OPINION OF ADVOCATE GENERAL POIARES MADURO
delivered on 30 September 2009 [1]

1. The concern that pharmacists in need of money may compromise their professional obligations is not new. It has been a matter of concern at least since Shakespeare's Romeo convinced a 'caitiff wretch' of an apothecary to sell him poison with the lines:

'… famine is in thy cheeks,

Need and oppression starveth in thine eyes,

Contempt and beggary hangs upon thy back;

The world is not thy friend nor the world's law;

The world affords no law to make thee rich;

Then be not poor, but break it, and take this.' [2]

2. To follow the lines of Shakespeare we could say that at the core of this case is the extent to which guaranteeing the quality of pharmaceutical services requires making some pharmacists rich. In fact, the Asturian authorities, and those of other Member States with similar rules, justify their rules, which limit the opening of new pharmacies, mostly on the basis of the need to preserve the right financial incentives for the broadest and best possible provision of pharmaceutical services. In their view, this requires, on the one hand, protecting existing pharmacies from the 'dangers' of competition and, on the other hand, attracting pharmacists to less profitable areas by restricting access to the most profitable areas. I have no doubt that the financial conditions under which a service is provided can affect the provision of that service. It is legitimate for States to base their regulation on such concerns when they are instrumental to the pursuit of a public goal such as the protection of public health. On the other hand, it is not sufficient for States to simply invoke that possible link to justify any set of rules. Legislation which affords particular financial advantages to some economic operators over others must be properly scrutinised. The question in this case belies an easy answer. On the one hand, protecting human health is of paramount importance, and the Court must defer to the Member States' judgments in this complex area. On the other, it is the duty of this Court to remedy situations in which local political processes have been captured to provide lucrative benefits for established locals at the expense, amongst others, of nationals of other Member States.

1 — Original language: English.
2 — William Shakespeare, *Romeo and Juliet*, Act 5, Scene 1.

This duty cannot be abdicated simply because a case raises public health issues. Indeed, the need for an impartial arbiter is greatest where issues at stake involve, not just financial gain, but human health. Accordingly, in responding to the questions raised in this case, I will attempt to balance the competing interests, both deferring to the Member States' policy judgments and carefully examining their implementation schemes for signs of '*political capture*' under the requirements of coherence and consistency that have been developed in the case-law of this Court with respect to national legislation hindering free movement.

I – Factual and legal context

3. The plaintiffs in these cases are both Spanish citizens who are qualified pharmacists but are not accredited to open a pharmacy. They have practised their profession for several years in veterinary pharmacies. As they aim to operate their own pharmacy, they wish to obtain permission to open a new pharmacy within the Autonomous Community of Asturias in Spain. The relevant permit was denied to the plaintiffs by a decision of the Ministry of Health and Public Health Services of the Principality of Asturias on 14 June 2002. This decision was confirmed by the Asturian Governing Council on 10 October 2002. The plaintiffs have mounted a legal challenge to this decision before the Tribunal Superior de Justicia de Asturias.

4. The decisions of the Asturian authorities are based on Decree 72/2001 of 19 July 2001 regulating pharmacies and pharmaceutical dispensaries in the Principality of Asturias which establishes a system of licensing including certain restrictions on the establishment of pharmacies within the Autonomous Community as well as a system governing the award of licences between competing candidates. The plaintiffs claim that this decree violates their right to freedom of establishment under Article 43 EC. In view of the doubts surrounding the legality of the decree in the light of Community law, the national court has referred the following two questions to the Court of Justice:

'Should Articles 2, 3 and 4 of Decree 72/2001 dated 19 July of the Principality of Asturias regulating pharmacies and pharmaceutical dispensaries, and Sections 4, 6 and 7 of the Annex thereto, be considered to be in breach of Article 43 of the EC Treaty? (Case C-570/07)'

and

'Does Article 43 [EC] preclude the legislation of the Autonomous Community of the Principality of Asturias concerning authorisation for the establishment of pharmacies? (Case C-571/07)'

5. As noted above, the legislation challenged provides for the limitation of the opening of new pharmacies and sets out criteria for distinguishing between competing candidates for licences to open a new pharmacy. The most important limitations consist of a quantitative restriction limiting the number of pharmacies in an area by reference to the population of that area and a geographical restriction preventing the establishment of a pharmacy within 250 metres of another pharmacy. The specific provisions are as follows:

'*Article 2.* Units of population

1. In each pharmaceutical zone 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 zones and in all municipalities there may be at least one pharmacy.

Article 3. Calculation of population

For the purposes of this decree, the calculation of population shall be carried out on the basis of the data derived from the most recent version of the municipal register.

Article 4. Minimum distances

1. The minimum distance between pharmacies shall, as a general rule, be 250 metres, irrespective of the pharmaceutical zone to which they belong.

2. That minimum distance of 250 metres must also be observed in relation to public health centres in any of the pharmaceutical zones, irrespective of whether they are public or private health centres under contract to provide non-hospital or hospital care, 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 zones in which there is only one pharmacy or in towns which currently have only one pharmacy and in which it is not foreseeable, in the light of its characteristics, that new pharmacies are to be opened.

In both cases, reasons must be given for the non-applicability of the distance requirement to a public health centre. [3]

6. In order to distinguish between competing candidates for licences under these arrangements the legislation sets out various criteria. Professional and teaching experience are assigned points based on a variety of criteria. More points are awarded for professional experience in towns with fewer than 2 800 inhabitants than for other types of practice. The act also provides the following:

'1. The circumstances and qualifications set out in the present scale must be evidenced by official certificates from the relevant authorities or person responsible.

2. For the purposes of assessment of professional and teaching experience, calculations shall be made in full months even if the periods worked were interrupted. Interrupted periods of work may be accumulated in units of 21 days or 168 hours which are the equivalent of one month, until that minimum period is arrived at.

3 — Decree 72/2001.'

In cases where a person was contracted on a part-time basis, qualifications for professional experience shall be calculated in the same way as above in relation to full days worked.

3. Only one professional activity shall be counted for the same period, except in the case of two part-time activities.

4. Professional experience as a qualified pharmacist or joint-owner of a pharmacy or any other type of qualification shall not be assessed if one or more of those activities has previously been used to obtain authorisation for establishment.

5. In the case of joint-ownership of a pharmacy in which no more than two owners are involved, 50% of the points attributed for the qualifications of each of them shall be taken into account. If more than two owners are involved, 50% of the points for qualifications awarded to the owner with the highest number of points and 50% of those awarded to the owner with the fewest points shall be assessed.

6. A further 20% shall be added for professional qualifications for professional experience obtained within the Principality of Asturias.

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

(a) Pharmacists who have not been accredited to operate a pharmacy.

(b) Pharmacists who have been accredited to operate a pharmacy in pharmaceutical zones or towns with a population of less than 2 800 inhabitants.

(c) Pharmacists who have carried out their professional activities within the Principality of Asturias.

(d) Pharmacists who have the best academic qualifications. [4]

4 — Annex: Scale of qualifications required for accreditation to operate a pharmacy.'

II – Analysis

A – *Admissibility*

7. Some of the parties argue that this case is not admissible because the plaintiffs are Spanish nationals challenging Spanish regulations. However, the Court has consistently found such cases to be admissible. [5] It is solely for the national court to determine the need for a preliminary ruling in order to enable it to deliver judgment. [6] The Court will give such a ruling unless it is quite obvious that the ruling sought bears no relation to the main action. [7] The national court may need the interpretation of Community law requested, even if the factual situation at issue is purely internal, since 'such a reply might be useful to it if its national law were to require, in proceedings such as those in this case, that a national producer must be allowed to enjoy the same rights as those which a producer of another Member State would derive from Community law in the same situation.' [8] As I have previously explained, I believe that this approach is warranted in the light of the spirit of cooperation between the national courts and the Court of Justice and in view of the need to avoid situations in which the application of national law in combination with the application of Community law brings about adverse treatment of a Member State's own nationals. [9] Therefore, the Court should provide the requested interpretation of Article 43 EC in the present case.

B – *Existence of a restriction on freedom of establishment*

8. Community law does not detract from the power of the Member States to organise their health and social security systems. [10] Although pharmacies are commercial undertakings, they also represent part of the healthcare system. Thus, as part of their power to organise such systems, Member States may adopt provisions intended to govern the

5 — Case C-448/98 *Guimont* [2000] ECR I-10663, paragraph 23; Joined Cases C-515/99, C-519/99 to C-524/99 and C-526/99 to C-540/99 *Reisch and Others* [2002] ECR I-2157, paragraph 26; Case C-6/01 *Anomar and Others* [2003] ECR I-8621, paragraph 41; Case C-451/03 *Servizi Ausiliari Dottori Commercialisti* [2006] ECR I-2941, paragraph 29; Joined Cases C-94/04 and C-202/04 *Cipolla and Others* [2006] ECR I-11421, paragraph 30; Case C-380/05 *Centro Europa 7* [2008] ECR I-349, paragraph 69.

6 — See, e.g., *Centro Europa 7*, paragraph 52.

7 — *Centro Europa 7*, paragraph 53.

8 — *Guimont*, paragraph 23.

9 — My Opinion in *Centro Europa 7*, point 30.

10 — Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, paragraph 18; Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 22.

organisation of pharmacies, just as they do for other health services. [11]

9. Nevertheless, Member States are required to exercise their competence in this area in a manner that is consistent with the freedoms guaranteed by the Treaty, including the freedom of establishment. [12] The case-law of the Court has been clear that any national measure that is liable to hinder or render less attractive the exercise by Community nationals of the freedom of establishment guaranteed by the Treaty will amount to an interference with rights guaranteed by Article 43 EC, even when the relevant national measure is applicable without discrimination on grounds of nationality. [13]

10. Interference with fundamental freedoms often manifests itself as an obstacle to access to the national market that results from measures which protect the market-shares of already established operators in the national market. [14] Prior authorisation requirements that allow an activity to be pursued only by certain economic operators who satisfy predetermined requirements constitute a restriction. [15] Specifically, 'national legislation under which the pursuit of an activity is subject to a condition linked to the economic or social need for that activity constitutes a restriction in that it tends to limit the number of providers of services'. [16] On this basis, national legislation that permitted new outpatient dental clinics only where the local authorities considered that there was a need for additional clinics was found to restrict freedom of establishment. [17] Such limitations are analogous to those that have been found to constitute a barrier to free movement of goods by protecting the positions of established economic operators, thereby hindering access to the national market for products originating in other Member States. [18]

11. Applying these standards to the rules at issue in this case, which permit new pharmacies to be opened only subject to location and population requirements, it is clear that these rules do amount to a restriction on the freedom of establishment. These requirements allow the establishment of new pharmacies only where there is prior authorisation, and

11 — *Apothekerkammer des Saarlandes and Others*, paragraph 18; Case C-141/07 *Commission* v *Germany*, paragraph 22.

12 — *Apothekerkammer des Saarlandes and Others*, paragraph 18; Case C-141/07 *Commission* v *Germany*, paragraphs 22 and 23.

13 — *Apothekerkammer des Saarlandes and Others*, paragraph 22; Case C-169/07 *Hartlauer* [2009] ECR I-1721, paragraph 33.

14 — See my Opinion in *Cipolla and Others*, point 59.

15 — *Apothekerkammer des Saarlandes and Others*, paragraph 23; *Hartlauer*, paragraph 34; Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraph 42.

16 — *Hartlauer*, paragraph 36.

17 — *Hartlauer*, paragraph 39.

18 — On this point, see my Opinion in Joined Cases C-158/04 and C-159/04 *Alfa Vita Vassilopoulos and Carrefour-Marinopoulos* [2006] ECR I-8135, point 47.

that authorisation is granted only where the conditions relating to location and population are satisfied. They are, in fact, directly analogous to the requirement at issue in *Hartlauer* that a need be shown before an outpatient clinic could be opened. Where the population is not sufficient for the national authorities to find a need for a new pharmacy, one cannot be opened. By freezing access to the market, the measures in question have the effect of hindering those who wish to establish a pharmacy within the territory of Asturias from doing so and, thus, will hinder the establishment of pharmacies from outside the Member State.

C – *Whether such a restriction can be justified*

12. Establishing that the national legislation restricts the freedom of establishment is only the first step in our inquiry. Such national measures may be justified if they satisfy four conditions. Specifically, 'they must be applied in a non-discriminatory manner; they must be justified by imperative requirements in the general interest; they must be suitable for securing the attainment of the objective which they pursue; and they must not go beyond what is necessary in order to attain it.' [19]

1. Non-discriminatory application

13. The principle provisions of the Decree, the population and minimum distance requirements, are non-discriminatory. They apply equally to all pharmacists. [20] This is also true of the criteria established by the Asturian authorities in relation to the assessment of competing applications for licences to open pharmacies, which give higher priority to pharmacists who have previously worked in underserved areas. [21] In principle, any pharmacist, regardless of origin, has the same possibility to benefit from this provision.

14. However, the criteria giving additional priority to applicants who have practised as pharmacists within the territory of Asturias [22] amount to impermissible discrimination on grounds of nationality. This is true even though, like the provision benefiting

19 — Case C-55/94 *Gebhard* [1995] ECR I-4165. See also Case C-140/03 *Commission* v *Greece* (Opticians) [2005] ECR I-3177.

20 — See, e.g., Case C-141/07 *Commission* v *Germany*, paragraph 33.

21 — See Point 7(b) of the Annex to Decree 72/2001.

22 — See Points 6 and 7(c) of the Annex to Decree 72/2001.

pharmacists from underserved areas, it is facially blind to national origin and a pharmacist from another Member State working in Asturias could benefit from the provision. This is because it treats experience gained in Asturias as somehow of more value than equivalent experience gained in other Member States. [23] Such a criterion cannot be justified under this Court's case-law, as the attribution of equal value to qualifications obtained in other Member States is critical to free movement.

15. This conclusion is not drawn into question by the fact that Spanish pharmacists from outside Asturias are also disadvantaged by such a policy. The Court has been clear that in order for discrimination to be established 'it is not necessary for all undertakings in a Member State to be advantaged in comparison with foreign undertakings. It is sufficient that the preferential system set up should benefit a national provider of services'. [24] The according of priority by the Asturian authorities to those who have practised their profession within Asturias clearly disadvantages pharmacists coming from outside the principality, including those from other Member States, as well as Asturian pharmacists who have chosen to exercise their right to freedom of establishment in other Member States. [25] Such a policy amounts to a discriminatory restriction on freedom of establishment which is precluded by the Treaty.

16. Accordingly, in assessing the other elements that must be met in order for the law to be justified, I will limit my analysis to the non-discriminatory elements of the law.

2. Public interest goal

17. The public interest goal pursued by the population and geographical restrictions is the protection of public health through the provision of good pharmaceutical services in all areas of the territory of Asturias. The protection of public health is, without doubt, an imperative requirement in the general

23 — See *Gebhard*, paragraph 38. It must be noted furthermore that the advantage given to pharmacists with previous experience in Asturias is unrelated to the goal of promoting establishment in less populated areas as it is given to all pharmacists established in Asturias regardless of whether they contributed to that goal by having previously established themselves in less populated areas of Asturias.

24 — Case C-141/07 *Commission* v *Germany*, paragraph 38; Case C-353/89 *Commission* v *Netherlands* (Mediawet) [1991] ECR I-4069, paragraph 25.

25 — See Case C-456/05 *Commission* v *Germany* [2007] ECR I-10517, paragraph 58. See also Case C-340/89 *Vlassopoulou* [1991] ECR I-2357 and Case C-238/98 *Hocsman* [2000] ECR I-6623.

interest. [26] Many of the parties' arguments appear focused on the question of which approach is best designed to protect public health and, in particular in this case, to achieve the broadest territorial provision of good pharmaceutical services: one that facilitates the opening of pharmacies and simultaneously promotes competition between them or one that limits the opening of pharmacies in more populated areas in order to restrict competition and favour their opening in less populated areas of the country. The parties cite conflicting evidence, including the experience in different Member States, to establish that their preferred approach is the best for the protection of public health.

18. On this question, I consider it sufficient to note that each Member State has discretion to design its own system of public health protection and the Court is required to give considerable deference to the Member State. [27] That is particularly the case when the absence of a policy consensus is supported by the existence of important policy differences among Member States. The fact that one Member State imposes less strict rules than another or prioritises one concern over another does not mean that either set of rules is incompatible with Community law. [28] Moreover, this Court has expressly recognised that the planning of medical services, including their even distribution throughout a State, is within the scope of this discretion. [29] When considering pharmaceuticals products and services, this Court has determined that price fixing [30] and limiting competition [31] are possible techniques to achieve these public health goals.

19. While aims of a purely economic nature cannot justify restricting the fundamental freedoms, [32] they can be justified where necessary to make the health system function economically. [33] In particular, 'interests of an economic nature concerning the maintenance of a balanced medical and hospital service open to all' may present a suitable public interest. This can include the planning of such services' 'geographical distribution, their organisation and the facilities with which they are provided, and even the nature of the

26 — *Apothekerkammer des Saarlandes and Others*, paragraph 27; *Hartlauer*, paragraph 46; Case C-141/07 *Commission* v *Germany*, paragraphs 46 and 47.

27 — See *Apothekerkammer des Saarlandes and Others*, paragraph 19.

28 — Case C-294/00 *Gräbner* [2002] ECR I-6515, paragraph 46.

29 — Case C-141/07 *Commission* v *Germany*, paragraph 61.

30 — Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 122.

31 — Case C-141/07 *Commission* v *Germany*, paragraph 59.

32 — Footnote 29 above.

33 — Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraph 73.

medical services which they are able to offer, in a way which, first, meets, as a general rule, the objective of guaranteeing in the territory of the Member State concerned sufficient and permanent access to a balanced range of high-quality hospital treatment and, secondly, assists in ensuring the desired control of costs and prevention, as far as possible, of any wastage of financial, technical and human resources.' [34] Accordingly, I conclude that ensuring a distribution of pharmacies throughout the territory should be considered an imperative requirement in the general interest, and that the Member State is not required to use the vehicle of free competition to attempt to provide high-quality pharmaceutical services.

3. Whether the Decree is appropriate for the achievement of the goals cited and does not go beyond what is necessary to do so

20. While the judgment of the national legislative process and regulatory bodies, whose greater proximity to local conditions and specialised knowledge make them best placed to identify the best way of meeting the goals of public policies such as the protection of public health, must be given proper consideration, deference to such bodies does not come without risks. [35] That same proximity might also make those entities the object of 'regulatory capture' by the special interests dominant in that area at the expense of the interests of consumers and potential out of State and domestic competitors. There is particular reason for concern in a case such as this one, where the policy choice made by the local government provides lucrative benefits to established operators at the expense of new market entrants.

21. It is in this respect that one may understand the increased importance that the requirement of consistency and coherence has acquired in the case-law of the Court in reviewing how the national legislation pursues its stated goals. The coherence and consistency requirement lays down that 'the 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.' [36] This requirement allows the Court to differentiate between legislation that genuinely pursues a legitimate public goal and legislation that might even have been originally aimed at the pursuit of such goal but has become captured by certain special interests. It is a requirement that can be said to protect

34 — Case C-141/07 *Commission* v *Germany*, paragraphs 60 and 61.

35 — See *Apothekerkammer des Saarlandes and Others*, paragraph 19.

36 — *Apothekerkammer des Saarlandes and Others*, paragraph 42.

the integrity of the regulatory and legislative process and proper political accountability. In my view such requirement plays a fundamental role in the assessment to be made in the present cases.

22. Thus, in *Hartlauer*, the Court accepted the State's argument that it might need to limit the number of medical practices for purposes of maintaining a well-functioning medical system. However, it found that the regulation did not genuinely reflect a concern to attain this objective because independent outpatient clinics and group practices can have identical impacts and the legislation only covered the former. Likewise, while the Court did not question that limitations on television advertising for medical and surgical products could be justified on public health grounds, it found that the particular legislation at issue in *Coporación Dermoestética* was not justified because it applied to national but not local television stations. [37] In contrast, when finding justified German laws that require pharmacies to be owned by pharmacists and hospitals to obtain pharmaceuticals only from local pharmacies, the Court did so by relying heavily on the presumed coherence and consistency of the provisions. [38]

23. The Court has applied the same technique to other sensitive areas. In the context of gambling, for example, the Court found that certain strict limits on the number of gambling licences that a State would authorise were justified only if they were coherent and consistent in light of the stated goal of reducing criminal and fraudulent activity by encouraging gamblers to use licensed outlets. [39] The Court reasoned that if the number of licences were set so low that authorised operators would not provide an attractive alternative to unlicensed operators, the legislation would not satisfy this requirement. [40]

24. Accordingly, we must assess the extent to which the legislation actually promotes in a consistent and coherent way the goals that the Member State has put forward to justify it. There are two primary justifications given to support the restrictions. First, it is argued that restricting access to the market ensures that quality pharmaceutical services are

37 — Case C-500/06 *Coporación Dermoestética* [2008] ECR I-5785, paragraphs 37 to 39.

38 — Case C-141/07 *Commission* v *Germany*, paragraphs 51 to 57; *Apothekerkammer des Saarlandes and Others*, paragraphs 41 to 50.

39 — *Placanica*, paragraph 55.

40 — *Placanica*, paragraph 55.

available. Second, it is argued that the population and location restrictions will ensure universal access to pharmacies by forcing them to spread throughout the territory. I will address these arguments in turn.

(a) Quality of pharmaceuticals services

25. The first argument, which figured predominantly in the debate surrounding the recent cases *Apothekerkammer des Saarlandes and Others* and *Commission* v *Italy*, [41], involving German and Italian requirements that pharmacies must be operated by pharmacists, plays a less predominant role in the present cases. It is however mentioned by some of the parties and it appears to be linked to the risk that increased competition among pharmacies may, to use a colloquial expression, lead pharmacists to 'cut corners'.

26. As a preliminary matter, I note that the State bears the burden of demonstrating that the measure is appropriate and necessary for the provision of a higher quality service. [42] Shakespeare aside, no basis appears to exist in the record to say that increased competition will lead the pharmacists to lower the quality of their services. I cannot but notice, in this respect, that there is a degree of inconsistency in the rationale behind large parts of the reasoning of some of the parties and the Member States. At times, pharmacists are portrayed as being primarily motivated by financial gain to the extent that they would all seek to practise only in heavily populated areas and, if subject to competition, ready to allow profit to prevail over their professional obligations. At other times, when in possession of a 'monopolist' position in a populated area, pharmacists are assumed to conduct their business dominated by their professional obligations and devoted primarily to the provision of quality pharmaceutical services. In the arguments of several of the parties, competition appears to transform saints into sinners.

27. Moreover, it must be recalled that the nature of pharmaceutical services has substantially changed: before the pharmacist himself or herself would 'compose' the medicines. Today, the pharmacist only dispenses medicines that are 'composed' somewhere else and

41 — Case C-531/06 [2009] ECR I-4103.

42 — *Deutscher Apothekerverband*, paragraph. 123.

subject to strict legal requirements including, for example, requirements as to whether a medication can be dispensed without a prescription. The Court has, itself, recognised this by accepting the sale of non-prescription medicines over the internet. [43] Accordingly, I do not consider that the Member State has demonstrated that a limitation on competition is necessary or proportionate to the goal of providing high quality pharmaceutical services.

28. It must be recognised that in the recent cases, *Apothekerkammer des Saarlandes and Others* and *Commission* v *Italy*, involving national rules limiting pharmacy ownership to pharmacists, the Court found that the need to ensure the reliable provision of good quality medicinal products to the public may justify limitations on the access to ownership of pharmacies. [44] Those cases, however, turned on the pharmacists' professional training, experience and responsibility, which the Court considered might lead the pharmacists' pursuit of profit to be tempered by other professional interests. [45] Furthermore, the Court accepted that restriction on the basis of the particular assumption that pharmacists enjoyed genuine professional independence. [46] Such independence resulted from their professional obligations and from the fact that they were separate from the production and distribution of the goods sold in their pharmacies [47] thus enabling them to resist pressures to encourage over-consumption of medicinal products to a greater degree than non-pharmacists and ensuring that the restriction in question truly served the relevant public health goal.

29. This reasoning in fact supports the argument against the compatibility of the Asturian legislation with Community law. As pharmacists in Asturias will be required to provide a certain level of service, not only by law but also by their professional obligations, there should be little reason to worry that competition will cause them to reduce service in violation of their legal and ethical duty. If additional protections were required for pharmacists to fulfil their professional

43 — *Deutscher Apothekerverband*.

44 — *Apothekerkammer des Saarlandes and Others*, paragraphs 28 and 39; Case C-531/06 *Commission* v *Italy*, paragraph 52.

45 — *Apothekerkammer des Saarlandes and Others*, paragraphs 37 to 39.

46 — Ibid., paragraphs 33 to 37.

47 — This separation from the production and wholesale of pharmaceutical products constitutes, in my view and in light of the previous case-law of the Court, the fundamental reason why the Court accepted the rules limiting access to ownership to pharmacists. See paragraph 40 where the Court noted that pharmacists employed by manufacturers or wholesalers of pharmaceutical products could be seen to lack the requisite independence. As a consequence, only where such independence of pharmacists from the manufacturing or wholesale of pharmaceutical products is guaranteed can such rules be considered to satisfy the requirements of consistency and coherence imposed by Community law.

obligations, the Court in *Apothekerkammer des Saarlandes* and *Commission* v *Italy* would not have been able to conclude that the requirement of pharmacist ownership was appropriate to the goal of providing a high quality of care.

(b) Assuring a broad and balanced geographical distribution of pharmacies

30. The stronger argument invoked by the parties supporting the Decree regards the need to assure a broad and balanced geographical distribution of pharmacies. In other words, to ensure, as much as possible, universal availability of pharmaceutical services to the population. We must distinguish between the two criteria used to attain this goal: the population requirement and the requirement of a minimum distance between pharmacies. Both of these criteria must be assessed as to whether they are appropriate to meet the goal of geographical distribution and as to whether they go beyond what is necessary to meet this aim.

31. Maximum population requirements may, in principle, be appropriate to meeting the goal of broad distribution of pharmacies. By limiting the ability of pharmacists to open pharmacies in more profitable urban areas, the rule leads them to look for other opportunities. However, this is not an automatic effect. Indeed, if opening in less populated areas were profitable in itself, it would, in all likelihood, take place independently of any geographical restrictions. In fact, it would increase in direct relation to the ease with which a pharmacy could be opened and the amount of competition for market shares of more populated areas. Instead, if, as some of the parties have argued, the problem lies in the fact that there is a low probability of profit in less populated areas, then the risk is that no one would be interested in opening a pharmacy in such areas anyway. After all, why would someone devote him or herself to a loss-making activity simply because he or she does not have access to a profit-making activity? Simply restricting openings in more populated areas would not satisfy the requirement of coherence and consistency in the pursuit of the stated public goal. It is only when the policy of restricting openings in more populated areas is linked to the policy favouring those who have previously open in less populated areas that the system as a

whole makes sense. When giving priority to pharmacists who have previously establish pharmacies in areas with fewer than 2,800 inhabitants, the Decree creates an incentive for pharmacists to establish themselves in under-populated areas which might otherwise be without a pharmacy, in return for an increase in their chances of being awarded a licence to operate a pharmacy in a more populated area (which is rendered more profitable by the restrictions) at a later stage. It is plausible that the prospect of being entitled to operate a pharmacy in a highly-populated area in circumstances where others will be prevented from opening a competing pharmacy may indeed encourage pharmacists to provide services, for a time, in under-populated areas. As some of the parties supporting the current regime acknowledged at the hearing, it is the prospect of a future monopolistic rent in a heavily populated area that leads pharmacists to being willing to install themselves initially in less populated areas. However, this will only be so if service in such under-populated areas does in fact grant those who carry out such services priority in the allocation of licences in well-populated areas.

32. As explained above, a closer look at the coherence and consistency of the Decree is required in order to ensure that it actually forwards this goal and is not the result of capture by the already established pharmacists. [48] Two components of the Decree raise concern. First, such a system would have to benefit those who open pharmacies in underserved areas over those who simply wait for an opening in a lucrative area. However, Point 7 of the Annex gives higher priority to unaccredited pharmacists than to those accredited to operate in zones with populations under 2 800 inhabitants. Moreover, under Point 4 of the Annex, once a pharmacist opens a pharmacy in an underserved area, he loses the benefit of his prior professional experience when attempting to open another pharmacy. The impacts of these provisions are mitigated somewhat by the provision in Point 1(a) of the Annex giving more points for practice in an underserved area. However, they raise concerns as to the coherence and consistency of the provision.

33. Second, in order for the regulations to be regarded as genuinely pursuing the goal of universal coverage, it is necessary that licences in well-populated areas be available to those who have practised in under-populated

48 — Case C-324/98 *Telaustria and Telefonadress* [2000] ECR I-10745; Case C-231/03 *Coname* [2005] ECR I-7287; Case C-458/03 *Parking Brixen* [2005] ECR I-8585; Case C-410/04 *ANAV* [2006] ECR I-3303; Case C-260/04 *Commission* v *Italy* [2007] ECR I-7083; C-347/06 *ASM Brescia* [2008] ECR I-5641.

areas when the holders of the more lucrative licences for well-populated areas wish to cease to operate their pharmacies. A system that gives holders of licences for pharmacies in well-populated areas a proprietary interest in such licences, and permits them to sell or to transfer these licences to the person of their choice, has the effect of limiting the number of licences available to those who have 'served their time' in under-populated areas. It would require those seeking to move from a pharmacy in an area of low population to a pharmacy in an area of high population to pay a price for the relevant licence, a price which will have been inflated to take account of the extra profit which the restrictions on the establishment of competing pharmacies enable such a pharmacy to generate. [49] Such a system would undermine the incentive structure said to underpin an approach which limits establishment of pharmacies in order to encourage the establishment of pharmacies in under-populated areas. Furthermore, such a system would also represent the enrichment of individual pharmacists on the basis of the restriction of competition in the pharmacy sector; exactly the kind of regulatory capture the freedoms guaranteed by the Treaty are designed to combat. Restrictions on the right of establishment must be justified by the exigencies of the common good and must not be a tool for private enrichment.

34. Turning to the question of whether the population requirement would go beyond what is necessary had it been better designed to make lucrative urban monopolies available to rural operators, I note that no other clearly preferable schemes have been proposed by the parties. The Commission argues that, rather than setting a maximum number of pharmacies, Asturias should mandate a minimum number of pharmacies per person and halt the establishment of all new pharmacies until that minimum is met. However, such a system creates a collective action problem. No individual pharmacist would have an incentive to open a less-lucrative rural pharmacy. As such, it does not seem well-designed to generate a large increase in the number of pharmacies in under-populated areas. The Commission points to Navarre, where such a plan was temporarily implemented. However, noting that the Navarre plan was modified to provide for a maximum number of pharmacies and that several of the smallest communities in Navarre lost their pharmacies under the plan, I cannot conclude that

49 — It was noted at the hearing that some individuals have paid extremely high prices for licences to operate pharmacies in highly populated areas. The fact that such licences may be able to command such high prices is indicative of the fact that a system which may have started out as a means to provide a geographically-balanced system of pharmaceutical services has been transformed into a purely economic market, somewhat detached from its original aims. It is obvious that liberalisation of such a system may impact negatively on those who have paid significant sums for licences whose value has been inflated by restrictive measures imposed by the Asturian authorities. It has, however, always been the case that when Community law operates so as to remove restrictions on the fundamental freedoms, such liberalisation can have a negative impact on the previous beneficiaries of such restrictions. In *Centro Europa 7* for example, the Court held that Community law required that a broadcaster be permitted to broadcast on the frequencies allocated to it under national licensing legislation notwithstanding the impact that this had on the interests of 'de facto' users of the same frequencies (see paragraphs 40 and 108 to 116 of the judgment). Whether, in this type of case, there is any viable legal claim against the State by those who invested on that market on the basis of certain expectations as to how the market was regulated is a classic question of national law which is not, however, for this Court to address.

Asturias exceeded its discretion in failing to adopt such a model.

35. It has also been argued that a fully liberalised model has worked well in other Member States. [50] However, that was a matter of strong dispute between the parties and, as stated before, there was contradictory evidence to that effect. In such context, I would have argued that a system limiting the opening of new pharmacies in more populated areas in order to promote openings in less populated areas would be justified if it were set up in a coherent and consistent manner. However, for the reasons mentioned above, that is not the case in a system such as that in place in Asturias.

36. As to the geographic requirement that no pharmacy be established within 250 meters of another, or within 250 meters of a public health clinic, I must first consider whether this requirement is appropriate to attaining the goal of distribution of pharmacies throughout the territory. First, one can see that such a policy will encourage such distribution by ensuring that pharmacies do not cluster in small central business districts or close to health centres while leaving other areas without a pharmacy. The measure is not completely consistent, as there are no minimum distance requirements as regards pharmaceutical zones with only one pharmacy. [51] However, this exception does not undermine the adequacy of the provision as clustering would not be an issue where there is only one pharmacy. Moreover, it seems to be reasonable to recognise that in such small zones the business area may be too small to otherwise allow for the pharmacies to spread.

37. The second justification is that this requirement adds to the profit to be obtained by a pharmacy operating in an urban area, thus increasing the incentive for pharmacists to establish businesses in underserved areas in order to eventually obtain accreditation to operate in a well-populated area. As to this goal, it appears that this requirement has been consistently and coherently applied. The parties have not brought forward evidence of any recent exceptions being granted that

50 — See observations submitted on behalf of Blanco Pérez, Chao Gómez and Plataforma para la libre apertura de farmacias, page 38 (Spanish version); see also written observations of the Commission, pages 27 and 28 (Spanish version).

51 — Article 4(2).

would undermine the stated purpose of the rule.

38. Whether the figure of 250 metres goes beyond what is necessary to achieve this aim is a more difficult question. Some of the parties argue that this number is outdated and not suited to the higher population density found in many areas today. It may also be that this requirement benefits a few long-established and well-positioned pharmacies at the expense of other urban pharmacies, thus decreasing the potential future profit for most individuals who decide to spend some time as pharmacists in under-populated areas. The evaluation of this requirement depends on many issues, such as population density and the distribution of the population within a community, and there is not sufficient evidence before this Court to allow it to decide this question. It is for the national court to evaluate this question, in light of its greater knowledge of the circumstances existing in Asturias, bearing in mind the degree of interference with the right of establishment, the nature of the public interest evoked and the degree to which, in the light of the number and distribution of pharmacies within Asturias and the distribution of the population, universal coverage could be achieved through less restrictive means.

III – Conclusion

39. In the light of the above I propose that the Court answer the questions referred as follows:

'— Article 43 EC precludes national legislation such as that at issue in the main proceedings under which authorisation is necessary for the setting-up of a new pharmacy and priority is given to those who have practised within a part of that Member State's territory.

— Article 43 EC precludes legislation such as that at issue in the main proceedings under which the authorisation for the setting-up of a new pharmacy is subject to a population requirement with the purpose of promoting the setting-up of pharmacies in less-populated areas if such purpose is not pursued in a coherent and consistent manner, notably if the same legislation does not clearly benefit those who open pharmacies in underserved areas over those who simply wait for an opening in a lucrative area and grants a proprietary interest in the pharmaceutical licence in such a way as to undermine the effectiveness of the incentive scheme.

— As to the requirement imposing a minimum distance between pharmacies, it is for the national court to determine whether the specific distance imposed is justified, bearing in mind the degree of interference with the right of establishment, the nature of the public interest invoked and the degree to which, in the light of the number and distribution of pharmacies within the region and the distribution and density of the population, universal coverage could be achieved through less restrictive means.'