

Sector Inquiry Health

The Supply of Medicines from a Competition Perspective

Imprint

Owner, publisher and editor:
Federal Competition Authority (BWB)
Radetzkystraße 2, 1030 Vienna
Vienna, 2021

Date: March 2021

Copyright and liability:

The reproduction of excerpts from this publication is only permitted if the source is referenced; no other rights may be exercised without the written permission of the media owner.

Please cite as: BWB (2021), *Sector Inquiry Health: Interim Report 3: The Supply of Medicines from a Competition Perspective*, BWB/AW-458, Vienna.

This report does not contain any trade secrets. Any confidential information has been removed. This has been done to prevent sensitive corporate information provided by market participants being made known to their competitors.

This report has been drawn up to the best of the author's knowledge and with the greatest possible care on the basis of discussions with stakeholders, data and information that have been communicated to the BWB, and publicly available sources. Please note that, despite the care with which it has been

prepared, all information in this publication is provided without guarantee, and no liability is accepted by either the Federal Competition Authority or the author.

All terms used in this report to refer to persons include men and women equally, and are to be understood as gender-neutral.

The following report is a summary and consists only of parts of the German version of *Sector Inquiry Health: The Supply of Medicines from a Competition Perspective*.

Feedback: Please send your comments on this publication to wettbewerb@bwb.gv.at.

Introduction

The Federal Competition Authority (**BWB**) has been analysing the Austrian healthcare market since early 2017. In the course of this Sector Inquiry, the BWB is evaluating the competitive framework conditions on particular submarkets of the healthcare market. The goal is to identify possible distortions of competition, and highlight options that will give undertakings greater scope for action and deliver benefits for consumers. The first interim report on one of these submarkets, *The Austrian Pharmacy Market*, was published in 2018, and the second interim report, *Healthcare in Rural Areas*, in 2019.

For several years, what are in some ways significant challenges have been faced with regard to the supply of medicines, a situation to which various factors have contributed. These problems have become even more significant in the very recent past, partly against the background of the SARS-CoV-2 pandemic. This third interim report (the “**Sector Inquiry**”) therefore examines the supply of medicines from a competition perspective, concentrating on Austria, but also taking account of the European and global dimensions. Even though there are no quick fixes for the multifaceted challenges associated with the supply of medicines, it is the ambition and aim of this Sector Inquiry to explore the main aspects of the subject in a structured fashion, stimulate discussion and introduce possible solutions from a competition perspective.

The Sector Inquiry is based on information requested from market participants, academic literature and relevant publications, and in-depth discussions with undertakings, interest groups, institutions active on the health market, ministries and the health spokespersons of the parties that form the Austrian Federal Government during the current, 27th legislative period.

Work on the Sector Inquiry began in March 2020, coinciding with the first peak of the COVID-19 pandemic. It therefore seemed pertinent to ask whether the COVID-19 pandemic was having immediate impacts on the supply of medicines (on supply chains, for example). The discussions with the stakeholders and undertakings mentioned above did not provide any concrete evidence of lasting shortages or large-scale supply bottlenecks directly connected with the pandemic. Nor were there any indications of this in the responses received from market participants at the wholesale level or the information supplied by various institutions. A comparison of the notifications of medicines in short supply published in the Medicine Shortages Catalogue of the Austrian Federal Office for Safety in Health Care (**BASG**) from April 2020 to December 2020 also found no significant trend that suggested the COVID-19 pandemic was

having a direct influence on the total number of shortages, although a rise in notifications during the last two months of 2020 was to be noted.¹

Nonetheless, the possibility cannot be ruled out that the availability of individual medicines or vaccines has been, or is being, limited temporarily as a consequence of the COVID-19 pandemic.

Finally, for the sake of clarity, please note that it is not possible for any remarks made in this Sector Inquiry to set a legal precedent for the casework of the BWB and other authorities, institutions or courts in any specific instance. Furthermore, please note that this English translation is merely intended for information purposes. Should there be discrepancies between the German and English versions or in any other case of doubt, the German version is to be regarded as the authoritative text.

¹ BASG, Medicine Shortages Catalogue, <https://medicineshortage.basg.gv.at/vertriebseinschraenkungen/faces/adf.task-flow? id=main-btf& document=WEB-INF/main-btf.xml& afrLoop=999432201580649& afrWindowMode=0& afrWindowId=null>; see the more detailed discussion of this point in section 1.2 of the full Sector Inquiry.

Executive summary

A brief overview and summary of the main aspects of the subject and the conclusions reached are given below.

The Sector Inquiry begins by outlining the current situation with regard to the supply of medicines in Austria. Shortages of medicines increased twentyfold in the European Union between 2000 and 2018.² As of 1 December 2020, 415 medicines were listed in the Medicine Shortages Catalogue of the Austrian Federal Office for Safety in Health Care.³ About 85 % of these products were recorded as out of stock or only partially available on this date. The reasons for the unavailability of medicines reported to the BASG included, above all, supply-side issues such as capacity bottlenecks, delays in production and shortfalls of active ingredients. One demand-side issue that also played a significant role was a high level of additional demand. The vast majority (more than 98 %) of the medicines affected by shortages are only available on prescription. Furthermore, most of the medicines in question (just under 70 %) are listed in the Reimbursement Codex (EKO) of the Austrian Federation of Social Insurances. It may therefore be assumed that follow-on products, generics in particular, tend to be hit worse by shortages. As far as their areas of application were concerned, it was medicines for the treatment of the nervous and cardiovascular systems that were affected above all.

Particular attention is paid to selected regulatory framework conditions relevant for the supply of medicines. Several national sources of law mention the supply of medicines as a matter for regulation. Recently, in particular, further legal policy action has been taken with the Ordinance of the Federal Minister of Social Affairs, Health, Care and Consumer Protection on Ensuring the Medicines Supply. In part, however, these sources of law are based on different definitions of key concepts and regulate different fields of activity. Against this background, it would be expedient from a competition perspective to make this patchwork of apparently similar provisions more substantively coherent and eliminate the contradictions between them.

European sources of law also play an important role in the medicines field. The framework conditions for placing medicines on the market are regulated with a very great deal of detail, at the level of the

² European Parliament, 16 July 2020 and 17 September 2020, “Medicine shortages in the EU: causes and solutions”, <https://www.europarl.europa.eu/news/en/headlines/society/20200709STO83006/medicine-shortages-in-the-eu-causes-and-solutions>.

³ BASG, Medicine Shortages Catalogue, https://medicineshortage.basg.gv.at/vertriebseinschraenkungen/faces/adf.task-flow?_afPfm=main-btf&_afPfm=document=WEB-INF/main-btf.xml&_afPfm=afrLoop=999432201580649&_afPfm=afrWindowMode=0&_afPfm=afrWindowId=null.

manufacturers for instance, in various EU directives that are intended to be transposed by the Member States. Their transposition in other Member States and third countries shows that, from a competition perspective, predictability could be increased by longer lead times. The relatively high degree of regulation in the medicines field in general could ultimately prevent shortages of medicines being dealt with adequately, at least in the short term.

The legal framework conditions for the pricing of medicines in Austria constitute one significant aspect of the matter. Apart from this, the treatment of selected issues in German, Swiss, Danish and Italian law is also compared. Both parallel trading, which is protected in principle by the free movement of goods under European law, and the allocation of quotas of medicines are connected with pricing as well. Against the background of the free movement of goods, but also from a cartel law perspective, there are limits on the extent to which parallel trading can be restricted. With regard to security of supply and parallel trading, it may be asked from a legal policy point of view whether particular medicines are, or are to be, a good like any other.

The provisions of the Austrian Pharmacy Act concerning the ownership of pharmacies are also analysed against the background of the shares held by medicine wholesalers in community pharmacies.

When producers allocate quotas of medicines, the level of demand should be calculated on the basis of a representative reference period, and the approach taken explained in a transparent manner to their immediate customers, within the bounds of what is permissible under cartel law.

In summary, it is concluded that, from a competition perspective, the (legal policy) arrangements that are in place need to be optimised in certain respects. Transparency, and the predictability and security of medicine supplies could be improved in the interests of all concerned by making judicious adjustments.

Furthermore, market developments relating to the supply of medicines and possible causes of medicine shortages are discussed. There may be numerous reasons for such shortages, including production problems, complex logistical and distribution requirements, regulatory demands or fluctuations on the demand side.⁴ The section that deals with this topic focusses on competition economics aspects of the factors that cause shortages, considering in particular market concentration (among both active ingredient producers and final product manufacturers), medicine wholesalers and the shares they hold in community pharmacies, and the pricing situation, especially as it relates to parallel exports.

⁴ Institute for Advanced Studies, "Lieferengpässe bei Arzneimitteln – Ein globales Problem mit nationalen Folgen", 377, <https://www.sozialversicherung.at/cdscontent/load?contentid=10008.728008&version=1575388512>.

In comparison to other research-intensive industries, such as the chemicals and automotive industries, the pharmaceuticals sector is relatively weakly concentrated, as measured by its concentration rate, because there is a large number of major pharmaceuticals companies (big pharma) who control similar shares of the entire sector. However, particular segments are likely to be far more strongly concentrated. Moreover, a significant consolidation process has taken place in the pharmaceuticals industry recently as a result of merger activity. If the figures are looked at over the last 30 years, the number of undertakings, which was originally 110, has shrunk to about 30. This represents a 70 % reduction. On account of the increasing amounts invested in mergers and takeovers during the last few years, it is to be assumed that this trend will have intensified even further of late. In particular, there has been a geographical concentration of production at the level of the active ingredient producers as well, especially in China and India. The profit margins in the pharmaceuticals industry are also very high in comparison to the research-intensive software industry, which could be indicative of a certain degree of market or pricing power.

In the field of medicine wholesaling, increasing vertical integration between the medicine wholesalers and community pharmacies has been observed in Austria since 2013. The shareholdings in community pharmacies owned by medicine wholesalers (including related undertakings) have increased continuously and relatively rapidly in Austria since 2013. Between 2013 and 2020, the average number of pharmacies in which medicine wholesalers held shares grew from about twenty-one to approximately thirty-three, going up by just under 50 %. These increasing shareholdings could prompt misgivings from the perspective of competition economics. Firstly, they enable the medicine wholesalers to exert influence over community pharmacies' turnover and prices. Secondly, the community pharmacies' ordering patterns might alter permanently as a result, strengthening the medicine wholesalers' positions in terms of their market shares, and having an impact on the breadth and depth of the range of products on sale.

The analysis of the price situation showed that, on average, the prices in the higher-priced segment in Austria are not among the lowest in Europe. However, it is not ruled out that the prices of particular medicines or in particular areas of the medicine market are nonetheless very low compared to those elsewhere in Europe as well. When the data gathered from medicine wholesalers who had been requested to provide information were analysed, it was found prices were higher on average in the countries to which medicines are exported than those that can be charged in Austria. It is evident from the available data, however, that price differences alone are not enough to conclusively explain the volumes of parallel exports. Generally, raising prices is not a measure that is to be recommended as a means to improve the medicine supply situation by reducing parallel trading. However, it would be possible to consider adjusting wholesale and/or pharmacy margins.

Competition recommendations

- Action to limit the maximum permissible stakes medicine wholesalers are able to own in community pharmacies.
- Evaluation of the price components of medicines, in particular the statutory mark-ups (wholesale and pharmacy mark-ups).
- Apart from classic competitiveness policy measures, such as accelerating the introduction of e-health applications and digitalisation or improving medicines infrastructure, other measures of this kind should be taken as well, such as the creation of financial incentives that are compatible with European law. For example, the health insurance funds could reimburse the costs of medicines or active ingredients that have demonstrably been produced in the European Union. Good manufacturing practice (GMP) conformity, ecology and fair working conditions should be among the factors taken into consideration if this approach is pursued.
- The drafting of a transparent catalogue of criteria for indispensable medicines or active ingredients, whose production in the European Union should be particularly focussed on when incentives are set as part of competitiveness policy.
- As a matter of principle, dependence on individual suppliers should be reduced and purchasing processes expanded to involve multiple suppliers (including suppliers outside the European Union). Ultimately, more competition in this field will result in greater security of supply. An evaluation of the effectiveness of Section 9 para. 4 Federal Cartel Act (KartG), which was adopted specifically to protect innovation potential and innovation-based competition when start-up businesses are taken over, may offer support for more ambitious legal policy ideas.
- Better coordination and harmonisation of the parallel export rules in the EU's Member States, for instance with regard to reference periods, the groups to which the rules apply etc.
- Amendments to the legislation, for instance an expansion of the group of those entitled to notify the BASG of medicine shortages under the Ordinance on Ensuring the Medicines Supply, the simplification of the Falsified Medicines Directive (FMD) and the harmonisation of the criteria for certification.
- Steps to ensure producers are more transparent when setting country-specific medicine quotas, and do so on the basis of a catalogue of criteria.
- A continuing focus on current initiatives concerned with the supply of medicines, such as those taken by various task forces at the national and European levels.

Austrian Federal Competition Authority

Radetzkystraße 2, 1030 Vienna

+43 1 245 08 - 0

wettbewerb@bwb.gv.at

bwb.gv.at