as a consequence, the provision of medicinal products might well not be reliable and of good quality.

76 Accordingly, the Member State may, in view of that risk, adopt legislation under which only one pharmacy may be set up in relation to a certain number of inhabitants (see paragraph 57 above).

77 The effect of laying down such a condition may be to channel the setting-up of pharmacies towards parts of the national territory where access to pharmaceutical services is lacking since, by preventing pharmacists from setting up in areas where there is already a sufficient number of pharmacies, it encourages them to do so in areas where there are too few.

78 It follows that that condition is likely to result in an even distribution of pharmacies throughout the national territory; in that way to ensure that the population as a whole has adequate access to pharmaceutical services; and, as a consequence, to improve the reliability and the quality of the provision of medicinal products to the public.

79 Next, it should be pointed out that the mere application of the condition linked to units of population may not be enough to prevent the concentration of pharmacies, within a geographical area determined in accordance with that condition, in certain attractive parts of that area. Such a concentration of pharmacies might result in the duplication of structures, while other parts of the same area might suffer from a lack of pharmacies.

80 In these circumstances, it is permissible for a Member State to lay down supplementary conditions designed to prevent such a concentration, such as a condition comparable to that at issue in the cases before the referring court, in accordance with which there must be a minimum distance between pharmacies.

81 By its very nature, that condition enables such a concentration to be avoided and is thus likely to lead to a more even distribution of pharmacies within a given geographical area.

82 As a result, the 'minimum distance' condition also leads members of the public to be more confident that they have a pharmacy nearby and, in consequence, that they have quick and easy access to adequate pharmaceutical services.

83 Arguably, such conditions for access are necessary *a fortiori* in view of the fact that medicinal products may need to be administered urgently and that customers of pharmacies include persons with reduced mobility, such as people who are elderly or seriously ill.

84 Thus, the 'minimum distance' condition is complementary to the condition linked to units of population and may therefore help to achieve the objective of distributing pharmacies evenly throughout the national territory, of ensuring accordingly that the population as a whole has adequate access to pharmaceutical services and of improving, as a consequence, the reliability and the quality of the provision of medicinal products to the public.

85 Lastly, it should be observed that attainment of the objective sought by the two abovementioned conditions is furthered through the application of certain criteria, in accordance with Decree 72/2001, at the stage of selecting licensees for new pharmacies.

86 Under point 7(b) of the Annex to Decree 72/2001, in the event that several applicants score an equal number of points on the scale of qualifications pursuant to which licensees for new pharmacies are selected, licences are to be granted in accordance with an order of priority in which precedence is given, after the categories of pharmacist described in point 7(a), to pharmacists who have held a licence to operate a pharmacy in areas or towns with a population of fewer than 2 800 inhabitants.

87 Since the geographical areas with a population of fewer than 2 800 inhabitants are generally considered by pharmacists to be less attractive (see paragraph 72 above), that licensing condition is designed to encourage pharmacists to set up in those areas, with a view to being rewarded later, when licences are again granted for the opening of new pharmacies.

88 However, Mr Blanco Pérez and Ms Chao Gómez submit, as does the Plataforma para la Libre Apertura de Farmacias, that the body of rules at issue in the cases before the referring court cannot be regarded as appropriate for attaining the objective relied on, since its effect is to deny certain pharmacists any access to independent professional activity, while pharmacists already established on the market benefit from disproportionate advantages.

89 That line of argument cannot succeed.

90 First of all, it should be observed that the freedom of establishment of economic operators must be weighed against the imperative requirements of the protection of public health, and the seriousness of the objectives pursued in that domain may justify restrictions which have adverse consequences, and even substantial adverse consequences, for certain operators (see, to that effect, Case C-183/95 *Affish* [1997] ECR I-4315, paragraphs 42 and 43).

91 Secondly, according to the file, the competent authorities are to organise at least once a year a procedure for issuing licences for setting up new pharmacies in step with demographic developments. Thus, by decision of 14 June 2002, the Autonomous Community of Asturias launched a licensing procedure for the opening of 24 new pharmacies on its territory with effect from 2002.

92 Lastly, under point 4 of the Annex to Decree 72/2001, neither professional experience as a pharmacy licence-holder or joint licence-holder, nor any other type of qualification, is to be taken into consideration if one or the other has previously been used to obtain a licence to set up a pharmacy. Similarly, point 7(a) of that annex states that, in the event that several candidates score an equal number of points on the scale, the licences are to be granted in accordance with an order of priority in which precedence is given to pharmacists who have not held a licence to operate a pharmacy.

93 Through the use of those criteria, the effect of such national legislation is to favour pharmacists who have not yet obtained a licence to set up a pharmacy and, accordingly, it is designed to ensure that more pharmacists have access to independent professional activity.

94 While it is apparent from the above that legislation such as that at issue in the cases before the referring court is generally appropriate to attaining the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality, it is also essential that the way in which that legislation pursues that objective is not inconsistent. According to the case-law of the Court, the various rules – and the national legislation as a whole – are appropriate for ensuring attainment of the objective relied upon only if they genuinely reflect a concern to attain that objective in a consistent and systematic manner (see, to that effect, *Hartlauer*, paragraph 55, and *Apothekerkammer des Saarlandes and Others*, paragraph 42).

95 It is necessary, therefore, to determine whether, in fixing the minimum number of inhabitants per pharmacy, as a rule, at 2 800 or 2 000 inhabitants and the minimum distance between pharmacies, as a rule, at 250 metres, Decree 72/2001 seeks in a consistent and systematic manner to ensure that the provision of medicinal products to the public is reliable and of good quality. In that regard, Law 16/1997 must also be taken into account, since Decree 72/2001 implements that law.

96 On that point, it should be noted that the two conditions laid down in Decree 72/2001 – applicable throughout the territory concerned – are supposed to ensure the reliable and satisfactory provision of medicinal products to the public on the basis of standards, applied across the board, which necessarily take into account ordinary demographic factors, regarded as average. It follows that the uniform application of conditions conceived on that basis might well be unsuccessful in ensuring adequate access to pharmaceutical services in areas which have certain special demographic features.

97 That may be the case, first, in certain rural areas where the population is generally dispersed and less numerous. The effect of that special feature may be that, were the condition of the minimum number of 2 800 inhabitants to be uniformly applied, certain inhabitants concerned would find themselves beyond reasonable reach of a pharmacy and would thus be denied adequate access to pharmaceutical services.

98 In that respect, it should be noted that the national legislation provides for certain adjustment measures which make it possible to mitigate the consequences of applying the basic rule of 2 800 inhabitants. Under the second subparagraph of Article 2(3) of Law 16/1997, the Autonomous Communities may establish units of population smaller than 2 800 per pharmacy for rural, mountainous or tourist areas, or for areas where, by reason of their geographical, demographic or public health characteristics, pharmaceutical services would not be possible if the general criteria were applied, and thereby make a pharmacy situated in that special area more accessible for the local population.

99 Secondly, strict application of the other condition laid down in Decree 72/2001, relating to the minimum distance between pharmacies, poses a risk that adequate access to pharmaceutical services cannot be ensured in certain geographical areas which are densely populated. In those areas, the population density around a pharmacy may be significantly higher than the number of inhabitants set as the standard density. In those specific circumstances, application of the condition requiring a minimum distance of 250 metres between pharmacies could well give rise to a situation in which more than 2 800 inhabitants live inside the perimeter laid down for a single pharmacy – or,

indeed, in the circumstances envisaged in Article 2(3) of Law 16/1997, more than 4 000 inhabitants. Accordingly, it is possible that the inhabitants of areas such as those described may, because of the strict application of the 'minimum distance' rule, experience difficulty in having access to a pharmacy in circumstances which allow adequate pharmaceutical services to be provided.

100 That being so, those consequences can still be mitigated, even in such a case, in view of the flexibility provided for in Article 2(4) of Law 16/1997, under which the minimum distance between pharmacies is fixed 'as a general rule' at 250 metres: thus, depending on the concentration of the population, the Autonomous Communities are able to authorise a shorter distance between pharmacies, and thereby increase the number of pharmacies available in areas with a very high population density.

101 In that regard, it should be pointed out that, in order to attain in a consistent and systematic manner – in a situation such as that described in paragraph 99 above – the objective of ensuring adequate pharmaceutical services, the competent authorities might even be disposed to interpret the general rule as meaning that a licence may be granted for opening a new pharmacy within a distance of less than 250 metres, not only in highly exceptional cases, but whenever the strict application of the general 250 metre rule risks being unable to ensure adequate access to pharmaceutical services in certain geographical areas with a high population density.

102 In those circumstances, it is for the referring court to determine whether the competent authorities make use – as described in paragraphs 98, 100 and 101 above – of the power conferred by such provisions in every geographical area with special demographic features, in which the strict application of the basic '2 800 inhabitants' and '250 metres' rules risks preventing the establishment of a sufficient number of pharmacies to ensure adequate pharmaceutical services.

103 In the light of all the above, it must be held that, subject to the considerations set out in paragraphs 94 to 100 above, the legislation at issue in the cases before the referring court is appropriate to the aim pursued.

104 It remains to be examined, fourthly, whether the restriction on the freedom of establishment goes beyond what is necessary to attain the aim pursued, that is to say, whether there are less restrictive measures by means of which that aim could be achieved.

105 On that point, Mr Blanco Pérez and Ms Chao Gómez submit, inter alia, as do the Plataforma para la Libre Apertura de Farmacias and the European Commission, that it is sufficient to set a minimum number of pharmacies for specified geographical areas. In that way, admittedly, no licence for setting up a new pharmacy would be issued – as under the current system – in areas where there was already an adequate number of pharmacies, until each of the specific geographical zones had the minimum number of pharmacies required. However, as soon as each of those areas had the minimum number of pharmacies, the opening of new pharmacies would be possible.

106 In that connection, it should be pointed out, however, that in the light of the discretion enjoyed by the Member States in relation to the protection of public health, referred to in paragraph 44 above, a Member State may consider that the 'minimum number' system is less effective than the current system in enabling the objective to be met of ensuring that the provision of medical products is reliable and of good quality in areas which are not very attractive.

107 First of all, under the current system, the factor which prompts pharmacists to establish themselves in areas without pharmacies is the fact that they are prevented from setting up in areas which already have a sufficient number of pharmacies, the basis for this being an objective demographic criterion, that is to say, pharmacists may not set up in those areas until the number of inhabitants in those areas rises beyond the threshold fixed. Thus, theoretically, that system does not leave pharmacists who wish to pursue an independent professional activity any choice other than to establish

themselves in areas where there are no pharmacies, in which the provision of medicinal products to the public is inadequate and where the establishment of pharmacies is therefore authorised.

108 Secondly, a Member State – such as the Kingdom of Spain – may legitimately structure the territorial distribution system at regional level, that is to say, it may confer on the various regions the task of organising the distribution of pharmacies between the geographical areas of their respective territories.

109 However, the situation in the various regions may differ considerably so far as the establishment of pharmacists is concerned.

110 Specifically, it is conceivable that, within certain regions, there are one or more geographical areas in which the minimum number of pharmacies required has not yet been reached. Accordingly, it is only in those 'pharmacy-deprived' areas that the possibility of establishing new pharmacies is open.

111 On the other hand, the situation in other regions may be that all their geographical areas already have the minimum number of pharmacies required and – under the alternative 'minimum number' system described in paragraph 105 above – pharmacists would thus be free to set up anywhere in the regional territory, including the more attractive areas. However, that situation might run counter to the national objective, as it follows from Law 16/1997, of channelling pharmacists towards areas where there are no pharmacies, in whatever region: it is possible that the pharmacists concerned would tend to swell the numbers of pharmacists in regions where the minimum number has already been reached – and where, as a consequence, there are no restrictions on the opening of pharmacies – instead of setting up in areas where there are no pharmacies, in the regions where the minimum number has not been reached.

112 Accordingly, it cannot be held that the legislation at issue in the cases before the referring court goes beyond what is necessary to attain the objective pursued.

113 Having regard to the above, the answer to the first part of the questions referred is that Article 49 TFEU must be interpreted as not precluding, in principle, national legislation, such as that at issue in the cases before the referring court, which imposes restrictions on the issue of licences for the opening of new pharmacies, by providing that:

— in each pharmaceutical area, a single pharmacy may be opened, as a general rule, per unit of 2 800 inhabitants;

— a supplementary pharmacy may not be opened until that threshold has been exceeded, that pharmacy being established for the fraction above 2 000 inhabitants; and

— each pharmacy must be a minimum distance away from existing pharmacies, that distance being, as a general rule, 250 metres.

114 Nevertheless, Article 49 TFEU precludes such national legislation in so far as the basic '2 800 inhabitants' and '250 metres' rules prevent, in any geographical area which has special demographic features, the establishment of a sufficient number of pharmacies to ensure adequate pharmaceutical services, that being a matter for the national court to ascertain.

The second part of the questions referred for a preliminary ruling, relating to the selection criteria for licensees for new pharmacies, as set out in points 4, 6 and 7(a) to (c) of the Annex to Decree 72/2001

115 By the second part of its questions, the referring court essentially inquires whether Article 49 TFEU precludes criteria, such as those set out in points 4, 6 and 7(a) to (c) of the Annex to Decree 72/2001, under which licensees for new pharmacies are to be selected.

116 As regards the criteria provided for in points 4 and 7(a) and (b) of that annex, the considerations set out in paragraphs 86, 87, 92 and 93 above show that they contribute, in accordance with Article 49 TFEU, to achieving the general interest objective referred to.

117 In those circumstances, it remains to be considered whether Article 49 TFEU precludes the criteria provided for in points 6 and 7(c) of that annex, given that Article 49 TFEU requires, in particular, that the criteria applicable in the context of an administrative authorisation scheme not be discriminatory (see *Hartlauer*, paragraph 64).

118 In this connection, it should be borne in mind that the principle of non-discrimination prohibits not only direct or overt discrimination on grounds of nationality but also all covert forms of discrimination which, by the application of other distinguishing criteria, lead to the same result (see Case C-212/99 *Commission* v *Italy* [2001] ECR I-4923, paragraph 24, and Case C-224/00 *Commission* v *Italy* [2002] ECR I-2965, paragraph 15).

119 Thus, unless objectively justified and proportionate to its aim, a provision of national law must be regarded as indirectly discriminatory if it is intrinsically liable to affect the nationals of other Member States more than the nationals of the State whose legislation is at issue and if there is a consequent risk that it will place the former at a particular disadvantage (Case C-212/05 *Hartmann* [2007] ECR I-6303, paragraph 30).

120 In the present case, point 6 of the Annex to Decree 72/2001 states that a further 20% is to be added for professional qualifications for professional experience obtained within the Autonomous Community of Asturias.

121 Secondly, it emerges from point 7(c) of that annex that, in the event that several candidates score an equal number of points on the scale, licences are to be granted in accordance with an order of priority in which precedence is given, after the categories of pharmacist described in point 7(a) and (b), to pharmacists who have pursued their professional activities within the Autonomous Community of Asturias.

122 Thus, by dint of those two criteria, the selection process favours pharmacists who have pursued their activities on part of the national territory. Obviously, such a criterion can be more easily met by national pharmacists, who more often pursue their economic activities on the national territory, than by pharmacists who are nationals of other Member States, who more frequently pursue those activities in another Member State (see, by analogy, *Hartmann*, paragraph 31).

123 The Consejería de Salud y Servicios Sanitarios and the Principado de Asturias contend, however, that the difference in treatment can be justified by the need to maintain a level of quality in the pharmaceutical service, given that its quality would be impaired if pharmacists who had set up in business were not immediately capable of providing pharmaceutical services. If pharmacists are to be able to operate immediately in this way, they need, in particular, to be acquainted with the health programmes provided for by the regional administration, and the way in which the pharmacies in that region operate.

124 Such arguments cannot be upheld since, under Article 1(1) and (2) of Directive 85/432 and Article 45(2)(e) and (g) of Directive 2005/36, holders of evidence of formal qualifications in pharmacy at university level must be able to gain access to the activities of preparation, testing, storage and supply of medicinal products in pharmacies open to the public and the activities of provision of information and advice on medicinal products. In those circumstances, the requirements referred to in paragraph 123 above cannot be relied upon to justify unequal treatment such as that at issue in the cases before the referring court.

125 In the light of the foregoing, the answer to the second part of the questions referred is that Article 49 TFEU, read in conjunction with Article 1(1) and (2) of Directive 85/432 and Article 45(2)(e) and (g) of Directive 2005/36, must be interpreted as precluding criteria, such as those set out in points 6 and 7(c) of the Annex to Decree 72/2001, under which licensees for new pharmacies are to be selected.

Costs

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

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

1. Article 49 TFEU must be interpreted as not precluding, in principle, national legislation, such as that at issue in the cases before the referring court, which imposes restrictions on the issue of licences for the opening of new pharmacies, by providing that:

— in each pharmaceutical area, a single pharmacy may be opened, as a general rule, per unit of 2 800 inhabitants;

— a supplementary pharmacy may not be opened until that threshold has been exceeded, that pharmacy being established for the fraction above 2 000 inhabitants; and

— each pharmacy must be a minimum distance away from existing pharmacies, that distance being, as a general rule, 250 metres.

Nevertheless, Article 49 TFEU precludes such national legislation in so far as the basic '2 800 inhabitants' and '250 metres' rules prevent, in any geographical area which has special demographic features, the establishment of a sufficient number of pharmacies to ensure adequate pharmaceutical services, that being a matter for the national court to ascertain.

2. Article 49 TFEU, read in conjunction with Article 1(1) and (2) of 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, and Article 45(2)(e) and (g) of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications must be interpreted as precluding criteria, such as those set out in points 6 and 7(c) of the Annex to Decree 72/2001 of 19 July 2001, regulating pharmacies and dispensaries in the Principality of Asturias (Decreto 72/2001 regulador de las oficinas de farmacia y botiquines en el Principado de Asturias), under which licensees for new pharmacies are to be selected.

[Signatures]