ÖBIG

Pharmaceutical Pricing and Reimbursement Information project

GERMANY

May 2008

Commissioned by
European Commission, Health and Consumer Protection Directorate-General and
Austrian Ministry of Health, Family and Youth

Pharmaceutical Pricing and Reimbursement Information

GERMANY

Pharma Profile

Finial version, May 2008

PPRI Participants
German Institute for Medical Documentation and Information (DIMDI): Hans-Peter Dauben
Ministry of Health: Ulrich Dietz, Silke Baumann

PPRI Pharma Profile - Authors
Department of Health Care Management, Faculty of Economics and Management, Berlin University of Technology: Tom Stargardt, Reinhard Busse
German Institute for Medical Documentation and Information (DIMDI): Hans-Peter Dauben

PPRI Pharma Profile - Editorial team
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG: Ingrid Rosian-Schikuta
WHO Regional Office for Europe: Trine Lyager Thomson (editor-in-chief)

Executive summary

Background

The German health care system is characterized by a predominance of mandatory Social Health Insurance (SHI) with multiple competing sickness funds and a private/ public mix of providers (Bismarck model). In 2005, about 85.4% of the population were covered by comprehensive SHI. This is complemented by three co-existing schemes: private health insurance and two specific governmental schemes for civil servants. A large number of regulatory, managerial and even planning competences in SHI are delegated to the corporatist level of self-governmental sickness funds and provider associations or to joint committees of these actors. Within self-governing structures, federal legislation promoted competition at the level of sickness funds regarding the provision of services while centralizing decision-making powers on the benefit basket and quality assurance towards the federal level to secure uniform standards. The corporatist level is represented by the non-profit, quasi-public sickness funds and their associations and associations of SHI-affiliated physicians' and dentists' on the provider side.

Ambulatory health care is mainly delivered by private for-profit providers working in single or, less frequently, group practice. The regional physicians' associations divide the financial resources in separate funds for family physicians and specialist physicians and distribute the resources among their members according to the nationally uniform scale of relative point values and regionally adapted rules. Hospitals are financed on a dual basis: Investments for hospitals enlisted in hospital plans are planned by the 16 state governments and financed by state and federal governments jointly, while sickness funds finance recurrent expenditures and maintenance costs of hospitals with DRGs.

Pharmaceutical System

While the Ministry of Health is responsible for the supervision of self-governmental decision-making bodies, and prepares legislative actions of the German parliament, the most powerful self-governmental institution, the Federal Joint Committee, issues directives that are legally binding for all actors in Statutory Health Insurance. Besides it groups pharmaceuticals for reference pricing. The federal associations of sickness funds are responsible for setting reference prices. Other tasks related to the pharmaceutical market are to negotiate rebates with pharmaceutical providers and to negotiate a framework contract with the associations of pharmacists for the services provided by pharmacists under SHI. To support decision-making by the Federal Joint committee, the Institute for Quality and Efficiency (IQWiG) commissions HTA and makes recommendations for the in- or exclusion of technologies, e.g. pharmaceuticals, into the SHI benefit basket. Drug licensing and supervision is undertaken 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 supervise the safety of pharmaceuticals and medical devices.

The pharmaceutical industry in Germany is among the most powerful in developed countries and contributes significantly to the export market. Around 975 pharmaceutical companies with 113,002 workers operate in Germany (2005). Of the € 39.5 billion spent on drugs in 2005, € 34.1 billion was spent in one of the 21,476 pharmacies. The public share of total pharmaceutical expenditures was 71.3%, of which 69.9% were spent by statutory health insurance, 0.1% by statutory pension insurance, 0.4% by statutory accident insurance and 0.8% by public households. Private expenditure, accounted for 28.7% of total pharmaceutical expenditure, of which 6.1% was spent by private health insurance, 3.6% by employers, and 19.0% by private households (and not for profit organizations).

Pricing

The regulation of pharmaceutical prices differs between the inpatient sector and the ambulatory sector. While hospitals may negotiate prices with wholesalers or manufacturers, the distribution chain and prices are much more regulated in the outpatient market. Besides temporal price freezes, ex-factory prices are basically determined in both sectors by manufacturers without negotiations involving governmental agencies, direct price or profit controls and public procurement. No external or internal price referencing, cost-plus pricing or profit controls are applied in Germany. However, price setting by companies takes into consideration regulations in other parts of the market, e.g. reimbursement regulation through reference pricing.

Statutory pricing is used for prescription drugs and for prescribed drugs with OTC status that are exceptionally a part of the SHI benefit package at the level of wholesaler and pharmacies. Accordingly, the Pharmaceutical Price Ordinance stipulates fixed mark-ups on manufacturers' selling prices and thereby guarantees identical prices for prescription drugs in all German pharmacies. In addition, it enables the manufacturer to determine the ex-wholesaler and the ex-pharmacy price of the drug by setting the ex-factory price. Since Statutory Health Insurance Modernisation Act in 2004, prices of non-prescription drugs are no longer subject to regulation. Pharmacies in Germany are allowed to compete in terms of OTC drug prices in addition to quality of service.

Besides the official prices in accordance with the Pharmaceutical Price Ordinance, to some ex-tent, cash discounts can be negotiated between manufacturers, wholesalers and pharmacies. In addition, pharmaceutical providers have been obliged to give rebate to sickness funds. While some rebates are mandatory for all drugs provided under SHI (e.g. the pharmacy rebate of € 2.30 per package), others depend on the existence of contractual agreements (e.g. rebates to an individual sickness fund) or special drug characteristics.

Reimbursement

Unlike many other countries, Germany does not have a positive list of SHI-reimbursable pharmaceuticals. Therefore, every prescription drug that has received admission to the market is covered under SHI. A few, but important exceptions exist: Drugs for trivial diseases (common colds, drugs for the oral cavity with the exception of antifungals, laxatives and drugs for motion sickness) are legally excluded from the benefits' package for insured over 18 years. Life-style drugs have also been legally excluded from the benefit catalogue. In addition, the Social Code Book allows the Minister of Health to exclude inefficient drugs, that is,

those not effective for the desired purpose or combined more than three drugs, the effect of which cannot be evaluated with certainty.

The coverage of drugs is also regulated in the Directive on Pharmaceutical Care of the Federal Joint Committee, which limits the prescription of some drugs to certain indications (for example, anabolics to cancer patients), specifies that they may only be used after failed non-pharmaceutical treatments or in a few cases, disallow any prescription on the account of sickness funds (for example, drugs to stop smoking). OTC drugs are not reimbursed by sickness funds except for children below the age of 12. Exceptions to this general exclusion have also been delegated to the Federal Joint Committee which lists OTC drugs and the indications for which they may be prescribed in its pharmaceutical directive.

In general full reimbursement is granted for all reimbursable drugs and reimbursement is not linked to specific patient subgroups or indications. Currently, co-payments are set to 10% of the drugs' price. Due to a minimum of € 5.00 and a maximum of € 10.00, insured are only price sensitive in a price range below € 5.00 and between € 50.00 and € 100.00. Drugs prices 30% below their reference price are exempted from co-payments. To guarantee access for the poor or to people with substantial health care needs, upper limits for cost-sharing under SHI have been introduced. As the reimbursement of non-prescription drugs (e.g. fully reimbursed for children below the age of 12) and co-payments (no co-payments below the age of 18) are linked to age, this could be interpreted as three reimbursement categories depending on age. An individual appeal procedure for patients and doctors does not exist. However, if reimbursement has been denied for a service, a patient may go to court and sue its sickness fund successfully for reimbursement if he can prove that in his case the service has been adequate, appropriate and efficient.

Reimbursement of pharmaceuticals has been further regulated by reference pricing since 1989, as a means of exerting indirect price control. The reference price system establishes an upper limit for sickness fund reimbursements. Pharmaceuticals are categorised by the Federal Joint Committee if a potential group contains at least three different pharmaceuticals. Affected third parties are consulted through a hearing process. If pharmaceuticals with different active ingredients are classified, so-called reference values to adjust for the different strength of each active ingredient are calculated thereafter. Finally, the federal associations of sickness funds determine the reference price of each drug. This is – generally speaking – conducted in a way, so that about one third of the drugs are available at or below the reference price.

Rational use of pharmaceuticals

Basically, a differentiation between binding and non-binding prescription guidelines has to be made. While non-binding guidelines are mainly issued by medical associations for the treatment of a particular disease, the only binding guideline, the Directive on Pharmaceutical Care, is issued by the Federal Joint Committee and covers only a very small segment of the market. Nevertheless, regular efficiency controls based on a physician's average amount of prescriptions and sickness funds' reclaims from individual physicians are in place, e.g. due to prescribing drugs excluded from the benefit catalogue or not licensed for the respective indication (off-label use).

Drug budgets of varying strictness were a prominent measure to contain pharmaceutical expenditures from 1993 basically until 2001. Since 2002, the so called regional spending caps have been abolished and were replaced by negotiated practice-specific targets of cost-control and appropriate prescriptions. The new initiative is supported by a long-overdue introduction of a uniform feed-back system for drug prescriptions, which came into operation for the outpatient doctor in March 2003. Physicians exceeding 125% of the prescription target are required to compensate the respective sickness fund, unless they can prove that prescriptions were necessary from a medical point of view. The prescription feed-back system GAmSI monitors the attainment of negotiated goals. Physicians receive a three-monthly overview of the aggregate prescription volume of their specialist group in the region and their individual prescription volume. Thus, they are able to adjust their future prescription behaviour according to the provided data.

Advertising and industry behaviour towards health professionals and the general population is regulated by the Medical Advertising Act, which is in line with the Directive 2001/83/EC. A distinction is made between prescription drugs and non-prescription drugs. While for prescription drugs advertising is only allowed among health professionals, non-prescription drugs may be advertised to the general population. However, advertising to the general population may not contain references to reports or research papers, recommendations of physicians, references to case history, or be accompanied with contests, trial offers or vouchers. It is further restricted for infectious diseases, malignant growth, addiction diseases and pathologic complications during pregnancy, delivery, and childbed. For health professionals, donations or extraordinary benefits through advertising are restricted, e.g. giveaways are only allowed if these are of low value and must not exceed an appropriate amount. Samples are limited to two per annum. The respective activity has to be documented thoroughly to make sure that it can be displayed to the responsible authority. Budget ceiling or taxes on promotional expenditure are not imposed.

Regulations regarding generic substitution (see section 5.5.1) and pressure resulting from drug budgets (see section 5.1) have changed prescription behaviour of physicians and have had a significant impact on SHI expenditure. Data also reveals an increasing readiness of physicians to prescribe generics, amounting to 74.2% of all potential generic prescriptions in 2005 and a market share of 57.3% in total prescription volume (see Table 5.2), one of the highest shares among EU and OECD countries. Despite substantial improvements in appropriate and cost-efficient prescribing, efficiency reserves for generic prescribing in 2005 still amounted to € 1.3 billion.

Current challenges and future developments

Controlling pharmaceutical expenditure within SHI in order to ensure equal access to pharmaceutical care is one of the main challenges for the German health care system. As the country already dedicates a large amount of GDP on health, it is not realistic to increase this share as fast as demand for health growths. If cost containment and increasing efficiency in prescribing fails to meet policy objectives in the long run, the pharmaceutical benefit basket will probably have to be reduced in order to ensure a financial basis for the SHI system.

Table of contents

List of tables and figures

List of abbreviations

AMIS	Arzneimittelinformationssystem (DIMDI) / Pharmaceutical information system
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte / Federal Institute for Pharmaceuticals and Medical Devices
BMG	Bundesministerium für Gesundheit / Federal Ministry of Health
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information / German Institute for Medical Documentation and Information
DRG	Diagnosis related groups
EMEA	European Medicine Agency
GDP	Gross Domestic Product
GGE	General Government Expenditure
HE	Health Expenditure
HTA	Health Technology Assessment
IQWIG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen / Institute for Quality and Efficiency in Health Care
NCU	National Currency Unit
NHS	National Health Service
Mio.	Million
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
PEI	Paul-Ehrlich Institute
PPP	Pharmacy Purchasing Price

PPRI	Pharmaceutical Pricing and Reimbursement Information project
SGB	Social Code Book
SHI	Social Health Insurance
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WHO	World Health Organisation
WP	Work Package

Introduction

The German pharma profile was prepared by the Department of Health Care Management of the University of Technology, Berlin on behalf of and in cooperation with the German Institute for Medical Documentation and Information (DIMDI).

This document is part of the contributions of DIMDI and its representative, Dr. Dauben, head of international affairs, to the Pharmaceutical Pricing and Reimbursement Project (PPRI).

The document is partly based on the DIMDI health technology report “Methods for the comparative evaluation of pharmaceuticals”, written by Zentner A; Velasco-Garrido M; Busse R (2005). (available via http://gripsdb.dimdi.de/de/hta/hta_berichte/hta122_summary_en.pdf). The pharma profile is extending this document regarding the much more detailed structure of the PPRI template. The pharma profile also includes new data and information on the German health care system based on the health care reforms till 2007.

1 Background

1.1 Demography

The Federal Republic of Germany is situated in central Europe and covers an area of about 357,000 km^2. Germany has 82.5 million inhabitants, with 42.1 million women and 40.4 million men (2005). Of the 82.5 million inhabitants 65.7 million live in the western part, 13.4 million in the eastern part, and 3.4 million in Berlin. Since reunification, the population in the eastern part decreased from 14.6 million in 1991 to 13.4 million in 2005 (excluding the eastern part of Berlin), attributable to migration to the west and the very low birth rate in the east. The population density is unevenly distributed and varies between 74 inhabitants per km^2 in Mecklenburg Western-Pomerania and 3,807 inhabitants per km² in Berlin.

The share of the population below 15 years of age decreased from 25% in 1970 to 14.1% in 2005, whereas the share of those over 64 years old remained at around 15% until 1993, and has since increased to 19.3% in 2005 (see Table 1.1). The share of the age group above 80 years has increased slightly over the last ten years to 4.5% in 2005 and is predicted to grow (Federal Statistical Office 2004a). Although there is no comprehensive national strategy in Germany, the government has initiated small programs and measures to cope with the ageing of population. In addition, the retirement age was raised from the age of 65 years to the age of 67 years. In 2007, a law came in force in which insures a parent in maternity leave 67% of the salary earned before. This measure aims to compensate for a loss of income due to children. Further measures to change demographic trends, e.g. improving childcare are in discussion.

By 2004, life expectancy at birth reached 76.6 years for men and 82.0 years for women, an increase of 4.5 and 3.4 years respectively since 1990. Life expectancy had been below the EU-15 average during the 1990s but has reached figures around average, i.e. 0.1 years above and 0.3 years below the EU-15 average in 2004 respectively. The age-standardized mortality rate decreased substantially between 1991 and 2004, by about a quarter. In fact, the substantial decrease in (age-standardized) mortality during this period was observable in most causes of death including cardiovascular diseases (causing more than a third of all deaths) and neoplasms (causing about a quarter of deaths). Increases were observed in infectious and parasitic diseases, being mainly due to sepsis and viral hepatitis. Mortality from diabetes has remained at the same level. In 2005, the standardized mortality rate of 628.5 per 100,000 was only marginally above the EU-15 average (620.75 per 100,000), i.e. the gap had become substantially smaller since 1990 (WHO 2007).

Table 1.1: Germany - Demographic indicators 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population in 1,000 (1)	81,661	82,188	82,340	82,482	82,532	82,501	82,438
Population density per km^2 (1)	229	230	231	231	231	231	231
Population aged 0-14 (in % of total)	16	16	15	15	15	14	14
Population aged 15-64 (in % of total) (1)	68	68	68	68	67	67	67
Population aged > 64 (in % of total) (1)	16	16	17	17	18	19	19
Life expectancy at birth, total (2)	76.8	78.4	78.8	78.8	78.7	79.4	n.a.
Life expectancy at birth, females (2)	80.0	81.3	81.6	81.5	81.4	82.0	n.a.
Life expectancy at birth, males (2)	73.4	75.2	75.7	75.8	75.9	76.6	n.a.

Source: (1) Federal Statistical Office of Germany 2005, (2) WHO European Health For All Database, January 2007.

1.2 Economic background

Germany's gross domestic product (GDP) amounted to a total of € 2,241 billion and to € 25,662 per capita in 2005. The GDP per inhabitant in Purchasing Power Parity reached US $28,816. In 1995 GDP growth of 3.8% was on a high level and has been much lower since then, reaching a growth rate of -0.2% in 2003. Since that time GDP growth rose to 1.2% for 2004 and to 2.8% for 2006. The economic turnaround also facilitated employment. The unemployment rate dropped by 2%points from 12.1% to 10.2% between January 2006 and 2007.

Governmental spending is € 1,038 billion or 47% of GDP. In terms of total government spending as a percentage of GDP in the 19 OECD member states within the EU, Germany ranges in the middle field (OECD 2004). The German health care sector is affected by a general tendency to privatisation as well as the formation of holding companies (especially hospitals). Consolidation in the health care market has lead to mergers among sickness funds, decreasing the number of funds from over a thousand in the 1990s to about 250 in 2006.

Table 1.2: Germany - Macroeconomic indicators 1995, 2000 - 2005

Variable (in NCU or percentage)	1995	2000	2001	2002	2003	2004	2005
GDP (billion €)	1,848	2,063	2,113	2,143	2,162	2,207	2,241
GDP per capita at real 2000 prices	22,867	25,103	25,379	25,338	25,277	25,693	n.a.
GDP / capita[1] in PPP US$ (2)	22,063	25,562	26,314	27,140	27,625	28,816	n.a.
Annual economic growth rate in %[1] (1)	3.8	2.5	2.5	1.4	0.9	2.1	1.5
General government expenditure (GGE) (billion €) (2)	1,012	930	1,005	1,030	1,047	1,038	n.a.
GGE in % of GDP (2)	54.8	45.1	47.6	48.1	48.4	46.9	n.a.
Exchange rate (NCU per €), annual rate	-	-	-	-	-	-	-

GDP = Gross Domestic Product, GGE = General government expenditure, NCU = National Currency Unit, PPPa = Purchasing Power Parity

Source: (1) Federal Statistic Office, (2) OECD Health Data 2007

1.3 Political context

Germany is a federal republic consisting of 16 states (*Länder*). Each of the states has a constitution consistent with the republican, democratic and social principles embodied in the national constitution (known as the Basic Law or *Grundgesetz*). Based on the constitution, the federal system is divided into three parts: the legislation, the administration and the judiciary. The constitutionally-defined bodies with legislative functions on the federal level are the Federal Assembly (*Bundestag*) and the Federal Council (*Bundesrat*).

The Federal Assembly is made up of 614 members, elected every four years. Since 2005, the 'grand coalition' of Christian Democrats and Social Democrats has held the parliamentary majority and formed the government. The main functions of the Federal Assembly are to pass laws, elect the Chancellor and control the government. The Federal Council, which represents the sixteen federal states, does not consist of directly-elected representatives but of three to six members – depending on population size – from each of the sixteen state governments. The main function of the Federal Council is to approve laws passed by the Federal Assembly. About half of all bills require the formal approval of the Federal Council, while in other cases the Assembly may overrule a negative vote by the Council. The President is currently Horst Köhler. His major tasks are to sign new laws, formally appoint the chancellor and the federal ministers and to fill the role of head of state.

Legislative authority lies principally with the 16 federal states (*Länder*), except in areas for which this authority is explicitly given to the federal level. The Federation's legislative authority falls into three different categories:

- legislation which is exclusively regulated at the federal level (mainly pertaining to foreign affairs, defence, monetary matters, citizenship, unity of tax and trading zone, air transport and some elements of taxation)

- legislation necessary to establish uniform laws for the whole country

- framework legislation, though the states retain a considerable amount of legislative latitude, e.g. in higher education, nature conservation, landscape management, regional planning and water management.

The states can fill in any gaps left by federal legislation or in areas not specified by the constitution. Thus they are responsible for culture and education almost in their entirety as a manifestation of their “cultural sovereignty”. They are also responsible for legislation defining the powers of local government and the police. All administration, such as tax collection, lies in the hands of the states, and their bureaucracy implements most federal laws and regulations. Difficulties can arise due to the fact that the Federal Council is often dominated by states led by parties that are a minority in the Federal Assembly and not part of federal government.

The Federal Government’s Cabinet consists of the Chancellor, who is head of the government, and the federal ministers. The Chancellor chooses the ministers and proposes them to the President for appointment or dismissal. He also determines the number of ministers and their responsibilities. The Chancellor is in a strong position primarily due to the fact that he establishes the guidelines for government policy. The federal ministers run their departments independently but within the framework of these guidelines. Besides the legislature and the executive, the various separate court systems (administrative, constitutional, civil courts and social courts) represent a strong third pillar which is in line with the constitutional idea of sharing power of decision-making.

1.4 Health care system

1.4.1 Organisation

The German health care system is characterized by a predominance of mandatory SHI with multiple competing sickness funds and a private/ public mix of providers (Bismarck model): In 2005, about 85.4% of the population were covered by comprehensive SHI (72.5% mandatorily and 12.9% voluntarily) (GBE 2007). This is complemented by three co-existing schemes of health security coverage: In 2005, about 10% percent took private health insurance which includes about 5% civil servants, retired civil servants and their dependants with free governmental care and private insurance policies covering the remainder. 2% were covered by specific free governmental schemes. Another at least 0.2% of the population, i.e. at least 170,000, were not covered by any third-party payer scheme.

Sickness fund membership is mandatory for employees whose gross income does not exceed a certain level (€ 3,975 in 2007). Those earning above that level may choose to stay insured as so-called voluntary members or to switch to private health insurance. Contribu-

tions for SHI are proportional to income from gainful employment up to a level (€ 3,563 in 2007). They include non-earning spouses and children without any surcharges. The sickness funds are the collectors, purchasers and payers of statutory health insurance and long-term care insurance.

Since 1996 there is free choice of sickness funds and the possibility to switch sickness funds after an 18 month contract period. Although there are several funds only accessible to a special group of people, e.g. farmers fund and “closed” company health insurance funds. Funds are obliged to contract with any applicant. The introduction of a risk structure compensation scheme since 1994 has led to a narrowing of contribution rate differences but did not equalize risk structures. To improve the mechanism and avoid risk selection, the risk structure compensation scheme, accounting for differences in the income of funds and the age, sex and invalidity, was complemented by a high expenditure pool (2002) and the number of chronically ill enrolled in disease-management programmes (2003). From 2009, the risk structure compensation scheme will also compensate differences in actual morbidity and need of care.

Health care for the populous country has traditionally been organized on a decentralized basis, characterized by a federal distribution of state functions, the subsidiarity principle of private over public providers, and a comparably strong delegation of competences to self-governmental actors in SHI. While ambulatory care is almost exclusively delivered by strictly regulated private for-profit providers, hospital care is delivered by a mixture of public and private providers with increasing tendency. Most acute hospitals are enlisted in “hospital plans” and are thereby regulated and financed basically by the same mechanisms regardless of ownership. From 1991 to 2005, the number of beds in private for-profit hospitals increased from 4% to 12.5% in general (acute) hospitals. However, 99% of hospital beds are accessible to SHI-insured since they are contracted by the sickness funds.

At the national level, the Federal Assembly, the Federal Council and the Federal Ministry for Health are the key actors, responsible for passing health reforms concerning statutory insurance. The *Länder* are responsible for planning inpatient capacities and financing investments in hospitals, nursing homes and institutions for social care. In addition, they supervise corporatist actors and pharmaceutical manufacturers in their constituency.

A large number of regulatory, managerial and even planning competences in SHI are delegated to the corporatist level of self-governmental sickness funds and provider associations or to joint committees of these actors. Within self-governing structures, federal legislation promoted competition at the level of sickness funds regarding the provision of services while centralizing decision-making powers on the benefit basket and quality assurance towards the federal level to secure uniform standards.

The corporatist level is represented by the non-profit, quasi-public sickness funds and their associations and associations of SHI-affiliated physicians’ and dentists’ on the provider side. The German Hospital Federation has increasingly been integrated into decision-making bodies of the SHI structures. Joint committees of payers and providers have the duty and right to define benefits, prices and standards (federal level) and to negotiate horizontal contracts, to control and sanction their members (regional level). The vertical implementation of decisions

taken by higher levels is combined with a strong horizontal decision-making and contracting involving elected representatives of actors involved in the actual care process. Their directives are legally binding for actors in SHI although subject to appeal at social courts. Since 2004, SHI decision-making has been integrated into the trans-sectoral Federal Joint Committee. Legitimized patient organizations have been given the right to participate in consultations but not to vote. In addition, there are a vast number of organizations representing professional and manufacturers' interests and welfare organizations. There are about 40,000 to 60,000 health-related self-help groups with about 3 million members.

1.4.2 Funding

Total health expenditure accounted for € 239 billion or € 2,900 per inhabitant in 2005 according to the Federal Statistical Office. While total health expenditure increased from 10.5% to 10.7% of GDP between 1995 and 2005, SHI expenditures increased much less as a share of GDP (see table 1.3). This was achieved by a variety of cost-containment measures including sectoral budgets, rational prescribing, price reductions and downsizing.

SHI financed 56.9% of total health expenditure in 2005. From 1949 until mid-2005, contributions have been shared equally between the SHI-insured employees and their employers. Since July 2005, the parity is shifted towards employees, reaching a financing mix of approximately 54:46. Currently, contribution rates vary between sickness funds; the average contribution rate amounted to 14.6% of gross income in 2005. From January 2009 contribution rates will not differ between sickness funds any more but will be fixed on a national level.

Private households (and non-profit organizations) contributed 13.5% of the total expenditure on health in 2005. This includes direct payments and co-payments, informal payments are uncommon. In 2004, co-payment amounts have been increased and standardized to € 10 per inpatient day and to € 5–10 for services and products in ambulatory care. Exemptions apply once more than 2% of the gross household income per annum has been spent on co-payments, or 1% of the gross household income for a sufferer from a serious chronic illness. Coupled with increased direct payments for excluded benefits, out of pocket payments are therefore expected to rise further.

9.2% of total expenditures were spent by private health insurers in 2005. This includes substitutive health insurance (incl. self-employed and high earning voluntarily insured) and supplementary health insurance for persons with SHI coverage. There are 48 private health insurers providing mainly substitutive and supplementary coverage through risk-oriented premiums. The role of complementary coverage is small (except for civil servants and their dependents).

5.7% of total expenditures were financed by governmental sources at the level of federal government, the *Länder* and the municipalities. Statutory retirement insurance contributes 1.5% of total health expenditure, mainly for medical rehabilitation of employees, while statutory (work-related) accident insurance finances 1.7% (in 2005). Since 1995, long-term care has been financed as a separate branch of statutory insurance, which contributes 7.5% of total health insurance. The remaining 4.2% were financed directly by employees.

Table 1.3: Germany - Health expenditure, 1995, 2000 - 2005

Health expenditure	1995	2000	2001	2002	2003	2004	2005
THE in NCU (Million €)	193,991	212,423	220,660	228,088	233,735	233,788	239,357
THE in % of GDP	10.5	10.3	10.4	10.6	10.8	10.6	10.7
THE per capita in NCU (€)	2,380	2,580	2,680	2,770	2,830	2,830	2,900
Public HE in % of THE	77.1	76.0	75.5	75.5	74.9	73.0	73.1
Private HE in % of THE	22.9	24.0	24.5	24.5	25.1	27.0	26.9

GDP = Gross Domestic Product, HE= Health Expenditure, THE = Total Health Expenditure, NCU = National Currency Unit

Source: Federal Statistical Office 2004a, Federal Statistical Office 2007.

1.4.3 Access to health care

1.4.3.1 Outpatient care

Ambulatory health care is mainly delivered by private for-profit providers working in single or, less frequently, group practice. A total number of 343,520 medical doctors (see Table 1.4) provide inpatient and outpatient health care for the German population in 2005. In 2004, outpatient clinics with employed physicians (MVZ) were legalized by law and its number is growing since. Patients have free choice of physicians, psychotherapists (since 1998), dentists, pharmacists and emergency care. SHI-insureds have basically free access to 96% of all ambulatory physicians, while 4% are not SHI-affiliated and treat only patients who are privately insured or pay directly. SHI-affiliated physicians offer almost all medical specialities in ambulatory care. Family physicians (general practitioners, internists, and pædiatricians in family practice, that is about half of SHI-affiliated ambulatory physicians) are not generally gatekeepers. Yet, their coordinating competence has been strengthened in recent years. Since 2004, sickness funds have been obliged to offer gate-keeping models to their insured. Also, a user charge of € 10 for the first physician contact per 3 months and any further non-referred visit has been introduced to raise funding and reduce unnecessary or non-coordinated visits.

All SHI-affiliated physicians and (since 1998) psychological therapists are mandatory members of regional physicians' associations. These are obliged to secure the provision of ambulatory care during practice hours and out-of-hour in their particular region. In turn they traditionally have a monopoly to provide ambulatory primary and secondary care and negotiate contracts with the various sickness funds collectively for all SHI-affiliated physicians in their region on an annual basis. Sickness funds transfer fixed per-capita amounts according to the number of SHI-insured living in the region to the physicians' associations, which leads to de facto budgets for ambulatory physician services. The regional physicians' associations divide the financial resources in separate funds for family physicians and specialist physicians and distribute the resources among their members according to the nationally uniform scale of relative point values and regionally adapted rules.

In addition to their income from the regional physicians' associations (for SHI-insureds), SHI-affiliated physicians receive reimbursement from private health insurers and other sources mainly on a fee-for-service basis although elements of per-capita and case-fee payments have been increased in recent years.

Table 1.4: Germany - Outpatient care 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total number of doctors (1)	313,291	329,511	334,676	337,800	340,708	342,473	343,520
Number of doctors per 1,000 inhabitants	3.8	4.0	4.1	4.1	4.1	4.2	4.2
Total number of outpatient doctors (1)	180,555	190,034	192,366	193,962	195,172	196,116	197,009
thereof General Practitioners (1)	44,670	44,107	44,326	44,303	44,128	43,882	43,503
thereof dentists (1)	60,616	63,202	63,854	64,484	64,609	64,997	65,207
Number of out-patient doctors per 1,000 inhabitants	2.2	2.3	2.3	2.4	2.4	2.4	2.4
Number of out-patient clinics departments (2)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	269 [1]

Source: (1) GBE 2007, (2) Federal Association of SHI Physicians 2007

[1] at 30th September 2005, around 550 by February 2007.

1.4.3.2 Inpatient care

Acute inpatient care is delivered by a mix of public, private not for profit, and for-profit providers (52.2%, 35.3% and 12.5% of acute hospital beds in 2005) with regard to the ability of the hospital to provide the respective services and in accordance with the level of care assignment of each hospital. The number of beds and average length of stay in acute hospitals have been reduced substantially (to 633 per 100,000 and 8.6 days in 2005) over the last decade. The traditional strict separation between ambulatory and hospital care has been eased in recent years by promoting ambulatory surgery and certain outpatient clinics at hospitals as well as trans-sectoral disease-management programmes and trans-sectoral integrated delivery networks. Yet, in 2005 only 7% of hospital physicians were accredited for SHI-affiliated ambulatory care.

Hospitals are financed on a dual basis: Investments for hospitals enlisted in hospital plans are planned by the 16 state governments and financed by state and federal governments jointly, while sickness funds finance recurrent expenditures and maintenance costs of hospitals. Doctors in inpatient care are employees of hospitals. Patients have to pay a standardized co-payment of € 10 per inpatient day.

The German adaptation of the Australian system of diagnosis-related groups (DRG) is becoming the sole system of paying for recurrent hospital expenditures (except mainly for psychiatric care), replacing the previous mixed payment system. Since January 2004, hospitals have been obliged to document their care activities according to the DRG scheme. From

2005, payment is adjusted gradually from individual hospital budgets, which vary greatly, to uniform base rates by 2009. The DRG payment system was developed step by step and will be adjusted continuously by the stakeholders involved with technical support from the Institute for the Development of the Hospital Payment System. Since 2003, regulations for minimal volumes apply for certain types of major surgery and transplantations.

Table 1.5: Germany - Inpatient care 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Number of inpatient doctors	132,736	139,477	142,310	143,838	145,536	146,357	146,511
Number of inpatient doctors per 1,000 inhabitants	1.6	1.7	1.7	1.7	1.8	1.8	1.8
Number of hospitals	2,325	2,242	2,240	2,221	2,197	2,166	2,139
Number of acute care beds	609,123	559,651	552,680	547,284	541,901	531,333	523,824
thereof in private sector	n.a.	n.a.	n.a.	48,615	53,933	61,282	65,351
Acute care beds per 1,000 inhabitants	7.5	6.8	6.7	6.6	6.6	6.4	6.4
Average length of stay in hospital	11.4	9.7	9.4	9.2	8.9	8.7	8.6

Source: Federal Association of SHI Physicians 2005, Federal Statistical Office.

2 Pharmaceutical system

2.1 Organisation

Decisions on health care provision in Germany are generally not determined only by governmental institutions e.g. the Ministry of Health (BMG) but also by self governmental institutions e.g. the physicians' association. The pharmaceutical market is thus partly under direct governmental supervision and partly regulated by self-governing and self-regulating institutions. Within the legislation process 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*). Self-governmental institutions of health care provision have the right to express their position regarding law proposals in special committees. The Federal Association of SHI-accredited Physicians, associations of the pharmaceutical industry, hospital groups, the pharmacists' association, sickness fund boards, and other interest groups all participate in the political decision-making process on behalf of their members.

It should also be mentioned that the judiciary in Germany plays a more important role in the decision making process than in many other European countries. In the past, the courts often decided on 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. Furthermore, so-called "social courts" frequently intervened to safeguard an equitable provision of health care services.

Drug licensing and supervision for human drugs is undertaken 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 supervise the safety of pharmaceuticals and medical devices. The criteria for licensing pharmaceuticals are: quality, safety and scientifically proven efficacy. This includes the results of phase I to phase III (controlled clinical) studies. In addition drugs may be granted admission to the market by the European Medicine Agency (EMEA).

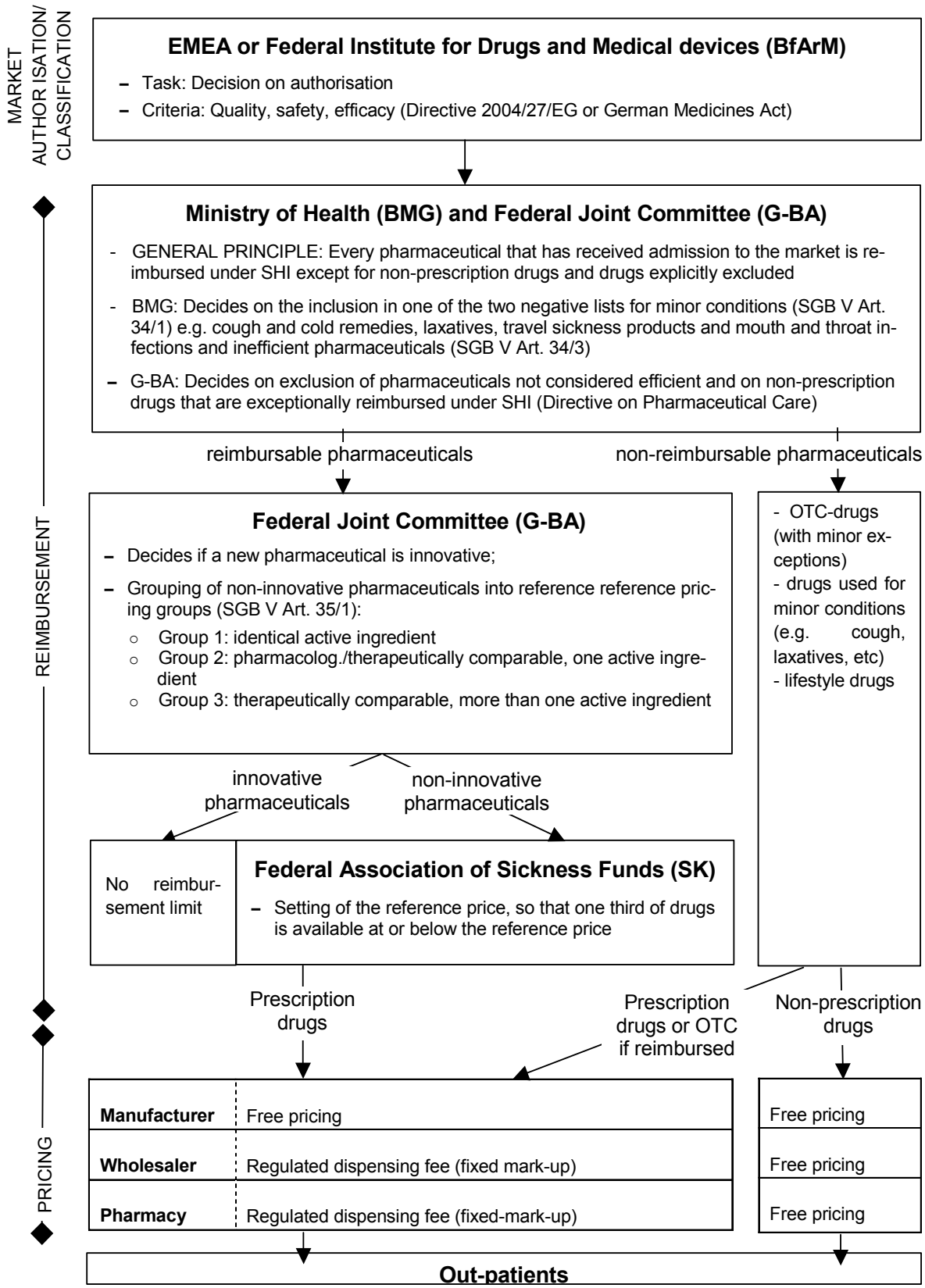
There is no explicit benefit catalogue for pharmaceuticals. A so-called positive list that should have included all pharmaceuticals covered by the sickness funds was foreseen by law twice, but never implemented. Therefore, every drug, which has received admission to the market and is not an OTC, is covered by the sickness funds and thus included in the benefit package of the insured (§§ 31, 34 SGB V). However, § 34 SGB V states some exemptions from comprehensive coverage. Insured aged over 18 years are excluded from 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). The Federal Joint Committee can issue indication based exemptions if those drugs are standard therapy for severe diseases. As part of the SHI Modernization Act (2004), lifestyle drugs have been legally excluded from reimbursement. Therefore, drugs for erectile dysfunction as well as anti-smoking drugs and others are no longer reimbursed by the sickness funds (§ 34/1 SGB V). In addition, the Social Code Book allows the Minister of Health to exclude inefficient drugs (i.e. they are not effec-

tive 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 October, 1991. Additionally, drugs for trivial diseases which can usually be treated by treatments other than drugs may be excluded (§ 34/2 SGB V).

While no reimbursement limit exists for drugs considered innovative, the reimbursement of all other drugs is restricted by the German reference pricing system according to § 35 SGB V. It defines a reimbursement limit for groups of comparable pharmaceuticals. The grouping procedure is done by the Federal Joint Committee. Subsequently the federal associations of the sickness funds set reference prices. Despite the existence of reference prices, the manufacturer is free to decide on the price of his product (see figure 2.1). However, the difference between the drug's price and the reference price is paid by the insured in addition to the regular co-payments. However, this is rarely the case, as only for 7.1% of the pharmaceuticals available on the market were priced above the reference price in 2005.

Despite free pricing on the manufacturer level, direct price regulation is imposed on pharmacies and wholesalers, whose mark-ups are legally defined for prescription drugs and for non-prescription drugs exceptionally covered under SHI. For OTC not covered under SHI, free pricing is applied for all levels of pharmaceutical providers (see Figure 2.1).

Figure 2.1: Germany - Flowchart of the pharmaceutical system (original illustration)



2.1.1 Regulatory framework

Pharmaceutical policy seeks to balance targets of public health, health care, and industrial policy. Public health and health care policy is primarily concerned with safeguarding quality and safety, improving health, and containing costs for SHI. At the same time, industrial policies seek to protect national labour markets and industries and their international competitiveness. Regulations concerning the pharmaceutical market therefore present a dichotomy: On the one hand, regulations concerning pharmaceutical pricing are remarkably liberal; on the other hand, the surcharges on ex-factory pharmaceutical prices are extremely regulated. Only recently, the structure and price regulations in the pharmaceutical distribution chain have been addressed by health policy.

Cost-containment has concentrated on the SHI market and has relied especially on indirect price controls through reference prices since 1989 and on regional spending caps (1993-2001). Since then, the pharmaceutical market has been reorganized stepwise, starting with ad hoc price cuts and rebate measures to counterbalance the lifting of spending caps which were replaced by practice-specific prescription targets in 2002. Furthermore, the legally fixed dispensing fees for wholesalers and pharmacies that had previously guaranteed identical prices for non-prescription drugs in all German pharmacies were lifted in 2004 (Stargardt-/Schreyögg/Busse 2007).

2.1.1.1 Policy and legislation

The two most relevant laws regarding pharmaceutical policy are the Social Code Book V (SGB V) and the Pharmaceutical Act (see table 2.1). The SGB V regulates the SHI benefit basket, the contractual relationship between sickness funds and pharmaceutical providers (manufacturer, wholesaler, pharmacies), and is the legal basis for cost containment strategies. The paragraphs regulating pharmaceutical care are spread within the fifth chapter of the SGB V (benefits due to disease). §§ 31, 34, 35, 35a regulate the entitlements to pharmaceutical care. § 91 and § 92 identify the tasks of the Federal Joint Committee. In §§ 129, 129a, 130, 130a and 131 pharmacies, hospital pharmacies and manufacturers of pharmaceuticals are regulated. Due to combining the set of policies to a more comprehensive approach, 15 amendments to the SGB have been made since it has been enacted in 1988 (Steffen 2006). Most of these changes were related to drug regulation policy. The most recent amendments to the SGB V were conducted with the Act to Improve Efficiency in Pharmaceutical Care (2006), which improved reference pricing and introduced prescribing targets, and the Act to Strengthen Competition in Statutory Health Insurance (2007), which extended the assignment of the Federal Joint Committee and the Institute for Quality and Efficiency by introducing maximum prices for patented innovations combined with cost-utility analysis of drugs.

The Pharmaceutical Act stipulates general issues regarding pharmaceuticals, regulates the procedure for market authorisation, and drug dispensing. Moreover, it contains specifications regarding safety of pharmaceuticals as well as regulations regarding the continuous monitoring of pharmaceutical products. Besides, the Directive on Pharmaceutical Care, a decree issued by the Federal Joint Committee based on the Social Code Book, is mainly concerned with the coverage of benefits and assuring that SHI services are adequate, appropriate, and

efficient. It seeks to clarify rules for patients' access and to steer behaviour of all office-based physicians. Therefore, the directive which includes general regulation regarding prescribing behaviour, may also exclude certain pharmaceuticals not considered efficient (e.g. rapid-acting insulines analogues for diabetes mellitus 2 are excluded as long as cost of treatment with a rapid-acting insulin analogue is more expensive than cost of treatment with human insulin analogue insulines), but also contains a list of reimbursable non-prescription drugs which are covered under SHI.

In addition, the Pharmacy Act regulates issues of dispensing drugs, the Medical Advertising Act restricts advertising and a ministerial decree, the Pharmaceutical Price Ordinance, regulates dispensing fees for pharmacists and wholesalers by defining mark-ups on the manufacturers' prices.

Table 2.1: Germany - Major laws relevant for the pharmaceutical sector

Name in local language (German)	Abbreviation	Name in English
Arzneimittelgesetz	*AMG*	*Pharmaceutical Act*
Arzneimittelpreisverordnung	*AmPreisV*	*Pharmaceutical Price Ordinance*
Arzneimittelrichtlinie	*AMR*	*Directive on Pharmaceutical Care*
Gesetz über das Apothekenwesen	*ApoG*	*Pharmacy Act*
Heilmittelwerbegesetz	*HWG*	*Medical Advertising Act*
Sozialgesetzbuch V	*SGB V*	*Social Code Book V*

2.1.1.2 Authorities

The Ministry of Health is responsible for overall planning and prepares legislative actions of the German parliament. While decisions are mostly taken by self-governmental bodies, it is the ministry's task to supervise the decision-making bodies and procedures. Supervision and enforcement can be divided into several levels: formal governmental approval of (or lack of objection to) decisions taken by self-regulatory bodies or governmental veto of self-regulatory decisions if these are not taken according to the law, the federal government's right to intervene where no decisions have been taken, and legal action against institutions that do not fulfil their legal duties.

The most powerful self-governmental institution, the Federal Joint Committee, issues directives relating to all sectors based on the legislative framework of the Social Code Book. It is composed of 4 additional bodies, each of which passes directives for a distinct field of regulation. They consist of actors involved in the respective field. While federal associations of sickness funds (decision-making powers) and patient representatives (no vote) are represented in all of the four committees, the composition of providers varies, i.e. the Federal Association of SHI Physicians is represented in the Committee on Ambulatory Care, the Committee on "Physician Issues", but not the Committee on Dental Care where the Federal Association of SHI Dentists is represented. The German Hospital Association delegates representatives to the Committee on Hospital Care and the Committee on Physician Issues. These joint committees consist of various joint sub-committees that prepare recommenda-

tions, conclusions, and directives, partly supported by working groups. The directives of the Federal Joint Committee are legally binding for actors in Statutory Health Insurance although subject to appeal at social courts.

Besides representing sickness funds within the Federal Joint Committee, the federal associations of sickness funds are responsible for setting reference prices. Other tasks related to the pharmaceutical market are to negotiate rebates with pharmaceutical providers and to negotiate a framework contract with the associations of pharmacists for the services provided by pharmacists under SHI. From 1st July 2008, the 8 different associations of sickness funds will be merged into one body, the Federal Association of Sickness Funds which will inherit the tasks and responsibilities of the associations.

The regulation and control of health technologies in Germany has in the past not been a major issue but with recent health care reforms HTA has become an increasingly important component in health care decision making as it relates to defining the basket of health services covered under the statutory system undertaken by the Federal Joint Committee. A HTA database has been established at the German Institute for Medical Documentation and Information (DIMDI), an institution within the scope of the Federal Ministry of Health, to support decision-making by the Federal Joint Committee and others. After the foundation of the Germany Agency for HTA in 2000, a second HTA institution, the Institute for Quality and Efficiency (IQWiG), was founded in 2004. The IQWiG commissions HTA and makes recommendations for the in- or exclusion of technologies, e.g. pharmaceuticals, into the SHI benefit basket although it does not have any decision-making powers.

Drug licensing and supervision is undertaken 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 supervise the safety of pharmaceuticals and medical devices. However, only a marginal beneficial effect of the new drug needs to be demonstrated with a relatively small sample in order for it to be sufficient to fulfil the efficacy criteria. This has led to the increased licensing of active substances with merely minor modifications. In addition, drugs for complementary medicine, such as homeopathic and anthroposophic drugs, are exempted from the licensing procedure 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 reliability of the final products. Licensing is, in any case, limited to five years, after which there is a need to apply for an extension which is usually granted. In accordance to European law, licensing time will change in the future and may vary on the product level.

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 benefits to the public interest, but still lack 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 appraise its therapeutic value.

This procedure is especially relevant for orphan drugs (i.e. those used to treat very rare diseases) when companies or authorities try to accelerate the licensing procedure. However, the procedure is very rarely adopted.

Table 2.2: Germany – Authorities in the regulatory framework in the pharmaceutical system 2006 (original illustration)

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Bundesministerium für Gesundheit (BMG)	Ministry of Health	Regulatory body	Overall planning and legislative authority, supervision over decision taken by self-governmental institutions, operating negative lists
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	Federal Institute for Pharmaceuticals and Medical Devices	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation and vigilance, classification for all drugs except for blood and blood products
Gemeinsamer Bundesausschuss (G-BA)	Federal Joint Committee	the most important self-governmental institution, consisting of representatives of sickness funds, providers and patients	Classification of pharmaceuticals into reference pricing, issuing Directive on Pharmaceutical care, excluding pharmaceuticals from SHI benefit basket
Paul Ehrlich Institut	Paul Ehrlich Institute	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation and vigilance, classification for blood and blood products
Institut für Qualität und Wirtschaftlichkeit (IQWiG)	Institute for Quality and Efficiency	Subordinated agency for evaluation (effectiveness, cost-utility etc.) of the G-BA	Conducting cost-utility analysis on pharmaceuticals if mandated by Federal Joint Committee or Ministry of Health
Spitzenverbände der Krankenkassen (until 30.06.2008)	Federal Associations of Sickness Funds	Third Party Payers	In charge of setting reference prices and prescribing targets
Spitzenverband Bund der Krankenkassen (from 01.07.2008)	Federal Association of Sickness Funds	Third Party Payers	In charge of setting reference prices and prescribing targets

2.1.2 Pharmaceutical market

This section gives an overview on the availability of pharmaceuticals as well as market figures.

2.1.2.1 Availability of pharmaceuticals

According to the Association of Research based Pharmaceutical Companies, a total of 8,933 different active ingredients have received market authorisation in Germany. Of all drugs dispensed by pharmacies in 2005 (1,620 million packages), 713 million (44%) were prescription-only drugs, 713 million (44%) were OTC medications sold in pharmacies and 194 million (12%) OTC-medication sold in drugstores and supermarkets (see table 2.3). Of the 648 million SHI-prescriptions in 2005, 100 million (15.5%) were prescribed OTC drugs and 548 million (84.5%) were prescription-only drugs. In terms of turnover, prescribed OTC drugs accounted only for 6% of the in the SHI-drug market, whereas 94% of the SHI turnover was spent on prescription-only drugs. The number of generics available on the German market can only be estimated from their share in SHI prescription volume (57% of 1620 million packages) or SHI turnover (35%) as no other data is available.

The Federal Institute for Pharmaceuticals and Medical Devices (BfArM) reports the availability of 53,468 pharmaceuticals on the German market. As this figure represents the number of admissions granted by the BfArM, each different package size (related to European authorization) and / or strength (related to national authorization) as well as each generic copy of a drug that has already received admission to the market is counted as an additional pharmaceutical. Therefore, and in accordance with the international definition of the term 'pharmaceutical', table 2.3 does contain data from SHI market and industry. The numbers of authorized products are based on the official national register of pharmaceutical and are available via the AMIS database system.

Table 2.3: Germany - Number of pharmaceuticals 1995, 2000 - 2006[1]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005
Authorised							
- acive ingrediendts(1)	n.a.	9,615	9,684	9,651	9,449	8,992	8,933
- authorized products (2)	12,013	25,441	29,629	33,973	38,276	43,815	49,510
- parallel imports (2)	1540	4529	6028	7229	8341	9170	10172
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM							
% of packages (1)	n.a.	n.a.	n.a.	45%	47%	47%	47%
% of turnover (1)	n.a.	75%	77%	79%	82%	84%	81%
Reimbursable	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Generics							
% of packages (3)	42%	49%	50%	52%	54%	55%	57%
% of turnover (3)	33%	32%	30%	30%	30%	34%	35%
Parallel traded (1)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = Prescription-Only Medicines, n. a. = not available

Source: (1) VFA Statistics 2001-2006, (2) AMIS database provided by DIMDI, (3) Schröder/Nink 2007.

2.1.2.2 Market data

The pharmaceutical market has grown from € 26.4 billion in 1995 to € 39.5 billion in 2005. While the overall market had an average annual growth rate of 4.0% until 2004, the generics increased their market share in total turnover from 33% in 1995 to 35% in 2005. The annual number of prescriptions remained stable over the last years, thus indicating an increase in the average value per prescription. Pharmaceutical imports and exports have more than doubled within the last 10 years, from € 6.4 billion to € 14.8 billion and from € 18.0 billion to € 27.9 billion respectively (see table 2.4). Despite large increases in foreign trade, the pharmaceutical industries' contribution to the German trade surplus has only increased by € 1.5 billion.

Of the € 39.5 billion spent on drugs in 2005, € 34.1 billion was spent on pharmacies in ambulatory care and € 3.2 billion on acute hospital care (Federal Statistical Office 2006). SHI is responsible for roughly 70% (€ 27.6 billion) of turnover. Of this, € 23.0 billion are generated in pharmacies while € 2.7 billion are generated in acute care hospitals. The remaining € 1.9 billion were spent in other dispensaries (e.g. drugstores) or other inpatient care facilities.

Table 2.4: Germany - Market data 1995, 2000 – 2005

In million NCU / €	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescriptions by volume (million packages) (1)	n.a.	1,582	1,607	1,620	1,609	1,460	1,620
No. of annual prescriptions by value (billion €) (2)	26.4	31.6	34.2	35.8	36.8	35.8	39.5
Pharmaceutical sales							
Sales at ex-factory price level (billion €) (1)	n.a.	15.5	17.1	18.6	19.2	18.0	21.3
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at pharmacy retail price level (billion €) (3)	22.1	27.3	29.4	30.6	32.1	32.0	34.1 (2)
Sales at hospitals (billion €) (3)	2.4	2.8	2.8	3.0	3.0	3.1	3.2
Sales of generics (billion €) (4)	8.7	10.1	10.3	10.7	11.2	12.4	n.a.
Sales of parallel traded pharmaceuticals (billion €) (1)	n.a.	1.0	1.6	2.5	2.5	1.8	n.a.
Exports and imports							
Total pharmaceutical exports (billion €) (1)	18.0	21.0	22.5	23.2	23.5	24.4	27.9
Total pharmaceutical imports (billion €) (1)	6.4	10.2	11.2	11.7	12.4	13.1	14.8

Sources: (1) VFA Statistics 2001-2006, (2) GBE 2007, (3) Federation of Pharmacists' Organizations 2007 (4) estimated from Schwabe 2007

An analysis of prescription data is undertaken annually by a sickness fund affiliated institute. Although this report does not provide patient data which could be used to evaluate appropriateness, it is nevertheless of value for assessment of trends in physicians' prescription behaviour. The report is based on virtually all drug prescriptions in the ambulatory care sector (GKV-*Arzneimittelindex*), and is jointly maintained by several corporatist associations. It does not include prescriptions paid by private health insurance, drug supply in hospitals or OTC drugs. Based on this, the top selling pharmaceutical in turnover has been Durogesic (fentanyl), followed by Pantozol (pantoprazol) and Nexium Mups (esomeprazol) (see table 2.5).

Table 2.5: Germany - Top 10 best selling pharmaceuticals in turnover, by active ingredient, 2005

Position	Pharmaceutical (active ingredient)
1	Durogesic (Fentanyl)
2	Pantozol (Pantoprazol)
3	Nexium Mups (Esomeprazol)
4	Plavix (Clopidogrel)
5	Zyprexa (Olanzapin)
6	Risperdal (Risperidon)
7	Viani (Salmeterol + Fluticason)
8	Rebif (Interferon beta -1a)
9	Iscover (Clopidogrel)
10	Enbrel (Etanercept)

Source: Schwabe 2007

2.1.2.3 Patents and data protection

Patent protection is organized in accordance with the European Patent convention. Therefore, original pharmaceuticals enjoy a market protection of 20 years. Thereafter, generics may enter the market. An exceptional prolongation of patent protection by six months can be applied for when the pharmaceutical has been approved for the therapy of children since the European Commission passed a corresponding directive on 26th January 2007 (Müllens/Butzer/Seibert-Grafe et al. 2007). Additional exceptions apply for orphan drugs (Gericke/Riesberg/Busse 2005).

2.1.3 Market players

This section describes the key players in the pharmaceutical system except authorities which have been introduced in 2.1.1.2. It gives an overview of the key players in production, distribution, dispensing, prescription, and use of pharmaceuticals and their influence on pharmaceutical policy making.

2.1.3.1 Industry

The pharmaceutical industry in Germany is among the most powerful in developed countries and contributes significantly to the export market. Around 975 pharmaceutical companies with 113,002 workers operate in Germany (2005) (see table 2.6). The organization of the German pharmaceutical industry changed in the 1990s, when the large, research based and international companies formed their own organization, the Association of Research-based Pharmaceutical Companies (41 manufacturers representing about two-thirds of the market). Thus, the remaining Federal Association of the Pharmaceutical Industry (about 280 members) has mainly become the organization of small and medium size companies although also including some of the large companies. The split was partly attributable to disagreements over whether to support negative or positive prescription lists. Two other associations of pharmaceutical companies represent pharmaceutical manufacturers with special interests: The Federal Association of Pharmaceutical Manufacturers (128 members) for producers of over-the-counter medications and the smaller German Generics Association (29 members) for generics producers. The latter has recently been complemented by an organization called Pro Generics (17 members in 2006), which represents internationally active generic manufacturers.

The associations' aims are to lobby their interest in public and to influence politicians and bureaucrats. Sometimes lobbying groups of the pharmaceutical industry are 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, has twice – in 1995 and in 2003 – not been implemented for this reason (Busse/Schreyögg/Henke 2005). In addition, the pharmaceutical industry filed several court cases arguing that sickness funds were not authorized to set (indirect) price controls for patented drugs by including them in the reference price scheme. Yet, the Federal Constitutional Court (December 2002) and the European Court of Justice (early 2004) approved the sickness funds' role in influencing prices in the SHI market, as institutions acting in a publicly delegated function.

Table 2.6: Germany - Key data on the pharmaceutical industry 1995 – 2005

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies (1)	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	975
- research-oriented (1)	n. a.	n. a.	45[4]	44[4]	42[4]	39[4]	41[4]
- generic producers (2)	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	~58
- biotech (1)	222[3]	332[2]	365[2]	360[1]	350[1]	346[1]	375[1]
Number of persons employed (1)	122,847	113,950	114,267	114,990	118,720	113,989	113,002

[1] partly included in total numbers of companies. [2] bio- and gentech, [3] bio- and gentech 1998, [4] Members of the Association of Research-based Pharmaceutical Companies

Source: (1) Federal Association of the Pharmaceutical Industry 2006, (2) German Generics Association.

2.1.3.2 Wholesalers

While for the inpatient sector, pharmaceuticals are distributed directly from manufacturers to the respective hospital pharmacies, the distribution of drugs for the outpatient sector is mainly organised via wholesalers. This is because on average, a pharmacy is supplied three times a day, from two different wholesalers and therefore direct distribution is not profitable for most drugs. The large wholesaler companies are organised in the Federal Association of Wholesalers (Phagro). In total, 16 different wholesaler companies (see table 2.7) with 12,197 employees operate in Germany. Four wholesaling companies are present nationwide, while twelve are regional wholesalers each with one to five warehouses. Monthly, between 60,000,000 and 70,000,000 drugs are being delivered (2.2 million drugs per day). Besides the members of Phagro, a large number of very small wholesaling companies operate specialised segments (e.g. vaccination) of the pharmaceutical market.

As manufacturers try to switch to direct distribution for high priced products and OTC in order to save wholesaler margins and to increase their control over product placement and dispensing, the wholesaler market is currently in a transitional phase. In addition mail-order pharmacies have reduced the amount of drugs being supplied via wholesalers (Phagro 2007).

Table 2.7: Germany - Key data on pharmaceutical wholesale 1995 - 2005

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of wholesale companies	na	na	na	na	Na	16[1]	16[1]
Total number of warehouses	na	na	na	na	na	129[1]	na

[1] Members of the Federal Association of Wholesalers.

Source: Clement et al. 2005.

2.1.3.3 Pharmaceutical outlets / retailers

Pharmaceuticals may be dispensed by hospital, institutional, and “public” (though privately owned) community pharmacies and, if they are not labelled “pharmacy-only”, by drug stores. There are no dispensing physicians in Germany, and the dispensing of hospital pharmacies to the outpatient sector is restricted to patients discharged at the weekend. As drugstores are only allowed to sell a very small fraction of OTC drugs, pharmacies basically enjoy a monopoly on dispensing drugs. In addition, the pharmacy itself has to operate in a separate location. Therefore an integration of pharmacies into supermarkets or department stores is not possible (Schöffski 1995).

2.1.3.3.1 Pharmacies

Community pharmacies clearly dominate the distribution of drugs. Of the 1,620 million packages sold in 2005, 88% were sold in pharmacies and only 12% in drug stores, which accounted for 6% of the total turnover in the pharmaceutical market. Drugstores mainly sell vitamins, minerals and some phytotherapeutic products, while nicotine replacement items,

homeopathic drugs and anthroposophic drugs, for example, have to be sold in pharmacies (pharmacy-only OTC). Of the OTC medications dispensed in ambulatory care in 2005 (907 million packages) 194 million (21%) were sold in drug stores while 713 million packages (79%) were sold by pharmacies (VFA 2006).

Ownership of a pharmacy is limited to trained pharmacists and the number of pharmacies to be owned per pharmacist is limited to 4 (before 2004: 1), which prohibits wholesalers from vertical integration. As there are no regulations concerning the entry of a pharmacy (e.g. licencing), the density of pharmacies is relatively high compared to international standards. It has decreased since 1995 (2,870 inhabitants per pharmacy) to 3,825 inhabitants per pharmacy in 2005 (see Figure 2.2). Community pharmacies are all privately owned (see table 2.8), operated by self-employed pharmacists who are mandatory members of pharmacists' chambers. Together with the German Pharmacists' Organization, the pharmacists' chambers form the Federation of Pharmacists' Organizations. Until 2003, pharmacies had a monopoly over drug dispensing in outpatient care. However, the introduction of e-commerce and extended allowances to hospital pharmacies, which may also give medications to SHI-insured if their funds have negotiated an agreement with the hospital, did not lead to significant market changes.

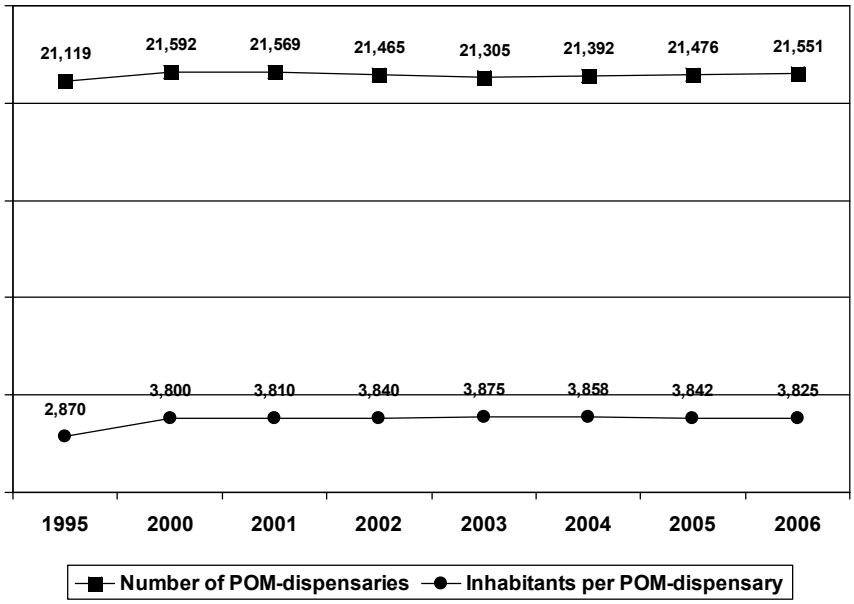
Table 2.8: Germany - Retailers of pharmaceuticals 1995, 2000 - 2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005
Number of community pharmacies	21,119	21,592	21,569	21,465	21,305	21,392	21,476
No. of private pharmacies	21,119	21,592	21,569	21,465	21,305	21,392	21,476
No. of public pharmacies	0	0	0	0	0	0	0
Number of hospital pharmacies	634	563	560	545	522	502	492
Number of other POM dispensaries: __none____	n. apl.	n. apl.	n. apl.	n. apl.	n. apl.	n. apl.	n. apl.
Total number of POM-dispensaries	21,753	22,155	22,129	22,010	21,827	21,894	21,968
No. of internet pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	~1420
No. of OTC dispensaries, like drugstores: _____	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; No. = number

Source: GBE 2007.

Figure 2.2: Germany - Number of POM-dispensaries and number of inhabitants per POM-dispensary 1995 and 2000 – 2006



POM = prescription-only medicines; All POM-dispensaries = including branch pharmacies, SD-doctors, and other university pharmacies, policlinic pharmacies and hospital pharmacies acting as community pharmacies

Source: Federation of Pharmacists' Organizations 2007

2.1.3.3.2 Internet pharmacies

Since enforcement of the SHI Modernization Act in 2004, the structure of the pharmaceutical sector has changed. The internet trade in OTC drugs grew substantially in the first few months. By July 2005, 1% of SHI expenditures for pharmaceuticals were taking place via the internet (BMG 2006). In 2006, internet trade with pharmaceuticals had an estimated market share of about 4% of the pharmaceutical market. According to the Federation of Pharmacists' Organizations, about 1,420 pharmacies had obtained licenses to trade drugs via the internet until December 2005. In addition to national internet pharmacies, for which the same regulation applies as for community pharmacies, numerous pharmacies from other European countries may offer drugs in the German market in accordance with the free movement of goods within the EU.

2.1.3.3.3 Dispensing doctors

Office-based physicians may not dispense medications. Incidentally, they may hand over sample packages acquired through detailing of the pharmaceutical industry to patients for free.

2.1.3.4 Hospitals

While in the outpatient sector the so-called public pharmacies are responsible for the supply of pharmaceuticals, the inpatient sector is mostly supplied by hospital pharmacies which organisationally belong to the hospital sector. Hospitals have either installed a hospital pharmacy in their hospital, are supplied with pharmaceuticals by the hospital pharmacy of another hospital, or enter into a supply contract with a public pharmacy (Schöffski et al. 2002). In each hospital, a commission consisting of a senior physician from each department, a controller, and the hospital pharmacist decides on the drugs listed on the hospital formulary based on scientific publications, personal experience as well as business data. Decisions to add or to cancel drugs from the formulary are made several times a year. As a basic rule, pharmaceuticals are then stocked for a four-weeks-consumption in the hospital pharmacy.

The SHI Modernization Act in 2004 extended allowances to hospital pharmacies, which now may also give medications to SHI-insured if their funds have negotiated an agreement with the hospital. From August 2002, hospital pharmacies had already received an allowance to deliver certain medications, especially chemotherapies, directly to office-based physicians.

2.1.3.5 Doctors

The Federal Association of SHI Physicians sends representatives into the Federal Joint Committee which issues the Directive on Pharmaceutical Care. Thus, representatives of physicians are directly involved into priority setting regarding pharmaceuticals, the forming of pharmaceutical groups for reference pricing, and into decisions on the exclusion of pharmaceutical benefits from SHI coverage. In addition, regional associations of SHI physicians negotiate with associations of the sickness funds practice-specific budgets and prescribing targets (see section 5.1).

2.1.3.6 Patients

Since 2004, patient organizations can be accredited by the Federal Ministry of Health to send delegates to the Federal Joint Committee. Although these delegates do not have the right to vote, they may express their concerns and thereby influence decisions or submit applications to be decided upon by the committee. Besides the Council of Disabled People, the three other organizations represent institutions for informing and counselling patients and consumers, namely the Federation Consumer Centres, the Federal Alliance of Patient Centres and Initiatives, and the German Alliance Self-Help Groups, an alliance of contact centres to promote the development of self-help groups (Hundertmark-Mayser/Möller 2004). Furthermore, the mainly publicly funded Foundation for the Testing of Consumer Goods (and Services) and other consumer protection agencies have started to investigate contribution rates, the service quality, and benefit package of sickness funds, and to evaluate the performance of hospitals and other providers and to advise the public accordingly.

2.2 Funding

This section provides an overview of the funding of pharmaceuticals. This includes pharmaceutical expenditure and the allocation of funds for pharmaceuticals.

2.2.1 Pharmaceutical expenditure

Total Pharmaceutical Expenditure (TPE) rose steadily from € 26.4 billion in 1995 to € 34.2 billion in 2001 and to € 39.5 billion in 2005. The average annual increase in TPE from 1995 to 2005 was 4.15%. The share of TPE as a percentage of total health expenditure also increased from 13.9% in 1995 to 15.7% in 2003 and 16.5% in 2005 respectively (see table 2.9). According to the Federal Statistical Office the share of TPE on Germany's GDP was 1.76% in 2005. The average share of TPE on the Total Health Expenditure (THE) in 2004 among the 15 EU member states before the 2004 enlargement was 15.3 %. Portugal's respective share was the highest with 23.1%, while Luxembourg's share was the lowest with 8.5%. Germany's share equalled the EU average of 15.3%, placing the country in the centre of the TPE/THE ranking (OECD 2006).

Of the € 39.5 billion spent on drugs in 2005, € 35.9 billion was spent on pharmacies in ambulatory care and € 3.2 billion on acute hospital care (Federal Statistical Office 2006). Of the € 34.0 billion spent on drugs in pharmacies in 2005, € 25.5 billion were spent on prescription drugs and € 4.4 billion on over-the-counter (OTC) medication. Total expenditure on self-medication was € 5.4 billion in 2005, while expenditure for OTC that are covered by SHI were € 1.57 billion in 2005. In real prices, expenditure on OTC drugs increased until 1997, decreased between 1997 and 1999 and has stayed relatively unchanged since, while prescription drug costs rose continuously.

The public share of pharmaceutical expenditure on total health expenditure (THE) was 11.7% in 2005. The development of the public share of pharmaceutical expenditure on total health expenditure has been quite similar to the general development of the pharmaceutical market: From a share of 10.1% of PE on THE in 1995 it rose to 11.3% in 2002. The exclusion of non-prescription drugs from public coverage lead to a decrease to 10.5% in 2004 which was followed again by an increase in 2005.

Table 2.9: Germany - Total pharmaceutical expenditure 1995, 2000 - 2005

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
TPE (in billion)	26.4	31.6	34.2	35.8	36.8	35.8	39.5
TPE in % of Total Health Expenditure	13.9	14.9	15.5	15.7	15.7	15.3	16.5
TPE per capita in (in €)	331	384	415	435	444	433	479
Public PE in % of THE	10.1	10.5	11.1	11.3	11.3	10.5	11.7
Private PE in % of THE	3.8	4.4	4.4	4.4	4.4	4.8	4.8

NCU = National Currency Unit, TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure

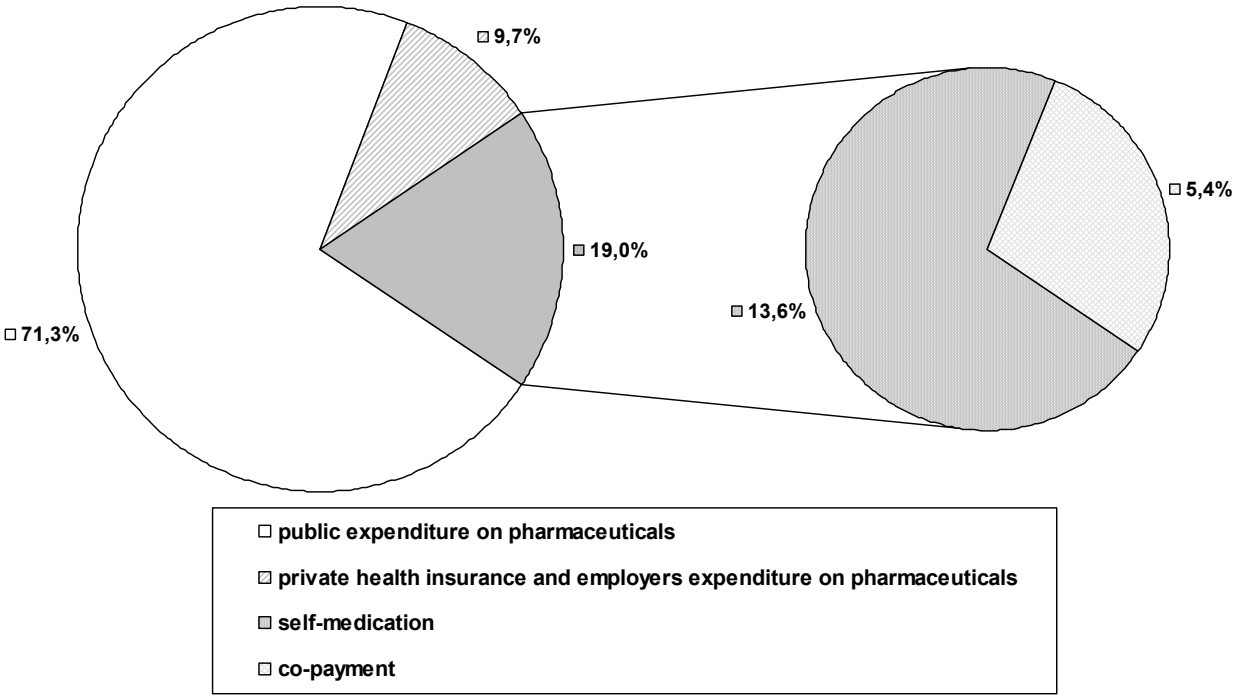
Source: Federal Statistical Office 2004 and 2006.

2.2.2 Sources of funds

The public share of total pharmaceutical expenditures (€ 39.4 billion in 2005) was 71.3%, of which 69.9% were spent by statutory health insurance, 0.1% by statutory pension insurance, 0.4% by statutory accident insurance and 0.8% by public households. Private expenditure accounted for 28.7% of total pharmaceutical expenditure, of which 6.1% was spent by private health insurance, 3.6% by employers, and 19.0% by private households (and not-for profit organizations). Expenditure by private households can be separated in self-medication (13.6%) as well as co-payments (5.4%) according to SHI figures (see figure 2.3). The share of non-reimbursable prescription drugs on self-medication is negligible, since this applies only to life-style drugs. Informal payments for pharmaceuticals are uncommon.

As a result of cost-sharing measures, the share of private pharmaceutical expenditure has increased throughout the 1990s, accounting for up to 26% of pharmaceutical expenditures in 1998, but decreased again to 18% in 2003, i.e. the same level as in 1992. In 2005 private household expenditures increased again to 19% due to the enforcement of the SHI Modernization Act. It is worth mentioning that co-payments and corresponding exemption mechanisms have a long tradition in the German health care system, most traditionally in pharmaceuticals (see section 4.4.2).

Figure 2.3: Germany - Share of private and public pharmaceutical expenditure 2005



Source: Federal Statistical Office 2007, Nink/Schröder 2007.

2.3 Evaluation

Evaluation of pharmaceutical technologies in Germany was not a major issue in the past. Although German regulations, especially licensing for pharmaceuticals, meet international standards, the evaluation of pharmaceutical technologies did not receive the attention it deserved. Generally, there is widespread consensus on health policy goals e.g. quality of care, safety, access and cost containment. However, because of different political views on the use of a more market based approach to allocate resources, there is an ongoing debate on the instruments to reach these goals.

With regard to cost containment of pharmaceutical expenditure, a wide range of measures is applied. Some policies were successful, some not – some measures were sustainable while other did not last for a long time. While the discussions are mainly driven by the need for change, public funded structured research programs to evaluate the impact of changes in pharmaceutical policies do not exist. Therefore decisions on regulatory changes are more often dominated by political interests than lead by economic evidence (Sauerland 2001).

With regard to the Directive 89/105/EEC, which became known as the 'Price Transparency Directive', Germanys' licensing and evaluation procedures do not interfere with current EU legislation. In Germany, all pharmaceutical products – provided these have passed the national registration process – are without delay reimbursable. Exclusion of drugs from the benefit catalogue and setting of reimbursement limits may only occur subsequently. A positive list or a fourth hurdle which could potentially lead to interference with the above mentioned Directive 89/105/EEC is not planned.

3 Pricing

3.1 Organisation

The regulation of pharmaceutical prices differs between the inpatient sector and the ambulatory sector. While hospitals may negotiate prices with wholesalers or manufacturers, the distribution chain and prices are much more regulated in the outpatient market. Besides temporal price freezes, ex-factory prices are basically determined in both sectors by manufacturers without negotiations involving governmental agencies, direct price, or profit controls and public procurement. However, price setting by companies takes into consideration regulations in other parts of the market, e.g. reimbursement regulation through reference pricing (see section 4.3).

Statutory pricing is used for prescription drugs and for prescribed drugs with OTC status that are exceptionally a part of the SHI benefit package at the level of wholesaler and pharmacies. Accordingly, the Pharmaceutical Price Ordinance stipulates fixed mark-ups on manufacturers selling prices and thereby guarantees identical prices for prescription drugs in all German pharmacies. In addition, it enables the manufacturer to determine the ex-wholesaler and the ex-pharmacy price of the drug by setting the ex-factory price. Since the Statutory Health Insurance Modernisation Act in 2004, prices of non-prescription drugs are no longer subject to regulation (see table 3.1). As in Norway (Anell/Hjelmgren 2002) and Iceland (Almarsdóttir/Morgall/Grimsson 2000) – two European countries that deregulated their OTC markets in 1996 and 2000, respectively –, pharmacies in Germany are allowed to compete in terms of OTC drug prices in addition to quality of service.

Besides the official prices in accordance with the Pharmaceutical Price Ordinance, to some extent, cash discounts can be negotiated between manufacturers, wholesalers, and pharmacies. In addition, pharmaceutical providers have been obliged to give rebate to sickness funds. While some rebates are mandatory for all drugs provided under SHI (e.g. the pharmacy rebate of € 2.30 per package), others are based on contractual agreements (e.g. rebates to an individual sickness fund) or special drug characteristics.

Table 3.1: Germany - Ways of pricing of pharmaceuticals (original illustration)

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Free pricing for all products set by the manufacturer/ importer.	Free pricing for non-prescription drugs.	
Statutory Pricing	Not applied.	Mark-ups at the wholesaler and pharmacy levels for prescription drugs are regulated by decree.	
Price Negotiations	Not applied.		
Discounts / rebates	Rebates from list prices to wholesalers/ pharmacies, hospitals and sickness funds.	Rebates from list prices to pharmacies and hospitals.	Rebates from list prices to sickness funds.
Public Procurement	Not applied.		
Institution in charge of pricing	- manufacturer: free pricing - margins for wholesaler and pharmacies: limited by law		
Legal Basis	Mark-up schemes: Pharmaceutical Price Ordinance Rebates to sickness funds: SGB V		

Officially, reimbursement decisions are not linked to drug prices but connected to the medical values of the drug. In the long run, however, budget impact and therefore prices may have an impact on the reimbursement status. When drugs for the treatment of erectile dysfunction or improvement of sexual potency entered the market in mid-1998, this lead to the exclusion of lifestyle drugs from the SHI benefit package.

3.1.1 Statutory pricing

As already mentioned above, statutory pricing only applies to prescription drugs and for prescribed drugs with OTC status that are exceptionally a part of the SHI benefit package at the level of wholesaler and pharmacies. Mark-ups on ex-manufacturer prices to determine wholesaler prices and on wholesaler prices to determine pharmacy prices are regulated by the Pharmaceutical Price Ordinance (see section 3.4.2). The decree is issued by the Ministry of Health and depends on approval by the Federal Council.

3.1.2 Negotiations

Price negotiations are not applied in Germany. However, pharmaceutical companies and sickness funds may negotiate on rebates (see section 3.5.1).

3.1.3 Free pricing

Besides temporal price freezes (see section 3.5.3), free pricing is applied for all drugs at the level of the manufacturer. Additionally, it is applied for non-prescription drugs at the level of wholesalers and pharmacies since 2004.

3.1.4 Public procurement / tendering

Public procurement is not applied in Germany.

3.2 Pricing procedures

As already described in section 3.1, manufacturers are free to set ex-factory prices. No external or internal price referencing, cost-plus pricing or profit controls are applied in Germany. Although a reference pricing scheme exists, it is only used as a method of reimbursement regulation, because manufacturers are not restricted to set prices at or below the reference price (e.g. 7.1% of all packages available in 2005 were priced above their reference price) (BKK 2006). Therefore, the German reference pricing scheme will be described in section 4.3.

Table 3.2: Germany - Pricing procedures (original illustration)

Pricing procedure	In use: Yes / no	Level of pricing[1]	Scope[2]
Internal price referencing	No	-	-
External price referencing	No	-	-
Cost-plus pricing	No	-	-
Other, e. g. indirect profit control	No	-	-

3.2.1 External price referencing

External price referencing is not applied in Germany.

3.2.2 Internal price referencing

The German reference pricing scheme is not applied as a tool for price regulation, rather as method to set reimbursement limits. Therefore, it is described in section 4.3. Internal price referencing as a method to regulate pharmaceutical prices is not applied in Germany.

3.2.3 Cost-plus pricing

Cost-plus pricing is not applied in Germany.

3.2.4 (Indirect) Profit control

Profit controls are not applied in Germany.

3.3 Exceptions

3.3.1 Hospitals-only

For hospitals, prices (or rebates on the 'official' manufacturer's price) are negotiated between the hospital pharmacies and pharmaceutical companies. Usually, hospital pharmacies cooperate with each other to increase their bargaining power. According to AWO, 80% of German hospitals were organised in about 40 purchaser groups in 2005 (AWO 2005). These cooperations constitute an important instrument for lowering the cost of acquisition of pharmaceuticals. The trend to horizontal strategic alliances is also documented in a study by Vera conducted in North Rhine Westphalia, according to which 55% of the interviewed hospitals stated that horizontal alliances are of vital importance (Vera 2005).

As the prices/ rebates are negotiated between each hospital and the pharmaceutical companies, information on the amounts is strictly confidential and not publicly available. As a consequence, it is nearly impossible to make a statement on the bargained discounts. It can be assumed that the discounts depend on the size of the hospital or the hospital chain and on the type of drug. Only Schreyögg et al. 2006 pointed out the difference between the 'official' ex-manufacturer price and the bargained price in a study on the cost of inpatient treatment of cystic fibrosis. In the study the average rebate on all drugs used for the treatment of cystic fibrosis was 54.9%. Since the participating provider was the second largest cystic fibrosis facility in Germany, the average rebate for drugs used for the treatment of cystic fibrosis in Germany in total will be lower. It can be concluded, however, that the difference between the price paid by a hospital pharmacy for a pharmaceutical and the official ex-manufacturer price of the pharmaceutical can vary immensely among hospitals.

For pharmaceutical companies the distribution via hospital pharmacies increases diffusion and awareness of a drug. This is because a large number of patients can be reached via hospitals and because physicians in the outpatient sector will usually continue treatment with the same pharmaceutical after discharge. In a study by Roth-Isigkeit and Harder, 82% of 207 general practitioners interviewed stated that most discharge documents only list the brand name of the pharmaceutical product but do not list its active ingredient (Roth-Isigkeit/Harder 2005).

3.3.2 Generics

Generic prescribing has been encouraged in Germany for a long time. Pharmacists are obliged to substitute brand-preparations with cheaper generics except for those prescriptions for which the prescribing physicians explicitly rules out substitution (§ 129/1 SGB V). In addition, each sickness fund may contract with manufacturers and pharmacies and thus determine a preferred manufacturer(s) for generic substitution. This has increased bargaining power of sickness funds when negotiating rebates with generic manufacturers.

For generics, basically the same rules apply as for original products. Besides, manufacturers have to give a 10% rebate on generic preparations to sickness funds since April 2006 when the Act to Improve Efficiency in Pharmaceutical Care was enacted. In 2005, generics had

market shares of 34.6 % in sales and 57.3% in volume (Schwabe 2007). In the off-patent market, the market shares of generics are 68.3% and 74.2% respectively.

3.3.3 Over-The-Counter pharmaceuticals

Free pricing at the level of manufacturers is applied for all OTC. While for non-prescription drugs free pricing is also applied at the level of pharmacies and wholesalers, statutory pricing is applied at the level of pharmacies and wholesalers if OTCs are exceptionally reimbursable e.g. for children or for one of 46 indications defined by the Federal Joint Committee. The mark-ups in the corresponding Pharmaceutical Price Ordinance will be described more detailed in section 3.4.1 (pharmacy remuneration).

3.3.4 Parallel traded pharmaceuticals

There is no difference made between parallel imports and other pharmaceuticals for pricing. Manufacturers are free to set prices, while wholesaler and pharmacy surcharges are regulated. However, pharmacists are obliged to dispense parallel traded pharmaceuticals if their price is at least 15% or € 15 below the price of their 'German' counterpart by law (§ 129/2 SGB V).

3.3.5 Other exceptions

No exceptions from the above mentioned pricing scheme exist.

3.4 Margins and taxes

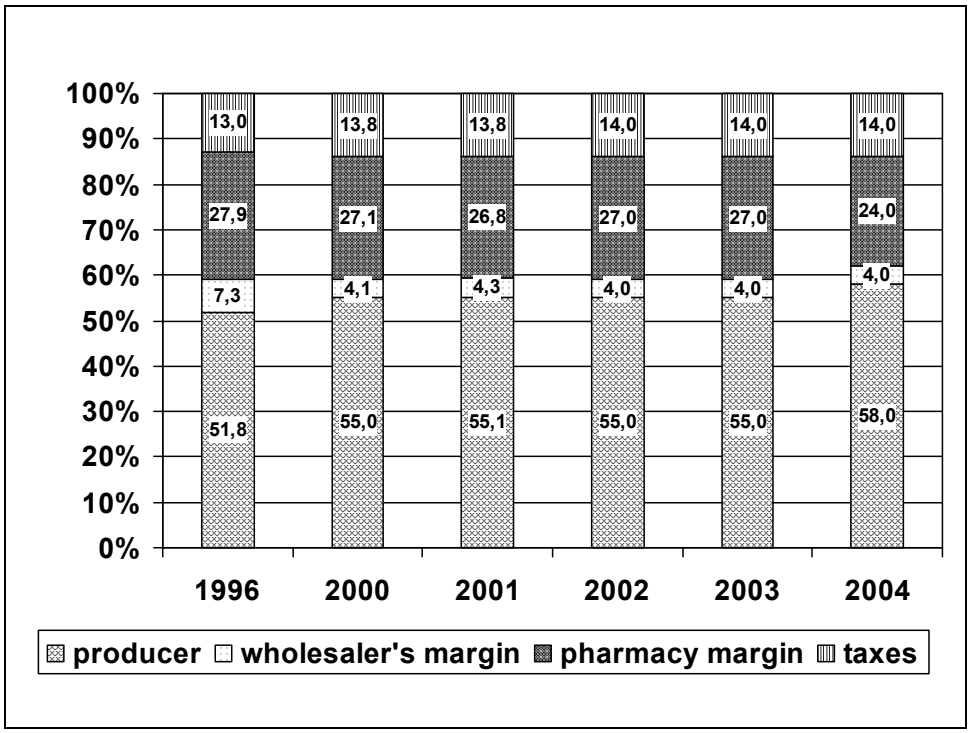
Surcharges of wholesalers and pharmacies are regulated according to the Pharmaceutical Price Ordinance. Currently, two different versions of the decree exist. The new version, which has been issued in 2004 and the old version, issued before 2004. The main difference between the two versions is the replacement of the regressive mark-ups on the wholesaler price for pharmacies in the old version by a flat fee of € 8.10 plus a fixed mark-up of 3% in the new version. Because of lower mark-ups priced for drugs below € 25, the old version has been kept valid for those non-prescription drugs that are exceptionally reimbursed under SHI, while the new version is valid for prescription drugs (see table 3.3).

Table 3.3: Germany - Regulation of wholesale and pharmacy mark-ups 2005 (original illustration)

Wholesale mark-up			Pharmacy mark-up		
Regulation (yes/no)	**Content**	**Scope***	**Regulatio (yes / no)**	**Content**	**Scope***
Yes	Regressive mark-ups	Prescription drugs and reimburs-able OTC	Yes	1) € 8.10 + 3% of price 2) Regres-sive mark-ups	1) prescription drugs 2) reimbursable OTC
No	-	OTC that are not re-imbursable	No	-	OTC that are not reimburs-able

Of a theoretical end-user price of € 100 in 2004 within the SHI market, drug manufacturers received about € 58.00, wholesalers € 4.00 and pharmacists € 24.00. Tax accounted for € 14.00 (see figure 3.1). Statistics regarding to the amount of rebates negotiated between wholesalers and pharmacies or between manufacturers and wholesalers as well as between manufacturers and hospitals are not available.

Figure 3.1: Margins and taxes 1996, 2000 - 2005



Source: VFA Statistics 2004-2006.

3.4.1 Wholesale remuneration

As can be seen in table 3.4 and 3.5, pharmaceutical wholesalers are remunerated by a regressive scheme of flat-fees and mark-ups (percentages) to be added to the ex-factory prices. While the flat-fees are only placed to avoid strategic pricing of drugs, the fixed percentages are considered the main element of the scheme. The regulations are based on the old (for reimbursable OTC) and the new version (for prescription drugs) of the Pharmaceutical Price Ordinance. Different from the pharmacy mark-up scheme (see section 3.4.2), the wholesaler mark-ups represent maximum mark-ups that can be undercut. For non-prescription drugs sold to other payers than SHI, wholesalers may freely determine prices. From the perspective of wholesalers, the average wholesaler margins accounted for 4.0% in 2004.

Table 3.4: Germany - Wholesale mark-up scheme for prescription drugs

Ex-Factory Price in €	Maximum Mark-up in % of Ex-factory price	Fixed Mark-up in €
0.00 - 3.00	15.0%	-
3.01 - 3.74	-	0.45
3.75 - 5.00	12.0%	-
5.01 - 6.66	-	0.60
6.67 - 9.00	9.0%	-
9.01 - 11.56	-	0.81
11.57 - 23.00	7.0%	-
23.01 - 26.82	-	1.61
26.83 – 1,200.00	6.0%	-
Over 1,200.00	-	72.00

Source: Regulation on the prices of medicines (AMPreisV)

Table 3.5: Germany - Wholesale mark-up scheme for reimbursable OTC

Ex-Factory Price in €	Maximum Mark-up in % of Ex-factory price	Fixed Mark-up in €
0.00 – 0.84	21.0%	
0.85 – 0.88		0.18
0.89 – 1.70	20.0%	
1.71 – 1.74		0.34
1.75 – 2.56	19.5%	
2.57 – 2.63		0.50
2.64 – 3.65	19.0%	
3.66 – 3.75		0.70
3.76 – 6.03	18.5%	
6.04 – 6.20		1.12
6.21 – 9.10	18.0%	
9.11 – 10.92		1.64
10.93 – 44.46	15.0%	-
44.47 – 55.58		6.67
55.59 – 684.76	12.0%	
Over 684.76	3.0%	+61,63

Source: Regulation on the prices of medicines (AMPreisV)

3.4.2 Pharmacy remuneration

Since 2004, pharmacists are paid a flat-fee of € 8.10 per package and a fixed mark-up of 3% on the wholesaler price (calculated with the maximum wholesaler mark-up) for prescription-only drugs. In addition, the retail price contains an additional 19% VAT (16% before January 1, 2007). The margin of 3% is calculated from the manufacturer's price plus the relevant margin for wholesalers (excluding VAT). The scheme is calculated so that the sum of margins remained the same for pharmacists when the old version of the Pharmaceutical Price Ordinance was replaced by the current version. For non-prescription drugs that are reimbursed under SHI, the old version of the Pharmaceutical Price Ordinance is still valid (see table 3.6).

For non-prescription drugs sold to other payers than SHI, pharmacies may freely determine prices. Two years after deregulation, a study conducted in 256 pharmacies showed that only 7.5% of the prices of five selected drugs diverted from the price recommendation of the manufacturers (Stargardt/Schreyögg/Busse 2007).

Table 3.6: Germany - Pharmacy mark-up scheme for reimbursable OTC pharmaceuticals

Ex-Factory Price in €	Maximum Mark-up in % of Ex-factory price	Fixed Mark-up in €
0.00 – 1.22	68.0%	
1.23 – 1.34		0.83
1.35 – 3.88	62.0%	
3.89 – 4.22		2.41
4.23 – 7.30	57.0%	
7.31 – 8.67		4.16
8.68 – 12.14	48.0%	
12.15 – 13.55		5.83
13.56 – 19.42	43.0%	
19.43 – 22.57		8.35
22.58 – 29.14	37.0%	
29.15 – 35.94		10.78
35.95 – 543.91	30.0%	
Over 543.91	8.3%	+118.24

Source: Regulation on the prices of medicines (AMPreisV)

The average pharmacy margin in terms of gross pharmacy retail prices was 24.0% in 2004. The average turnover (exclusive VAT) per pharmacy amounted to € 1.63 million in 2005. Prescription-only drugs accounted for 72.9% (or € 25.5 billion) of the total turnover of pharmacies of € 35.0 billion in 2005 (Federation of Pharmacists' Organizations 2007).

3.4.3 Remuneration of other dispensaries

Other dispensaries, e.g. drugstores are prohibited from selling prescription drugs. Therefore free pricing is applied.

3.4.4 Value-added tax

The retail price for pharmaceuticals contains an additional 19.0% of VAT, which is the standard VAT since January 1, 2007 (16% before 2007). This VAT rate applies to all products no matter whether these are reimbursable or non-reimbursable. With regard to VAT on prescription-only drugs Germany ranks fourth within the EU member states (Federation of Pharmacists' Organizations 2007). According to the Federal Association of German Pharmacies, the increase in VAT accounted for an increase pf 2.7 % in SHI expenditures on pharmaceuticals within the first four months of 2007.

3.4.5 Other taxes

There are no special taxes for pharmaceuticals in addition to the above mentioned VAT of 19.0%.

3.5 Pricing related cost-containment measures

This section contains a description of the price control mechanisms currently used in Germany.

3.5.1 Discounts / Rebates

Rebates are an instrument frequently used in Germany for cost containment. Basically, there are four different types of rebates: 1) rebates of pharmaceutical providers (manufacturer, wholesaler, pharmacies) granted to all sickness funds, so-called 'forced' rebates or 'collective' rebates, 2) rebates negotiated between individual sickness funds and a single or a group of pharmaceutical providers, 3) rebates negotiated between pharmaceutical providers and hospitals and 4) rebates granted by one pharmaceutical provider to another pharmaceutical provider (e.g. from the wholesaler to a pharmacy or a manufacturer to a pharmacy).

The group of 'forced' rebates is made up of

- the rebate of the manufacturer for drugs which are not subject to reference pricing, currently 6% (in 2004: 16%) (§ 130/1 SGB V),
- the rebate of pharmacies' to SHI for prescription drugs, currently € 2.30 per package (€ 2.00 until April 2007),
- the rebate of pharmacies' to SHI of 5% for non-prescription drugs (§ 130 SGB V),
- and the rebate of the manufacturers to SHI for generic preparations (§ 130a/3b SGB V), currently 10%.

While being forced to grant rebates by law and subject to free pricing at the same time, manufacturers may simply avert rebates by increasing prices. Therefore, discount policy targeting manufacturers is strongly connected to price freezes (see section 3.5.3). In 2005 rebates for SHI from manufacturers, wholesalers, and pharmacists amounted to € 1.7 billion or 6.2% of pharmacy turnover (VFA 2007).

Compared to the first group of rebates, the second group, rebates between pharmaceutical providers and individual sickness funds, is a comparatively new approach. Since 2004, sickness funds may negotiate various rebate agreements with manufacturers, wholesalers, and pharmacies. Although these rebates have a legal basis (§ 130 SGB V and § 130a), they are rather commercially negotiated discounts that may cover specific indications, individual drugs, or all drugs produced or supplied by a pharmaceutical provider. However, the amount of discount granted to a sickness fund is strongly connected with the sickness funds ability to influence patients' choices of drugs. The health care reforms passed in April 2007 therefore greatly enlarged sickness funds steering abilities by allowing them to share discounts with third parties (e.g. physicians or pharmacists).

The two other groups of rebates, rebates between pharmaceutical providers and hospitals and rebates between pharmaceutical providers and pharmaceutical providers are fully commercial rebates. Information on the amount of these is therefore strictly confidential and not publicly available. While rebates between pharmaceutical providers can be in cash only, rebates between pharmaceutical providers and hospitals can be discounts in kind as well. In addition rebates between pharmaceutical providers are restricted to the limited scope of the wholesaler mark-ups as the net price of a drug (off rebates) may not be below the official ex-manufacturer price.

3.5.2 Margin cuts

As described in 3.4.1 and 3.4.2 wholesaler and pharmacy remuneration was changed in 2004. While for pharmacies these changes aimed at reducing incentive to dispense high priced pharmaceuticals (moving from a regressive mark-up to combination of fee for service and mark-up), reduction in wholesaler margins aimed at internalising previously granted 'forced' rebates of wholesalers to SHI. Although this can be interpreted as a cut in margins, the composition of retail prices remained more or less the same over the last years as shown in figure 3.1 in section 3.4.

3.5.3 Price freezes / Price cuts

Temporarily, free pricing of manufacturers has been restricted by price freezes. In 1993 and 1994, between October 2002 and December 2004 (§ 130/3a SGB V) and between November 2005 and March 2008 (§ 130/2 SGB V), manufacturers are obliged to hand over a price increase of a drug compared to the prices at the beginning of the price freeze to SHI as an additional rebate. Although manufacturers may be theoretically able to raise prices, increases will affect revenue negatively, as increases in the wholesaler and pharmacists' mark-ups would have to be granted as a rebate, too. Nevertheless, price freezes are considered by law a special construct of a rebate to SHI, but no direct price regulation.

Although the only official price cut for drugs has been applied in 1993, the introduction of a rebate (see section 3.5.1) in combination with a price freeze has basically the same effect as a price cut.

3.5.4 Price reviews

As there is no direct price regulation in Germany, no price reviews are applied.

4 Reimbursement

4.1 Organisation

Unlike many other countries, Germany does not have a "positive list" of SHI-reimbursable pharmaceuticals. The Health Care Structure Act of 1993 had included a mandate for a positive list to be developed by the Federal Ministry of Health. This regulation, however, was dropped only weeks before it was supposed to be put into effect on 1st 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 criticized by both the sickness funds and the Social Democratic Party. The SHI Reform Act of 2000 again introduced the mandate for a positive list, which the Federal Ministry of Health, supported by an expert commission, consequentially submitted to the Federal Council at the end of 2002. However, the opposition – having the majority in the Council – threatened to reject the proposal. Following opposition and government negotiations for the SHI Modernization Act, the ministry's mandate for compiling a positive list was withdrawn again.

Therefore, until 2003, market entry for most drugs meant SHI coverage, but there were a few but important exceptions:

- Drugs for "trivial" diseases (common colds, drugs for the oral cavity with the exception of antifungals, laxatives and drugs for motion sickness) are legally excluded from the benefits' package for insured over 18 years (§ 34/2 SGB V).

- The Social Code Book allows the Minister of Health to exclude "inefficient" drugs, that is, those not effective for the desired purpose or combined more than three drugs, the effect of which cannot be evaluated with certainty (§§ 2, 12, 34/3 and 70 SGB V). The evaluation of these drugs takes into account the peculiarities of homeopathic, anthroposophic and phytotherapeutic drugs. A negative list according to these principles came into effect on 1st October 1991 and contained more than 2,000 drugs in 2003. The Federal Joint Committee publishes the brand names for these substances.

- The coverage of drugs is also regulated in the Directive on Pharmaceutical Care of the Federal Joint Committee, which is legally binding and limits the prescription of some drugs to certain indications (for example, anabolics to cancer patients), specify that they may only be used after failed non-pharmaceutical treatments or in a few cases, disallow any prescription on the account of sickness funds (for example, drugs to stop smoking).

Since 2004, the SHI Modernization Act has brought substantial changes to the coverage by adding two other groups of excluded drugs:

- so-called life-style drugs have been legally excluded from the benefit catalogue. The Federal Joint Committee is responsible for defining the exact extent of this regulation in its pharmaceutical directive.

- OTC drugs may no longer be reimbursed by sickness funds except for children below the age of 12. The task to define exceptions to this general exclusion has also been delegated to the Federal Joint Committee which lists OTC drugs and the indications for which they may be prescribed in its pharmaceutical directive.

The addition of the two groups also affected the two negative lists (for drugs for trivial diseases and inefficient drugs) and the work of the Federal Joint Committee. While the two negative lists still exist, they are now considerably smaller as they are only applicable for prescription-only drugs.

Another issue that has increasingly received attention is the prescription and SHI coverage of drugs for off-label use, raising concerns about access to innovations as well as pharmacovigilance and liability. Generally, drugs not licensed at all for the German pharmaceutical market or not licensed for the respective indication may not be prescribed by any physician except under clinical trial conditions. Sickness funds may not fund clinical research and may basically not cover prescriptions of unlicensed drugs or for unlicensed indications. The SHI Modernization Act took internationally a pioneering role by introducing an expert committee to clarify rules for off-label use. The committee is affiliated to the Federal Institute of Pharmaceuticals and Medical Devices and consists of nominated representatives from the Institute, from scientific medical societies, physicians' associations, manufacturers, sickness funds, SHI medical review boards, representatives of pharmacists, and patient interest groups. Based on a jurisdiction from the Federal Social Court on criteria for the access to off-label use drugs, the committee started with defining rules and conditions for the prescription and SHI-financing of oncological medications that are not yet licensed for the required indication.

4.2 Reimbursement schemes

Unlike other countries, the same reimbursement scheme is valid for all SHI insured (85% of population). This is because regulations within the SGB V and through the directives of the Federal Joint Committee are legally binding for all sickness funds. Nevertheless, there is a trend towards more differentiation between the sickness funds regarding pharmaceutical care. In combination with special rebate agreements, sickness funds are allowed to reduce or abandon co-payments for specific drugs. This is, however, not influencing the physicians' rights to prescribe drugs or limiting patient's access to drugs under SHI.

4.2.1 Eligibility criteria

A service provided under SHI has to be adequate, appropriate, and efficient. Therefore the criteria for excluding pharmaceuticals from the benefit package are mainly product specific or economic criteria. When the Federal Joint Committee amended the Directive on Pharmaceutical Care to exclude drugs for the treatment of erectile dysfunction (which was later found

not to be in accordance with current law by Social Courts and finally lead to an exclusion of lifestyle drugs directly by the legislator), it argued that varying individual behaviour does 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, thus so-called life-style drugs were not considered essential.

Setting reimbursement limits through reference pricing (see section 4.3), the Federal Joint Committee uses the criteria of 'medical and therapeutic value' e.g. by deciding if the drug is considered as an innovation or not and the criteria 'lack of alternative therapies' e.g. a group is only formed if it contains at least three pharmaceuticals. Before 2004, 'patent status' was the criteria used to decide on a drug being innovative or not. Due to the launch of me-too preparations, the criteria were modified. Now, only drugs with a therapeutic advantage e.g. a different mechanism of action or less side-effects are considered innovative.

4.2.2 Reimbursement categories and reimbursement rates

In general full reimbursement is granted for all reimbursable drugs and reimbursement is – with only few exceptions stipulated by the Directive on Pharmaceutical Care – not linked to specific patient subgroups or indications. As the reimbursement of non-prescription drugs (e.g. fully reimbursed for children below the age of 12) and co-payments are linked to age, this could be interpreted as three reimbursement categories depending on age (see table 4.1). An individual appeal procedure for patients and doctors does not exist. However, if reimbursement has been denied for a service, a patient may go to court and sue its sickness fund successfully for reimbursement if he can prove that in his case the service has been adequate, appropriate, and efficient.

To guarantee access for the poor or to people with substantial health care needs, upper limits for cost-sharing under SHI have been introduced. An SHI-insured person is eligible for exemption from user charges for benefits covered by statutory health insurance once more than 2% of the gross household income per annum has been spent on co-payments, or 1% of the gross household income for a sufferer from a serious chronic illness. According to studies of differing methodologies, the number of people fully exempt from co-payments tripled between 1993 and 2000 from 10% to about 30% of the SHI-insured population (Gericke/Wismar/Busse 2004). In 2003 about 48% of prescriptions were exempted from co-payments (Gericke/Wismar/Busse 2004). The share decreased to 29% in 2004, because the general exemption due to poverty or other reasons had been abolished, and the regulations for partial exemption had been tightened.

Table 4.1: Germany - Reimbursement of pharmaceuticals (original illustration)

Reimbursement category	Reimbursement rate	Characteristic of category
Children <12 years	100%	Prescription and non-prescription drugs
Children <18 years	100%	Prescription drugs and a few non-prescription drugs linked to specific indications.
Adults	100% except for regular co-payment (10% of drug price, minimum € 5, maximum € 10 with an annual upper limit dependant on income)	Prescription drugs and a few non-prescription drugs linked to specific indications.

4.2.3 Reimbursement lists

As already described in section 4.1 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 October, 1991. It was revised in 1993 and in 2000 and contained about 2,000 drugs in 2003. Additionally, drugs for trivial diseases which can usually be treated other than by drugs may be excluded (§ 34/2 SGB V).

The exclusion of non-prescription drugs from the benefit package in 2004 has also affected the two negative lists. While the two negative lists still exist, they are now considerably smaller as they are only applicable for prescription-only drugs. In addition, a small (positive) list issued by the Federal Joint Committee contains non-prescription drugs that are exceptionally reimbursed under SHI. Currently, the reimbursement list is part of the Directive on Pharmaceutical Care and contains 46 indications for which OTCs are still reimbursed under SHI.

4.3 Reference price system

Reimbursement of pharmaceuticals has been further regulated by reference pricing since 1989, as a means of exerting indirect price control. The reference price system establishes an upper limit for sickness fund reimbursements, based on § 35 SGB V, which stipulates that reference prices be defined for drugs with the same or similar substances or with comparable efficacy. When being implemented between 1989 and 1992 no fixed fee co-payment had to be paid on top of the price differential for the affected drugs. It is noteworthy that because of competition within the reference-price groups and the legal obligation for physicians to inform patients that they are liable for the price difference (Giuliani/Selke/Garattini 1998). Only 1,973

pharmaceuticals were priced above their reference price, representing 7.1% of the 27,908 pharmaceuticals subject to reference pricing in 2005 (BKK 2006).

Pharmaceuticals are categorised by the Federal Joint Committee if a potential group contains at least three different pharmaceuticals. Affected third parties are consulted through a hearing process. If pharmaceuticals with different active ingredients are classified, so-called reference values to adjust for the different strength of each active ingredient are calculated thereafter. Finally, the federal associations of sickness funds determine the reference price of each drug within a group.

Using a variety of criteria, pharmaceuticals are classified into three levels (types) of groups, also taking bioavailabilities into account (Schneeweiss/Schöffski/Selke 1998). At the fist level, all pharmaceuticals with the same active ingredient are grouped together, e.g. an original drug and its generic competitor. If pharmaceuticals with different active ingredients are therapeutically and pharmacologically comparable to the pharmaceuticals grouped at level 1, level 2 groups are formed. Thus, a level 2 group consist for example of the original drug and their generic copies and related me-too drugs and – if available – their generic copies. Level 3 groups are formed for drugs with several active ingredients, hence with combinations of active ingredients, if considered therapeutically comparable. In forming level 2 and 3 groups, patented pharmaceuticals are included unless they are novel and their application constitutes a therapeutic improvement. Novelty is accepted if the first active ingredient of the potential group is still protected by patent. A therapeutic improvement, e.g. reduced side-effects, however, must be proven – if possible by means of comparative studies (Stargardt/Schreyögg/Busse 2005).

After grouping pharmaceuticals the federal associations of sickness funds determine reference prices by using a mathematical formula. The formula contains the percentage of prescriptions available at or below the reference price and the percentage of drugs available at or below the reference price, an adequate choice between treatment methods is to be ensured. Generally speaking, reference prices are set in a way, where about one third of the drugs are available at or below the reference price. Reference prices are revised annually (Stargardt/Schreyögg/Busse 2005).

4.4 Private pharmaceutical expenses

Private pharmaceutical expenditure as a share of total expenditure increased from 3.8% of total expenditure in 1995 to 4.8% in 2005. While out-of-pocket payments relate to co-payments for benefits partly covered under SHI, direct payments relate to drugs not considered reimbursable. Decision making on private pharmaceutical expenditure is therefore linked with the reimbursement status of a drug (see section 4.1). Out-of-pocket payments as well as direct payments are meant to increase rational prescribing and offer a substantial source of income for sickness funds.

4.4.1 Direct payments

Basically, for all pharmaceuticals that are not reimbursed, patients are faced with direct payment. This belongs to most of the non-prescription drugs (for exceptions see section 4.2.2), lifestyle drugs and drugs priced above their reference price.

4.4.2 Out-of-pocket payments

Cost-sharing or co-payments and corresponding exemption mechanisms have a long tradition in the German health care system, most traditionally in pharmaceuticals, for which cost-sharing was introduced in 1923 and has existed ever since (Gericke/Wismar/Busse 2004). Nominal co-payments were in place from 1977 until 1989, when reference prices were introduced. Between 1989 and 1992 no co-payment had to be paid for reference-priced drugs except for the price differential between the reference price and the actual price (Busse/Riesberg 2004). Since 1993 flat-rate co-payments have to be paid again for all drugs – in addition to the differential between the actual and reference prices. In 1993, the co-payment amount was linked to the price of the drug sold – an idea re-introduced from 2004 in a modified form. From 1994 until 2003, it was linked to package size as providing an incentive to patients to ask for larger package sizes (see table 4.3). The graded scheme was meant to provide an incentive for physicians to prescribe larger package sizes with lower average costs-per-dose resulting in overall cost savings per patient treated.

Currently, co-payments are set to 10% of the drugs' price. Due to a minimum of € 5 and a maximum of € 10, insured are only price sensitive in a price range between € 0 and € 5 and between € 50 and € 100 (see table 4.2). Drugs prices 30% below their reference price are exempted from co-payments. Total cost-sharing under SHI (excluding direct payments) is limited to 2% of income or 1% of income for a chronic condition. Children below the age of 18 years are excluded from co-payments.

Table 4.2: Germany – Reimbursement rates and patient co-payment rates, 2006 (original illustration)

Price of drug	Co-payment rate in %	Reimbursement rate in %
€ 0 - € 5	100%	0%
€ 5 - € 50	Flat rate: € 5	10% - 90%
€ 50 - € 100	10%	90%
> € 100	Flat rate: € 10	> 90%

4.4.2.1 Fixed co-payments

Please see section 4.4.2.

4.4.2.2 Percentage co-payments

Please see section 4.4.2.

4.4.2.3 Deductibles

In addition to regular co-payments as described in section 4.4.2, SHI-insured may contract for a deductible in return for a reduction in contributions at their sickness fund. As this is beyond the scope of a 'standard' SHI contract and refers to patients' choice as well as to each sickness fund, this is beyond the scope of this report.

4.5 Reimbursement in the hospital sector

Reimbursement in the hospital sector varies greatly from the outpatient sector. While in the outpatient sector care by physicians and pharmaceutical care are reimbursed separately, in the inpatient sector all services are reimbursed jointly to the hospital. Before 2004, hospitals received a per diem rate under SHI. Since 2004, all hospitals are required to document their activity using DRGs and, with some exceptions (e.g. psychiatric care), are now almost entirely paid through this reimbursement mechanism. Therefore, pharmaceutical care is only a part of the basket of services delivered under a DRG. The hospital itself is responsible that all services provided are in accordance with the level of care assignment and that they are suitable and adequate for the insured.

4.6 Reimbursement related cost-containment measures

4.6.1 Major changes in reimbursement lists

Due to the exclusion of non-prescription drugs from reimbursement in 2004, the two negative lists are much smaller, because they now contain prescription drugs only. In addition, a small (positive) list for those non-prescription drugs that are exceptionally reimbursed under SHI was introduced (see section 4.2.3). Besides the existence of these lists, there have been two unsuccessful attempts to introduce a positive list of all SHI-reimbursable pharmaceuticals (see section 4.1).

4.6.2 Introduction / review of reference price system

When being introduced in Germany on 1st January 1989 reference pricing initially affected all pharmaceuticals – with or without patent protection (Giuliani/Selke/Garattini 1998). Between 1989 and 1995 pharmaceuticals were grouped and reference prices were set initially (see section 4.3). Later patented pharmaceuticals with marketing authorisation subsequent to 1st January 1996 were excluded from reference pricing. The SHI Modernisation Act revoked these exemptions on 1st January 2004. Since then, only pharmaceuticals considered an innovation are now excluded from reference pricing. Pricing procedures also changed. While at the beginning prices were set in a way that half of all pharmaceuticals within a group had to be available at or below the reference price, it is currently only one third of all pharmaceuticals within a group.

4.6.3 Introduction of new / other out-of-pocket payments

As already described in section 4.4.2, the co-payment scheme was continuously changed. While it started as a prescription fee, it later depended on the number of packages, the package size or on the price of the drug consumed. Table 4.3 gives an overview of pharmaceutical co-payments for adults since 1977. In addition, a co-payment of € 10 for the first physician visit in a quarter has been introduced in 2004.

Table 4.3: Germany - Co-payment for pharmaceuticals (adults)

Year	Co-payment		
before 1977	20% of the price, with a maximum of € 1.28 per prescription (a prescription may contain more than one drug)		
1977 – 1981	€ 0.51 per prescription		
1983	€ 0.77 per prescription		
1984 – 1989	€ 1.02 per prescription		
1989 – 1992	€ 1.53 per package, drugs subject to reference prices are excluded		
1993	€ 1.53 per package (drug price <€ 15.34)	€ 2.56 per package (€ 15.34<price<€ 25.56)	€ 3.58 per package (drug price >€ 25.56)
1994 – 1996	€ 1.53 per package (small size)	€ 2.56 per package (medium size)	€ 3.58 per package (large size)
1997	€ 2.04 per package (small size)	€ 3.07 per package (medium size)	€ 4.09 per package (large size)
1997 – 1998	€ 4.60 per package (small size)	€ 5.62 per package (medium size)	€ 6.65 per package (large size)
1999 – 2001	€ 4.09 per package (small size)	€ 4.60 per package (medium size)	€ 5.11 per package (large size)
2002 – 2003	€ 4.00 per package (small size)	€ 4.50 per package (medium size)	€ 5.00 per package (large size)
since 2004	10% of drug price, minimum € 5.00, maximum € 10.00		
Since 2006	10% of drug price, minimum € 5.00, maximum € 10.00, drugs priced 30% below their reference price are exempted from co-payments		

Source: Steffen 2006

4.6.4 Claw-backs

The Pharmaceutical Expenditure Limitation Act had obliged the members of the Association of Research-Based Pharmaceutical Companies to pay a lump sum of € 204.5 million in 2003 after the industry had effectively protested against the planned reintroduction of reference prices for certain patented drugs. Despite their payment, the scope of the reference pricing scheme was extended one year later, in 2004.

Additional claw-backs have been used in combination with drug budgets for the Regional Association of SHI Physicians as well as in combination with practice-specific drug budgets. For the description of the drug-budgets, it is referred to section 5.1.

4.6.5 Reimbursement reviews

The Federal Joint Committee classifies new pharmaceuticals according to their degree of innovation and effectiveness with comparative pharmaceuticals. If the efficacy or safety is superior to existing drugs, manufacturers will continue to be free to set the prices without regulatory interference. If they are equal to those products already on the market, the new product would be included into the reference pricing system. Since 2004, the Institute for Quality and Efficiency may assist the Federal Joint Committee by commissioning HTA on drugs. Reports are available at http://www.iqwig.de/.

New evidence might lead to an additional evaluation and a revision of the decision to include pharmaceuticals into reference pricing. Therefore, it is the Federal Joint Committee and its members (Federal Association of Sickness Funds, Federal Association of Physicians, representatives of patient's organisations) who may request reimbursement reviews. However, as most information is already available when deciding on a potential innovation, reimbursement reviews are rarely conducted.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

Drug budgets of varying strictness were a prominent measure to contain pharmaceutical expenditures from 1993 basically until 2001. Since 2002, the so called regional spending caps have been abolished and replaced by negotiated practice-specific targets of cost-control and appropriate prescriptions. The new initiative is supported by a long-overdue introduction of a uniform feed-back system for drug prescriptions, which came into operation for the use of individual ambulatory physicians only in March 2003.

The spending caps, introduced in 1993, imposed a real reduction in pharmaceutical expenditure, accounting for € 13.7 billion in 1992 (western part). Based on the 1991 expenditure of € 12.5 billion, it restricted future spending to a maximum of € 12.2 billion per year. From 1994 to 1997, each regional physicians' association (western and eastern part) was formally liable for any overspending with no upper limit, even if total pharmaceutical spending remained below the cap. At the same time the spending cap was introduced, the reform act imposed a price cut of 5% for existing drugs not covered by reference pricing and a price freeze for new drugs, applicable to 1993 and 1994.

The result of the three cost-containment measures in the Health Care Structure Act of 1993 – i.e. a price moratorium, new cost-sharing regulations and the spending caps – in their first year of operation was a reduction of 18.8% in sickness funds' costs for pharmaceuticals. This figure represented a reduction of € 2.6 billion from 1992's expenditure for the sickness funds, € 1.2 billion more than had been required. Of these savings, € 0.5 billion was attributable to price reductions. Almost another € 0.5 billion was the result of the new cost-sharing regulations. About 60% of the total reduction was attributable to changes in physicians' prescription behaviour. Physicians reduced the number of prescriptions by 11.2% and increased their prescriptions for generics instead of the original products.

Between 1994 and 1997, the spending cap levels were subject to regional negotiations between the associations of sickness funds and the 23 regional physicians' associations in both parts of Germany. Regional caps were exceeded in some of the 23 regions in 1994 even though national figures remained within the total (hypothetical) spending cap. Some of the regions also exceeded the 1995 "budget" and therefore, in September 1996, the sickness funds instigated proceedings to claim back money from nine regions which have overspent their "budget" by up to 11.3%. The regional physicians' associations resisted payment, arguing that they could not effectively manage overall or physician-specific drug expenditure, due to untimely and unspecified data. Despite the rises in pharmaceutical expenditure in 1996 – when nation-wide spending exceeded the cap, leading to agreements in several states to even out the overspending in coming years – the spending cap proved to be an effective method of short-term reduction and long-term modification of pharmaceutical expenditure (Busse/Schreyögg/Henke 2005).

With the Second SHI Restructuring Act, the regional spending caps for pharmaceuticals were abolished from 1998 and were replaced by practice-specific target volumes. Physicians exceeding 125% of the prescription target were required to compensate the respective sickness fund, unless they could prove that prescriptions were necessary from a medical point of view and prescribed at a possibly low price they could evade sanctions altogether or reduce their amount. These prescription targets for individual practices have basically been maintained since then while the context for collective responsibilities for drug expenditures was amended by subsequent reforms.

The Act to Strengthen Solidarity in SHI reintroduced spending caps for pharmaceuticals at the regional level from 1999 (see table 5.1), initially strictly capped at a legally set limit. Regional physicians' associations became liable for any over-spending up to 105% of the cap. As a kind of compensation, debts resulting from the former spending cap were waived. To protest against the reintroduction of collective liability, several physicians filed constitutional complaints. The Federal Constitutional Court declined to debate their case until the threat of collective sanctions for overspending a regional spending cap for drugs had been realized. In fact, collective sanctions have never been executed due to legal uncertainties to charge persons without individual infringement. Yet, regional spending caps for pharmaceuticals continued to be met with substantial resistance.

At the end of 2001, regional spending caps were re-abolished. Instead, the introduction of negotiated target volumes for individual practices and related data management was made obligatory. The associations of sickness funds which previously had insisted on regional spending caps became now obliged to accept the target volumes and – lately – to provide prescription feedback to SHI affiliated physicians.

As a first step toward achieving the individual target volumes, each physicians' association subtracts certain types of drugs and drugs for patients with certain indications from the yearly gross budget. Subsequently it allocates the remaining budget to different medical specialties, usually on the basis of prescription volumes of the year before. In most regions the budget of each specialty is again divided into two sub-budgets, one for the treatment of retirees and non-retirees, based on the respective prescription volumes of the previous year. These sub-budgets are finally divided by the number of cases of retirees and non-retirees, resulting in a target of how much can be prescribed on average per retired and non-retired person for each specialty. The targets for individual physicians for the current year are calculated ex-post by multiplying the total number of treated cases (retirees and non-retirees) for each physician by the target of each speciality (Busse/Schreyögg/Henke 2005).

Table 5.1: Germany - Regional spending caps and practice-specific prescribing targets

	Regional spending caps / drug budgets	Practice-specific prescribing targets / drug budget
1989 – 1992	-	practice-specific budgets stipulated by law, but not implemented due to data requirements
1993	regional budgets regulated by law	
1994 – 1997	regional budget negotiated between self-governmental partners	
1998	-	practice-specific budgets negotiated between self-governmental partners
1999	regional budgets regulated by law	
2000 – 2001	regional budget negotiated between self-governmental partners	
since 2002	-	practice-specific budgets negotiated between self-governmental partners

Source: Schreyögg/Busse 2005.

In addition to the practice-specific prescription targets, in 2007 a new regulation was enacted. For highly prescribed substances a cap on average prescription costs (costs per DDD) was introduced. Every (regional) physicians' association has own targets, which is binding for all physicians in this area. In case that a physician excesses the target by more than 10%, he has to reimburse the deficit on his own costs.

5.2 Prescription guidelines

Basically, a differentiation between binding and non-binding prescription guidelines has to be made. While non-binding guidelines are mainly issued by medical associations for the treatment of a particular disease, the only binding guideline, the Directive on Pharmaceutical Care, is issued by the Federal Joint Committee and contains mainly the general principles related to prescribing drugs and only to a very small extent restrictions for particular drugs. Nevertheless, regular efficiency controls, based on a physician's average amount of prescriptions and sickness funds' reclaims from individual physicians, are in place, e.g. due to prescribing drugs excluded from the benefit catalogue or not licensed for the respective indication (off-label use).

Although practice-specific prescribing targets (see section 5.1) set incentives to prescribe generics instead of brand name products, regulation of prescription volume is far too general as to be interpreted as a prescription guideline. However, physicians who exceed their individual target limit by more than 15% are advised in written form to critically reconsider their prescription behaviour. Above the legal limit for over-prescribing and paying-back at 125% of the individual target, the physicians are asked to justify the over-spending. In addition to practice-specific prescribing targets, so called 'soft targets' referring to the share of certain products (e.g. generics) among prescriptions, are negotiated between the regional associations of SHI physicians and sickness funds. However, failing on the soft targets is not penalised.

5.3 Information to patients / doctors

Currently, patient information on the rational use of pharmaceuticals is not being produced systematically. There is no widely recognized institution or agency which has the sole responsibility. Sickness funds and associations of patients provide information on pharmaceuticals but not on a regular basis. Besides databases implemented by DIMDI since 2004, the IQWiG is mandated to issue appropriate information for patients on treatment guidelines and recommendations for disease management programmes.

While drug budgets were implemented (see section 5.1), physicians increasingly received prescription feed-back and information from their regional physicians' association, from sickness funds and through their accredited commercial practice software. Together with the revised target volumes, an early information system was provided to physicians, containing a representative sample of pharmacies in each region so physicians' associations could forecast the prescription volumes of certain specialist groups and individual physicians. Those physicians who exceeded the target receive the information as an early warning. Since 2000, every SHI-affiliated physician has been informed about the real prescription behaviour of physicians in the region, based on a federal information system about SHI-covered prescriptions, abbreviated as GAmSI (Federal associations of the sickness funds 2007). Since 2003, they have also received a three-monthly overview of the aggregate prescription volume of their specialist group in the region and their individual prescription volume. Thus, physicians are able to adjust their future prescription behaviour according to the provided data. The prescription feed-back system GAmSI monitors the attainment of negotiated goals. It is based on indicators that have been agreed at federal level and have up to now focussed merely on cost-containment purposes rather than on quality, safety, or equity: An increase in the share of prescriptions as well as turnover from generics and parallel imports, and a decrease in the share of disputed drugs and me-too drugs.

Advertising and industry behaviour towards health professionals and the general population is regulated by the Medical Advertising Act, which is in line with the Directive 2001/83/EC. A distinction is made between prescription drugs and non-prescription drugs. While for prescription drugs advertising is only allowed among health professionals, non-prescription drugs may be advertised to the general population. However, advertising to the general population may not contain references to reports or research papers, recommendations of

physicians, references to case history, or be accompanied with contests, trial offers or vouchers. It is further restricted for infectious diseases, malignant growth, addiction diseases and pathologic complications during pregnancy, delivery, and childbed. For health professionals, donations or extraordinary benefits through advertising are restricted, e.g. giveaways are only allowed if these are of low value and must not exceed an appropriate amount. Samples are limited to two per annum. The respective activity has to be documented thoroughly to make sure that it can be displayed to the responsible authority. Budget ceiling or taxes on promotional expenditure are not imposed.

5.4 Pharmaco-economics

The first legal implementation on Health Technology Assessment took place in 2000 by the introducing the German Agency for HTA at the DIMDI. Based on this experience and subsequent to a report on the over-, under- and misuse (Advisory Council of the Concerted Action in Health Care 2001), the government promoted the introduction of the Institute of Quality and Efficiency in Health Care (IQWiG), which was established in June 2004. Its task has been to evaluate effectiveness of pharmaceuticals and thus increase transparency regarding reimbursement decisions. As part of the Act to Strengthen Competition in Statutory Health Insurance, the IQWiGs scope broadened and does include cost-utility analysis. In 2008, reports of the IQWiG will be used to ensure that prices for pharmaceuticals are appropriate to their effectiveness. However, the set of methods by which economic evaluation will be conducted are still matter of heated discussions between the stakeholders, especially from perspective of the pharmaceutical industry (Schulenburg et al. 2007).

Currently, health-economic evaluation is not conducted for obtaining market authorisation or to obtain reimbursement status. As prices are solely determined by the manufacturers and without governmental interventions (see section 3.1), results from health-economic analysis will only be included into pricing decisions if considered necessary by the manufacturer.

5.5 Generics

Regulations regarding generic substitution (see section 5.5.1) and pressure resulting from drug budgets (see section 5.1) have changed prescription behaviour of physicians and have had a significant impact on SHI expenditure. Data also reveals an increasing readiness of physicians to prescribe generics, amounting to 74.2% of all potential generic prescriptions in 2005 and a market share of 57.3% in total prescription volume (see Table 5.2), one of the highest shares among EU and OECD countries. Despite substantial improvements in appropriate and cost-efficient prescribing, efficiency reserves for generic prescribing in 2005 still amounted to € 1.3 billion (Schwabe 2007).

Table 5.2: Germany - Development of the generic market in the out-patient sector, 2000 - 2005

Generic market share	2000	2001	2002	2003	2004	2005
Volume (number of generic prescriptions per year in % of total prescriptions)	49.0	50.2	52.3	54.3	55.2	57.3
Turnover (in % of total pharmaceutical turnover)	31.9	30.0	29.9	30.4	34.3	34.6

Source: Schwabe 2007.

5.5.1 Generic substitution

Until 2002, pharmacists were only allowed to substitute drugs if explicitly indicated by physicians on the prescription. In August 2002, the German Government introduced a scheme for generic substitution, the so-called aut-idem regulation. Pharmacists were requested to substitute non-patented pharmaceuticals above a certain substitution price line by other products. Physicians were only able to avoid this measure if they explicitly marked on the prescription that they did not want the pharmacists to replace the branded product. However, due to launching of high priced dummies, the substitution line was pushed upward and therefore the aut-idem scheme from 2002 was replaced by another regulation. Since 2004, pharmacists are obliged to substitute an original branded product by a generic if either the active ingredient is prescribed or substitution is not explicitly ruled out by the prescribing physician. Since 2007, each sickness fund may additionally contract with pharmacies of a generic to be used for substitution based on special contracts he sickness funds have with manufacturer(s).

Nevertheless, there is still no incentive for pharmacies to substitute drugs, as by generic substitution the prescription value is decreased and thus the possible mark-up on the manufacturer's price reduced (see section 3.4). 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.

5.5.2 Generic prescription

Physicians are not obliged to prescribe generics. However, the dispensing of generics may be in their interests, as their prescribing is restricted by drug budgets (see section 5.1).

5.5.3 Generic promotion

Occasionally, there is generic promotion towards physicians. A research institute of the sickness funds annually publishes a report on public pharmaceutical expenditure also reporting on potential savings through generic prescribing or the use of parallel drugs. However, systematic campaigns regarding generic prescribing are not conducted.

5.6 Consumption

Because of data protection, sickness funds are not allowed to analyse administrative data on patient level. However, some sickness funds offer online feedback systems if ordered by the insured. In addition, a so-called “gatekeeper programs” that also include a pharmacies with enlisted patients, are offered to the insured. Pharmaceutical consumption of patients participating in a “gatekeeper program” will be monitored and patients will be advised on drug interactions by the pharmacy where they are enlisted. Data on patient compliance is not available.

6 Current challenges and future developments

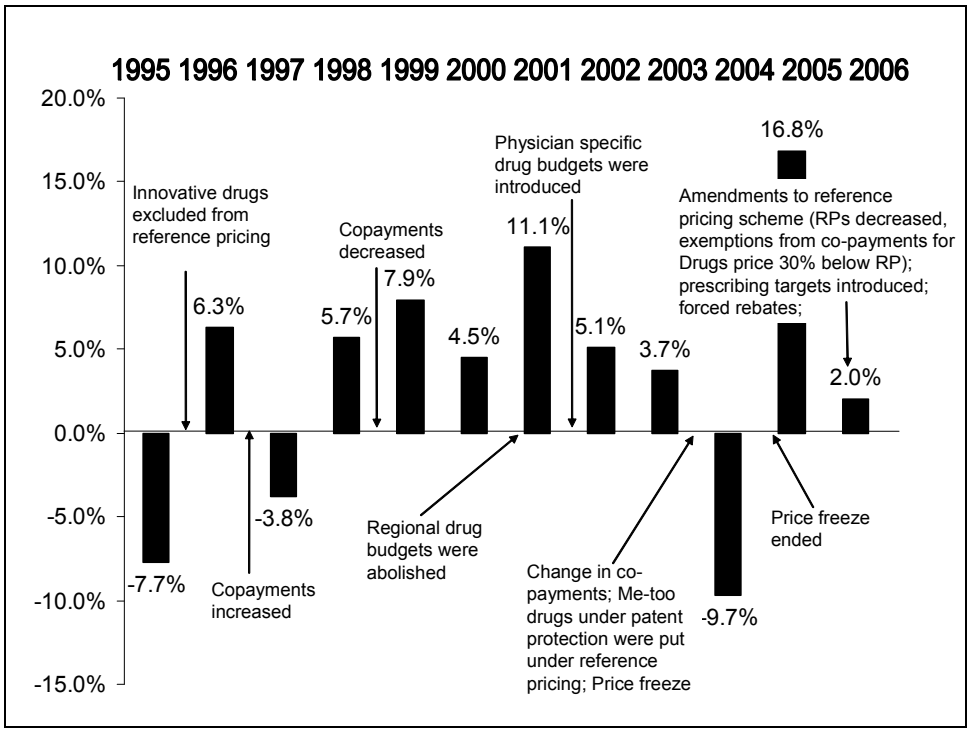
6.1 Current challenges

Controlling pharmaceutical expenditure within SHI in order to ensure equal access to pharmaceutical care is one of the main challenges for the German health care system. As the country already dedicates a large amount of GDP on health, it is not realistic to increase this share as fast as demand for health growths. If cost containment fails to meet policy objectives in the long run, the pharmaceutical benefit basket will probably have to be reduced in order to ensure a financial basis for the SHI system.

Therefore, cost containment and increasing efficiency in prescribing seem to be the most important policy goal. To influence expenditure growth, regulation was permanently changed in the last ten years. Some policies were successful, some not – some measures were sustainable while others did not last for a long time (see figure 6.1): After innovative drugs were excluded from reference pricing, SHI expenditure grew in the following year by 6.3%. An increase in co-payments lead to negative expenditure growth in 1997, while a decrease in co-payments in 1998 lead to an expenditure growth of 7.9% in 1999. After the abolishment of regional drug budgets, expenditure grew by 11.1% in 2001. The introduction of physician specific prescribing targets decreased expenditure growth to 5.1% in 2002 and 3.7% in 2003. In 2004, major changes in reimbursement regulation e.g. including me-too drugs into reference pricing, the increase of co-payments, a price freeze, and the exclusion of OTC drugs from the benefit package - led to a decline of expenditure in 2004. However, when the price freeze ended at the beginning of 2005, drug expenditure increased, again.

Nevertheless, the ‘grand coalition’ of Christian Democrats and Social Democrats which holds the parliamentary majority and formed the government since 2005, is struggling to find compromises on the instruments to reach policy goals. In addition, the period of economic growth since 2006 also increases SHI income from contributions and thus reduces financial pressure on the system. Nevertheless, in the long run, a decision on either cost containment or exclusions from the benefit package will have to be taken.

Figure 6.1: Annual growth of public pharmaceutical expenditure and changes in pharmaceutical policy (original illustration)



6.2 Future developments

Joint decision-making of all sickness funds dominated the German health care system for a long time. Nevertheless, health policy-makers are cautiously supporting selective contracts, while maintaining collective contracts as the major form of purchasing and trying to retain a system with equal access and service quality for all insured population. The existence of both, rebate agreements between individual sickness funds and pharmaceutical providers as well as reimbursement limits valid for all sickness funds through reference pricing, can be seen as one example. Possibilities for selective contracting are therefore increasing only gradually, as in the Act to Strengthen Competition in Statutory Health Insurance, enforced from 2007. The issue will remain a subject for debate.

The handling of innovations is another important question in the pharmaceutical sector, and should be an important target when implementing cost containment strategies. Some recent measures to improve quality and expenditure control are associated with less return of investment for innovations, e.g. the Act to Strengthen Competition in Statutory Health Insurance in 2007 enabled the Federal Joint Committee to set reimbursement limits for innovative drugs. From 2008, reports of the Institute for Quality and Efficiency IQWiG will be used by Federal Joint Committee to ensure that prices for innovative pharmaceuticals are appropriate to their effectiveness. Therefore, the scope of the (IQWiG) has been broadened and does now include cost-utility analysis. It will be a major question for which drug classes reimbursement limits for patented innovation will be set and how much an additional QALY – or another measure of utilities – will be valued in Germany.

7 References

Advisory Council of the Concerted Action in Health Care (2001). Jahresgutachten 2000/2001. Bedarfsgerechtigkeit und Wirtschaftlichkeit - Band I bis III: Zur Steigerung von Effizienz und Effektivität der Arzneimittelversorgung in der gesetzlichen Krankenversicherung (GKV).
Available at: http://dip.bundestag.de/parfors/parfors.htm (21.06.2007)

Almarsdóttir A, Morgall J, Grimsson A (2000). Cost containment of pharmaceutical use in Iceland: the impact of liberalization and user charges. In: *Journal of Health Services Research & Policy 5(2): 109-113.*

Anell A, Hjelmgren J. (2002). Implementing competition in the pharmacy sector: lessons from Iceland and Norway. In: *Applied Health Economics and Health Policy 1(3):149-156.*

AWO (2005). Deutschland Pharmazie. In: AWO-Branchenprofil.
Available at: http://portal.wko.at/wk/pub_detail_file.wk?AngID=1&DocID=185297
(21.06.2007)

BKK Bundesverband (2006). Arzneimittelvertragspolitik.
Available: https://www.bkk.de/bkk/powerslave,id,505,nodeid,.html

Bundesministerium für Gesundheit [Federal Ministry of Health] (2006). Vorläufige Rechnungsergebnisse der gesetzlichen Krankenversicherung (KV 45), 1.-2. Quartal 2006. Bonn, 2006.

Busse R, Riesberg A (2004). *Health Care Systems in Transition: Gremany.* Copenhagen. WHO Regional Office for Europe on behalf of the European Observatory on Health Care Systems and Policies.

Busse R, Schreyögg J, Henke K-D (2005). Pharmaceutical Regulation in Germany: improving efficiency and controlling expenditures. In: *International Journal of Health Planning and Management 20(4): 329-349.*

Clement W., Tuma M., Walter E. Wien, (2005) *The European Pharmaceutical Wholesale Industry: Structure, Trends and socio-economic Importance (http://www.ipf-ac.at/pdf/Studien/Gesamttext_Wholesale2005.pdf)*

Council of the European Communities (1989): Directive 89/105/EEC of 21 December 1988. In: *OJ No L 40: 8.*

Federal Association of the Pharmaceutical Industry (2006). Pharma-Daten.

Federal associations of the sickness funds. GKV-Arzneimittel-Schnellinformation (GAmSi). Essen, 2007. http://www.gamsi.de (15. 01. 2007).

Federal Statistical Office (2007). Gesundheit, Ausgaben 1996 – 2006. Wiesbaden: 2007.

Federal Statistical Office (2004a). Gesundheit, Ausgaben, Personal 2002. Wiesbaden: 2004.
Available at: http://www.gbe-bund.de (21.06. 2007)

Federal Statistical Office (2004b). Aktueller Stand ausgewählter Indikatoren. Wiesbaden: 2004. Available at: http://www.destatis.de (21.06. 2007)

Federal Statistical Office (2004c). Federal Health Monitoring System. Wiesbaden: 2004. available at: http://www.gbe-bund.de (21.06. 2007).

Federation of Pharmacists' Organizations [ABDA] (2007). Jahresbericht 2005/2006 der ABDA – Bundesvereinigung Deutscher Apothekerverbände, der Bundesapothekerkammer – Arbeitsgemeinschaft Deutscher Apothekerkammern und des Deutschen Apothekerverbandes e.V. sowie weiterer Institutionen der Apotheker.
Available at: http://www.abda.de/jahresbericht.html (21.06.2007)

Gericke C, Riesberg A, Busse R (2005). Ethical issues in funding orphan drug research and development. In: *Journal of Medical Ethics 31(3): 164-168*.

Gericke C, Wismar M, Busse R (2004). *Cost-sharing in the German health care system. Diskussionspapier 2004/4*, Technische Universität Berlin, Fakultät Wirtschaft und Management. Berlin.

GBE (2007): Gesundheitsberichterstattung des Bundes (Statistics), Available at www.gbe-bund.de (19. 6. 2007).

Giuliani G, Selke G, Garattini L (1998). The German experience in reference pricing. In: *Health Policy 44(1): 73-85.*

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*. K-D Henke and C Dräger (eds). Baden-Baden: Nomos, 47-57.

Hundertmark-Mayser J, Möller B (2004). Selbsthilfe im Gesundheitsbereich. Gesundheitsberichterstattung des Bundes Heft 23. Berlin, Robert-Koch-Institut.

Müllens M, Butzer R, Seibert-Grafe M, Zepp F (2007). EU-Verordnung über Kinderarzneimittel: Mehr Sicherheit. In: *Deutsches Ärzteblatt 104(5): A226/ B206/ 202.*

Nink K, Schröder H (2007). Ökonomische Aspekte des deutschen Arzneimittelmarktes 2005. In: Schwabe U, Paffrath D (eds). *Arzneiverordnungsreport 2006.* Heidelberg: Springer Medizin Verlag.

OECD (2004). Organisation of Co-operation and Economic Development. OECD Health Data 2004. Paris.

OECD (2006). Organisation of Co-operation and Economic Development. OECD Health Data 2006. Paris.

Phagro (2007). Präsentation. Vollversorger als fester Bestandteil der Handelskette.
Available at: http://www.phagro.de

Roth-Isigkeit A, Harder S (2004). Die Entlassungsmedikation im Arztbrief. Eine explorative Befragung von Hausärzten/-innen. In: *Medizinische Klinik 2005; 10(2): 87-93.*

Sauerland D (2001). The German strategy for quality improvement in health care: still to improve. In: *Heath Policy 56(2): 127-147.*

Schneeweiss S, Schöffski O, Selke G (1998). What is Germany's experience on reference based drug pricing and the etiology of adverse health outcomes or substitution? In: *Health Policy 44(3): 253-260*.

Schöffski O (1995). *Die Regulierung des deutschen Apothekenwesens. Eine ökonomische Analyse.* Bade-Baden: Nomos.

Schöffski O et al. (eds) (2002). *Pharmabetriebslehre.* Berlin, Heidelberg: Springer-Verlag.

Schreyögg J, Busse R (2005). Physician drug budgets in Germany: effects on prescription behaviour. *Journal of Pharmaceutical Finance, Economics & Policy;* 14(3): 77-95.

Schreyögg J, Hollmeyer H, Blümel M, Staab D, Busse R. (2006). Hospitalisation Costs of Cystic Fibrosis. In: *Pharmacoeconomics 24(10): 999-1009.*

Schulenburg J, Vauth C, Mittendorf T, Greiner W (2007). Methoden zur Ermittlung von Kosten-Nutzen-Relationen für Arzneimittel in Deutschland. In: *Gesundheitsökonomie & Qualitätsmanagement; 12(S1):S1-S26.*

Schwabe (2007). Arzneiverordnungen 2005 im Überblick. In: Schwabe U, Paffrath D (eds). *Arzneiverordnungsreport 2006.* Heidelberg: Springer Medizin Verlag.

Stargardt T, Schreyögg J, Busse R (2005). Arzneimittelfestbeträge: Gruppenbildung, Preisberechnung mittels Regressionsverfahren und Wirkungen. In*: Das Gesundheitswesen, 67(7):469-478*.

Stargardt T, Schreyögg J, Busse R (2007). Pricing Behaviour of Pharmacies after Market Deregulation for OTC Drugs: The Case of Germany. Accepted in: *Health Policy*.

Steffen J (2006). Sozialpolitische Chronik. Die wesentlichen Änderungen in der Arbeitslosen-, Renten-, Kranken-, und Pflegeversicherung sowie bei der Sozialhilfe (HLU) und der Grundsicherung für arbeitssuchende – von den siebziger Jahren bis heute.
Available at: http://www.arbeitnehmerkammer.de/sozialpolitik/ (21.06.2007)

Vera A (2005). Strategische Allianzen im deutschen Krankenhauswesen – Ein empirischer Vergleich von horizontalen und vertikalen Operationen. In: *Zeitschrift für Betriebswirtschaft, 76(9): 835-865.*

VFA (2003). German Association of Research-Based Pharmaceutical Companies. Statistics 2003. Berlin: VFA.

VFA (2004). German Association of Research-Based Pharmaceutical Companies. Statistics 2004. Berlin: VFA.

VFA (2005). German Association of Research-Based Pharmaceutical Companies. Statistics 2005. Berlin: VFA.

VFA (2006). German Association of Research-Based Pharmaceutical Companies. Statistics 2006. Berlin: VFA.

WHO (2007). European Health for All Database. World Health Organization Regional Office for Europe. Last Update: January 2007.