



Reports of Cases

OPINION OF ADVOCATE GENERAL
WAHL
delivered on 12 March 2015¹

Case C-497/12

Davide Gullotta
Farmacia di Gullotta Davide & C. Sas
v
Ministero della Salute
Azienda Sanitaria Provinciale di Catania
(Request for a preliminary ruling

from the Tribunale Amministrativo Regionale per la Sicilia (Italy))

(Requests for preliminary rulings — Jurisdiction of the Court — Admissibility of the questions — Factual elements of the main proceedings confined within one Member State — Scope of the Charter of Fundamental Rights of the European Union — Freedom of establishment — Public health — Para-pharmacies)

1. In its case-law, the Court has consistently stressed that the preliminary ruling procedure is an instrument of cooperation between the Court of Justice of the European Union and the national courts, by means of which the former provides the latter with the points of interpretation of EU law which the national courts need in order to decide disputes pending before them.² The Court has also emphasised the spirit of cooperation inherent in that procedure, which requires national courts to have regard to the task entrusted to the Court, namely to assist them in the administration of justice in the Member States, and not to deliver advisory opinions on general or hypothetical questions.³

2. These principles are of even greater significance these days, to the extent that the Court is called upon, year after year, to deliver an unprecedented number of decisions, the majority of which concern precisely requests for a preliminary ruling.⁴ For some preliminary rulings, the Court must interpret provisions in new areas of EU law and, for others, it must apply key principles of the EU legal order to novel sets of circumstances which may raise particularly delicate ethical or socio-political issues.⁵

1 — Original language: English.

2 — See, for example, judgments in *The Chartered Institute of Patent Attorneys*, C-307/10, EU:C:2012:361, paragraph 31, and *Danske Slagterier*, C-445/06, EU:C:2009:178, paragraph 65. See also judgment in *Meilicke*, C-83/91, EU:C:1992:332, paragraph 22.

3 — See, among many, judgments in *Kamberaj*, C-571/10, EU:C:2012:233, paragraph 41; *Zurita García and Choque Cabrera*, C-261/08 and C-348/08, EU:C:2009:648, paragraph 36; and *Schneider*, C-380/01, EU:C:2004:73, paragraph 23.

4 — In recent years, there has been a steady increase of incoming cases. This phenomenon reached its peak in 2013, the year in which the Court delivered its highest ever number of judgments and also received the highest ever number of new cases. In that year, requests for preliminary rulings accounted for almost 60% of those cases (see the *Annual Report 2013* of the Court).

5 — To mention but a few: judgments in *Pringle*, C-370/12, EU:C:2012:756; *Z*, C-363/12, EU:C:2014:159; *D.*, C-167/12, EU:C:2014:169; *International Stem Cell Corporation*, C-364/13, EU:C:2014:2451; and *Gauweiler and Others*, C-62/14, pending.

3. Although the Court has, in the past, been relatively reluctant to decline jurisdiction under Article 267 TFEU and generous in assessing the admissibility of requests, one may now wonder whether the Court should not adopt a more rigorous stance on those issues. As I have argued on a previous occasion, the substantial broadening of the Court's jurisdiction as a result of the entry into force of the Treaty of Lisbon, coupled with the expansion of the European Union over the last decade, 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.⁶

4. The present case offers, to my mind, an opportunity to provide further clarification of the Court's case-law on those issues, by drawing attention to some recent decisions of the Court that seem to indicate certain developments. These developments, to my mind, are in line with the analysis suggested in this Opinion.

I – Legal framework

5. 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).

6. Law No 537/1993 later re-categorised 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 Classes A or B. Under Article 8(14) of Law No 537/1993, the cost of medicinal products falling within Classes A or 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.

7. 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 product — '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.

8. Decree-Law No 223/2006, converted into Law No 248/2006, 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' products).

9. More recently, Decree-Law No 201/2011, converted into Law No 214/2011, further extended the categories of medicinal product 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. That legislation was implemented by a Ministerial Decree of 18 April 2012. Lastly, Decree-Law No 1/2012, converted into Law No 27/2012, has increased the number of pharmacies provided for in the 'pianta organica': from one pharmacy for every 4 500 persons, the law now provides that there is to be one pharmacy for every 3 300 persons.

⁶ — See my Opinion in Joined Cases *Venturini*, C-159/12 to C-161/12, EU:C:2013:529, points 22 to 25.

II – Facts, procedure and the questions referred

10. Mr Davide Giuseppe Gullotta ('the applicant') is a qualified pharmacist registered with the Ordine dei Farmacisti di Catania (Catania Order of Pharmacists) and manages a para-pharmacy in Italy.

11. In the case before the referring court, the applicant challenged before the Tribunale Amministrativo Regionale per la Sicilia ('the TAR Sicilia') Order No 0034681 of the Ministero della Salute (Ministry of Health) of 13 August 2011 ('the contested order') refusing the applicant's request to be allowed to sell medicinal products for which a medical prescription is required but the cost of which is not eligible for reimbursement by the SSN. The applicant claimed that the Italian legislation applied by the Ministero della Salute in the contested order is incompatible with EU law on several grounds.

12. In the context of those proceedings, the Italian court, entertaining doubts as to the compatibility of the Italian legislation at issue with EU law, decided to stay the proceedings and to refer the following three questions for a preliminary ruling:

- '(1) 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 entered in the relevant professional register but does not own a pharmacy included 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 Italian national health service, but wholly by the citizen — and which thereby 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 within the national territory?
- (2) Must Article 15 of the Charter of Fundamental Rights of the European Union ["the Charter"] be interpreted as meaning that the principle therein established also applies, without restriction, to the profession of pharmacist, and that the public-interest aspect of that profession does not justify the application of different arrangements to the proprietors of pharmacies and to the proprietors of para-pharmacies as regards the sale of the medicinal products referred to in Question 1 above?
- (3) Must Articles 102 [TFEU] and 106 [TFEU] be interpreted as meaning that the prohibition of the abuse of a dominant position must apply without restriction to the profession of pharmacist, inasmuch as a pharmacist who owns a traditional pharmacy, and sells medicinal products under a contractual arrangement with the [SSN], benefits from the ban on the sale of Class C medicinal products by proprietors of para-pharmacies, without this being properly justified on the basis of the undeniably special features of the profession of pharmacist arising from the public interest in the safeguarding of public health?'

13. Having been served a copy of the judgment of the Court in *Venturini*,⁷ which concerned the same national legislation as that at issue before it, the TAR Sicilia informed the Court by letter of 1 August 2014 that it wished to maintain the second and third questions referred for a preliminary ruling.

14. Written observations in the present proceedings have been submitted by Mr Gullotta, Federfarma, by the Italian, Greek and Spanish Governments, as well as by the Commission. The Court decided to proceed without a hearing.

⁷ — C-159/12 to C-161/12, EU:C:2013:791.

III – Analysis

15. Before examining, in turn, each of the questions referred, I consider it useful to make some preliminary remarks regarding two distinct but closely related concepts: the jurisdiction of the Court under Article 267 TFEU and the admissibility of requests for preliminary rulings. Indeed, the parties who have submitted observations in the present proceedings seem to confuse those two concepts somewhat. That is hardly surprising since, in the past, the Court has not always adopted a coherent terminology in its case-law.

A – Preliminary remarks on the jurisdiction of the Court and the admissibility of requests for preliminary rulings

16. The role and functions of the Court are regulated, just like those of any other institution of the European Union, by the principle of conferral. In that regard, Article 13(2) TEU provides: '[e]ach institution shall act within the limits of the powers conferred on it in the Treaties, and in conformity with the procedures, conditions and objectives set out in them'.

17. Accordingly, the Court's jurisdiction is framed by the system of judicial remedies established by the Treaties, which are available only when the conditions set out in the relevant provisions are fulfilled.⁸

18. As concerns the preliminary ruling procedure, Article 267 TFEU expressly makes the jurisdiction of the Court subject to a number of conditions.⁹ More specifically, under the first paragraph of that provision, the questions referred must concern provisions of EU law the interpretation or validity of which is in doubt in the main proceedings. Furthermore, under the second paragraph of that provision, the body making the reference must be a court or tribunal of a Member State and a decision on the question referred must be necessary in order to enable it to give judgment in the main proceedings. That last condition means, in particular, that there must be a genuine dispute pending before the referring court, and that the answer to be provided by the Court has to be relevant for the resolution of that dispute.¹⁰

19. These conditions must be fulfilled not only at the moment when the Court is seised by the national court, but also throughout the proceedings. If those conditions are not fulfilled, or are no longer fulfilled, the Court must decline jurisdiction, and it may do so at any time in the procedure.¹¹

20. If, on the other hand, the information provided by the referring court is insufficient for the Court positively to establish its jurisdiction or, rather, to provide an answer that may be useful to the referring court, the reference may be declared inadmissible. The information which must be included in a request for a preliminary ruling is set out in Article 94 of the Rules of Procedure. That information serves, in fact, a dual purpose: not only 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 23 of the Statute of the Court of Justice.¹²

21. The two situations described above (lack of jurisdiction and inadmissibility of the request) thus relate to different procedural issues. Whereas lack of jurisdiction essentially reflects a limit to the competence of the Court, in that it has not been granted the power to rule in certain situations, inadmissibility typically arises because of an error of procedure, owing to non-observance of the procedural rules on the part of the referring court.

8 — See, to that effect, judgment in *Unión de Pequeños Agricultores v Council*, C-50/00 P, EU:C:2002:462, paragraphs 44 and 45.

9 — Cf. judgment in *Torralbo Marcos*, C-265/13, EU:C:2014:187, paragraph 27 and case-law cited.

10 — On this issue, see my Opinion in Joined Cases *Torresí*, C-58/13 and C-59/13, EU:C:2014:265, points 19 to 81.

11 — See Article 100(2) of the Rules of Procedure of the Court of Justice ('the Rules of Procedure').

12 — See, *inter alia*, order in *Viacom*, C-190/02, EU:C:2002:569, paragraph 14 and case-law cited.

22. From a theoretical point of view, therefore, those two situations should be distinguished.¹³ However, there is also a more practical aspect to that distinction. Lack of jurisdiction cannot, in principle, be remedied or corrected by the referring court. Accordingly, a reference dismissed for lack of jurisdiction is doomed never to be considered by the Court unless, obviously, there were key elements of fact of which the Court had been unaware.¹⁴ By contrast, a national court whose request is held to be inadmissible can, where appropriate, make a new request for a preliminary ruling to the Court which satisfies all the conditions set out in Article 94 of the Rules of Procedure.¹⁵

23. Certain parallels can be drawn between requests for preliminary rulings and direct actions. In the context of direct actions, too, the EU Courts normally distinguish between cases in which they lack jurisdiction and cases in which the application is inadmissible. For example, an action for annulment is dismissed on grounds of lack of jurisdiction if the applicant challenges the validity of acts adopted by national authorities,¹⁶ or of judgments delivered by national courts¹⁷ or by other international courts.¹⁸ Likewise, the EU Courts have declared their lack of competence as regards actions for damages directed against non-EU bodies such as administrative authorities of Member States.¹⁹

24. Contrariwise, procedural errors made by an applicant which bar the continuation of the action lead merely to a declaration that the application is inadmissible. That is typically the case of, for instance, actions for annulment lodged outside the two-month time-limit provided for in Article 263 TFEU,²⁰ actions lodged by individuals who are not represented by a lawyer,²¹ or infringement actions launched without proper observance of the pre-litigation stage of the procedure laid down in Article 258 TFEU.²²

25. That said, the difference between lack of jurisdiction and inadmissibility should not be over-emphasised since, in practice, they both lead to the same result. The Court dismisses the request from the national court without entering into a discussion concerning the substance of the questions referred.

B – Question 1

26. By its first question, the TAR Sicilia essentially seeks the Court's guidance as to the compatibility with the EU rules on freedom of establishment of a national 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.

27. I must immediately point out that, in my view, the present question should be regarded as having been withdrawn by the referring court.

13 — The two situations are, in fact, referred to separately in Article 53(2) of the Rules of Procedure, which reads: 'Where it is clear that the Court has no jurisdiction to hear and determine a case or where a request or an application is manifestly inadmissible, the Court may, after hearing the Advocate General, at any time decide to give a decision by reasoned order without taking further steps in the proceedings.'

14 — It should be borne in mind that the relevant facts and applicable national laws are established by the national court in its request for a preliminary ruling. The Court will not, as a rule, question those aspects of the request. See, for example, judgment in *Trespa International*, C-248/07, EU:C:2008:607, paragraph 36 and case-law cited.

15 — See, to that effect, Naômé, C., *Le renvoi préjudiciel en droit européen — Guide pratique*, Larcier, Brussels: 2010 (2nd ed.), pp. 85 and 86.

16 — See order in *Killinger v Germany and Others*, C-396/03 P, EU:C:2005:355, paragraphs 15 and 26.

17 — See, for example, order in *Kauk v Germany*, T-334/11, EU:T:2011:408.

18 — See, for example, order in *Calvi v European Court of Human Rights*, C-171/14 P, EU:C:2014:2281.

19 — See, notably, order in *Gluiber v Germany*, T-126/98, EU:T:1998:237.

20 — See, for example, order in *Alsharghawi v Council*, T-532/14 R, EU:T:2014:732.

21 — As provided for in Article 19 of the Statute. See, for example, order in *ADR Center v Commission*, C-259/14 P, EU:C:2014:2417.

22 — See, among many, judgment in *Commission v France*, C-225/98, EU:C:2000:494, paragraph 69.

28. An analogous question was referred to this Court by the TAR Lombardia in the abovementioned *Venturini* case.²³ A copy of the Court's judgment in that case was communicated to the TAR Sicilia by the Court's Registry. In response, the TAR Sicilia stated that it wished to maintain the second and third questions, although it did not take an express position as regards the first question. From that response, it can therefore be inferred, *a contrario*, that the referring court intended to withdraw the first question. The overall tenor of the TAR Sicilia's response, in which that court takes note of the judgment in *Venturini*, seems to support such a reading.

29. I will thus deal with Question 1 only briefly, since that will give me an opportunity to emphasise some important procedural issues.

1. Jurisdiction of the Court

30. The admissibility of the first question is contested by Federfarma. Federfarma points out that all aspects of the proceedings before the referring court are confined to Italy. Accordingly, to the extent that the EU rules on freedom of establishment are not applicable, the question should be considered hypothetical.

31. It is true that, according to settled case-law, 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, not necessary to enable the national court to make a ruling. Since the Treaty rules do not apply to the case before the referring court, an answer to the questions referred is not relevant for the resolution of the dispute.²⁴

32. That said, the Court has, in a number of cases, accepted jurisdiction and given judgment despite the factual situation being purely internal to one Member State.

33. In my Opinion in *Venturini*, I attempted to provide a brief overview of those cases, grouping them into three main lines of decisions. In the first line of decisions ('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 contested national legislation could not be ruled out on the basis of the information contained in the case-file. In the second line of decisions ('the *Guimont* case-law'), the Court considered the questions referred to be admissible, despite the internal character of the main proceedings, in so far as the interpretation of EU law sought appeared useful to the referring court, since national law required it to grant the same rights to a national as those which a national of another Member State in the same situation would derive from EU law, that is to say, national law forbade reverse discrimination against its own nationals. Finally, in a third line of decisions ('the *Thomasdüngrer* case-law'), 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.²⁵

34. After identifying these lines of decisions, I argued that they constituted a correct application of Article 267 TFEU. Indeed, they concerned cases in which, despite all relevant *factual* elements being confined within a single Member State, the relevant *legal* elements were not. However, I also added that, in some of those cases, the Court seemed to have established its jurisdiction on the basis of mere

23 — EU:C:2013:791.

24 — See, inter alia, judgments in *USSL n° 47 di Biella*, C-134/95, EU:C:1997:16, paragraph 19; *RLSAN*, C-108/98, EU:C:1999:400, paragraph 23; and *Omalet*, C-245/09, EU:C:2010:808, paragraph 12.

25 — See my Opinion in *Venturini*, EU:C:2013:529, points 32 to 52.

assumptions, without undertaking any real examination as to whether the relevant conditions were fulfilled. Indeed, the requests for preliminary rulings did not contain any element enabling the Court to establish positively its jurisdiction. That approach I considered — and still consider to this day — problematic.²⁶

35. Since the Court's jurisdiction in situations which are purely internal to a single Member State constitutes an exception to a general principle, I suggested in *Venturini* that the Court ought to be more rigorous in verifying that the relevant conditions are fulfilled.²⁷ In particular, I proposed that the Court decline jurisdiction in cases where neither the case-file, nor the text of the order for reference, set out the reasons explaining why the Court might have jurisdiction despite the purely internal character of the main proceedings. In that regard, I stressed that, in those types of situation, it should be the duty of the national court to explain to the Court why, for example, the application of the national measure under scrutiny is potentially capable of hindering the exercise of a fundamental freedom by foreign economic operators, or to indicate the existence, within its national legal order, of a rule or principle forbidding reverse discrimination which is capable of being applied to the situation under consideration.²⁸

36. Subsequently, in *Airport Shuttle Express*, Advocate General Kokott came to a similar conclusion. In her Opinion, she, too, voiced some criticism concerning a number of rulings in which the Court answered the questions referred despite the apparent lack of any cross-border aspect to the factual elements of the main proceedings. Advocate General Kokott suggested that the Court should be more thorough in assessing its jurisdiction under Article 267 TFEU in cases which seem purely internal to one Member State. She acknowledged that the Court may still need to answer in some of those cases, for example, where the applicable national law precludes reverse discrimination. However, Advocate General Kokott emphasised that, in those circumstances, it is the task of the national court to provide the Court with detailed, up-to-date and reliable information on that aspect of national law. In the absence of such information in the order for reference, the Court should not lightly assume its jurisdiction and thus generally ought to refuse to answer the questions referred.²⁹

37. Since then, a number of decisions handed down by the Court seem to signal greater stringency in the Court's evaluation of its jurisdiction under Article 267 TFEU when, despite the fact that the dispute is purely internal, a national court seeks interpretation of the Treaty provisions on the fundamental freedoms.

38. In fact, in the abovementioned judgment in *Airport Shuttle Express*, the Court followed the Opinion of Advocate General Kokott and declined jurisdiction with regard to the question posed by the national court on the interpretation of Article 49 TFEU. The Court noted that the main proceedings concerned a situation which was purely internal to Italy and that the request for a preliminary ruling contained no information on how the national measures challenged by the applicants were capable of affecting foreign economic operators. The Court accordingly concluded that the interpretation of Article 49 TFEU sought had no bearing on the disputes pending before the referring court.³⁰

26 — Ibid., points 53 to 55.

27 — Ibid., points 24 and 55.

28 — Ibid., points 38, 42 to 44, 50 and 51.

29 — Opinion of Advocate General Kokott in Joined Cases *Airport Shuttle Express*, C-162/12 and C-163/12, EU:C:2013:617, points 26 to 60.

30 — See judgment in *Airport Shuttle Express*, C-162/12 and C-163/12, EU:C:2014:74, paragraphs 28 to 51.

39. In *Tudoran*, the Court declined to rule on a question which concerned the compatibility with Articles 49 and 56 TFEU of certain provisions of the Romanian Code of Civil Procedure, to the extent that the situation at issue in the main proceedings was purely internal to Romania and that there was no indication, in the request for a preliminary ruling, that the abovementioned *Guimont* or *Thomasdüniger* case-law³¹ could be of application.³²

40. Likewise, in *Szabó*, the Court declined jurisdiction with regard to one of the questions referred as the main proceedings concerned a case which was purely internal to Hungary and the referring court had not explained why the EU provisions of which it sought an interpretation could apply to those proceedings.³³

41. The Court has followed a similar approach in other cases which did not concern the fundamental freedoms but which, because of the lack of any connection with EU law, have been deemed to be purely internal to the relevant Member State. For example, in *C*, the Court declined to answer a request for a preliminary ruling which concerned the interpretation of a provision of Directive 2004/80/EC relating to compensation for crime victims³⁴ since the applicant in the main proceedings was the victim of a violent crime committed in the territory of the Member State in which she resided. The Court stressed, first, that Directive 2004/80 provides for compensation only where a violent intentional crime has been committed in a Member State other than that in which the victim is habitually resident. It then went on to point out that, according to settled case-law, even in a purely internal situation, the Court may provide the requested interpretation where national law obliges the referring court to prevent reverse discrimination against its own nationals. Yet, the Court added that it would not be its role to take such an initiative if it was not apparent from the order for reference that the national court is actually under such an obligation. Notably, nothing on that subject was mentioned in the order for reference in that case.³⁵

42. Furthermore, in *De Bellis and Others*, the Court declared itself incompetent to answer a question on the principle of protection of legitimate expectations since the situation under consideration lacked any connection to EU law and the relevant national provisions did not contain any explicit reference to EU law. The conditions laid down in the *Thomasdüniger* case-law were thus not fulfilled.³⁶

43. In the light of these recent decisions, I would conclude that the Court seems no longer to presume, in cases which are purely internal, that the conditions for its jurisdiction are met when the case-file contains only vague evidence to suggest this. In such cases, the Court now requires referring courts to provide a more comprehensible and substantiated explanation of the reasons why it is believed that the Court has jurisdiction.

44. This development in the Court's case-law on the assessment of its jurisdiction under Article 267 TFEU is to be welcomed. The Court's willingness to cooperate with national courts must not, in my view, lead it to answer questions which might be hypothetical and, as such, where its jurisdiction is doubtful at best.

45. Against that background, had that question not been withdrawn, the Court could have perhaps raised *ex officio* the issue concerning its jurisdiction to answer.³⁷ Indeed, it is common ground that all factual elements of the main proceedings are confined to Italy: the applicant is an Italian national who resides and operates a para-pharmacy in Italy. No reference to any cross-border element is to be found

31 — See *supra* point 33.

32 — Order in *Tudoran*, C-92/14, EU:C:2014:2051, paragraphs 34 to 42.

33 — Order in *Szabó*, C-204/14, EU:C:2014:2220, paragraphs 15 to 25.

34 — Council Directive of 29 April 2004 (OJ 2004 L 261, p. 15).

35 — See C-122/13, EU:C:2014:59.

36 — See C-246/14, EU:C:2014:2291.

37 — See, for example, judgment in *Romeo*, C-313/12, EU:C:2013:718, paragraph 20 and case-law cited.

in the order for reference. Nor does that order give any other information as to why an interpretation of Article 49 TFEU could nevertheless be useful for the resolution of the dispute. In particular, it is not indicated that any relevant provision of Italian law is to be construed in the same manner as EU law. What is more, nowhere is it stated that the applicants might, in the case before the referring court, be protected by a national rule forbidding reverse discrimination.

46. The fact that one or more orders for reference emanating from the same Member State might, on a previous occasion, have referred more specifically to a rule or principle prohibiting reverse discrimination to the detriment of own nationals is no sound basis for assuming that such a rule or principle would also apply in the case currently pending before the referring court. Such an assumption would amount to pure speculation, as the Court is not (and cannot be) in a position to know with certainty the scope of that rule or principle, or its position in the hierarchy of norms, or the relevant legislative or judicial developments in that Member State.³⁸

2. Substance

47. As to the substance of the first question referred, in the unlikely event that the Court would wish to deal with it, the answer is in any event clear to me.

48. In *Venturini*, the Court held that the national legislation at issue was liable to hinder or render less attractive the establishment on Italian territory of a pharmacist who is a national of another Member State and has the intention of operating a para-pharmacy there. Consequently, that legislation constituted a restriction on the freedom of establishment for the purposes of Article 49 TFEU. Yet, the Court found that such legislation was appropriate to guarantee attainment of the objective of ensuring that the supply of medicinal products to the public is reliable and of good quality and, therefore, of ensuring the protection of public health, and did not appear to go beyond what was necessary to attain that objective.³⁹

49. Since the national legislation material to the main proceedings is the same as that examined by the Court in *Venturini*, the answer to Question 1 — had it not been withdrawn — would have to be identical: Article 49 TFEU must be interpreted as not precluding national legislation, such as that at issue before the referring court, which does not allow a qualified pharmacist to offer for retail sale, in the para-pharmacy owned by that pharmacist, prescription-only medicinal products the cost of which is borne not by the SSN but by the purchaser.

C – Question 2

50. By its second question, the TAR Sicilia essentially asks whether Article 15 of the Charter (‘freedom to choose an occupation and right to engage in work’) must be interpreted as precluding national legislation, such as that at issue before the referring court, which draws a distinction, as regards the right to sell the medicinal products referred to in Question 1, between pharmacists who own pharmacies and pharmacists who own para-pharmacies.

1. Jurisdiction of the Court

51. The Italian Government and the Commission contend that the Court has no jurisdiction to answer the second question referred by the TAR Sicilia, to the extent that the Charter does not apply to the situation at issue in the main proceedings.

38 — Cf. my Opinion in *Venturini*, EU:C:2013:529, points 42 to 45, and Opinion of Advocate General Kokott in Joined Cases *Airport Shuttle Express*, EU:C:2013:617, points 54 and 55.

39 — EU:C:2013:791.

52. I do not believe that position to be correct.

53. According to a line of authority, by now well-established, the scope of the Charter in relation to actions of the Member States is set out in Article 51(1) thereof, under which the provisions of the Charter are addressed to Member States only when they are implementing EU law.⁴⁰

54. That provision also confirms the settled case-law to the effect that the fundamental rights guaranteed within the EU legal order are designed to be applied in all situations regulated by EU law, but cannot be applied outside those situations.⁴¹ Where a legal situation does not fall within the scope of EU law, the Court has no jurisdiction to rule on it and any Charter provisions relied upon cannot, of themselves, form the basis for such jurisdiction.⁴²

55. It should also be pointed out in this context that the concept of ‘implementing Union law’, as referred to in Article 51(1) of the Charter, requires a certain degree of connection above and beyond the fact that the matters covered are closely related or that one of those matters has an indirect impact on the other.⁴³ In order to determine whether national legislation involves the implementation of EU law for the purposes of Article 51 of the Charter, some of the points to be determined are: (i) whether that legislation is intended to implement a provision of EU law; (ii) the nature of that legislation and whether it pursues objectives other than those covered by EU law, even if it is capable of indirectly affecting EU law; and also (iii) whether there are specific rules of EU law on the matter or capable of affecting it.⁴⁴ In particular, the Court has found that fundamental EU rights could not be applied in relation to certain national legislation because the provisions of EU law in the relevant subject area did not impose any obligation on Member States with regard to the situation at issue in the main proceedings in that case.⁴⁵

56. It is in the light of these principles that I will now examine whether the legal situation which gave rise to the case before the referring court falls within the scope of EU law for the purposes of Article 51 of the Charter.

57. Unfortunately, the order for reference does not contain any specific information on that issue. However, despite the evident shortcomings of that order, I am of the view that the answer to that question should be in the affirmative. My interpretation of the connection between the facts of the case and the EU law provisions applicable in the main proceedings is as follows.

58. On the one hand, it would seem that the legislation at issue was not, *stricto sensu*, intended to implement EU law: the legislation governs, with the more general objective of protecting public health, the retail sale of medicinal products throughout the Italian territory so as to ensure that the supply of those products to the public is reliable and of good quality.⁴⁶

59. In this context, it should be recalled that, by virtue of Article 168(7) TFEU, EU action in the field of public health must respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States are to include the management of health services and medical care and the

40 — See, among many, judgment in *Åkerberg Fransson*, C-617/10, EU:C:2013:105, paragraph 17, and order in *Sociedade Agrícola e Imobiliária da Quinta de S. Paio*, C-258/13, EU:C:2013:810, paragraph 18.

41 — See, inter alia, order in *Boncea and Others*, C-483/11 and C-484/11, EU:C:2011:832, paragraph 29, and judgment in *Åkerberg Fransson*, EU:C:2013:105, paragraph 19.

42 — See, to that effect, order in *Currà and Others*, C-466/11, EU:C:2012:465, paragraph 26, and judgment in *Åkerberg Fransson*, EU:C:2013:105, paragraph 22.

43 — Judgment in *Siragusa*, C-206/13, EU:C:2014:126, paragraph 24. See also, to that effect, the case-law cited.

44 — *Ibid.*, paragraph 25 and case-law cited.

45 — *Ibid.*, paragraph 26, and judgment in *Julián Hernández and Others*, C-198/13, EU:C:2014:2055, paragraph 35.

46 — Cf. judgment in *Venturini*, EU:C:2013:791, paragraphs 40 and 63.

allocation of the resources assigned to them. Furthermore, the Court has held that it is in principle 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 of protection may vary from one Member State to another, Member States must be allowed discretion in that regard.⁴⁷

60. On the other hand, however, EU law contains specific rules — namely, Articles 49 and 52(1) TFEU — which are, in principle, capable of affecting the applicability of the legislation at issue before the referring court.

61. In that regard, the Court has held that, where a Member State relies on overriding requirements in the public interest in order to justify rules which are liable to obstruct the exercise of one of the fundamental freedoms, such justification, provided for by EU law, must be interpreted in the light of the general principles of EU law, in particular the fundamental rights now guaranteed by the Charter. Thus the national rules in question can fall under the exceptions provided for only if they are compatible with the fundamental rights the observance of which is ensured by the Court.⁴⁸

62. It follows that that obligation to comply with fundamental rights squarely falls within the scope of EU law and, consequently, within that of the Charter. The use by a Member State of exceptions provided for by EU law in order to justify an obstruction of a fundamental freedom guaranteed by the Treaty must, therefore, be regarded — as the Court held in *Pfleger* — as ‘implementing Union law’ for the purposes of Article 51(1) of the Charter.⁴⁹

63. Turning back to the present case, Articles 49 and 52(1) TFEU do impose some obligations on the Italian authorities with regard to the situation at issue before the referring court. Among others, the measure constituting a restriction on the freedom of establishment (the limitations on the retail sale of certain medicinal products) must be applied in a non-discriminatory fashion; it must be appropriate to achieve the legitimate public policy objective pursued; and it must not go beyond what is necessary to achieve that objective.⁵⁰

64. I am therefore of the view that the Court has jurisdiction to answer the second question referred by the TAR Sicilia. Nevertheless, I have serious doubts as concerns the admissibility of that question.

2. Admissibility

65. According to settled case-law, in the context of the cooperation instituted by Article 267 TFEU, the need to provide an interpretation of EU law which can be of use to the referring court makes it necessary for that court to define the factual and legislative context of the questions referred or, at the very least, to explain the factual circumstances on which those questions are based.⁵¹ In that context, the Court has emphasised that it is important for the national court to set out the specific reasons why it is unsure as to the interpretation of EU law and why it considers it necessary to refer questions

47 — See to that effect, among others, judgments in *Blanco Pérez and Chao Gómez*, C-570/07 and C-571/07, EU:C:2010:300, paragraph 44, and *Venturini*, EU:C:2013:791, paragraph 59.

48 — See judgment in *Pfleger and Others*, C-390/12, EU:C:2014:281, paragraph 35 and case-law cited.

49 — *Ibid.*, paragraph 36. See also Opinion of Advocate General Sharpston in the same case, EU:C:2013:747, points 36 to 46.

50 — See to that effect, among many, judgments in *Hartlauer*, C-169/07, EU:C:2009:141, paragraph 44, and *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraph 25.

51 — See, among many, judgment in *Mora IPR*, C-79/12, EU:C:2013:98, paragraph 35; and orders in *Augustus*, C-627/11, EU:C:2012:754, paragraph 8, and *Mlamali*, C-257/13, EU:C:2013:763, paragraph 18.

to the Court for a preliminary ruling.⁵² In particular, the Court has stressed the need for the order for reference to include at least a minimum explanation of the reasons for the choice of the provisions of EU law whose interpretation is sought and the connection, as perceived by the referring court, between those provisions and the national legislation applicable to the proceedings pending before it.⁵³

66. As mentioned in point 20 above, those requirements with regard to the content of a request for a preliminary ruling appear expressly in Article 94 of the Rules of Procedure, of which the national court is — as the Court has recently emphasised — supposed to be aware and which it is bound to observe rigorously.⁵⁴

67. In the light of these principles, I take the view that, as concerns the second question referred in the present case, the order for reference does not satisfy those requirements.

68. The order for reference does not explain, even in summary terms, why the referring court considers the interpretation of Article 15 of the Charter to be necessary for the purposes of resolving the dispute pending before it. The national court merely states that it has doubts as to whether the principles enshrined in that provision may fully apply to the profession of pharmacist, even though that profession has been placed under a number of obligations that lie in the general interest.

69. On that point, I would not hesitate to say that any worker and any undertaking active within the internal market — whether or not required to discharge one or more obligations in the general interest — is to enjoy the right enshrined in Article 15 of the Charter. I also find it difficult to deny that the legislation at issue before the referring court is capable of partially limiting that right.⁵⁵

70. However, once it is established that that restriction is justified by the need to protect public health,⁵⁶ I fail to see what additional aspects of incompatibility, between the national law at issue and EU law, Article 15 of the Charter potentially brings into the equation.

71. Indeed, Article 52(1) of the Charter accepts that limitations may be imposed on the exercise of rights such as those set forth in Article 15 of the Charter, as long as the limitations are provided for by law, respect the essence of those rights and freedoms and, subject to the principle of proportionality, are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.⁵⁷

72. It is barely necessary to point out in this context that the Charter also recognises as a fundamental right, in Article 35, that any individual must have access to preventive health care and benefit from medical treatment.

73. Against that background, one would have expected to find some explanation in the order for reference as to why the referring court believed that the national legislation at issue did not properly balance those two fundamental rights, or why that legislation did not respect the essence of the right provided for in Article 15 of the Charter.

52 — See, to that effect, judgment in *Mora IPR*, EU:C:2013:98, paragraph 36; and orders in *Mlamali*, EU:C:2013:763, paragraph 20, and *Talasca*, C-19/14, EU:C:2014:2049, paragraph 19.

53 — See, to that effect, judgments in *Asemfo*, C-295/05, EU:C:2007:227, paragraph 33, and *Mora IPR*, EU:C:2013:98, paragraph 37. See also order in *Laguillaumie*, C-116/00, EU:C:2000:350, paragraphs 23 and 24.

54 — See order in *Talasca*, EU:C:2014:2049, paragraph 21.

55 — See *supra* points 48 and 49.

56 — *Ibid.*

57 — See judgment in *Schaible*, C-101/12, EU:C:2013:661, paragraph 27 and case-law cited.

74. In the absence of any explanation on these crucial aspects, I have to conclude that the second question referred by the TAR Sicilia is inadmissible to the extent that the order for reference does not comply with Article 94 of the Rules of Procedure.

3. Substance

75. With regard to the substance of the issue raised by the referring court in Question 2, I will limit my analysis to the following.

76. I cannot see, either in the order for reference or in the observations lodged by Mr Gullotta, anything to cast doubt on the fact that the national legislation at issue has struck a fair and appropriate balance between, on the one hand, the freedom to choose an occupation and the right to engage in work, and, on the other hand, the right to health care. Nor do I find anything to suggest that the right provided for in Article 15 of the Charter has been so harshly fettered that the essence of that right can be considered to be compromised.

77. On that basis, I do not believe that Article 15 of the Charter precludes legislation such as the national legislation at issue before the referring court.

D – Question 3

78. Finally, by its third question, the referring court in substance asks whether Articles 102 and 106 TFEU must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which reserves the retail sale of certain medicinal products only to pharmacies, to the exclusion of para-pharmacies.

1. Admissibility

79. With regard to the third question, too, I must voice my doubts concerning admissibility. Once again, the order for reference lacks any explanation as to why the referring court considers that the legislation at issue does not comply with Articles 102 and 106 TFEU.

80. In the first place, as regards Article 102 TFEU, I do not quite understand whether, in the view of the referring court, each (or some) of the over 15 000 pharmacies located throughout the Italian territory should be considered to hold a *single* dominant position, or whether those entities should be considered to hold a *joint* dominant position. In the second place, even assuming that a position of dominance could be established, it would remain to be determined in what way that position might be illegitimately exploited with a view to eliminating competition from the relevant market(s).

81. With regard, next, to Article 106 TFEU, it must be pointed out that, recently, the Court has once again confirmed its case-law to the effect that a Member State is in breach of the prohibitions laid down in Article 106(1) TFEU, read in conjunction with Article 102 TFEU, if it adopts any law, regulation or administrative provision that creates a situation in which a public undertaking or an undertaking on which it has conferred special or exclusive rights is led, merely by exercising the preferential rights conferred upon it, to abuse its dominant position or where those rights are liable to create a situation in which that undertaking is led to engage in such abuse. The Court has also made it clear that an infringement of Article 106(1) TFEU, read in conjunction with Article 102 TFEU, requires the establishment of a potential or actual anti-competitive effect liable to result from the fact that the State has conferred special or exclusive rights on some undertakings.⁵⁸

⁵⁸ — See, among others, judgments in *Commission v DEI*, C-553/12 P, EU:C:2014:2083, paragraphs 41 to 46; *MOTOE*, C-49/07, EU:C:2008:376, paragraph 49; and *Connect Austria*, C-462/99, EU:C:2003:297, paragraph 80.

82. Against that background, it becomes evident that — assuming that the legislation at issue could be regarded as conferring on pharmacies special or exclusive rights for the purposes of Article 106(1) TFEU — it would still have to be understood how, in the view of the referring court, pharmacies may be induced to abuse their dominant position by virtue of the special or exclusive rights granted.

83. Yet, no explanation whatsoever is provided on any of those matters. In those circumstances, it is therefore impossible to understand why or how Articles 102 and 106 TFEU could preclude national legislation such as that at issue before the referring court.⁵⁹

84. In fact, I observe that a rather similar question was put to the Court in *Servizi Ausiliari Dottori Commercialisti*, in which an Italian court asked the Court whether Articles 102 and 106 TFEU precluded national legislation which reserved exclusively to Tax Advice Centres — public limited companies authorised by the Italian Ministry of Finance — the right to engage in certain tax advice and assistance activities. In its decision, the Court stressed that the mere creation of a dominant position through the grant of special or exclusive rights is not in itself incompatible with the Treaties. A breach of Articles 102 and 106(1) TFEU thus requires not only that the national legislation at issue have the effect of granting special or exclusive rights to certain undertakings, but also that such legislation can lead those undertakings to abuse a dominant position. Yet, the Court found that neither the order for reference nor the written observations provided it with the factual and legal information which could enable it to determine whether the requirements as to the existence of a dominant position or of abusive conduct, within the meaning of Articles 102 and 106(1) TFEU, were fulfilled. It thus declared the question inadmissible.⁶⁰

85. The same conclusion is, in my opinion, warranted in the present case.

2. Substance

86. As mentioned above, I cannot find, either in the order for reference or in the observations lodged by Mr Gullotta, anything to suggest a possible breach of Articles 102 and 106(1) TFEU.

87. Consequently, I see no reason why Articles 102 and 106 TFEU should be interpreted as precluding national legislation, such as that at issue before the referring court, which reserves the retail sale of certain medicinal products only to pharmacies, to the exclusion of para-pharmacies.

E – Final remarks

88. In the year 2014, there were almost 40 cases in which the Court dismissed requests for preliminary rulings either because they were wholly inadmissible, or because of a clear lack of jurisdiction. In an equally significant number of cases, requests from national courts have been *partially* dismissed on those grounds. The vast majority of those cases exhibited precisely the types of procedural issue which have been examined in the present Opinion: (i) questions on the interpretation of fundamental

59 — The Court has in fact stated that the need for precision, in the order for reference, with regard to the factual and legislative context applies especially in the sphere of competition, which is characterised by complex factual and legal situations: see order in *Laguillaumie*, EU:C:2000:350, paragraph 19 and case-law cited.

60 — C-451/03, EU:C:2006:208, paragraphs 20 to 26.

freedoms despite all aspects of the main proceedings being confined within one Member State,⁶¹ (ii) questions on the interpretation of the Charter in cases which presented no clear connection with EU law,⁶² or (iii) orders for reference which failed to describe the basic factual and legislative context of the questions referred.⁶³

89. Regrettably, it is not unusual for national courts to refer questions to the Court casting doubt on the compatibility of national laws with EU law by reference to a relatively significant number of EU provisions, but without explaining why each of those provisions might be relevant to the case under consideration. Analogous problems are raised by references which, conversely, query the compatibility of national laws with EU law without identifying any specific provisions of EU law.

90. This practice is not acceptable. Every case dismissed on procedural grounds results in a significant waste of resources for both the national court making the reference and the EU judiciary (in particular, because of the required translation of the order for reference into all official languages of the European Union). The administration of justice is also delayed vis-à-vis the parties in the main proceedings, without producing any benefits.

91. Article 19(1) TEU designates as guardians of the EU legal order and of the judicial system of the EU both the Court and the courts and tribunals of the Member States. Indeed, both the European Union and the national judiciaries have been entrusted with the task of ensuring the full application of EU law in all Member States and of ensuring judicial protection of an individual's rights under that law.⁶⁴

92. In the light of this key constitutional principle, the Court of Justice is willing to do its utmost to help national courts to fulfil their judicial function within the EU legal order. Yet, the Court is also conscious of the limits placed upon its own activities by the Treaties.

93. National courts ought also to be mindful of those limits. In particular, they should be aware of recent decisions indicating that the Court is adopting a stricter approach in the assessment of its jurisdiction to answer questions under Article 267 TFEU and of the admissibility of such questions.

94. More generally, national courts should always bear in mind that the principle of sincere cooperation which underlies the procedure in Article 267 TFEU⁶⁵ applies reciprocally. They ought to help the Court ... to help them.

IV – Conclusion

95. In the light of the foregoing considerations, I propose that the Court declare that the second and third questions referred for a preliminary ruling by the Tribunale Amministrativo Regionale per la Sicilia in Case C-497/12 are inadmissible.

61 — See, inter alia, judgment in *Airport Shuttle Express*, EU:C:2014:74; and orders in *Tudoran*, EU:C:2014:2051, and *Szabó*, EU:C:2014:2220.

62 — See, inter alia, orders in *Kárász*, C-199/14, EU:C:2014:2243; *Pańczyk*, C-28/14, EU:C:2014:2003; and *Šíroká*, C-459/13, EU:C:2014:2120.

63 — See, inter alia, orders in *Herrenknecht*, C-366/14, EU:C:2014:2353; *Hunland-Trade*, C-356/14, EU:C:2014:2340; and *3D I*, C-107/14, EU:C:2014:2117.

64 — Cf. Opinion 1/09, EU:C:2011:123, paragraphs 66 to 69.

65 — See *supra*, point 1.