Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

21 June 2012*

(Article 49 TFEU — Freedom of establishment — Public health — Pharmacies — National licensing scheme for the operation of pharmacies — Establishment of branch pharmacies — Conditions which differ according to whether the pharmacy is a private pharmacy or a University of Helsinki pharmacy — University of Helsinki Pharmacy having specific tasks in connection with pharmacy teaching and pharmaceutical services)

In Case C-84/11,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Korkein hallinto-oikeus (Finland), made by decision of 21 February 2011, received at the Court on 24 February 2011, in the proceedings brought by

Marja-Liisa Susisalo,

Olli Tuomaala,

Merja Ritala,

intervening party:

Helsingin yliopiston apteekki,

THE COURT (Third Chamber),

composed of K. Lenaerts, President of the Chamber, J. Malenovský, R. Silva de Lapuerta, G. Arestis and T. von Danwitz (Rapporteur), Judges,

Advocate General: P. Mengozzi,

Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 15 February 2012,

after considering the observations submitted on behalf of:

— Ms Susisalo, M. Tuomaala and Ms Ritala, by A. Kuusniemi-Laine, J. Väyrynen and A. Laine, asianajajat,

— Helsingin yliopiston apteekki, by K. Joenpolvi, asianajaja, and T. Kauti, lakimies,

— the Finnish Government, by H. Leppo and J. Heliskoski, acting as Agents,

* Language of the case: Finnish.

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

— the European Commission, by E. Paasivirta and I.V. Rogalski, acting as Agents,

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

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 49 TFEU and 106(2) TFEU.

2 The reference has been made in proceedings between Ms Susitalo, Mr Tuomaala and Ms Ritala and the Lääkealan turvallisuus- ja kehittämiskeskus (the Finnish Medicines Agency) ('FIMEA') and Helsingin yliopiston apteekki (University of Helsinki Pharmacy) ('UHP') concerning an application by the latter to transfer one of its branches to the Tammisto district in Vantaa, and in proceedings between Ms Susitalo and FIMEA concerning an application by Ms Susitalo for permission to open a branch in the same district.

Legal context

3 Under Paragraph 38 of the Law on medicines (Lääkelaki), in the version applicable to the cases in the main proceedings ('the Law on medicines'), medicines may be sold to the public only from pharmacies, within the meaning of Paragraphs 41 and 42 thereof, and branch pharmacies and 'medicine chests' within the meaning of Paragraph 52. Pharmacies must, pursuant to Paragraph 39, be established within the country so that, wherever possible, the population has access to medicines without difficulty.

4 Pursuant to Paragraph 40 of the Law on medicines, a pharmacy business may be operated with a licence which is issued in respect of a municipality or a part thereof by the Lääkelaitos (National Agency for Medicines).

5 According to Paragraph 41(1) of the Law on medicines, the decision to establish a new pharmacy in a municipality or a part thereof is made by the Lääkelaitos where this is required for the availability of medicines, which must be evaluated on the basis of the number of inhabitants in the area, the existing pharmacy services there and the establishment of other healthcare services. The decision is taken on the initiative of the Lääkelaitos or that of the municipality. The Lääkelaitos may also order the change of area served by the pharmacy and its transfer to another part of the municipality if this is necessary in order to secure pharmacy services.

6 Pursuant to Paragraph 42(1) of the Law on medicines, the University of Helsinki has the right to a pharmacy in the City of Helsinki and the University of Kuopio has the right to a pharmacy in the City of Kuopio. In addition to the sale of medicines, the task of those pharmacies is to carry out practical training for pharmacy students and to carry out research on pharmaceutical services. According to the draft law which led to the adoption of the Law on medicines, the UHP, in addition to dispensing medicines, must undertake teaching and research duties and special services relating to the manufacture of certain rare medicinal preparations.

7 Under Paragraph 43(1) of the Law on medicines, a pharmacy licence may be granted to a national of a State belonging to the European Economic Area, who is an authorised pharmacist ('proviisori') and who has not been declared bankrupt or declared incompetent and for whom no trustee has been

appointed. Where there are a number of applicants, the pharmacy licence is, in accordance with the second subparagraph thereof, granted to the applicant who has overall the best qualifications for operating a pharmacy.

8 The operation of branch pharmacies is regulated by Paragraph 52 of the Law on medicines, the first subparagraph of which provides that such a branch may be opened in an area which, on account of the sparseness of its population, is not regarded as fulfilling the operational prerequisites for an independent pharmacy, but where a pharmacy is required for the availability of medicines. A branch pharmacy may be established at the initiative of the Lääkelaitos or the municipality. The Lääkelaitos grants the licence on application to the pharmacist who has the best qualifications for operating such a branch, taking account of the location of the pharmacy and other operating conditions. The Lääkelaitos may authorise a pharmacist to operate up to three branch pharmacies.

9 In accordance with Paragraph 52(3) of the Law on medicines, the University of Helsinki may operated up to 16 branch pharmacies, each one of which must be issued a licence from the Lääkelaitos.

10 The Lääkelaitos was replaced by FIMEA from 1 November 2009.

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

11 The questions referred for a preliminary ruling arise from two sets of proceedings concerning applications to open branch pharmacies.

12 The first concerns an application by UHP to transfer one of its 16 branch pharmacies to the Tammisto district of Vantaa. The Lääkelaitos upheld that application by decision of 28 February 2008. Ms Susitalo, Mr Tuomaala and Ms Ritala, who are pharmacists, brought an action for annulment against that decision which was dismissed by the Helsingin hallinto-oikeus.

13 The second concerns an application by Ms Susitalo regarding the opening of a branch pharmacy also in the Tammisto district of Vantaa which was rejected by the Lääkelaitos by decision of 23 June 2008. Since the action for annulment against that decision was rejected by the Helsingin hallinto-oikeus, Ms Susitalo appealed to the referring court.

14 On the view that the outcome of the proceedings before it depended on the interpretation of European Union law, the Korkein hallinto-oikeus decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

‘(1) Is Article 49 TFEU, which deals with the right of establishment under EU law, to be interpreted to mean that it precludes application of the provisions of Finland’s Law on medicines with respect to the pharmacies operating licence scheme, for the reason that conditions set for [UHP] to set up branch pharmacies differ from the conditions set for private pharmacies as follows:

(a) By a licence granted by [FIMEA] on the basis of Paragraph 52(1) of the Law on medicines, a private branch pharmacy may be set up in an area which (because of the sparseness of its population) cannot be regarded as having adequate operational prerequisites for an independent pharmacy, but where (for the availability of medicines) a pharmacy business is required; and a private pharmacist may, on the basis of a separate licence granted for each branch pharmacy, operate a maximum of three branch pharmacies. On the other hand, a branch pharmacy of [UHP] may be set up by a licence granted in each case by FIMEA on the basis of Paragraph 52(3) of the Law on medicines, and discretion in the granting of such a licence is not limited by the provisions of the Law on medicines or by other national regulations in any way other than that UHP may have a maximum of 16 branch pharmacies.

(b) When determining the place of establishment of a private branch pharmacy, FIMEA must take account of the location of the pharmacy. There is no corresponding regulation regarding the places of location of [UHP] branch pharmacies, and these branch pharmacies are located in various parts of Finland.

(2) If the Court of Justice takes the view that, in the light of the answers to the questions set out above, Article 49 TFEU precludes the branch pharmacy licence scheme as it applies to [UHP], the Supreme Administrative Court requests a preliminary ruling from the Court of Justice on the following questions:

(a) is the restriction on the freedom of establishment stemming from [UHP's] branch pharmacy licence scheme justified by overriding reasons in the general interest arising from its particular tasks relating to research on pharmaceutical services and pharmacy teaching, which are necessary and in accordance with the principle of proportionality, taking account of the fact that no corresponding particular tasks are laid down in the case of its branch pharmacies?

(b) do the particular tasks, explained above, laid down in law with respect to [UHP] mean that it may be regarded as an undertaking providing services of general economic interest as referred to in Article 106(2) TFEU, and if so, does the said TFEU provision give entitlement to derogate from the requirements regarding administrative advance authorisation set by Article 49 TFEU and by the case-law of the Court of Justice in the case of Helsinki University's branch pharmacies, taking account of the fact that no corresponding particular duties are stipulated in the case of [UHP] branch pharmacies?'

The jurisdiction of the Court

15 UHP challenges the jurisdiction of the Court to answer the questions referred, in particular on account of the fact that the disputes in the main proceedings do not contain any cross-border elements.

16 In that connection, it should be recalled that, although, in view of the division of responsibilities in the preliminary-ruling procedure, it is for the referring court alone to determine the subject-matter of the questions which it proposes to refer to the Court, in exceptional circumstances, it will examine the conditions in which the case was referred to it by the national court, in order to assess whether it has jurisdiction (Joined Cases C-92/09 and C-93/09 *Volker und Markus Schecke and Eifert* [2010] ECR I-11063, paragraph 39).

17 That is the case in particular where the problem referred to the Court is purely hypothetical or where the interpretation of a Community rule which is sought by the national court has no relation to the actual facts of the main action or to its purpose. Thus, the Court has declined jurisdiction where it was obvious that the provision of Community law referred to the Court for interpretation was incapable of applying (Case C-567/07 *Woningstichting Sint Servatius* [2009] ECR I-9021, paragraph 43 and the case-law cited).

18 According to settled case-law, the provisions of the Treaty on freedom of establishment and the freedom to provide services do not apply to purely internal situations in a Member State (see, to that effect, Joined Cases C-54/88, C-91/88 an C-14/89 *Nino and Others* [1990] ECR I-3537, paragraph 11; Case C-134/94 *Esso Española* [1995] ECR I-4223, paragraph 17; and Case C-389/05 *Commission* v *France* [2008] ECR I-5397, paragraph 49).

19 It is clear from the order for reference and the written observations submitted to the Court that all the elements of the disputes in the main proceedings are situated in Finland. Therefore, it appears that the exercise of the right of establishment in Article 49 TFEU is not relevant in these proceedings.

20 However, even in a purely internal situation such as those at issue in the main proceedings, the Court's answer may nevertheless be useful to the referring court, in particular if its national law required it to grant the same rights to a Finnish national as those which a national of another Member State in the same situation would derive from European Union law (see, Joined Cases C-570/07 and C-571/07 *Blanco Pérez and Chao Gómez* [2010] ECR I-4629, paragraph 39; Case C-393/08 *Sbarigia* [2010] ECR I-6333, paragraph 23; and Case C-245/09 *Omalet* [2010] ECR I-13771, paragraph 15).

21 At the hearing, the representative of the applicants in the main proceedings argued that in Finnish administrative law there are rules which ensure that Finnish nationals do not suffer reverse discrimination. In those circumstances, it is not obvious that the interpretation of European Union law sought would be of no use to the referring court.

22 Therefore, the Court has jurisdiction to answer the questions referred for a preliminary ruling.

Consideration of the questions referred

23 By its questions, which it is appropriate to examine together, the referring court asks essentially whether Article 49 TFEU must be interpreted as meaning that it precludes a national law, such as that at issue in the main proceedings, which provides a licensing scheme for the operation of branch pharmacies which is different for UHP than for private pharmacies.

24 Those questions refer to pharmacists who oppose the transfer of one of UHP's branch pharmacies claiming that the national law is incompatible with European Union law as far as it lays down conditions more favourable for the operation of UHP's branch pharmacies than those for private branch pharmacies. It is true that the restrictions laid down by the Law on medicines as to the operation of private branch pharmacies as such may be justified. However, the aim of the Law on medicines does not require the UHP to have 16 branch pharmacies, since all of its specific duties set out in Paragraph 42 thereof could equally be carried out by three branches.

25 Thus, the questions do not seek to ascertain whether Article 49 TFEU precludes a national law concerning the operation of private branch pharmacies, but whether that provision precludes that law from laying down a specific licensing scheme for the operation of branch pharmacies applicable to UHP which is more favourable than that which applies to private pharmacies.

Preliminary observations

26 In order to answer the questions referred, it should first be noted that, pursuant to Article 168(7) TFEU, as clarified by the case-law of the Court, EU law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions to govern the organisation of health services such as pharmacies (*Blanco Pérez and Chao Gómez*, paragraph 43 and the case-law cited).

27 In exercising that power, however, the Member States must comply with European Union law, in particular the provisions of the Treaty on fundamental freedoms, including freedom of establishment. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the healthcare sector (see, to that effect, Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, paragraph 18; Case C-345/09 *van Delft and Others* [2010] ECR I-9879, paragraph 84; and Case C-89/09 *Commission* v *France* [2010] ECR I-12941, paragraph 41).

28 When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to

afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States should be allowed a measure of discretion (see, to that effect, Case C-531/06 *Commission* v *Italy* [2009] ECR I-4103, paragraph 36, and *Blanco Pérez and Chao Gómez* paragraph 44 and the case-law cited).

29 Furthermore, no provision of European Union law lays down rules concerning access to activities in the pharmacy field, which seek to set the conditions for opening new pharmacies or any branch pharmacies in Member States (see, to that effect, *Blanco Pérez and Chao Gómez*, paragraph 45).

30 Therefore, it is appropriate to examine, on the basis of the abovementioned criteria, whether the law at issue in the main proceedings is a restriction within the meaning of Article 49 TFEU as far as it lays down rules for the operation of branch pharmacies which are more favourable for UHP than for private pharmacies.

The existence of a restriction on the freedom of establishment

31 Article 49 TFEU requires the abolition of restrictions on the freedom of establishment. According to their wording, the Treaty provisions on freedom of establishment are aimed at ensuring that foreign nationals are treated in the host Member State in the same way as nationals of that State. Moreover, according to settled case-law, Article 49 TFEU precludes any national measure which, even if applicable without discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by Union nationals of the freedom of establishment that is guaranteed by the Treaty (see, to that effect, Case C-371/10 *National Grid Indus* [2011] ECR I-12273, paragraphs 35 and 36).

32 As to the question whether the law at issue in the main proceedings is discriminatory, it must be observed that that law concerns, without distinction, any national, Finnish or of another Member State, who wishes, as a private pharmacist, to establish a branch pharmacy in Finland. Therefore, it is not discriminatory within the meaning of Article 49 TFEU.

33 However, it must be observed that, under that law, private pharmacies may open only three branches in Finland, the operating licence for which is, furthermore, subject to the existence, in the geographical area concerned, of a sparse population which does not justify the existence of an independent pharmacy, whereas UHP has the right to have 16 branch pharmacies regardless of the number of inhabitants in the area concerned.

34 It must be held that the preferential system granted to UHP, in terms of the number of branch pharmacies allowed and the conditions for the operating licences of those branches, is likely to deprive a private pharmacist of the right to set up a branch pharmacy in one of the 16 geographical areas in which the UHP has established a branch, which is likely to render less attractive the pursuit, by private pharmacists from other Member States, of their activities in Finland through a permanent establishment. The fact that the restrictive effects of that preferential system affect home country nationals and those from other Member States alike is not such as to exclude that preferential system from the scope of Article 49 TFEU (see, to that effect, Case C-353/89 *Commission* v *Netherlands* [1991] ECR I-4069, paragraphs 24 and 25).

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

The justification of the restriction on the freedom of establishment

36 It is settled case-law that restrictions on freedom of establishment which are applicable without discrimination on grounds of nationality may be justified by overriding reasons relating to the general interest, provided that the restrictions are appropriate for securing attainment of the objective pursued and do not go beyond what is necessary for attaining that objective (*Blanco Pérez and Chao Gómez*, paragraph 61).

37 It is also apparent from Article 52(1) TFEU that the protection of public health can justify restrictions on the fundamental freedoms guaranteed by the Treaty, such as the freedom of establishment. More specifically, restrictions on the freedom of establishment may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality. The importance of that objective is confirmed by Article 168(1) TFEU and Article 35 of the Charter of Fundamental Rights of the European Union, under which, inter alia, a high level of protection for human health is to be ensured in the definition and implementation of all policies and activities of the European Union (*Blanco Pérez and Chao Gómez*, paragraphs 63 to 65).

38 In the present case, it is common ground that the UHP sells medicines to the public just like private pharmacies. However, the referring court, the Finnish Government and the UHP have submitted that the UHP was, pursuant to the Law on medicines, required to carry out specific tasks relating to the teaching of pharmacy students and must undertake research relating to pharmaceutical services and special services relating to the manufacture of certain rare medicinal preparations, whereas such a legal obligation is not imposed on private pharmacies.

39 The Finnish Government argued, in that regard, that the UHP, on account of the allocation of specific tasks by the law, an essential role in ensuring the public has access to safe and high quality medicines, which is the aim of the Law on medicines.

40 In that context, it must be observed that the competence of the Member States, which is referred to in paragraphs 27 to 29 of this judgment, to adopt provisions intended to organise health services such as pharmacies, and to decide both the level of protection of public health and the way in which that level must be achieved, requires that the Member States are entitled to ensure the protection of public health by imposing specific tasks on one or more pharmacies.

41 As the Commission states, the UHP's tasks concerning training and pharmaceutical research and the manufacture of rare magistral preparations fall within the scope of the protection of public health.

42 It follows from the foregoing that, in the light of the objective pursued by the Law on medicines to ensure a certain level of protection of public health by means of imposing legal obligations, the preferential system reserved to the UHP by the national law at issue in the main proceedings as regards the operating conditions for branch pharmacies in Finland concerned are necessary, in so far as — which is for the referring court to verify — the branches of the UHP actually participate in the accomplishment of the specific tasks relating to the teaching of pharmacy students, research on pharmaceutical services and the manufacture of rare pharmaceutical preparations which have been allocated to UHP.

43 The fact that private pharmacies also participate in practice, as one of the applicants in the main proceedings observed, inter alia, in the teaching of students and offering them training places does not change that assessment. Unlike the UHP, private pharmacies offer students training places on an optional basis and are free to do so according to their own interests. Furthermore, the teaching dispensed to students is only one of the tasks imposed on the UHP.

44 Therefore, the answer to the first question is that Article 49 TFEU must be interpreted as meaning that it does not preclude a national law, such as that at issue in the main proceedings, which provides for a licensing scheme for the operation of branch pharmacies specific to the UHP which is more favourable than that applicable to private pharmacies, provided that — which is for the referring court to verify — the branches of the UHP actually participate in the accomplishment of the specific tasks relating to the teaching of pharmacy students, research on pharmaceutical services and the manufacture of rare pharmaceutical preparations conferred on the latter by national law.

Costs

45 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 (Third Chamber) hereby rules:

Article 49 TFEU must be interpreted as meaning that it does not preclude a national law, such as that at issue in the main proceedings, which provides for a licensing scheme for the operation of branch pharmacies specific to the Helsingin yliopiston apteekki which is more favourable than that applicable to private pharmacies, provided that — which is for the referring court to verify — the branches of the Helsingin yliopiston apteekki actually participate in the accomplishment of the specific tasks relating to the teaching of pharmacy students, research on pharmaceutical services and the manufacture of rare pharmaceutical preparations conferred on the latter by national law.

[Signatures]