

Assessing demand for public pharmacies – a never-ending story

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Background

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Comment

Public pharmacies are heavily regulated in Austria. The opening of new (or the relocation of existing) pharmacies is subject to approval by the district authority. Approval will be granted only if there exists a viable need for the new public pharmacy.

Background

Until June 1 2016 the relevant provisions of Section 10 of the Pharmacies Act provided as follows:

"1. Authorization 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 on 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 meters, 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 neighboring pharmacies will be reduced and fall below 5,500.

3. A need, within the meaning of para 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 with health funds...

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

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5. Where the number of permanent inhabitants, as defined in para 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 they work, have recourse to services or use means of transport in that area.

6. The distance referred to in para 2(2) above, may, in exceptional cases, be ignored where the local conditions urgently so require, in the interest of insuring 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."

In its February 13 2014 judgment, the European Court of Justice (ECJ)(1) held that although an EU member state may create a system of prior authorisation for the establishment of new healthcare providers, Article 49 of the Treaty on the Functioning of the European Union – in particular, the requirement that the desired objective be achieved in a consistent manner – must be interpreted as precluding legislation such as Section 10 of the Pharmacies Act.

This is because Section 10(5) sets a rigid limit on the "people remaining to be served" as an essential criterion for determining whether a need for a new pharmacy exists, which the authorities cannot depart from even to account for particular geographical conditions.

Following the ECJ's judgment, the Austrian legislature amended Section 10 of the Pharmacies Act by inserting Paragraph 6a in June 2016:

"The number of people that will remain to be served by one or more of the neighboring existing pharmacies according to para 2(3) is to be undercut if it is badly needed in the interest of proper supply with medicinal products in consideration of the pharmaceutical supply of the population by the existing pharmacies including doctor's dispensaries in rural or isolated regions because of particular local circumstances."

By way of a June 30 2016 order, the ECJ(2) clarified that the criterion relating to the strict limit on the number of "persons who continue to be served" set out by the Pharmacies Act cannot be generally applied when determining whether there is a need to open a new pharmacy. Further, the ECJ's reference to rural or isolated regions and to persons with reduced mobility was not intended to limit the scope of its assessment of the consistency of national legislation to that type of region and category of persons.(3)

Following the ECJ's decision, the Austrian legislature deleted the words "rural or isolated regions" from Section 10(6a) in December 2016.(4)

Decisions

In a July 12 2016 decision following an appeal for a pharmacy licence, the Regional Administrative Court of Upper Austria(5) granted a licence to open a pharmacy in Leonding, provided that it was at least 500 metres away from the closest existing public pharmacy. The regional court held that following the ECJ's two decisions, it must disregard Section 10(2)(3) of the Pharmacies Act, which it considered as infringing EU law. The court held that EU law also applies in cases not involving nationals from other member states, to avoid Austrian nationals from being discriminated against.

Following an appeal by a neighbouring pharmacist, in its March 29 2017 decision,(6) the Supreme Administrative Court remanded the regional court's decision in order to investigate further the need for a new pharmacy on the basis of the expert opinion of the Chamber of Pharmacists. The Supreme Administrative Court held that the infringement of EU law by Section 10 of the Pharmacies Act which had existed before the act was amended in June 2016 stemmed from the application of the strict limit on the number of "persons who continue to be served", which the ECJ had held to be contrary to Article 49 of the Treaty on the Functioning of the European Union – in particular, the requirement that the desired objective be achieved in a consistent manner – because the competent authorities could not depart from that limit to take account of particular local conditions. The criterion

therefore could not generally be applied when determining the need for a new pharmacy. However, the Supreme Administrative Court ultimately held that the ECJ's assertions did not directly apply to the case at hand.

According to prior decisions from the Constitutional Court and the Supreme Administrative Court, there is significant public interest in maintaining national legislation (although it may infringe EU law) for a transitional period before the law can be amended to comply with EU law. According to the Supreme Administrative Court, during this transitional period, a discrimination against Austrian nationals can be justified. The court referred to an October 6 2011 decision,⁽⁷⁾ wherein the Constitutional Court had held that a 16-month transition period was acceptable. In the case at hand, because the Regional Administrative Court's decision was made only 12 days after the ECJ issued its decision, the Regional Administrative Court could not yet consider the provision of the Pharmacies Act as discriminating.

Comment

The Supreme Administrative Court's argument to deny the direct application of EU law where national law infringes EU law is doubtful: the court based its argument on the date of the 2016 decision (June 30 2016). However, this decision was meant to clarify the February 13 2014 decision. Calculated from this date, the period to bring national law in line with EU law was not 12 days, but over two years.

Both the Regional Administrative Court and the Supreme Administrative Court ignored the legislature's June 2016 amendment to Section 10 of the Pharmacies Act, which allowed a deviation from the strict 5,500 person limit. Regardless, this June 2016 amendment could not help the applicant in the case at hand because the amendment was limited to rural or isolated regions and Leonding, a city with approximately 28,000 inhabitants – close to the Upper Austrian capital Linz, cannot be considered rural or isolated.

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Endnotes

(1) C-367/12 – *Sokoll-Seebacher I*.

(2) C-634/15 – *Sokoll-Seebacher II*.

(3) ECJ C-634/15, Margin Number 32.

(4) *Federal Law Gazette I* 103/2016.

(5) LVwG-050013/47/GF/NU.

(6) RA 2016/10/0141-6.

(7) G41/10.

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