Statistics

2008

The Pharmaceutical Industry in Germany

Verband Forschender
Arzneimittelhersteller e.V.
German Association
of Research-Based
Pharmaceutical Companies

The German Association of Research-Based Pharmaceutical Companies (VFA) is the trade association of the research-based pharmaceutical companies and their more than 100 subsidiaries and affiliate companies in Germany. With its annotated data collection "Statistics", the association represents and explains the development of the pharmaceutical industry in Germany.

The Pharmaceutical Industry in Germany

Verband Forschender
Arzneimittelhersteller e.V.
German Association
of Research-Based
Pharmaceutical Companies

Verband Forschender
Arzneimittelhersteller e.V.
German Association
of Research-Based
Pharmaceutical Companies

At a Glance

Facts and Figures 2007 [1)]

1. Pharmaceutical Industry

Sales	Total	31.15	EUR billion
	Includes foreign sales worth	17.59	EUR billion
	Export ratio	56	percent
Capital spending	Research-based pharma. comp. (VFA)	1.49	EUR billion
Employees	Pharmaceutical industry in total	112,550	
	Research-based pharma. comp. (VFA)	90,100	
Price trends	SHI pharmaceuticals	- 9	percent
2000 to 2007	Private consumption (total)	+ 13	percent
Price structure	Manufacturers' share in retail prices (incl. VAT)	57	percent

2. Research and Development (R&D)

New molecular entities	launched in 2007	31	substances
R&D spending	Research-based pharma. comp. (VFA)	4.52	EUR billion
R&D employees	Research-based pharma. comp. (VFA)	17,000	
Research and development	Average cost	800	USD million
of a new medicine	Average R&D period	12	years
Genetically manufactured	Share of Germany in registered		
substances	patents	9	percent

3. Pharmaceuticals in the Health Care System

Pharmaceutical	Share in gross domestic product 2007	1.8	percent
expenditures	Share in health care spending 2007	16.4	percent
	Share in health care spending 1992	15.9	percent
SHI	Total expenditures	153.6	EUR billion
	includes pharma. expenditures worth	27.8	EUR billion
	in percent of total expenditures	18.1	percent
SHI pharmaceutical prices	Change over previous year	-1.3	percent

[1)] All data for 2007 unless otherwise specified.

4. German Pharmaceutical Market

Number of pharmaceuticals	90% of all prescriptions are issued for	1,850	pharmaceuticals
Pharmacy market	Sales at retail prices	39.2	EUR billion
	SHI prescriptions	30.1	EUR billion
	Self-medication	4.3	EUR billion
	Private prescriptions	4.9	EUR billion
Innovative pharmaceuticals	Sales share of new molecular entities over the past 5 years	5.2	percent
Generics	Sales share in the generics-eligible SHI market	74.4	percent
Reference prices	Share of prescriptions in the SHI market	72.5	percent
Parallel imports	Sales share in the pharmacy market	8.9	percent

5. The International Pharmaceutical Market

Worldwide sales	Total	712	USD billion
	Germany's share in 2007 (constant exchange rate)	3.5	percent
	Germany's share in 1998	5.2	percent
Per-capita sales in 2007	Germany	352	USD
In comparison:	USA	672	USD
	Japan	727	USD
	France	427	USD
	United Kingdom	250	USD

The German Association of Research-Based Pharmaceutical Companies (VFA) is the trade association of the research-based pharmaceutical companies in Germany. It represents the interests of 46 globally leading research-based pharmaceutical companies and more than 100 subsidiaries and affiliated companies in the areas of health, research and economic policy.
The VFA member companies make up more than two-thirds of the German pharmaceutical market and employ approx. 90,000 people in Germany. They ensure therapeutic progress in the field of pharmaceuticals and safeguard pharmaceutical therapy at a high level.
About 17,000 employees are engaged in the research and development of pharmaceuticals in Germany. Every year, the research-based pharmaceutical companies invest about EUR 4.52 billion in pharmaceutical research for new and improved medication in Germany alone.

German Association of Research-Based Pharmaceutical Companies
Hausvogteiplatz 13 10117 Berlin Phone +49 30. 20604-0 Fax +49 30. 20604-222 www.vfa.de

Contents

The Pharmaceutical Industry in Germany 2007

The year 2007 was both a bright and a dark one for the pharmaceutical industry in Germany: On the one hand, there are successful innovations for patients, which represent either new or first-time drug treatment options for severe or most serious diseases. The increased research and development investments of the VFA companies in Germany have also made a contribution in this respect: The companies expended more than EUR 4.5 billion – that is more than EUR 12 million per day – in 2007. The number of employees in the R&D sector has continued to increase as a result: 17,000 workers, i.e. more than one out of five employees, are concerned with the research and development of new treatment options. And the "pipeline" of the companies is well-filled: More than 350 projects are promising success by the year 2011, which means their prospects for marketing authorization are good. Additional success is expected primarily in the fight against cancer and cardiovascular diseases. The production of pharmaceuticals in Germany has also continued to grow – by more than 10 percent in 2007. Exports play an increasingly important role, while the domestic market is losing its significance: While less than one-third of the pharmaceuticals produced in Germany went abroad in 1995, this figure is at 56.5 percent today. In the global competition, the German pharmaceutical industry seems well prepared as one of the most important industries of the future.

However, the other side of the coin is revealed by the other data presented to you in "Statistics." Most serious is the fact that few innovative pharmaceuticals reach patients, and when they do, they are delayed. Only 5.2 percent of pharmaceutical sales are made with products that are younger than five years. In this respect, Germany almost ranks last in Europe. In Scandinavian countries as well as in Belgium, France and Italy, the share of spending for modern pharmaceuticals is twice or three times as high. Germany is at risk to lose its status as the leading market in Europe, if it continues to obstruct innovations based on government overregulation.

For decades, politicians have been attempting to keep SHI expenditures in check with ever-increasing cost containment measures, when it is the political sector (apart from the demographic development) that is the greatest driver of expenses. Even though prices for pharmaceuticals in statutory health insurance have significantly decreased over the past few years, expenditures have clearly increased. The main driver of prices during the past year was the value-added tax increase. In a European comparison, the German price level for pharmaceuticals is in the medium range.

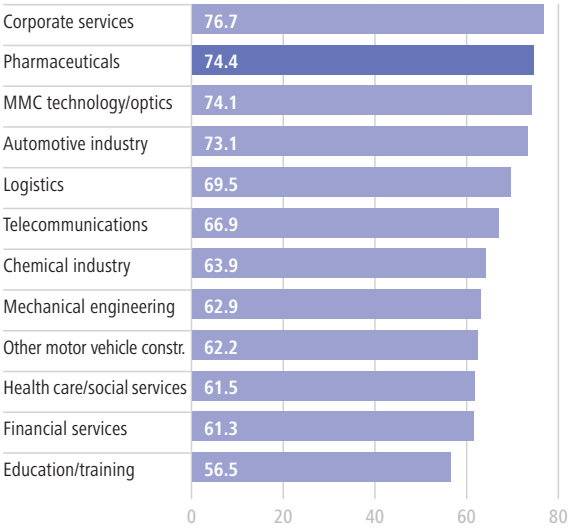
However, to what extent the research-based pharmaceutical companies located in Germany will be able to benefit from the globally increasing demand for pharmaceuticals in the future health care market will continue to depend on government intervention. The innovative power of the pharmaceutical industry remains unbroken.

The Pharmaceutical Industry and the Economy

With a net added value of almost EUR 100,000 per employee, the pharmaceutical industry is among one of the most efficient industries in Germany. At the same time, it is considered the industry with the best future prospects. Exports play a greater and greater role in this respect: In 2007, the share of exports rose again to reach 56.5 percent. Production in Germany was increased once more by more than 10 percent. However, in an international comparison, Germany has fallen behind some more: While about nine percent of the global production of pharmaceuticals still came from Germany in 1990, this number has decreased to currently seven percent. And while the overall number of employees in the VFA member companies shrunk last year, a new high was reached for employees in research and development: The research-based pharmaceutical companies continue to bank on innovation!

The Future-oriented Pharmaceutical Industry

Index (possible points achieved in percent)

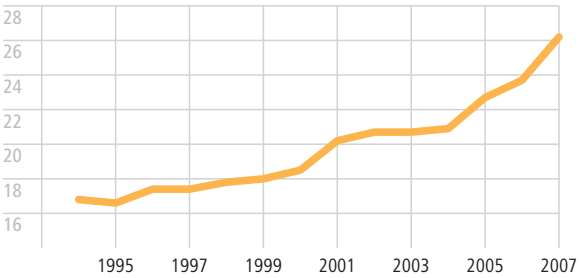


Source: IW Consult

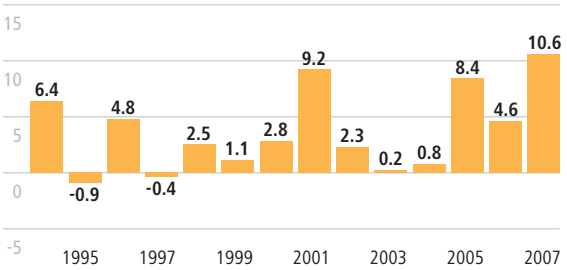
Apart from the industries of "Corporate services" and "Medical, measuring and control technology", the pharmaceutical industry has the best future prospects out of 34 analyzed German industries. It strongly benefits from expected technological and societal changes and has one of the best growth and development prospects.
In this respect, the above-average R&D orientation of the industry also has a positive effect. The employment development also shows that the pharmaceutical industry is already benefiting from this change: Contrary to the trend, the number of jobs even increased by 14.4 percent in Germany from 2000 to 2005. Particularly negative, however, is the regulatory framework, which obstructs the pharmaceutical industry above average.

Production of Pharmaceutical Products in Germany

in EUR billion



Change over previous year in percent



2007: provisional data

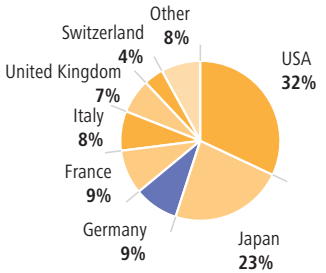
Source: Federal Statistical Office, VFA

For detailed data, see Appendix, page 56

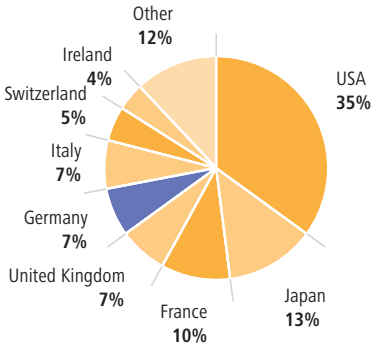
In 2007, Germany produced pharmaceuticals worth EUR 26.2 billion, a 10.6 percent increase over the previous year. Contrary to many other products, the production of pharmaceuticals is impacted less by the economic situation than by government intervention to regulate the health care sector. Regulations regarding pricing and prescription restrictions limit predominantly domestic demand. Particularly drastic legislation has therefore resulted in small or even negative growth rates in production, which was last observed in 2003 and 2004. The share of pharmaceutical production in overall industrial production has been stagnating at two percent for years.

Production in Europe, Japan and the USA

1990: EUR 136 billion



2006: EUR 351 billion



Japan: 2005, USA: 2003

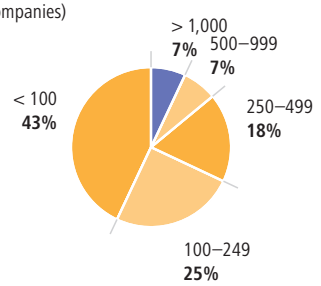
Source: OECD, EFPIA, Pharmaceutical associations of the European countries, VFA

In an international comparison, Germany has been unable to maintain its position as a production location for pharmaceutical products. Seven percent of the overall pharmaceutical production from Europe, Japan and the USA, which was worth EUR 351 billion in 2006, came from Germany. In 1990, this share was still at nine percent. On the other hand, pharmaceutical production strongly increased in countries such as the United Kingdom, Sweden or Denmark, which have continuously promoted their R&D activities for many years. In addition, especially Ireland has evolved as a key production location for pharmaceuticals during the past few years.

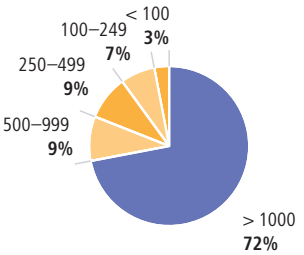
Companies and Output Value based on Corporate Size

Classification of the companies according to number of employees in 2005

Companies (268 companies)



Output value (EUR 23.3 billion)



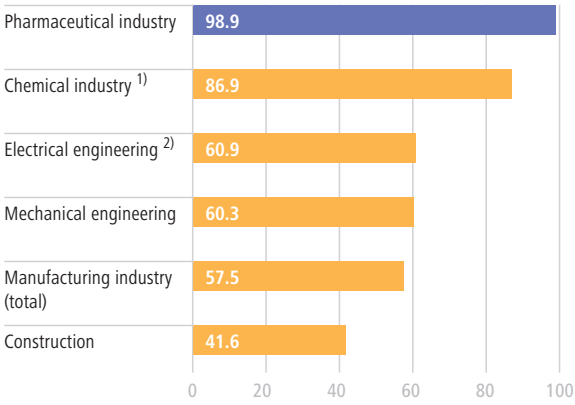
Companies with 20+ employees

Source: Federal Statistical Office

With small, medium-sized and large companies, the pharmaceutical industry in Germany has a mixed structure. Companies with more than 1,000 employees represent seven percent of all companies but are responsible for the largest part of the overall output with 72 percent.

Added Value

Net added value per employee in 2005 in EUR 1,000



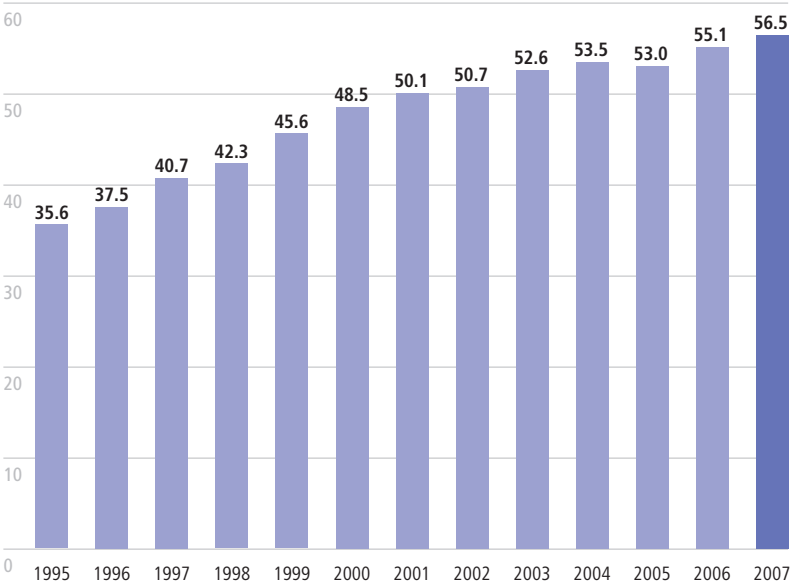
1) incl. pharmaceutical industry
2) Office machinery, computing devices, electrical engineering

Source: Federal Statistical Office

With a net added value of almost EUR 100,000 per employee in 2005, the pharmaceutical industry is among the best performing and most productive industries in Germany.

Export Ratio of the Pharmaceutical Companies in Germany

Foreign sales in percent of total sales



Due to continued regimentation, the domestic pharmaceutical market is becoming less and less significant for the pharmaceutical companies in Germany. In contrast, the export ratio has increased from about 36 percent in 1995 to about 57 percent in 2007.

In the international comparison, Germany has nonetheless lost its significance as a production location for pharmaceutical products: While Germany was still the third-largest producer of pharmaceuticals (after the United States and Japan) at the start of the 1990s, it now ranks fifth (after the United States, Japan, France and the United Kingdom).

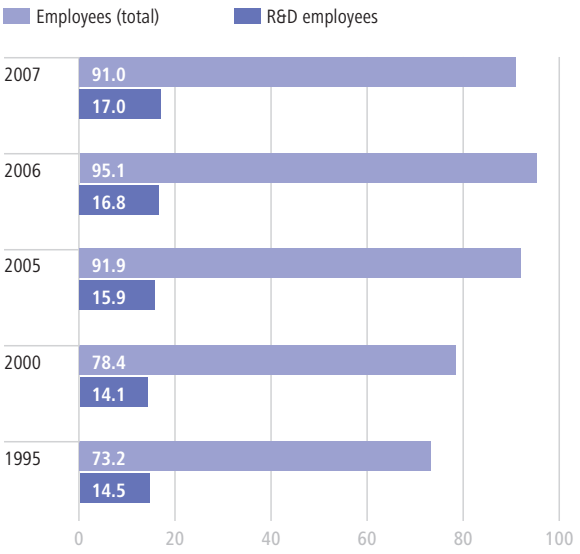
2007: provisional data

Source: Federal Statistical Office

For detailed data, see Appendix, page 56

Employees of the VFA Member Companies

Number in thousands



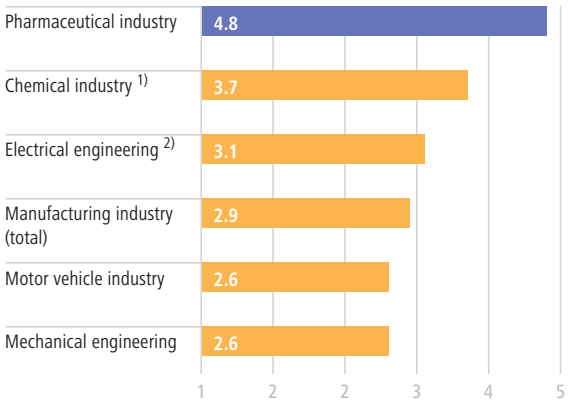
2007: provisional data

Source: VFA

In 2007, the number of employees in the VFA member companies decreased by 4,000 to more than 91,000, which corresponds to a 4.4 percent reduction compared to the previous year. In contrast, the number of employees in research and development increased (by 1.4 percent to 17,000). This shows Germany's high potential as a research location. Especially the research-based pharmaceutical companies depend on qualified workers that they find in Germany.

Capital Spending

in percent of sales



As of: 2006

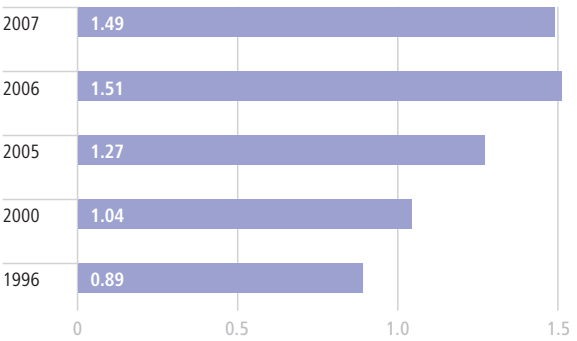
1) incl. pharmaceutical industry
2) Office machinery, computing devices, electrical engineering

Source: Federal Statistical Office

With a capital spending share of 4.8 percent of sales, the pharmaceutical industry is among the industries in Germany with above-average capital spending. This triggers considerable additional production and employment in the other industries, as was shown in a study by the German Institute for Economic Research. These indirect production and investment effects increase the industry's added value roughly by another 90 percent. Especially business sectors that provide great added value and employment volume are pulled along by the pharmaceutical industry, e.g. research and development services. Each job in one of our companies creates another job in other industries.

Capital Spending of the VFA Member Companies

in EUR billion



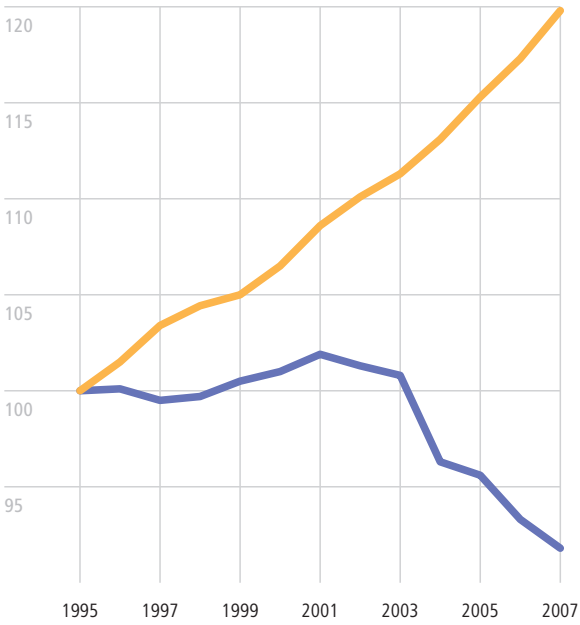
2007: provisional data

Source: VFA

In 2007, the research-based pharmaceutical companies in Germany have maintained their high capital spending level. At EUR 1.49 billion, the 2007 volume was only slightly below the previous-year level (-1.4 percent) and, despite the decrease, still significantly higher than during prior years. As a result, the guarded behavior from the first half of the decade has not continued, and the industry has greater trust again in Germany as an industrial location.

Price Trends

1995 = 100



Private consumption (total)

SHI pharmaceuticals

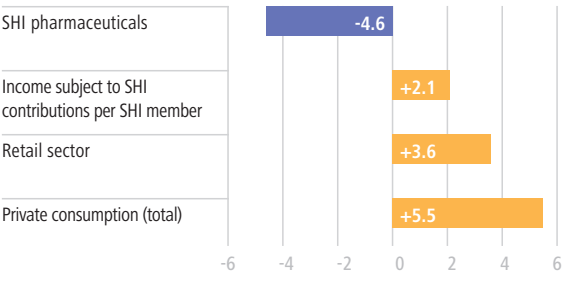
Source: Federal Statistical Office, WIdO

For detailed data, see Appendix, page 57

Up until 2003, prices for pharmaceuticals barely changed. Over the past four years, they have significantly decreased. Today, pharmaceuticals are about eight percent cheaper than they were 12 years ago. In contrast, prices for all consumer goods and services have increased by almost 20 percent since 1995.

Price Changes: A Comparison

Price increase from 2004 to 2007 in percent

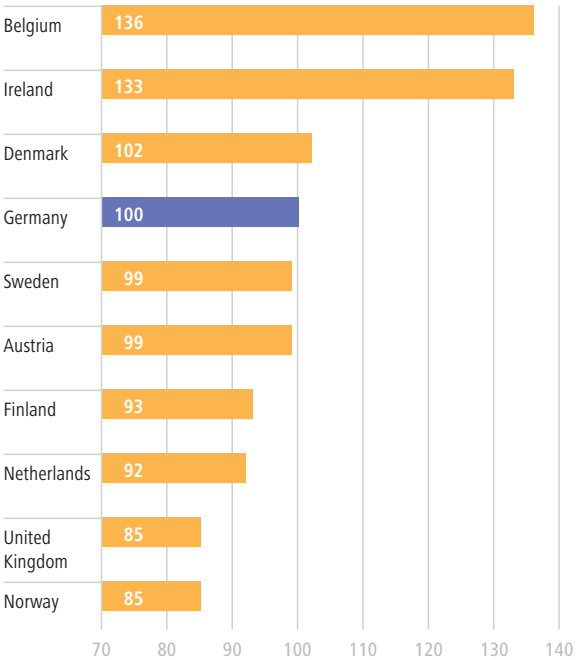


Source: Federal Statistical Office, German Federal Ministry of Health, WIdO

The prices of pharmaceuticals that were provided to patients insured through statutory health insurance decreased by 4.6 percent over the past three years. In contrast, retail prices increased by 3.6 percent and prices for private consumption were up 5.5 percent. The income of SHI members that is subject to contributions increased by 2.1 percent.

Pharmaceutical Prices: A European Comparison

Germany = 100



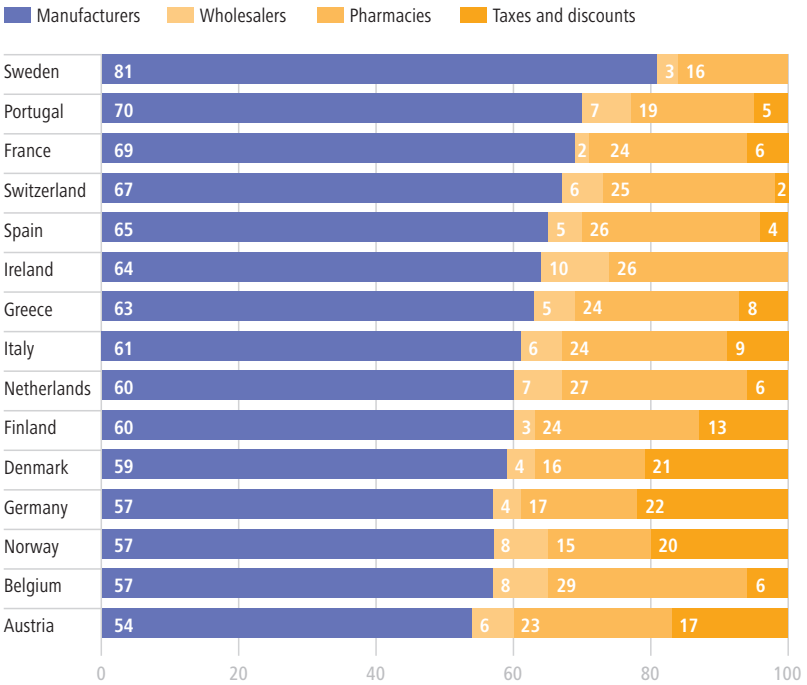
Source: SNF-rapport 05/08 (Bergen May 2008)

Pharmaceuticals in Germany are not more expensive than in many other industrialized nations. This was confirmed by the latest study of a research institute, commissioned by the Norwegian ministry of health. The survey examined the drug prices of 200 of the most frequently sold molecular entities in 10 European countries. The results show Germany in the medium range of the compared countries, on a par with Denmark, Sweden and Austria.

Since the period of investigation (first half of 2007), pharmaceutical prices in Germany have again decreased by more than two percent.

Price Structure in Europe

Shares in percent



With a manufacturer's share of 57 percent of the retail price, Germany is located in the bottom segment of the European ranking. Pharmaceuticals are subject to the full value-added tax rate in Germany. In most other European countries, the tax burden for pharmaceuticals is either reduced or waived completely.

As of: 2006

S, F, NL, D, I, A: only prescribed or reimbursed pharmaceuticals

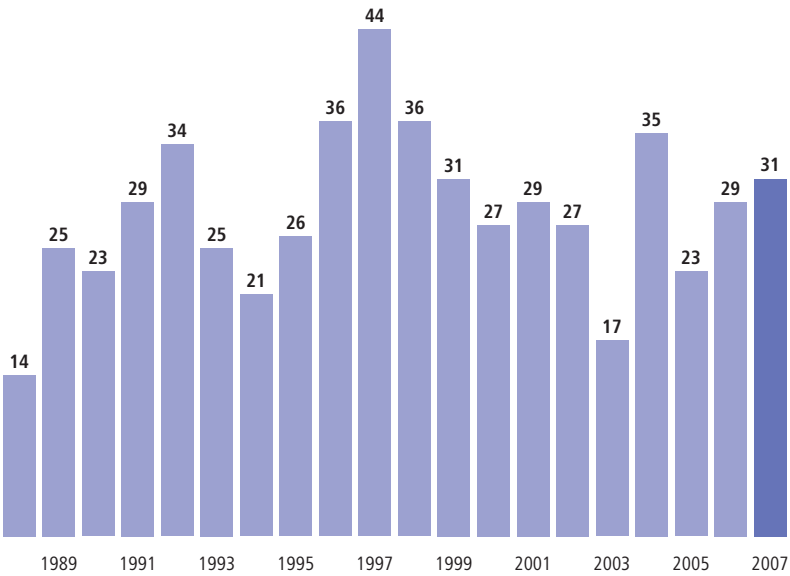
Source: EFPIA, Pharmaceutical associations of the European countries, VFA

The Pharmaceutical Industry and Innovation

At EUR 4.52 billion, research and development expenditures have reached a new high. As a result, the research-based pharmaceutical companies invest more than EUR 12 million each day in the development of innovative drugs. The result is impressive: Last year, 31 new molecular entities were submitted for marketing authorization in Germany. The focus was on serious and chronic diseases: Diabetes patients can now lower their blood sugar levels more safely, AIDS viruses can be controlled more effectively, and this is the first time that pharmaceutical therapies become available for a series of rare diseases. Various types of cancer can now also be treated more effectively. And the industry has more ambitious research projects for the next few years. More than 350 projects currently in the development phase have prospects of being submitted for marketing authorization by the end of 2011.

New Molecular Entities in Germany

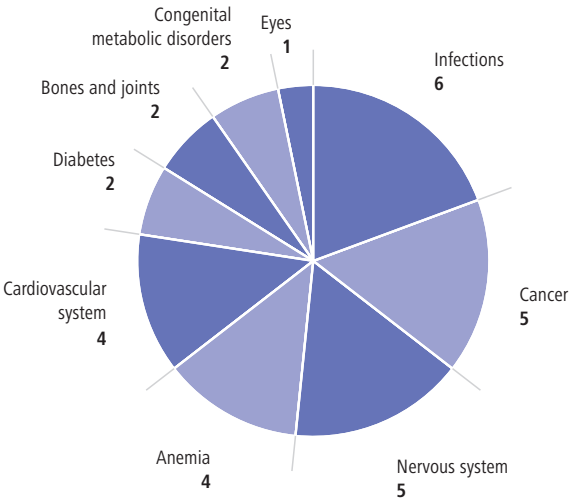
Number



Source: Pharmazeutische Zeitung, VFA

In 2007, 31 pharmaceuticals based on NMEs (new molecular entities) were launched in the German market. Based on the global research process, the number of substances launched in Germany is closely connected to the international development of pharmaceuticals. Unless their importance is merely local, most new molecular entities receive marketing authorization in all key markets in a timely manner. This is the only way to balance the costs for the research and development of an NME, which globally amount to USD 800 million on average, within its limited patent term.

New Molecular Entities and their Applications 2007

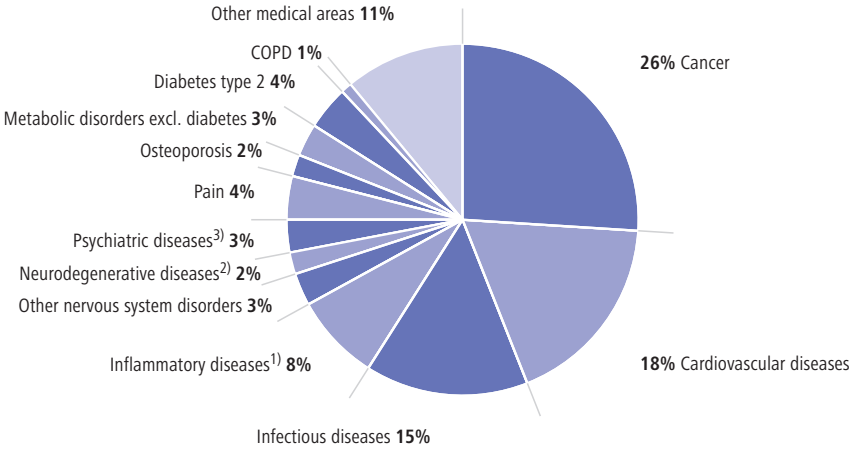


Source: VFA

In 2007, research-based pharmaceutical companies facilitated great advances in medicine again based on new or novel pharmaceuticals. Diabetes patients can now use drugs to lower their blood sugar levels without the risk of hyperglycemia. Various types of cancer can now be treated more effectively. There is a novel way for containing AIDS viruses. A new class of antibiotics has become available for skin infections. For the first time, there are also pharmaceuticals for Hunter syndrome, Huntington's chorea and paroxysmal nocturnal hemoglobinuria, three rare genetic diseases that cause organ damage or blood clots, among others. Furthermore, children will benefit e.g. from new drugs for epilepsy and leukemia. Overall, research-based pharmaceutical companies launched 31 pharmaceuticals with new molecular entities this year, eight of them orphan drugs.

Pharmaceutical Projects of the VFA Member Companies Promising Success by 2011

Distribution to various medical areas, overall number of projects: 358



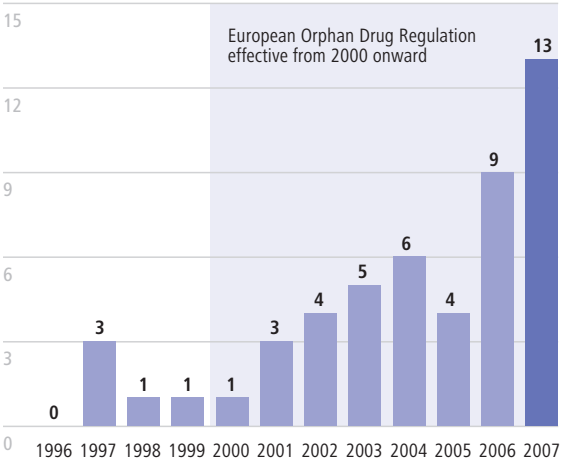
Source: VFA

1) Rheumatoid arthritis, asthma, multiple sclerosis, Crohn's disease, etc.
2) Alzheimer's disease, Parkinson's disease
3) Depression, schizophrenia, etc.
4) Each individual one accounts for 1% or less

The VFA member companies are working on thousands of drugs. Pharmaceutical projects for some 110 diseases have progressed so far that they may lead to marketing authorization by the end of 2011. Most of these projects will target cancer (26 percent), cardiovascular diseases (18 percent) and infectious diseases (15 percent). But a particularly large number of drugs are also being developed for inflammatory diseases such as rheumatoid arthritis and for type-2 diabetes (the so-called adult onset diabetes). A total of 93 percent of the projects are concerned with severe diseases, some of them even life-threatening; only seven percent address less severe health disorders such as the common cold or incontinence.

Marketing Authorizations for Orphan Drugs in the European Union

Number



Source: VFA

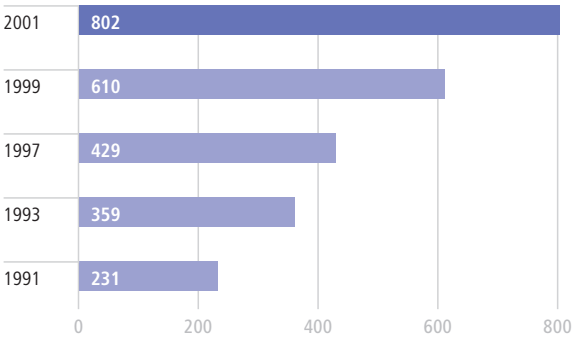
Since the start of 2000, companies have had the opportunity to apply for "orphan drug status" for a pharmaceutical being developed in Europe, if said drug is for a disease that affects no more than 2,000 EU citizens. This status is associated with lower marketing authorization fees, free scientific consulting and exclusive marketing rights for a maximum of 10 years.

The regulation is effective: While only one orphan drug on average was approved per year prior to the regulation, this number has increased to about 11 (median value for the years 2005 to 2007). A total of 46 orphan drugs received marketing authorization in the EU since 2000. About 500 more are being developed (as of July 2008).

As a result, the Orphan Drug Regulation is a good example of how meaningful political regulatory activity can increase pharmaceutical research in areas desired by society.

Development Costs for a new Pharmaceutical

in USD million



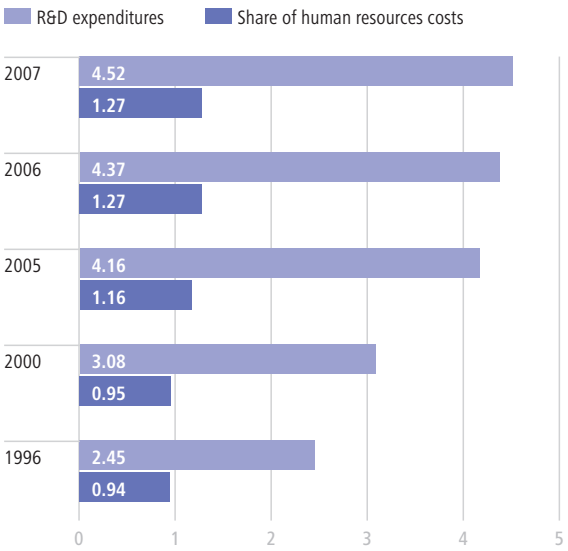
Source: Di Masi J. et al., Tufts University (1991); Office of Technology Assessment (1993); Myers and Howe (1997); Office of Health Economics & Lehman Brothers (1999); Tufts University (2001)

In 2001, an average of USD 800 million was required for the research and development of a new drug with a new molecular entity.

More than half of these expenditures are spent on clinical development, especially the logistically expensive, multinational phase III studies. The requirements with regard to proven safety, efficacy, tolerability and quality during the marketing authorization process have increased steadily. Another reason for the strong cost increase is the growing complexity of the diseases to be treated. Examples include multiple sclerosis or Parkinson's disease for which researchers must take into account many physical processes to identify possibilities for risk-free pharmaceutical therapy.

R&D Expenditures of the VFA Member Companies

in EUR billion

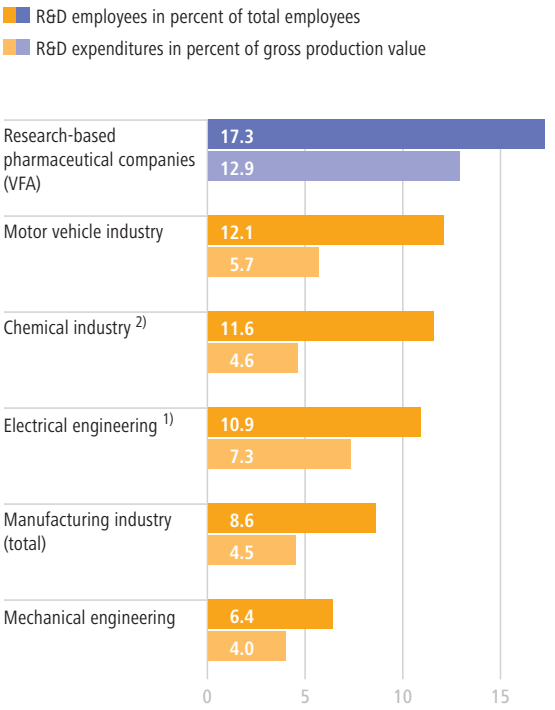


2007: provisional data

Source: VFA

In the VFA member companies, research and development expenditures in Germany have increased by 3.5 percent to EUR 4.52 billion in 2007. This roughly corresponds to the growth trend of the past few years.
Pharmaceutical research is oriented on long-term objectives. Since a new pharmaceutical only reaches the market after about 10 to 12 years, the current increase in R&D spending is based on corporate decisions that were made a long time ago. As a result, the constant political intervention in this field only shows its effect with a considerable delay; in the medium term, an adjustment to the increasingly difficult framework in Germany cannot be ruled out.

R&D Intensity



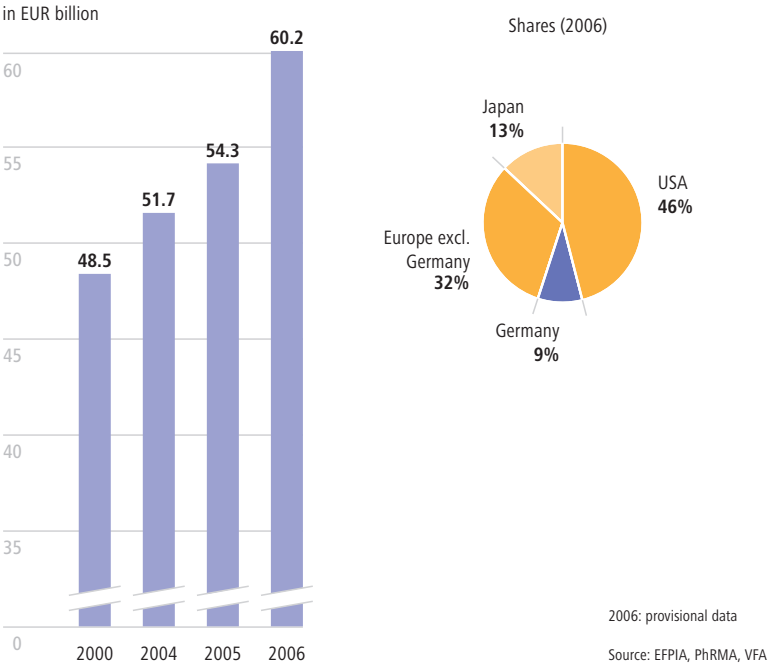
As of: 2005

1) Office machinery, computing devices, electrical engineering
2) incl. pharmaceutical industry

Source: Stifterverband Wissenschaftsstatistik, VFA

The research and development of new pharmaceutical substances is highly cost- and labor-intensive. In 2005, the R&D intensity of the pharmaceutical industry, measured by the share of R&D employees compared to the overall number of employees and the share of R&D expenditures compared to sales, topped all other industries in Germany.

R&D Expenditures in Europe, Japan and the USA

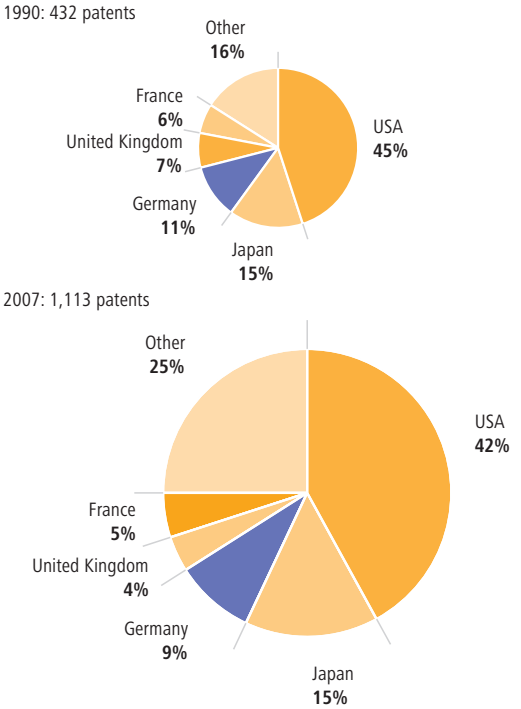


2006: provisional data

Source: EFPIA, PhRMA, VFA

In 2006, the R&D expenditures of the pharmaceutical companies in Europe, Japan and the USA increased to EUR 60.2 billion. This corresponds to a 52 percent increase since 2000 (adjusted for exchange rate fluctuations). Calculated in local currency, R&D expenditures in the USA (61 percent) and Japan (57 percent) have risen more strongly than in Europe (39 percent). Almost half of global R&D expenses continue to be made in the United States.

Patent Applications for Genetically Manufactured Pharmaceuticals



Published patent applications effective in Germany, IPC main classification and subclassification (A61K)

Source: German Patent Office

For detailed data, see Appendix, page 57

In 2007, 11,499 patents were registered for pharmaceuticals in Germany, with 1,113 applications (less than 10 percent) for genetically manufactured drugs. In 2001 and 2002, this share was still at 20 percent.

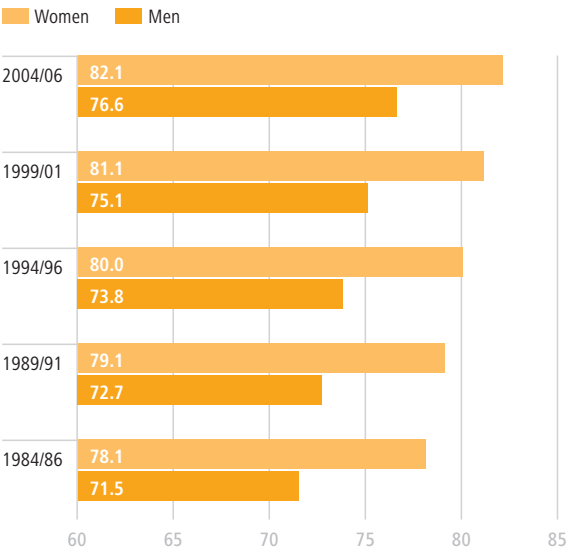
Since 1990, the share of patent applications from the United States has gone down slightly. Patent applications from Germany, which were at 16 percent in 2003, have decreased to nine percent again (2007: 102 applications). Japan, whose share shrank to five percent in the meantime, recorded increases again during the past few years and ranks higher than Germany once more with 173 applications. The "Other" category, whose share has increased significantly, is dominated by Switzerland, Sweden and Canada.

The Pharmaceutical Industry and the Health Care Sector

The share of innovative pharmaceuticals that are rated as innovations or significant therapeutic improvements even by critical experts has been steadily growing for 15 years. The innovations of the research-based pharmaceutical companies share in the responsibility for the constantly rising life expectancy in Germany: It is currently greater than 82 years for women and 77 years for men. This is four and five years more respectively than just 20 years ago. The share of health care spending in the gross domestic product is still below 11 percent and is therefore only slightly higher than 10 years ago. About 15 percent of Germany's total health care expenditures are spent on pharmaceuticals. As a result, Germany ranks in the lower third in a comparison of the key pharmaceutical markets. In the SHI segment, pharmaceutical expenditures have been growing by about 9.3 percent since 2005. Apart from the greater needs of an aging society and the elimination of care deficits with guideline-oriented pharmaceutical therapy, the 2007 value-added tax increase represented the main driver of expenses.

Life Expectancy Trends in Germany

in years

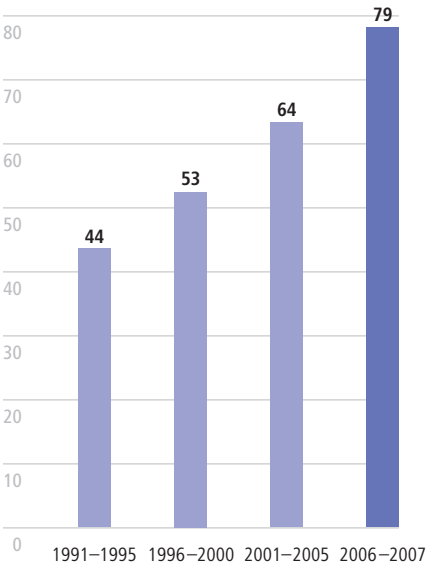


Source: Federal Statistical Office

Thanks to new pharmaceuticals among others, the average life expectancy in Germany has increased by four years for women and five years for men over the past 20 years. For example, several drugs targeted at tumors have helped make the median lifetime after the cancer diagnosis significantly longer for many patients and prevent a relapse in many cases. This applies e.g. for breast, colon and renal cell cancer and some types of leukemia and lymphoma. For many diseases, prevention based on pharmaceuticals is increasingly successful. New vaccines, e.g. against rotaviruses, pneumococci and cervical cancer, contribute in this respect. Physicians know more and more precisely what drugs can best protect patients suffering from diabetes or hypertension from secondary diseases. Finally, due to new pharmaceuticals, an increasing number of rare diseases have also become more treatable or treatable at all.

Increasing Therapeutic Benefits of Innovative Pharmaceuticals

Share of the new molecular entities rated an innovative pharmaceutical or significant therapeutic improvement (in percent)

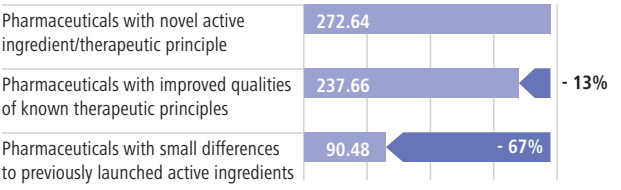


Source: Arzneiverordnungs-Report 2007, Fricke (2008)

Of the 58 molecular entities that received marketing authorization in Germany for the first time during the past two years, 46 (i.e. 80 percent) were rated innovations or therapeutically relevant improvements – even by critical experts. The share of the new molecular entities that can be considered innovative in this respect has continuously increased over the past 15 years.

Improved Substances save Money

Average costs per prescription in the 2006 SHI market in EUR



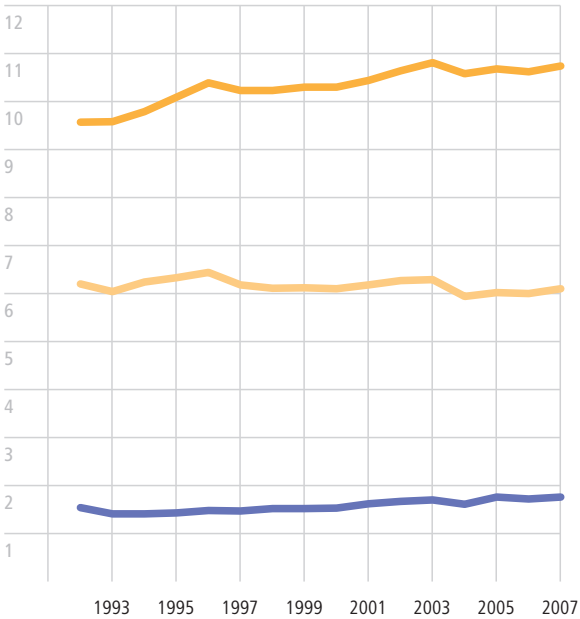
Source: Arzneiverordnungs-Report 2007

Active ingredients whose molecular structure resembles substances that have already been launched often realize therapeutic benefits, e.g. through improved pharmacokinetics or fewer side effects. After all, there is a reason why many of these products are part of the essential drug list of the World Health Organization (WHO), while the original product is not listed.

In addition, molecular variations promote the price competition between patented substances of a given substance class. The latest data of Arzneiverordnungs-Report 2007 (p. 171) show that pharmaceuticals with a novel active ingredient or therapeutic principle cost an average of EUR 270 per prescription while substances associated with the improvement of the pharmacological quality of previously known therapeutic principles cost about 13 percent less on average. As a result, they offer a greater benefit at a reduced price. Me-too drugs with small differences to previously launched substances are even more cost-effective. Their price is about one-third of pharmaceuticals with a novel active ingredient or therapeutic principle.

Health Care Expenditures and National Product

Share in the gross domestic product in percent



From 2006 onward: provisional estimate

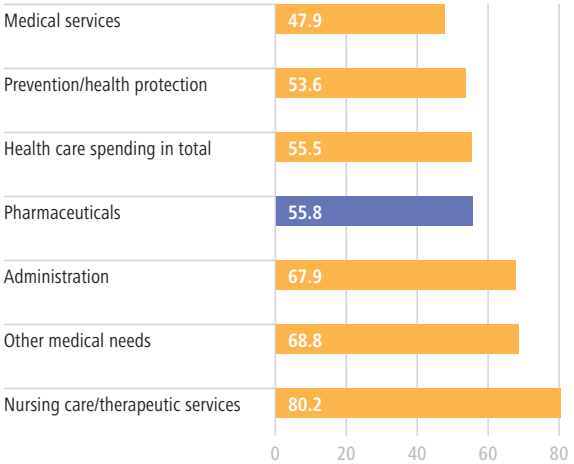
Source: Federal Statistical Office, VFA

For detailed data, see Appendix, page 58

The service expenditures of the statutory health insurance funds have been stable for more than 12 years. Based on the various intervention measures by the legislature, the share in the gross domestic product has even decreased rather than increased. The share of pharmaceutical expenditures in the GDP is consistently below two percent. More than two-thirds of the expenses for pharmaceuticals are shouldered by the statutory health insurance funds. About one-fifth is financed directly by the private households in the form of copayments and self-medication, and 12 percent are covered by other sponsoring institutions.

Health Care Spending Trends

Increased expenditures 1992 to 2006 (in percent)

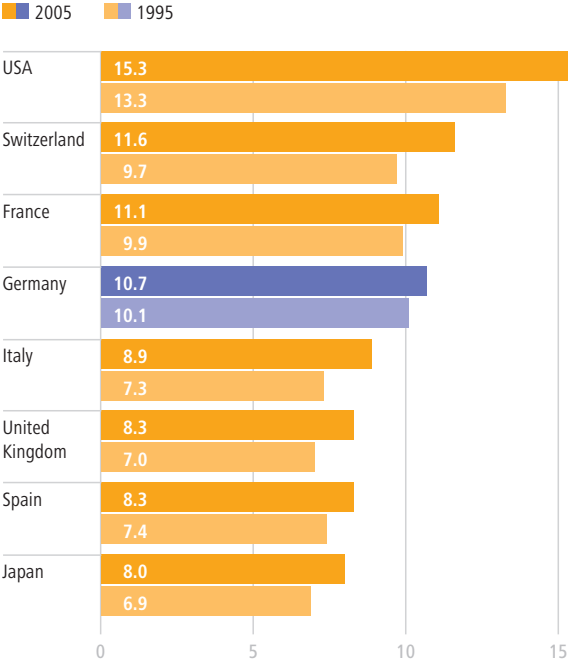


Source: Federal Statistical Office

This long-term comparison between 1992 and 2006 (last available figure) shows that, compared to other health care expenditures, expenses in the pharmaceutical sector did not increase more than health care spending overall.

Health Care Spending in Europe, Japan and the USA

in percent of GDP



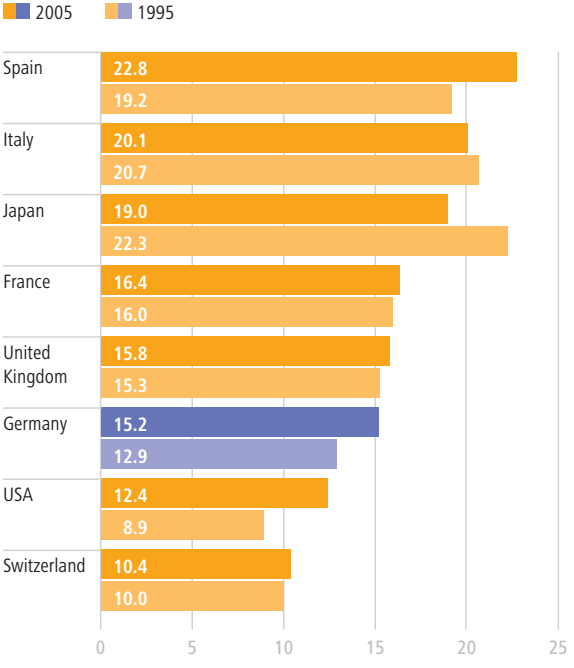
2005: Japan, Spain estimated; United Kingdom: different methodology

Source: OECD

In an international comparison, Germany (after the United States, Switzerland and France) spends the fourth largest share of its gross domestic product on health care services.

Pharmaceutical Expenditures in Europe, Japan and the USA

in percent of total health care expenditures



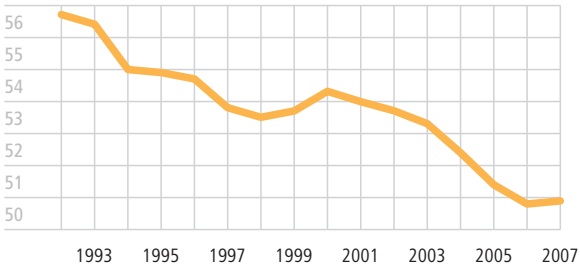
2005: Japan 2004, United Kingdom 1997 (last available figure)

Source: OECD

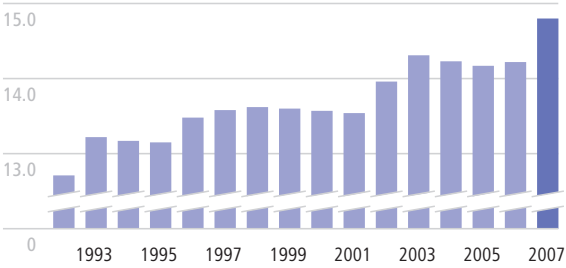
With regard to pharmaceutical expenditures, Germany remains significantly below the level of most other European countries and Japan with a share of 15.2 percent in overall health care expenditures.

The Financing of the Statutory Health Insurance System

Employees' wages in percent of GDP



SHI contribution rate in percent



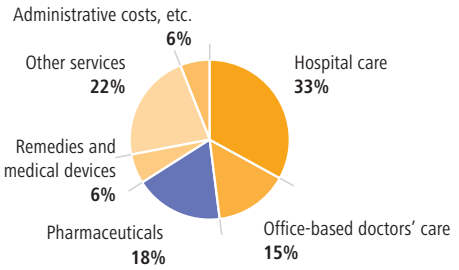
Source: Federal Statistical Office, BMGS

For detailed data, see Appendix, page 59

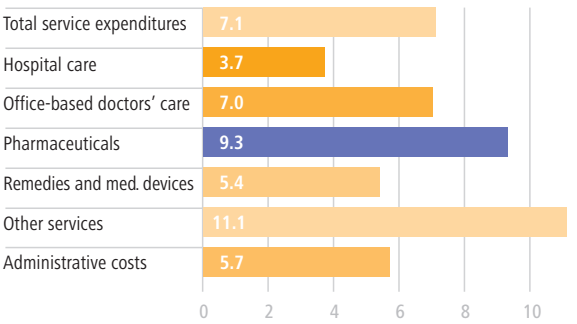
For years, statutory health insurance (SHI) has been facing the problem of increasing expenditures and decreasing revenues. One important reason for the striking increase in SHI contribution rates is the weaker growth of employees' wages, which represent the most important basis for the funding of statutory health insurance. Between 1992 and 2007, the share of employees' wages in the gross domestic product (GDP) decreased from 55.7 to 49.9 percent. At the same time, the average SHI contribution rate increased from 12.7 to 14.8 percent.
In 2004 and 2005, another increase in contribution rates was prevented exclusively by transferring expenses to insured patients and service providers, especially pharmaceutical companies.

Expenditures in the Statutory Health Insurance System 2007

in EUR billion (percent)



Change over 2005 in percent



provisional data

Source: German Federal Ministry of Health

For detailed data, see Appendix, page 60

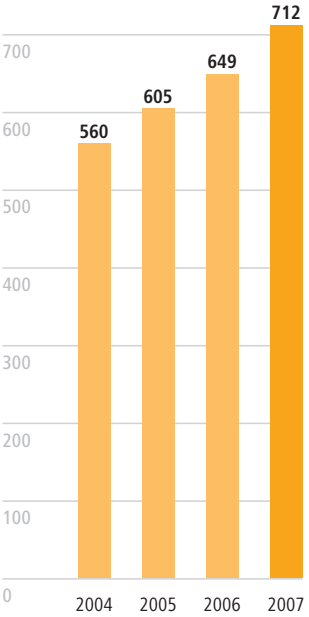
At EUR 50.8 billion, one-third of the total SHI expenditures in the amount of EUR 153.6 billion is spent on hospital care. Together, expenditures for office-based doctors' care (EUR 23.1 billion; 15 percent) and pharmaceuticals (EUR 27.8 billion; 18 percent) represent another third. A total of EUR 8.1 billion (5.6 percent) was used to cover administrative costs. Due to the value-added tax increase effective January 1, 2007, expenditures in some service areas (especially pharmaceuticals) exhibited above-average growth. Expenditures for preventive medicine were also significantly higher. Of the overall expenditures of statutory health insurance, only four percent (EUR 6.4 billion) fall to the manufacturers of patented pharmaceuticals.

The Pharmaceutical Market

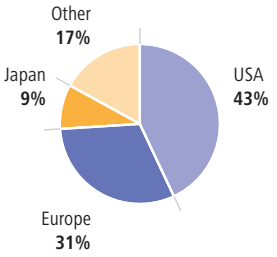
Despite all the efforts made by the research-based pharmaceutical companies, fewer and fewer innovative drugs in Germany reach patients: In 2006, only about five percent of the total expenses were made for innovative pharmaceuticals launched during the past five years. This brings Germany to the bottom of the table in Europe. One reason for this is the reference price system, which has included patented active ingredients since 2005. Today, almost three-fourths of all pharmaceuticals prescribed in Germany are subject to this regulation. Over the past few years, sales growth has been primarily achieved by drugs for serious and the most severe diseases. The share of genetically manufactured pharmaceuticals is also increasing continuously.

The Pharmaceutical Market Worldwide

in USD billion



Shares (2006)



Sales at manufacturers' prices in the pharmacy market

Shares for 2007: audited global sales

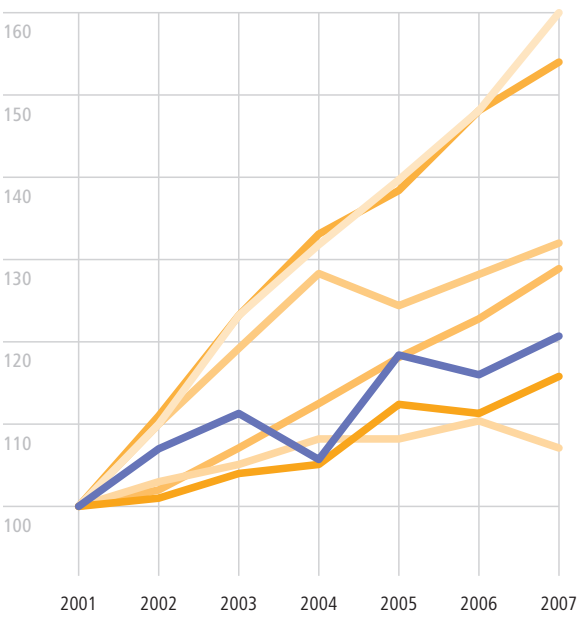
Source: IMS Health, VFA

From 1998 to 2006, global pharmaceutical sales have more than doubled. With about 43 percent, the United States remains the largest individual market worldwide. Over the past three years, the growth of this market, which always was above average until the first few years of the new millennium, has approached the moderate dynamics of the European markets. Europe's share in the world market has grown primarily due to the strengthened position of the euro. The strongest growth in 2007 was exhibited by Eastern European, Latin American and Asian markets.

Germany's share in the world market has decreased from 5.2 percent in 1998 to 3.5 percent in 2007 (at a constant U.S. dollar exchange rate).

Development of the Largest Pharmaceutical Markets

2001 = 100



Sales increases adjusted for exchange rate fluctuations

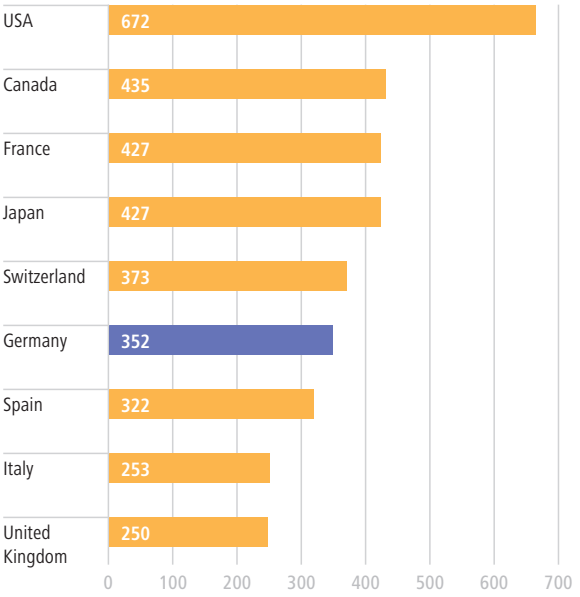
Sales in Germany adjusted for manufacturers' discounts from 2003 onward

Source: IMS Health, VFA

With a volume of about USD 31 billion in 2007, Germany is the third largest market for pharmaceuticals in an international comparison and at the same time one of the markets exhibiting below-average growth. This is due to the cost containment measures of the legislature. From 2001 to 2007, sales in the German pharmacy market increased by about 20 percent, while the U.S. and Spanish pharmacy markets increased by more than 50 percent during the same period. In the United Kingdom and France, sales increases were also larger than in Germany.

Per-capita Sales of Pharmaceuticals

2007 in USD (adjusted for purchasing power)



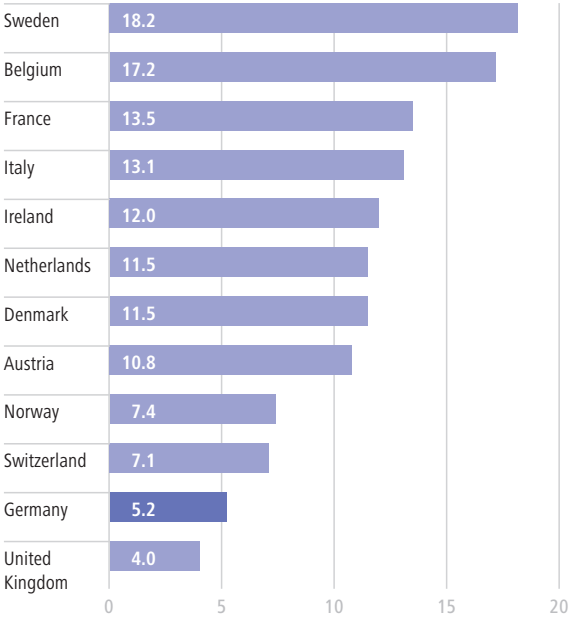
Sales in the pharmacy market at manufacturers' prices

Source: IMS Health, OECD, VFA

With regard to per-capita sales (sales in the pharmacy market at manufacturers' prices), Germany ranks in the middle in the international comparison. In a comparison of the European countries, Germany lies behind France and Switzerland. Also in non-European industrial nations such as the USA, Canada and Japan, per-capita sales are higher than in Germany.

New Molecular Entities: A European Comparison

Market share of new molecular entities launched during the past five years in percent

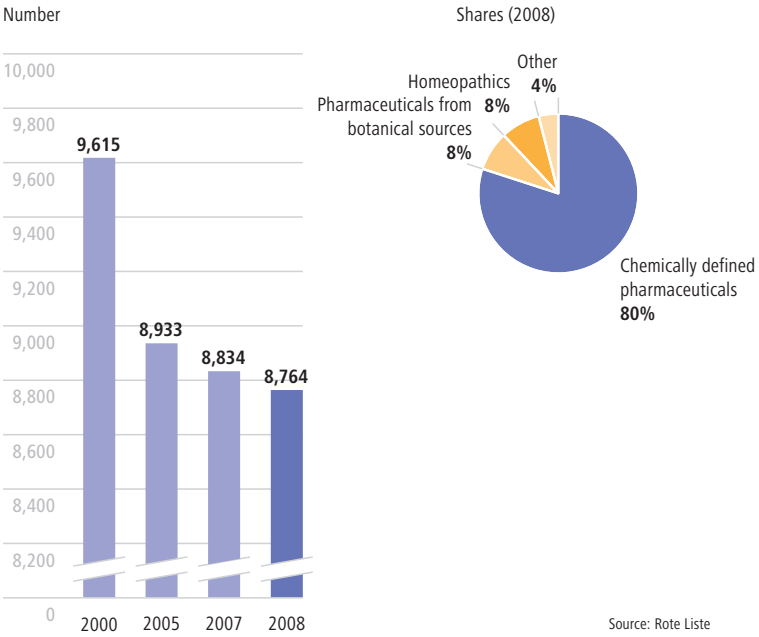


As of: 2006

Source: Pharmaceutical associations of the European countries, VFA

When it comes to enthusiasm for innovation, Germany ranks near the bottom in Europe. In 2006, only 5.2 percent of expenditures in Germany were made for innovative pharmaceuticals launched during the previous five years. As a result, Germany spends less on novel pharmaceuticals than most other European countries, despite the fact that an equally large number of pharmaceuticals receive marketing authorization domestically. However, they are prescribed less frequently or they have lower prices.

Number of Pharmaceuticals in Germany

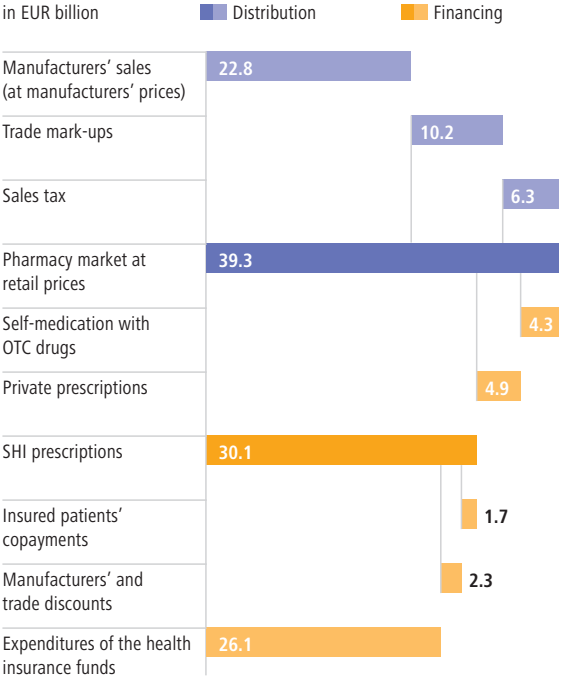


Source: Rote Liste

This year, the number of pharmaceuticals has decreased further. The well-known German drug directory known as the "Rote Liste" currently includes 8,764 product listings – 70 less than last year – including many rarely used pharmaceuticals. Based on evaluations made by statutory health insurance, 90 percent of physicians' prescriptions are for only 1,850 pharmaceuticals.

The number of available pharmaceuticals is often represented imprecisely. For example, if not just the individual product but all of its dosage forms and concentrations are counted separately, one may arrive at numbers of 40,000 pharmaceuticals or more. However, this mode of counting is not customary in other countries and is therefore inappropriate for the purpose of comparisons.

From Manufacturer to Patients: Distribution and Financing of Pharmaceuticals in the Pharmacy Market 2007



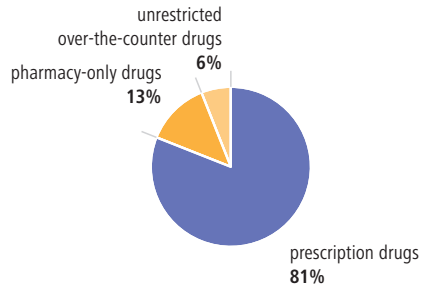
Simplified representation of the most important cash and service flows (with approximate values)

Source: VFA

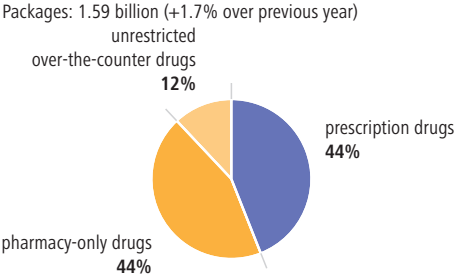
In 2007, the pharmaceutical companies provided pharmaceuticals for human consumption worth EUR 22.8 billion (at manufacturers' prices) via pharmacies for outpatient treatment. After adding the wholesale and pharmacy mark-ups as well as sales tax, this corresponds to a market volume of EUR 39.3 billion at retail prices.
A total of 11 percent of this amount was for self-medication, 12 percent for private prescriptions outside of statutory health insurance, and 77 percent for SHI prescriptions. The latter category was financed through copayments by insured patients (5.6 percent), manufacturers' and pharmacy discounts (7.6 percent) and the health insurance funds themselves (86.7 percent).

Sales and Packages Sold through Pharmacies 2007

Sales: EUR 21.6 billion (+3.8% over previous year)



Packages: 1.59 billion (+1.7% over previous year)



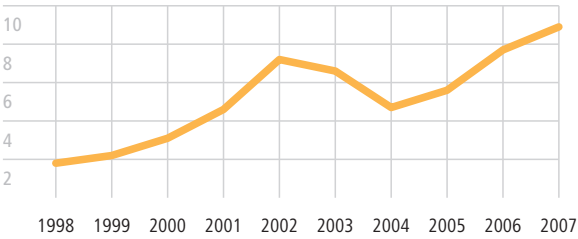
Sales at manufacturers' prices minus manufacturers' discounts pursuant to the German Social Code V

Source: InsightHealth, VFA

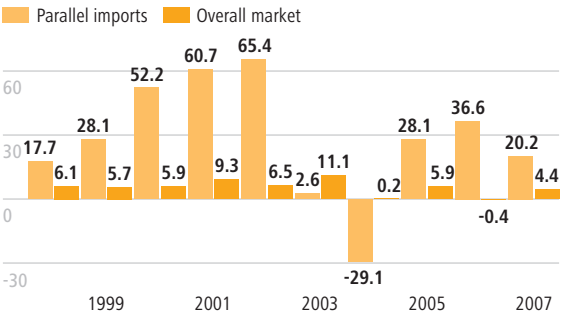
After the previous-year decrease, sales in the German pharmacy market increased again slightly in 2007. After deduction of the legally mandated discounts, net sales were EUR 21.6 billion, i.e. 3.8 percent more than the year before. The companies' mandatory discounts for the benefit of statutory health insurance increased from EUR 1.04 billion during the previous year to EUR 1.22 billion. However, the actual net sales are lower due to the discount agreements concluded between health insurance funds and manufacturers, and the amount of the individual, contractually agreed discounts is unknown. In 2007, the number of packages sold reached a volume of 1.59 billion, which represents a 1.7 percent increase over the previous year. With 700 million packages, this was the first time that more prescription drugs than pharmacy-only products (699 million) were sold.

Parallel Imports

Market share in percent



Growth rates (in percent)



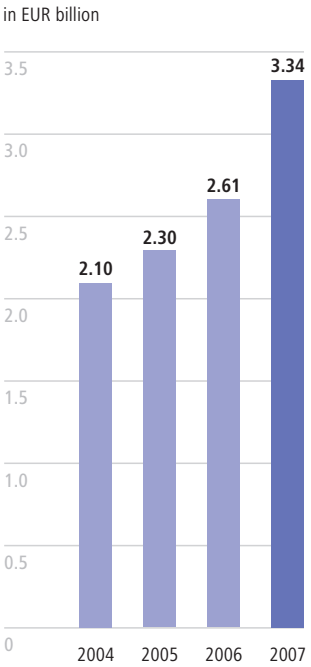
Sales at pharmaceutical manufacturers' prices

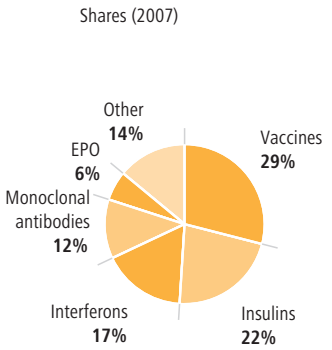
Source: IMS Health, InsightHealth, VFA

From 1998 to 2007, the market share of pharmaceutical parallel imports in the pharmacy market increased from less than two percent to almost nine percent. This was due in large part to targeted government support. Beginning in 2004, the introduction of a minimum price difference for imported products to the original products has only partially interrupted this development.

Parallel imports mainly focus on patented innovative pharmaceuticals. As a result, the research-based pharmaceutical companies suffer considerable sales losses in the domestic market. In 2007, the importers generated sales worth more than EUR 2 billion.

Sales of Genetically Manufactured Pharmaceuticals





Sales at manufacturers' prices in the pharmacy market

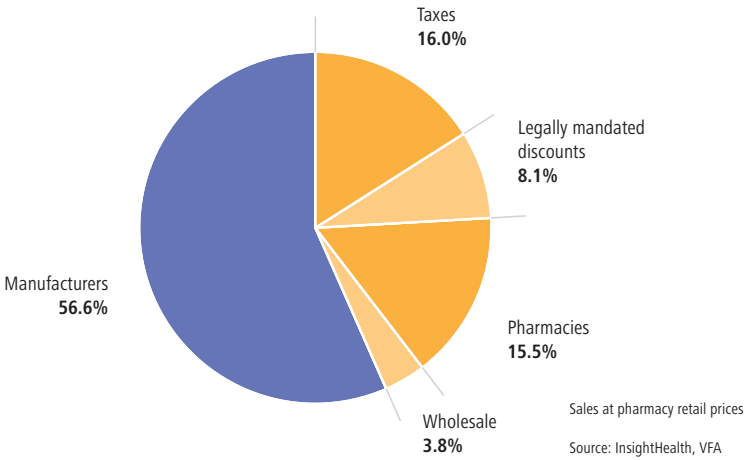
Source: InsightHealth; VFA

The share of pharmaceuticals with genetically manufactured substances in the pharmacy market is constantly increasing: For EUR 3.34 billion in sales (at manufacturers' prices) it was 14.6 percent in 2007. In 2000, this share was still at 7.6 percent. In addition, there are the sales in the hospital sector, but no detailed data were available for this segment.

More than half of sales were recorded for vaccines and insulins to treat diabetes. Additional important applications include interferons used for immune disorders, monoclonal antibodies against cancer and EPO (erythropoietin) against anemia.

Sales Distribution in the SHI Pharmaceutical Market 2007

Shares in percent



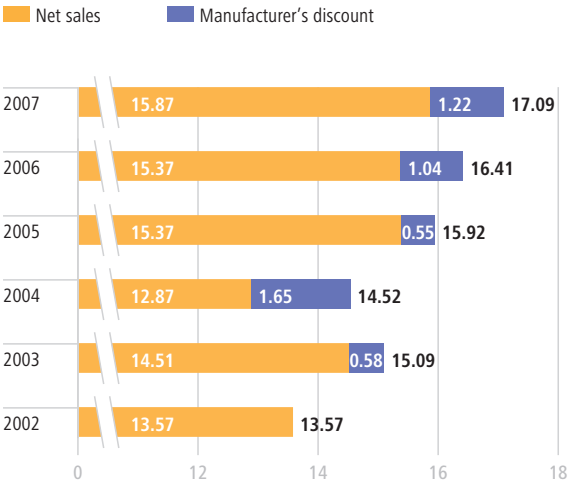
Sales at pharmacy retail prices

Source: InsightHealth, VFA

In 2007, gross sales with proprietary medicinal products in the SHI market (at pharmacy retail prices incl. VAT without rebate deduction) were EUR 28.1 billion.
Based on the German Contribution Rate Safeguarding Act, the SHI Modernization Act and the Economic Efficiency of Pharmaceutical Care Act, the discounts the pharmaceutical companies as well as wholesalers and retailers must grant to statutory health insurance have been changed several times between 2002 and 2006. In 2006, the mandatory rebate was expanded again for the manufacturers. Due to the value-added tax increase to 19 percent, the share of taxes included in the gross sales increased to 16 percent.

Manufacturers' Sales in the SHI Pharmaceutical Market

in EUR billion at manufacturer's prices

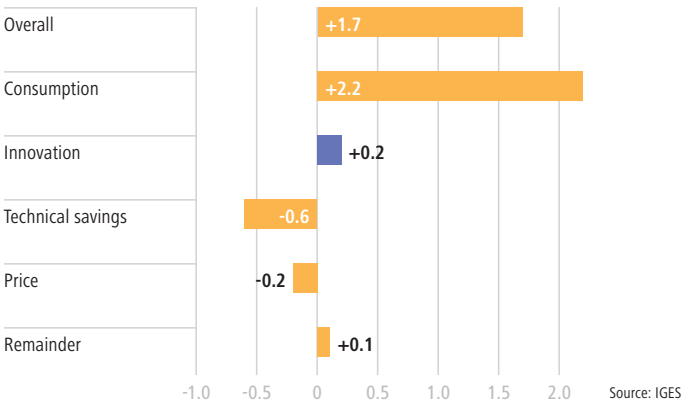


Source: InsightHealth, VFA

Due to the additional discount of 10 percent on generics-eligible active ingredients effective April 1, 2006, the manufacturer's discount more than doubled from 2005 to 2007. As a result, the 2007 manufacturers' net sales decreased to about EUR 15.9 billion. Therefore, the real sales increase of the manufacturers in 2007 was only 3.3 percent compared to the previous year.

Sales Growth 2007: Driven by what Components?

Change in sales in EUR billion

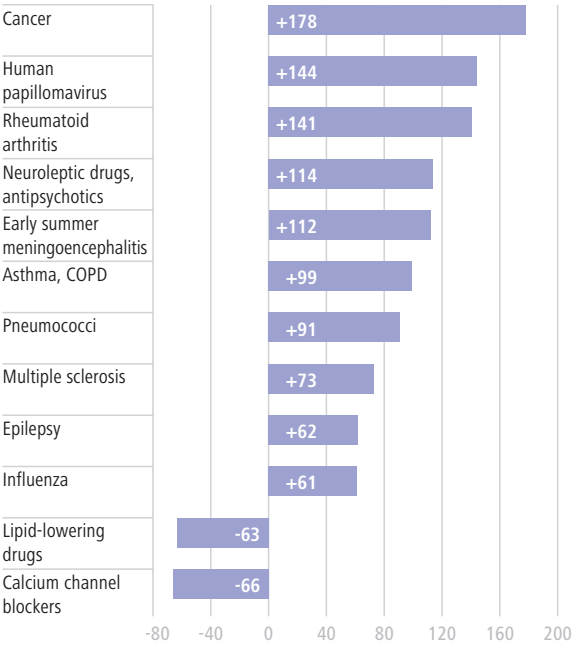


Source: IGES

The sales increase in the SHI market worth EUR 1.7 billion in 2007 was determined by opposite components that either had a sales-increasing or decreasing effect. Consumption (increase in the prescribed daily doses) and innovative pharmaceuticals have caused an additional demand of about EUR 2.2 billion and EUR 0.2 billion respectively. In contrast, "technical" savings, e.g. selection of more cost-effective drugs, including those with active ingredients whose patents expired in 2007, or larger packages, have led to almost EUR 0.6 billion in savings. If the value-added tax rate had not been increased, savings from the price components would have been almost EUR 1 billion instead of EUR 0.2 billion.
As during the past two years, the dominant factor in the dynamics of the pharmaceutical market are medical and therapeutic needs.

Changes in Sales 2007 based on Health Disorders

Changes in sales in EUR million



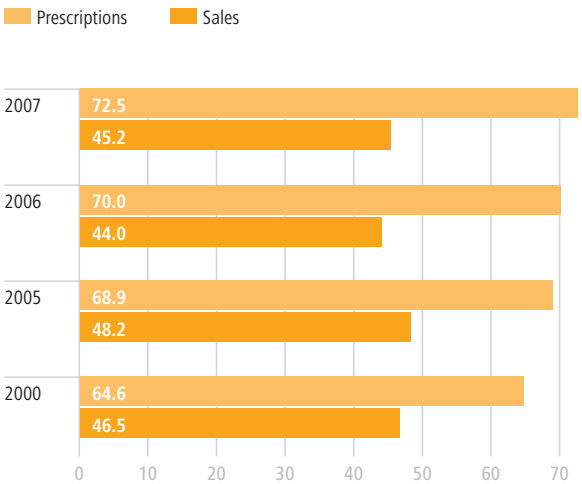
Disorders of more than +/- EUR 60 million

Source: IGES

Sales increases were recorded predominantly for the therapy of serious or life-threatening diseases, primarily cancer, and – in the case of vaccines, e.g. against human papillomavirus or early summer meningoencephalitis – for the prevention of diseases. Sales decreases were recorded especially for those categories of diseases for which classes of active ingredients are used that could be prescribed more cost-effectively due to expired patents or price reductions.

Reference Prices in the SHI Market

Shares in percent



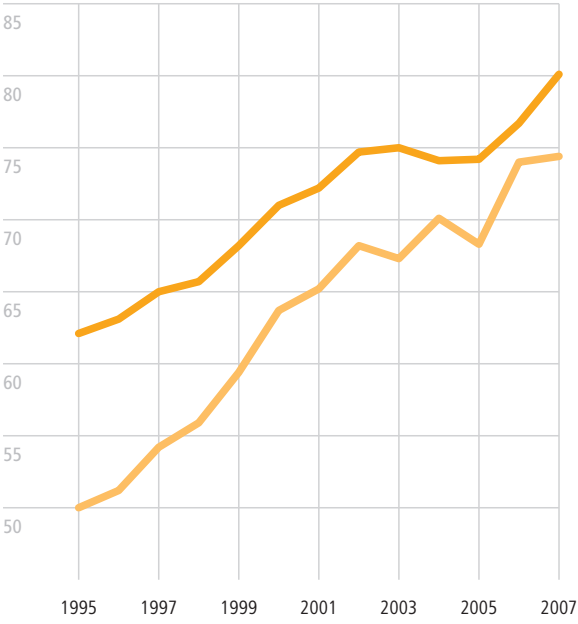
As of: July 1 of the given year

Source: SHI Office for Pharmaceutical Reference Prices, VFA

Over the past two years, indirect price regulation based on reference prices has been significantly expanded again. In 2007, almost three-fourths of all pharmaceuticals prescribed in Germany were subject to this regulation. As a result, this share is the highest since reference prices were introduced. The sales share of pharmaceuticals subject to reference prices also increased again last year – despite a reduction in reference prices. Effective 2005, many reference price categories also include patented active ingredients. This involves additional, considerable burdens, especially for the research-based pharmaceutical companies. Since mid-2007, about 28,600 proprietary medicinal products with about 430 active ingredients have been subject to reference prices. As a result, the statutory health insurance funds will probably save more than EUR 3.4 billion in 2008.

Generic Drugs in the SHI Market

Shares in the market eligible for generic drugs (in percent)



Source: Arzneiverordnungs-Report 2007 (up until 2006), VFA (2007)

For detailed data, see Appendix, page 60

When patents expire, the imitation products of other manufacturers (generic drugs) can also be authorized for marketing beside the original pharmaceuticals. In Germany, 78 percent of SHI prescriptions – and at 49 percent almost half of all sales in the entire market – are generated in this so-called generics-eligible market. During the past 12 years, Germany has evolved into the world's most generics-friendly country. Often, original products lose almost their entire market share to generic drugs within just a few months after patent expiration. On average, more than 80 percent of all prescriptions and about 75 percent of sales in the generics-eligible market were generated by imitation products in 2007.

The Production of Pharmaceutical Products in Germany

Year	Production of pharm. products in EUR billion	Changes over previous year in percent
2007	26.219	10.6
2006	23.700	4.6
2005	22.654	8.4
2004	20.893	0.8
2003	20.720	0.2
2002	20.672	2.3
2001	20.200	9.2
2000	18.500	2.8
1999	18.000	1.1
1998	17.812	2.5
1997	17.380	-0.4
1996	17.442	4.8
1995	16.641	-0.9
1994	16.800	6.4

2007: provisional data

Distinction according to technical company segments

Source: Federal Statistical Office, VFA

Sales of the Manufacturers of Pharmaceutical Products

in EUR billion

Year	Domestic sales	Foreign sales	Total	Export ratio in percent
2007	13.6	17.6	31.2	56.5
2006	13.2	16.2	29.4	55.1
2005	13.1	14.8	27.9	53.0
2004	11.4	13.1	24.4	53.5
2003	11.1	12.4	23.5	52.6
2002	11.4	11.7	23.2	50.7
2001	11.2	11.2	22.5	50.1
2000	10.8	10.2	21.0	48.5
1999	11.3	9.4	20.7	45.6
1998	11.4	8.4	19.8	42.3
1997	11.4	7.9	19.3	40.7
1996	11.6	6.9	18.5	37.5
1995	11.6	6.4	18.0	35.6

2007: provisional data

Distinction according to technical company segments

Source: Federal Statistical Office

Price Trends

1995 = 100

Year	Private consumption (total)	SHI pharmaceuticals
2007	119.8	91.8
2006	117.3	93.3
2005	115.3	95.6
2004	113.1	96.3
2003	111.3	100.8
2002	110.1	101.3
2001	108.6	101.9
2000	106.5	101.0
1999	105.0	100.5
1998	104.4	99.7
1997	103.4	99.5
1996	101.5	100.1
1995	100.0	100.0

Source: Federal Statistical Office, WIdO

Patent Applications for Genetically Manufactured Pharmaceuticals

Number

Country of origin	1990	1995	2004	2005	2006	2007
USA	192	352	684	597	517	468
Japan	66	28	143	162	198	173
Germany	49	65	172	157	146	102
United Kingdom	29	41	93	78	64	42
France	25	41	95	81	57	52
Other	71	118	345	300	319	276
Total	432	645	1,532	1,375	1,301	1,113

Published patent applications effective in Germany, IPC main classification and subclassification (A61K)

Source: German Patent Office

Health Care Expenditures and Gross National Product

Share in the gross domestic product in percent

Year	Health care spending in total	SHI service expenditures	Pharmaceutical expenditures
2007	10.74	6.10	1.76
2006	10.62	6.00	1.72
2005	10.68	6.02	1.76
2004	10.58	5.94	1.61
2003	10.81	6.29	1.70
2002	10.64	6.27	1.67
2001	10.44	6.18	1.62
2000	10.30	6.10	1.53
1999	10.30	6.12	1.52
1998	10.23	6.11	1.52
1997	10.23	6.18	1.47
1996	10.39	6.44	1.48
1995	10.09	6.33	1.43
1994	9.79	6.24	1.41
1993	9.58	6.04	1.41
1992	9.57	6.20	1.54

2006 onward: provisional estimate

Source: Federal Statistical Office, VFA

The Financing of the Statutory Health Insurance System

in EUR billion

Year	Gross domestic product (GDP)	Employees' wages	Employees' wages in %	SHI contribution rate in %
2007	2,364.9	1,181.0	49.9	14.80
2006	2,307.2	1,149.4	49.8	14.22
2005	2,241.0	1,129.9	50.4	14.17
2004	2,207.2	1,134.5	51.4	14.23
2003	2,161.5	1,131.1	52.3	14.31
2002	2,143.2	1,128.7	52.7	13.96
2001	2,113.2	1,120.6	53.0	13.54
2000	2,062.5	1,100.0	53.3	13.57
1999	2,012.0	1,059.5	52.7	13.60
1998	1,965.4	1,032.3	52.5	13.62
1997	1,915.6	1,010.7	52.8	13.58
1996	1,876.2	1,006.6	53.7	13.48
1995	1,848.5	997.0	53.9	13.15
1994	1,780.8	961.9	54.0	13.17
1993	1,694.4	938.7	55.4	13.22
1992	1,646.6	917.2	55.7	12.71

Source: Federal Statistical Office, German Federal Ministry of Health

Expenditures in the Statutory Health Insurance System

in EUR billion

Area	1995	2004	2005	2006	2007
Total spending without RBFE	124.0	139.9	143.6	147.6	153.6
Total expenditures on health care services	117.0	131.1	134.8	138.5	144.3
Hospital care	40.7	47.6	49.0	50.3	50.8
Office-based doctors' care	19.7	23.0	21.6	22.2	23.1
Pharmaceuticals	16.4	21.8	25.4	25.9	27.8
Remedies and medical devices	8.6	8.2	8.2	8.2	8.6
Other services	31.63	30.4	30.6	31.9	34.0
Administrative expenses, etc.	7.0	8.8	8.8	9.1	9.3

RBFE: risk-based fiscal equalization

2007: provisional data

Source: German Federal Ministry of Health

Generic Drugs in the SHI Pharmaceutical Market

Shares in the market eligible for generic drugs (in percent)

Year	Prescriptions	Sales
2007	80.1	74.4
2006	76.7	74.0
2005	74.2	68.3
2004	74.1	70.1
2003	75.0	67.3
2002	74.7	68.2
2001	72.2	65.2
2000	71.0	63.7
1999	68.2	59.4
1998	65.7	55.9
1997	65.0	54.2
1996	63.1	51.2
1995	62.1	50.0

Source: Arzneiverordnungs-Report 2007 (up until 2006), VFA (2007)

Imprint

Published by
Verband Forschender Arzneimittelhersteller e.V.
Hausvogteiplatz 13
10117 Berlin

Design
Adler & Schmidt Kommunikations-Design, Berlin

Photo Credits
Boehringer Ingelheim GmbH Titel
Chiron Vaccines 6
picture alliance 20, 30, 40

Printer
Ruksaldruck

August 2008

For additional VFA media,
please visit
www.vfa.de/publikationen
on the Internet.

German Association
of Research-Based
Pharmaceutical Companies
Hausvogteiplatz 13
10117 Berlin
Phone +49 30 20604-0
Fax +49 30 20604-222
www.vfa.de