

## Healthcare & Life Sciences - Austria

### Demand assessment for public pharmacies

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The Pharmacies Act requires an assessment to be performed before a public pharmacy can be established.

#### Facts

By an administrative decision dated August 14 2013, the Ministry of Health granted an application for the establishment of a public pharmacy in the district capital of Krems upon Danube and dismissed a neighbouring pharmacist's objection to its establishment. The ministry based its decision on the expert opinion of the Chamber of Pharmacists, which stated that even after the new pharmacy was established, the neighbouring pharmacy would still have a customer potential of 6,492 people (including 2,546 patients from the local outpatient clinic). According to this opinion, the outpatient clinic treated approximately 75,000 patients per year.

The ministry also considered a representative study of 2,000 interviews, which found as follows:

- Each Austrian visits a pharmacy 12.25 times per year.
- For 46% of outpatient clinic patients, the pharmacy closest to the clinic is also the pharmacy closest to their domiciles.
- On average, an outpatient clinic patient visits a pharmacy close to the clinic 1.54 times per year.

Based on these figures, the outpatient clinic in question created an additional client potential of 5,092 people. Since the clinic had two entrances – one closer to the new pharmacy and one closer to the established pharmacy – the ministry found that the additional client potential could be allocated equally so that each pharmacy had the potential to receive business from 2,546 people.

The neighbouring pharmacist appealed this decision before the Supreme Administrative Court.

#### Legal background

Section 10 of the Pharmacies Act states:

*"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*

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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.

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 a February 13 2014 judgment the European Court of Justice (ECJ)<sup>(1)</sup> held that although a 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 (TFEU) – 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 lays down, as an essential criterion for determining whether a need for a new pharmacy exists, a rigid limit on the "people remaining to be served", which authorities cannot depart from, even to account for particular local geographical conditions.

## Decision

In its March 27 2014 decision, the Supreme Administrative Court<sup>(2)</sup> interpreted the ECJ's decision to mean that, in principle, an EU member state may create a system of prior authorisation for establishing new healthcare providers (eg, pharmacies) where this is deemed necessary in order to fill possible gaps in access to public health services and for avoiding the duplication of structures so as to ensure that public healthcare:

- meets the needs of the population;
- covers the entire territory; and
- takes into account geographically isolated or otherwise disadvantaged regions.<sup>(3)</sup>

If a prior administrative authorisation scheme is to be justified even though it derogates from a fundamental freedom (ie, the right to healthcare), it must be based on objective, non-discriminatory criteria known in advance in such a way as is adequate to circumscribe the exercise of the national authority's discretion.<sup>(4)</sup> Consequently, the ECJ found that the criteria provided for in national legislation – such as that at issue in this case – were sufficiently objective in nature.<sup>(5)</sup>

According to the Supreme Administrative Court, the ECJ therefore objected only to the rigid limit of 5,500 "people remaining to be served" established by Section 10 of the Pharmacies Act where a new pharmacy is necessary to provide the population of a geographically isolated, inaccessible or otherwise disadvantaged region with sufficient care. In the presence of such prerequisites, the authorities must not apply the 5,500 person limit. However, if the grant of a concession for such reasons is not required under EU law, the limit may still be applied.

In this case, since the new pharmacy was to be established in the centre of Krems, where several pharmacies already existed, and the distance between the new pharmacy and the closest established pharmacy was only 1.6 kilometres, the Supreme Administrative Court held that the limit of 5,500 people remaining to be served was applicable.

Although the 5,500 person limit was exceeded according to the expert's opinion, the Supreme Administrative Court did not consider this opinion sufficient to quantify the customer potential. Without considering the additional potential of the 2,546 patients from the clinic, the customer potential of the appealing pharmacist would fall well below 5,500. As such, the Supreme Administrative Court remanded the decision in order to investigate the customer base further.

## Comment

The ECJ held that the rigid limit of people remaining to be served was inapplicable because, in rural regions with a small population density, even where incoming users are considered, establishing a new pharmacy could still reduce the number of remaining customers for existing pharmacies below the threshold.

However, the ECJ's decision cannot be interpreted as an acceptance of the 5,500 person limit in urban regions. The Supreme Administrative Court's decision 'interprets away' the ECJ decision for

urban regions; it would thus have been appropriate if the Supreme Administrative Court had referred the question to the ECJ.

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#### Endnotes

- (1) C-367/12.
- (2) 2013/10/0209.
- (3) ECJ C-367/12, Paragraph 24.
- (4) ECJ C-367/12, Paragraph 27.
- (5) ECJ C-367/12, Paragraph 38.

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