Reports of Cases

OPINION OF ADVOCATE GENERAL
WAHL
delivered on 5 September 2013 [1]

Joined Cases C-159/12, C-160/12 and C-161/12

Alessandra Venturini
v
A.S.L. Varese and Others
Maria Rosa Gramegna
v
A.S.L. Lodi and Others
Anna Muzzio
v
A.S.L. Pavia and Others

(Request for a preliminary ruling from the Tribunale Amministrativo Regionale della Lombardia (Italy))

(Freedom of establishment — Admissibility — Factual elements of the main proceedings confined within one Member State — Public health — National legislation restricting the sale of prescription-only medicinal products the cost of which is wholly borne by the customer — Para-pharmacies)

1. Ms Venturini, Ms Gramegna and Ms Muzzio – the applicants in the main proceedings ('the applicants') – are qualified pharmacists registered with the 'Ordine dei Farmacisti di Milano' (the Milan Order of Pharmacists) and owners of retail outlets known as 'para-pharmacies'.

2. In essence, the applicants argue before the Tribunale Amministrativo Regionale della Lombardia (Regional Administrative Court for Lombardy; 'the TAR Lombardia') that, by preventing them from selling medicinal products for which a prescription is required, the cost of which, however, is not borne by the national health service but by the customer, the domestic regulations ('the legislation at issue') place an impermissible restriction on the freedom of establishment under Article 49 TFEU.

3. The applicants are all Italian nationals, who are already established in Italy, and their action is directed against Italian legislation. None of them seems to have made use of any of the Treaty freedoms in connection with the situation under examination in the main proceedings.

4. From a factual point of view, therefore, the applicants' situation appears to be confined within a single Member State. No cross-border elements can in fact be identified in the case before the referring court.

5. In those circumstances, does this Court have jurisdiction to answer the question referred by the TAR Lombardia for a preliminary ruling on the interpretation of Article 49 TFEU?

1 — Original language: English.

6. This, in my view, is the crucial issue arising in the present proceedings and, accordingly, the point which I will address first in the present Opinion. In the second part of this Opinion, after proposing by way of interim conclusion that the request for a preliminary ruling be treated as admissible, I will illustrate the reasons why I disagree with the applicants regarding the alleged incompatibility with Article 49 TFEU of the legislation at issue.

I – Legal framework

7. In Italy, Law No 468/1913 defined the provision of pharmaceutical services as 'a primary State activity' which could only be engaged in by municipal pharmacies or by private pharmacies operating under government licence. An administrative instrument for controlling supply was set in place: the 'pianta organica', which is a form of territorial grid designed to ensure the even distribution of medicinal products throughout the national territory. Importantly, the subsequent Royal Decree No 1265/1934 confined the selling of all medicinal products exclusively to pharmacies (Article 122).

8. Law No 537/1993 later recategorised medicinal products on the basis of the following classes: 'Class A' for essential medicinal products and medicinal products for chronic diseases; 'Class B' for medicinal products (other than those falling into 'Class A') of significant therapeutic interest; and 'Class C' for medicinal products other than those falling within Class A or Class B. Under Article 8(14) of Law No 537/1993, the cost of medicinal products falling within Class A or Class B is to be wholly borne by the 'Servizio Sanitario Nazionale' (SSN) (the Italian national health service), whereas the cost of medicinal products in Class C is to be wholly borne by the customer.

9. Subsequently, Article 85(1) of Law No 388/2000 abolished 'Class B', whereas Article 1 of Law No 311/2004 created a new category of medicinal products – 'Class C-bis' – to cover medicinal products for which a prescription is not required and which, unlike products falling within the other categories, may be publicly advertised (usually referred to as 'over-the-counter drugs'). As in the case of Class C medicinal products, the cost of Class C-bis medicinal products is to be borne by the customer.

10. Decree-Law No 223/2006, later converted into Law No 248/2006 ('the Bersani Decree'), allowed the opening of new commercial outlets, distinct from pharmacies. These are usually referred to as 'para-pharmacies' and are authorised to sell over-the-counter medicinal products ('Class C-bis'). More recently, Decree-Law No 201/2011, now converted into Law No 214/2011, further extended the categories of medicinal products that can be sold by para-pharmacies, so that they can now offer to the public some of the Class C medicinal products for which no medical prescription is required.

II – Facts, procedure and the question referred

11. On 30 June 2012, the applicants each submitted a request to the relevant 'Azienda Sanitaria Locale' (ASL) (local health authority), as well as to the relevant Municipalities, the 'Ministero della Salute' (Ministry of Health) and the 'Agenzia Italiana del Farmaco' (Italian Medicines Agency), for authorisation to sell to the public medicinal products for which a prescription is required but the cost of which is wholly borne by the customer, as well as all the prescription-only proprietary drugs for veterinary use, the cost of which is wholly borne by the customer.

12. On 15 and 17 August 2011, respectively, the ASL rejected all those requests on the ground that, under the domestic legislation in force, the relevant medicinal products could only be sold in pharmacies. Similar refusals were given by the Ministry of Health on 16 and 18 August 2011, respectively. I will refer to all those decisions collectively as 'the decisions at issue'.

13. The applicants contested the decisions at issue before the TAR Lombardia, claiming that the Italian legislation on which they were based was incompatible with EU law.

14. In the context of those proceedings, the Italian court, entertaining doubts as to the compatibility of the legislation at issue with the Treaty on the Functioning of the European Union ('the Treaty'), decided to stay the proceedings and refer to the Court the following question:

'Do the principles of freedom of establishment, non-discrimination and the preservation of competition under Article 49 et seq. TFEU preclude national legislation which does not allow a pharmacist, who is qualified and listed in the relevant professional register but does not own a pharmacy on the "pianta organica" [territorial grid], also to offer for retail sale, in the para-pharmacy owned by that pharmacist, pharmaceutical products which are subject to a prescription in the form of a "ricetta bianca" – that is to say, pharmaceutical products the cost of which is borne not by the [national health service] but wholly by the citizen – and which accordingly also establishes in that sector a prohibition on the sale of certain categories of pharmaceutical product, as well as a quota in relation to the number of commercial outlets which may be established in the national territory?'

15. Written observations in the present proceedings have been submitted by Ms Venturini, Federfarma, the Italian, Spanish and Portuguese Governments, and by the Commission. At the hearing on 15 May 2013, oral argument was presented on behalf of Ms Venturini, Federfarma, the Spanish Government and the Commission. Regrettably, the Italian Government did not participate in the hearing, notwithstanding the complexity of the national legislation at issue and despite the fact that its written observations are particularly succinct.

III – Analysis

A – *Admissibility*

16. Both in its written observations and at the hearing, Federfarma disputed the admissibility of the present request for a preliminary ruling. It argued essentially that, in the absence of any cross-border element, the question referred by the TAR Lombardia has no connection with EU law and is thus hypothetical. In particular, Federfarma relied on the conclusion reached by the Court in *Sbarigia*.[2]

17. At the hearing, Ms Venturini pointed out that, although there was no actual cross-border element in the case before the referring court, the legislation at issue potentially had significant restrictive effects on the possibility for operators based in other Member States to become established in Italy. This meant that the question should be treated as admissible. The Commission also disputed Federfarma's argument, referring primarily to the ruling in *Blanco Pérez*,[3] in which the factual circumstances were substantially identical to those of the case currently pending before the TAR Lombardia and in which the Court of Justice accepted jurisdiction.

18. I agree with the Commission and the applicants that, in the light of the Court's consistent case-law, Federfarma's objections should be dismissed.

2 — Case C-393/08 [2010] ECR I-6337.

3 — Joined Cases C-570/07 and C-571/07 *Blanco Pérez and Chao Gómez* [2010] ECR I-4629.

19. However, it must also be recalled that the Court's case-law on the admissibility of questions referred by national courts in cases where all factual elements are confined within a single Member State has come under criticism from a number of Advocates General,[4] as well as from legal academics.[5]

20. Admittedly, some of the criticism levelled against that case-law is not without foundation. If interpreted too broadly, that particular line of authority could be taken to mean that, in virtually any case in which an operator invokes the EU internal market provisions before a national court in order to contest the validity of domestic regulatory legislation, the Court must make a ruling – even though that legislation may have been adopted for perfectly legitimate purposes and its impact on intra-Union trade may be marginal, insignificant or purely hypothetical.

21. Such a broad interpretation is neither useful nor tenable. Indeed, it would carry with it the risk that the Court might interpret EU rules despite there being no actual threat to the uniform application of EU law,[6] giving a ruling which could be wholly alien to the factual and legal context of the case before the referring court[7] and thereby extending the scope of EU law beyond the limits set in the Treaty.[8]

22. Furthermore, the expansion of the Court's jurisdiction as a result of the entry into force of the Lisbon Treaty, coupled with the substantial increase in membership of the European Union over the last decade, culminating in the recent accession of Croatia, might have a significant impact on the Court's ability to dispose of cases with the necessary swiftness, while maintaining the quality of its decisions.[9] The Court's statistics of the last years, in fact, attest to a clear and steady increase in the number of requests for preliminary rulings.[10]

23. I am therefore of the opinion that a more in-depth reflection by this Court on the issues concerning the admissibility of requests for preliminary rulings would, at this moment, be both timely and appropriate. To that end, before explaining in more detail why I believe that the question referred by the TAR Lombardia in the present case is admissible, I will offer some general thoughts on that issue which are intended as a contribution to such a reflection.

24. While I do not believe that the Court's case-law on this point should be overturned or its scope radically limited, I am convinced of the need to construe that case-law narrowly so as to avoid the risks attendant upon an excessive expansion of the Court's jurisdiction.

25. My suggestions should not be seen, however, as pertinent only as regards the admissibility of requests for preliminary rulings concerning national legislation which allegedly restricts intra-Union trade. Far from it. There is a more general problem which goes beyond the approximately 100 cases referred to the Court every year on issues concerning the fundamental freedoms – and it is a problem which may well carry implications for all requests for preliminary rulings.

4 — See, in particular, the Opinion of Advocate General Darmon in Joined Cases C-297/88 and C-197/89 *Dzodzi* [1990] ECR I-3763; the Opinion of Advocate General Tesauro in Case C-346/93 *Kleinwort Benson* [1995] ECR I-615; the Opinion of Advocate General Jacobs in Case C-28/95 *Leur-Bloem* [1997] ECR I-4161; and the Opinion of Advocate General Saggio in Case C-448/98 *Guimont* [2000] ECR I-10663.

5 — Hatzopoulos, V., 'De l'arrêt "Foglia-Novello" à l'arrêt "TWD Textilwerke" – La jurisprudence de la Cour de justice relative à la recevabilité des renvois préjudiciels', *Revue du Marché Unique Européen* (3)1994, pp. 195 to 219, at p. 217; Simon D, 'Questions préjudicielles', *Journal de droit international* 118(2) 1991, pp. 455 to 457, at p. 457; and Fenger, N., 'Article 177', in Smit, H. and Herzog, P. (eds.), *The Law of the European Community: a commentary to the EEC Treaty,* Matthew Bender & Co., New York: 1997, pp. 5-443 to 5-470, at p. 5-466.

6 — The Opinion of Advocate General Jacobs in *Leur-Bloem*, point 47.

7 — The Opinion of Advocate General Tizzano in Case C-267/99 *Adam* [2001] ECR I-7467, point 34.

8 — The Opinion of Advocate General Darmon in *Dzodzi*, points 10 and 11.

9 — See, for example, the analysis made by the House of Lords, European Union Committee, 16th Report of Session 2012-13, 'Workload of the Court of Justice of the European Union: Follow-Up Report', 29 April 2013, pp. 9 and 24.

10 — According to the Court's Annual Reports (see, for example, the reports from 2004, p. 183, and from 2012, p. 90), there were 224 requests for preliminary rulings in 2000, 249 requests in 2004, 385 requests in 2010, and 404 such requests in 2012.

1. The Court's case-law

26. At the outset, I would call to mind the fact that, according to a well-established principle of EU substantive law, the Treaty provisions on the fundamental freedoms 'are not applicable to activities which are confined in all respects within a single Member State'. [11]

27. The need for a cross-border element in order for the Treaty provisions on fundamental freedoms to be applicable is consistent with the very purpose of those provisions. To paraphrase Advocate General Tesauro in *Hünermund*, that purpose is 'to liberalise intra-[Union] trade [and not to] encourage the unhindered pursuit of commerce in individual Member States'. [12] In the same vein, Advocate General Tizzano emphasised, in *CaixaBank France*, that an interpretation of the Treaty provisions on the fundamental freedoms which extended their applicability beyond their own limits 'would be tantamount to bending the Treaty to a purpose for which it was not intended: that is to say, not in order to create an internal market in which conditions are similar to those of a single market and where operators can move freely, but in order to establish a market without rules. Or rather, a market in which rules are prohibited as a matter of principle, except for those necessary and proportionate to meeting imperative requirements in the public interest'. [13]

28. Thus, where the factual situation in the case before the referring court lacks any connection with the exercise of a fundamental freedom, an examination of the compatibility of the relevant domestic legislation with the EU provisions invoked is, in principle, unnecessary for the national court to make a ruling. To the extent that the Treaty rules do not apply to the case before a referring court, an answer to the questions referred is not relevant for the resolution of the dispute and, consequently, those questions should be regarded as hypothetical.

29. However, this principle of substantive law must be reconciled with some general principles of a procedural nature. I hardly need to point out that a relatively 'generous' approach by the Court with regard to the admissibility of preliminary rulings is clearly rooted in the very text of the Treaty. Article 267 TFEU, in fact, requires only that a question of interpretation of EU rules '[be] raised before any court or tribunal of a Member State'. It is then, as a matter of principle, up to that court or tribunal to decide whether 'it considers that a decision on the question is necessary to enable it to give judgment'.

30. The ample jurisdiction of the Court under Article 267 TFEU is also in keeping with the spirit of cooperation, between the Court of Justice and the national courts, which 'must prevail in the preliminary ruling procedure'. [14]

31. Accordingly, the Court has consistently held 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 referred concern the interpretation of EU law, the Court is in principle bound to give a ruling. [15] The Court may refuse to rule on a question referred for a

11 — See, in particular, Case C-134/95 *USSL No 47 di Biella* [1997] ECR I-195, paragraph 19; Case C-108/98 *RI.SAN.* [1999] ECR I-5219, paragraph 23; Case C-97/98 *Jägerskiöld* [1999] ECR I-7319, paragraph 42; and Case C-245/09 *Omalet* [2010] ECR I-13771, paragraph 12.

12 — The Opinion of Advocate General Tesauro in Case C-292/92 *Hünermund and Others* [1993] ECR I-6787, points 1 and 28.

13 — The Opinion of Advocate General Tizzano in Case C-442/02 *CaixaBank France* [2004] ECR I-8961, point 63. Even though the Opinion of Advocate General Tizzano – just like that of Advocate General Tesauro, mentioned in the previous footnote – was concerned with the notion of 'restriction' under the Treaty provisions on fundamental freedoms, I take the view that their considerations on the point are, *mutatis mutandis*, also relevant with regard to the admissibility of cases concerning the compatibility of domestic measures with those Treaty provisions.

14 — Joined Cases C-261/08 and C-348/08 *Zurita García and Choque Cabrera* [2009] ECR I-10143, paragraph 36, and Case C-571/10 *Kamberaj* [2012] ECR, paragraph 41.

15 — See, inter alia, Case C-119/05 *Lucchini* [2007] ECR I-6199, paragraph 43 and case-law cited, and Joined Cases C-509/09 and C-161/10 *eDate Advertising and Martinez* [2011] ECR I-10269, paragraph 32 and case-law cited.

preliminary ruling only where it is quite obvious that the interpretation of EU law sought is wholly unrelated to the actual facts of the main proceedings or to its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to enable it to give a useful answer to the questions referred. [16]

32. The need to reconcile the abovementioned principles of substantive law with those procedural principles has led the Court, in a number of cases, to consider questions referred to be admissible despite all factual elements of the main proceedings being confined within a single Member State. Although such Court decisions cannot be classified into neatly defined groups, three main lines of decisions can, in my view, be identified.

33. In a first line of decisions, arguably starting with *Oosthoek*, [17] and more recently confirmed in *Blanco Pérez* ('the *Oosthoek* case-law'), the Court pointed out that, although the facts of the case were confined within one Member State, certain cross-border effects of the challenged domestic legislation could not be ruled out. [18] The questions referred were therefore held to be admissible.

34. The reasoning of the Court is, in my view, correct, so long as it is not understood as raising a presumption, or quasi-presumption, that the Court should rule in each and every case where effects on intra-Union trade cannot *a priori* be excluded.

35. Indeed, there is no reason to limit the Court's jurisdiction, in the context of preliminary rulings, to cases which have an *actual* and *direct* cross-border element. To the extent that there are sufficient grounds for considering that national legislation is *capable* of producing the cross-border effects which are relevant, for example, under Articles 34, 35, 45, 49, 56 or 63 TFEU, then that legislation is falling squarely within the scope of those Treaty provisions.

36. Moreover, it seems to me that it would not be sensible to adopt the premiss that, in order to be examined by the Court, all possible violations of the fundamental freedoms must of necessity be raised in the context of legal proceedings brought by a party who has already exercised (or is attempting to exercise) one of those freedoms. Such a strict interpretation of the principles regulating the admissibility of preliminary references would preclude the Court from ruling on national regulations which might severely hinder access to national markets and which, for that very reason, have discouraged foreign operators from trying to do so. It is often easier for nationals of the Member State concerned – since the investment required on their part is smaller, they do not face linguistic barriers, and they are better acquainted with both the domestic legal system and local administrative practice – to challenge national regulations which are incompatible with the rules on the internal market. For example, it could be argued that, in the case before the TAR Lombardia, it is purely by chance that all the elements are confined within a single Member State. The applicants could just as easily have been nationals of another Member State.

37. I thus agree with Advocate General Geelhoed, who argued in *Reisch* that 'it is the nature and substance of the national measure that determine whether the Court answers questions referred to it for a preliminary ruling, not the facts in the main proceedings'. [19]

16 — See, inter alia, *Lucchini*, paragraph 44 and case-law cited, and *eDate Advertising and Martinez*, paragraph 33 and case-law cited.

17 — Case 286/81 *Oosthoek's Uitgeversmaatschappij* [1982] ECR 4575.

18 — See also Joined Cases C-321/94 to C-324/94 *Pistre and Others* [1997] ECR I-2343, paragraph 45, and Case 298/87 *Smanor* [1988] ECR 4489, paragraphs 8 to 10.

19 — The Opinion of Advocate General Geelhoed in 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, point 88.

38. Clearly, when there is an actual cross-border element in the main proceedings, the importance for the referring court of the Court's interpretation of the Treaty rules is immediately evident. When, on the other hand, the facts are all confined within one Member State, cross-border effects cannot be presumed. Accordingly, unless that aspect is evident from the case-file, it is the duty of the referring court to explain to the Court why the application of the measure under scrutiny is potentially capable of hindering the exercise of a fundamental freedom by foreign economic operators. In the absence of any detailed explanations on that point, the Court is, to my mind, entitled to decide that a case is hypothetical, or that there is insufficient information for it to be able to give a useful interpretation of the Treaty rules.

39. In a second line of cases, starting with *Guimont*,[20] and again recently confirmed in *Blanco Pérez* ('the *Guimont* case-law'), the Court considered the questions referred to be admissible, despite all aspects of the main proceedings being confined within one Member State, in so far as the interpretation of EU law sought appeared useful to the referring court 'if its national law were to require it to grant a [national of that Member State] the same rights as those which a national of another Member State would derive from EU law in the same situation'.[21]

40. This line of authority, if properly construed, is in my view sound. I would suggest, however, that it has evolved a little too far.

41. I do find the *ratio* underlying this line of decisions to be correct: to the extent that there is a domestic rule or principle prohibiting reverse discrimination, and the national regulations challenged can also apply to foreign operators, the national court may need assistance from the EU judicature to interpret correctly the pertinent EU provisions. This is so notwithstanding the fact that – strictly speaking – those EU provisions are not directly applicable to the case under consideration, but, arguably, apply only in an indirect manner,[22] through reference made to them in national laws. In those circumstances, the Court's jurisdiction is accordingly justified since, in the absence of a ruling on its part, the referring court would effectively be unable to give judgment in the dispute before it.

42. Yet, the existence of such a rule on reverse discrimination and its applicability in the main proceedings cannot, in my view, be taken for granted, as the Court seems to have done in some of its previous decisions on this point.[23] Otherwise, essentially all requests for preliminary rulings on the compatibility with the fundamental freedoms of domestic regulatory legislation would be admissible, regardless of the fact that the impact of that legislation on intra-Union trade is no more than an abstract possibility, and that its connection with the situations governed by the relevant EU rules is remote.

43. Moreover, the Court should also ensure that the national legislation concerned is capable of being applied also to cross-border situations and that it does not only concern situations governed by national laws.[24] It goes without saying that no reverse discrimination can arise where the national legislation challenged cannot in any circumstances apply, for example, to foreign operators or goods.

20 — Case C-448/98 [2000] ECR I-10663.

21 — *Blanco Pérez*, paragraph 39; Case C-451/03 *Servizi Ausiliari Dottori Commercialisti* [2006] ECR I-2941, paragraph 29; and Joined Cases C-94/04 and C-202/04 *Cipolla and Others* [2006] ECR I-11421, paragraph 30. See also *Guimont*, paragraph 23.

22 — See the reference to the indirect application of EU provisions in *Leur-Bloem*, paragraph 26, and Case C-130/95 *Giloy* [1997] ECR I-4291, paragraph 22. See also the Opinion of Advocate General Kokott in Case C-280/06 *ETI and Others* [2007] ECR I-10893, points 54 and 55.

23 — See, inter alia, *Reisch and Others*, paragraph 26; *Servizi Ausiliari Dottori Commercialisti*, paragraph 29; and Case C-6/01 *Anomar and Others* [2003] ECR I-8621, paragraph 41.

24 — See the Opinion of Advocate General Jacobs in *Pistre and Others*, points 37 and 38, and the Opinion of Advocate General Cosmas in Case C-63/94 *Belgapom* [1995] ECR I-2467, point 14.

44. In the light of those considerations, I take the view that the referring court must explicitly indicate the existence, within its national legal order, of such a rule or principle against reverse discrimination. The referring court should also point out that the national rule challenged is capable of being applied to cross-border situations, unless this is evident from the case-file.

45. I believe that where no mention is made on these points in the order for reference or, *a fortiori*, where it is clear that such a rule or principle against reverse discrimination does not exist in the national legal order,[25] or that the measure can only apply to purely internal situations, the Court should decline jurisdiction, unless there are other, compelling, reasons for not doing so.

46. Lastly, there is a third line of decisions, starting with *Thomasdünger*,[26] and more recently confirmed in *Allianz* ('the *Thomasdünger* case-law'), in which the Court stated that it has jurisdiction to give preliminary rulings on questions concerning EU law in situations where the facts of the cases before the referring courts are outside the direct scope of EU provisions, but where those provisions are made applicable by national law, which has adopted, for internal situations, the same approach as that provided for under EU law.[27]

47. This third line of decisions constitutes, to my mind, the corollary to the *Guimont* case-law: in the *Guimont* cases, too, the application of the relevant EU rules in the cases before the referring courts was indirect and depended on an (explicit or implicit) reference being made to those rules in national laws.

48. As the Court repeatedly stressed, neither the wording of Article 267 TFEU nor the aim of the procedure established by that provision suggests that the Treaty makers intended to exclude those situations from the jurisdiction of the Court.[28] Moreover, the Court considered that it is in the interests of the European Union that, in order to forestall future divergences in interpretation, provisions or concepts taken from EU law should be interpreted uniformly, irrespective of the circumstances in which they are to apply.[29]

49. Accordingly, the Court has accepted jurisdiction, for example, in cases where national competition rules were openly modelled after Articles 101 and 102 TFEU and an interpretation of those provisions was sought in order to apply the corresponding national rules in a consistent manner.[30] Likewise, that reasoning was followed in cases which concerned fiscal rules that were implementing a provision in an EU directive and extending it to similar, purely internal, situations;[31] or fiscal rules which took the Community Customs Code as a model so as to provide a single procedure for comparable situations.[32]

25 — Case C-84/11 *Susisalo and Others* [2012] ECR, paragraph 21, and *Omalet*, paragraphs 16 and 17.

26 — Case 166/84 [1985] ECR 3001.

27 — *Dzodzi*, paragraphs 36 and 37; *Leur-Bloem*, paragraph 25; Case C-217/05 *Confederación Española de Empresarios de Estaciones de Servicio* [2006] ECR I-11987, paragraph 19; Case C-32/11 *Allianz Hungária Biztosító and Others* [2013] ECR, paragraphs 17 to 23; and Case C-2/97 *IP* [1998] ECR I-8597, paragraph 59.

28 — *ETI and Others*, paragraph 22 and case-law cited.

29 — *Allianz Hungária Biztosító and Others*, paragraphs 17 to 23. Legal commentators have observed that the Court decisions in those cases contribute to the emergence of a '*jus communae europeum*'; see Tridimas, T., 'Knocking on heaven's door: Fragmentation, efficiency and defiance in the preliminary reference procedure', *Common Market Law Review* (40) 2003, pp. 9 to 50, at p. 47.

30 — See *ETI and Others*, paragraphs 19 to 29, and *Allianz Hungária Biztosító and Others*.

31 — *Leur-Bloem*, paragraph 25.

32 — Case C-1/99 *Kofisa Italia* [2001] ECR I-207, paragraphs 30 to 32.

50. That line of decisions, too, I consider to be acceptable, provided that the underlying principles are applied in accordance with very strict conditions: although the reference to the pertinent EU rules need not necessarily be made in the very text of the domestic law to be applied,[33] it must nonetheless be sufficiently unambiguous or, as the Court has at times stated, 'direct and unconditional'.[34] More importantly, the Court has jurisdiction in those cases only when it is clear that the interpretation given by the Court will be binding upon the national court; the case will otherwise be hypothetical,[35] resulting in a misuse of the procedure laid down in Article 267 TFEU.[36]

51. Finally, since the Court has jurisdiction to consider only the provisions of EU law invoked and not the national rules which refer to those provisions, its interpretative role must remain confined within particularly strict boundaries. For example, it is for the referring court to assess the limits which national laws may set to the application of the EU provisions invoked.[37] By the same token, it will in principle be for the referring court to apply the interpretation given by this Court to the circumstances of the case before it.[38]

52. It is thus the duty of the national court making a reference to indicate clearly, in its request for a preliminary ruling, all the domestic rules and principles which would enable this Court to determine whether it is necessary to give an answer to the national court and whether its answer would be binding upon that court.

53. I would conclude that in the three lines of decisions discussed, the Court has correctly accepted jurisdiction since, despite all relevant *factual* elements being confined within a single Member State, the relevant *legal* elements were not.

54. However, I must add that, as has been shown above, in some cases the Court seems to have established its jurisdiction on the basis of mere assumptions, without undertaking any real examination as to whether the relevant conditions were fulfilled.

55. I believe that that approach is rather problematic. The Court's jurisdiction in situations which are purely internal to a single Member State constitutes an exception to a general principle and, as such, must be narrowly construed.

56. I would emphasise that the 'spirit of cooperation' which must prevail in the context of the preliminary reference procedure works both ways:[39] the Court should do its utmost to assist the referring courts to interpret and apply EU law correctly, but those courts should also endeavour to assist this Court by providing it with all the information and evidence required to ensure that it is able to exercise its interpretative function consistently with the aim of Article 267 TFEU.[40] This is especially important when the information and evidence to be provided by the referring courts is necessary for the Court to establish that it does indeed have jurisdiction.

33 — *Allianz Hungária Biztosíto and Others*. See also the Opinion of Advocate General Kokott in *ETI and Others*, point 39.

34 — Case C-482/10 *Cicala* [2011] ECR I-14139, paragraph 19 and case-law cited, and Case C-583/10 *Nolan* [2012] ECR, paragraph 47.

35 — See *Kleinwort Benson*, paragraphs 16 to 25; *Allianz Hungária Biztosíto and Others*, paragraphs 22 and 23; *ETI and Others*, paragraphs 24 to 26; *Leur-Bloem*, paragraph 31; *Kofisa Italia*, paragraphs 30 and 31; *Adam*, paragraphs 30 to 32; and Case C-306/99 *BIAO* [2003] ECR I-1, paragraph 92.

36 — See, to that effect, Opinion 1/91 of 14 December 1991 [1991] ECR I-6079, paragraph 61. See also the Opinion of Advocate General Tesauro in *Kleinwort Benson*, point 27.

37 — Case C-88/91 *Federconsorzi* [1992] ECR I-4035, paragraph 10, and *Dzodzi*, paragraphs 41 and 42.

38 — See, for example, *Allianz Hungária Biztosíto and Others*, paragraph 29, and *ETI and Others*, paragraph 51.

39 — See Case 244/80 *Foglia* [1981] ECR 3045, paragraph 20.

40 — As early as 1974, the Court held that the preliminary ruling procedure 'is essential for the preservation of the [Union] character of the law established by the Treaty and has the object of ensuring that in all circumstances this law is the same in all States of the [European Union]': see Case 166/73 *Rheinmühlen-Düsseldorf* [1974] ECR 33, paragraph 2.

57. More generally, the problems caused by an inadequate description of the factual and legal background to the questions referred are obviously not confined to internal market cases only. Indeed, those problems may arise in connection with any request for a preliminary ruling, irrespective of the field of EU law concerned.

58. A failure on the part of the national court to provide all the pertinent information and evidence regarding the key issues of a dispute seems to me to fall short of the requirements laid down in Article 94 of the Rules of Procedure, [41] and should consequently lead the Court – as a rule – to decline jurisdiction; where appropriate, the Court may also do this by reasoned order under Article 53(2) of the Rules of Procedure. [42]

59. Certainly, the Court may decide to try to fill the *lacunae* in a request for a preliminary ruling by asking for clarifications from the referring court or tribunal – pursuant to Article 101 of the Rules of Procedure – or, when possible, by extracting the necessary information from the documents attached to the order [43] or from the parties' submissions. [44]

60. However, those 'remedies' should, in my view, be regarded as rather exceptional, and applicable only in so far as the gaps in a request are fairly limited and/or concern issues which are not essential for a full and clear understanding of the core issues. To my mind, the order for reference should be a self-standing document which contains all the relevant information. Any other documents should serve only as supplementary sources of information [45] and those supplementary sources cannot, I would argue, cure situations in which an order for reference lacks even the most basic information.

61. To the extent that an order for reference is incomplete or unclear, the right of the Member States (and, if applicable, other parties) [46] to submit observations in those proceedings in which they may have an interest risks being compromised. For example, despite the fact that a Member State's legislation is drafted in similar terms, or that equivalent legal issues may arise in its own domestic legal order, the government of that Member State might fail to intervene for the simple reason that it was not in a position fully to appreciate the subject-matter or scope of the proceedings. [47] Not only can this be detrimental for those parties, it can also impair the Court's ability to exercise its judicial role, which is to give rulings under Article 267 TFEU against the background of informed submissions from all interested parties. [48]

62. Moreover, any attempt by the Court to gather the information and evidence missing from a request for a preliminary ruling necessarily involves a more or less intensive use of the Court's limited resources. As a consequence, the additional efforts undertaken by the Court not only interfere with the correct and speedy handling of those cases, but may also, indirectly, have a certain impact on the timely disposal of other cases pending before the Court.

41 — *Foglia*, paragraphs 17 and 18.

42 — Case C-291/96 *Grado and Bashir* [1997] ECR I-5531, paragraph 14; C-458/93 *Saddik* [1995] ECR I-511, paragraphs 18 and 19; and Case C-361/97 *Nour* [1998] ECR I-3101, paragraphs 19 and 20.

43 — Case C-316/93 *Vaneetveld* [1994] ECR I-763, paragraph 14, and Case C-17/94 *Gervais and Others* [1995] ECR I-4353, paragraph 21.

44 — Case C-18/93 *Corsica Ferries* [1994] ECR I-1783, paragraph 13, and *Vaneetveld*, paragraph 14.

45 — Cf. Barnard, C. and Sharpston, E., 'The changing face of Article 177 references', *Common Market Law Review* (34) 1997, pp. 1113 to 1171, at p. 1153.

46 — These parties may in fact be unaware of the content of the documents annexed to the order for reference, which are typically not translated into other languages. Nor do they have access to the submissions of the parties to the main proceedings, unless they have already decided to enter observations in the proceedings.

47 — The Court has already had the opportunity to stress that 'the information provided in orders for reference does not serve merely to enable the Court to give helpful answers, but also to enable the governments of the Member States and other interested parties to submit observations in accordance with Article 20 of the EC Statute of the Court of Justice', and that 'it is the Court's duty to ensure that that possibility is safeguarded, bearing in mind that, by virtue of [Article 20 of the EC Statute of the Court of Justice], only the order for reference is notified to the interested parties'. See, among many, Case C-190/02 *Viacom* [2002] ECR I-8287, paragraph 14 and case-law cited.

48 — Barnard, C. and Sharpston, E., op. cit., p. 1151.

63. Now that I have made those general remarks, I will turn to the admissibility of the question referred by the TAR Lombardia.

2. The admissibility of the question referred

64. It is common ground that all aspects of the main proceedings are confined within one Member State.

65. In the light of the information in the case-file, it appears that, whereas the *Guimont* and *Thomasdünger* case-law are not relevant to the case under consideration, the *Oosthoek* case-law is pertinent.

66. As alluded to above, it was also in application of the *Oosthoek* case-law that the Court accepted as admissible, in *Blanco Pérez*, the questions referred by the national court on the compatibility of the rules limiting the opening of new pharmacies in Asturias, despite the fact that the issue of incompatibility had been raised by two Spanish nationals who had not made use of the Treaty freedoms. The Court indeed observed, inter alia, that it was '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'. [49]

67. I understand this as meaning that, despite the facts all being confined to Spain, the potentially restrictive effects on cross-border situations of the legislation at issue in that case were so manifest that the Court could, immediately and without difficulty, assert jurisdiction. [50]

68. It is true that, as the Commission pointed out, the legal and factual background in that case is rather similar to that of the case currently before the TAR Lombardia. I am thus of the view that the Court's considerations in *Blanco Pérez* are, *mutatis mutandis*, equally valid here. The TAR Lombardia suggests, in the order for reference, that the legislation at issue may have restrictive effects which are not confined to Italy, to the extent that it may discourage nationals established in other Member States from establishing a business in Italy.

69. Unlike Federfarma, therefore, I believe that the circumstances of the present case can be distinguished from those in *Sbarigia*. The dispute in *Sbarigia* concerned the possible grant of an exemption in relation to the opening hours of a particular pharmacy, located in a specific area of the municipality of Rome. It was unclear how the decision in that case could have had any effect, directly or indirectly, actually or potentially, on any other operator established in another Member State. [51] Consequently, the Court rightly held the question referred to be inadmissible.

70. *Sbarigia* is, I would add, in line with well-established case-law. For example, a similar conclusion was reached by the Court in *Woningstichting Sint Servatius*, [52] in which the restriction of capital movements under challenge concerned solely one specific company, governed by the laws of that Member State, and was not capable of having any effect on the internal market. By the same token, in *van Buynder*, [53] the Court did not rule on whether the Belgian law which made the exercise of veterinary medicine subject to a number of conditions (such as possession of a lawful qualification in

49 — *Blanco Pérez*, paragraph 40.

50 — *Blanco Pérez*, paragraphs 54 and 55. I would also add that, in that case, potential cross-border effects also arose as a result of the fact that one of the provisions of the domestic laws at issue explicitly favoured pharmacists who had pursued their professional activities within the Autonomous Community of Asturias, thereby indirectly discriminating against operators coming from other Member States. See paragraph 117 et seq. of the judgment.

51 — See, in particular, *Sbarigia*, paragraphs 25 to 29.

52 — Case C-567/07 [2009] ECR I-9021, paragraphs 40 to 47.

53 — Case C-152/94 [1995] ECR I-3981.

veterinary medicine and entry in the register of veterinary surgeons) was compatible with Article 49 TFEU, in so far as the question was raised in the context of criminal proceedings brought against a Belgian national, on the ground that he had, in Belgium, carried out unauthorised veterinary measures without satisfying the conditions laid down in the abovementioned law.

71. In all those cases, the Court was quite right to conclude that the legality of the measures challenged by the applicants in the main proceedings could not depend on the interpretation of the Treaty rules on freedom of movement, to the extent that no cross-border effect of any sort could easily be identified. The situation in the present case is, however, different. For the reasons explained in point 68 above, the legislation at issue falls within the scope of Article 49 TFEU. Accordingly, I will now look in detail at the substantive issues raised in the case before the TAR Lombardia.

B – *Consideration of the question referred*

72. By its request for a preliminary ruling, the TAR Lombardia seeks the Court's guidance as to whether a domestic law which reserves to pharmacies the sale of pharmaceutical products for which a prescription is required, but the cost of which is not borne by the SSN but by the customer, is compatible with the EU rules on freedom of establishment.

1. Existence of a restriction

73. According to settled case-law, any national legislation 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. [54]

74. It seems to me that, in the present proceedings, a prerequisite for any interpretation is the identification of the market on which the legislation at issue is alleged to deploy its restrictive effects by hindering the establishment of foreign operators.

75. That element is not self-evident. The order for reference does not really elaborate on this point and Ms Venturini only refers, in a general way, to some restrictive effects vis-à-vis the professional activities of a pharmacist.

76. In that regard, I note that the administrative decisions which the applicants challenge in the main proceedings are not refusals of applications to open a pharmacy, but of applications merely for authorisation to sell certain specific medicinal products.

77. In fact, the applicants do not question the compatibility with the Treaty either of the domestic legislation limiting the number of pharmacies in accordance with the pianta organica, or of the legislation reserving the sale of Class A pharmaceutical products to pharmacies only. The only legislation that they are challenging is the rule prohibiting them from selling pharmaceutical products for which a prescription is required, but the cost of which is borne by the customer.

78. That leads me to believe that the possible restrictive effects of the relevant Italian legislation on the fundamental freedoms that are applicable in this case are not those relating to the opening of pharmacies in Italy, but those relating to the opening of retail outlets such as para-pharmacies.

54 — See Case C-299/02 *Commission* v *Netherlands* [2004] ECR I-9761, paragraph 15 and case-law cited, and Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, paragraph 27 and case-law cited.

79. Now that the market affected has been identified, it seems to me that the next step should be to consider whether the restrictive effects produced by the legislation at issue are those relevant under Article 49 TFEU. In other words, it is necessary to consider whether the legislation at issue can hinder the establishment of foreign operators on the Italian para-pharmacy market.

80. In its observations, Federfarma emphasises that para-pharmacies are, essentially, ordinary shops selling a variety of products, and the prohibition on the sale of certain medicines is not likely to discourage any foreign operator from setting up new para-pharmacies in Italy.

81. To my mind, however, if para-pharmacies were indeed shops whose core business was completely unrelated to the sale of medicinal products (like supermarkets, petrol stations, and so on), I would have had no hesitation in agreeing with Federfarma and in concluding that any restrictive effect allegedly produced by the legislation at issue had to be regarded as 'too uncertain and indirect',[55] 'purely speculative',[56] or 'too insignificant and uncertain',[57] and consequently not of such a nature as to hinder market access.

82. Yet I note that – despite not being wholly comparable to pharmacies – para-pharmacies do have a number of features in common with the former. For example: (i) they are subject to a number of specific health and pharmaceutical controls carried out by the competent Italian authorities; (ii) they must have equipment and facilities appropriate to guarantee an optimal conservation and distribution of medicinal products; (iii) they purchase medicinal products from the same distributive channels of pharmacies; and (iv) they must ensure the tracing of medicinal products sold by means of a specific code which is attributed by the Ministry of Health. In addition, both in pharmacies and in para-pharmacies, the sale of medicinal products must always be made in the presence of a qualified pharmacist. Furthermore, it is clear that the main business of para-pharmacies involves products which concern well-being, health and, more broadly speaking, medical treatments.

83. At the hearing, in response to a direct question, Ms Venturini and Federfarma gave rather different estimates as to the amount and the value of the pharmaceutical products for which the applicants seek an authorisation to sell. However, it seems to me that none of those estimates permits us to consider that business to be of negligible importance.

84. Under these circumstances, I see no reason to doubt the analysis undertaken by the national court, according to which the legislation at issue does indeed produce restrictive effects which may hinder the establishment in Italy of operators interested in selling those medicinal products.

85. In the light of these considerations, I am inclined to conclude that the legislation at issue constitutes a restriction of the freedom of establishment under Article 49 TFEU. In any event, however, this issue is not crucial for the answer to be given to the national court since, as I will now explain, the legislation at issue is justified by overriding reasons relating to the general interest.

2. Justification for the restriction

86. The Court has consistently held that restrictions on the 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.[58]

55 — Case C-69/88 *Krantz* [1990] ECR I-583, paragraph 11; Case C-379/92 *Peralta* [1994] ECR I-3453, paragraph 24; Case C-134/94 *Esso Espanola* [1995] ECR I-4223, paragraph 24; and Case C-67/97 *Bluhme* [1998] ECR I-8033, paragraph 22.

56 — Case C-169/91 *B & Q* [1992] ECR I-6635, paragraph 15.

57 — Case C-20/03 *Burmanjer and Others* [2005] ECR I-4133, paragraph 31.

58 — Case C-169/07 *Hartlauer* [2009] ECR I-1721, paragraph 44 and case-law cited, and Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, paragraph 25.

87. Since it is common ground that the legislation at issue applies without discrimination on grounds of nationality, our examination must rather focus, first, on what the objectives pursued by the legislation at issue are and, second, on whether the restriction is consistent with the principle of proportionality.

88. On the first point, I would observe, at the outset, that the relevant Italian laws are rather lengthy and complex, and do not easily allow the person interpreting them to identify the real objective(s) pursued by the legislature. Moreover, the written observations of the Italian Government are, regrettably, particularly laconic and contain only a number of vague statements referring to the objectives of protecting public health by preventing the overconsumption of medicinal products, and of protecting the public purse by preventing the dissipation of the limited financial resources that can be made available for health care.

89. Whereas these objectives are, in theory, certainly capable of constituting acceptable justifications,[59] their relevance in the case before the referring court appears rather dubious. Indeed, it is worth recalling once again that the legislation at issue concerns only medicinal products which are sold under medical prescriptions and which are paid for by the customer, and not by the SSN, and thus both demand and supply are fixed. Therefore, I do not see how the legitimate objectives referred to by the Italian Government can be effectively pursued by the legislation at issue.

90. However, the arguments put forward by the parties on that issue are not decisive. Indeed, it is much more important, to my mind, for the Court to be able to identify the objective aims pursued by the legislature, by looking at the very text of the national provisions, as interpreted and applied by the national courts.[60]

91. In the present case, the Court is assisted in this task by the information given in the order for reference as well as by some rulings of the Italian Constitutional Court to which the parties have extensively referred in the context of their written and oral arguments.

92. In its order for reference, the TAR Lombardia states that the aim pursued by the Italian legislation at issue is to protect public health by ensuring the even distribution of medicinal products throughout the national territory, preventing pharmacies from becoming concentrated solely in commercially more desirable areas.

93. These statements are confirmed by a number of decisions handed down by the Italian Constitutional Court, which has consistently held that the complex legal framework on pharmacies is intended to ensure and control the access of citizens to medicinal products and in this way to ensure the protection of the fundamental right to health.[61] The Italian Constitutional Court has also stated that pharmaceutical services are regulated so as to ensure an adequate distribution of medicinal products.[62] Equally important is the fact that, according to the Constitutional Court, the concrete aim pursued by the legislature is to ensure that pharmaceutical services are reliable in both territorial and temporal terms, and to provide a catchment area for the pharmacists, so as to prevent the disappearance of local pharmacies, which would in turn negatively affect the balanced distribution of pharmacies throughout the national territory.[63]

59 — See, in particular, *Apothekerkammer des Saarlandes and Others*, paragraph 33, and Case C-531/06 *Commission* v *Italy* [2009] ECR I-4103, paragraph 57.

60 — It is settled case-law that the scope of national laws, regulations or administrative provisions must be assessed in the light of the interpretation given to them by national courts (Joined Cases C-132/91, C-138/91 and C-139/91 *Katsikas and Others* [1992] ECR I-6577, paragraph 39 and case-law cited, and Case C-490/04 *Commission* v *Germany* [2007] ECR I-6095, paragraph 49 and case-law cited).

61 — Judgment of the Corte costituzionale of 10 March 2006, No 87, point 3; judgment of the Corte costituzionale of 14 December 2007, No 430, point 4.2.1.

62 — Judgment of the Corte costituzionale of 14 December 2007, No 430, point 4.2.1.

63 — Judgment of the Corte costituzionale of 4 February 2003, No 27, point 3.2.

94. In that regard, I would like to reiterate that, as the Court has consistently held, by virtue of Article 52(1) TFEU, the protection of public health can justify restrictions on the fundamental freedoms guaranteed by the Treaty, such as the freedom of establishment. [64] In particular, 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. [65]

95. Against this background, the Court accepted in *Blanco Pérez* that the objective of ensuring that the distribution of medicinal products matches the needs of the population, by means of a widespread and appropriately balanced network of pharmacies, through which a presence is guaranteed also in less economically advantageous areas, may constitute an overriding reason relating to the general interest. [66]

96. I do not see any reason why the Court's findings on this point in *Blanco Pérez* should not be equally applicable to the case under consideration. Admittedly, the Italian Government has not explicitly invoked that argument. However, it seems to me inconceivable that, in two cases which are substantially identical, the Court would reach different conclusions simply because, in one case, counsel adduced cogent and detailed legal argument and, in the other, such argument was conspicuously lacking. I therefore take the view that the objectives pursued by the legislation at issue may constitute a valid justification for a restriction of the freedom of establishment under Article 49 TFEU.

97. The second and final legal issue which must be examined is, then, whether the restriction brought about by the legislation at issue is consistent with the principle of proportionality. Indeed, as mentioned before, by contrast with the situation in *Blanco Pérez*, the applicants are not seeking to open up new pharmacies but only to be authorised to sell, in the para-pharmacies which they own, certain medicinal products which the law reserves to pharmacies.

98. Yet, that difference between the two cases seems to me to be immaterial here. It is indeed obvious that the special regime which the Italian legislature has established for pharmacies would run the risk of being undermined, at least in part, if other types of retail outlet were allowed to offer medicinal products whose sale is currently reserved to pharmacies.

99. Under the Italian system, pharmacies are entrusted with the provision of a public service and, to that end, they are placed under a number of specific obligations and are under a duty to respect certain limitations with regard to the way in which their business is carried out. The applicants do not deny that several of these obligations and limits are not imposed on other types of retail outlet: in particular, they are not imposed on para-pharmacies.

100. These obligations and limits entail significant extra costs for pharmacies. It cannot be ruled out that a substantial reduction of their monopoly over medicinal products would expose some of these pharmacies to the risk of losing economic viability, for it would deprive them of an adequate income. As with the opening of new pharmacies in *Blanco Pérez*, the extension of the range of medicinal products offered by para-pharmacies might drain considerable resources from pharmacies.

101. Whether – and, if so, to what extent and under what conditions – para-pharmacies could be allowed to sell other classes of medicinal product without the system of territorial distribution of pharmacies set up by the Italian legislature being thereby jeopardised, is a matter which is clearly not for this Court to decide.

64 — See, inter alia, *Hartlauer*, paragraph 46, and *Apothekerkammer des Saarlandes and Others*, paragraph 27.

65 — Case C-531/06 *Commission* v *Italy*, paragraph 52 and case-law cited, and *Apothekerkammer des Saarlandes and Others*, paragraph 28 and case-law cited.

66 — *Blanco Pérez*, paragraphs 70 to 73 and case-law cited.

102. It must be recalled, in this context, that the Court has consistently held that the EU Treaties do 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. [67] 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 health-care sector. [68]

103. In interpreting those principles, the Court has pointed out that, when assessing whether that obligation has been met, 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 some measure of discretion. [69]

104. Lastly, the Court has also pointed out that, where there is some uncertainty as to the existence or the 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. [70]

105. This means that, in a situation of uncertainty, a Member State can adopt regulations which are likely to avoid, or minimise, any risk that some parts of its territory will be left with an insufficient number of pharmacies and that, as a consequence, the provision of medicinal products might well not be reliable and of good quality everywhere. [71]

106. The guarantee that all medicinal products subject to prescription (irrespective of who is bearing the costs) are to be offered only by pharmacies seems to be designed precisely to avoid any such risk. Nothing has come to light in these proceedings to suggest that there may be another measure, an alternative to the measure provided for in the legislation at issue, which can offer the same level of assurance to the State as to the achievement of the objectives pursued, while being less restrictive for economic operators.

107. I am thus of the opinion that the legislation at issue is consistent with the principle of proportionality.

IV – Conclusion

108. In the light of the foregoing, I propose that the Court answer the question referred for a preliminary ruling by the Tribunale Amministrativo Regionale della Lombardia (Italy) as follows:

Article 49 TFEU must be interpreted as not precluding national legislation, such as that at issue in the main proceedings, which reserves to pharmacies the sale of pharmaceutical products for which a prescription is required, but the cost of which is borne by the customer.

67 — That principle is also reaffirmed in 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), which 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.'

68 — See, to that effect, *Hartlauer*, paragraph 29; Case C-531/06 *Commission* v *Italy*, paragraph 35 and case-law cited; and *Apothekerkammer des Saarlandes and Others*, paragraph 18 and case-law cited.

69 — Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 51 and case-law cited, and *Apothekerkammer des Saarlandes and Others*, paragraph 19 and case-law cited.

70 — *Apothekerkammer des Saarlandes and Others*, paragraph 30, and *Blanco Pérez*, paragraph 74.

71 — *Blanco Pérez*, paragraph 75.