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Managing pharmaceutical regulation in Germany: overview and economic assessment

Jonas Schreyögg, Klaus-Dirk Henke, Reinhard Busse[1]

Abstract

Rising costs in pharmaceutical expenditure have become a major concern for policy makers in Germany over the last years. Therefore the pharmaceutical market in Germany has been increasingly targeted by different kinds of regulations, focussing both on the supply and the demand side, using price, volume and spending controls. Specific regulations include price reductions, reference pricing, pharmacy rebate for sickness funds, increasing co-payments, an "aut-idem" substitution, parallel imports, negative list, guidelines, and finally spending caps for pharmaceutical expenditure per physicians' association. Although it is difficult to attribute certain effects to single measures, some measures like reference pricing and physician spending caps are more effective and long-lasting than others. Although highly disputed among physicians, the spending caps applied between 1993 and 2001 have limited pharmaceutical expenditure for an entire decade. However, while some measures do effectively control expenditures, their effect on allocative efficiency may be negative.

Zusammenfassung

Steigende Ausgaben für Arzneimittel stellen zunehmend ein Problem für Entscheidungsträger in Politik und Selbstverwaltung dar. Daher war der Arzneimittelmarkt in den letzten Jahren Ziel verschiedener Regulierungsformen, die sowohl auf der Angebotsseite als auch auf der Nachfrageseite ansetzen und sowohl Instrumente zur Preis, Mengen als auch Ausgabenregulierung nutzen. Sie umfassen dabei insbesondere Preisrabatte, Festbeträge, Zuzahlungen, „Aut-idem" substitution, Parallelimporte, Negativlisten, Leitlinien and Arzneimittelbudgets. Obwohl es

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schwierig ist, bestimmte Wirkungen monokausal auf einzelne Maßnahmen zu zurückzuführen, kann festgestellt werden, dass Arzneimittelbudgets und Festpreise nachhaltiger und effektiver als andere Regulierungsformen sind. Obwohl Arzneimittelbudgets bei niedergelassenen Ärzten sehr umstritten sind, waren sie hauptverantwortlich für die Begrenzung der Arzneimittelausgaben zwischen 1993 und 2001. Daneben existieren einige Regulierungsformen die zwar die Arzneimittelausgaben wirksam senken, deren allokative Effizienz jedoch insgesamt eher negativ ist.

1. Introduction

The German Social Health Insurance (SHI) system finished the year 2002 with a deficit of € 2.96 billion equal to 2.1 % of overall SHI expenditure. The situation was exacerbated by the deficits in the pension insurance and unemployment insurance schemes. Current economic and social policy debate is justifiably focused on questions concerning the total overhaul of social security in Germany (Henke 2002). In addition, the structural weaknesses of the German economy are evidenced by mass unemployment and a government debt that exceeds the criteria of the Maastricht Treaty.

In the last years the pharmaceutical market in Germany has been characterized by major growth rates of up to 8.7% in the year 2001. In the face of the miserable financial situation of the German sickness funds, regulation of the pharmaceutical market in Germany is therefore gaining in new importance in the public discussion.

This article reviews the policies both to contain costs and to improve the quality of drug therapy, i.e. to increase efficiency, over the last ten years.

2. Health Policy goals in Germany

In spite of changing political coalitions policy aims have not changed significantly in recent years. The current Government consisting of social-democrats and greens is rather emphasizing the goals of equal access and quality while politics under the former conservative-liberal government rather aimed at the goal of efficiency.

The German Government currently defines its major health policy goals as follows: “It is the aim of health policy to maintain and promote the health of our citizens and to restore it when they become ill. The opportunity to live healthier, longer and more active is something which must be guaranteed to each and every citizen to the greatest possible extent.” …. “All citizens, irrespective of their financial situation, place in society, or place of residence, must have access to the resources that allow them to maintain or regain their health.” (Federal Ministry of Health and Social Security 2003).

While there is widespread consensus in German society on the goals of “quality”, “efficiency” and “access” there is a heated debate on the instruments to reach these goals. Though competition is able to contribute to efficient solutions many actors of the system raise serious concerns when competition is suggested to reach these goals. Often a major trade-off is perceived between competition and equity or quality. On the other hand we have seen the failure of governmental regulation in many fields of the health care system. Regulatory measures are rarely lead by economic evidence and are too often dominated by political interests (Sauerland 1999).

In Germany’s statutory health insurance (SHI) system, sickness funds and providers of

health care have been required to pursue the goal of cost containment. This is operationalised as maintaining stability in the average SHI contribution rate which can only be achieved if the rate of increase of expenditure is not greater than that of contributory income (i.e. mainly wages and pensions up to certain threshold as well as unemployment benefits). In the ambulatory and hospital care sectors, the expenditure side has generally been quite well controlled through fixed budgets. Regarding the pharmaceutical market with its particularities, a wider array of cost containment measures was applied. Some policies were successful, some not – some measures were sustainable while other did not last for long time.

Compared to cost containment, issues of quality have generally received less attention. However, in 2001 the "Advisory Council of the Concerted Action in Health Care" published an extensive work on quality in health care especially regarding over-, under- and misuse (Advisory Council of the Concerted Action in Health Care 2001). Subsequently, the Government submitted a draft law suggesting the introduction of a 'German Centre for Quality in Medicine' similar to the National Institute of Clinical Excellence (NICE) in the UK. Regarding the pharmaceutical market this new centre would have been assigned to evaluate and classify new pharmaceuticals according to their degree of innovation and effectiveness. If the effectiveness is equal to products already on the market, the new product would have been immediately classified into the reference price system, i.e. a patent would have no longer secured a reference-price free marketing period (Busse/Wörz 2003). Although the introduction of this centre has passed legislation with the Social Health Insurance Modernisation Act and is to be introduced in 2004 it does not act as a "forth hurdle". It rather has the task to issue

guidelines and increase transparency regarding reimbursement decisions.

3. Decision making process

The status quo of regulation of pharmaceutical markets in Germany is characterized by several deficiencies. This is not at least the result of contradictory interests of the stakeholders in the health care system. Usually more than 70 interest groups voice their positions in parliamentary hearings on health care reform acts. It can be ruled out from the start that all stakeholders share the same objectives and that a health care reform or cost-containment policy can be based on one consistent approach. The system is determined by a diversity of interests and claims. Politicians, health care providers, industries, payers and experts are ultimately concerned with their own influence, social recognition, research funds and research projects (Henke 2001). They are all stakeholders in a complex system of (self-)governance.

Decisions on health care provision in Germany are generally not only determined by governmental institutions but also by self governmental institutions like the physicians' associations. The pharmaceutical market is thus partly under direct governmental supervision and partly regulated by self-governing and self-regulating institutions (see below).

The legislation process itself is also quite complicated, as most of the bills concerning the regulation of the pharmaceutical market require the formal approval of the Federal Assembly ("Bundestag") and the Federal Council ("Bundesrat"). The Federal Assembly consists of about 600 members being elected every four years. It is responsible for the

election of the German chancellor thus exerting influence on governmental politics and passing federal laws. Depending on their population size the governments of each of the 16 German states are sending 3 – 6 members into the Federal Council, which has to approve bills passed by the Assembly. In about half the cases the Assembly may overrule a negative vote by the Council. The requirement for being passed by both chambers applies especially to bills that are of vital interest to the federal states, such as those regarding financial affairs or their administrative powers. Passing laws that need the approval of both chambers is often difficult since the political majority in each chamber is typically held by opposing parties or coalitions. Therefore decisions can be delayed due to reconciliation or just for tactical reasons.

Self-governmental institutions of health care provision have the right to express their position regarding law proposals in special committees. This can either be seen as a form of corporatism in decision-making or the enforcement of private interests. The Federal Association of SHI-accredited Physicians, associations of the pharmaceutical industry, hospital groups, the pharmacists' associations, sickness fund boards and other interest groups all participate in the political decision-making process on behalf of their members. As a matter of fact, particularly the pharmaceutical industry is highly organised with several associations. Its associations are either influencing politicians and bureaucrats by passing them papers or trying to influence the public by press releases and other activities. Sometimes lobbying groups are even able to block an executed law from being implemented. For example the so called positive list, a catalogue of all drugs to be reimbursed by the sickness funds, was twice – in 1995 and in 2003 – not implemented for this reason.

It also has to be mentioned that the jurisdiction in Germany plays a more important role in the decision making process than in many other European countries. In the past German courts often blocked the execution of different health care acts in order to protect the principle of self-governance and at the same time to ensure accordance with European cartel law as described below. Furthermore, so-called “social courts” frequently intervened to safeguard an equitable provision of health care services. For example they judged that drugs for the treatment of erectile dysfunction have to be reimbursed by the sickness funds and cannot be excluded from reimbursement (unless the law is changed).

Drug licensing and supervision is being done by the Paul-Ehrlich-Institute (blood, blood products, sera and vaccines) and the Federal Institute for Pharmaceuticals and Medical Devices (BfArM) (all other drugs), which are the official national licensing bodies for pharmaceuticals and at the same time supervising the safety of pharmaceuticals and medical devices (Busse 2000).

Drug licensing for new drugs became mandatory only in 1976. This is done through mandated processes specified by the Pharmaceutical Act (AMG) which took effect in 1978 and a set of guidelines issued by the Ministry of Health. The criteria for licensing pharmaceuticals are: scientifically proven efficacy and safety. This includes the results of phase I to phase III (controlled clinical) studies. However, only a marginal beneficial effect of the new drug needs to be demonstrated with a small sample in order for it to be sufficient to fulfil the efficacy criteria. According to § 22 AMG manufacturers have to hand in several documents including information on the drug itself (e. g. name, package size, adverse reactions, given dosage, expected effect, etc.), pharmaceutical, biological,

chemical and clinical studies regarding the effects of the drug and special information due to characteristics of the drug (e. g. several substances of content, special techniques for storing, radioactivity, etc.).

Cost-effectiveness is of no importance for the licensing procedure. This has led to the increasing licensing of active substances with merely minor modifications rather than the introduction of real product innovations. In addition drugs for complementary medicine as homeopathic and anthroposophic drugs are exempted from the licensing procedure according to the AMG since they are subject to registration only. Requirements for registration refer mainly to the quality of the basic products and the manufacturing process as well as to the durability of the final products. Licensing is, in any case, limited to five years, after which one needs to apply for an extension which is usually granted. During this time all of them may be prescribed on the account of the statutory health insurance with a few legally fixed exceptions.

Between 1978 and 2001, approximately 35,571 drugs have been licensed and about 1,750 homeopathic substances registered (BAH 2002). Unlike in other countries of the European Union, a substantial number of pre-AMG drugs are still on the market. These had to apply for licensing within an appointed time or be removed from the market. The original deadline was 30th of April 1990 and 70,000 drugs were removed by January 1993 accordingly. Since a substantial number of drugs did not have a chance to prove their efficacy, another deadline (31st of December 1999) for submitting licensing applications was established. If a manufacturer renounced its application for licensing a certain drug, the drug may be marketed until the end of 2004 without any proof of therapeutic benefit. According to estimates about 5,300 pre-AMG drugs were removed

from the market in 2003 which is nearly one tenth of all registered pharmaceuticals (BfArM 2003). However, on 31st of July 2003, 10,189 applications for licensing of pre-AMG drugs were still not dealt with (BfArM 2003). Therefore it is likely that even in the coming years there will be several pre-AMG drugs on the market.

Besides regular licensing, an accelerated licensing process is also possible. This is intended for drugs which, on the basis of their potential therapeutic value, show considerable public interest, but still no sufficient data with which to judge therapeutic efficacy. In this case, it can be decreed that within a certain period data should be systematically collected on the drug's efficacy in order to reappraise its therapeutic value. This procedure is relevant for orphan drugs (i.e. those used to treat very rare diseases) and in instances when companies try to expedite the licensing procedure. However, this procedure is very rarely adopted.

Next to the mentioned national licensing procedure, manufacturers are also free to use the centralised procedure at the European Agency for the Evaluation of Medicinal Products (EMEA) in London which grants market authorization in all EU member states which came into effect in Germany on 1st of January 1995. Based on this directive, a manufacturer whose drug has been admitted in another country as a "Reference Member State" may also apply for the drug's licensing in Germany. Among the countries most frequently used as "Reference Member State" Germany is currently ranking number four (BfArM 2003).

4. Trends in expenditures of the pharmaceutical market

The German pharmaceutical market is currently the third biggest of the world. The sales volumes of the pharmaceutical industry at manufacturer prices accounted for € 22.5 billion in 2001. Research based pharmaceutical companies contributed an amount of € 21.3 billion to these sales. Exports of pharmaceutical drugs and substances increased to € 19.8 billion in 2001 and lead to a surplus of € 7.4 billion in the year 2001. Pharmaceutical companies in Germany are operating their businesses with about 115,000 employees (2001) and the 45 leading research based companies employed of staff of 80,116 employees out of which 14,166 are directly concerned with R&D. In the year 2001 a sum of € 3.4 billion was spend on R&D.

Total pharmaceutical expenditure has increased in most years during the last 10 years, as shown in table 1. The share of pharmaceuticals as a percentage of public and total health expenditure has also been growing gradually after the effective cost-containment measures of the Health Care Structure Act of the year 1992. Thus the growth of pharmaceutical expenditure exceeded Germany's growth of the public health expenditure as well as the growth of the total health care expenditure in almost every year since 1994 and 1996 respectively.

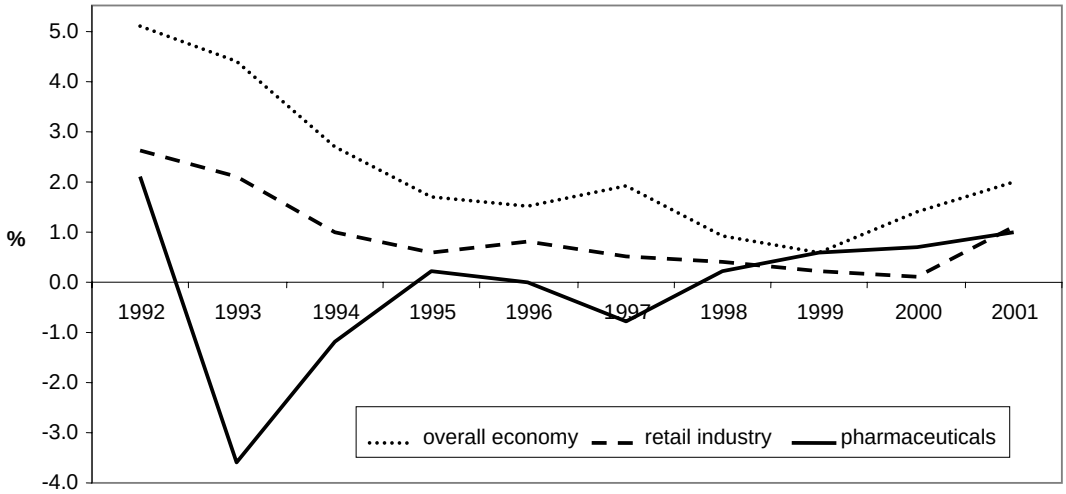
Table 1: Pharmaceutical expenditure in current values by payer, 1992-2001

Expenditure by payer	Unit	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	1992-2001
Sickness Funds	€ billion (% change to previous year)	18.74	16.00 (-15%)	16.84 (+5%)	17.98 (+7%)	18.95 (+5%)	18.23 (-4%)	19.08 (+5%)	21.0 (+10%)	22.00 (+5%)	24.20 (+10%)	+29%
	% of pharm. exp.	72.42	66.20	66.53	67.37	67.65	64.24	63.71	66.87	67.92	69.30	
	% of total SHI exp.	18.93	16.13	15.64	15.93	16.25	15.77	16.14	17.29	17.69	18.78	
Private Health Insurance	€ billion (% change to previous year)	0.96	0.99 (+3%)	1.01 (+2%)	1.08 (+7%)	1.13 (+5%)	1.20 (+6%)	1.30 (+8%)	1.66 (+28%)	1.81 (+9%)	1.94 (+7%)	+102%
	% of pharm. exp.	3.70	4.10	3.99	4.05	4.03	4.23	4.34	5.29	5.59	5.55	
	% of total PHI exp.	8.03	7.69	7.34	7.44	7.64	7.58	7.97	9.65	10.13	10.39	
Private Households	€ billion (% change to previous year)	4.75	5.69 (+20%)	5.93 (+4%)	6.09 (+3%)	6.35 (+4%)	7.29 (+15%)	7.87 (+8%)	6.86 (-13%)	6.65 (-3%)	6.80 (+2%)	+43%
	% of pharm. exp.	18.34	23.54	23.43	22.82	22.67	25.69	26.28	21.81	20.53	19.50	
	% of total private	27.28	30.56	29.55	28.35	27.74	25.58	29.87	25.73	25.03	24.47	
Others	€ billion (% change to previous year)	1.45	1.49 (+3%)	1.53 (+3%)	1.54 (+1%)	1.58 (+2%)	1.66 (+6%)	1.7 (+2%)	1.93 (+12%)	1.93 (+2%)	1.99 (+3%)	+37%
	% of pharm. exp.	5.54	6.16	6.05	5.81	5.64	5.84	5.67	6.14	5.96	5.65	
	% of total other exp.	4.16	3.98	3.96	3.41	3.22	3.49	3.57	3.90	3.89	3.93	
Total pharma-ceutical expenditure	€ billion (% change to previous year)	25.90	24.17 (-7%)	25.31 (+5%)	26.69 (+4%)	28.01 (+5%)	28.38 (+1%)	29.95 (+6%)	31.45 (+5%)	32.39 (+3%)	34.93 (+8%)	+35%
	% of total health exp.	15.87	14.38	14.05	13.76	13.80	13.92	14.37	14.68	14.83	15.46	

Source: Authors' calculations based on data from Federal Statistical Office of Germany 2003b.

This growth of pharmaceutical expenditure cannot be attributed to the price increases of established products as the price index for pharmaceuticals that primarily contains these products has only risen very moderately (Figure 1).

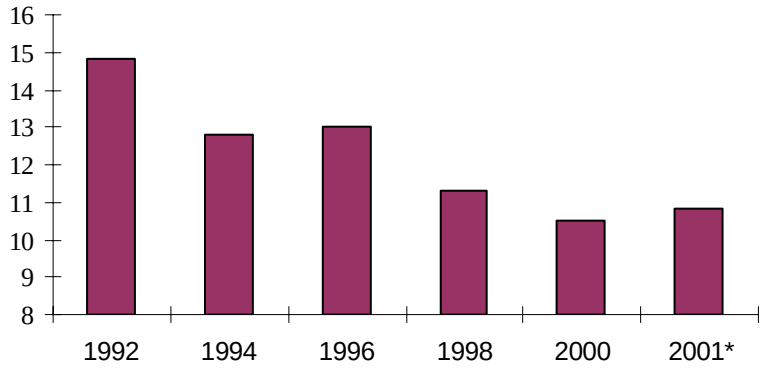
Figure 1: Price growth as annual changes in percent



Source: Federal Ministry of Health and Social Security 2002; Federal Statistical Office of Germany 2003a+b.

At the same time the number of drugs prescribed per person even declined while package sizes remained approximately the same (Figure 2).

Figure 2: Number of prescriptions per insurant and year for SHI



Source: VFA, Statistics, 2002 (package size has not changed significantly)

A better explanation is the introduction and market penetration of new and expensive medicines. These products are neither in reference price regulating schemes, nor indirectly under price competition by potential competitors. As they are new, their initial market price is unlikely to be part of any price index basket. Furthermore the German fee-for-service system for reimbursing outpatient services certainly encourages prescriptions of branded products by doctors to retain patients. In addition it has to be considered that the pharmaceutical industry in Germany is among the most powerful in developed countries and is as a serious economic factor considerably able to influence political decisions.

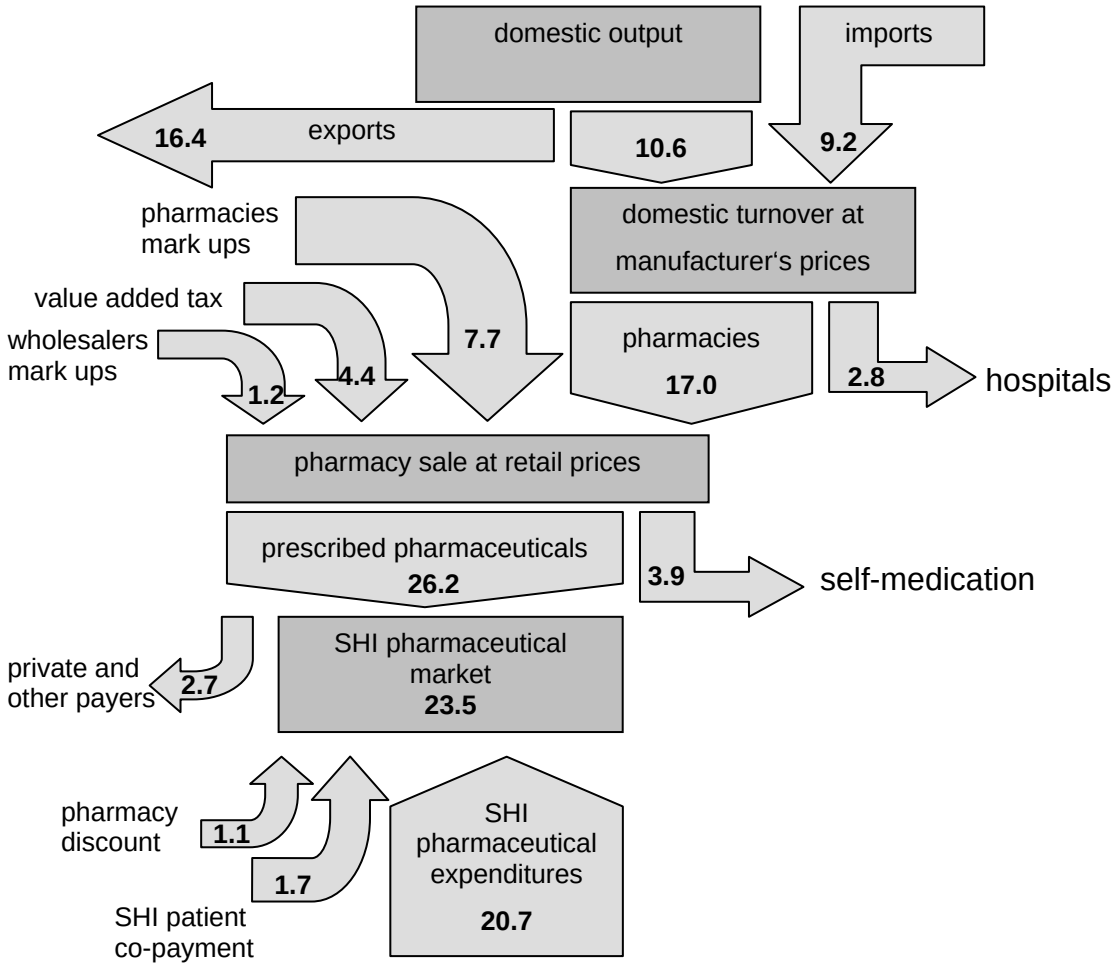
The financing structure of the pharmaceutical market in Germany is primarily dominated by sickness funds. In 2001, about 78% (€ 23.5 billion[2]) of the sold drugs

[2] This figure differs from the SHI expenditure for pharmaceuticals of 24.2 billion presented in table 1 because it only contains pharmaceutical expenditure which can directly be assigned to patients and therefore does not include e.g. pharmaceuticals for general practice supplies.

were paid by sickness funds. This included € 3 billion for OTC drugs, which were prescribed by physicians. Self medication accounted for 13% of drug sales. The remaining 9% of the drugs sold were either paid directly by patients or by private health insurance companies.

The pharmaceuticals are dispensed by “public” and hospital pharmacies providing prescribed drugs and over-the-counter drugs (OTC). “Public” pharmacies are actually privately owned but are called public, since they have a public mandate to open at certain times and stock up precisely defined drugs. They have nearly a monopoly over drug dispensing and sold drugs for € 30.1 billion in 2001 while hospitals purchased drugs with an ex-factory price worth € 2.8 billion. The sum of € 30.1 billion does consist of ex-factory prices (€ 17 billion), surcharges by wholesalers (€ 1.2 billion) and pharmacies (€ 7.7 billion) as well as a value-added tax (€ 4.2 billion). The following figure 3 summarizes the production, distribution and funding of drugs.

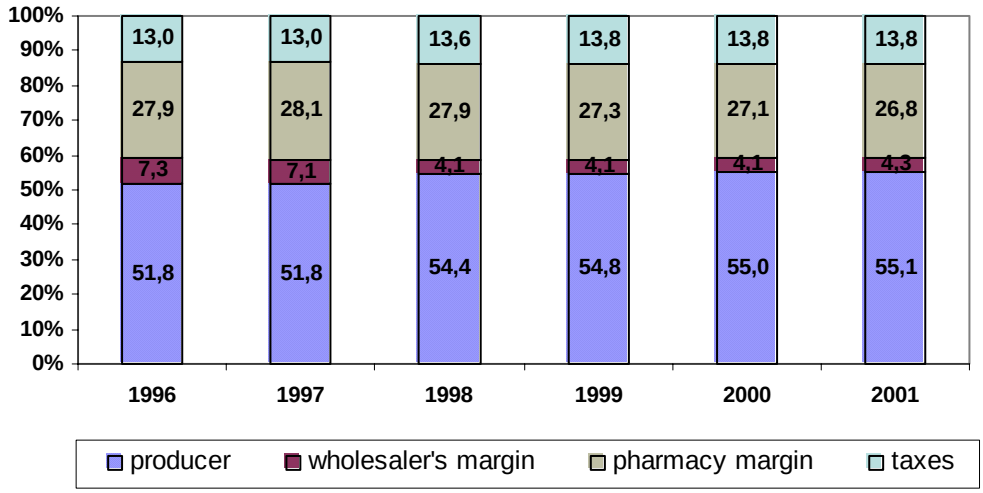
Figure 3: Production, distribution and funding of pharmaceuticals in Germany in 2001



Source: VFA 2002.

The composition of retail prices remained more or less the same over the last years as shown in figure 4. However, there is a slight increase of margins in favor of the manufacturers, as wholesalers suffered from heavy competition and several legal interventions. Pharmacies as well as wholesalers are reimbursed at legally determined mark ups. The wholesalers mark ups represent the maximum amount and can be reduced by rebates while the final pharmacies mark ups are fixed.

Figure 4: Composition of retail prices



Source: VFA 2002.

The structure of the pharmaceutical market has not changed significantly over the last 25 years and has continuously been defended by both the pharmaceutical industry and the physicians' associations as beneficial for the "clinical freedom" of physicians. In spite of this the share of prescribed drugs without any or clear evidence of therapeutic effectiveness has decreased over the last 20 years from 46.2% to 19.0% (Schwabe/ Paffrath 2003). This should be mainly due to new information campaigns for prescribing physicians conducted by the physicians' associations.

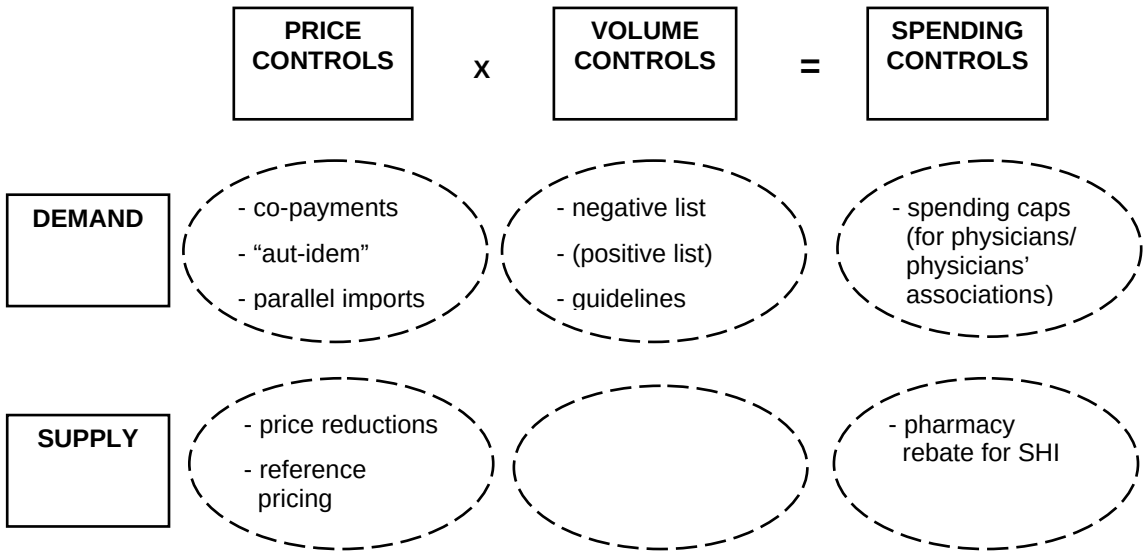
5. Interventions into the pharmaceutical market

Regulations concerning the pharmaceutical market present a dichotomy. On the one hand, the distribution of drugs through wholesalers and pharmacies and their respective surcharges on ex-factory prices are regulated in great detail. On the other hand,

regulations concerning the pharmaceutical industry's pricing and the need to prove efficacy are remarkably liberal.

Until the 1970s the pharmaceutical sector was relatively unregulated. Companies could set their prices individually and all available drugs could be prescribed. Products only had to be registered with the Federal Health Office as drugs. Registration regulations called for only minor examinations concerning possible toxic effects. The growing realization that a significant proportion of drugs possessed a level of effectiveness which was unproven and questionable led to the introduction of the mandate for drug licensing in the Pharmaceutical Act (effective from 1978). This mandate for drug licensing was followed by several forms of demand and supply interventions into the pharmaceutical market in Germany. Figure 5 visualises all types of market interventions used to control the German pharmaceutical market.

Figure 5: Types of market interventions in the German pharmaceutical market



5.1 Interventions affecting demand

The general target of demand side interventions in the pharmaceutical market is to control price, volume or overall spending at the point of utilization. There are several instruments used to prevent consumers and providers from misallocation of resources. At the same time equal access has to be ensured to a culturally defined extent e.g. in Germany children do not have to bare co-payments for drugs.

5.1.1 Price control

In order to lower the financial burden for sickness funds the German government imposed co-payments on all kinds of pharmaceuticals reimbursed by the sickness funds in 1977. At the same time co-payments were introduced as a means to reduce the moral hazard induced by patients and providers. Therefore another objective was to increase allocative efficiency by distracting patients and providers from demanding unnecessary resources.

Co-payments have a long tradition within the German pharmaceutical sector. Though co-payments were increased over the years, out-of-pocket payments as a percentage of the total pharmaceutical expenditure remained stable at less than 5% until 1992 (when it was 3.5%). Through the Health Care Structure Act, cost-sharing was regulated anew in two steps, the first being the introduction of new co-payments according to the price per package (1993) and later according to pack size (1994). Co-payments were primarily linked to different pack sizes in order to provide an exacter collection scheme. These measures doubled patient out-of-pocket payments to 7.5% in 1993 and to 8.8% in 1994 as percentage of pharmaceutical expenditure. In 1997, the Health Insurance

Contribution Exoneration Act and only six months later the 2nd SHI Restructuring Act increased co-payment levels twice quite sharply to € 2.04/ 3.07/ 4.09 according to different pack sizes being equal to 10% of total pharmaceutical expenditure and only six months later the 2nd SHI Restructuring Act in 1997 increased it further to € 4.60/ 5.62/ 6.65. (Table 2). The new co-payment levels also meant that around one sixth of SHI pharmaceutical expenditure was borne in 1998 by patients as out-of-pocket payments. When the new coalition government come into power in 1998 they decreased the co-payments through the Act to Strengthen Solidarity in Statutory Health Insurance to € 4.09/ 4.60/ 5.11 equal to around 11% of pharmaceutical expenditure effective from 1st of January 1999. With the Health Care Modernization Act co-payment regulations will again be changed with effect of 2004. Patients then have to pay a share of 10% for all prescribed drugs irrespective of package size with a minimum of 5 Euro and a maximum of 10 Euro per pack.

Table 2: Co-payment scheme in SHI for pharmaceuticals, 1994-2004

Package size	1994-1996	1.1.-30.6.1997	1.7.1997-31.12.1998	1999-2001	2002-2003	From 2004
Small	€ 1.53	€ 2.04	€ 4.60	€ 4.09	€ 4.00	10% of retail price (min. € 5 and max. € 10)
Medium	€ 2.56	€ 3.07	€ 5.62	€ 4.60	€ 4.50	
Large	€ 3.58	€ 4.09	€ 6.65	€ 5.11	€ 5.00	

Source: Authors' compilation

To ensure equal access for everybody there were, until 2003, several exemptions from co-payments:

- children and adolescents aged below 18 years
- pregnant women if drugs are needed due to pregnancy
- patients who were exempted by status (welfare recipients, unemployment aid recipients, students, etc.)
- insurants with a low monthly income (single persons < € 952, person with one child < € 1309; for each additional relative in the household the limit is raised by € 238)
- chronic sick persons from further co-payments if they spent more than 1% of their income for treatment of the same disease
- generally all insurants above a limit of 2% of their income

In 2001 about 47% of prescriptions were exempted from co-payments (Schwabe/Paffrath 2002). But so far there is no evidence how many people for any reason do not apply for exemptions from co-payments.

From the beginning of 2004 with the introduction of the SHI Modernization Act exemptions have been reduced to drug prescriptions for children below the age of 12 and above the age of 12 if drugs are prescribed for treatment of developmental disorders or severe diseases. But the limits of 1% of income for persons with chronic diseases and of 2% of income for all other insurants have been retained.

Apart from the simple shift of funding from sickness funds to private households it is difficult to separate the effects of co-payments from other regulatory measures.

Another possibility of “price regulation” is generic substitution, which is generally targeted at the replacement of expensive branded products with phased out patents by cheaper generic products. Until 2002 pharmacists were only allowed to substitute drugs if explicitly indicated by physicians on the prescription. However physicians permitted substitution only in 5% of all prescription which led to insignificant savings (Schöffski 1996).

In August of 2002, Germany introduced a scheme for generic substitution with the “Pharmaceutical Expenditure Containment Act”. Under this so called “aut idem regulation” pharmacists are requested to substitute non-patented pharmaceuticals above a certain substitution price line by other products. But physicians are able to avoid this if they explicitly indicate on the prescription that they do not want the pharmacists to replace it.

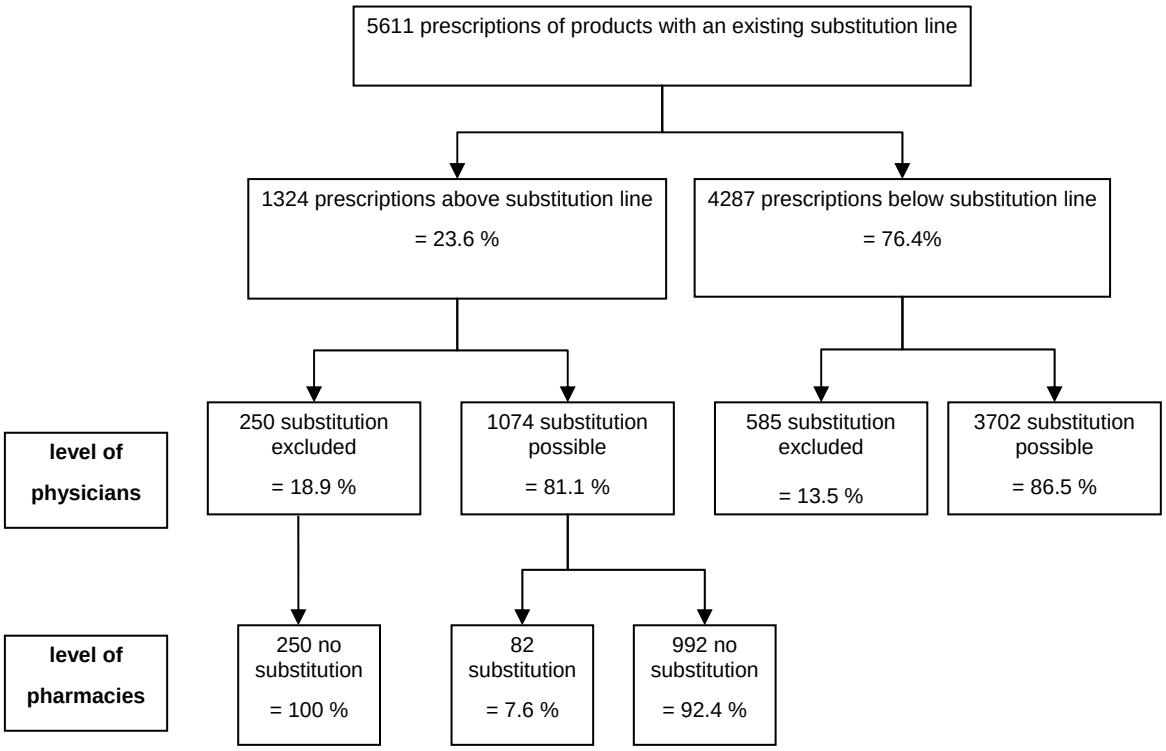
The Federal Committee of Physicians and Sickness Funds defines certain classes of replaceable active ingredients and pharmaceutical forms. The association of sickness funds “Bundesverband der Betriebskrankenkassen (BKK)” is responsible to list all available alternatives to each class of defined active ingredients and pharmaceutical forms. Afterwards a price line is defined for each class of drugs. For setting the price line, first of all the average selling price of the three most expensive drugs and the three cheapest drugs of each class is calculated. Finally the price difference between the calculated average prices of each class is divided into three parts of identical size. If, for

example the average prices of the most expensive drugs is € 100 and that of the cheapest is € 40, then the difference is divided into three parts of € 20. Finally for the price line one of the three parts is added to the average price of the three cheapest drugs, in our example the price line would be at 60 (40+20) (SGB V 129).

According to the new “aut idem” regulation pharmacists have to substitute a prescribed drug if its price is above the substitution price line of this specific class and substitution is not prohibited by the physician on the prescription. But the pharmacists do not received any incentives in terms of additional payments or anything else if they do so. If the physician does not explicitly specify the drug on the prescription and only defines the active ingredient then pharmacists have to choose a drug below the substitution price line. The substitution price line is updated every the three months (SGB V § 129).

In theory this regulatory scheme sounded very convincing and the Ministry of Health expected a major effect. However in practice this substitution scheme apparently does not work so far as pharmacists do not consistently substitute drugs above the substitution line. A random analysis of prescriptions in southern Germany for ten selected substitution classes during two weeks revealed that pharmacists only substituted 7.6% of prescriptions which were above the substitution price line and not excluded for substitution by physicians (Pharmafakt 2002) (Figure 6).

Figure 6: Random analysis of substituted prescriptions in southern Germany



Source: Calculations based on a study of Pharmafakt 2002.

There are several reasons for this result. First of all there is no incentive for pharmacists to substitute drugs, as for them a substitution means a reduction of prescription value and thus alleviating possible margins on the manufacturer's price. In addition pharmacists might be faced with major compliance problems since they have to convince the patients that the alternative drug is as good as the original drug prescribed by the physician. Anyway there are no court-proven sanctions for pharmacists for not following the "aut idem" obligation.

Secondly the pharmaceutical industry can easily manipulate the price-line by launching

high priced dummies which are not really intended to be sold but affecting the average price of the three most expensive products in one substitution class. At latest after three months the updated new substitution price line of the specific substitution class will be significantly higher than before. In this way pharmaceutical companies are able avoid substitution of their “real” products.

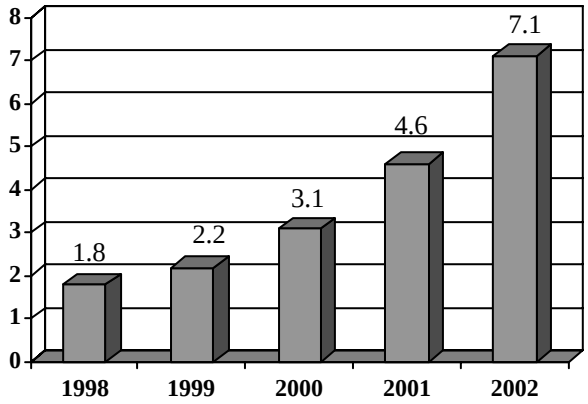
Considering agency theory it seems obvious that physicians and pharmacists have little incentives to invest in the information about availability of generics or their effectiveness and prices (Hellerstein 1998). Therefore certainly something has to be done to provide more incentives for generic substitution, but the existing aut-idem scheme is most likely the wrong way. In 2002 the savings for the sickness funds through the substitution scheme were estimated to be € 45 million (Ärztezeitung 2003). In addition there might be some indirect savings due to decreased prices of often substituted products.

The German legislature has already reacted to the first results of the “aut-idem” scheme. From the beginning of 2004, with the introduction of the SHI Modernization Act, the need for calculating the substitution price line is being lifted and instead reference prices for replaceable active ingredients and pharmaceutical forms will automatically be set below the substitution price line.

The “Pharmaceutical Expenditure Containment Act” also obliged pharmacists to generate at least 5.5% in 2002 and 7.0% in 2003 of their turnover by officially listed parallel imports which can be sold at a lower price than the domestic equivalent. Although the price difference of domestic products and parallel imports is shrinking

with increasing convergence of prices in EU countries this regulation is expected to contribute significant savings for the sickness funds. As a first result, the market share of parallel imports increased significantly in the year 2002, even bypassing the target for 2003 (Figure 7).

Figure 7: Market share of parallel imports as percentage of total pharmacy sales



Source: VFA 2003.

5.1.2 Volume control

Volumes can either be influenced by soft measures like prescription guidelines or harder instruments like positive or negative lists. In 1983, Germany introduced a negative list, which contains all approved pharmaceuticals not covered by the sickness funds for insured persons over 18 years old (Henke/Ade/Murray 1994). The list included drugs generally used for minor conditions e.g. cough and cold remedies, laxatives, travel sickness products and mouth and throat infections (§ 34(1) SGB V). At the beginning of the nineties the Ministry of Health was empowered to expand this list by judicial decree.

In addition the Social Code Book allows the Minister of Health to exclude “inefficient” drugs (i.e. they are not effective for the desired purpose) or drugs with combinations

which cannot be evaluated with certainty (§§ 2, 12, 34(3) and 70 SGB V). The evaluation of these drugs has to take into account the peculiarities of homeopathic, anthroposophic (drugs generated from natural sources based on a philosophy about the affinity of humans to nature) and phytotherapeutic drugs. A negative list according to these principles came into effect on 1st of October 1991. It was revised in 1993 and in 2000 and contains currently about 2,200 drugs. Additionally, drugs for "trivial" diseases (such as common colds) which can usually be treated by treatments other than drugs may be excluded (§ 34(2) SGB V). But so far a list of this type has not yet been worked out.

Supplementary to the negative list, the 1993 Health Care Structure Act had called for a "positive list" of reimbursable pharmaceuticals to be developed by the Federal Ministry of Health. This should had been designed to include only those pharmaceuticals which provided effective and necessary treatment, diagnosis or prevention of severe diseases. Therefore an "Institute for Medicines" with a board of 11 independent experts was established, which compiled an initial list of reimbursable drugs in March 1995. Subsequently all interest groups of the German health care system were invited by the Ministry of Health to discuss the draft list (Schöffski 1996).

Finally this list was dropped only weeks before it was supposed to be put into effect on 1st of January 1996. The Federal Minister of Health decided not to pursue the idea of a "positive list" and justified this by citing the successful cost-containment measures in the pharmaceuticals sector, the otherwise rising costs for chronic patients due to OTC purchases and, most importantly, the threat to smaller pharmaceutical companies. While this decision was welcomed by the pharmaceutical industry, it was faced with criticism

by both the sickness funds and the Social Democratic Party (Busse 2000).

However, the Reform Act of SHI 2000 again introduced the mandate for a positive list which has to be passed by the Federal Assembly and the Federal Council upon proposal of the Federal Ministry of Health. The Ministry was supported by an expert commission when preparing the proposal. The submitted draft was discussed in plenary sessions in the Federal Assembly in 2003. Referring to the EU Transparency Directive (EEC 89/105) of 21st December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems, pharmaceutical companies would have had the chance to reapply or apply for inclusion into the positive list (Deutscher Bundestag 2003). The association of research based pharmaceutical companies criticized again the draft for the positive list as unfair. They claimed that all people should have access to newly developed innovations no matter which insurance they have (VFA 2003). Since the conservative party and the liberals who hold the majority in the Federal Council already announced to refuse approval of the positive list, the Ministry agreed to drop the idea in the summer of 2003.

Next to negative and positive lists are the coverage of drugs by the sickness funds regulated through pharmaceutical guidelines by the Federal Committee of Physicians and Sickness Funds, which are part of the contract between the two sides at the federal level. These guidelines, which are legally binding and therefore could be used in malpractice lawsuits, attempt to steer the appropriate use of different groups of pharmaceuticals. They limit the prescription of certain drugs to certain indications (e.g. anabolics to cancer patients), specify that they may only be used after non-

pharmaceutical treatments were unsuccessful (e.g. so-called chondroprotective drugs) or in a few cases, disallow any prescription on the account of the sickness funds (e.g. drugs to quit smoking). However, the overall effect of these guidelines is doubtful, especially since very few drugs with mainstream indications were and are affected.

In mid-1998, the Federal Committee amended its pharmaceutical guidelines to exclude drugs for the treatment of erectile dysfunction and drugs to improve sexual potency such as Viagra. The committee argued that individually very different behaviour would not allow the determination of a standard of disease upon which to base economic considerations. In its opinion, the responsibility of the sickness funds ends where personal lifestyle is the primary motive for using a drug. This case demonstrated that the criteria for exclusions are less explicit than for medical technologies, so that decisions de-facto depend on the common will of both sides. Accordingly, the Federal Social Court disapproved of the general exclusion of drugs for the treatment of erectile dysfunction and instead demanded measures against their misuse.

In early 1999, the Federal Committee passed completely new pharmaceutical guidelines. These stated explicitly that the licensing of pharmaceuticals is a necessary but not sufficient precondition for coverage by the social health insurance system (Busse 2000). Apart from the above-mentioned legal exclusions, the guidelines listed five reasons for not including drugs in the benefits' catalogue of the sickness funds:

1. they are not necessary for treating diseases – as in the case of Viagra;

2. other pharmaceuticals are more effective and/ or cost-effective;

3. non-pharmaceutical strategies are more effective and / or cost-effective;

4. combination therapy if monotherapy is more effective and / or cost-effective; or

5. they have not been proven to be effective.

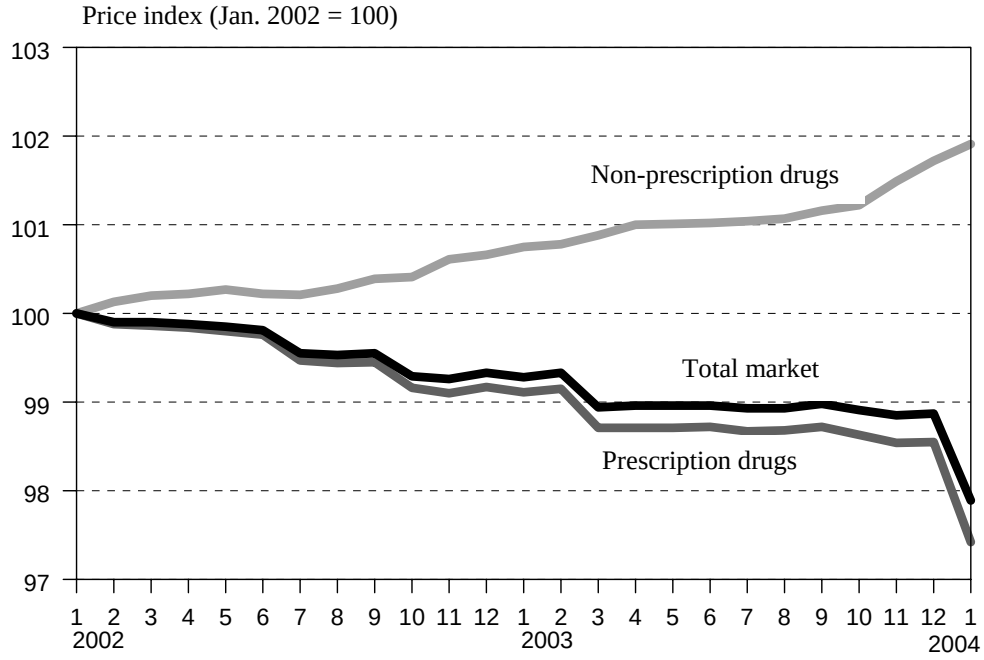
The numbers of drug groups for which prescriptions are limited or prohibited were greatly enlarged. Examples were anti-rheumatic drugs for external use (for reasons 2 and 3 above) and lipid-lowering drugs (for reasons 3 and 4). Additionally, an annex listed all groups with legal and other prescription exclusions and limitations; in case of limitations, reasons for exceptions and the necessary documentation were provided.

The Federal Committee expected savings of around € 500 million. However, these pharmaceutical guidelines were never implemented since the pharmaceutical industry filed a lawsuit against them successfully. Initially in March 1999 one court argued that the guidelines violated cartel law since the Federal Committee is a joint committee of sickness funds and physicians. Two other courts approved the rejection arguing guidelines were only supposed to specify prescription practices of physicians but are not allowed to exclude certain drugs. Therefore the proposed guidelines exceeded the competences of the Federal Committee and would have to be approved by legislation.

With effect of 2004 as part of the SHI Modernization Act, “lifestyle drugs” are now being legally excluded from reimbursement. Therefore drugs for erectile dysfunctions as well as anti-smoking drugs and others are not anymore reimbursed by the sickness funds. In addition the Act also excludes any non-prescription drugs from reimbursement with beginning of 2004. Drugs for children under 12 and certain indications will be

exempted. One major reason for this is certainly the price increase of non-prescription drugs over the last years as shown in figure 8.

Figure 8: Development of prices for prescription and non-prescription drugs reimbursed by the Sickness Funds



Source: Wido, GKV-Arzneimittelindex: Preisinfo 02/2004.

5.1.3 Overall spending control

To control the overall spending of pharmaceuticals in Germany, a spending cap was imposed by the Health Care Structure Act in 1993 calling for a considerable reduction in pharmaceutical expenditure which was € 13.6 billion in 1992 (in the former west Germany). Based on the expenditure of € 12.5 billion in the year 1991, it reduced future spending to a maximum of € 12.2 billion per year. In the case of overspending in 1993, any excess spending up to € 142 million each would have been clawed back from the physicians' associations (from physician remuneration) and the pharmaceutical

industry. Since 1993, the physicians' associations (in the western as well as in the eastern parts) were legally liable for any overspending with no upper limit; this liability was in force for every single association in the case of overspending, even if total pharmaceutical spending remained below the cap. At the same time the spending cap was introduced, the reform act also imposed a price cut of 5 percent for existing drugs not covered by reference pricing, 2 percent for OTC-drugs also outside the reference price system and a price freeze for new drugs. All three measures were applied for the years 1993 and 1994.

Apart from the overall spending cap imposed by the Health Care Structure Act, the physicians' individual prescribing of pharmaceuticals was monitored too. If they prescribed more than 15 percent of the average spending of their medical specialty in their region, they became subject to economic monitoring. If they exceeded a limit 25 percent of the average, their income was automatically reduced if physicians were unable to prove that the risk structure of their patients justified the level (Henke/Murray/Ade 1994).

The result of all three cost-containment measures in the Health Care Structure Act of the year 1992 - i.e. a price cut moratorium, new cost-sharing regulations and the expenditure cap - in their first year of operation was a reduction of 18.8% in sickness funds' expenditures for pharmaceuticals in the ambulatory sector. This figure represents a reduction for the sickness funds of € 2.61 billion from 1992's expenditure or € 1.12 billion more than had been required. Of these savings, around € 500 million was attributable to price reductions. Almost another € 500 million was the result of the new cost-sharing regulations. Only about 60% of the total reduction was attributable to

changes in physicians' prescribing behaviour. Physicians reduced the number of prescriptions by 11.2% and increased their prescriptions for generics instead of the original products.

Due to subsequent increases, regional caps were exceeded in some of the 23 regions in 1994 even though national figures remained within the total (hypothetical) spending cap. While this remained the case for the western states in 1995 as well, overspending occurred in the eastern states (which were not affected by the 1993 cap) where the increase in pharmaceutical expenditure was so high that per capita expenditure in 1995 was almost 13% higher than in the west. However, some regions also exceeded the budget of the year 1995 and therefore, in September 1996, the sickness funds instigated proceedings to claim back money from nine regions which had overspent their budget by up to 11.3%. The physicians' associations resisted payment, arguing they could not effectively manage overall or physician-specific drug expenditure, due to untimely and unspecified data and sanctions against overspending were again not executed.

Despite the rises in pharmaceutical expenditures in 1996 and subsequent years – when nation-wide spending exceeded the cap, leading to agreements in several states to even out the overspend in coming years – the spending cap proved to be an effective method of short-term reduction and long-term modification of pharmaceutical expenditures. A review of published studies showed that the initial reduction was mainly attributable to physicians who had on average prescribed drugs of a higher quality, while the others reduced their prescriptions mainly on the basis of price (Busse/Howorth 1999).

Although the spending caps reduced pharmaceutical expenditures of sickness funds it

may have caused certain substitution effects into other health care sectors as physicians avoided exceeding drug budgets by increased referrals to specialists and hospitals (Henke/Murray/Ade 1994; Schulenburg 1997). According to one study the frequency of referrals from primary care physicians to specialists increased over 11% from 1992 to 1993. The referral behaviour was even more striking concerning the treatment of chronic diseases like Parkinson's disease, hypertension, asthma, ulcers and cancer. A similar pattern could be observed for the number of hospital admissions. Again admissions for chronic diseases rose significantly e.g. for Parkinson's disease and Hypertension about 24%. According to this study the reduction of pharmaceutical expenditure of € 2.61 billion in the year 1993 was partly compensated by estimated additional costs of € 720 million for increased referrals and admissions (Schöffski 1996).

With the 2nd SHI Restructuring Act the regional spending caps for pharmaceuticals were abolished from 1998 and were replaced by practice-specific soft targets according to different groups of specialists but excluding both certain types of drugs and drugs for patients with certain indications (i.e. opiate addicts, patients post transplantation etc.). Anyway it was more than doubtful that there would have been any effective mechanisms of sanctioning over-prescribing. Under the new system a regional gross budget (including patient co-payments and pharmacy discounts) for pharmaceutical spending is negotiated between the associations of sickness funds physicians and the associations of sickness funds on a regional level. Subsequently this regional gross budget is broken down by the association of sickness funds physicians for individual physicians according to their medical specialty.

As a first step in order to achieve these individual targets each physicians' association allocates the overall yearly gross budget to different specialties usually on the basis of prescription volumes of the year before e.g. for internists 15% of the overall budget. In most regions the budget of each specialty is again divided into two sub-budgets being one for the medical treatment of retired and one for non-retired persons, e.g. € 100 for retired and € 50 for non-retired persons (based on the proportions of prescription volumes for retired and for non-retired persons of the year before). These sub-budgets are finally divided by the number of cases of retired and non-retired persons.[3] As a result each specialty receives a target of how much can be prescribed per retired and non-retired person. The individual targets for each physician for the current year is calculated ex-post by multiplying the total number of treated cases (separated for non-retired and retired) for each physician with the target of each specialty.

Physicians who exceed the limit by more than 15% are advised in written form to watch their prescription behaviour. The legal limit for over-prescribing and paying-back had been set at 125% of the individual target (§ 106(5a) SGB V). Those physicians who exceed the target by 25% are asked to explain and prove the reason for over-prescribing. If their stated arguments are not sufficient they have the liability to recourse and thus usually pay back the sum between the over-prescribed amount and 115% of the target. The amounts paid back by physicians are allocated to the sickness funds according to the number of cases of each sickness fund being treated by the concerning physician. Table 3 shows exemplarily for Berlin to what extent physicians exceeded their practice

[3] One person is counted as a case if he or she is receiving medical treatment at least once in a quarter of a year. Therefore one person can be counted at maximum four cases per year.

specific soft targets in 2002. 4% of all physicians exceeded their target by more than 15% and 12% of all physicians exceeded their target by more than 25%. In Berlin the recourse procedure for the years 1998 and 1999 have been finished and overall amounts of € 2.2 million in 1998 and € 2.4 million (1999) have been claimed back by the sickness funds. Therefore in both cases 0.3% of the overall pharmaceutical expenditure in Berlin has been claimed back.

Table 3: Exceedance of practice specific soft targets in Berlin, 2002

Specialties	Exceedance of targets between 15% and 24.99%		Exceedance of targets of more than 25%		Sum
	Number of providers	In % of all providers of the specialist group	Number of providers	In % of all providers of the specialist group	Number of all providers in the specialist group
Anaesthetists	0	0	16	16.67	96
Ophthalmologists	15	5.43	38	13.77	276
Surgeons	3	1.48	13	6.40	203
Gynaecologists	5	0.97	38	7.36	516
Otorhinolaryngologists	5	2.15	15	6.44	233
Dermatologists	3	1.60	10	5.35	187
Internists (general)	41	5.92	89	12.86	692
Internists (specialist)	3	1.01	63	21.28	296
Pediatrists	3	1.04	21	7.29	288
Pneumologists	1	2.17	2	4.35	46
Oral Surgeons	2	4.76	12	28.57	42
Neurologists	22	7.61	104	35.99	289
Child Psychiatrists	1	3.70	4	14.81	27
Psychiatrists	4	7.14	16	28.57	56
Orthopaedists	17	6.25	35	12.87	272
Psychotherapists	5	1.7	18	6.00	300
Urologists	12	8.11	32	21.62	148
Physiotherapists	2	6.45	7	22.58	31
General practitioners	84	5.10	162	9.83	1648
Others	0	0	2	11.8	17
Sum	228	4.03	697	12.31	5663

Source: KV-Blatt/Budget-Bulletin 03/03, Berlin 2003.

Next to these practice specific soft targets, certain targets are defined regarding the proportion of generics, re-imports and me-too products that have to be reached as percentage of the whole drug budget of each physician. In contrast to the practice specific soft targets these targets are not related to any sanctions for the physicians.

While retaining targets for individual practices, the Act to Strengthen Solidarity in SHI re-introduced collective spending caps at the end of 1998 for pharmaceuticals at the regional level. Physicians' associations were now liable for any over-spending up to 105% of the overall net budget. The overall net budget is calculated by subtracting patient co-payments and pharmacy discounts from the gross budget, which is, as already mentioned, negotiated between the associations of sickness funds and the associations of sickness funds physicians on regional level. As a kind of compensation, debts resulting from the former spending cap (see above) were waived. Subsequently physicians filed several constitutional complaints which were not accepted by the Federal Constitutional Court arguing that sanctions would have to be executed before any mandate can be taken (BVerfG, 1 BvR 2254/99; BVerfG, 1 BvR 2260/99).

These collective spending caps for pharmaceuticals at regional level were therefore never executed since there was legal uncertainty about the possibility of charging someone without individual infringement. Thus they were abolished when the new Minister of Health Ulla Schmidt came into office at the beginning of 2001. Subsequently drug expenditures rose more than 10% the first half of 2001 compared to the previous year (Breyer 2002).

Nevertheless the new system of spending caps also raises the question to what extent savings achieved by practice spending caps are offset by the cost of increased referrals to specialists and admissions to hospitals. In this context opportunity cost of time spent for patients and physicians at referred specialists and hospitals and thereby the loss of economic productivity should also be taken into account. On the other hand expenditure data of table 1 shows that the initial introduction of spending caps led to a sharp reduction of pharmaceutical expenditure which might have reduced unnecessary prescriptions. It also has to be considered that the share of public pharmaceutical expenditure as percentage of total public expenditure in year 2001 has not even reached the level of the year 1992, before the drug budgets were introduced.

5.2 Interventions affecting supply

5.2.1 Price control

One possibility of direct price regulation is to impose a price cap as a political given maximum price for certain products. Reference pricing can be interpreted as a kind of price cap which establishes an upper limit for the costs reimbursable by the sickness funds.

The initial intention for the introduction of reference pricing was the fact that there were several products on the German pharmaceutical market with similar effectiveness and quality but at very different prices. To achieve more transparency on the pharmaceutical market and prevent physicians from prescribing too expensive non-patented drugs reference pricing was introduced in the year of 1989.

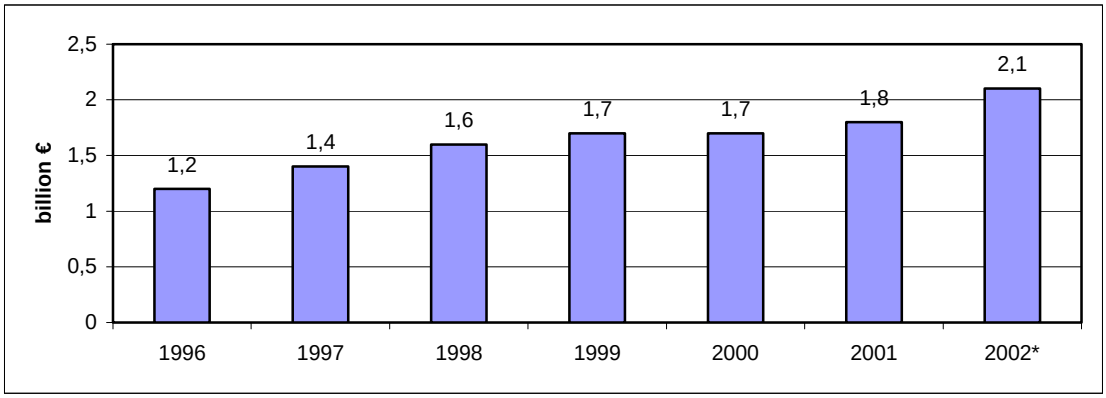
The legal basis for reference pricing in Germany is codified in § 35 SGB V. This stipulates that reference prices are defined:

- for drugs containing the same substance,
- for drugs with similar substances and
- for drugs with comparable efficacy.

While the Federal Committee of Physicians and Sickness Funds is responsible for the identification and classification of drugs, the federal associations of sickness funds do the actual price-setting.

Due to lowered prices for drugs formerly above the reference price, these regulations led to decreasing prices for reference priced drugs but the pharmaceutical industry partly compensated these through above-average increases for non-reference-priced drugs. The German Association of Research-based Pharmaceutical Companies is estimating the savings for the sickness funds to € 2.1 billion for the year 2002 (Figure 9).

Figure 9: Reduced expenditures for sickness funds due to reference pricing



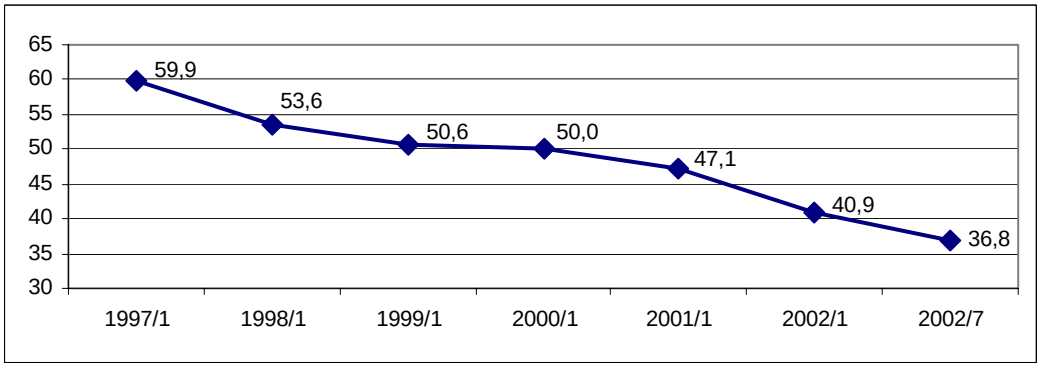
Source: BKK for various years; VFA 2002.

So far it is very difficult to evaluate the health effects of the reference pricing scheme since the aggregated data which is available is either biased or not specific enough (Schneeweiß/Schöffski/Selke 1998; Giuliani/Selke/Garattini 1998). For patients, reference prices had two effects. Generally, pharmaceuticals priced at or below the reference price for that substance were co-payment free (until 1992). More specifically, if a patient insured with a sickness fund wished to use a more expensive alternative, he or she had to pay the difference out of their own pocket. For all prescribed drugs without a reference price, the patient had to pay a co-payment of € 1.53 per package - instead of € 1.02 previously (§31 SGB V). These new regulations led to an increase of co-payments by about one third but subsequently - due to the increasing number of reference-priced drugs - by the year 1992 it fell to the level of the year 1988.

Since 1996, newly licensed drugs with protection we are not covered by the reference pricing scheme anymore. This measure actually aimed at boosting innovations and

therefore stabilizing the position of the pharmaceutical industry. But its effect was rather disappointing as it primarily encouraged the launch of active substances with merely minor modifications. Subsequently the share of reference-priced drugs as percentage of the total pharmaceutical expenditure was declining (Boehringer Ingelheim 2003) (Figure 10). Therefore it seems that this regulation led to substitution effects to unregulated parts of the market. It is likely that reduced expenditures for sickness funds for reference-priced drugs were offset by these effects.

Figure 10: Market share of reference-priced drugs as percentage of the total pharmaceutical expenditure



Source: BKK for various years, Boehringer Ingelheim 2002.

The Act to Strengthen Solidarity in SHI introduced tighter regulations for the setting of reference prices, i.e. they now may not be higher than the highest price in the lowest third of the market. For 202 out of a total of 446 drug groups with reference prices, prices were supposed to be lowered from 1st of April 1999 for a reduction of expenditure of approximately € 281 million. However, this reduction was stopped legally and reference prices altogether came under legal threat when a pharmaceutical

company successfully sued. On 6th of January 1999, the Higher Regional Court in Düsseldorf (Germany) argued that price setting by the sickness funds violated European Union cartel regulations since sickness funds would cartelize in terms of setting the prices for reimbursement unilaterally. Therefore, the health minister had to put reference prices on a new legal basis, i.e. fixing them through an ordinance issued by the Ministry of Health. The Ministry of Health took over responsibility for setting prices until the end of the year 2003. In the year 2004 a judgement will be taken by the European Court of Justice either approving the legal basis for sickness funds to set reference prices or not. As part of the Health Care Modernization Act new patent products will immediately be included in the reference pricing scheme if no added benefit can be proven from 2004.

3.2.2. Volume control

During the nineties a trend could be followed that health authorities e.g. in France introduced supply-side regulatory measures to limit the volume of pharmaceutical products. They can either be implemented as marketing spending limits or as product volume caps. Marketing spending limits restrict the budget a drug company is allowed to spend on the marketing of certain products and has therefore an indirect effect on the sold volume. In contrast to this product volume caps directly restrict the volume of certain products. Although there are regulations regarding the advertisement of pharmaceuticals as in most other European countries, Germany has not implemented any of these harder measures to control the volume at the point of supply.

3.2.3 Overall spending control

A type of overall spending control mechanism is the legally defined rebate on pharmaceutical products paid by sickness funds. Another measure which can be classified as such was the agreement with the Association of Research Based Pharmaceutical Industry to pay a lump-sum of € 400 million for the year 2002. This sum was negotiated between the German Government and the Research Based Pharmaceutical Industry in order to replace an intended law to decrease reimbursement prices for drugs with patent protection by 4% with expected savings of € 960 million for the sickness funds. This deal again demonstrates the lobbying power of the pharmaceutical industry in Germany.

4. Conclusion and results

The effects of the implemented types of market interventions regarding the efficiency of allocation and the control of pharmaceutical expenditures have been very different so far. In contrast to ordinary economic theory, supply-side interventions are apparently the most effective in the German context. Although the pharmaceutical industry claims that reference pricing assumes a wrong comparability of new drugs which in fact contain slight but possibly important differences, the expenditure reductions for sickness funds have been significantly. The reference pricing scheme might also be able to increase the efficiency of allocation since it encourages price competition and at the same time avoids rationing induced by other instruments like physician spending caps.

Physician spending caps had probably the most significant effect of all demand-side interventions on pharmaceutical expenditures. SHI expenditure on pharmaceuticals as a

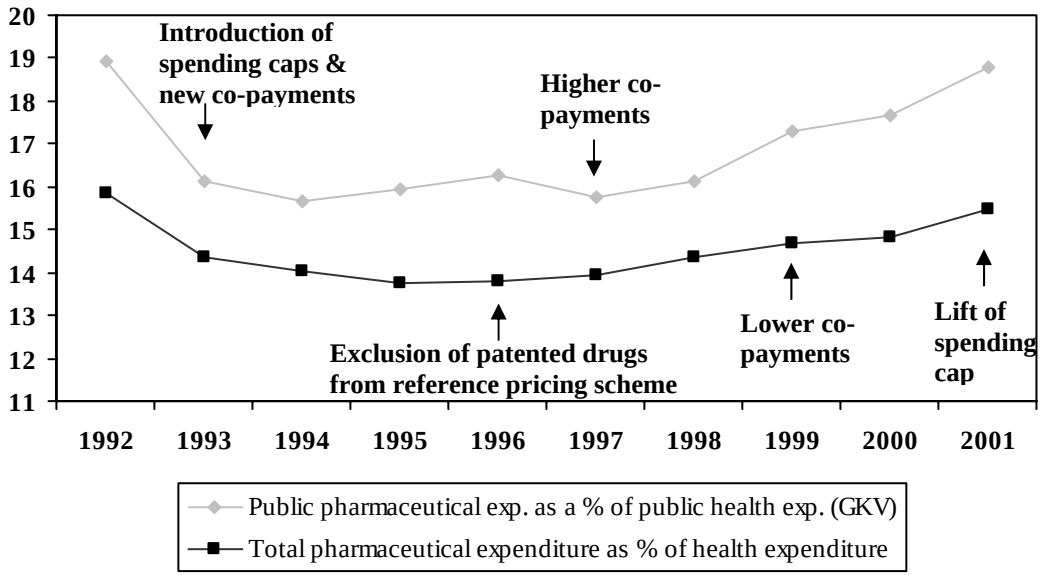
percentage of total SHI expenditure fell dramatically and only reached the pre-budget level again in 2001, i.e. the year in which the cap was lifted. But caps always implicate the threat of under-provision of certain groups by rationing and set off certain substitution effects in other areas which are partially offsetting the savings in pharmaceutical expenditure. Therefore it remains unclear whether physician spending caps in fact improved the allocation of resources in a positive way.

Although demand-side volume controls like negative and positive lists in a way induced rationing they at least encourage allocative efficiency. Especially a positive list in Germany could be a chance to identify innovations with minor changes of active ingredients and therefore encourage “real” innovations. In contrast to the negative list this would also have major implications on the level of pharmaceutical expenditure.

The effects of demand-side price controls in Germany are rather questionable. Generic substitution schemes in Germany do obviously not work satisfactorily. It will be difficult to provide incentives to pharmacists to substitute the products accordingly without forcing them legally. Apart from the sheer shift of funding of resources the co-payment scheme is likely to have only a minor effect on the demand of pharmaceuticals and therefore on the allocation of resources. To cause a significant effect on the allocation of resources co-payments would have to be much higher and preferably raised proportionally as a certain percentage of the demanded product.

Figure 11 summarizes the most important regulations of the nineties in Germany and shows their effect on the public and total pharmaceutical expenditure in Germany.

Figure 11: Pharmaceutical expenditure as % of health expenditure



Source: Author's calculations based on data from Federal Statistical Office of Germany 2003.

Finally, questions regarding the regulation of pharmaceuticals must be posed in the context of the whole economy. It has to be considered that the health care sector is a labour-intensive growth market which employs about 4.5 million persons; i.e. about one seventh of the employed labour force in Germany. Therefore every future instrument used to increase efficiency and control expenditure will have to be measured in the light of this argument.

References

Advisory Council of the Concerted Action in Health Care. 2001. *Appropriateness and Efficiency*, Vol. I-III. Bonn.

Ärztezeitung. 2003. http://www.aerztezeitung.de/docs/2003/03/11/046a0408.asp?cat=/politik/arzneimittelversorgung/aut_idem, accessed 5/6/2003.

BAH (Federal Association of Pharmaceutical Manufacturers). 2002. *Der Arzneimittelmarkt in Deutschland in Zahlen 2001*. Bonn.

BfArM (Federal Institute for Drugs and Medical Devices). 2003. Homepage: http://www.bfarm.de/de/gb_ver/index.html, accessed 8/20/2003.

Boehringer Ingelheim. 2003. *Pharma Report 03/2003*. Ingelheim.

BMGS (Federal Ministry of Health and Social Security). 2002. *Social security at a glance*. Bonn.

BMGS (Federal Ministry of Health and Social Security). 2003. *Public health insurance – data and facts*, http://www.bmgs.bund.de/downloads/Kennzahlen_und_Faustformeln_4 Q2002.pdf, accessed 5/3/2003.

BMGS (Federal Ministry of Health and Social Affairs). 2003. *Pharmaceutical price index*, http://www.bmgs.bund.de/download/statistiken/stattb2002/05/5.02.pdf, accessed 5/3/2003.

Breyer F. 2002. Reimbursement and Cost Containment – A German Perspective. *Pharmacoeconomics*; 20 (Suppl. 3): 87-94.

Busse R. 1999. Priority-setting and rationing in German health care. Health Policy 1999; 50: 71-90.

Busse R. 2000. *Health Care Systems in Transition – Germany*. Copenhagen: European Observatory on Health Care Systems.

Busse R. 2001. The German Health Care System – An Introduction Description. In *Gesundheitssysteme am Scheideweg: Zwischen Wettbewerb und Solidarität*, Henke K-D and Dräger C (eds), Nomos: Baden-Baden, 47-57.

Busse R, Howorth C. 1996. Germany's spending cap for pharmaceuticals – Effects on cost and quality. In *Fixing health budgets – experiences from Europe and North America*, Schwartz FW, Glennerster H, Saltman RB (eds.), Wiley: Chichester, 109-127.

Busse R, Wörz M. 2003. German plans for “health care modernization”. *Eurohealth*; 9(1): 21-24.

Deutscher Bundestag. 2003. *Printing no. 15/800*. Berlin.

Federal Association of SHI Physicians in Berlin, KV-Blatt, Budget-Bulletin, Berlin 2003.

Federal Ministry of Health and Social Security, pharmaceutical price index, Berlin 2002.

Federal Statistical Office (Statistisches Bundesamt). 2003a. *Price index*, http://www.destatis.de/indicators/d/vpi001vj.htm, accessed 5/3/2003.

Federal Statistical Office. 2003b. *Gesundheit, Ausgaben und Personal 2001*. Wiesbaden.

Giuliani G, Selke G, Garattini L. 1998. The German experience in reference pricing. *Health Policy*; 44: 73-85.

Hellerstein JK. 1998. The Importance of the Physician in the Generic versus Trade-Name Prescription Decision. *RAND Journal of Economics*; 29: 108-136.

Henke, K.-D., The permanent crisis in German healthcare, in: Eurohealth 2002; 8; 26-28.

Henke K-D. 2001. The Allocation of National Ressources in Health Care in Germany Between Competition and Solidarity. In *Gesundheitssysteme am Scheideweg: Zwischen Wettbewerb und Solidarität*, Henke K-D and Dräger C (eds), Nomos: Baden-Baden, 47-57.

Henke K-D, Ade C, Murray MA. 1994. The German Health Care System: Structure and Changes. *Journal of Clinical Anesthesia*; 6: 252-262.

Henke K-D, Murray MA, Ade C. 1994. Global Budgeting in Germany: Lessons for the United States. *Health Affairs*; 13(3): 7-21.

Perleth M, Busse R, Schwartz FW. 1999. Regulation if health-related technologies in Germany. *Health Policy*; 46: 105-126.

Pharmafakt (Company for market research), Random test on substituted prescriptions in southern Germany based on data from a data processing centre for pharmacy bills of the Association of Sickness Funds physicians in southern Germany, conducted in October 2002 on behalf of the pharmaceutical industry, München 2002.

Research Institute of Regional Sickness Funds (Wido). 2004. *GKV-Arzneimittelindex: Preisinfo 02/2004*. Bonn.

Sauerland D., The German strategy for quality improvement in health care: still to improve, in: Health Policy 2001; 56; 127-147.

Schneeweiß S, Schöffski O, Selke GW. 1998. What is Germany's experience on reference based drug pricing and the etiology of adverse health outcomes or substitution? *Health Policy*; 44: 253-260.

Schöffski O. 1996. Consequences of Implementing a Drug Budget for Office-Based Physicians in Germany. *PharmacoEconomics*; 10(Suppl. 2): 37-47.

Schulenburg JM. 1997. Management of cost containment and utilization of pharmaceuticals in Germany. *Health Policy*; 41(Suppl.): 45-53.

Schwabe U, Paffrath, D. 2003. *ArzneiverordnungsReport 2002*. Springer: Berlin.

VFA (Association of research based pharmaceutical companies). 2003. *Press release no. 004/2003*. Berlin.

VFA (Association of research based pharmaceutical companies). 2002. *Statistics 2002*. Berlin.