Sector Inquiry Health

FEDERAL COMPETITION AUTHORITY

Fairness matters!

Part I:

The Austrian Pharmacy Market

Summary

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Table of contents

I. Executive Summary

In Austria there are currently **1,357 community pharmacies**.[1] This number has **increased by 10%** over the last decade, with the majority of new pharmacies being opened in locations that did not previously have a pharmacy. With **15.4 pharmacies per 100,000 people**, Austria has a **lower pharmacy density** than the European average. However, there is also an alternative source guaranteeing patients will get the medicines they need, namely dispensing doctors. At **€ 3.7 billion**, **expenditure for pharmaceutical products** makes up some **13.5%** of the overall public health costs of € 27.3 billion. In 2016 **total sales by community pharmacies** amounted to approximately **€ 3.98 billion**, € 2.69 billion of which was borne by health insurance funds and € 1.29 billion of which represented private sales.

The pharmacy business is **tightly regulated** in Austria. From an economic perspective, the pharmacy market deals with **credence goods**, i.e. consumers cannot ascertain the quality of a product even after having purchased it or know whether it really was the product they needed. Additionally, **consumers** are **not price sensitive, at least** where prescription-only medicines are concerned.

Some regulation of the pharmacy market is necessary because of the **public interest** in, for example, the guaranteed and **reliable supply of medicinal products**.

This first report deals with any restraints on competition possibly existing in the areas of **market entry**, **ownership** and **operating rules** applicable to community pharmacies.

Anti-competitive regulations exist in the following areas:

- **Needs assessment** and, consequently, near monopolistic position of community pharmacies
- **Prohibition of chains and of third-party ownership**
- Restriction of **number of branches**
- Restriction of **opening hours**
- Restrictions on **provision of additional services**
- Restrictions on **online sales** of OTC medicines
- Restriction of pharmacy **delivery services**
- **Prerogative of pharmacies** to sell OTC medicines

Based on this, we conducted an analysis to determine the extent to which **competitive processes** could be implemented in the investigated areas of the pharmacy market (and/or for the services rendered by pharmacies) without threatening the reliable supply of medicinal products. We also considered the **expected positive effects of such processes**.

[1] Where "pharmacy" is used in this text, the term denotes a community pharmacy within the meaning of Section 1 of the Austrian Pharmacy Act (Act on the regulation of Austrian pharmacies of 18 December 1906), original version in Reich Law Gazette No. 5/1907 as amended by Federal Law Gazette I No. 127/2017.

Our recommendations:

1. ABOLITION OF NEEDS ASSESSMENT
Implementation by way of a legal measure

Likely positive effects:
- Improved supply to consumers thanks to increased number of pharmacies
- Increased quality competition among pharmacies
- Price competition in the OTC market

2. LIBERALISATION OF BRANCH SYSTEM
Implementation by way of a legal measure

Likely positive effects:
- Economies of scale
- Guaranteed supply of medicinal products, particularly in rural areas

3. RETENTION OF PROHIBITION OF CHAINS AND OF THIRD-PARTY OWNERSHIP

Vertical integration would massively increase the likelihood of a negative impact, such as barriers to market entry, foreclosure of "other" pharmacies and a shift in the product mix (width and depth) in favour of products offered by the wholesaler.

4. LIBERALISATION OF OPENING HOURS
Implementation by way of a legal measure (bringing pharmacy opening hours into line with general retail hours)

Likely positive effects:
Improved supply of medicinal products to consumers

5. LIBERALISATION OF SERVICES
Implementation by way of a legal measure

Likely positive effects:
- Increased quality competition among pharmacies
- Increased contribution of pharmacies as health facilities to public health

6. LIBERALISATION OF ONLINE PHARMACIES
Implementation by way of a legal measure

Likely positive effects:
- Stimulation of (price) competition among Austrian online pharmacies, between Austrian online pharmacies and bricks-and-mortar pharmacies, and between Austrian and international online pharmacies.

7. LIBERALISATION OF DELIVERY SERVICES

Implementation by way of a legal measure and revision of code of professional conduct

Likely positive effects:

- Improved (broader) supply of medicinal products to consumers
- Transparency and equal treatment of pharmacies

8. LIBERALISATION OF OTC MARKET

Implementation by way of a legal measure

Likely positive effects:

- Improved (broader) supply of OTC medicines to consumers
- Increased price competition with drugstores entering the market
- Increased quality competition, particularly in relation to advisory services

II. Background

In 2017 BWB started its sector inquiry of the healthcare market based on Section 2 para. 1 no. 3 of the Austrian Competition Act (WettbG). BWB is authorised to conduct a **general inquiry into an economic sector** where circumstances suggest that competition in that sector is restricted or distorted. Over the past few years BWB has received numerous complaints about the healthcare market, while having also looked in depth into individual areas of the market as part of regular merger control procedures.[2]

The **pharmacy market** was considered one of those areas of the healthcare market that should be investigated more closely as part of the sector inquiry.

The public interest in a **reliable supply of medicines to the population is a legitimate reason for imposing constraints on competition**. However, competition brings broader access to goods and creates lower prices for consumers. From a competition perspective, this report therefore examines whether the current regulation of the pharmacy market is really necessary to guarantee the reliable supply of medicines to the population or whether (partial) liberalisation of the market, taking public interests into account, would be more beneficial to consumers. The system of solidarity is not being called into question here. Rather, the **existing system's deficiencies in terms of competition are highlighted and, having considered the situation as a whole, changes suggested that could improve competition**.

Competition will only have a positive impact if the **specifics of the pharmacy market** and its intrinsic potential for market failure are considered. The products being traded on the pharmacy market are medicinal products. If patients do not take medicinal products correctly their health could be negatively affected or they could die. Yet at the same time these products are critical to public health. Consequently, the **demands on the production, distribution and use of medicinal products are high**.

From the perspective of competition economics, medicines are referred to as **credence goods**. These are goods where the consumer cannot ascertain the quality of the product even after having purchased it or know whether it really was the product they needed, which means that there is a significant **information asymmetry** between the supplier (physician or pharmacist) and the consumer (patient).[3] Additionally, not all market participants have access to the relevant information such as price and quality (**little market transparency**). Consumers are also **not price sensitive**, at least where refundable medicines are concerned, as they usually do not have any choice in the type of medicine, and the costs are usually borne by their health insurance fund, less the prescription fee.

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[2] Cf. e.g. BWB/Z-2736 (Vienna Higher Regional Court acting as Cartel Court, 3 November 2015, 27 Kt 40,41/15), BWB/Z-2750 (Vienna Higher Regional Court acting as Cartel Court, 9 February 2016, 27 Kt 2/16w, 27 Kt 3/16t-68; Austrian Supreme Court of Justice acting as Supreme Cartel Court, 7 July 2016, 16 Ok 5/16w).

3 Cf. e.g. *Dulleck/Kerschbamer/Sutter*, The Economics of Credence Goods: An Experiment on the Role of Liability, Verifiability, Reputation, and Competition, American Economic Review 2011, 530 (530): "*Generally speaking, credence goods have the characteristic that though consumers can observe the utility they derive from the good ex post, they cannot judge whether the type or quality of the good they have received is the ex ante needed one*."

All in all, therefore, some **regulation of the pharmacy market** is certainly necessary. A basic need for regulation does not mean, however, that any kind of regulation would be justifiable. Rather the positive effects of competitive processes should also be used in this market. Competition demands comparable services. In contrast to the services rendered in hospitals or by physicians, which cannot really be compared, the **services rendered in pharmacies can indeed be compared and are therefore basically competitive**.

The Austrian pharmacy market is characterised by a **high degree of regulation**. Within Europe as a whole, there is no uniform competition or regulation policy regarding pharmacies. However, numerous EU Member States have striven to **extensively deregulate and liberalise** the market over the past few decades.

III. Approach taken by BWB

Our inquiry covers three areas of the market: entry into the pharmacy market, ownership of pharmacies and operating rules applicable to pharmacies. We explain each of these areas in greater detail and examine whether a (partial) lifting of (competition) restrictions would be feasible from an economic standpoint, considering legitimate public interests, and which positive competitive processes would be likely.

The BWB inquiry is based on existing **academic literature**, existing **investigations of other national competition authorities** and **experience reports** from other countries that have already liberalised and/or deregulated their pharmacy markets. In the course of our inquiry we submitted several **requests for information** to various market participants in accordance with Section 11a para. 1 no. 1 WettbG. Additionally, we also conducted **interviews with market participants**. Our analysis of existing constraints on competition took account of the specifics of the Austrian pharmaceutical market. Owing to the currently extremely high level of regulation, the majority of our recommendations would require **new legislation or amendments to existing acts**.

IV. The pharmacy market in Austria

1. Health expenditure in Austria

In 2016[4] total **health expenditure** amounted to € 39.6 billion in Austria, which equates to 11.2% of GDP. In contrast, health expenditure in 1990 was still only around € 11.4 billion.[5] With total public health costs of € 27.3 billion, the largest portion was attributable to in-patient care (€ 12.6 billion), followed by expenditure for out-patient care (€ 6.9 billion) and for pharmaceutical products and medical durables and non-durables (€ 3.7 billion). These expenses for pharmaceutical products cover the expenditure for the pharmacy and the hospital market including 10% Austrian VAT. Private spending on medicines amounted to € 2.6 billion in 2016.

In the period between 1990 and 2015 both public and private expenditure for pharmaceutical products soared.[6] The reasons behind this development are, among others, an ageing population with a greater need for medicinal products, patients increasingly turning to the OTC market for self-medication, a shift in the range of epidemiological diseases towards chronic conditions, and the more frequent use of innovative medicines. Even though public-sector costs for medicines have been kept in check by certain measures[7] introduced in the past few years, the medicinal products market remains a **huge cost driver** for both public and private health spending. **This is why a review of the potential deficiencies in competition economics is particularly relevant.**

2. Number of pharmacies

In Austria medicines are dispensed to consumers in pharmacies, in hospitals and by dispensing doctors. In 2017 there were **1,357 pharmacies** in Austria, all of which were managed under private law as independent companies based on a licence granted to a pharmacist. In addition, there were also 28 branch pharmacies. This is 17 pharmacies more than in 2015 and, in a medium-term comparison, 140 more than in 2007. Broken down by provinces, the highest number of pharmacies is found in Vienna, at 325, followed by Lower Austria with 237 pharmacies, Upper Austria with 201, Styria with 197, the Tyrol with 121, Carinthia with 97, Salzburg with 90, Vorarlberg with 51 and Burgenland with 38 pharmacies. While the number of pharmacies has remained stable in Burgenland and Vorarlberg in the last few years, it has risen the most strongly in the provinces of Lower Austria, Upper Austria, Styria and Vienna. These figures

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[4] During the research period comprehensive data on health expenditure was only available up until 2016.

[5] Cf. Statistics Austria, Overview - Health expenditure in Austria according to the System of Health Accounts (SHA) 1990-2016, in € millions; http://www.statistik.at/web_en/statistics/PeopleSociety/health/health_expenditure/027971.html (accessed on 7 May 2018).

[6] In contrast, private spending for pharmaceutical products in 1990 amounted to € 654 million and public spending to € 775 million; cf. Statistics Austria, Overview - Health expenditure in Austria according to the System of Health Accounts (SHA) 1990-2016, in € millions; http://www.statistik.at/web_en/statistics/PeopleSociety/health/health_expenditure/027971.html (accessed on 7 May 2018).

[7] For example: reduction of VAT on medicinal products from 20% to 10%, conclusion of a framework agreement between the Main Association of Austrian Social Security Institutions and the pharmaceutical industry, and encouraging physicians to be more economic in their prescription behaviour.

show that there is **both a demand for new pharmacies from consumers and an economic incentive for pharmacists** to set up and operate those pharmacies.

Compared internationally, **pharmacy density** is **relatively low** in Austria, at 15.4 pharmacies per 100,000 of the population. The OECD average for 2015 was 25 establishments per 100,000 people.[8] Spain heads the statistics at 47.2 establishments per 100,000 population. Countries like Ireland (37.5), France (34) and Italy (29.9) also show a high density (15), while Finland (14.9) and Sweden (13.3) are roughly level with Austria, and Denmark brings up the rear at 3.9. These statistics include only community pharmacies, and other modes of dispensing medicinal products such as hospital pharmacies or dispensing doctors are not included. In some of the countries named, consumers primarily receive their medicines from dispensing doctors. This also applies to rural areas in Austria, where physicians dispense the necessary medicines.

According to the Austrian Chamber of Pharmacists, 94.3% of the Austrian population can reach the nearest pharmacy within 10 minutes despite the low number of pharmacies in Austria by international standards.[9]

In Austria there are around **840 dispensing doctors** who distribute medicinal products to their patients without using a pharmacy as intermediary. In addition, there are **43 hospital pharmacies** operated within hospitals.[10]

3. Sales in pharmacies

In 2016 the pharmacy market saw an **increase in both value and volumes**. The community pharmacy market posted an increase of 5% in sales in euro and an increase of 1.6% in the number of packs sold, while the hospital pharmacy market grew by 6.3% and 1.8% respectively.[11]

In 2016 Austrian pharmacies generated **total sales** of approximately € 3.98 billion, € 2.69 billion of which was borne by health insurance funds and € 1.29 billion of which attributable to private sales.[12] Comparing these figures with 2012, this equates to an increase in total sales of € 600 million, with a similar rise having taken place with regard to both health insurance fund and private sales. The median pharmacy generated total sales of around € 2.9 million in 2016. The total volume of the **OTC market**, the market with non-prescription medicines, amounted to some € 821.3 million in Austria in 2016, at pharmacy sales prices.[13]

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[8] OECD Health at a Glance 2015, Pharmacists and pharmacies (https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2015/pharmacists-and-pharmacies_health_glance-2015-67-en) (accessed on 7 May 2018).

[9] Austrian Chamber of Pharmacists, The Austrian Pharmacy - Facts and Figures 2017, 7. However, this figure does not say anything about out-of-hours pharmacies.

[10] 12 of those in Vienna, 11 in Upper Austria, six in Lower Austria, five in Styria, three in Carinthia and two each in Burgenland and Salzburg. The provinces of Tyrol and Vorarlberg each have one hospital pharmacy.

[11] Pharmig, Facts & Figures 2017 - Medicinal Products and Health Care in Austria.

[12] Austrian Chamber of Pharmacists, The Austrian Pharmacy - Facts and Figures 2017, 8. Private sales include other products such as personal care products in addition to OTC products.

[13] Cf. Statista, Share of sold OTC medicines in Austria by indication in 2016.

As far as **online pharmacies** in Austria are concerned, there are only limited sales figures available (for more information on online sales please refer to Point VII.3.). Online selling of non-prescription medicines has only been **allowed by law since 2015**. At present, **52 pharmacies** are registered with the Austrian Federal Office for Safety in Health Care (BASG) as mail-order pharmacies.[14]

4. Remit of pharmacies

As a general rule, pharmacies **stock** about 6,000 different medicinal products, or some 19,500 medicine packs on their shelves.[15] Pharmacies are supplied by **pharmaceutical wholesalers** or directly from the **manufacturers** of pharmaceutical products. Currently there are six full-line pharmaceutical wholesalers as well as numerous wholesale companies offering a limited product range.[16] Deliveries are made several times a day, with Austrian wholesale logistics being highly regarded internationally.

The products offered by pharmacies are **prescription-only medicines**[17], pharmacy-only medicines (**OTC medicines**) and **ancillary products**, for example cosmetic products that are not solely used for decorative purposes.[18] The prices and margins for medicinal products are subject to **comprehensive legal regulations and official control**. The regulation "Österreichische Arzneitaxe" stipulates a degressive mark-up scheme as well as remuneration rates for producing magistral preparations. The prices given in the regulation are **maximum prices**.[19] Pharmacies may enter into **price competition** on non-refundable medicinal products, i.e. those medicines that have not been included in the reimbursement scheme by the Main Association of Austrian Social Security Institutions. No price competition is possible on refundable medicinal products, as the (fixed) costs are borne by the statutory social insurance funds.

Pharmacies not only offer **medicinal products** in the narrow sense but also stock other products, such as high-end personal care products or dietary supplements. Apart from supplying medicinal products and advising customers on their use, pharmacies may also offer services such as dietary advice and health promotion services. Pharmacies' **classic medicine advice service**, helping customers to choose the correct drug, has lost some of its significance over the last few decades. It is doctors who prescribe medicines to consumers and provide advice on them. Pharmacists dispense those medicines to consumers, explain how to take them correctly, and provide information about any possible interactions. This separation between the writing of the prescription and dispensing, the only exception to which arises in the case of dispensing doctors, is still considered a sensible precaution. It avoids conflicts of interest and other risks, such as pharmacists primarily dispensing those medicinal

[14] See the list of registered and audited Austrian mail-order pharmacies maintained by BASG: https://versandapotheken.basg.gv.at/versandapotheken/verify/main?_afrLoop=81834163732998711&_afrWindowMode=0&_adf.ctrl-state=172skn1dut_4 (accessed on 7 May 2018).
[15] Austrian Chamber of Pharmacists, The Austrian Pharmacy - Facts and Figures 2017, 8.
[16] In 2016 there were 280 wholesale companies in Austria (source: Austrian Association of Full-Line Pharmaceutical Wholesalers - PHAGO).
[17] Roughly 80% of all medicinal products are available by prescription only.
[18] This ancillary range has not been expressly regulated by law.
[19] Section 1 para. 2 of the Regulation of the Federal Ministry of Social Affairs of 10 April 1962 prescribing Austrian medicine prices (Österreichische Arzneitaxe 1962), original version in Federal Law Gazette No. 128/1962 as amended by Federal Law Gazette II No. 338/2017.

products that are financially more beneficial to them, e.g. because they have entered into agreements with drugs companies or with health insurance funds. Pharmacists still have greater leeway with OTC medicines, as they can advise customers on a large range of available products.

V. Market entry for pharmacies

1. Legal framework conditions

Section 9 of the Austrian Pharmacy Act (ApothekenG) stipulates that all pharmacies require an **official authorisation (licence)**. Section 10 ApothekenG specifies the prerequisites for a licence being granted: a licence must be granted to a new community pharmacy if a doctor is based permanently in the area (para. 1 no. 1) and there is a need for a new pharmacy (no. 2). "Need" is defined in Section 10 para. 2 ApothekenG in negative terms. Three criteria are defined which, if applicable (alternatively), mean that there is no need for a pharmacy: if, at the time of the application, there is already, in the municipality where the proposed pharmacy is to be located, a doctor's dispensary, and fewer than two positions for doctors under contract to health insurance funds pursuant to Section 342 para. 1 of the General Social Insurance Act (ASVG) are occupied by general practitioners (no. 1), or if the distance between the location of the proposed pharmacy and the location of the closest existing community pharmacy is less than 500 metres (no. 2), or if the number of patients who continue to be served by one of the existing surrounding pharmacies would fall below 5,500 as a result of the new pharmacy (no. 3). There is also no need according to the law if, at the time of the application, a doctor's dispensary already exists in the municipality (para. 3 no. 1) as well as a group practice under contract with health insurance funds which is filled in a certain manner (para. 3 no. 2).

The Austrian regulation concerning the needs assessment for new pharmacies has been the subject of several European[20] and national legal cases.[21] In 2016 alone, the provisions pertaining to the needs assessment in the ApothekenG were amended twice.

Without going into detail in this inquiry about the currently required needs assessment, it can be stated from a competition point of view that it **restricts free competition among pharmacies**.

[20] Cf. ECJ 13 February 2014, C-367/12, *Sokoll-Seebacher;* ECJ 30 June 2016, C-634/15, *Sokoll-Seebacher and Naderhirn.*

[21] Cf. Judgments of the Constitutional Court 15.103/1998; 17.681/2005; 18.241/2007; 18.513/2008 and the Administrative Court 27 March 2014, 2013/10/0209, 25 April 2014, 2013/10/0022; 12 August 2014, 2012/10/0181; 8 October 2014, Ro 2014/10/0096; 22 April 2015, 2013/10/0077.

2. Competition assessment

The needs assessment as it exists today means that pharmacies are **not under any competitive pressure**, securing even those pharmacies' economic survival that are run inefficiently or that provide only unsatisfactory services to consumers. Within the geographical area that they serve, pharmacies more or less have a **monopoly**. The negative effects associated with monopolies are, however, less severe in the case of pharmacies because of the statutory pricing rules (and maximum prices in particular) as well as several other operating rules.

The current needs assessment is **excessively detailed** from a competition point of view. The deregulation of pharmacies' market entry would allow pharmacies to compete with each other and have **positive** effects for consumers, as well as generating substantial welfare effects. As shown by the example of other deregulated countries, a deregulation of market entry for pharmacies does not have **any negative effects on the supply of medicinal products**. In addition to **abolishing or modifying the needs assessment**, the **other tight provisions** that further restrict competition among pharmacies (see Point VII.) **should also be relaxed**.

3. Positive effects of deregulation

a) Improved supply due to higher number of pharmacies

If pharmacies' market entry were deregulated, this would result in a **rise in the number of pharmacies** – as seen in areas recently liberalised. Studies conducted in deregulated pharmacy markets clearly show such a rise.[22] A larger number of pharmacies would mean a **higher pharmacy density** and consequently **better access** to medicinal products as well as **shorter waiting times**.

An open market makes it easier to adapt when there is a change in urban population density rather than having to wait for the results of a needs assessment.[23] Deregulation would likely result in new pharmacies mostly being established in areas that promise high profits, i.e. **urban areas**. Owing to the high number of potential customers there, pharmacists could expect the biggest profits and consequently greater likelihood of economic survival. For their part, consumers prefer to use pharmacies that are easy to reach, such as those near hospitals, doctors or traffic junctions. The basic assumption is that new pharmacies will enter into the market as long as pharmacists are able to generate acceptable profits. Once the market of urban pharmacies is saturated, profits will go down, no new pharmacies will enter the market, and some will even exit from it. The number of pharmacies would not drop more strongly than would make sense in a market expected to consolidate anyway. Once there is saturation in central areas with

[22] Cf. e.g. *Vogler/Habimana/Arts*, Does deregulation in community pharmacy impact accessibility of medicines, quality of pharmacy services and costs? Evidence from nine European countries, Health Policy (2014) 311; *Rudholm*, Entry of new pharmacies in the deregulated Norwegian pharmaceuticals market - Consequences for costs and availability, Health Policy (2008) 258; cf. for Spain CNMC, E/CNMC/003/15, Study of the Retail Medicine Distribution Market in Spain (2015) 86. OFT, Evaluating the impact of the 2003. OFT study on the Control of Entry regulations in the retail pharmacies market: Office of Fair Trading (2010).

[23] Cf. also Judgment of the Federal Constitutional Court of 11 June 1958, 7, 377 - pharmacy judgment, paragraph 114.

high profit rates, the **periphery** with lower profit rates will also see the establishment of new pharmacies.

Experience from other deregulated countries shows that the **deregulation of market entry does not have any negative impact** on the supply of medicinal products. **New pharmacies** will be set up **in rural areas** too, and the survival of existing rural pharmacies will not be threatened by new pharmacies in cities or the periphery since there will be a continued need for them in the countryside, even if the profit margin in rural pharmacies will be smaller, which incidentally is also the case in a regulated market.

Austria has a **large number of pharmacists**, with enough human resources for new pharmacies.[24] In addition, with its pharmacies on the one hand and its currently 840 **dispensing doctors** on the other, the system of medicine supply in Austria is dualistic.[25] In some countries governments have developed incentives to stop rural pharmacies from closing their businesses.[26]

b) Increased quality competition among pharmacies

Liberalised market entry and the resulting competition among pharmacies will result in **increased quality competition** and a **better service** for consumers. Competition based on quality is not really happening at the moment, with poor service having little in the way of negative consequences. In a liberalised market, quality competition will be the major driving force and **unique selling point** for pharmacies as prices are mostly fixed. Markets without entry barriers are more receptive to consumers' needs. Pharmacies could take advantage of the liberalisation and resulting competition to **establish themselves as important service providers in the healthcare market**.

Currently, about 70% of medicinal products dispensed are prescription-only medicines, which means that neither consumers nor pharmacists have much choice in the matter. However, this also means that the **quality of the service** provided to the consumer becomes more and more important. Consumers particularly favour competent and friendly pharmacy staff, short waiting times, additional services (e.g. advice on general health concerns, vaccination services) and convenient opening hours. Section 10 of the Regulation on the Operation of Pharmacies (ABO) sets forth that pharmacists must provide information and advice to consumers if this is deemed necessary for reasons of pharmacovigilance, if the medicine being dispensed requires advice or if the consumer asks for advice. Consumers must be able to speak with a pharmacist and get personal advice and information every time they buy a medicinal product. On average, a consultation takes about **four to five minutes per consumer**.[27] Customer

[24] In Austria there were 5,647 pharmacists in 2014. Compared internationally, Austria employs a very high number of pharmacists in pharmacies (4 per pharmacy); Austrian Chamber of Pharmacists, The Austrian Pharmacy - Facts and Figures 2017, 32.

[25] Basically speaking, doctors' dispensaries are only a substitute for community pharmacies (cf. Judgment of the Constitutional Court 15.103/1998). The law stipulates only one (specific) case where a doctor's dispensary is given priority over a community pharmacy. The reasons given in the related material (AA-202, 22nd legislative period, 5) are that the rural population's medical care must be guaranteed and medical practices in these regions are often only economically viable if run in combination with a dispensary (cf. Judgment of the Constitutional Court 20.054/2016).

[26] Cf. for instance Denmark, Norway or the UK.

[27] Cf. *Vogler/Arts/Sandberger*, Impact of pharmacy deregulation and regulation in European countries (Gesundheit Österreich Forschungs- und Planungs GmbH), 2012, 175.

surveys conducted in 2015 have shown that, compared with the retail industry, customer satisfaction with pharmacies has significantly fallen.[28] This is mainly due to **waiting times being too long and opening hours being too short** (cf. Point VII.1.).

Alongside classic medicine advice services, Austrian pharmacies offer a **variety of services designed to promote customer loyalty** such as "Apothekenruf", a round-the-clock hotline to get information about the nearest open pharmacy[29], medication management by appointment[30] or health checks. With regard to those ancillary services that a pharmacy is allowed to provide, the ABO imposes considerable restrictions. All of the services offered must always be concerned with advice and information about healthcare, nutrition or a healthy lifestyle.[31] A mere loose connection to "health" is not sufficient according to the Administrative Court (VwGH).[32]

As long as the population's supply of medicinal products is not threatened and the operation of the pharmacy itself not impeded, we recommend that, as well as abolishing or modifying the needs assessment, the **relevant legal rules and regulations be relaxed** to allow pharmacies to increasingly compete with each other on quality by providing additional services (see Point VII.2.).

c) Price competition in the OTC market

Following deregulation of market entry, pharmacies will primarily engage in keen competition on quality, with some **price competition** in the OTC market also to be expected.

Pharmacies' sales are mostly health insurance fund sales, generated by medicinal products with a fixed price. However, OTC medicines are starting to play an increasingly significant role in the pharmacy market. In 2017 a total of **€ 853 million** was spent on the OTC market, **2.1% more** than one year earlier.[33] While consumers are free to choose the OTC product they want, they must bear the costs for those medicinal products themselves. With health awareness rising, self-medication is becoming increasingly attractive, be it to treat coughs and colds without having to consult a doctor and wait in a full waiting room, be it to obtain nutrients and vitamins in an effort to boost one's own health. The OTC medicines offered are almost perfect substitutes from the customer's perspective as pharmacies offer mostly the same products and sell hardly any own brands. **Price competition** on the OTC market is therefore a likely scenario. Economic theory claims and international studies show that the OTC market experiences price competition (to a limited extent at least) after deregulation[34], resulting in lower prices.[35] In Austria this price competition is limited due to **little price transparency** for consumers and **restraints on competition**

[28] Survey by Kreutzer Fischer Partner, December 2015. The results in 2015 were significantly lower than the reference values of 2012. Only 71% of respondents were "on the whole" satisfied with their last buying experience in a pharmacy, which is eight percentage points down on 2012.
[29] Austrian Chamber of Pharmacists, The Austrian Pharmacy - Facts and Figures 2016, 16.
[30] Austrian Chamber of Pharmacists, The Austrian Pharmacy - Facts and Figures 2016, 16.
[31] Cf. VwGH 25 January 2017, Ro 2014/10/0085.
[32] Cf. VwGH 25 January 2017, Ro 2014/10/0085.
[33] 2017 annual report of the Austrian Self Care Association (IGEPHA), 10. Private sales in the consumer health market amounted to € 1.125 billion in 2017.
[34] Cf. e.g. *Stargardt/Schreyögg/Busse,* Pricing behaviour of pharmacies after market deregulation for OTC drugs: the case of Germany, Health Policy (2007) 30.
[35] Cf. e.g. Denmark, France, Hungary and the United Kingdom.

imposed on pharmacies.[36] Additional measures should be taken in this area too in order to facilitate price competition among pharmacies.

In conclusion, BWB recommends **abolishing the needs assessment or modifying it considerably**. This would lead to a higher number of pharmacies and better services for consumers. Pharmacies would be competing more intensely on quality (of their advisory services in particular). As far as OTC medicines are concerned, price competition and consequently lower prices are to be expected. These recommendations would have to be implemented by legal measures.

VI. Ownership of pharmacies

When looking into the question of competition in connection with a liberalisation of the pharmacy market, the current **regulation of ownership** and management of pharmacies should also be considered. In Austria, the situation is such that there are **few full-line pharmaceutical wholesalers** while **wholesalers and pharmacies have close ties**. It is therefore likely that wholesalers plan to further expand into the pharmacy market (**vertical integration**). Considering the current structure of those wholesale suppliers, this would lead to an even **stronger oligopoly** and have a **negative impact** on the market overall. It is therefore not advisable to abolish the current prohibitions of cumulation and third-party ownership. However, BWB recommends allowing pharmacists to run more than one branch.

1. Legal framework conditions

Section 2 ApothekenG regulates the **prohibition of cumulation**. Accordingly, pharmacists who already hold a licence to operate a pharmacy are excluded from being granted another licence. This applies to holders of an Austrian pharmacy licence and also to individuals who are authorised to operate a pharmacy in another EEA Member State or in Switzerland. Furthermore, Section 2 para. 2 ApothekenG also specifies a prohibition of cumulation for leaseholders and managers of a pharmacy; they are not allowed to lease or manage another pharmacy. This is because a pharmacy should be managed by a pharmacist in accordance with the **principle of personal management** (see Sections 4 and 12 ApothekenG). Section 4 ApothekenG specifies in this context that a pharmacy must be managed by the licence holder, leaseholder or manager, and management must be personal. The manager of the pharmacy must personally fulfil their management duties, significantly influence major business operations through their own personal actions or by taking decisions or giving instructions, and continuously monitor the business.[37] A licence is only granted to those

[36] When pharmacies launch well-considered price campaigns, in compliance with legal requirements, their customer base will prove to be more loyal. In this context, pharmacists must take account of the current ban on advertising the prices of medicinal products (see Section 18 of their Code of Conduct in accordance with Section 25 of the Act on the Chamber of Pharmacists). Promoting the price (including concessions or vouchers) of ancillary products is admissible to a certain extent.

[37] Explanatory notes on the government bill in annex 760 to the shorthand verbatim records of the National Council, 18th legislative period, p. 5. Section 17 et seq. ApothekenG allows a pharmacy being managed by a leaseholder. Section 2 ABO 2005 specifies that agreements that restrict the manager's management rights with regard to the powers granted to them under pharmacy law are legally ineffective. The pharmacy manager also bears responsibility for the professional pharmaceutical side of the entire business. Cf. also Section 10 para. 2 of the Code of Conduct for Pharmacists, which obliges pharmacists to personally manage the pharmacy and prohibits adverse ancillary services.

individuals who are personally qualified pursuant to Section 3 ApothekenG and are thus generally authorised to carry out the profession of pharmacist (Section 3b ApothekenG).[38]

A basic consequence of these provisions is a **prohibition of chains and of third-party ownership** since a licence holder must have obtained authorisation to carry out the profession of pharmacist and may only operate one single pharmacy. Pharmacy chains set up by wholesale suppliers, for example, are therefore not admissible. The European Court of Justice (ECJ) has dealt with the prohibition of third-party ownership of pharmacies several times and ruled that it is basically not contrary to Union law.[39]

The prohibition of third-party ownership is relaxed by the provision set forth in Section 12 ApothekenG. Accordingly, a pharmacy must normally be operated by the licence holder as a **sole proprietorship**. However, para. 2 prescribes an exception whereby it is admissible to establish and operate a pharmacy under the **legal form of a partnership** (e.g. OG – partnership with unlimited personal liability of all partners, KG – limited partnership)[40] if the licence holder is the partner with exclusive management authorisation and power of representation, is entitled to take any measures necessary to reliably supply medicinal products to the population, and owns more than half of the entire pharmacy. This means that no other partner may manage the pharmacy.[41]

According to this provision, a licence holder may hold an economic stake in another pharmacy subject to compliance with the conditions set forth in Section 12 ApothekenG. Within these limitations, a third-party company such as a pharmaceutical wholesaler may also hold a stake.

Another provision in the ApothekenG also relaxes the ban on managing more than one single pharmacy. Section 24 ApothekenG stipulates that the owner of a community pharmacy must be given authorisation to operate a **branch pharmacy** in a locality which does not have a pharmacy or dispensing doctor if that locality is not further away than four kilometres from the site of the pharmacy and there is a need for a dispensary of medicinal products. These branch pharmacies are subject to more lenient requirements regarding operating hours (Section 24 para. 4 ApothekenG) and less strict minimum requirements regarding premises (Section 24 para. 5 ApothekenG).

[38] Cf. on the topic of compliance with EU law ECJ 19 May 2009, C-171/07, *Apothekerkammer des Saarlandes* and C-172/07, *Neumann-Seiwert*.
[39] ECJ 19 May 2009, C-171/07, *Apothekerkammer des Saarlandes* and C-172/07, *Neumann-Seiwert.*
[40] Paragraph 3 also allows a silent partnership where the conditions of para. 2 are met. Legal entities such as a GmbH (limited liability company), an AG (public limited company), private foundations or KGs with a legal entity as the personally liable partner (e.g. GmbH & Co. KG) are expressly forbidden.
[41] Cf. VwGH 3 December 1982, 82/08/0191.

2. Competition assessment

The ownership provisions create **restrictions** for pharmacists and other entrepreneurs in that they are not allowed to run several pharmacies at the same time and thus generate synergies. If the prohibition of third-party ownership were abolished and the pharmacy market liberalised, the question arises of who would open up new pharmacies and what would be the consequences from a competition perspective?

There are three conceivable **categories of operators for pharmacies**: (a) natural persons who are **pharmacists**, (b) (natural and legal) **persons** who are neither pharmacists nor working in the pharmaceutical sector, as well as (c) (natural and legal) persons working as **manufacturers and wholesalers** in the pharmaceutical sector.[42]

a) Pharmacists

In accordance with applicable Austrian law, pharmacies are run by trained pharmacists. Operators of pharmacies are interested in **making a profit**. However, they also run their businesses as professional pharmacists with a **professional** mindset.[43]

The current restriction of the activity to trained professional pharmacists is feasible from a competition point of view, as the public **interest in a reliable and safe supply of medicinal products** is of paramount importance in the pharmacy market.[44] In this context, liberalisation to also allow natural and legal persons from outside the pharmaceutical industry to operate a pharmacy would be conceivable if there were an accompanying legal regulation ensuring that the pharmacy was headed by someone technically qualified. If an establishment were operated by someone from the pharmaceutical sector or by a **company outside the pharmaceutical sector** there would be the **risk** that consumers would be **advised with sales figures in mind**. This risk cannot simply be countered by qualified pharmacy staff being employed, as pharmacists working as employees would not be in a position to act contrary to instructions they receive from their employer, i.e. the operator of the pharmacy.[45]

b) Pharmaceutical manufacturers and wholesalers

A very specific situation arises when pharmaceutical wholesalers or manufacturers **push their way into the pharmacy market**.

At present, **six full-line wholesalers** dominate the Austrian market, some of them accounting for considerable market shares.[46] The **three top companies** together hold a **market share of 75-85%** of the wholesale market for pharmaceutical products

[42] Cf. also the breakdown in ECJ 19 May 2009, C-171/07 *Apothekerkammer des Saarlandes* and C-172/07, *Neumann-Seiwert,* paragraph 36.
[43] Cf. ECJ 19 May 2009, C-171/07, *Apothekerkammer des Saarlandes* and C-172/07, *Neumann-Seiwert,* paragraph 37.
[44] Cf. for example Judgment of the Constitutional Court 15.103/1998.
[45] Cf. also ECJ 19 May 2009, C-171/07, *Apothekerkammer des Saarlandes* and C-172/07, *Neumann-Seiwert*, paragraph 54.
[46] In addition, there were 280 wholesale companies in Austria in 2016. Community pharmacies are supplied by both full-line wholesale companies and wholesalers with a limited product range.

supplied to **pharmacies and doctor's dispensaries**.[47] These wholesalers offer the entire or nearly the entire range of medicinal products. Generally speaking, wholesalers store medicinal products and supply them to pharmacies as required. Pharmacies are usually supplied three times a day with complex logistics behind the whole system. Due to the pricing and marketing of medicinal products being regulated, wholesalers have **little influence on the prices and quantities for consumers or on the quality of the products**. Consequently, wholesalers have time and again tried to improve their position in the market, for instance by acquiring **shareholdings in pharmacies**. The provision of Section 12 para. 2 ApothekenG allows wholesalers to own a shareholding in a pharmacy. Where **wholesalers hold a stake**, they can **influence sales and prices** by controlling those pharmacies' ordering behaviour. The wholesaler's market share increases and profits rise, particularly because they extend lower discounts to the pharmacies concerned.[48]

As early as in 2003 the Cartel Court examined a merger and the aspect of vertical integration when a wholesaler intended to acquire a 49% stake in a Viennese pharmacy. During the proceedings the Court ruled that the critical limit was **3% of total pharmacy sales of a community pharmacy**; where that limit is exceeded, the wholesaler's influence on the community pharmacy market is deemed problematic from a competition point of view.[49] The critical limit for a wholesaler's influence over and above shareholdings pursuant to Section 12 ApothekenG, e.g. through trade credits or silent partnerships, was set at a **market share of 10-12%**. At present the pharmaceutical wholesalers with the largest market shares own shareholdings of **more than 3%** each and have thus already **exceeded the critical limit** determined by the Cartel Court.

Buying or establishing a pharmacy entails **very high costs**, which usually cannot be borne by pharmacists alone.[50] An alternative to financing via suretyships or debt capital is for a wholesaler to acquire a **shareholding** in the pharmacy as defined in Section 12 ApothekenG. The wholesaler's strategic interest in such an acquisition lies in securing their position as the **main wholesale supplier** to the pharmacy concerned. Investment income alone is usually insignificant for wholesalers. More important is the status as main supplier to the pharmacy. Wholesalers have also stated that making deliveries several times a day, as is common in Austria, mean high logistics costs. The legally stipulated wholesale margin is therefore only profitable if the average quantities per delivery are at an acceptable level. This presupposes that pharmacists obtain their products from **one sole wholesaler**. In the case of shareholdings, a **supply quota of 50-90%** of the pharmacy's total purchasing is generally stipulated for a (mostly non-cancellable) term of **10-15 years**. Meanwhile, supplementary agreements give wholesalers additional opportunities to exert influence, such as selecting the tax consultant to be used by the pharmacy, imposing rules concerning the organisation of the pharmacy's business or stipulating certain marketing measures.

In addition to the shareholding itself, **further contractual relationships** are also established in the form of **trade credits, deferrals of payments or other financing**

[47] The supply of hospital pharmacies is to be demarcated from the market definition used here. Cf. on the demarcation of the objectively relevant market e.g. Vienna Higher Regional Court 24 April 2003, 27 Kt 446/02; EK Comp/M.1716 Gehe/Herba; COMP/M.5433 - Sanacorp/v.d. Linde.
[48] Cf. also expert opinions on 27 Kt 446/02, 12.
[49] Vienna Higher Regional Court acting as the Cartel Court 24 April 2003, 27 Kt 446/02.
[50] The purchase price for a pharmacy usually equals its annual sales, sometimes even exceeding it.

aids. Together with the shareholding, or as an alternative to it, suretyships are agreed, which are usually tied to **very long maturity periods** (10 years as a rule, sometimes longer or even for unlimited periods). In return, wholesalers are guaranteed purchases that usually amount to around **50-80% of the pharmacy's total demand** or minimum sales are laid down. Such purchase and supply agreements are usually entered into in connection with **other contracts**, e.g. agreements on advance payments or trade credits. These contractual agreements allow wholesalers to exert **substantial influence on the ordering behaviour** of pharmacies, far exceeding the potential influence through shareholdings pursuant to Section 12 ApothekenG.

Based on the information obtained during our sector inquiry, the share of **purchase agreements strengthening wholesalers' influence** is assumed to be around **20-30%** in relation to the total number of pharmacies.

It can be assumed that wholesalers will **push into the pharmacy market even more strongly** as soon as it is liberalised, as has been observed in other European countries.[51] In many countries in Europe certain **groups of persons or companies are excluded** from operating a pharmacy, and in several countries doctors or companies that are engaged in the pharmaceutical industry may not run a pharmacy.

Vertical integration would entail **negative consequences** for the Austrian pharmacy market and its customers.[52] First, it can be expected that **market entry barriers** would increase (market foreclosure). Competing wholesalers would find it more difficult to enter into the market as they would have to enter both levels at the same time and would need more capital and knowledge. Sole proprietors/pharmacists would also be prevented from entering into the market as opening a new pharmacy would still, as before, require substantial funds. Forward integration enables an **exclusive supply** of integrated pharmacies, possibly **narrowing the sales market for competing wholesalers considerably**. In addition, such integration may lead to a wholesaler taking advantage of their market position, cutting off other pharmacies from a comparably cheap supply of medicinal products.

As far as pharmacies and consumers are concerned, the mix of products offered is of greatest importance. **Product mix width and depth** are crucial in this context,[53] as they determine how likely a consumer is to buy a product. Competitors can distinguish themselves from one another by the depth of their product mix. However, this also requires more retail space and/or storage facilities, which in turn raises costs. Pharmacies are only partially free in selecting the products they want to offer. They are required to have enough medicinal products in stock to enable them to reliably supply them to the population.[54] This is why pharmacies will distinguish themselves particularly with regard to the OTC products they offer and their ancillary range, and if

[51] In 2004 two vertically integrated pharmacy chains in Iceland held 85% of total market shares and three vertically integrated pharmacy chains in Norway 97%. Cf. on vertical integration also *Vogler/Habimana/Arts*, Does deregulation in community pharmacy impact accessibility of medicines, quality of pharmacy services and costs? Evidence from nine European countries, Health Policy (2014) 145.

[52] Cf. Cartel Court 27 Kt 446/02, 12.

[53] Cf. *Morar*, Konsequenzen der Aufhebung des Fremd- und Mehrbesitzverbots auf die Apothekenpraxis [Consequences of abolishing the ban on third-party and multiple ownership on pharmacies in practice], in Nellen/Hahn (eds.), Zukunft der Apotheken in Deutschland: rechtliche und wirtschaftliche Fragen [The future of pharmacies in Germany: legal and economic implications] (2008) 32.

[54] Cf. Section 4 ABO and Section 35 ABO on branch pharmacies.

there is vertical integration they will be influenced by wholesalers' interests, which narrows offerings for consumers.[55] Furthermore, wholesalers can supply their own and other pharmacies at **higher prices**. This does not have any impact on the integrated pharmacies within the group, while other pharmacies will have to accept lower margins or pass on the higher costs to their customers.

In conclusion, a **full liberalisation of the ownership regulations is not recommended**. Owing to the current **market structure** in the wholesale market for pharmaceutical products for delivery to community pharmacies, it can be assumed that full liberalisation of the ownership regulations would **support existing oligopolistic structures** and have **negative consequences** such as market entry barriers, foreclosure of other pharmacies and a shift of the product mix (width and depth) towards goods offered by the wholesaler. Rather we recommend **continuing to monitor the market**, as wholesale suppliers' influence on the pharmacy market is already considerable.

3. Permitted branch pharmacies

Pursuant to Section 24 ApothekenG, an operator of a community pharmacy is currently allowed to operate one further branch pharmacy. According to the statutory provisions, **branch pharmacies function as "surrogates"**[56] because they are less important than community pharmacies with regard to supplying medicinal products to the population. For example, the rules on operating hours and the minimum requirements regarding premises are less strict (para. 4). Otherwise, the branch pharmacy is not bound by any further restrictions, which means that a branch pharmacy can be run like a community pharmacy in terms of size or product range. The locality of the branch must not be further than four kilometres from the site of the parent pharmacy (para. 1).

Upon liberalisation of the pharmacy market it can be assumed that not only more community pharmacies would be established but more branch pharmacies too. This would generate substantial **welfare effects**. Pharmacies could achieve **economies of scale**, and consumers would get **improved access to pharmacies**, particularly in **rural areas**. In some areas a community pharmacy might not be profitable, but a branch pharmacy might very well make economic sense. Likewise, where a community pharmacy is under threat of closure, it could be continued as a branch pharmacy.[57] An expansion of the permitted number of branch pharmacies can only be effected by way of legal measures.

Experience from countries like Germany and Denmark shows that the number of branch pharmacies goes up considerably following liberalisation.[58] In Germany an

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[55] Cf. *Morar*, Konsequenzen der Aufhebung des Fremd- und Mehrbesitzverbots auf die Apothekenpraxis [Consequences of abolishing the ban on third-party and multiple ownership on pharmacies in practice], in Nellen/Hahn (eds.), Zukunft der Apotheken in Deutschland: rechtliche und wirtschaftliche Fragen [The future of pharmacies in Germany: legal and economic implications] (2008) 35.

[56] Cf. VwGH B 2090/99, Judgment of the Constitutional Court 15.868; VwGH 31 January 2005, 2004/10/0185.

[57] Cf. Germany where the closure of pharmacies could be prevented in some cases by turning them into branches (https://www.bvr.de/p.nsf/0/90A4FC22D12EB85FC1257CED003CA7B1/$file/55.pdf (accessed on 13 December 2016).

[58] In Germany the number of branch pharmacies rose from 632 to 3,478 in total between 2004 and 2010.

operator of a community pharmacy may run up to three branch pharmacies, compared with seven in Denmark.

After a certain period of time, a pharmacy will no longer grow economically due to constraints regarding its premises. While the management of one single branch pharmacy and the related expansion of business can stimulate economic growth, significant effects will be lost when the number of branches is restricted to one. If the permitted **number** of branch pharmacies were **raised by law,** substantial **economies of scale** could be achieved, for instance because of staff being used at all locations, improved purchasing conditions and shared storage.

In conclusion, the number of admissible branch pharmacies **should be increased** and the establishment of branch pharmacies facilitated, e.g. by expanding the admissible distance between branch and parent pharmacy. This would require the enactment of legal measures.

VII. Restrictions on operating a pharmacy

The operation of a pharmacy is subject to extensive legal regulation, which has an impact on pharmacies' competitiveness and can lead to drawbacks for consumers.

1. Opening hours

Section 8 ApothekenG specifies the **operating hours and out-of-hours duties** of community pharmacies. The competent district administration authority determines the operating hours taking local circumstances into account, such that the total weekly operating time does not exceed 48 hours and a daily lunchtime closing of about two hours is observed. If there are several community pharmacies in the area, the same operating hours must be specified for all. The district administration authority must also prescribe on-call duties or an out-of-hours rota during closing times in areas with several community pharmacies (para. 2 and para. 5). The on-call pharmacies must then be permanently available. In areas with just one pharmacy the pharmacy manager or a generally authorised pharmacist must be quickly reachable even outside fixed operating hours to dispense medicinal products in urgent cases (para. 3). The numerous regulations issued by the competent authorities specify some highly diverging rules on operating hours.

From a competition point of view, opening hours are a **decisive factor** for consumers when choosing a pharmacy.[59] Consumers prefer to make their purchases, including those of medicinal products, during their lunch breaks or at the end of their working day, i.e. between five and seven o'clock in the evening. However, buying medicines

[59] Cf. e.g. *Hakonsen/Sundell/Martinsson/Hedenrud*, Consumer preferences for over-the-counter drug retailers in the reregulated Swedish pharmacy market, Health policy (2016) 327. Cf. in general on the significance of opening hours for competition: *Ferris*, Time, space, and shopping: the regulation of shopping hours, Journal of Law, Economics, and Organization (1990) 55; *Ferris*, On the economics of regulated early closing hours: some evidence from Canada, Applied Economics (1991) 1393; *Inderst/Irmen*, Shopping Hours and Price Competition, European Economic Review (2005) 1105; *Morrison/Newman*, Hours of Operation Restrictions and Competition among Retail Firms, Economic Inquiry (1983) 107.

during the usual retail hours is currently not always possible and sometimes even legally prohibited.

Trading with medicinal products can basically be compared to general retail trade. However, the current restrictions on opening hours prevent pharmacists from making use of their **entrepreneurial freedom** and from competing with other pharmacies on **extended opening hours**. At present, the **system** regulating opening times during lunchtime closing and off-peak hours is **complex and non-transparent** with many special rules. The supply of medicinal products will not be endangered by opening hours being liberalised provided that they are brought into line with **general retail hours** and provided that out-of-hours obligations are regulated. It will be easier for consumers to obtain medicinal products because they can expect extended opening hours in a competitive environment.[60] To ensure reliable supply, regulating core time would continue to make sense. In addition, the regulation of **nationwide out-of-hours duties** should be maintained in order to guarantee the rapid and sufficient supply of medicinal products.

In conclusion, we recommend **extending the opening hours** of pharmacies. This would require the enactment of legal measures.

2. Services

Strict legal regulations apply with regard to the equipment of a community pharmacy and the services to be rendered there, and these considerably limit the extent and kind of services and consequently **quality competition among pharmacies**.

Pursuant to Section 6 ApothekenG the premises of a community pharmacy used to prepare, sell and store medicinal products, and used for the provision of an out-of-hours service must meet the obvious requirements that arise when considering the **importance of the pharmacy's reliable operation for public health**. In this context, Section 26 ABO specifies in detail that, in terms of their type, size, number, location and equipment, the pharmacy's premises must guarantee that the **pharmacy can be properly operated**, i.e. that medicinal products can be properly dispensed, that information and advice about those medicinal products can be provided, that the medicinal products can be impeccably developed, manufactured, tested, stored and packaged, including own brands, and that all other pharmacy-related activities can also be provided. The furnishings and equipment of the pharmacy's retail space must also be adequate, in keeping with the **expected appearance of a pharmacy**. In accordance with Section 1 ABO a community pharmacy's primary remit is to ensure that the population is reliably supplied with medicinal products. This includes in particular: dispensing medicinal products in small quantities, preparing medicines according to a prescription, advising customers on self-medication, or informing and advising patients and users of medicinal products. In addition, pharmacists are entitled to render the following services in particular: **advice in matters of health and nutrition**, information on health education with the aim of promoting a healthy lifestyle, health promotion and monitoring, health-related services in cooperation with other healthcare professionals, arrangement of other healthcare services, involvement in

[60] Cf. e.g. *Kügler/Weiss*, Time as a strategic variable: business hours in the gasoline market, Applied Economics Letters (2016) 1051.

local healthcare provision and home-care services, pharmacy laboratory, performance of environmental testing, as well as the development of health-related information media including trading with them or offering them for rent.

Alongside **classic advisory services**, Austrian pharmacies also offer **additional services** to promote customer loyalty,[61] such as the "Apothekenruf" hotline, medication management and health checks (blood pressure, blood sugar, cholesterol, weight and waistline, vascular screenings, allergies, muscle strength and COPD testing). **Other offers or usage** of pharmacy premises are **highly limited**. These limitations are partly based on ambiguous legal provisions and also on the type of operational permit, and are therefore generally characterised by a **lack in transparency**.

According to a recent VwGH ruling[62], pharmacy activities that are merely **somehow related to the matter of health** are not allowed. Where a consulting room in a pharmacy is dedicated to the provision of dermocosmetic and Ayurvedic services or massage therapy, this would not constitute an activity belonging to the operation of a pharmacy. The admissibility of setting up a consulting room in a pharmacy for certain customer meetings or consultations, or for general consultation hours depends on whether this hinders the regular operation of the pharmacy and whether the impression of the building being a pharmacy is maintained. According to this ruling from the VwGH, which is stricter in its interpretation of ancillary services than the Austrian Chamber of Pharmacists[63], the **mixed used of operational premises is to be interpreted very narrowly**, and the use of rooms for activities unrelated to regular pharmacy activities is not compatible with the granting of an operating permit pursuant to pharmacy law.

As long as the population continues to be reliably supplied with medicinal products, the pharmacy is operated according to the rules, and the pharmacy offering services has the expected appearance of a pharmacy, **relaxing the rules** on services rendered by pharmacies and any possible ancillary activities will contribute considerably to **quality competition** among pharmacies. Consumers will benefit from such competition on quality and the related **service differentiation** among pharmacies. Pharmacies in turn can exploit **synergies** by using their existing premises and tapping in to the knowledge they already have and, being a health facility, they can make a significant contribution to public health. Mixed or other use by third parties of separate rooms could be enabled as long as the pharmacy can continue to operate as required. We recommend not interpreting the required link to health too narrowly, as seems to currently be the case.

[61] Cf. Austrian Chamber of Pharmacists, The Austrian Pharmacy - Facts and Figures 2016, 16.
[62] Cf. VwGH 25 January 2017, Ro 2014/10/0085.
[63] Cf. the explanatory notes on Section 27 ABO, footnote 8, https://www.apotheker.or.at/internet/oeak/newspresse.nsf/e02b9cd11265691ec1256a7d005209ee/ac0a716b3c2ed30fc1256fbf00319103!OpenDocument (accessed on 7 May 2018).

3. Online sales

Austrian pharmacies have been permitted to sell medicines online since 2015, with this permission extending exclusively to **non-prescription medicines (OTC products)**.[64] The legal basis for online sales of medicinal products can be found in the Austrian Medicinal Products Act (AMG) and in the Distance Selling Regulation (Fernabsatz-VO). At present, **52 pharmacies** have registered with the Austrian Federal Office for Safety in Health Care (BASG) and been included in the mandatory list of mail-order pharmacies.[65]

This low figure is surprising considering that online sales amounted to approximately 4.5% of total trading volume back in 2013;[66] and these figures have risen further over the past few years. In 2014 some 19% of Austrian retailers maintained their own online shop.[67] As also seen in the European Commission's sector inquiry into the electronic commerce of consumer goods and digital content in the EU[68], the greatest advantage for consumers is that price transparency increases with online selling as consumers are able to instantaneously obtain and compare product and price information online. Since prices of products can be compared across several online retailers this leads to increased price competition, affecting both online and offline sales. Alternative online distribution models such as online marketplaces have made it easier for retailers to access customers.

While 61.6% of Austrian consumers made online purchases in the past 12 months, the share of consumers who buy medicines online is still much smaller. This is because medicinal products are usually bought when they are needed. Someone suffering from a cold will need medication and thus relief immediately, and will therefore visit a local pharmacy and not wait for delivery from an online shop. Online selling is suitable for those products that consumers find embarrassing to ask for in a pharmacy (e.g. fungus infections or hair restorers) and for those (chronically ill) consumers who always need the same medicines and therefore want to compare prices and buy ahead.[69]

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[64] Cf. Federal Law Gazette I No. 48/2013; Distance Selling Regulation (Fernabsatz-VO), Federal Law Gazette II No. 105/2015. Cf. on Union law *Nemetz*, Internetapotheken - Post DocMorris. Zum Verbot des Versandhandels für Arzneimittel im Internet [Online pharmacies - After the DocMorris ruling. On the prohibition of the mail-order selling of medicinal products on the Internet], ecolex 2004, 991. Foreign mail-order pharmacies were already supplying non-prescription medicines to Austrian customers before 2015.

[65] https://versandapotheken.basg.gv.at/versandapotheken/verify/main?_afrLoop=81834163732998711&_afrWindowMode=0&_adf.ctrl-state=172skn1dut_4 (accessed on 7 May 2018).

[66] Austrian Chamber of Commerce survey of 2014 on the usage of information and communication technologies (ICT) in enterprises (in German with an English summary), http://www.statistik.at/web_de/statistiken/energie_umwelt_innovation_mobilitaet/informationsgesellschaft/ikt-einsatz_in_unternehmen/index.html (accessed on 7 May 2018).

[67] Austrian Chamber of Commerce survey of 2014 on the usage of information and communication technologies (ICT) in enterprises (in German with an English summary), http://www.statistik.at/web_de/statistiken/energie_umwelt_innovation_mobilitaet/informationsgesellschaft/ikt-einsatz_in_unternehmen/index.html (accessed on 7 May 2018).

[68] Report from the Commission to the Council and the European Parliament, Final Report on the E-commerce Sector Inquiry, SWD(2017) 154 final.

[69] In Germany online pharmacies sell mostly strong brands, high-end products, treatments for taboo conditions and long-term medication.

a) Legal framework conditions

Section 59 AMG prescribes that medicinal products may only be dispensed by pharmacies. It is expressly forbidden to offer medicines for self-selection or through distance selling channels (para. 9).[70] An exception applies to those non-prescription medicines licensed or registered in Austria which are offered by way of distance selling either within Austria by community pharmacies or delivered to Austria by pharmacies located in another EEA Member State which are correspondingly authorised in accordance with legal provisions applicable in those countries (para. 10).

Section 59a AMG defines distance selling with medicinal products in greater detail: those pharmacies that offer medicinal products by way of distance selling must notify the Austrian Federal Office for Safety in Health Care (BASG), prior to assuming this activity, of the name of the operator as well as their address, the date the activity is commenced and the URLs of the websites used for that purpose including any further identification details (para. 2). In addition, the websites used for distance selling must meet certain criteria. The BASG is obliged to publish a list of all pharmacies selling online via its Internet portal (para. 4). Medicinal products sold by way of distance selling may only be supplied in quantities in line with normal individual demand and must be packaged, transported and delivered such that their quality and effectiveness is not impaired. Furthermore, they may only be handed over, against verifiable evidence, to the person who was named to the pharmacy by the party who placed the order.

The Fernabsatz-VO contains further provisions pertaining to the online selling of medicinal products.[71] Pharmacies within Austria are only allowed to dispense non-prescription medicines that are licensed or registered in Austria by way of distance selling. The medicinal products must be sold and delivered **from the pharmacy's premises**. They may only be delivered in quantities that are in line with normal individual demand, and no minimum ordering quantity is allowed.

Online pharmacies, like physical pharmacies, are subject to **strict provisions on price advertising**.[72] For example, no discounts or special prices may be offered and no two-price advertising employed.

b) Competition assessment

Ultimately, the online selling of medicinal products is subject to **substantial restrictions** in Austria. For example, a **real pharmacy** must exist and the deliveries must originate from it. The pharmacy must fulfil all conditions pursuant to the ApothekenG pertaining to community pharmacies and undergo a needs assessment prior to its establishment. In addition, the online pharmacy is forbidden from **advertising special prices** (in contrast to foreign online pharmacies), which puts them at considerable competitive disadvantage compared with foreign online pharmacies.

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[70] Cf. however the provision in Section 8a ApothekenG pertaining to pharmacies' own delivery services. Cf. also Section 50 para. 2 of the Austrian Trade Act (GewO 1994), according to which toxins, medicinal products, medical aids (excluding contact lenses) are not allowed to be sold to consumers by mail order.
[71] Regulation of the Federal Minister of Health on the dispensing of medicinal products for human use by way of distance selling (Fernabsatz-VO), original version in Federal Law Gazette II No. 105/2015.
[72] Cf. for instance the restriction in Section 18 para. 3 no. 5 of the Code of Conduct of Pharmacies according to which price advertising is forbidden for medicinal products, except for actual price labels.

For consumers, the online selling of medicinal products offers **numerous advantages**, as it does with other goods. For example, it gives consumers sufficient time to gather information and to compare prices. Shopping online is easy as orders can be placed at any time of the day or night, and deliveries are made to buyers' homes or a given address. Consumers also appreciate that they can place their orders anonymously, meaning their orders are treated discreetly. Lastly, medicinal products are usually much cheaper online. Mail-order pharmacies will also **significantly improve** the supply of medicinal products **in rural areas**.

Online selling is however also viewed sceptically, with some reason, particularly where **safety** is concerned. This is a particular issue with prescription-only medicines as they pose a higher potential risk to human health. One of the largest problems with international online pharmacies is the trade in counterfeit medicines. The World Health Organization (WHO) assumes that half of all medicinal products sold on the Internet worldwide are counterfeit. Opponents of online selling frequently assert that even non-prescription medicines can lead to health risks if consumers do not use them appropriately. The counterargument is that community pharmacies do not usually provide extensive advice about OTC products and consumers may also visit several pharmacies to acquire a product that a particular pharmacy refuses to sell. OTC products generally need responsible consumers irrespective of how the products are sourced.

Austrian online pharmacies are faced with **strong competition from foreign mail-order pharmacies**, which have been serving the Austrian market for more than ten years now. The ECJ has found that traditional pharmacies are better placed to provide patients with individually-tailored advice given by their staff and to ensure a supply of medicinal products in cases of emergency. In so far as mail-order pharmacies cannot, given the limited services that they offer, adequately replace such services, it must be held that **price competition** is a more important factor of competition for mail-order pharmacies than for traditional pharmacies, since price competition lays the basis for their potential to access the market directly and to continue to be competitive in it.[73] In Austria, there is still **considerable potential to expand online sales** of medicinal products. A liberalised online market for medicinal products, and consequently a higher number of mail-order companies, would lead to **lower prices for OTC medicines** for consumers.

If the requirement for a bricks-and-mortar pharmacy were abolished, while maintaining the necessary safety and quality provisions (e.g. with regard to procurement and storage of medicinal products), this would **stimulate competition** among Austrian pharmacies and lead to **cheaper prices** and **better quality** (of advice) for consumers. Competition among Austrian and foreign mail-order companies (the latter not required to comply with these provisions) would be enhanced, and the **competitiveness** of Austrian pharmacies raised. Relevant operating provisions, also applicable to online pharmacies, would ensure that public interests were upheld, most notably the safe and reliable supply of medicinal products. Moreover, relaxing the restrictions on promoting the prices of medicinal products is also recommended, as it would bring advantages for customers of physical pharmacies.

[73] Cf. ECJ 19 October 2016 – C-148/15, paragraph 24.

In conclusion, BWB recommends **liberalising the online sale of OTC medicines** by Austrian pharmacies. This would require the enactment of legal measures.

4. Pharmacy delivery services

Section 8a ApothekenG allows community pharmacies to deliver **urgently needed medicinal products** to patients within a perimeter of six kilometres using their **own delivery services**.[74] The pharmacy does not need to operate the service itself, it must only organise delivery. In practice, delivery methods vary greatly (delivery is either by the Red Cross or a social service, by taxis or pharmacists themselves). Statistics about the current number of delivery services are not available.[75] Both prescription-only and non-prescription medicines may be delivered, on condition they are needed urgently. A need for those medicines must not have been foreseeable.[76]

In accordance with Section 11 ABO medicinal products may only be delivered by a pharmacy's own delivery services as defined in Section 8a ApothekenG and in justified individual cases. The **"Pharmacy Delivery Services" Regulation**[77] issued by the Austrian Chamber of Pharmacists defines the conditions for providing delivery services. These include written permission from the Chamber's respective provincial branch office. Provisions are in place governing the admissible delivery area (deviating from the six-kilometre radius of Section 8a ApothekenG) and changing on-call rotas where several pharmacies operate in the same area.[78] In addition, any reasonable interests of the surrounding pharmacies should be considered too.[79]

The **delivery of urgently needed medicines** is an essential part of the supply of medicinal products in rural areas. The possibility of getting urgently needed medicines that cannot be obtained from a community pharmacy or ordered in advance online is highly **beneficial to consumers**, as it realises the principle rooted in the Austrian system that pharmacies should guarantee the reliable supply of medicinal products.

From a competition point of view, the Regulation by the Austrian Chamber of Pharmacists causes a lack of **transparency and discriminates** against pharmacies intending to offer delivery services. It also imposes **territorial restrictions** on pharmacy delivery services, by narrowing the legally prescribed delivery radius. Accordingly, any **regulations** in the Chamber's Regulation **deviating** from Section 8a ApothekenG are to be **rejected**. Additionally, the **perimeter** defined in Section 8a ApothekenG should be **fully removed**, from both a medicines supply and a competition point of view. The current restriction does not seem proportionate, given that lawmakers have already once found the supply factor to be too restrictive and

[74] Cf. also Section 1 para. 5 of the Act on the Dispensing of Prescription-only Medicines (RezeptpflichtG), according to which prescription-only medicines may only be dispensed in pharmacies.
[75] The highest concentration of delivery services is currently found in Vienna.
[76] Cf. Supreme Court of Justice 4 Ob 158/12g.
[77] Resolution of the Executive Committee of the Austrian Chamber of Pharmacists of 21 January 1987.
[78] Cf. Section 1 para. 6 and Section 1 para. 5 of the Austrian Chamber of Pharmacists' Regulation "Pharmacy Delivery Services".
[79] Cf. Section 1 para. 3 lit b of the Austrian Chamber of Pharmacists' Regulation "Pharmacy Delivery Services".

expanded it accordingly.[80] This should ensure that **every consumer in Austria can make use of pharmacy delivery services**.

Possible redundancies and **interchangeable services** might result from **online selling** of non-prescription medicines and their **delivery by physical pharmacies**. It is questionable in this context whether there are objective grounds for allowing the delivery of prescription-only medicines while banning mail orders of the same drugs. This appears to constitute unequal treatment or at least an **unobjective constraint on competition** between online pharmacies and community pharmacies.

In conclusion, BWB recommends extending the **admissible perimeter** for delivering medicinal products by law and opening up delivery services to all pharmacies by means of **non-discriminatory and transparent rules**.

5. Prerogative of pharmacies to sell OTC medicines

In Austria medicinal products are dispensed by pharmacies. Non-prescription drugs, or **OTC medicines**, may not be dispensed to consumers by other operators such as drugstores, supermarkets or petrol stations in Austria, or only to a very limited extent. Basically, **pharmacies** have the **prerogative** to sell medicinal products.

Non-prescription medicines may be sold outside pharmacies in many European countries.[81] There is a clear **trend in the direction of liberalisation.** Despite OTC medicines being sold outside pharmacies, pharmacies still generate 86% of OTC turnover.[82] The ways in which OTC medicines are sold outside pharmacies vary greatly across Europe. Pharmacies in Denmark, for example, operate separate outlets outside community pharmacies. In the Netherlands OTC products are available in supermarkets, and in Sweden a limited range of OTC medicines may be sold in supermarkets or even petrol stations.

OTC medicines account for a **large share** of the medicinal products sold overall. The total volume of the **OTC market**, the market with non-prescription medicines, amounted to some **€ 821.3 million** in 2016, at pharmacy sales prices.[83] The value of the OTC segment in the community pharmacy market amounted to 16% in 2017.[84] In terms of per capita expenditure for OTC medicines, Austria ranks tenth.[85] The annual growth rate in the OTC segment was 6.3% between 2012 and 2016.[86] Treatments for ailments such as coughs and colds, stomach aches and digestive problems, as well as painkillers and RA medication top the list with a market share of more than 45%.[87]

[80] The admissible perimeter was extended from 4 km to 6 km (Federal Law Gazette I No. 80/2013).
[81] Cf. for example Denmark, Ireland, Italy, Norway, Portugal, Sweden and the United Kingdom.
[82] Study by Nicholas Hall - Benchmarking the World of OTC by order of IGEPHA, Perspektiven für den OTC-Markt in Österreich [Prospects for the Austrian OTC market] (2017) 5.
[83] Cf. Statista, Share of sold OTC medicines in Austria by indication in 2016.
[84] 2017 annual report of the Austrian Self Care Association (IGEPHA), 4.
[85] Study by Nicholas Hall - Benchmarking the World of OTC by order of IGEPHA, Perspektiven für den OTC-Markt in Österreich [Prospects for the Austrian OTC market] (2017) 18.
[86] Study by Nicholas Hall - Benchmarking the World of OTC by order of IGEPHA, Perspektiven für den OTC-Markt in Österreich [Prospects for the Austrian OTC market] (2017) 4.
[87] 2017 annual report of the Austrian Self Care Association (IGEPHA), 12.

In a survey **57%** of Austrian respondents stated that they could imagine buying **non-prescription medicines in drugstores**.[88] 15% of those respondents would only buy there if staff with pharmaceutical training were available for consultation. 14% of respondents would buy OTC medicines in a drugstore if they were on sale at a lower price. Other possible dispensaries such as petrol stations or vending machines got an approval rate of 15%. Broken down by age groups, the 50 to 59-year-olds were most in favour of allowing non-prescription medicinal products to be dispensed in drugstores (70%).

a) Legal framework conditions

In accordance with Section 57 para. 1 AMG, medicinal products may only be sold by manufacturers, pharmaceutical distributors or wholesalers to a **limited group of customers**, such as community pharmacies, hospital pharmacies and dispensing veterinary doctors. Furthermore, medicinal products may only be **dispensed by pharmacies**. An exception to this rule is contained in Section 59 para. 3 AMG, which regulates the sale of small quantities. In this context, the Federal Minister of Health and Women's Affairs (BMGF) and the Federal Minister of Economics and Labour (BMWFW) are obliged to jointly issue a **Regulation**[89] in which they list those medicinal products that **do not pose a risk to the life or health of humans or animals, even if used inappropriately**, in a way that is predictable considering everyday life experience, and that could therefore be dispensed by drugstores or businesses that are entitled to manufacture medicinal products pursuant to the GewO. This Regulation predominantly lists teas, herbs and oils in its annex. In accordance with Section 59 para. 6 AMG the BASG is entitled, upon the licence holder's application, to exclude medicinal products by administrative decision from the prerogative of pharmacies if they pose no threat on the basis of their specific composition or indications for use. Other provisions such as Section 59 para. 6 AMG, which **prohibits the offering of medicinal products for self-selection or through distance selling**, or Section 10 para. 2 ABO[90], which specifies that consumers must be able to speak with a pharmacist and get **direct personal advice** and information every time they get a medicine, further cement the pharmacy prerogative.

According to these statutory provisions, prescription-only medicines may only be dispensed by pharmacies.[91] The sale of OTC medicines is also a basic prerogative of pharmacies. This covers complementary medicine such as homoeopathy, Schuessler tissue salts or Bach flower remedies and also vitamins, as well as medicines such as painkillers or cough, cold and flu remedies. With regard to OTC drugs, there are **not many products** that are allowed to be **dispensed both by pharmacies and by other operators** such as drugstores. In addition, there are product groups that do not constitute medicinal products and can be sold in both pharmacies and drugstores, such

[88] Survey by MAKAM Research, April 2016.
[89] Regulation of the Federal Minister of Health and Women's Affairs and the Federal Minister of Economics and Labour concerning the dispensing and labelling of certain medicinal products for retail (Classification Regulation - *Abgrenzungsverordnung* 2004), original version in Federal Law Gazette II No. 122/2004.
[90] Cf. also Section 5 ApothekenG.
[91] Cf. exceptions set forth in Sections 57 and 58 AMG such as handing out samples.

as certain dietary supplements[92] or cosmetic products. Consumers can also buy some medical devices from both pharmacies and drugstores.

b) Competition assessment

From a competition point of view, community pharmacies have a **monopoly** on selling OTC medicines. After having passed the needs assessment (see Point V.), pharmacies are not under any competition pressure. They have a "guaranteed" customer base, which means that there is no motivation for them to compete on quality or price in the OTC market.

However, if the OTC market were to be liberalised, there would be (increased) quality and price competition. **Liberalisation** can take various forms:

(1) Even if the **prerogative of pharmacies were maintained**, **abolishing the restrictions on selling and promoting** OTC medicines in community pharmacies would stimulate the OTC market and intensify competition. Possible scenarios are offering OTC medicines in self-service areas (products are price labelled and consumers select them by themselves) or advertising special prices. This would increase **price transparency** for consumers and enable them to choose the OTC medicines they want at a price they are willing to pay. It is doubtful, however, if this would give pharmacies **sufficient incentive** to compete with each other on prices.

(2) **Expanding the range** of those OTC medicines that may be dispensed outside pharmacies under existing statutory provisions and within the existing system. In this case, any potential risk to health would be considered at the stage of deciding whether a medicinal product should be available on prescription only. Medicinal products that may be dispensed by pharmacies and other operators (see Section 59 para. 3 AMG) should be selected by determining whether they pose a risk to life or health, if used inappropriately, in a way that is predictable considering everyday life experience. The Regulation can be modified by **adding further medicinal products** to this list or, if this is not possible owing to the extremely **strict definition** laid down in Section 59 para. 3 AMG, even by international comparison, by **expanding** the definition. The **advantage** for consumers would be that they could acquire the most common OTC medicines (i.e. those that are harmless, where there is no risk to human health) even outside pharmacies. This would result in a **broader and thus improved supply** of OTC medicines to consumers (particularly also in rural areas), and the new dispensaries[93] would start **competing on price** with existing pharmacies. Furthermore, consumers can use the extended shopping hours for buying their OTC medicines too. Finally, in all likelihood pharmacies would **compete** with the new dispensaries **on quality**, and the quality of their **advisory services** in particular.

    The definition in Section 59 para. 3 AMG concerns inappropriate use. It is doubtful whether the prerogative of pharmacies alone can guarantee that a consumer will use a medicine appropriately. This could only be achieved by attaching more

[92] Cf. Regulation of the Federal Minister of Health and Women's Affairs on dietary supplements (*Nahrungsergänzungsmittelverordnung* – NEMV), original version in Federal Law Gazette II No. 88/2004 as amended by Federal Law Gazette II No. 97/2010.

[93] This includes drugstores or businesses that are entitled to manufacture medicinal products pursuant to the GewO (cf. Section 59 para. 3 AMG).

importance to **advice** (which, incidentally, is also required for selling medicinal products online) from a pharmacist, and this requirement would have to be made obligatory for extended dispensaries too (e.g. by mandatory employment of a pharmacist to provide such advice). In addition, rules and regulations on storing medicinal products as well as **quality and safety standards**, as currently apply to pharmacies, would have to be extended to other dispensaries too. These measures would reduce the risk of increased inappropriate use or abuse to a justifiable extent.[94]

It is unlikely that new dispensaries with their restricted opportunities would sell such huge volumes as to threaten pharmacies' survival. This assumption is confirmed by figures from other European countries, according to which most OTC medicines are dispensed by pharmacies even in countries with liberalised markets.

One critical point, however, is that dispensaries belonging to a chain (which applies to both pharmacies and other dispensaries such as drugstores) could establish **considerable market power**. Typically, this involves negative consequences for competitors, manufacturers and consumers such as a tightening of the **product mix width and depth** and therefore a **smaller range of products for consumers**. Pharmacies are legally obliged to keep extensive stocks, which might be disadvantageous when compared with other dispensaries. However, extensive stocks may also give pharmacies a competitive edge over less well assorted providers. Discriminating against pharmacies compared with other dispensaries by prescribing strict rules on selling and stocking OTC medicines in the event of liberalisation should be avoided at all cost. A general relaxation of the restrictions on the sale and advertising of OTC medicines by pharmacies in particular might be worth considering in this context (see above).

(3) Abolishing the prerogative of pharmacies and **allowing the sale of OTC medicines without restriction by other dispensaries too** (possibly with completely free pricing). Such a complete liberalisation of the OTC market would undoubtedly **improve the supply** of consumers with OTC medicines, resulting in strong **price competition** and lower prices. This scenario does not take account of the fact that certain OTC medicines are not suitable for being dispensed in supermarkets or petrol stations, for example, in a broad, unfiltered manner. In contrast, there is already a certain product overlap between drugstores and pharmacies, and the requirement for a pharmacist to be available for advice as well as certain **quality and safety standards** could easily be implemented in drugstores. **Opening up the market without restraints** is not in any case recommended since the public interest in **guaranteeing the population a reliable supply of medicinal products could not be sufficiently secured**. It is doubtful whether a sufficient number of pharmacies would remain and continue to supply at least prescription-only medicines when faced with lower profit margins after extensive liberalisation of the OTC market.

[94] There have been no economic studies showing that deregulation causes an increased use of OTC medicines or implying a causal connection between deregulation in the field of OTC medicines and health risks.

In conclusion, **liberalisation of the OTC market is recommended** because of the **positive effects for consumers** (better access, lower prices). Adherence to existing quality and safety standards concerning the storage and dispensing of medicinal products must be guaranteed, and the provision of adequate advice to consumers on any risks posed by medicines are equally important. Irrespective of the form, as described above, liberalisation would require the enactment of legal measures.

Index of abbreviations

ABO	Apothekenbetriebsverordnung	*Regulation on the Operation of Pharmacies*
AMG	Arzneimittelgesetz	*Austrian Medicinal Products Act*
ApothekenG	Apothekengesetz	Austrian Pharmacy Act (Act pertaining to the regulation of Austrian pharmacies of 18 December 1906)
ASVG	Allgemeines Sozialversicherungsgesetz	General Social Insurance Act
Fernabsatz-VO	Fernabsatz-Verordnung	Distance Selling Regulation
RezeptpflichtG	Bundesgesetz über die Abgabe von Arzneimitteln auf Grund ärztlicher Verschreibung	Act on the Dispensing of Prescription-only Medicines
WettbG	Wettbewerbsgesetz	Austrian Competition Act

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IX. Appendix

The Austrian pharmacy market – Recommendations from a competition point of view

	Problem	Consequences	Solutions	Positive effects
1	**Needs assessment**			
	A community pharmacy can only be operated after obtaining an official authorisation (licence). A licence will only be granted if there is a need for a new pharmacy. Need is defined in the negative in the law, and depends particularly on the current supply of medicinal products (e.g. by another community pharmacy or doctor's dispensary), the distance to any existing pharmacy and the size of the population to be supplied with medicines.	- Within their territory, pharmacies hold a near monopoly position. - Pharmacies are not under any competitive pressure. - Even pharmacies that are run inefficiently or that provide only unsatisfactory services to consumers do not have to fear for their economic survival. - Hardly any quality competition between community pharmacies. - Hardly any price competition between community pharmacies, where possible within the framework of the strict statutory price regulations.	Abolition of modification of needs assessment by legal measures. Adherence to prohibition of chains and of third-party ownership, meaning that the licence holder will continue to need authorisation to carry out the profession of pharmacist and can only operate one single community pharmacy. Consequently, no further vertical integration of pharmaceutical wholesale suppliers on the pharmacy market and any related risks such as, for example, market foreclosure.	- Higher pharmacy density and therefore improved supply of medicinal products to population (particularly also in rural areas). - Increased quality competition among community pharmacies (quality competition as major driving force and unique selling point for pharmacies, more advisory and other services). - Price competition where possible within the framework of the strict statutory price regulations (particularly in the areas of personal care products, dietary supplements, OTC medicines).
2	**Branch pharmacies**			
	The operator of a community pharmacy may run one additional branch pharmacy. The locality of the branch must not be further than four kilometres from the site of the parent pharmacy. The rules on operating hours and the minimum requirements regarding premises are less strict for branch pharmacies.	- Limitation to two pharmacies prevents economies of scale.	Increasing the number of admissible branch pharmacies to three per pharmacist by legal measure. Strengthened market position of a pharmacist within a certain territory is balanced by positive effects.	- Higher pharmacy density and therefore improved supply to population (particularly also in rural areas). - Generates scale economies for pharmacists.
3	**Opening hours**			
	Opening hours and out-of-hours obligations of community pharmacies are regulated by a complex system of rules with the result that community	- Restriction of pharmacies' entrepreneurial freedom to set their own opening hours.	Bringing opening hours in line with general retail hours by legal	- Extended opening hours of pharmacies and thus better supply of medicinal products

	pharmacies are extremely limited in setting their opening hours and are not allowed to open for customers during off-peak times.	- No quality competition among community pharmacies with individual opening hours not being allowed. - Limited supply of medicinal products to consumers (particularly during off-peak times).	measures while continuing to secure an out-of-hours service.	to consumers during lunch breaks or off-peak times. - Increased quality competition as pharmacies make individual use of extended opening hours.
4	**Services**			
	Strict statutory regulations on the provision of services at community pharmacies and on (additional) use of pharmacy facilities.	- No quality competition among community pharmacies with the provision of additional services not being allowed. - Competence of pharmacy as pivotal health facility not sufficiently used.	Relaxing the statutory regulations with the aim of expanding the services offered at pharmacies, using the professional skills of pharmacy staff. Facilitating (mixed) used of pharmacy facilities by other service providers while guaranteeing that regular pharmacy operations are not interrupted.	- Using synergies by increasingly involving pharmacies as pivotal health facilities. - Increased quality competition among pharmacies.
5	**Online sales**			
	Entering the online marketplace for medicinal products is difficult for Austrian companies owing to high regulation. Currently, there are only a handful of Austrian pharmacies offering medicinal products online. There is considerable potential to expand online sales.	- Austrian pharmacies are at a considerable competitive disadvantage compared with foreign mail-order pharmacies. - Highly restrictive control of entry regulations (e.g. requirement of a bricks-and-mortar pharmacy) as well as operating restrictions. - Low price competition.	Part liberalisation of online selling by abolishing the requirement of a physical pharmacy by legal measures.	- Better supply of medicines to consumers (particularly in rural areas). - Increased price competition among online pharmacies and between online pharmacies and physical pharmacies. - Increased quality competition (improved advisory and other services at bricks-and-mortar pharmacies).
6	**Delivery services**			
	Within a perimeter of six kilometres, community pharmacies may deliver urgently needed medicinal products to consumers using their own delivery services. The delivery methods vary greatly in practice. Both prescription-only and non-prescription medicines may be delivered, on condition they are needed urgently. The “Pharmacies’ Delivery Services” Regulation issued by the Austrian Chamber of Pharmacists defines the conditions for providing	- Lacking transparency and unequal treatment caused by the Chamber’s Regulation. - Little competition on comparable services among community pharmacies and online pharmacies.	Abolition of all provisions in the Chamber’s Regulation that deviate from statutory provisions. Removal of the prescribed delivery perimeter by legal measures.	- Better supply to population (particularly in rural areas). - Intensified competition among community pharmacies and online pharmacies.

	delivery services, including the requirement for written permission from the Chamber's respective provincial branch office.			
7	**OTC medicines**			
	Pharmacies have a statutory prerogative to sell OTC medicines. A limited range of OTC medicines may be dispensed both by community pharmacies and by others such as drugstores.	- Community pharmacies monopolise OTC medicines. - Only limited price and quality competition among community pharmacies in the OTC market.	Liberalisation of the dispensing of OTC medicines. Relaxation of the restrictions applying to the sale and advertising of OTC medicines. Possibly, expansion of the range of OTC medicines allowed to be dispensed both by community pharmacies and others such as drugstores by legal measures. At any rate, advisory services provided to consumers by trained pharmacists must be guaranteed and the existing high quality and safety standards pertaining to OTC medicines maintained (also in dispensaries other than pharmacies).	- Improved supply of OTC medicines to consumers. - Price competition among pharmacies and possible additional dispensaries (lower prices for OTC medicines). - Price transparency for consumers. - Quality competition among pharmacies and possible additional dispensaries, with improved advisory and other services.