



## Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

13 February 2014\*

(Freedom of establishment — Public health — Article 49 TFEU — Pharmacies — Adequate supply of medicinal products to the public — Operating authorisation — Territorial distribution of pharmacies — Establishment of limits essentially based on a demographic criterion — Minimum distance between pharmacies)

In Case C-367/12,

REQUEST for a preliminary ruling under Article 267 TFEU from the Unabhängiger Verwaltungssenat des Landes Oberösterreich (Austria), made by decision of 24 July 2012, received at the Court on 1 August 2012, in the proceedings brought by

**Susanne Sokoll-Seebacher,**

Third party:

**Agnes Hemetsberger,** successor to Susanna Zehetner,

THE COURT (Fourth Chamber),

composed of L. Bay Larsen, President of the Chamber, M. Safjan, J. Malenovský (Rapporteur), A. Prechal and S. Rodin, Judges,

Advocate General: P. Mengozzi,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- Mrs Sokoll-Seebacher, by E. Berchtold-Ostermann, Rechtsanwältin,
- Mrs Hemetsberger, by C. Schneider, Rechtsanwalt,
- the Austrian Government, by C. Pesendorfer, acting as Agent,
- the Czech Government, by M. Smolek, J. Vláčil and T. Müller, acting as Agents,
- the Portuguese Government, by L. Inez Fernandes and A.P. Antunes, acting as Agents,
- the European Commission, by G. Braun and I. Rogalski, acting as Agents,

\* Language of the case: German.

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,  
gives the following

### **Judgment**

- 1 This request for a preliminary ruling concerns the interpretation of Article 49 TFEU and Articles 16 and 47 of the Charter of Fundamental Rights of the European Union ('the Charter').
- 2 The request has been made in proceedings brought by Mrs Sokoll-Seebacher, concerning the opening of a pharmacy in the municipality of Pinsdorf, in the Province of Upper Austria.

### **Relevant provisions of Austrian law**

- 3 Paragraph 10 of the Law on Pharmacies (Apothekengesetz), as amended by law published in BGBl. I, 41/2006 ('the ApG') provides:

‘1. Authorisation to open a pharmacy shall be granted where:

- (1) a doctor is already permanently established in the municipality where the pharmacy is to be opened and where
- (2) there exists a need for a new pharmacy to be opened.

2. Such a need does not exist where:

- (1) on the date that the request is submitted, there is already, in the municipality where the proposed pharmacy is to be located, a doctor's dispensary and fewer than two (full-time) positions for doctors operating under contract to health funds ... are occupied by general practitioners, or where
- (2) the distance between the location of the proposed pharmacy and the location of the closest existing public pharmacy is less than 500 metres, or where
- (3) as a result of the establishment of the new pharmacy, the number of people that will remain to be served by one of the existing neighbouring pharmacies will be reduced and fall below 5 500.

3. A need, within the meaning of point 2(1) above, does not exist where, on the date that the request is submitted, there is, in the municipality where the proposed pharmacy is to be opened,

- (1) a doctor's dispensary and
- (2) a group practice under contract to health funds ...

...

4. The people to be served, within the meaning of point 2(3) above, are those permanent inhabitants living within a radius of less than four kilometres, by road, from the permanent location of one of the existing neighbouring public pharmacies who, because of local conditions, will continue to be served by that existing pharmacy.

5. Where the number of permanent inhabitants, as defined in point 4 above, is lower than 5 500, account must be taken, when ascertaining whether a need exists, of the people who are to be served by virtue of the fact that they work, have recourse to services or use means of transport in that area.

6. The distance referred to in point 2(2) above, may, in exceptional cases, be ignored where the local conditions urgently so require, in the interest of ensuring an adequate supply of medicinal products to the public.

7. An expert's report shall be prepared by the Austrian Chamber of Pharmacists to establish whether there is a need for a new pharmacy to be opened. ...

...'

4 Paragraph 47(2) of the ApG, relating to the 'Lock-out period', provides:

'An applicant's request for authorisation must also be rejected by the district administrative authorities without taking any further steps in the procedure where a previous request by another applicant seeking authorisation to open a new pharmacy in the same location has been rejected on the grounds that one of the conditions set out in Paragraph 10 was not met, where fewer than two years have passed since that last decision made in that case was notified and where no essential change has occurred in the local conditions on which that earlier decision was based. ...'

#### **The dispute in the main proceedings and the questions referred for a preliminary ruling**

5 By decision of 29 December 2011, the District Governor of Gmunden (Bezirkshauptmann von Gmunden) rejected Mrs Sokoll-Seebacher's request seeking authorisation to open a pharmacy in the municipality of Pinsdorf, on the ground that no need existed within the meaning of Paragraph 10 of the ApG.

6 That refusal is based on an expert's report from the Austrian Chamber of Pharmacists of 12 April 2011, and the supplementary observations to that report of 25 October 2011. According to those documents, opening a new pharmacy would have resulted in the number of people potentially served by Mrs Zehetner's pharmacy, located in the municipality of Altmünster, which is adjacent to the municipality of Pinsdorf, falling well below the threshold of 5 500 people, since Mrs Zehetner's customer base would be reduced to 1 513 people.

7 Mrs Sokoll-Seebacher contested that decision arguing that, in the supplementary observations to the expert report, the Austrian Chamber of Pharmacists took into consideration the existing direct road link between the neighbouring municipalities of Pinsdorf and Altmünster, which, under Austrian railways' infrastructure plan, would shortly be removed. According to Mrs Sokoll-Seebacher, that fact should have been taken into consideration. Moreover, the Austrian Chamber of Pharmacists should have also taken into consideration the fact that Mrs Zehetner, when she opened her pharmacy, was perfectly aware that the number of people she would serve would never reach 5 500.

8 In those circumstances, the Unabhängiger Verwaltungssenat des Landes Oberösterreich, decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. Do the rule of law considerations inherent in Article 16 of the Charter and/or the considerations of transparency inherent in Article 49 TFEU preclude a national provision such as point 3 of Paragraph 10(2) of the ApG at issue in the [main proceedings], pursuant to which the condition whether there is a need to establish a new public pharmacy is not specified at least in essence in the legislation itself but its elaboration is left in considerable respects to the national courts, since

it cannot be excluded that a scheme of that kind affords a significant competitive advantage to interested parties from Austria, individually and as a whole, over nationals from other Member States?

2. If Question 1 is answered in the negative: Does Article 49 TFEU preclude a national provision such as point 3 of Paragraph 10(2) of the ApG, which in relation to the crucial condition whether a need is deemed to exist sets a rigid threshold of 5 500 people without allowing for any departure from that general rule, since *de facto* under a scheme of that kind it does not appear possible to ensure (without more) the achievement in a consistent manner of the legislative objective pursued, in terms of paragraphs 98 to 101 of the [judgment in Joined Cases C-570/07 and C-571/07 *Blanco Pérez and Chao Gómez* [2010] ECR I-4629]?
3. If Question 2 is also answered in the negative: Do Article 49 TFEU and/or Article 47 of the Charter preclude a provision such as point 3 of Paragraph 10(2) of the ApG which has been interpreted, as result of the case-law of the highest national courts concerning the verification of the existence of a need, to include additional detailed criteria – such as whether an application has priority in time, the blocking effect of an existing application in relation to subsequent applications, the two-year lockout period following the rejection of an application, criteria for determining the number of ‘permanent inhabitants’ and ‘incoming users’ and for allocating the customer base in the event of an overlap between the four-kilometre radius surrounding each of two or more pharmacies, etc. – since, as a result, it is not possible to ensure that, as a general rule, the provision will be applied in a manner that is foreseeable and calculable and within a reasonable period and, hence, the legislative provision cannot be considered appropriate, in fact, to ensure the achievement in a consistent manner of the legislative objective pursued (see paragraphs 98 to 101 and 114 to 125 of the Court’s judgment in *Blanco Pérez*) and/or the provision of an adequate pharmaceutical service must be regarded as *de facto* not ensured and/or discrimination must be presumed as between applicants from Austria amongst themselves or between them and applicants from other Member States?’

### *Admissibility*

- 9 First, Mrs Zehetner and the Austrian Government challenged the admissibility of the request for a preliminary ruling on the ground that the dispute in the main proceedings does not have any cross-border elements and relates to a purely internal situation.
- 10 In that regard, it should be recalled that, while national legislation such as that at issue in the main proceedings – which applies indiscriminately to Austrian nationals and to nationals of other Member States – is, generally, capable of falling within the scope of the provisions relating to the fundamental freedoms established by the FEU Treaty only to the extent that it applies to situations connected with trade between the Member States, it is far from inconceivable that nationals established in Member States other than the Republic of Austria have been or are interested in operating pharmacies in that Member State (see, to that effect, Joined Cases C-159/12 to C-161/12 *Venturini and Others* [2013] ECR, paragraph 25 and the case-law cited).
- 11 While it is admittedly clear from the case-file before the Court that the applicant in the main proceedings is an Austrian national and that all the factual aspects of the main proceedings are confined to one Member State, namely the Republic of Austria, the legislation at issue in the main proceedings is nevertheless capable of producing effects which are not confined to that Member State.

- 12 Moreover, even in a purely internal situation such as that at issue in the main proceedings, where all the factors are confined to a single Member State, a response could nevertheless be useful for the referring court, in particular if its national law were to require it to grant to an Austrian national the same rights as those which a national of another Member State would derive from European Union law in the same situation (*Venturini and Others*, paragraph 28 and case-law cited).
- 13 That first objection of inadmissibility must therefore be rejected.
- 14 Second, Mrs Zehetner, without explicitly raising an objection of inadmissibility in that regard, expresses doubts as to whether the request for a preliminary ruling explains, to a sufficient extent, the link between the provisions of European Union law and the national legislation applicable in the main proceedings. The request for a preliminary ruling is difficult to understand because it sets out the positive law of Austria only in a rudimentary manner.
- 15 In that regard, it is the Court's settled case-law that the need to provide an interpretation of European Union law which will be of use to the referring court requires that the referring court define the factual and legal context of its questions or, at the very least, that it explain the factual circumstances on which those questions are based (see, inter alia, Case C-134/03 *Viacom Outdoor* [2005] ECR I-1167, paragraph 22; Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA and Others* [2005] ECR I-10423, paragraph 45; and C-284/12 *Deutsche Lufthansa* [2013] ECR, paragraph 20).
- 16 The Court has also stressed that it is important for the referring court to set out the precise reasons why it was unsure as to the interpretation of European Union law and why it considered it necessary to refer questions to the Court for a preliminary ruling. The Court has thus ruled that it is essential that the referring court provide at the very least some explanation of the reasons for the choice of the provisions of European Union law which it requires to be interpreted and of the link it establishes between those provisions and the national legislation applicable to the dispute before it (see, inter alia, Case C-318/00 *Bacardi-Martini and Cellier des Dauphins* [2003] ECR I-905, paragraph 43, and *ABNA and Others*, paragraph 46).
- 17 In the present case, the presentation, in the order for reference, of the background to the dispute in the main proceedings and the description of the national law applicable allowed the applicant in the main proceedings and the governments of the Member States to submit written observations on the questions referred. Moreover, the order for reference sets out the European Union legislation of which the referring court seeks an interpretation and gives a sufficient explanation of the link between that legislation and the national legislation applicable in the main proceedings.
- 18 In those circumstances, the request for a preliminary ruling must be held to be admissible.

### *Substance*

#### The first and second questions

- 19 By its first and second questions, which should be examined together, the referring court asks, in essence, whether Article 16 of the Charter and/or Article 49 TFEU must be interpreted as precluding national legislation such as that at issue in the main proceedings, in so far as, according to that referring court, that legislation does not lay down sufficiently precise criteria for determining whether there is a need to supply medicinal products such as to justify the opening of a new pharmacy and, if not, whether Article 49 TFEU, in particular the requirement that the desired objective be achieved in a consistent manner, precludes such legislation in so far as it lays down, as an essential criterion for establishing such a need, a rigid limit, which cannot be departed from, with respect to the number of 'people remaining to be served'.

- 20 First of all, it should be noted that the referring court raises questions about the interpretation not only of Article 49 TFEU, relating to the freedom of establishment, but also of Article 16 of the Charter setting out the freedom to conduct a business.
- 21 Article 16 of the Charter provides that '[t]he freedom to conduct a business in accordance with European Union law and national laws and practices is recognised'. Thus, when identifying the scope of the freedom to conduct a business, Article 16 of the Charter refers specifically to European Union law.
- 22 That reference to European Union law must be understood as meaning that Article 16 of the Charter refers, inter alia, to Article 49 TFEU, which guarantees the fundamental freedom of establishment.
- 23 In those circumstances and given that the questions referred concern the freedom of establishment only, the national legislation at issue in the main proceedings should be assessed with regard to Article 49 TFEU alone.
- 24 Second, it should be borne in mind that, according to the settled case-law of the Court, Article 49 TFEU must be interpreted as not precluding, in principle, a Member State from adopting a system of prior authorisation for the establishment of new healthcare providers, such as pharmacies, where this proves indispensable for filling in possible gaps in access to public health services and for avoiding the duplication of structures, so as to ensure the provision of public health care which is adapted to the needs of the population, which covers the entire territory and which takes account of geographically isolated or otherwise disadvantaged regions (see, to that effect, *Blanco Pérez and Chao Gómez*, paragraphs 70 and 71 and the case-law cited).
- 25 The Court has thus held that national legislation setting out certain criteria to which the issue of licences to open new pharmacies is subject is generally appropriate for attaining the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality (see, to that effect, *Blanco Pérez and Chao Gómez*, paragraph 94; see orders of 17 December 2010 in Case C-217/09 *Polisseni*, paragraph 25 and of 29 September 2011 in Case C-315/08 *Grisoli*, paragraph 31).
- 26 The Court has also held that it must be taken into account that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level of protection may vary from one Member State to the other, Member States must be allowed a measure of discretion (*Blanco Pérez and Chao Gómez*, paragraph 44 and the case-law cited).
- 27 More specifically, it follows from the Court's settled case-law that a prior administrative authorisation scheme cannot render legitimate discretionary conduct on the part of the national authorities which is liable to negate the effectiveness of provisions of European Union law, in particular those relating to a fundamental freedom such as the freedom of establishment. Therefore, if a prior administrative authorisation scheme is to be justified even though it derogates from a fundamental freedom, it must be based on objective, non-discriminatory criteria known in advance, in such a way as adequately to circumscribe the exercise of the national authorities' discretion (C-169/07 *Hartlauer* [2009] ECR I-1721 paragraph 64 and the case-law cited).
- 28 In the case in the main proceedings, it should be noted that the national legislation in question makes the issue of the authorisation to open a new pharmacy conditional on the existence of a 'need' which is presumed to exist unless at least one of the different specific situations set out in that legislation excludes it.

- 29 More specifically, according to that legislation, when establishing whether a need to create a new pharmacy is absent, account is to be taken of the number of healthcare providers present in the area concerned when the request is submitted, the distance between the pharmacy to be opened and the closest existing one and the number of ‘people remaining to be served’ by one of the existing pharmacies. That number is determined by reference to a radius calculated from the location of the existing pharmacy and includes, predominantly, all the permanent inhabitants residing in that area thus measured and, where appropriate, also all the people who have certain connections with that area, which are also specified in that legislation.
- 30 Among those criteria, those relating to the number of the healthcare providers or permanent inhabitants in the different areas or to the distance between the pharmacies constitute objective data which cannot, in principle, give rise to difficulties of interpretation or assessment.
- 31 However, as regards the criterion relating to the connections which people have with the area concerned, it is true that that criterion is not completely unambiguous. Nevertheless, first, that criterion is not the main criterion for determining the number of ‘people remaining to be served’, since it comes into play only where appropriate and, second, the different connections are defined in an objective manner and are verifiable, inter alia, by means of statistical data.
- 32 In those circumstances, it must be considered that the criteria provided for in national legislation, such as that at issue in the main proceedings, are sufficiently objective in nature.
- 33 Moreover, it is not apparent from the order for reference that criteria other than those expressly provided for in the national legislation at issue in the main proceedings and, therefore, not known in advance by economic operators, could also be taken into consideration when establishing whether a need to open a new pharmacy is absent.
- 34 In that regard, the fact that the criteria set out in Paragraph 10 of the ApG have been defined in national case-law does not, in itself, prevent interested economic operators from acquainting themselves with those criteria in advance.
- 35 Finally, having regard to the case-file before the Court, there are no grounds for finding that the criteria laid down by that legislation could be considered discriminatory.
- 36 In that regard, it should be noted, in particular, that, in a situation such as that set out at paragraph 28 above, there is a presumption in favour of the need to establish a new pharmacy. Therefore, it is not for the different applicants who wish to open a new pharmacy to show whether such a need exists in the present case.
- 37 Accordingly, the outcome of the procedure for issuing authorisation is not dependent, in principle, on the fact that only certain applicants, be they domestic nationals or nationals from other Member States, are in possession, if necessary, of information showing the existence of such a need, which would place them in a privileged position vis-à-vis competitors not in possession of such information.
- 38 It follows that national legislation such as that at issue in the main proceedings must be considered to be based on objective, non-discriminatory criteria known in advance, such as to circumscribe sufficiently the exercise of the discretion that the national authorities enjoy in that regard.
- 39 Third, it should be noted that, according to the Court’s settled case-law, national legislation is appropriate for securing attainment of the objective sought only if it genuinely reflects a concern to attain that objective in a consistent and systematic manner (see, to that effect, *Hartlauer*, paragraph 55; Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, paragraph 42; *Blanco Pérez and Chao Gómez*, paragraph 94; and Case C-539/11 *Ottica New Line di Accardi Vincenzo* [2013] ECR, paragraph 47).

- 40 In that regard, it is ultimately for the referring court, which has sole jurisdiction to assess the facts and interpret the national legislation, to determine whether and to what extent such legislation satisfies those conditions. However, the Court, which is called on to provide answers of use to the referring court, may provide guidance based on the documents relating to the main proceedings and on the written and oral observations which have been submitted to it, in order to enable the referring court to give judgment (*Ottica New Line di Accardi Vincenzo* paragraphs 48 and 49 and the case-law cited).
- 41 To that end, it should be recalled that the uniform application, over the entire territory concerned, of conditions relating to the demographic density and the minimum distance between pharmacies, laid down by national legislation governing the opening of a new pharmacy, might well be unsuccessful, in certain circumstances, in ensuring adequate access to pharmaceutical services in areas which have certain special demographic features (see, to that effect, *Blanco Pérez and Chao Gómez*, paragraph 96).
- 42 More specifically, as regards the conditions relating to demographic density, the Court considered that the uniform application of those conditions, without any possibility of derogation, would lead, in certain rural areas where the population is generally dispersed and less numerous, to certain inhabitants concerned finding themselves beyond reasonable distance of a pharmacy and thus possibly being denied adequate access to pharmaceutical services (see, to that effect, *Blanco Pérez and Chao Gómez*, paragraph 97).
- 43 As regards the dispute in the main proceedings, Paragraph 10 of the ApG provides that no need justifying the opening of a new pharmacy exists where, as result of it being opened, the number of 'people remaining to be served' by one of the existing neighbouring pharmacies, namely the number of permanent inhabitants living within a radius of less than four kilometres, by road, from that location would be reduced and would fall below 5 500. However, where the number of those inhabitants is lower, under that same law, account must be taken, when ascertaining whether a need exists, of people who would be served due to that fact that they work, that they have recourse to services or that they use means of transport in that pharmacy's area of supply ('the incoming users').
- 44 In order to provide a useful response for the referring court, it is helpful to highlight two points which may be described as follows.
- 45 First, there are people who live beyond the radius of 4 kilometres, by road, of the location of the nearest pharmacy and who are therefore not taken into account, as permanent inhabitants, either within the area of supply or in any other existing area. While it is true that those people may be considered to be 'incoming users', in one or more areas, the fact remains that their access to pharmaceutical services is thus dependent on circumstances which are not such as to ensure that they have, in principle, permanent and continuous access to that care, since that access is linked only to work undertaken or to use of means of transport in a given area. It follows that for certain people, in particular those living in rural areas, access to medicinal products may prove to be inadequate, given that, in addition, national legislation such as that at issue in the main proceedings does not provide for any maximum distance between a person's place of residence and the closest pharmacy.
- 46 That is all the more true as regards the people coming within the category referred to in paragraph 45 above, given that, in addition, some of them are people with reduced mobility, either temporarily or in the long term, such as old, disabled or sick people. First, their health may require that medicinal products be administered urgently or frequently and, second, their links with the different areas are, on account of their health, very weak, sometimes non-existent.
- 47 Second, where the opening of a new pharmacy is sought in the interests of all the people who live in the territory making up a new pharmacy's prospective area of supply, and beyond the four-kilometre radius, the opening of that new pharmacy would be bound to result in a reduction, in some situations

below the threshold of 5 500 people, of the number of permanent inhabitants living within existing pharmacies' areas of supply still remaining to be served. That would, in particular, be the case in rural regions where the population density is generally low.

- 48 It appears to be clear from the national legislation – although that is a matter for the referring court to establish – that, in order for a request seeking authorisation to open a new pharmacy in those circumstances to be successful, the number of 'incoming users' must be sufficient to compensate for the relative decrease in the number of residents 'remaining to be served' in the areas affected by the opening of the new pharmacy. Accordingly, the decision to be taken in relation to that request would depend, in fact, not on the evaluation of the accessibility of the pharmaceutical services in the newly planned area, but on whether the areas affected by the opening of the pharmacy are capable of accommodating 'incoming users' and how many such incoming users there are.
- 49 However, in rural, isolated and infrequently 'visited' regions, there is a danger that the number of 'people remaining to be served' would not reach the limit strictly required and, consequently, that the need justifying the establishment of a new pharmacy may be considered insufficient.
- 50 Accordingly, the application of the criterion relating to the number of 'people remaining to be served', gives rise to a danger that equal and adequate access may not be guaranteed for certain people living in rural and isolated regions situated outside the existing pharmacies' areas of supply, in particular for people with reduced mobility.
- 51 In the light of all the foregoing considerations, the answer to the first two questions is that Article 49 TFEU, in particular the requirement that the desired objective be achieved in a consistent manner, must be interpreted as precluding legislation such as that at issue in the main proceedings, which lays down, as an essential criterion for determining whether a need for the opening of a new pharmacy exists, a rigid limit on the 'people remaining to be served', where the competent authorities cannot depart from that limit to take account of particular local geographical conditions.

The third question

- 52 Given the answer to the first two questions, there is no need to answer the third question.

### **Costs**

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

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

**Article 49 TFEU, in particular the requirement that the desired objective be achieved in a consistent manner, must be interpreted as precluding legislation such as that at issue in the main proceedings, which lays down, as an essential criterion for determining whether a need for the establishment of a new pharmacy exists, a rigid limit on the 'people remaining to be served', where the competent authorities cannot depart from that limit to take account of particular local geographical conditions.**

[Signatures]