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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Germany

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-- Germany--

1. Introduction

1. Health expenditures have been rising worldwide in the last decades, putting a strain on health care and health insurance systems. Governments and legislators all over the world have considered and introduced measures to curb health care expenditure, including expenditure on pharmaceuticals whilst securing appropriate care for citizens and maintaining the beneficial effects of competition as much as possible.

2. This contribution provides an overview over the general market for pharmaceuticals in Germany (2.) and the distribution system of pharmaceuticals (in particular: prescription-only- medicine) (3.). This is followed by a discussion of the most important regulations concerning quality control and curbing expenditures (4.). In the following section (5.) a description of selected cases by the Bundeskartellamt shows the relevance of competition law enforcement even in a highly regulated environment. The contribution ends with some concluding remarks (6.).

2. The market for pharmaceuticals

3. In 2012, the market volume for pharmaceuticals in Germany was roughly € 39 billion measured in end-consumer prices, the vast majority of which were prescription-only pharmaceuticals (around 80%).¹ The distribution of pharmaceuticals is done mainly through the roughly 21.000 pharmacies, which relate to one pharmacy per 3.900 citizens on average.² Approximately 900 companies are registered in Germany as being active in the pharmaceutical industry, i.e. producers of licensed pharmaceutical products, amongst them Bayer (probably best known for its invention of Aspirin). These companies spend up to 15 % of their annual turnover on internal research and development (R&D).³

4. The market for pharmaceutical products is quite complex and there are several ways to subcategorize the relevant products. One subdivision can be done by looking at access to pharmaceuticals. Some products are admitted for sale only by pharmacies, others can be sold in pharmacies and other stores, such as drugstores. Those pharmaceuticals that are restricted to pharmacies can be further divided into those that need a prescription by a doctor (prescription only medicine, POM) and those that do not (over-the-counter pharmaceuticals, OTCs). POMs account for the large majority of turnover generated with pharmaceuticals in Germany. In Germany, health insurance is compulsory and over 80% of the population are insured in the statutory health insurance (SHI, *gesetzliche Krankenversicherung*), which usually covers only POMs). As a consequence, roughly 80% of health expenditure on pharmaceuticals is therefore borne

¹ See German Pharmacies – Figures Data Facts 2012, available at http://www.abda.de/fileadmin/assets/ZDF/ZDF_2012/ABDA_ZDF_2012_Brosch_engl.pdf

² See German Pharmacies – Figures Data Facts 2012. This figure relates to a relatively high population density in Germany.

³ See German Pharmacies – Figures Data Facts 2012.

by the SHI and the rest by private health insurance funds, private individuals, employers and others. Therefore, most regulations concerning the distribution of pharmaceuticals relate to POMs and their coverage by the SHI. These are described below.

3. The Distribution of Prescription-Only Medicine

5. POMs can be distributed using different distribution channels. In Germany, hospitals dispensing medicine to their inpatients usually purchase the products directly from the producers, partially also through hospital pharmacies. But the vast majority (measured in expenditure) of pharmaceuticals in general and POMs in particular are distributed through pharmacies. Pharmacies are generally supplied by wholesalers and only occasionally also by the producers directly. This also applies to online pharmacies, which are allowed since 2004, but are subject to the same legal rules that apply to brick-and-mortar pharmacies, when based in Germany. Pharmacies selling medication online need a permission granted by public authorities.

6. There are different categories of POMs, depending on their features and how they relate to each other. There are patent-protected original pharmaceuticals and patent-free generics containing the same active ingredient (generics), which can be produced once the patent-protection on the active ingredient has ended. Some degree of competitive pressure on patent-protected originals can arise also from pharmaceuticals containing different active ingredients but having the same effects (pharmacological equivalent), pharmaceuticals achieving a comparable therapeutic result (therapeutic equivalent) as well as through parallel imports of the originals.⁴

7. Producers of pharmaceutical products are generally free to set their ex-factory prices not only for generics but also for POMs. The final retail price is calculated by adding fixed regulated maximum amounts of wholesale and pharmacy surcharges. Distributors like wholesalers and pharmacies are reimbursed with a fixed premium per package and regulated maximum surcharges on the ex-factory prices, which are regulated as specific percentages of the ex-factory price on a decreasing scale. These regulated maximum surcharges determine the retail prices, thereby securing homogenous prices for a specific drug across pharmacies. The fact, that these surcharges are regulated on a decreasing scale reduces the incentives for the distribution of expensive pharmaceuticals by pharmacists. Competition on the wholesale focuses on quality aspects of delivery services, but wholesalers can also grant pharmacies a rebate on their (regulated maximum) surcharge, which exerts competitive pressure at the wholesale level. Pharmacies, however, cannot enter into price competition and reduce the final retail prices of POMs for the end-consumer.

⁴ Parallel imported pharmaceuticals are products where a third party company, independent of the original marketing authorisation holder or manufacturer, purchases the pharmaceuticals in another Member State of the EU or EEA and imports them to Germany - parallel to the original pharmaceutical entrepreneur selling the products in Germany. Thereby, price differences between Member States can be taken advantage of. Medicinal products that are licensed and marketed outside the EU or EEA cannot be imported in parallel.

4. Regulation⁵

8. As shown by the data concerning the market features described above, the vast majority of pharmaceuticals traded in Germany are POMs, meaning patients are prescribed a certain medication by their doctor and hand in the prescription at the pharmacy. Given that the vast majority of citizens are insured in the SHI, the rules and regulations concerning the interplay between SHI and the pharmaceuticals industry (producers and distributors) have the largest influence on overall health expenditure on pharmaceuticals. This contribution consequently focuses on regulations influencing the distribution of POMs covered by the SHI.

9. Overall, the demand for POMs tends to be price inelastic. In view of the mandatory health insurance in Germany, the patient receiving the POM does not (directly) bear the expense. It is the health insurances that have to bear the costs. Therefore, the patient may have little incentive to demand a lower-cost substitute (moral-hazard problem)⁶. A number of different, sometimes overlapping, regulations have been enacted to remedy this and other adverse effects. This contribution concentrates on describing the main long-term regulations. In principal, they aim at steering demand towards less costly substitutes, limiting the potential for producers to abuse monopoly positions granted by patents as well as maintaining incentives for innovation whilst providing incentives for investment into real "breakthrough" innovations as opposed to "me-too" innovations.⁷ At the same time, a sufficient level of quality of pharmaceutical products and their distribution to patients has to be insured.

4.1 Quality Control

10. The control of the quality of pharmaceuticals is regulated in several different ways, the most important ones being the obligation to obtain a licence for a new product and several quality assessment measures.

11. In general, pharmaceuticals can only be marketed in Germany once they are licensed. In the EU, there are different possibilities to obtain such a licence. A national licence procedure in Germany is sufficient if the pharmaceutical product is exclusively intended for marketing in Germany. In the course of the licensing procedure the competent authority evaluates whether a pharmaceutical product is effective, safe and achieves a certain pharmaceutical quality. This process secures a minimum standard of quality of

⁵ There are a number of regulations influencing the systems described. Some of the most relevant national laws are the German Social Code, Book Five (SGB V); the Medicinal Products Act (AMG); the Regulation on the Prices on Medicine (AmPreisV); the Law on Pharmacies (ApoG). Some of the most relevant national Acts amending relevant laws include the Act for Sustainable and Socially Balanced Financing of Statutory Health Insurance (AMNOG); the Law securing contribution rates (Beitragssicherungsgesetz, BSSichG); the Health System Modernisation Act (GMG); the Act on the Advancement of Organizational Structures in Statutory Health Insurance Funds (GKV OrgWG) and the German Economic Optimization of Pharmaceutical Care Act (AVWG).

⁶ The term „moral hazard“ originates from the insurance sector and in economic theory describes situations where one party will have the incentive to act less carefully because the potential consequences (resulting costs) will be (partly or in total) borne by another party.

⁷ „Me-too“ or „follow-on“ innovations relate to such (patent-protected) innovations that are only minor variations of already established products and have no or marginal therapeutic improvement, as opposed to „breakthrough“ innovations. The former have been reported particularly as a means to circumvent strict price regulation or to prolong patent-protection (see OECD DEELSA/ELSA/WD(2000)1).

pharmaceutical products. A license can also be applied for under the Decentralised Procedure (DCP) to achieve marketing authorisation for several EU countries at the same time.⁸

12. In addition to other institutions that conduct assessments of the quality and effects of pharmaceutical products, in particular the Federal Joint Committee (G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany⁹, and the Institute for Quality and Efficiency in Health Care (IQWiG), a German organisation responsible for assessing the quality and efficiency of medical treatments,¹⁰ are tasked with conducting benefit assessments of pharmaceuticals, especially for new drugs with new active ingredients. The results of these assessments are published and also have relevance with regard to price setting and SHI decisions and/or negotiations with producers on which pharmaceuticals are to be reimbursed and how much the health insurers will reimburse (see below).

13. However, not only the quality of pharmaceutical products themselves is ensured by regulation. Naturally, prescribing doctors also have to fulfil a number of criteria to be allowed to practise and treat patients and wholesalers of pharmaceuticals need to be licensed by the relevant authorities. Similarly, pharmacies are subject to a number of quality assuring regulations. In Germany, only pharmacists may operate a pharmacy, with a view to guarantee the proper supply of the population with pharmaceuticals. The additional ban on third-party and multiple ownership as well as limiting each pharmacy to not more than 4 stores stresses the personal responsibility and liability of self-employed pharmacists in the healthcare sector.¹¹ However, that does not hinder pharmacies from introducing new and efficient business models, such as franchising, which has been implemented in Germany.

4.2 Curbing Health Expenditure

14. Health expenditures have been rising for a long time. The large majority of expenditure is on POMs and borne by the statutory health insurance. Therefore, a number of regulations have been introduced with the aim to influence expenditure and price setting, whilst avoiding a chilling of beneficial competition and innovation. The most important regulations are the German Reference Pricing System and the possibility of Rebate Contracts.

4.2.1 German Reference Pricing System

15. Germany already introduced its Reference Pricing System¹² in 1989, as the first country to do so. Since then, a large number of countries have introduced similar systems (including the majority of

⁸ For an EU wide licence, an application has to be made to the European Commission for the Centralised Licensing Procedure. In order to gain marketing authorisation for several EU countries at the same time, the pharmaceutical entrepreneur must initiate a so-called Decentralised Procedure (DCP) in one selected Member State or submit an application for Mutual Recognition (MRP). For more information on all possible procedures see http://www.bfarm.de/EN/Drugs/licensing/zulassungsverfahren/_node.html

⁹ The Federal Joint Committee (G-BA) issues directives for the benefit catalogue of the statutory health insurance funds for more than 70 million insured persons and thus specifies which services in medical care are reimbursed by the SHI. For more information see <http://www.english.g-ba.de/>

¹⁰ For more information see <https://www.iqwig.de/>

¹¹ Regulations concerning pharmacies were subject to review by the European Court of Justice and found not to infringe European Law. See ECJ, joint cases C-171/07 and C-172/07.

¹² „Reference Pricing“ refers to a policy strategy that sets a standard price or reimbursement by insurances for a group of interchangeable therapeutic pharmaceuticals. This system is sometimes also called „maximum allowable cost program“.

European Member States) or are discussing their implementation as a cost-containment measure (for example the USA).¹³

16. The system works in principle as follows. The SHI, bearing the vast majority of health expenditure on POMs, does not automatically reimburse its insurees for the final retail price. It only reimburses prices based on the so-called reference prices (described in detail below) set by the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)¹⁴. Any difference between the reimbursable price set by the SHI and the actual retail price has to be borne by the patient, in addition to a general co-payment to be made by patients.¹⁵ These payments made by patients themselves allow for some degree of price competition above the price level reimbursed by the SHI and introduce a certain price-sensitivity of patients in general.

17. Establishing the relevant reference prices is achieved basically by clustering those pharmaceuticals, where a sufficient number of substitutes exist, according to active ingredients into one therapeutic market (pharmaceutical group) per active ingredient and setting a maximum price per cluster which is reimbursable by the SHI. The reference price is established in such a way that within each pharmaceutical group a sufficient number of drugs remain reimbursable. This ensures that there is a certain degree of choice and sufficient availability of drugs for the selected reference price. Within a pharmaceutical group, the reference price usually tends towards the lowest prices for the pharmaceuticals in the pharmaceutical group.

18. Originally only applied to generics, the reference price system now also covers pharmacological equivalent products, therapeutic equivalent active ingredients and, since 2011, also some new patent-protected originals. Until the introduction of the Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011, prices for new patent-protected drugs were unregulated. Now, the assessment of the added value of the new drug by the G-BA and IQWiG form the basis of decisions on the prices that statutory health insurance providers pay for new pharmaceuticals. If the assessment finds no added value, the reference pricing, setting a maximum reimbursement, applies. Otherwise, the health insurance and producer will negotiate a reimbursement price for the new drug.

4.2.2 *Rebate Contracts*

19. Apart from the reference pricing system, insurance companies and producers of pharmaceuticals can negotiate rebate contracts, offering a discount on specific pharmaceuticals manufactured by the contracting producer to the contracting health insurance. In return, the patients will in general only receive the prescribed active ingredient in drugs supplied by the contract partners, i.e. the producer retains (partial) exclusivity and can expect larger volumes of sales.

20. The possibility of such rebate contracts between insurance companies and producers of pharmaceuticals was first introduced in 2003. It had significant impact, however, only after 2007, when another legal reform made it possible to grant exclusivity to the producers of pharmaceuticals in the rebate contracts in return for the rebates granted to the insurance funds. Since then pharmacies are obliged to exchange a prescribed medicine with the substitute containing the same active ingredient that is the subject of a rebate contract between the insurance company of the patient handing in the prescription and the

¹³ See Joy Li-Yueh Lee et al, A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending, *The American Journal of Managed Care* 18 (11), 2012.

¹⁴ <http://www.gkv-spitzenverband.de/>

¹⁵ Patients have to pay 10% of the price themselves (minimum of € 5, maximum of € 10), unless the price is 30% below the reference price set by the SHI.

producer of the substitute. Patients can still decide to take the pharmaceutical originally prescribed to them, but then they would have to pay for the medicine themselves and only receive reimbursement from their insurance for the amount specified in the rebate contract for the substitute supplied by the contracting producer. Until 2009, the rebate contracts could cover the whole production range of one producer of pharmaceuticals. Since then, however, the rebate contracts can only relate to particular active ingredients, but include different pharmaceuticals with that ingredient and different package sizes.

21. These rebate contracts are subject to public procurement law when the contracted volumes reach the legal thresholds for the application of procurement law. In these cases, the tender procedures can be reviewed by the Bundeskartellamt's public procurement divisions and by courts. The vast majority of the tenders so far related to generics and in 2013, the public procurement divisions of the Bundeskartellamt reviewed nine tender procedures.

5. Examples of cases

22. The Bundeskartellamt has concluded a number of cases in the pharmaceutical industry. These involved merger control but also horizontal and vertical restraints of competition. The following examples are presented in chronological order.

5.1 *Sanacorp/ANZAG - Merger on the wholesale-level*

23. In 2001 the Bundeskartellamt prohibited the concentration plans of Sanacorp e.G. Pharmazeutische Grosshandlung, an amalgamation of individual pharmacists and pharmaceutical wholesaler, to acquire a majority holding in another pharmaceutical wholesaler, Andreae-Noris Zahn AG (ANZAG).

24. Apart from Sanacorp e.G. and ANZAG, several other suppliers were active at the cross-regional level of the German market. In addition, pharmacies were supplied by twelve pharmaceutical wholesalers which were exclusively active at regional level. As the joint company would have gained a dominant position in at least three German regions, the Bundeskartellamt had prohibited this merger project. The court of appeal, the Düsseldorf Higher Regional Court, revoked the prohibition decision. Upon the Bundeskartellamt's appeal on points of law the Federal Court of Justice revoked that decision and referred the case back to the Higher Regional Court which ultimately confirmed the Bundeskartellamt's prohibition. Controversial issues in this case were in particular the definition of the relevant geographic markets and the assessment of the competitive constraints by alternative suppliers.

25. In 2001, electronic ordering systems were used by which pharmacies placed their orders and were informed immediately on when to expect delivery of the products. This gave pharmacists in principle the option to switch to another wholesaler easily and without costs and pharmacies were usually supplied by several wholesalers. In view of the sophisticated ordering and delivery system used by pharmaceutical wholesalers, pharmacists expected to receive the products they ordered at least twice a day or even more frequently depending on the pharmacy's location, so that guaranteed frequency and reliability of delivery were the essential prerequisite for placing an order with any pharmaceutical wholesaler. If this prerequisite, which was taken for granted by the pharmacists, was equally fulfilled by all suppliers, price was the decisive factor in their choice of wholesaler. As final customer prices could not be changed, the prices were determined by rebates and payment conditions offered by the pharmaceutical wholesalers on the basis of the margins they were granted by the manufacturers, based on uniform sales prices. The switching opportunities between different wholesalers were however limited by their actual geographic market presence, necessary for delivery. In its second ruling the Higher Regional Court concluded on that basis that in the three geographic markets concerned the transaction would indeed lead to the creation of a dominant position by the parties.

5.2 *Fines against several associations and manufacturers for trying to bypass newly introduced price competition for OTCs*

26. In January 2008 the Bundeskartellamt imposed fines on several pharmacist associations and pharmaceutical manufacturers for asking pharmacists to observe the non-binding price recommendations of manufacturers.

27. Since the legal reform of 2004, pharmacies had been free to set their own prices for OTC pharmaceuticals (unless, in exceptional cases, costs are reimbursed by health insurance funds). In late 2003 the Federal Association of Pharmaceutical Manufacturers and nine regional pharmacy associations hosted several events at which pharmacies in different German cities were asked to refrain from price competition and to observe the non-binding price recommendations of the pharmaceutical manufacturers. The Bundeskartellamt found that the decisions of the regional pharmacy associations to hold these events in their respective federal states violated the prohibition of cartels. The Bundeskartellamt regarded the decision of the Federal Association of Pharmaceutical Manufacturers to support these events and provide speakers from its member companies as an indication of the association's participation in the infringement. However, since considerable time had passed between the association's actions and the conclusion of the proceedings and the effects on the market were relatively insignificant, the Bundeskartellamt imposed rather low fines, which have since become final.

5.3 *Fines on pharmaceutical distributor*

28. In May 2008 the Bundeskartellamt imposed a fine totalling € 10.34 million on Bayer Vital GmbH, the German pharmaceuticals distributor of Bayer group. Bayer Vital had influenced in an anticompetitive manner the resale prices of non-prescription medicines sold in pharmacies. Bayer Vital concluded target agreements in which pharmacies were promised an additional discount for “positioning Bayer products as premium products”. To obtain this “partnership bonus” the pharmacies had to essentially observe Bayer Vital’s non-binding price recommendation; time-limited price campaigns were tolerated, but not permanently low prices. In the Bundeskartellamt’s view those pharmacists who concluded such target agreements with Bayer Vital have also committed an administrative offence. However, as this was a minor accusation applying to each individual pharmacist, no prosecution proceedings have been brought against them.

5.4 *Joint venture of online pharmacies Medco and Celesio (Europaapotheek/DocMorris)*

29. In July 2010 the Bundeskartellamt cleared in first phase proceedings a joint venture between the US health service provider Medco Health Solutions, Inc. ("Medco") and Celesio AG ("Celesio") which was then mainly active in the pharmaceutical wholesale sector. The companies intended to merge their respective online pharmacies into the new joint venture. Medco (Europa Apotheek Venlo) and Celesio (Apotheek DocMorris) each operated an online pharmacy in the Netherlands.

30. In view of the overlaps in the online supply of pharmaceuticals for human use, the Bundeskartellamt conducted a market survey and questioned online pharmacies in Germany and the Netherlands, health insurance funds, private health insurance companies and associations.

31. The market investigations provided clear indications that the full-line retail market for prescription-only medicine would form a separate product market. However, the product market definition - as well as the geographic market definition - could finally be left open because the market did not have to be further differentiated according to the channels of distribution.

32. The merger therefore resulted in a combined market share of below five per cent in the retail sale of prescription-only medicines, whereby the parties faced competitive pressure from the many brick-and-

mortar pharmacies (some of them organised in purchasing co-operations). In addition, there were still strong competitors in the online pharmacy segment. Prior to the merger EuropaApotheek had already acquired the online pharmacy of the German pharmacy Fortuna-Apotheke. This merger project had also been cleared in preliminary examination proceedings in view of strong competition. In November 2012 Celesio sold DocMorris to the Swiss online pharmacy "Zur Rose". The Bundeskartellamt cleared this sale in preliminary examination proceedings.

5.5 *Other cases*

33. The Bundeskartellamt has also investigated other cases which, however, did not result in fines. For example, one investigation concerned pharmacies in a particular region that agreed upon prices for specific products and joint advertisement for these products, when a discount-pharmacy was trying to enter that regional market. Due to the regional market definition for pharmacies, the regional competition authorities are usually the competent authority and the Bundeskartellamt is only competent when the conduct affects more than one federal state (Bundesland). However, the Bundeskartellamt published general principles governing the approach to joint price marketing by pharmacies („Grundsätze über die Ausübung des Aufgreifermessens in Bezug auf die gemeinsame Preiswerbung von Apotheken“) in its annual report 2007/2008. Another investigation concerned a call by pharmacists associations to boycott a particular wholesaler that was acquired by a company also active as an online pharmacy.

6. **Conclusion**

34. Empirical research conducted for Germany and also for many other countries suggests that the introduction of a reference price system is an effective tool to reduce prices for pharmaceuticals and encourage switching behaviour from expensive drugs to lower priced alternatives.¹⁶ Rebate contracts between health insurers and producers of pharmaceuticals have shown to be another tool to introduce at least some level of competition in this highly regulated area.

35. While the health sector has many specific features so that governments and legislators may need to establish stronger and narrower boundaries than in other markets it should be all the more important to protect competition where it exists within these boundaries and to introduce the benefits of competition, such as lower prices, incentives to innovation and larger variety wherever this is feasible.

¹⁶

See for example Lee et al.: „A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending“, American J. of Managed Care 18 (4), 2012. Herr/Suppliet: „Co-Payment Exemptions and Reference Prices: an Empirical Study of Pharmaceutical Prices in Germany“ 2011, available at: http://www.york.ac.uk/media/economics/documents/herc/wp/11_18.pdf