

Court dismisses complaint against limitations on sale of medicinal products

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Introduction

Legislative background

Applicant's submissions

Government's submissions

Decision

Comment

Introduction

The Act on Medicinal Products (AMG)(1) and the Trade and Industry Act (GewO)(2) set strict rules on the sale of medicinal products. Broadly, only pharmacies may sell medicinal products to consumers. Pharmacies may also sell medicinal products not subject to prescription by distance selling, provided that:

- the purchaser buys only the quantity needed for personal use;
- the products are not negatively affected by shipping; and
- the pharmacy provides advice during the order process.

Drugstores may sell to consumers only a limited number of medicinal products (primarily officinal plants), which are listed in the Ordinance Concerning the Distribution and Labelling of Certain Medicinal Products for Retail Sale (delimitation ordinance).(3) However, they may not sell such products via self-service or mail orders.

The Constitutional Court recently considered a constitutional complaint against these limitations brought by German-Austrian drugstore chain dm.

Legislative background

Section 1(1) of the AMG defines 'medicinal products' in conformity with EC Directive 2001/83/EC.(4)

The dispensing of medicinal products in retail is limited to pharmacies according to Section 59(1) of the AMG, unless otherwise stipulated therein.

Section 59(3) of the AMG provides that the federal minister for social affairs, health, care and consumer protection, in agreement with the federal minister for digitisation and economy, must determine by ordinance those medicinal products which:

- do not pose a risk to the health or life of humans or animals, even if used in a manner not foreseeable in the light of everyday experience; and
- may therefore be dispensed by drugstores or tradespeople who are authorised to manufacture medicinal products pursuant to the GewO.

Based on Section 59(3) of the AMG, the annex to the delimitation ordinance contains a list of 282 (preparations of) substances that may be sold at retail and as sole ingredients of proprietary medicinal products not only in pharmacies but also in drugstores.

The distribution of medicinal products through self-service or distance selling is prohibited in accordance with Section 59(9) of the AMG. This type of drug dispensing is equally prohibited for pharmacies, drugstores and other traders. However, pursuant to Section 59(10) of the AMG, the prohibition of distance selling does not apply to non-prescription medicinal products sold by pharmacies in Austria where:

- such products are authorised or registered for human use within Austria; or
- a pharmacy in another European Economic Area (EEA) state imports such products into Austria and is authorised to do so under its domestic legislation.

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This provision implements Article 85c of EC Directive 2001/83/EC⁽⁵⁾ and ensures that public pharmacies which meet the requirements of this directive may sell medicinal products by distance selling. According to Section 59(11) of the AMG, the prohibition of distance selling also does not apply to cross-border shipping of non-prescription medicinal products for human use which comply with the national legislation of another EEA state and are dispensed by public pharmacies in the territory of that state. This restriction of the prohibition of distance selling was imposed in light of the European Court of Justice's 11 December 2003 judgment in *Doc Morris* (C-322/01).

Section 5 of the Pharmacy Act⁽⁶⁾ authorises the Ministry of Health to issue regulations on the training of pharmacists and the activities reserved for pharmacists in pharmacies. The activities reserved for pharmacists as pharmaceutical specialists are:

- dispensing medicinal products reserved for pharmacies;
- providing advice and information about medicinal products; and
- checking stocks of medicinal products in hospitals.

Section 50 of the GewO regulates commercial activities outside business locations and stipulates that mail-order sales of the following to consumers are prohibited:

- poisons;
- medicinal products;
- therapeutic aids (except contact lenses);
- weapons and ammunition; and
- pyrotechnic articles.

This prohibition also applies to the sale of goods from own production and purchased goods in the form of mail-order sales to consumers. Section 50 of the GewO also prohibits the sale of medicines and remedies through vending machines.

The provision prohibits distance selling only for those medicinal products that may be dispensed by drugstores and tradespeople other than pharmacists, whereas the prohibition of distance selling in the AMG, including the exceptions of Sections 59(9) to 59(11) thereof, relates to those medicinal products whose sale is reserved for pharmacies.

Applicant's submissions

The applicant submitted that the delimitation ordinance's prohibition of obtaining and dispensing non-prescription medicines did not comply with the legal basis of Section 59(3) of the AMG. According to the applicant, Section 59(3) of the AMG was based on the intended foreseeable use of medicines according to the experience of daily life. The applicant claimed that it was now known to everyone that medicinal products could have undesirable effects, so it was generally unforeseeable that consumers did not use medicinal products as intended. The applicant further claimed that, as a result, all non-prescription drugs had to be included in the delimitation ordinance and that, for this reason, the entire ordinance was unlawful.

Pharmacy proviso

Further, the applicant submitted that the reference in Section 57(1) of the AMG to the pharmacy proviso for non-prescription medicinal products in Sections 59(1) and 59(3) of the AMG violated the constitutionally guaranteed right to freedom to exercise a profession pursuant to Article 6 of the Basic Law (StGG).⁽⁷⁾ According to the applicant, these provisions did not stand up to a proportionality test, as drugstores could also fulfil the public interests of patient and consumer protection. The applicant claimed that the pharmacy proviso was not the least restrictive means of achieving such public interests as drugstores could also be required to employ pharmaceutical personnel to provide consumers with expert advice. The applicant claimed that merely protecting pharmacies from competition was not in itself a legitimate public interest. According to the applicant, the protection of the existence of pharmacies, which is constitutionally recognised by the needs test, also opposed the public interest in the best possible supply of medicines to the population.

The applicant claimed that even if the pharmacy proviso was considered necessary, an overall assessment of the regulation would have to classify it as disproportionate. The applicant held that an absolute prohibition of purchase and sale could not be justified by public interest, especially since the pharmacy proviso impaired the public interest in an optimal supply of therapeutic products.

According to the applicant, the aforementioned provisions also violated the principle of equality under Article 2 of the StGG and Article 7 of the Federal Constitution because drugstores had the same infrastructure as pharmacies and could guarantee the safety of medicines in the same way and provide the same qualified advice

to consumers. The applicant claimed that against this background, the less favourable treatment of drugstores in relation to pharmacies was unjustified. According to the applicant, the protection of the existence of pharmacies could not justify such unequal treatment either because the economic significance of the sale of non-prescription drugs was too small.

Self-service and mail-order sales

The applicant further objected to:

- the prohibition of self-service sales of medicinal products under Section 59(9) of the AMG; and
- the restriction of distance selling of medicinal products by pharmacies under:
 - Section 50(2) of the GewO;
 - Sections 59(9) to 59(11) and 59a of the AMG; and
 - the Ordinance on Distance Selling.

According to the applicant, these provisions violated:

- the right to freedom of occupation pursuant to Article 6 of the Federal Constitution; and
- the principle of equality pursuant to Article 2 of the StGG and Article 7 of the Federal Constitution.

The applicant further claimed that the legislature's objective regarding its absolute prohibition of the sale of medicinal products on a self-service basis was unclear and that, in any case, such intervention was disproportionate. The applicant stated that a ban on the sale of self-service medicines without exception could not be justified by the public interest in consumer protection. According to the applicant, this was particularly evidenced by the fact that the mail-order sale of medicinal products was (partly) permissible; however, it made no difference whether the consumer obtained the medicinal product at a distance or via self-service.

Regarding the prohibition of distance selling of medicinal products, the applicant objected to the fact that the legislature had provided for an exception from such prohibition only for pharmacies. According to the applicant, the resulting prohibition of mail-order sales of medicinal products constituted a disproportionate restriction on the freedom of drugstores to make sales. The applicant pointed out that online pharmacies could exist but online drugstores could not and claimed that there were no objective reasons for this unequal treatment. According to the applicant, drugstores, similar to pharmacies, had infrastructures that could guarantee the safety of medicines without restriction.

Government's submissions

The federal government submitted that the applicant's concerns did not apply.

Pharmacy proviso

According to the government, the contested provisions:

- protected health, children, young people and consumers; and
- ensured a functioning supply of therapeutic products.

The government held that these objectives represented important public interests.

The government highlighted that pharmaceuticals were not ordinary goods and that their uncontrolled distribution and consumption could have serious health consequences. Further, the government stated that according to pharmaceutical law, the prevention of health risks was not limited to the prescription requirement; instead, the pharmacy proviso for non-prescription drugs also protected health – namely, the prevention of those dangers to health that result from improper use. The government stated that the danger and risk potential of non-prescription drugs had been proven by numerous international studies. It pointed out that pharmacists had to check medical prescriptions and, if necessary, refuse to dispense drugs.

Further, the government claimed that the contested provisions also served youth protection because it was known that caregivers often dosed non-prescription medications improperly. The government highlighted that adolescent painkiller abuse was an internationally recognised problem. It claimed that if the restrictions on dispensing such medicines were lifted, children and adolescents would have easier access thereto, which would risk their increased and uncontrolled use. The government also maintained that the contested provisions protected consumers who were dependent on medicines to maintain or restore their health and were therefore in a particularly vulnerable position. Further, the government pointed out that counterfeit drug crime was on the rise.

According to the government, contrary to the applicant's submission, the contested provisions were suitable and necessary to achieve the public interest objectives of:

- health protection;
- consumer protection; and
- the protection of children and young people.

The government highlighted the special importance of pharmacies' advisory function because there was a greater need for consultation in the case of non-prescription medicines. The government stated that during personal consultations, pharmacists, who were specially trained for such purposes, could also determine the necessity of a medical clarification or a suspicion of drug abuse. The government held that pharmacists' duties were safeguarded by statutory professional and disciplinary law and it was therefore within the scope of the legislature to provide for a pharmacy requirement for non-prescription drugs as well.

According to the government, the applicant's argument that drugstores had to fulfil the same requirements as pharmacies was wrong, especially since pharmacists had to complete an aspirant year and an examination as well as a relevant course of study to qualify. Further, the government highlighted that pharmacists had to provide evidence of five years' pharmaceutical practice in a pharmacy to obtain a licence to operate a public pharmacy. According to the government, this additional professional qualification alone distinguished pharmacists from other professional groups such as druggists, who did not have to have equivalent specialist knowledge or comparable practical experience.

Self-service and mail order sales

The government further pointed out that the contested provisions did not restrict the sale of medicinal products itself but only their sale through specific distribution channels.

The government stated that the prohibition of self-service dispensing of medicinal products pursuant to Section 59(9) of the AMG safeguarded the advisory function of pharmacies because it ensured that consumers were professionally informed before making purchase decisions. The government held that this aimed to protect individuals who did not know of their need for information and advice or did not dare to ask. Further, the government held that such prohibition reduced the risk of a consumer using an unsuitable drug due to ignorance or confusion or incorrect use of a drug.

According to the government, nothing else applied to the restrictions on the dispensing of medicinal products by means of distance selling. It highlighted that the dispensing of medicinal products could take place only after the provision of expert advice of a pharmacist from the dispatching pharmacy if this was necessary for reasons of medicinal product safety or if the dispensing of the human medicinal product made advice necessary. The government further stated that according to Section 59a(1) of the AMG, medicines may be dispensed by mail order only by a public pharmacy (ie, under the supervision and responsibility of a pharmacy manager or another pharmacist with a general professional qualification) and that correct storage and packaging by pharmaceutical specialists must also be ensured for this distribution channel.

The government also highlighted that the Constitutional Court had already stated that a ban on mail-order sales of food supplements could be suitable and necessary to serve the public interests of consumer protection and health protection.⁽⁸⁾ The government claimed that it was precisely the form of distribution by mail order that could be used to distribute questionable products by circumventing official controls because the product quality guarantee was not given from the outset as in other retail trade; official control was almost impossible. According to the government, this was even truer regarding the prohibition of mail-order sales of non-prescription drugs by drugstores because such drugs were associated with significantly higher health risks. The government stated that mere claims for damages would be insufficient to prevent possible health risks and that the prohibition of mail-order sales did not exceed the limits of the legislature's scope of action.

Further, the government held that the contested dispensing restrictions for numerous over-the-counter drugs constituted a corrective for their release from the prescription obligation. It claimed that if such dispensing restrictions were abolished, many non-prescription drugs would have to be dispensed on the basis of their hazard potential and could be subject to prescription requirements again.

According to the government, the advice given by pharmaceutical staff could not be guaranteed elsewhere. It highlighted that pharmacies were subject to a diverse and strict regulatory regime to ensure both the pharmaceutical quality of the services provided and their independence from external influences. The government stated that pharmacies were not characterised merely by economic motives; pharmacists had to act according to professional criteria in the interests of the best possible patient care in accordance with professional law requirements.

Finally, the government highlighted that pharmacies could fulfil the public interest of a rapid and sufficient supply of medicines to the population only if they had the necessary earning power. The government recalled that the Constitutional Court had already ruled that, regarding the supply of medicines to the population,

regulations to restrict the freedom of acquisition could be permissible, depending on whether the existence of existing public pharmacies was threatened.

However, the government highlighted that pharmacies' entrepreneurial room for manoeuvre was severely limited in view of the numerous obligations under public law. It claimed that competition from drugstores in chain stores, as well as in distance selling, would put pharmacies under increased economic pressure, which would jeopardise their existence and thus the supply of medicines to the population, especially in rural areas. The government held that the applicant's assumption that the existence of pharmacies would not be endangered by a liberalisation of the market for non-prescription medicines was therefore incorrect.

Decision

On 3 March 2021 the Constitutional Court dismissed the complaint.⁽⁹⁾

The Constitutional Court held that against the background of the objections raised by the applicant, it need not examine the legal provisions which were the basis of the contested delimitation ordinance – namely:

- Section 59(3) of the AMG; and
- Sections 59(1) and 57(1) of the AMG, which are inseparably connected with Section 59(3).

The Constitutional Court held that these provisions meant that drugstores – such as those operated by the applicant – could not purchase or sell non-prescription medicinal products under Sections 57(1) and 59(1) of the AMG, respectively. Apart from various exceptions, which were irrelevant in this case, drugstores could therefore purchase and sell medicines only within the scope of the delimitation ordinance.

The Constitutional Court found that in enacting these provisions, the legislature had pursued several legitimate public interests, which therefore justified a restriction on the freedom to engage in commercial activities.

Pharmacy proviso

The Constitutional Court further found that the pharmacy proviso and the prohibition to purchase and sell non-prescription medical products by drugstores also aimed to achieve the aforementioned public interests. The Constitutional Court found that, in its statement, the government had correctly explained that pharmacies are subject to many regulations under public, professional and disciplinary law. In particular, pharmacies must have sufficient qualified pharmaceutical staff. Further detailed requirements exist regarding the material equipment of pharmacies (including a laboratory with necessary equipment and a duty room with sleeping facilities) and the handling and storage of medicinal products. Pharmacies must also:

- provide uninterrupted opening hours during the legally defined operating hours;
- be on call outside the defined operating hours; and
- report drug incidents.

In addition to these obligations, further restrictions exist which result from pharmacists' disciplinary and professional law. Against this background and the legislature's objective to ensure a functioning supply, the Constitutional Court found that the provisions were thus suitable to achieve the public interests pursued.

The Constitutional Court also found that the regulations outlined were proportionate. In this context, the applicant had submitted that drugstores could also fulfil the requirements for pharmacies envisaged by the legislature. However, the Constitutional Court found that the applicant had overlooked the fact that pharmacies are subject to many obligations under public law, professional ethics and disciplinary law, which are intended to ensure that the public interests pursued with the standardisation of the pharmacist proviso are achieved in a complex regulatory system. In view of the particular importance of these public interests, the Constitutional Court was unable to recognise that the contested provisions constituted a disproportionate encroachment on the applicant's right to freedom of occupation under Article 6 of the Constitution. For the same reasons, the Constitutional Court also found that the contested provisions did not violate the principle of equality pursuant to Article 2 of the StGG and Article 7 of the Federal Constitution.

The Constitutional Court found that there was no reason for it to initiate proceedings for an official review of the constitutionality of the relevant provisions of the AMG.

Regarding Section 59(3) of the AMG, the Constitutional Court found that the legislature differed based on the potential danger of the medicinal products concerned. Medicinal products which did not pose a risk to the health or life of humans or animals even if used in a way that would be unforeseeable based on everyday experience could also be sold by drugstores pursuant to the more detailed provisions of the delimitation ordinance.

The Constitutional Court found that the applicant's argument that all non-prescription medicinal products had

to be included in the delimitation ordinance could be countered by studies that the federal government had cited in its submission, which proved that the misuse of medicinal products was a significant problem. The Constitutional Court found that, against this background, the applicant's opinion that all non-prescription drugs had to be included in the delimitation ordinance lacked a comprehensible basis.

Self-service and mail-order sales

Regarding the restriction of the distance sale of non-prescription medicines by pharmacies, the Constitutional Court first referred to its comments on the constitutional admissibility of the pharmacy proviso. Insofar as the dispensing of such medicinal products was fundamentally and constitutionally reserved for pharmacies, there were no constitutional objections to regulations which would also restrict the distance selling of these medicinal products by pharmacies.

Further, the Constitutional Court referred to the fact that the legislature allowed the mail-order sale of medicinal products by pharmacies pursuant to Sections 59(10), 59(11) and 59a of the AMG. Pursuant to Section 59a(5) of the AMG, human medicinal products may be sent by distance selling only:

- in quantities which correspond to normal personal needs;
- where they are packaged, transported and delivered in such a way that their quality and efficacy is unimpaired;
- where they are demonstrably handed to the person notified by the person placing the order to the respective public pharmacy; and
- where advice is given during the ordering process pursuant to Section 59a(6) of the AMG.

Further, pharmacy managers are responsible for the mail-order sale of medicinal products and must ensure that:

- the medicinal product is dispensed only in a quantity which corresponds to the usual personal requirements;
- there is no minimum order quantity;
- the medicinal product is dispensed without unnecessary delay and only on confirmation of a receipt.

Pharmaceutical quality assurance systems must also ensure that a medicinal product is suitable for dispatch and is packaged, transported and delivered in such a way that its quality and efficacy is demonstrably unimpaired.

The Constitutional Court found that the prohibition of self-service dispensing of non-prescription medicinal products ensured that consumers receive adequate advice from qualified pharmaceutical staff. In view of the above and the purposes pursued by the prohibition of self-service dispensing, the Constitutional Court had no doubts as to the constitutionality of Section 59(9) of the AMG.

The Constitutional Court therefore found that the above provisions were suitable and necessary to ensure the public interests of drug safety and consumer protection. Accordingly, the Constitutional Court found that the following were not violated:

- the right to freedom to exercise a profession pursuant to Article 6 of the Federal Constitution; and
- the principle of equality pursuant to Article 2 of the StGG and Article 7 of the Federal Constitution.

On the prohibition of dispensing through vending machines (Section 52(2) of the GewO), the Constitutional Court referred to its explanations on the restriction of distance selling of medicinal products.

Comment

The decision is likely to disappoint those in favour of market liberalisation. However, most of the Constitutional Court's considerations are understandable. The public health-driven high degree of regulation of pharmacies triggers considerable costs, which are allocated over the whole product spectrum (ie, both prescription-only and over-the-counter medicines). This way, the higher purchase price for over-the-counter products subsidises the requirements that pharmacies must fulfil in the interest of public health (ie, opening hours and night service).

However, the government's argument, sustained by the court, that pharmacies provide extensive advice in respect of over-the-counter medicines seems questionable. Although pharmacies provide advice and recommend over-the-counter medicines on request, no particular advice is normally given if a customer requests a specific product (eg, aspirin).

For further information on this topic please contact [Rainer Herzig](mailto:herzig@preslmayr.at) at Preslmayr Attorneys at Law by telephone (+43 1 533 16 95) or email (herzig@preslmayr.at). The Preslmayr Attorneys at Law website can be accessed at www.preslmayr.at.

Endnotes

- (1) *Federal Law Gazette*, 185/1983, as amended.
- (2) *Federal Law Gazette*, 194/1994, as amended.
- (3) *Abgrenzungsverordnung*, *Federal Law Gazette II*, 122/2004, as amended.
- (4) EC Directive 2001/83/EC on the Community code relating to medicinal products for human use, *OJ*, 2001 L 311, 67.
- (5) *Id.*
- (6) *Federal Law Gazette*, 5/1907, as amended by *Federal Law Gazette I*, 75/2008
- (7) *Imperial Law Gazette*, 1867/142, as amended.
- (8) Constitutional Court, 16 222/2001.
- (9) V 75-76/2019-15, G 207/2019-15, G209/2019-15.

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