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# ENHANCING BENEFICIAL COMPETITION IN THE HEALTH PROFESSIONS

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**English/French**

# GERMANY

## 1. Introduction

The scoping paper suggests that if responses were provided for every health profession, the submissions could result in a huge amount of information. This submission therefore focuses as suggested on one single health profession. The pharmacist profession as a key player in the pharmaceutical distribution process is chosen because this is an area which is less regulated when compared to other health professions and thus the scope for antitrust enforcement may be broader than in other health professions.

## 2. Structure of pharmaceutical distribution

Before finished medicinal products may be marketed in Germany, they must undergo an authorisation process under the German Drug Law ("Arzneimittelgesetz"). In the course of the licensing procedures the efficacy, safety and adequate pharmaceutical quality of the finished medicinal products are reviewed. The vast majority of medicines can only be sold in a pharmacy or by a pharmacy through mail-order (Sections 43-45 Drug Law, "pharmacy-only medicines"). Many medicines may only be sold under prescription by a physician (Sections 48-49 Drug Law, "prescription-only medicines"). By 2002, about 48.700 medicinal products were cleared for marketing in Germany, which is estimated to be by far the highest number worldwide.

Pharmaceuticals are largely distributed in three stages: Pharmaceutical industry – pharmaceutical wholesalers – pharmacies – end customer. As in most countries, the pharmaceutical wholesale business is highly concentrated. The top three companies share more than two thirds of the total German pharmaceutical wholesale turnover and dominant market positions exist in several regions. In contrast, the pharmaceutical retail sector is highly fragmented due to the so-called "prohibition of ownership of multiple pharmacies" which was codified in the Law on Pharmacies ("Apothekenwesengesetz", LoP) and was slightly relaxed as of 1 January 2004. Even under the new LoP, pharmacies may not be run by limited liability companies (Section 8 LoP) but each pharmacist may now own up to four pharmacies (Sections 1 and 2 LoP). In 2001 there were about 21.590 pharmacies which were not affiliated to a hospital (so-called 'public' pharmacies). This number reflects a very high density of pharmacies with approximately one pharmacy per 3800 residents. In 2001 roughly 86% of medicines were sold through public pharmacies and the remaining 14% through hospital pharmacies. The public pharmacies' turnover in medicines amounted to approx. 31.8 bn Euro, of which 23.5 bn Euro were prescription-only medicines, 7.8 bn Euro non-prescription but pharmacy-only medicines and 0.5 bn Euro freely available medicines. According to a study undertaken by the Austrian Health Institute in 2001, the German gross distribution margins are very high when compared to other European countries which could indicate a relative inefficiency of the German distribution system.

## 3. German health insurance system and insurants' co-payments for medicines

A distinctive feature of the German health insurance system is the duality of private health insurance (PHI) and so-called statutory health insurance (SHI), which is a compulsory public health insurance. Basically all German residents have either a PHI or an SHI. Up to a certain income level (currently 3.862,50 Euro per month) all employees have to be a member of one of the more than 320 SHI funds. Only freelancers, civil servants or employees with an income above the threshold quoted above may quit the SHI and select a PHI. Currently, about 89% of German residents are members of the SHI funds and 9% are with a PHI. Employees and employers each pay 50% of the SHI contributions. The level of contributions

differs significantly according to SHI fund and in January 2004 amounted on average to 14,3% of gross salaried income. In recent years, competition for insurants has developed between the SHI funds because since 1996 insurants can chose into which fund they want to pay. Family members of the insurant who are not gainfully employed do not pay additional contributions, they are covered by the SHI fund of the insurant. When compared to the PHI, the result of this contribution structure in the SHI is a redistribution effect between all insurants. The beneficiaries are families and low-income households as well as the aged and sick.

Whether PHI patients have to pay for their medicines depends largely on their respective contract. In most PHI contracts, the insurants receive full (100%) reimbursement of the costs for all medicaments which they have purchased with a prescription from a doctor, even if those medicines could also be purchased without prescription. As a general rule, medicines purchased without prescription are not refunded by the PHI.

The SHI pays solely for prescription-only medicaments (some exceptions apply). For some groups of medicines, reference prices are set for therapeutic applications. The SHI pays only up to this reference price. Where the medicament price exceeds this limit, the insurants have to pay the difference. Irrespective of the reference price system, the insurant co-payments for SHI patients amount to 10% of the medicament's price, but at least 5 Euro and not more than 10 Euro per medicament. Persons under the age of 18 do not have to make any co-payments. The maximum limit of insurant co-payments is 2% of the yearly (gross) income and 1% for chronically ill patients.

## 4. Entry barriers for pharmacists and pharmacies

The conditions for operating a pharmacy are set out in the Law on Pharmacies (LoP). Anyone whishing to run a pharmacy needs a permit from the local health authority (Section 1 LoP). Only pharmacists who have a state-approved pharmaceutical diploma are entitled to a permit to run a pharmacy (Section 2 LoP). Apart from the German pharmaceutical diploma, the equivalent diplomas of the other EU and EEA member countries are also accepted without the need for specific accreditation. If the applicant holds the required diploma and meets the other requirements of Section 2 LoP, the local authority must grant the permit. Unlike in many other countries, no "demand" or "market" aspect is examined before granting the permit, hence there are no administrative restrictions as regards the specific location of new pharmacies or the total number of pharmacies.

The most important entry barrier is the restrictions on ownership of pharmacies. Pharmacies may not be run by limited liability companies (Section 8 LoP), with the exception of hospital pharmacies (Section 14 LoP). As a consequence, pharmacists who intend to open a new pharmacy have limited options to raise the required capital: They cannot raise equity from third parties like other entrepreneurs and must rely exclusively on bank loans. A pharmacist may own up to four pharmacies, all of which need to be located in the same district or in neighbouring districts (Sections 1 and 2 LoP). Where a pharmacist operates more than one pharmacy, he or she needs to nominate responsible pharmacists as managers for each of the additional pharmacies. These provisions prevent pharmacy chains (with more than four pharmacies) as well vertical integration between pharmacies and wholesalers or medicine suppliers.

## 5. Regulation on pharmaceutical prices and selection

In principle, pharmaceutical companies are not subject to restrictions as regards the setting of prices. In a situation where end users receive (full) reimbursement from their health insurance, the suppliers do not need to consider them when setting their prices. However, the suppliers' pricing strategies are constrained by several price and selection regulations for the SHI which are incorporated in the Fifth Book of the Code

of Social Law (CSL V). It is important to note that these regulations apply only to the medicines paid for by the SHI.

The most important constraint are the so-called reference prices for therapeutic applications which were introduced in 1989. Various organisations within the SHI system form the so-called Joint Federal Committee (JFC, Section 91 CSL V). The JFC classifies different medicines which contain the same or similarly active ingredients under one reference price group (Section 35 CSL V). In the next step, the SHI funds' associations set a uniform reference price for those groups. For medicines included in one of the reference price groups, the SHI funds pay only up to the reference price assigned to this group (Section 31 (2) CSL V). Where the price of the medicine exceeds this limit, the insurants have to pay the difference. This creates a strong incentive for pharmaceutical companies not to set their prices above the reference price. The incentive is reinforced by an obligation on the part of doctors to inform their patients about the additional payments when prescribing a medicine priced above the reference price and by an obligation on the part of the pharmacies to provide the patient with low-priced medicines. However, the reference price system is susceptible to strategies of the pharmaceutical industry to avoid having their medicines categorised in a reference price group, e.g. by filing so-called "pseudo patents" or "iterative patents". While in 1997 reference prices applied to approx. 60% of the medicines paid for by the SHI, in 2002 this proportion had dropped to 37%. With the recent SHI reform, this figure is expected to rise significantly during 2004.

Another (however much weaker) constraint on pharmaceutical suppliers are the general antitrust rules against excessive pricing. Article 82 EC-Treaty and Section 19 of the Act against Restraints of Competition (ARC) ban excessive pricing by market dominant undertakings.

The pharmaceutical wholesale margins and the pharmacy margins are regulated by the Pharmaceutical Price Ordinance (Arzneimittelpreisverordnung, PPO). The PPO sets fixed upper limits for the gross margins of prescription-only medicines sold in pharmacies. The PPO has resulted in uniform prices of prescription-only medicines at retail level.

## 6. Mail-order distribution of medicines

The extent to which the mail-order distribution of medicines was allowed or not under national and European law was controversially discussed in a series of legal disputes. Also due to the legal uncertainty, mail-order had not become a significant distribution channel in Germany, as opposed to other countries. After a decision of the European Court of Justice (ECJ) and the recent amendment to the LoP as of 1 January 2004, it has now been clarified that nearly all medicines can be distributed by mail order.

The LoP sets the conditions under which medicines can be ordered by mail. According to Section 11a LoP only pharmacies with a stationary outlet may distribute by mail-order. When delivering via mail pharmacies must set up a quality assurance system which includes inter alia safeguards ensuring that the medicines are well packaged and delivered on time to the ordering person. Pharmacies which deliver by mail must also offer their patients advisory services via phone. During the past months more mail-order pharmacies have entered the market. As compared to stationary pharmacies they offer price discounts of up to 30% on non-prescription medicines.

The discussions on the exact limits of the legality of mail-order distribution continue. In a recent case, in June 2004, a German drugstore chain started a test cooperation with a Dutch pharmacy delivering medicines to consumers. Under this model the drugstore collected prescriptions for medicines and forwarded the prescriptions to the Dutch mail-order pharmacy. Within 48 hours the medicines ordered could be picked up by the ordering person at the drugstore. In August 2004 the local health authority enjoined the drugstore chain from collecting prescriptions and from handing out pharmacy-only medicines

to patients. The local health authority held that the practice of the drugstore circumvented the distribution process as regulated by the LoP which only allowed distribution in pharmacies or by pharmacies via mail. In the meantime the drugstore chain has filed an appeal against the local health authority's decision.

## 7. Competition law exemption area

Neither the European nor the German competition law establishes a general exemption area for the health sector. However, the general competition law is not applicable to various practices and regulations of the SHI and its institutions.

In a recent judgement of March 2004 the ECJ held that the SHI funds are involved in the management of the social security system and in this regard fulfil an exclusively social function. Thus their activity had to be regarded as non-economic in nature and therefore SHI funds did not constitute undertakings within the meaning of Articles 81 and 82 of the EC Treaty. The result of this judgement is that the EC competition rules only apply to the SHI funds and other SHI institutions if they engage in operations whose purpose is not social but economic in nature.

In accordance with national law, the norms of the CSL V create a similar exemption area from the ARC for the SHI funds. Section 69 CSL V classifies the legal relationships covered by the CSL V, also those in relation to third parties, as belonging to the sector of social, thus public law. The provision thus creates a substantive exemption from the application of German competition law. However, in the Bundeskartellamt's opinion the application of German competition law is still possible in cases where statutory health insurance funds choose to take forms of action vis-à-vis their service providers (also including pharmacies) which are not provided for under the CSL V.

The introduction of further competitive elements to the SHI system is currently being discussed by the government and parliament. One of the consequences of introducing more competition into the health sector is that the scope of the exemption area is narrowed.

## 8. Competition law enforcement - case examples

***Reference price setting by SHI funds' associations***

In the past years several civil proceedings have been brought against the SHI funds before the German civil courts. These proceedings were initiated by pharmaceutical undertakings which were affected by the SHI reference price system. As explained above, the SHI funds' associations set a uniform reference price for certain groups of medicines. For medicines included in one of the reference price groups the SHI funds will not pay more than the reference price assigned to this group. The pharmaceutical undertakings held that in setting the reference prices the SHI funds' associations violated Article 81 EC Treaty. They requested an injunction prohibiting the application of the reference prices, and a compensation for the losses resulting from the setting of these amounts. The Federal Supreme Court as well as the Higher Regional Court Düsseldorf referred the question of the applicability of Article 81 EC Treaty to the ECJ for a preliminary ruling.

In March 2004 the ECJ decided that the SHI funds did not constitute undertakings within the meaning of Articles 81 and 82 EC Treaty. Furthermore, the ECJ held that, in determining the reference prices, the funds' associations did not pursue a specific interest separable from the exclusively social objective of the SHI funds. On the contrary, in making such a determination, the funds' associations in fact performed an obligation which was imposed on them by the CSL V and which was integrally connected with the activity of the sickness funds within the framework of the German statutory health insurance scheme. Thus Article 81 EC Treaty did not apply to the setting of reference prices by SHI funds' associations.

***Proposed merger between pharmaceutical wholesalers***

In September 2001 the Bundeskartellamt prohibited the concentration plans of Sanacorp e.G. Pharmazeutische Grosshandlung (turnover in Germany approximately 2 billion Euro) which planned to acquire a majority holding in Andreae-Noris Zahn AG (turnover in Germany approximately 2.5 billion Euro).

The Bundeskartellamt held that the concentration would have led to dominant positions gained by the firms involved on certain markets in the pharmaceutical wholesale sector in southern Germany and Mecklenburg-Western Pomerania. The German pharmaceutical wholesale sector was already characterised by a very tight market structure with only four firms operating nationally or cross-regionally. If the third and fourth-largest pharmaceutical wholesalers had joined forces to become the German market leader, the level of concentration would also have increased further at national level. The undertakings held large market shares in almost all the regional markets in Germany. In large parts of southern Germany and in Mecklenburg-Western Pomerania their market shares consistently added up to more than 40 per cent, with much higher percentages in some regional markets. The clear distance to the market share of the next largest competitors had remained stable in the last few years. The Bundeskartellamt assumed that as regards the firms' established distribution structures, the situation was unlikely to change fundamentally in the future.

The proposed merger is still pending as the Higher Regional Court Düsseldorf overturned the Bundeskartellamt's decision but was consequently overruled by the Federal Supreme Court.

## 9. Competition advocacy

In Germany, competition advocacy is entrusted to the independent Monopolies Commission and the Bundeskartellamt. Every second year the Monopolies Commission reviews recent antitrust policy issues (Section 42 ARC). At the request of the Federal Government as well as at its own initiative it delivers further expert opinions. The Monopolies Commission has repeatedly argued in favour of abolishing or limiting sector-specific exemptions from competition law and has advocated market liberalisation efforts. It most prominently proposed further liberalization in the health sector in its report of July 1998.

Contrary to the majority of competition authorities in OECD countries the Bundeskartellamt does not have any formalised rights or duties to comment on the general legislative process. However, the Bundeskartellamt frequently comments on general competition policy issues as part of its public relations work. In individual cases the Federal Ministry of Economics and Labour also now and then informally asks the Bundeskartellamt to comment on competition law aspects of legislative processes outside competition law. Sometimes the Bundeskartellamt is also asked to do so by other ministries or parliament. In the discussion paper on the meeting of the Working Group on Competition Law in September 2003 the Bundeskartellamt advocated reduction and/or abolishment of the several competition law exemption areas including the SHI funds' activities. The Bundeskartellamt also welcomes the ongoing liberalization efforts by the government in the health sector.