OECD REVIEWS OF REGULATORY REFORM

REGULATORY REFORM IN GERMANY

ELECTRICITY, GAS, AND PHARMACIES

-- PART II --

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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AND DEVELOPMENT

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SECTEURS DE L'ÉLECTRICITÉ, DU GAZ ET DES PHARMACIES – PARTIE II

FOREWORD

Regulatory reform has emerged as an important policy area in OECD and non-OECD countries. For regulatory reforms to be beneficial, the regulatory regimes need to be transparent, coherent, and comprehensive, spanning from establishing the appropriate institutional framework to liberalising network industries, advocating and enforcing competition policy and law and opening external and internal markets to trade and investment.

This report on *Electricity, Gas, and Pharmacies – Part II* analyses the institutional set-up and use of policy instruments in Germany. It also includes the country-specific policy recommendations developed by the OECD during the review process.

The report was prepared for *The OECD Review of Regulatory Reform in Germany* published in 2004**.** The Review is one of a series of country reports carried out under the OECD's Regulatory Reform Programme, in response to the 1997 mandate by OECD Ministers.

Since then, the OECD has assessed regulatory policies in 20 member countries as part of its Regulatory Reform programme. The Programme aims at assisting governments to improve regulatory quality — that is, to reform regulations to foster competition, innovation, economic growth and important social objectives. It assesses country's progresses relative to the principles endorsed by member countries in the 1997 *OECD Report on Regulatory Reform*.

The country reviews follow a multi-disciplinary approach and focus on the government's capacity to manage regulatory reform, on competition policy and enforcement, on market openness, specific sectors such as electricity and telecommunications, and on the domestic macroeconomic context.

This report was principally prepared by Sally Van Siclen in the Competition Division of the Directorate for Financial and Fiscal Affairs of the OECD. It benefited from extensive comments provided by colleagues throughout the OECD Secretariat, as well as close consultations with a wide range of government officials, parliamentarians, business and trade union representatives, consumer groups, and academic experts in Germany. The report was peer-reviewed by the 30 member countries of the OECD. It is published under the authority of the OECD Secretary General.

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Introduction

Layout of the Chapter

Community pharmacies[1] are just one part of the health system that is expected to be reformed over the next few years. In its 2000/2001 study, the Council of Experts for Concerted Action in the Health System noted the co-existence of excessive supply, shortages and incorrect supply.[2] Steps have been taken to ensure rational drug therapy, but further reform is planned. Despite the heavy regulation that is a necessary accompaniment to an insurance scheme, this chapter examines where there is scope for allowing greater freedom, and thus scope for incentives for greater efficiency, in pharmacies. In particular, the chapter examines:

- Do the restrictions on business structure promote consumer interests?
- Would cross-border trade or mail-order trade allow lower costs, while maintaining high-quality and safe delivery of medicines?

Following an introduction, the review will examine entry requirements for pharmacists and pharmacies, business structure restrictions, restrictions on mail-order/internet pharmacies, the system of pharmaceutical pricing, and advertising limits. Conclusions follow.

Pharmacies

1. Introduction

Community pharmacies and pharmacists provide a wide variety of professional and commercial services as part of an integrated health care system. In terms of professional services, the community pharmacist typically has more frequent contact with patients than do physicians, so can assist in determining medication effectiveness, patient tolerance to medications, and other related factors that affect the success of a patient treatment program. The pharmacist performs an important safety check in that, for each prescription dispensed, he or she must check to see that the information provided by the prescriber is complete, that the new medication will not interact with other medications including both prescribed and non-prescription medication, that the medication and dosage are appropriate for the patient's health condition, and that the patient has the appropriate information about the medication. The pharmacist can discuss with a patient the possible side effects, what foods, drinks, or activities should be avoided, what to do if the patient misses a dose, and how to store the medication. The pharmacist can be part of an overall disease management programme for chronic diseases, *inter alia* advising when a doctor should be seen.

A pharmacy is also a commercial business.

The Federal Government is pursuing the health policy objectives of health and consumer protection, where the latter includes ensuring drug safety and information and consultation of the patient. Among the objectives is to ensure the orderly supply of medicines to the entire population of Germany (supply at any

time, at all places with all necessary medicines) and to reduce the costs in the health system. Pharmacists are crucial to the integrated health system. The continuity of the pharmacy system means that pharmacies and pharmacists must comply with a large body of law and regulation, cumulated over 750 years, which constrains both their professional and commercial activities. In Germany, these include *inter alia*:

- Professional training requirements
- Restriction of authorisation to be a pharmacist to citizens of Member States of the European Union or stateless foreigners
- Premises and opening hour requirements
- Restriction of the form of the business to a sole proprietorship or partnership or an open commercial company, where all owners or partners are authorised pharmacists
- Restriction that each pharmacist may own at most one pharmacy in Germany (changed in 2003)
- Restrictions of which products must be carried and which products must not be carried
- Pricing restrictions (changed in 2003)
- Requirements that at least a certain fraction of prescriptions be filled by parallel imports
- Restriction of prescription drugs import to authorised persons and prohibition of mail-order prescription drugs (changed in 2003)
- Requirements to substitute low-priced drugs having the same active ingredients, effectiveness and pack size, and a comparable form, if the prescriber has not actively ruled out such substitution
- Prohibition of advertising of prescription drugs to consumers and of comparative advertising (changed in 2003).

Each of these, with two exceptions—the first and penultimate—are potential sources of abuse or constraint of efficiency.

Lest this list seem long, consider the relatively unrestricted entry in Germany as compared with a number of other members of the OECD:

- New pharmacies may locate anywhere including near incumbents
- Incumbents have no possibility to prevent the entry of a new pharmacy
- The number of new pharmacists is not constrained, neither by the number of pharmacist places at university nor by the number who may attempt or pass the Pharmaceutical Examination.

The regulation of pharmacy as a profession can be evaluated on the basis of the content of the OECD 1999 CLP Roundtable on the Professions. This roundtable examined the experience with regulation of the professions in a wide range of OECD Member countries. During the discussion, it was clear that there are sound economic arguments that regulation of quality, by some means, is necessary in these fields of

practice beyond the general framework of consumer protection laws. Essentially, the rationale is one of information asymmetries where the customers may not be sufficiently informed to avoid systemic market failure in the absence of *prior* quality assurance mechanisms. Specifically, the quality of a professional service is difficult for many consumers to observe or they may not know what services they need: They may use professional services infrequently. It may be difficult for consumers to judge quality, even after its delivery. The consequences of poor service can be substantial and potentially irreversible.

The Roundtable arrived at several conclusions, most addressed to ensuring quality while opening up entry. One, however, addressed competition in the markets for professional services:

- Restrictions on competition between members of a profession should be eliminated. This includes agreements to restrict price, to divide markets, to raise entrance barriers or to limit truthful advertising. Recognition of qualification of professionals from other countries should be promoted. Citizenship requirements should be eliminated.

2. An Overview of the Sector in Germany

Pharmacies are just one part of the overall health system. More detail about who pays who for what is provided later. Here, it is sufficient to note that about 90% of the population are members of one of several statutory health insurance funds (SHIs). The other 10% are covered by private health insurance. The SHIs compete for customers on the basis of contribution rates, though a reallocation mechanism might blunt those incentives for efficiency. The SHIs pay pharmacies for prescribed pharmaceuticals whereas the consumer pays for non-prescribed pharmaceuticals. Prices for prescription-only or pharmacy-only pharmaceuticals are heavily regulated, as described later.

In 2001, there were 21,569 community pharmacies each serving, on average, 3,810 persons in Germany. There were 45,869 pharmacists in the community pharmacies. (Hospital pharmacists at 1,823 persons and industrial and other pharmacists at 5,507 round out the total.) Pharmacies have a wide range of turnovers, with about 5% of those in western Germany having annual turnovers under € 250,000 (excluding VAT) and another roughly 2% of those in western Germany having annual turnover between € 2 million and € 2.25 million. The turnover of pharmacies in Germany is heavily skewed toward drugs (93.5% of the total), and more specifically toward prescription-only drugs (69.5% of the total) and less so toward pharmacy-only drugs (12.5% of the total without a prescription, 10% of the total with a prescription). In 2000, about 40% of community pharmacies in western Germany reported operating losses, though this figure can be difficult to interpret in light of persistent average operating losses and entry of new pharmacists. [Federal Union of German Association of Pharmacists 2001]

Generic pharmaceuticals, i.e., those that are no longer protected by patents, constitute 27 % of pharmaceutical sales in Germany in 2002. [VFA 2003] Among European countries, this is the highest share. Among drugs for which comparable generics are offered, more than 70 % of prescriptions are for generics. [VFA 2002a]

Drug usage is predominantly by the old. In Germany in 2001, 54 % of the expenditure on drugs was for pensioners. [Federal Union of German Association of Pharmacists 2001]

As compared with other OECD countries, Germany has relatively high spending on health at 10.6 % of GDP in 2000. While its per capita health spending grew relatively moderately over the 1990s, low GDP growth rates meant that the share of health spending in GDP grew over the decade. This is partly a reflection of German unification, which influenced both the level of GDP and the growth rates of health spending. Per capita spending on healthcare across OECD countries has outpaced overall per capita GDP growth (3.3% versus 2.2%) over the past decade. In 2000, OECD countries spent an additional 0.8 percentage point of their GDP on health care compared with 1990, bringing the OECD unweighted average up to 8.0 % (see Table 12).

Table 12. Growth of Expenditure on Health, 1990-2000

	Real per capita growth rates, 1990-2000 (in %)		Health spending as percent of GDP		
	Health Spending	GDP	1990	1998	2000
Australia	3.1	2.4	7.8	8.5	8.3
Austria	3.1	1.8	7.1	8.0	8.0
Belgium	3.5	1.8	7.4	8.5	8.7
Canada	1.8	1.7	9.0	9.1	9.1
Czech Republic	3.9	0.1	5.0	7.1	7.2
Denmark	1.7	1.9	8.5	8.4	8.3
Finland	0.1	1.8	7.9	6.9	6.6
France	2.3	1.4	8.6	9.3	9.5
Germany	2.2	0.2	8.7	10.6	10.6
Greece	2.8	1.9	7.5	8.7	8.3
Hungary (a)	2.0	2.7	7.1	6.9	6.8
Iceland	2.9	1.6	7.9	8.3	8.9
Ireland	6.6	6.4	6.6	6.8	6.7
Italy	1.4	1.4	8.0	7.7	8.1
Japan	3.9	1.1	5.9	7.1	7.8
Korea	7.4	5.1	4.8	5.1	5.9
Luxembourg (b)	3.7	4.5	6.1	5.8	6.0
Mexico	3.7	1.6	4.4	5.3	5.4
Netherlands	2.4	2.3	8.0	8.1	8.1
New Zealand	2.9	1.5	6.9	7.9	8.0
Norway	3.5	2.8	7.8	8.5	7.5
Poland (b)	4.8	3.5	5.3	6.4	6.2
Portugal	5.3	2.4	6.2	8.3	8.2
Slovak Republic	-	4.0	-	5.9	5.9
Spain	3.9	2.4	6.6	7.6	7.7
Switzerland	2.5	0.2	8.5	10.6	10.7
United Kingdom	3.8	1.9	6.0	6.8	7.3
United States	3.2	2.3	11.9	12.9	13.0
OECD Average (c,d)	**3.3**	**2.2**	**7.2**	**8.0**	**8.0**
EU Average (d)	**3.1**	**2.3**	**7.4**	**8.0**	**8.0**

(a) Hungary: 1991-2000.

(b) Luxembourg and Poland: 1990-1999.

(c) OECD averages exclude the Slovak Republic because of missing 1990 estimates.

(d) Unweighted averages.

For Sweden and Turkey, no recent estimates are available.

Source: OECD Health Data 2002.

Demand for pharmaceuticals continues to grow. In the first half of 2002, turnover in the statutory health insurance market rose by +7.8 per cent to € 11.9 billion (at retail prices). The number of prescriptions rose by 1 % to 403 million. However, a fall in the price level was expected for 2002 as a whole. The increasing prescription of prescription-only and highly effective preparations for serious illnesses is the decisive factor for the increased turnover. However, the share of drugs protected by patent has not increased overall. The proportion of patent-protected drugs in total turnover has been unchanged at 19 per cent since 1998, whereas the market share of generic drugs has risen from 45 per cent in 1998 to around 54 per cent in the first half of 2002.

Table 13: Turnover in the Statutory Health Insurance Drugs Market

Year	Turnover (pharmacy retail prices)		Turnover per prescription (pharmacy retail prices)	
	€ m	Change from previous year (%)	€	Change from previous year (%)
1st quarter 2001	5,464		26.43	
2nd quarter 2001	5,603		29.10	
1st half 2001	11,066		27.72	
1st quarter 2002	5,878	+ 7.6	28.64	+ 8.3
2nd quarter 2002	6,051	+ 8.0	30.59	+ 5.2
1st half 2002	11,930	+ 7.8	29.60	+ 6.8

Source: IMS Health

Table 14: Turnover and Prescriptions in the Statutory Health Insurance Drugs Market

1st Half 2002

Market Segment	Turnover (pharmacy retail prices)			Prescriptions		
	€ m	Share %	Change From previous year (%)	m	Share %	Change from previous year (%)
Total market	11,930	100.0	+ 7.8	403.1	100.0	+ 1.0
Drugs with a fixed amount	4,448	37.3	- 2.1	252.6	62.7	+ 0.1
Drugs without a fixed amount						
Patent-protected drugs	2,250	18.9	+ 21.2	20.	5.	+ 9.
Patent-free drugs without generic competition	3,002	25.2	+ 15.7	66.7	16.5	+ 0.9
Patent-free drugs with generic competition	2,230	18.7	+ 7.5	63.6	15.8	+ 1.9

Source: IMS, VFA

A comprehensive price comparison of the best selling and most-prescribed pharmaceutical active agents in Germany with prices in other European countries found that prices in Germany were low. The study [Schneider et al. 1999] compared prices in Germany and the other EU states and Switzerland on the basis of the daily dose of 47 of some of the best selling and frequently prescribed active agents, in order to make different pack sizes and dosages comparable.[3] The manufacturers' sale price per daily dose of an active agent reflects what the manufacturers receive per active agent. Exchange rates were used. Among the countries studied, **manufacturers' prices** in Germany were third from the lowest. Only Spain and Greece were lower. The price differences ranged from 15% below and 77% above. When comparing the **pharmacies' retail prices** (using exchange rates) Germany was fifth from the bottom of the 15 countries in the study. Only France, Portugal, Spain and Greece were cheaper than Germany. By contrast, Switzerland, Ireland, Austria, Belgium, Luxembourg, Finland, the United Kingdom, Denmark, the Netherlands and Italy have a higher price level. German drug prices are low compared with wage rates: An industrial worker in Germany needs to work for 2.9 minutes for the average price of (1998) DM 1.23 per daily dose, whereas his French and British counterparts work 3.6 and 3.7 minutes respectively for a daily dose. With the exception of Denmark, an industrial worker in every other European country had to work longer to earn enough for the average price of a daily dose of a drug than in Germany. It is worth bearing in mind, though, that generics constitute a large part of the basket of active ingredients used in the price study. This may have influenced the price comparisons.

Table 15: Retail Pharmacy Price for One Defined Daily Dose* According to Country

	Country Price per defined daily dose			Expended work time per defined daily dose
	in national currency	in DM (purchasing power parities)	in DM (foreign exchange rates)	in minutes (income situation)
Belgium	30.89	1.67	1.50	4.2
Denmark	5.02	1.19	1.32	2.3
Germany	1.23	1.23	1.23	2.9
Finland	4.21	1.41	1.38	3.8
France	4.05	1.07	1.21	3.6
Greece	143.27	1.29	0.85	5.6
Great Britain	0.46	1.41	1.35	3.7
Ireland	0.61	1.76	1.54	5.3
Italy	1,260.75	1.26	1.28	5.1
Luxembourg	29.22	1.43	1.42	3.4
Netherlands	1.47	1.41	1.30	3.7
Austria	10.56	1.54	1.50	4.5
Portugal	106.69	1.71	1.04	9.6
Switzerland	1.63	1.62	1.96	4.1
Spain	80.19	1.28	0.94	4.0

* Average in 1998 for those pharmaceuticals with the highest sales and prescription volume in Germany

Source: Reproduced from Schneider et al.

In Germany, the price received by drug manufacturers constitutes only, on average, 55% of the retail price. This compares with 65.8 % in the United Kingdom and 64.4 % in France, which were the highest in Europe. The distribution margin in Germany is relatively high by European standards. [European Federation of Pharmaceutical Industries' Associations 2000]

3. The Regulatory Framework

Pharmacies in Germany, as in the other OECD countries, are heavily regulated. In addition to those described in Table 16, the state intervenes in drugs pricing to a greater or lesser extent in all EU countries including Germany. For example, Ireland, Italy and Portugal set flat-rate surcharges, up to 50 %, for pharmacies. In Belgium, Denmark and France linear price surcharges are specified by the state, in a situation similar to that in Germany. The manufacturers' prices in Italy and Austria are regulated by the state.

Table 16: Regulation of Pharmacies in Selected Countries

	UK	France	Germany	Netherlands	Norway	US	Canada
Licence or contract required?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Location of new Pharmacies restricted?	Yes	Yes	No	No	Yes	No	No
Ownership structure restricted?	No	Yes	Yes	No	No	No	No
Number of stores per owner restricted?	No	Yes	Yes	No	Yes	No	No
Freedom to reduce prescribed drug prices?	No	Yes	No	Yes	Yes	Yes	Yes

Source: reproduced from Table 3.1, in Office of Fair Trading (United Kingdom) (2003), "The Control of Entry Regulations and Retail Pharmacy Services in the UK," January, citing Mossialos and Mrazek (annexe C), Mossialos, E. and M. Mrazek, 2002. "Entrepreneurial Behavior in Pharmaceutical Markets and the Effects of Regulation." In: R.B. Saltman, R. Busse, and E. Mossialos, *Regulating Entrepreneurial Behavior in European Health Care Systems*, Open University Pres, Buckingham, UK and Philadelphia, pp.146-162.

3.1. Pharmacist Training and Certification

The training of pharmacists in Germany is regulated in the Qualification Code for Pharmacists. The total duration of training is five years and is broken down into

- studies at a university for four years
- practical training[4] during a pre-registration period of eight weeks prior to the first section of the Pharmaceutical Examination
- practical training[5] for twelve months after passing the second section of the Pharmaceutical Examination
- the third and final part of the Pharmaceutical Examination.

Anyone who wants to pursue the profession of pharmacist in Germany needs certification as a pharmacist. Certification is granted among other things if the applicant is German or a citizen of another member state of the European Economic Area or a stateless foreigner under the relevant German law. The applicant must have successfully completed training as a pharmacist in line with the relevant European Directive.

Other foreign pharmacists cannot operate a pharmacy in Germany. Foreign pharmacists who can, in principle, operate a pharmacy in Germany may only operate those that have been operating in Germany for at least three years.

Box 14.Mutual Recognition of Diplomas in Pharmacy

The European Union has promoted mutual recognition of diplomas in pharmacy to facilitate freedom of establishment for pharmacists in the Community. The principal directive is Council Directive 85/433/EEC of 16 September 1985 "concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy." [Official Journal L 253, 24.09.1985] This has been amended a number of times in response to, e.g., countries joining the European Union and the unification of Germany.

The main elements of this framework, relevant here, are:

1. The Directives apply to activities, the access to and pursuit of which are subject to the conditions of professional qualification defined in Council Directive 85/432/EEC and which are open to holders of one of the diplomas, certificates or other formal qualifications in pharmacy referred to in the Directive.

2. Each Member State must recognise the formal qualifications listed in the Directive and awarded by other Member States to their citizens. They must give to such qualifications the same effect in their territory with regard to access to and the pursuit of the activities in question as the formal qualifications which they themselves award. Furthermore, when access to or the pursuit of the activity in a Member State requires additional professional experience, that Member State is obliged to accept as sufficient evidence a certificate issued by the competent authorities of the applicant's Member State attesting that he has pursued the said activities for an equivalent period.

3. Directive 90/658/EEC introduces a special arrangement for the recognition of formal qualifications awarded by the former German Democratic Republic: German nationals who are pursuing their professional activities in that territory on the basis of training which began before unification and does not conform to Community rules on training are to be granted recognition under the same conditions as other nationals of Member States at the time of the adoption of Directive 85/433/EEC, i.e. if they produce a certificate showing that they had at least three consecutive years' professional practice during the five years prior to the date of issue of the certificate.

More recently, Directive 2001/19/EC [Official Journal L 206, 31.07.2001] aimed to reduce the barriers to free establishment by:

requiring the host Member State to take into account the education received by the applicant, including education received in a Member State in which the profession in question is not regulated. Under this new rule host Member States will not be permitted to require two years' professional experience;

ensuring that the host Member State, when examining an application for recognition of a diploma, takes into consideration the experience acquired by the applicant after obtaining the diploma. The host Member State may no longer systematically require the applicant to take compensation steps, such as aptitude tests or an adaptation period, but must simplify and if possible eliminate these measures;

extending the automatic recognition procedure to *inter alia* pharmacists.

Source*: http://europa.eu.int/scadplus/leg/en/lvb/l23020b.htm*

There does not seem to be, *a priori*, a justification to exclude from the practice of pharmacy persons who are trained and certified as pharmacists, perhaps even in a German university and pharmacy, but who are not citizens of a Member State of the European Union. If a person receives training in a third country where the quality of the training cannot be checked by the appropriate German or Member State authorities, then the exclusion from pharmacy could be justified on the basis of protecting consumer health and safety. Illegal immigrants would, presumably, be excluded under a separate law.

Recommendation: Eliminate the citizenship requirement for certification for the practice of pharmacy.

3.2. Entry of New Pharmacies

Entry of a new pharmacy is relatively free in Germany. A pharmacy requires authorisation from the *Land* where the pharmacy will operate. Authorization is dependent on the qualifications of the person applying, the existence of the premises and the conformity of its fittings with the Pharmacies Operations Regulations. There are no geographic or numerical restrictions on the right to open a pharmacy. This pattern of free entry is the result of a 1958 High Court decision. However, as noted earlier, foreign pharmacists who are granted certification as pharmacists may not open a new pharmacy; they may only operate a pharmacy that has been operating at least three years.

3.3. Business Structure Restrictions

Regulations related to pharmacists are laid down in the "Law on Pharmacies" ("*Apothekengesetz*"). Any qualified pharmacist must be *ad personam* authorised to run a pharmacy. The "Law on Pharmacies" is based on the idea of the self-employed pharmacist running his own and only one pharmacy. This structure is intended to guarantee that the pharmacist devotes all his efforts to one pharmacy and feels personally responsible for his pharmacy in the public interest. Consequently, chains of pharmacies do not exist in Germany. However, in the 2003 reforms, the number of pharmacies that a single pharmacist may own was increased to four, though they must be located in the same or the neighbouring district. This is regarded as the first step towards a more liberal system.

In 1994, the ban on the ownership of more than one pharmacy was modified to adjust German legislation to European law. The amendment of the "Law on Pharmacies" entitled individuals who are authorised by German law to run a pharmacy, to run one or several pharmacies in other Member States according to the Member States' relevant legislation. Conversely, pharmacists running one or several pharmacies in one or more other Member States are entitled to run no more than one pharmacy in Germany (increased to four in 2003), in addition to the pharmacies run in other Member States on condition that the respective Member States do not impose an obligation on the pharmacist to be present in his pharmacy at all times.

Among the rationales for the ownership restrictions are:

- to maintain ethical and professional standards in the provision of pharmacy services;
- to provide a greater capacity to enforce professional standards; and
- to promote access to pharmacy services for all of the population.

However, in pursuit of these objectives, the ownership restrictions significantly hinder the development of potentially more effective structures for delivering some pharmacy services. The industry fragmentation frustrates the exploitation of economies of scale in pharmacy which could be passed onto the statutory health insurance funds or consumers as lower prices. Evidence from the United States suggests that economies of scale can exist in chain pharmacies up to about 80,000 prescriptions a year. [Schafermeyer et al. 1992] In this study, by far the largest cost item for dispensing was personnel, on average $3.69 out of $5.46. This study was performed in 1990; subsequent advances in information technology may well have extended the range of scale economies.

Further, the asymmetric treatment of non-German pharmacies—a pharmacist with German qualifications may own a chain of pharmacies so long as only four pharmacies of the chain are located in Germany—seems difficult to justify on any of the bases listed above. In Germany, the health insurance companies are calling for the licensing of pharmacies with external (i.e., non-pharmacist) and joint ownership because they assume that there would be greater scope for savings.

The Federal Organisation of German Pharmacy Associations [*Bundesvereinigung Deutscher Apothekerverbände (ABDA)*] rejects a removal/easing of external and joint ownership of pharmacies. It says that combining pharmaceutical and economic responsibility in the person of the pharmacy owner and operator offers a good guarantee that the pharmaceutical and economic interest in running the pharmacy remain in a balanced relationship and that the pharmaceutical interest in particular is not suppressed by the economic interest.

At the heart of the ownership restrictions is the argument that non-pharmacist owners might let commercial considerations over-ride professional ethics of pharmacists. Given the regulation and professional codes that govern pharmacists, one must ask whether costs imposed by existing ownership restrictions are proportionate to *additional* ethical and safety benefits to consumers.

- First, like other businesses, success in community pharmacy depends on providing a cost-effective, quality service. The quality and safety of the service provided depend, in the first instance, on the professional skills of the pharmacist. This would seem to be the case whether the pharmacist is a salaried employee or owns the business.

- Second, it is unclear whether commercial pressures on owner-pharmacists would be larger than those on employee-pharmacists, or not, since owner-pharmacists would have a substantial part of their wealth tied up in the pharmacy and depend on the profits of the pharmacy for much of their income. This is, though, an empirical question. If this is an empirically significant problem, then a solution would be to introduce a statutory offence for inappropriate or improper interference with the professional conduct of a pharmacist. In this way, not only would the pharmacy board be able to discipline the pharmacist but also the other party would be liable under the law.

- Third, it is in neither a pharmacist-proprietor's nor in a non-pharmacist proprietor's commercial interests to expose him- or herself to the risks of loss of income or profit, or litigation, due to his pharmacies being unsafe or incompetently run.

- Fourth, in general, the cause of most cases of serious harm to consumers will be professional misconduct. In these circumstances, if the threat of professional discipline or consumer litigation is a credible deterrent, then the deterrence would seem to apply whether the pharmacist is the owner of the pharmacy or not.

- Fifth, good pharmacists do not necessarily make good managers and businesspeople. By preventing non-pharmacist proprietors, the pharmacy business may be forgoing fresh sources of innovation, leadership and ideas that could improve the overall efficiency of pharmacies.

One concern that has been expressed in the specifically German context is that, if the business structure restrictions were lifted, then the drug wholesalers would simply enter the pharmacy market and the atomised structure would become an oligopoly. This concern is worthy of serious consideration, and indeed any reform of the health system should aim to keep those parts of the system that could be competitive, competitive. Part of the answer is that a market with five sizeable competitors plus a fringe of smaller firms can be competitive, depending on various features of the market—including high transparency for buyers, low switching costs for buyers--that keep less competitive interactions at bay. Another part of the answer is to expand the range of potential suppliers. In some countries, a large number of medicines can be sold by any sort of retailer to self-medicating consumers. Broadening the freedom to sell these products is one way to ensure that, for appropriate products at least, there is healthy competition. Such broadening of access may need to be accompanied by consumer education, either on the packaging or by the Ministry of Health, but this is the same sort of consumer information already provided (e.g., limit giving aspirin to children, do not use certain drugs when driving or operating machinery). If medicines for chronic illnesses can be safely purchased by mail-order from pharmacies located anywhere in the European Union or the EEA, then this would also open up retailing to include vastly more suppliers than an oligopoly of wholesalers.

So long as the strict control over pricing, products offered, opening hours, and advertising remain in place, consumers probably would not benefit very much if the only change were for pharmacies to consolidate into large chains. They would benefit to the extent that chains could offer an integrated medication record, available throughout Germany, so that a traveller who lost his medicine could get it replaced or so that new prescriptions could be screened. There would be greater incentives for cost savings if any business structure reform were part of an integrated reform to introduce competition in the provision of pharmaceutical retailing, while retaining the professional ethos of pharmacists. This would provide the chains with incentives to use their economies of scale and would induce them to pass these cost savings onto the SHIs and consumers.

Recommendation: Remove the restriction of ownership of pharmacies to pharmacists and the restriction of ownership to a single pharmacy. Introduce a prohibition of inappropriate or improper interference with the professional conduct of a pharmacist.

3.4. Cross-Border Trade/mail-order trade

There is debate in Germany over the opening up of the pharmacy business to mail-order pharmacies. This has been prompted by the establishment in 2000 of DocMorris, a mail-order/internet pharmacy in the Netherlands that sells to German consumers who are reimbursed by German health insurance funds. A few other OECD countries have adapted to mail-order/internet pharmacies by addressing the specific safety issues raised by them.

Until 2003, mail-order trade in medicines and thus also e-commerce in medicines had been prohibited in Germany for pharmacy-only medicines.[6] German patients and health insurers were already circumventing the ban before the European Court of Justice ruled on the compatibility of such a ban with the free circulation of goods. However, removing the prohibition on mail-order medicines, by itself, brings no relief to German pharmacies because they must comply with price maintenance rules and price advertising prohibitions.

On one side of the German debate over the sale of pharmaceuticals from other EU Member States via mail-order and the Internet were the health insurers, politicians, consumers' organisations and a small number of pharmacists. The pro-establishment pharmacists, organised under the banner of the *Bundesverband deutscher VersandapothekerInnen* (BVDVA), argue that extending traditional bricks and mortar pharmacies to where they can also deliver prescription drugs by mail-order will degrade neither the safety nor the quality of professional counselling provided. The BVDVA has developed a security standard with Deutsche Post and pharmacies will be able to offer counselling via a call centre. In terms of improving the services offered to consumers, the BVDVA will be able to maintain a patient's historical medical record which can reduce problems of drug interactions, side-effects and the like.[7]

On the other side of the German debate on mail-order/internet pharmacies was the main organisation of pharmacists, who fear the change could risk patients' health and threaten the livelihoods of German pharmacies. In particular, the pharmacists and wholesalers argue that safety can be compromised by counterfeit drugs and by inadequate consumer counselling, and that the most profitable drugs will be provided by mail-order and that this will result in the closure of bricks and mortar pharmacies. Studies by the Bavarian Ministry for Social Welfare show that if the online pharmacies were to gain just five percent of the German market, 20 to 30 percent of pharmacies in Germany would have to shut down. [Deutsche Welle 2002] Referring to the German prohibition on mail-order sales of pharmaceuticals, German pharmacy federations tried to have internet sales prohibited.

The particular internet/mail-order pharmacy that has shaken up German pharmacists is 0800 DocMorris. DocMorris is located just over the border in the Netherlands, within reach of German courier services who can pick up parcels and deliver them cheaply in Germany. Opened in June 2000, in 2001 DocMorris had a turnover of €5 million and in 2002 a turnover of €25 million. Three-quarters of the company's customers are from Germany. DocMorris is attractive to German consumers and health insurance funds because prices are considerably lower than those charged by German pharmacists, DocMorris is not limited by opening hours, medicines are delivered to the patient's door, and there is no risk of meeting the neighbours in the pharmacy. The success of DocMorris has encouraged imitation: A second Dutch mail-order/internet pharmacy is getting started and the German Association of Pharmacists has launched its own website, aponet.de, which allows customers to pre-order a prescription, but not to have it filled and mailed.

DocMorris, as a pharmacy operating in the Netherlands, is subject to Dutch law and regulation of pharmacies. The Dutch Ministry of Health has a specialized section to oversee pharmacies using mail-order. In addition, DocMorris received an ISO certification after a check of its internal processes. DocMorris has controls to address the safety concerns. DocMorris requires an original prescription for medications requiring a prescription, and accepts an order only after the prescription is verified. Narcotics cannot be ordered. DocMorris will directly bill statutory health insurance schemes,[8] if a panel doctor's prescription is presented, and does not require any co-payment from the patient although a co-payment for members of the German statutory health insurance is provided by the social code book 5. The medicines are delivered by a delivery service and acknowledged by signature, and normally only within the European Union. DocMorris screens medicines to identify whether a patient should not take the medicine in a second prescription together with that in a previously filled prescription. [Source: 0800docmorris.com]

German pharmacy federations had sued to block DocMorris. Following various rulings by national courts, the Frankfurt Regional Court submitted several Community law matters to the European Court of Justice for a preliminary ruling. The chief issue to be settled was the compatibility of a prohibition on mail-order sales of pharmaceuticals (§ 43 Section 1 of the Pharmaceutical Act (AMG)) and prohibition of import of pharmaceuticals by private persons (§ 73 Section 1 AMG), with the free movement of goods in accordance with Articles 28 and 30 of the EC Treaty. [*Zentrum für Europäische Integrationsforschung* 2003] The Advocate General has said that, "In so far as the prohibition on mail order trade and related advertising concerns medicines that have been authorised or do not require authorisation, the principle of proportionality will be infringed if the health-protection goals pursued by the country of import can be secured by other means." The Advocate General suggests as examples of less severe measures controls on ordering, dispatching, transporting and taking delivery of the medicines. Regarding medicines that require authorisation but have not been authorised in either Germany or the European Union, then the prohibition of mail-order is justified as being for the protection of human life or health. The Advocate General went on to address the ban on advertising pharmacy-only medicines for mail-order, concluding that the ban is not justified for authorised medicines or for medicines that do not need authorisation. For advertising prescription-only drugs to the general public, the crucial factor is the objective impression of the website. In particular, the simple presentation on the DocMorris website does not qualify it as "advertising" in the sense of Directive 92/28. [Advocate General 2003, para. 212] Thus, a website providing information can be distinguished from one providing promotion. In its decision, the European Court of Justice upheld the ban on Internet sales of prescription medicine, but said that the prohibition on Internet sales and advertisement of non-prescription medicines was unjustified. [Judgment of the European Court of Justice of 11 December 2003 in Case C-322/01 Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval.]

As part of the 2003 health reforms, the German Government permitted regulated and monitored mail-order trade, including in medicines which must be sold in pharmacies, in Germany and with the members of the European Economic Area (EEA). Pharmacies have to be registered and comply with all the standards of "bricks and mortar" pharmacies as well as several additional quality and safety standards related to advertising, website layout, technical equipment, dispatch matters, delivery, patient information and consultation in order to be accredited. The objective is to offer a safe and reliable opportunity to patients who would like to mail-order medicines.

Consumers are likely to benefit from mail order internet pharmacies:

- Access to drugs for patients for whom a trip to the pharmacy can be difficult, e.g., homebound, working persons in the case of great distances.
- The convenience of shopping 24 hours a day;[9] a complete selection of pharmaceutical products.
- Privacy for those who do not want to discuss their medical needs in a public place.
- Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront.
- Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

Brick and mortar pharmacies offer benefits and services that are often not available through mail-order and the Internet, such as immediate access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the effective delivery of health care.

The pharmacy regulators in some OECD countries have already established accreditation programmes for internet pharmacies. E.g., the Pharmaceutical Society of New Zealand requires an accredited pharmacy to comply with all the standards of a registered pharmacy, as well as provide the opportunity for meaningful consultation between patient and pharmacist and demonstrate compliance with rules on patient privacy and confidentiality and on advertising of medicines. In Canada, internet pharmacies must be accredited pharmacies and thus are overseen by the provincial Colleges of Pharmacy. Among European Union states, however, only three countries (Denmark, Netherlands and the United Kingdom) allow distance selling of pharmaceuticals. [Arruñada 2002] By contrast, some OECD countries (the Czech Republic, Hungary and Korea) prohibit internet pharmacies. [OECD 2001]

Mail-order/internet pharmacies can increase patient safety by increasing the ease of screening of prescriptions for adverse effects for the particular patient. One argument against internet pharmacies is that consumers would inevitably use more than one pharmacy. Traditionally, patients were encouraged to use a single pharmacy for all their medications because a consumer's medication record, if it existed, was paper-based and could not otherwise feasibly be maintained. (A medication record is a tool to reduce the risk of duplicating medicine, having one prescription interact harmfully with another, or experiencing allergic or adverse reactions to certain drugs.) However, advances in information technology mean that a medication record could be securely accessed from any pharmacy. Indeed, online computer-aided screening of prescriptions can, uniquely, review a prescription against a profile of all medications a patient has purchased from all the pharmacies that have submitted prescription claims for that patient. This problem is not small: One study of the medical literature found that as many as 28% of all emergency department visits were related to pharmaceuticals, and of these 70% were preventable. Common problems that resulted in emergency department visits were adverse drug reactions, non-compliance, and inappropriate prescribing. [Patel and Zed 2002]

Box 15: US Experience with Internet Pharmacies

The first Internet pharmacies began service to US consumers in early 1999. While public health officials agreed that state-licensed internet pharmacies offered consumers an alternative to "brick and mortar" pharmacies, they were concerned for consumer safety and health because not all Internet pharmacies adhered to state licensing requirements and standards and several consumers had been harmed by prescription drugs obtained from Internet pharmacies without a valid prescription. The General Accounting Office subsequently investigated.

The GAO found, in 2000, three types of Internet pharmacies selling prescription drugs directly to consumers:

Those that operate like traditional or mail-order pharmacies: they dispense drugs only after receiving prescriptions. These constituted 58% of the GAO's sample.

Those that dispense drugs without a physical examination by a physician, but on the basis of an authorisation by a physician affiliated with the pharmacy, who reportedly evaluates consumers' self-assessment via a medical questionnaire.[10] This practice tends to be largely limited to "lifestyle" drugs, such as those to alleviate allergies, promote hair growth, treat impotence, or control weight. These constituted 28% of the GAO's sample.

Those that dispense medication without a prescription. These were 13% of the GAO's sample.

State pharmacy boards had a number of specific difficulties in overseeing internet pharmacies beyond the borders of their jurisdiction.

Identification: Difficulty determining the physical location of an Internet pharmacy affiliated with an Internet Web site made it difficult to identify the companies and people responsible for selling prescription drugs.

Investigation: Traditional investigative tools—interviews, physical or electronic surveillance, and serving subpoenas to produce documents and testimony—are not necessarily adequate to compel disclosure of information from a pharmacy or pharmacist located out of state.

Discipline: Traditional enforcement mechanisms—disciplinary actions or sanctions against licensees—are not necessarily adequate to control a pharmacy or pharmacist located out of state.

In the face of jurisdictional limits, state pharmacy boards referred nonresident, unlicensed or unregistered Internet pharmacies to their counterpart boards in the states where the pharmacies are licensed. As late as 2003, only a handful of state legislatures had passed legislation to address issues that arise from online prescribing. However, the GAO believed that the current regulatory structure permitted traditional state pharmacy and medical boards to restrict online prescribing and verify disclosed information.

Federal agencies have taken a number of actions against illegal prescribing and dispensing of prescription drugs by domestic Internet pharmacies and their affiliated physicians. These include investigations or prosecutions by the Food and Drug Administration (FDA), the Department of Justice, the Drug Enforcement Agency (DEA), and the Federal Trade Commission (FTC), and increased seizures by the Customs Service of drug-containing packages entering the country. The FDA is increasing consumer education about internet pharmacies through its own website and brochures and the FTC provides consumer education about e-commerce more generally.

However, the FDA has found special difficulties in addressing foreign Internet pharmacies illegally selling prescription drugs to U.S. consumers and sees a need to work closely with foreign governments to share information and to develop mechanisms for cooperative law enforcement.

The VIPPs programme is an example of the reach of the long-established regulators extending even into cyberspace. The century-old National Association of Boards of Pharmacy (NABP) developed the Verified Internet Pharmacy Practice Sites (VIPPS) program in 1999, in cooperation with state and federal regulatory associations, professional associations, and consumer advocacy groups. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals and must demonstrate to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

Sources: GAO 2000; Hubbard 2003; National Association of Boards of Pharmacy.

Recommendation: Germany should bring mail-order/internet pharmacies which are part of authorised pharmacies located in a Member States of the European Union, into the regulatory framework. This means specifying the requirements of electronic trading and mail order and the corresponding quality assurance systems in drugs, pharmacy and advertising legislation and ensuring appropriate monitoring at national and European level.

- **This includes establishing a certification and control process to ensure that standards of pharmacy professional services are maintained, especially as regards authentication of prescriptions and consultation with patients, that delivery is safe and reliable, consumer privacy is protected, and that German consumers can identify "safe" pharmacies.**

- **It includes, too, consumer education to recognise a certified mail-order/internet pharmacy and to understand the safety benefits of choosing to buy only from certified pharmacies, whether bricks and mortar or internet.**

- **It also includes working toward sharing information and cooperative enforcement of laws and regulations with corresponding regulators in other Member States and with third countries.**

- **The prohibition on mail delivery will need to be modified to permit delivery of many classes of pharmaceuticals, while recognising that some classes of pharmaceuticals may not be appropriate for mail delivery.**

- **The restriction on advertising will need to be modified to allow websites to present, though not promote, their offerings. To ensure fair conditions of competition, any change would need to extend to purely bricks and mortar pharmacies as well.**

- **Many of these steps will require efforts at a European, as well as a national, level.**

3.5. Pharmaceutical Pricing

The subject of pharmaceutical pricing is complex, in part because many social, political and economic objectives are tied up in the pricing of what can be life-extending or quality of life-enhancing products. These raise issues related to the separation of beneficiary from payer, the tension between free movement and subsidiarity within the European Union, and the non-excludability of pharmaceutical R&D. These three issues are addressed in turn, and then the specificities of pharmaceutical pricing in Germany are discussed. However, since pharmaceutical pricing is necessarily part of a comprehensive health sector reform, very few specific recommendations can be offered.

The revenues to pay for pharmaceuticals do not come primarily from the beneficiaries but rather from insurance funds (from employees and employers) or from the state (from taxpayers). This gives rise to the standard market failure in insurance markets caused by "moral hazard" or "hidden action," in which consumers use more pharmaceuticals than is economically efficient because they do not have to pay the cost directly. (In the aggregate, of course, they do pay albeit in other ways, as taxpayers and insurance fund contributors.) Countries have typically responded to this market failure by the following policies to restrict the quantity and quality of pharmaceutical consumption:

(a) formularies – lists which set out the drugs that are covered and the conditions of coverage;

(b) reimbursement policies – policies related to the extent of health insurance coverage of pharmaceuticals (through co-payments, or ceilings on reimbursement);

(c) controls on prescribing doctors and pharmacists – either in the form of direct controls or in the form of financial incentives;

(d) controls on pharmacists' margins and entry and exit decisions; and

(e) controls on drug prices. [OECD 2001]

Germany applies many of these policies.

Pharmaceuticals, because they are so compact and valuable, thus tradable, expose the tension between the free movement objectives in the European Union and the subsidiarity principle of national regulation of the pricing of pharmaceuticals. There are efforts to reduce segmentation in the pharmaceutical sector within the European Union. Measures include *inter alia* the harmonisation of technical provisions within the Union and new registration procedures for medicines. Since the beginning of 1995, pharmaceutical companies have the option (and for biotechnology products the obligation) of submitting an application for registration of a new medicine to the European Agency for the Evaluation of Medicinal Products for a centralised authorisation procedure.[11]

The sale of medicines is substantially determined by the national health authorities in the Member States. Some national health authorities exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social security system for different categories of medicines. As a result, the prices for medicinal products differ among Member States. In addition, there are far-reaching differences in terms of brand and pack-size strategies and in distribution systems. These differences lead to national market segmentation.

But the free movement of pharmaceuticals reduces this market segmentation. In particular, there is substantial "parallel trade" of pharmaceuticals originally sold by drug manufacturers to wholesalers in a low-price Member State that are ultimately sold to consumers in a different, high-price Member State. This trade has grown rapidly (so that the market share of parallel-traded drugs has increased from 1.8 percent in 1998 to 7.1 percent in 2002), and is focused on high-priced pharmaceuticals. [VFA2003] The primary effect of parallel trade is to transfer profits from drug manufacturers to some parallel traders. Parallel trade may or may not lower the prices for pharmaceuticals in the high-price country. Parallel trade limits the ability of drug manufacturers to discriminate in their prices across different countries.

The third notable set of features of pharmaceuticals is that determined imitators cannot be excluded from knowledge created by pharmaceutical R&D and that pharmaceuticals require costly and time-consuming R&D, testing for efficacy and safety, registration and product launch. The process typically takes more than a decade, and the final return on any given expenditure on R&D is highly uncertain; hence, pharmaceutical companies engage in a portfolio of R&D both within and outside the companies to try to maintain a continuous flow of successful new products. Even large pharmaceutical companies can be dependent, at any given time, on relatively few pharmaceuticals.[12]

Clearly, R&D, testing, approval, monitoring of pharmaceuticals after they are released into the market place and so on must be compensated. However, it is unclear why pharmacists should receive higher payments for patented rather than generic drugs. (The usual life-cycle is for manufacturer's price to be high when the pharmaceutical is under patent and lower after the patent has expired and there is competition from generics.) True, pharmacists are under a professional obligation to continue their education and new medications require absorbing new information. But side-effects, drug interactions, incidence of allergic reactions and all the other demands of expertise and counselling time are probably not related so much to whether a medication is under patent as to whether the pharmaceutical is new (and so patients have never used it before) and other factors, such as whether the patients using a particular medication are likely to be chronically ill. But when the payment a pharmacist receives is related to the manufacturer's price, the payment is a function *inter alia* of whether the pharmaceutical is under patent or is generic.

The development of a drug benefits any consumer, anywhere the drug is available, who has a health condition which the drug can ameliorate. International political consensus points toward certain drugs being made available at low prices to particularly low-income consumers. However, there are concerns that it is individually rational for other consumers, who would normally pay for drug development, to not contribute toward drug development, secure in the expectation that the drugs will be developed in response to the financed demand of a third set of consumers. This is a classic example of positive externalities which are not internalized and result, at least theoretically, in under-provision, i.e., less than would be economically efficient. It is the non-excludability, and thus under-provision, that is the reason for much public funding of research.

3.5.1. Pharmaceutical Pricing in Germany

Since the late 1980s the German government has imposed a wide range of supply- and demand-side restrictions intended to curb the level of overall spending on pharmaceuticals. Thus, the setting of uniform retail prices is just one of the reasons there is not competition among pharmacies in Germany. Some of the

rules for pricing pharmaceuticals changed in 2003 in a direction to promote greater competition. For example, pricing restrictions for non-prescription medicines have generally been removed and state-specified retail margins on prescription-only medicines have been abolished. In addition to the remaining restrictions on pricing, pharmacists are required to substitute lower-priced, imported medicines under an import quota. Pharmacists are required to substitute low-priced drugs having the same active ingredients, effectiveness and pack size, and a comparable form, if the prescriber has not actively ruled-out such substitution. This system is described in more detail in this part of the review.

A community pharmacy in Germany sells three types of medicines:

- Prescription-only
- Pharmacy-only, which may be prescribed so long as they are not excluded by law (if it is prescribed, then the health insurance pays; if it is not prescribed, the consumer pays)
- Free-trade over the counter (which may also be sold by other retailers who have "specialist knowledge").

Until 2003, the margins of pharmacies and wholesalers for the first two categories of medicines had been subject to price control under the Drug Prices Ordinance. The only other products that may be offered for sale, according to the *Apothekenbetriebsordnung*, are those listed in Section 25 of the decree as "the usual goods sold in a pharmacy." These are ones that do not affect the orderly operations of the pharmacy such as items for babies, hygiene, pesticides and herbicides. [Ashurst et al. 1998] Since 2003, this restriction has been loosened to allow pharmacies to offer medical devices and products that generally support health care.

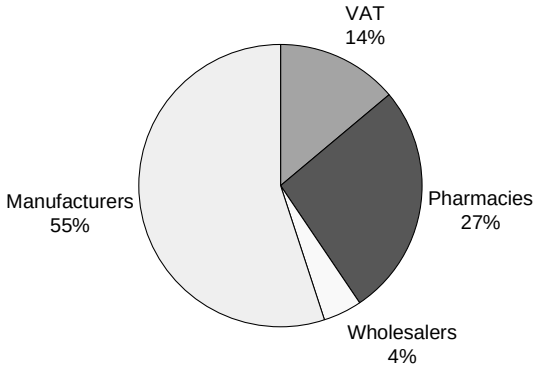
Pharmacies and pharmacists are just one part of the German health care system. A very brief overview, focused on the role of pharmacies, is provided here. It is worth noting that the 1999 Act on the revision of statutory health insurance says that the statutory health insurance funds do not operate as undertakings within the meaning of private law, and therefore that competition law does not apply to them.

- About 90% of the population is a member of one of several statutory health insurance funds (SHI). (The other 10% has private health insurance.) The SHIs compete for insured persons on the basis of contribution rates, but not on the basis of, e.g., coverage or co-payments. Contributions are paid by the insured, their employers and, for the unemployed, the State. When one SHI attracts disproportionately costly-to-serve persons, an equalisation mechanism transfers funds from the other SHIs.
- The SHIs pay pharmacies for prescribed pharmaceuticals. (Consumers pay a co-payment of 10% up to €10 per package. The minimum co-payment is €5 per package. Until 2003, consumers paid for any excess over the "reference price.") Consumers pay for non-prescribed drugs.
- Pharmacies pay drug wholesalers. Drug wholesalers each offer a full line of pharmaceuticals and provide inventory control.[13] Usually, a pharmacy has one major and one minor wholesaler. Drug wholesaling is a concentrated business in Germany, with the five major drug wholesalers accounting for perhaps 90% of the market. [ANZAG 2002]

- Controls on prescribers have influenced demand for pharmaceuticals. Physicians had prescription drug budgets from 1993 to 2001, but new legislation replacing these budgets requires the negotiation of pharmaceutical expenditures between the Institutes of Statutory Health Insurance (SHI) and the National Association of SHI-accredited Physicians, and individual prescription limits for physicians. [Aventis 2003]

Figure 15 shows the components that make up the retail pharmacy price.

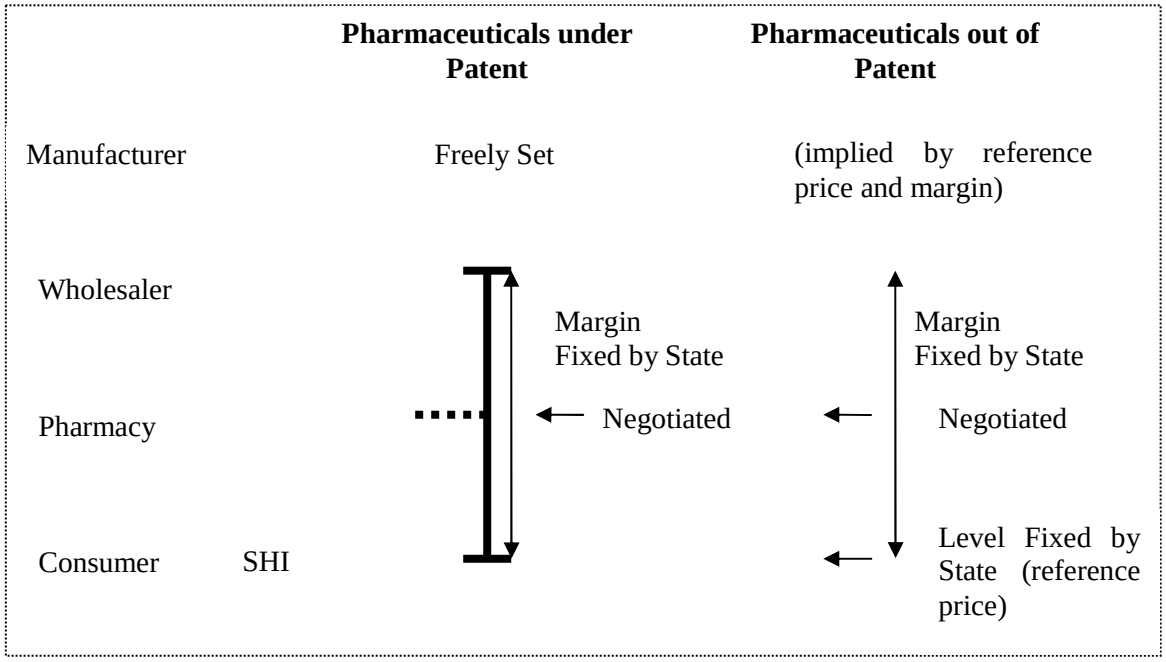
Figure 15: Components of Retail Pharmacy Price



Source: Verband Forschender Arzneimittelhersteller 2002.

Figure 16 below provides a simplified schematic of the main points under the pricing system in operation until 2003, omitting in particular the SHI rebate, the import quota and the *aut idem* requirements. This is described in detail below.

Figure 16: Pharmaceutical Pricing in Germany until 2003



Uniform Prices

Until 2003, retail prices were made to be uniform throughout Germany. The principal arguments advanced for the price maintenance is that the safety of medicines must not be endangered by competition on price, that the patient – particularly in the case of acute treatment – must not be subjected to the need to compare prices in the various pharmacies, and that medicines should be available promptly throughout the country. In addition, advertising prescription drugs to consumers and comparative advertising are prohibited under the Unfair Competition Law.

The Council of Experts for Concerted Action in the Health System [*Sachverständigenrat für die konzertierte Aktion im Gesundheitswesen*] already in its Special Study of 1995 (number 414) called for the lifting of mandatory pricing and allowing price competition for, at least, non-prescription medicines. The Council said that the arguments traditionally advanced for uniform pricing are especially unconvincing for non-prescription drugs, when people are self-medicating. They estimated that lifting mandatory price control for non-prescription medicines would result, at a conservative estimate, in a price fall of 15%, benefiting both the health insurance companies and patients. Furthermore, competition in pharmacy retail prices could also have an impact on the upstream commercial stages and initiate or stimulate competitive processes there. [Council of Experts 2002]

The Council of Experts noted, too, in the Special Study, that an expansion of the spectrum of non-prescription medicines should be discussed, i.e. the applicable delimitation to prescription-only medicines should be subjected to critical examination. They pointed out that patients have an increased level of information, improved means of getting personal advice, e.g. call centres, and the foreign experience with widening the spectrum on non-prescription medicines had been positive. Drug indications were being defined on behalf of the European Commission that can be used for self-medication. Ultimately, price competition could then extend to a good third of the pharmacy market.

The arguments for uniform pricing are unconvincing for prescription drugs for chronically ill persons as well. These patients are buying drugs month after month, so have opportunity to investigate prices in a wide variety of pharmacies. The argument is also not convincing where a sick person has an agent, such as a family member, to make the telephone calls to compare prices. Indeed, it is not the case that every consumer needs to compare prices for competition to work. It is sufficient for only a fraction of consumers to do so, and for the sellers to not be able to discriminate between the comparison shoppers and the free-riders.

The argument about ubiquitously prompt supply actually supports the idea of having differentiated prices, where pharmacies receive higher profits for supplying infrequently demanded products and lower profits for supplying frequently demanded products. Thus, for example, pharmacies located where there are numerous young families might have a different pricing pattern for baby care products from those located where most residents are elderly.

Recommendation: Eliminate State control of prices of non-prescription medicines and permit comparative advertising among non-prescription medicines. Price competition should trigger price reductions, which would benefit both health insurance funds and consumers. As compared with the reference price system, companies that offer lower prices will see an expansion in quantity sold, at the expense of the higher priced offerers. This will have the effect of encouraging upstream firms to compete and seek greater efficiency.

Reference Prices

Reference prices are the prices set by the State at which the SHIs reimburse prescribed drugs. If the retail price is above the reference price, the patient must pay the difference. However, consumer resistance is so high that usually the drug manufacturers readjust their prices to accommodate the reference price. Reference prices had not applied to drugs still under patent, although this changed in 2003 when the reference price system was extended to all prescription drugs. In addition, the reference price system was removed from non-prescription drugs under patent. (The exceptions are non-prescription medicines which are taken for special severe illnesses and which are reimbursed by the SHIs.) Reference prices are uniform throughout Germany. The reference price is set at the average price offered within a defined set of drugs, i.e., a level above the price offered by the lowest cost supplier.[14] There have been suggestions that the reference price system maintains higher prices than would be the outcome of free price competition.[15] This would not be surprising, since normally one would expect lower-priced competitors to displace higher-priced competitors in a market.

Retail and Wholesale Margins

Until 2003, the State specified the margin between retail price and manufacturer's price, but allowed bargaining between retailers and wholesalers within a constraint on maximum wholesale margins. The margins were not uniform. Rather, they were lower for higher priced pharmaceuticals. They ranged from 68% and 21% for the lowest priced items down to, respectively, 8.263% plus €118.24 (for items over €543.92) and 3% (for items over €61.63), both of these as percentages of the manufacturer's price. The idea was that distribution costs would rise at a lower rate than manufacturers' prices due to, e.g., innovative products. There were also surcharges for the retailer compounding one or more substances or selling outside of statutory shop opening hours.

In the other direction, there were rebates to the SHIs. The SHIs got a rebate of 6-10% of the retail price, taken out of the pharmacist's margin. Additionally, they got a rebate of 6% of the manufacturer's price for all pharmaceuticals which were reimbursed by the SHI. For all prescription-only medicines the wholesalers had to grant a rebate of 3%.

Given that the cost of efficiently providing pharmacy services varies from location to location, a fixed, nation-wide margin, independent of the costs of an individual pharmacy, meant that low-cost pharmacies receive high profits at the expense of SHI contributors, but without providing an equally valuable service in return. These high profits attract entry, which could be excessive in the sense of total costs of supplying pharmacy services being unnecessarily high. Blocking entry would not be efficient, since then the value of the right to enter would be expressed in the high purchase price of existing pharmacies.

Reforms in 2003 abolished the regulation of the retail margin. After 2003, the SHIs pay pharmacies a fixed consultation fee (€8.10), the wholesale price plus 3%, less a rebate of €2 per package for prescription pharmaceuticals.

The maximum margin for wholesalers is fixed by the State, but wholesalers compete to supply cooperatives of pharmacists. Until the 2003 reforms, this bargaining had been over the distribution of rents since none of the retail price, the reimbursement rate, or the manufacturer's price depended on the negotiated wholesale price.

Import Quotas

Since April 2002, pharmacists in Germany have been required to fill a certain percentage of prescriptions with lower-priced drugs which were originally sold outside Germany. (This is the result of an agreement between the Statutory Health Insurance funds and the pharmacists' federation.) This is the so called "import quota." In 2002 the quota was 5.5 % of turnover but from 1 January 2003 it has been 7 %.

The intent of the rule was to further limit spending on pharmaceuticals. The effect of this quota is to transfer some profits to authorised parallel importers[16] from drug wholesalers and drug manufacturers. (To the extent that the retail price is lowered, then some profits are also transferred to the SHIs.) Since the pharmacist is not incentived to make the most cost-saving substitutes, and since the import quota applies across all prescriptions, then this rule has only a very marginal effect on drug manufacturers' prices in Germany.

Generic Substitutions

The State require pharmacists to substitute low-priced drugs having the same active ingredients, effectiveness and pack size, and a comparable form, if the prescriber has not actively ruled-out such substitution. Essentially, generics are substituted for branded drugs. The *aut idem* regulation, effective as of 23 February 2002, has not had as large an effect on prices as had been expected because generics had already largely displaced branded drugs where they could. One concern that has been raised is who would be liable if the drug substituted under the *aut idem* rule had side-effects; would it be the doctor who prescribed the active ingredient or the pharmacist who substituted a generic form of the active ingredient?

Reform of pricing

Reform of the fixed margin system was supported by the health insurance companies in order to reduce costs. The associations responsible for pharmacies and pharmaceutical wholesale reject competition of this kind. They fear an increase in the consumption of drugs and obstructions to the procurement of drugs for the patient if he is forced by the health insurance companies, for example, to use the cheapest drug currently on the market. In its 2000/2001 study the Council of Experts for Concerted Action in the Health System [*Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen*] proposed removing the fixed prices for non-prescription drugs.

In January 2002 the **"**Round Table" in the health system recommended that the Drugs Prices Ordinance be revised with the following objectives: the surcharges to the drugs should reflect the work of the pharmacists and the pharmaceutical wholesaler. Price competition should be initiated where this is possible and reasonable from the point of view of health policy. In this connection it should also be a matter of passing on the economic advantages to the end consumer. Removing the second hand fixed prices for non-prescription drugs should also be examined. Furthermore, incentives should be created for the consumer to procure these drugs as cheaply as possible.

Many of these recommendations were taken up in the reforms in 2003, as has been noted throughout the text and in Box 16 below.

The German pharmaceutical pricing system reflects the complex social, political and economic trade-offs that have been made. Pharmaceutical pricing will necessarily form part of the comprehensive health reform, since reform can promote greater efficiency in pharmacies and more efficient choice among substitute pharmaceuticals. However, the reform will need to provide incentives to consumers to choose less expensive equivalent pharmaceuticals, when a choice is available. Otherwise, more efficient pharmacies and more competitive generic manufacturers will not be rewarded by attracting customers away from the higher priced pharmacies and manufacturers. For example, for consumers whose purchases are not fully reimbursed, the non-reimbursed part can be designed to give the consumer part of the cost-saving if he buys less-expensive equivalent pharmaceuticals.

3.6. Advertising

Advertising is strictly regulated and much advertising in this area is prohibited. In principle pharmacists are allowed to advertise their pharmacy. However, advertising restrictions are imposed by professional law, e.g. prohibition of excessive or misleading promotion. Advertising of medical products which are subject to prescription or which are not authorised in any Member State of the European Union is prohibited. Of those advertisements that are allowed, they must provide specific information as to the pharmaceutical's effects, side-effects, contraindications etc. Comparative advertising is strictly prohibited under the general law protecting competitors against unfair or misleading advertisements, the *Gesetz gegen den unlauteren Wettbewerb*. The Association of the German Pharmaceutical Industry has a self-regulatory code which prohibits false and misleading advertisements and has specific rules on labelling medical products. [Ashurst et al., pp. 53-4]

Accurate advertising of pharmacies that does not diminish the professional standing of pharmacists would enable those pharmacies that better satisfy consumers in those dimensions when pharmacies have commercial freedom to attract more customers. If pharmacies were freed to offer lower prices on some pharmaceuticals, then not being able to attract new customers by advertising the fact would blunt the pharmacies' incentives to offer the lower prices. Also, given that foreign mail-order/internet pharmacies are able to advertise on the internet, there would be a distortion of competition if domestic pharmacies could not also advertise in terms of informing consumers.

Recommendation: Remove the prohibition of advertising of pharmacy-only medicines by pharmacies, while ensuring that the advertising remains accurate, not misleading, and not tending to bring the profession into disrepute.

The Act on the Modernisation of the Statutory Health Insurance, which is part of agenda 2010, came into force on 1 January 2004 and addressed several issues raised in this report (see Box 16).

Box 16. Germany: The 2003 health reform

- Mail order trade of pharmacy-only drugs in Germany and with the EEA is allowed for registered pharmacies. Pharmacies have to comply with all standards of traditional pharmacies and several additional quality and safety standards (advertising, website layout, technical equipment, dispatch matters, delivery, patient information and consultation) to be accredited. The objective was to offer a safe and reliable opportunity to patients who would like to use mail order of medicines.

- Ownership restrictions for pharmacies have been loosened. Pharmacists may now own up to four pharmacies, which have to be located in the same or a neighbouring district. This is regarded as a first step towards a more liberal system. The ban on multiple ownership has not been lifted completely in order to gain experience with new basic conditions that will not influence consumer protection or drug safety (which were given top priority) in a negative way.

- Restrictions on products that may be carried in pharmacies have been loosened. Pharmacies may now offer medical devices and products that generally support health care.

- Pricing requirements for non-prescription medicines have generally been removed and thus price competition between pharmacies has been initiated. The SHI's will now only reimburse for non-prescription medicines when taken as a medication for special severe illnesses; in this case, medicines are still subjected to state-controlled retail margins.

- Retail margins have been abolished for prescription-only drugs. SHI's will reimburse pharmacists with a fixed consultation fee of EUR 8.10 and an additional 3% on the wholesale price (per package) to cover interest; pharmacists have to return a rebate of EUR 2 per package to the SHI's.

- Reference prices will be applied to drugs still under patent as well.

- Co-payments on drugs reimbursed by the SHIs will be raised from EUR 4-5 (depending on the size of the package) to 10% per package (depending on the price of the drug), with a minimum of EUR 5 and a maximum of EUR 10.

4. Conclusions

The intent of this review was not to consider the broader health reforms in Germany, which in any case are still taking form. Rather, it looked at those aspects of the pharmacy sector that could be made more efficient while protecting consumer health and safety, without yet having a precise view of the broader reform. Germany has relatively open entry for both pharmacies and pharmacists, in contrast to a number of other OECD members. Pharmaceutical prices seem to be low relative to prices in other European countries. This is likely to be a reflection of the high use of generics where they are available. These are both positive features of the German pharmacy sector.

- One focus of this review was on the business structure restrictions, both that pharmacies must be owned by pharmacists, and that pharmacists may own at most four pharmacies in Germany. These restrictions on business structure do not seem to promote consumer interests, since they do not allow economies of scale to be exploited. Consumers would benefit by the cost-savings being passed onto them through lower prices both directly, when they themselves pay, and indirectly, through lower contributions to the insurance funds, when the health insurance funds pay. Professionalism has not suffered in those countries where non-pharmacists are allowed to own pharmacies, and in any case the same professional disciplinary structure would apply both to pharmacist-employees and to pharmacist-owners.

- The second focus of this review was on mail-order trade in pharmaceuticals. Other countries have adapted their regulatory systems to maintain safe delivery of medicines from mail-order/internet pharmacies. Costs are lower, as the prices already being charged to German consumers indicate. The foreign experience suggests the protection that must be put into place to ensure high-quality pharmacy services and safe delivery. Germany, too, should raze its wall to cross-border mail-order European pharmacies and implement these changes.

Additional reforms, e.g. of pharmaceutical pricing and to make greater use of pharmaco-economics, *i.e.*, the use of benefit-cost analysis in the use of medicines, seem to be called for, but would need to be integrated into a comprehensive reform.

NOTES

[1] Only community pharmacies are reviewed here.

[2] Volume III and addendum (number 15 ff. and number 89 ff.).

[3] These active agents include mostly patent-free substances, such as diclofenac, acetylcystein, insulin, and nifedipin but as well as substances protected by patent (when the study was being compiled), such as omeprazol or simvastatin. The above-mentioned active agents can be found in all member states of the EU and this means that the prices per unit of active agent can be calculated. According to the authors of the study, those active agents that were used for the comparison account for 30 per cent of prescriptions and turnover on the German market of the statutory health insurance companies. The authors are not aware of any other study that covers anywhere near as much. The Federal Government is aware that the substances chosen were predominantly generic substances and thus the result of the study might be biased. Furthermore, the study was compiled on behalf of the research and development based manufacturers and the Federal Organisation of Germany Pharmacy Associations.

[4] Practical training in a pharmacy, half of which may, e.g., be in a hospital pharmacy, in the pharmaceuticals industry or in a drugs inspection centre.

[5] This is normally done in a pharmacy. Half of the period can voluntarily be passed in the pharmaceuticals industry, a hospital pharmacy, university or medicines inspection centre.

[6] Such trade was, however, permitted for medical devices and medicines which can be sold outside pharmacies.

[7] The German consumers' organisation finds that pharmacists generally do not now provide the service of overseeing drug interactions. Some associations of pharmacists have begun to address the issue.

[8] In the EU, about 65% of the pharmaceutical market (by value) is accounted for by products that are reimbursed. Thus, the ability of patients to be reimbursed if they buy from an Internet pharmacy is important to its gaining scale. However, two decisions in the European Court of Justice (Nicolas Decker v Caisse de Maladie des Employés Privés (28 April 1998, Case C-120/95) and Raymond Kohll v Union des Caisses de Maladie (28 April 1998, Case C-158/96)) upheld the right of every citizen to obtain goods and services related to medical care and treatment from whichever Member State they chose. [Ashurst et al, pp. 36, 37]

[9] A consumer survey performed for the Office of Fair Trading (United Kingdom) identified which non-price characteristics of pharmacies are valued by consumers. The most important factors for consumers when choosing a pharmacy for their National Health Service prescriptions (for which they are not price-sensitive) are location and convenience, where convenience includes proximity to home, doctor's surgery, or workplace, opening hours, or the ability to get the prescription filled at the same time as other activities, such as shopping. [OFT 2003, p. 39]

[10] The Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics, has found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." Attempts to stop this practice have not always been successful. [Hubbard 2003]

[11] See Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, O.J. N° L214.

[12] For example, in 2002 Aventis (a product of the merger of Hoechst of Germany and Rhône-Poulenc of France) got 10% of its sales (€ 2,030 m) from its best-selling product, *Allegra/Telfast*, € 1,563 million from its next-best selling Lovenox/Clexane, and € 1,261 million from its third-best selling *Taxotere*. [Aventis 2002, p. 20] In 2002, Aventis generated sales of € 17.59 billion, invested € 3.14 billion in research and development. [ibid., p. 13] Bristol-Myers Squibb's two biggest sellers were Pravachol ($ 2,266 million) and Plavix* ($ 1,890 million) out of total pharmaceutical sales of $ 14,676 million. [Bristol-Myers Squibb 2003 and own calculations]

[13] Some 5-10% of pharmaceuticals, mainly vaccines or genetically engineered products, by-pass the wholesalers. [Phoenix 2002]

[14] The reference price is determined by the average price of pharmaceuticals which:-

(a) are constituted of identical active ingredients;

(b) are constituted of pharmacologically and therapeutically comparable active ingredients; and

(c) which operate in a pharmacologically comparable manner. [Ashurst et al 1998]

[15] "My hypothesis today is this: if there were no longer a reference price system in Germany, then prices for generic products in Germany would probably be lower rather than higher." Walter Wenninger, Member of the Board, Bayer, quoted in EC 1998, p. 59.

[16] Parallel importers are specialists who redesign the foreign packaging and apply to the competent German authority for approval. Pharmaceutical wholesalers buy from these specialists since this is the only way to ensure that these products comply with applicable law in Germany.

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