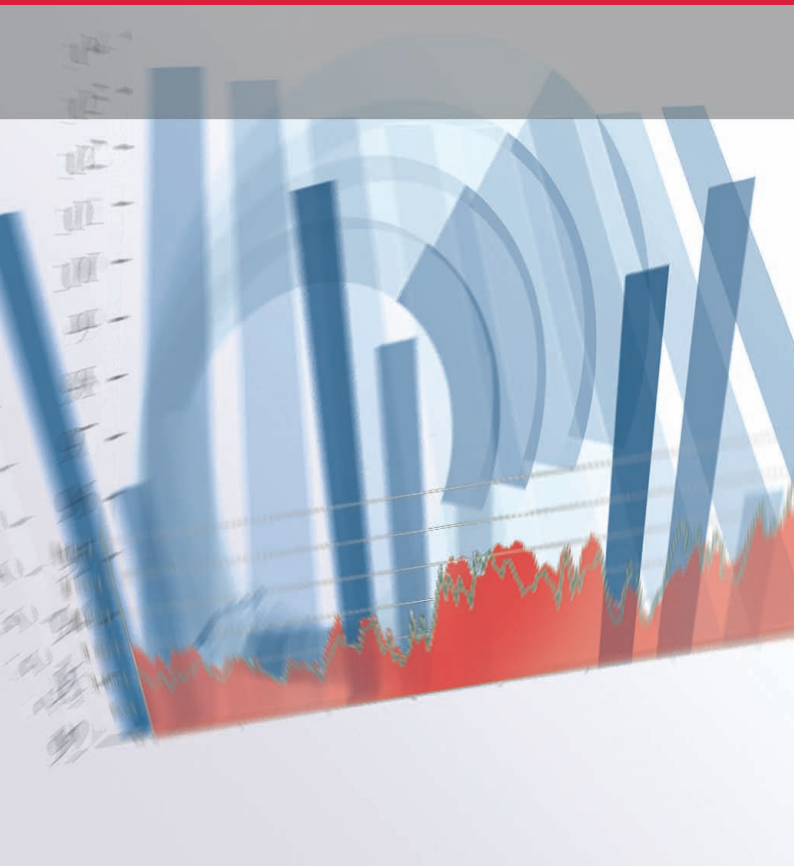
BPI German Pharmaceutical Industry Association

Pharma-Data 2012



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Preface

Again and again, statements such as “Drug expenditures in Germany are too high …” or “Pharmaceutical industry is the main cost driver …” make the national headlines. Very often the facts do not bear out these statements. But what does reality truly look like? How much money is spent on patient care in the German health care system? What are the main cost drivers in the system? How significant is the pharmaceutical industry for the economy in Germany?

The world is not as simple as it is often presented in the media by pharma critics. The pharmaceutical industry is not an homogenous industry. There is no such thing as THE pharmaceutical industry. Nearly 900 companies are listed in Germany. In addition, not all drugs are the same. There are highly innovative drugs that are marketed with new active substances. There are also improvements made to existing active substances which result in fewer side effects and better efficacy. There are generic versions of drugs which represent low-cost alterntatives to originator products and increase the therapeutic choices available to physicians. Last but not least, there are homeopathic, anthroposophic and phytotherapeutic drugs. This diversity in the spectrum of available drugs show that a simplistic, monolithic image of the drug market in Germany does not do justice to reality. And yet, drugs are primarily viewed from the perspective of costs, which is particularly clear when one reviews the political decisions made in the past years. The Act on the Reform of the Market for Medicinal Products (AMNOG) in particular has the declared goal of regulating the costs of innovative medicinal products. It requires manufacturers to negotiate rebates with the Federal Association of Statutory Health Insurance Funds (“GKV-Spitzenverband”) in order for their products to be eligible for reimbursement on the German market.

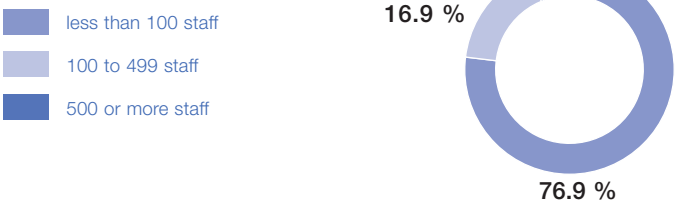
The problems presented by this situation are rapidly becoming apparent, especially the fact that the Federal Association of Statutory Health Insurance Funds has multiple ways of exerting influence. In addition, obligatory discounts, rebate / discount contracts and reference prices are further stressors on the pharmaceutical industry.

Overall, the goal must be to shift to a more fact-oriented discussion on ensuring an adequate drug supply in Germany. This year's "Pharma Data" is again intended to facilitate this discussion. Drugs are one of many cost drivers in the health care sector, but they are also life-saving and essential for treating many illnesses. Pharmaceutical companies are a significant economic factor in Germany, as is demonstrated by the more than 100,000 employees active in this industry. This 42nd edition of "Pharma Data" provides facts and background information on the pharmaceutical market with the aim of contributing to a factual, balanced discussion in the health care sector.

Sector structure

According to the trade register at the Federal Office for Statistics, a total of 899 pharmaceutical companies* are registered in Germany. Over the course of the last years, it has become increasingly difficult to determine the number of companies due to changing reporting groups at the Federal Office for Statistics on the one hand and methodical differences on the other hand. Additionally, there may be conglomerates consisting of several different companies, which in turn can be composed of individual firms and specialist business units. Accordingly, determining the number of specialist business units – as a core element of pharmaceutical production – as well as determining the number of contract manufacturers would seem appropriate. These data, however, are only partially captured by the Federal Office for Statistics.

Companies according to size in 2010 in %



Source: Calculation of the BPI, based on data of the VCI 2012 and of the Federal Office for Statistics 2012.

* In the “cost structure statistics”, the Federal Office for Statistics shows 240 companies (reporting category 20+). There are an additional 387 companies with less than 20 employees. The large number of registered companies can also be explained by the existence of many marketing authorisation holders that are considered pharmaceutical companies.

The pharmaceutical companies include medium-sized companies, as well as companies under owner-management and German branches of multinational corporations. Furthermore, biotechnology companies are to be considered. These companies primarily develop and / or produce pharmaceutical drugs and diagnostic products, and are partially included in the 899 companies mentioned above. It is still true that nearly 95 % of companies manufacturing pharmaceutical drugs in Germany employ less than 500 staff.

The German Pharmaceutical Industry Association [Bundesverband der Pharmazeutischen Industrie e. V. (BPI)] is the only association in Germany that represents the entire spectrum of the pharmaceutical industry on a national and international level. Small- and medium-sized companies as well as internationally active corporations are represented in the BPI. This includes pharmaceutical companies with R&D programmes, generic companies, companies from the fields of biotechnology, phytopharmaceuticals, homeopathic / anthroposophic medicine, as well as pharmaceutical service providers. With its 60 years of experience in the field of pharmaceutical drug research, development, drug approval, manufacturing and marketing, the BPI offers integrative solutions for the entire pharmaceutical market.

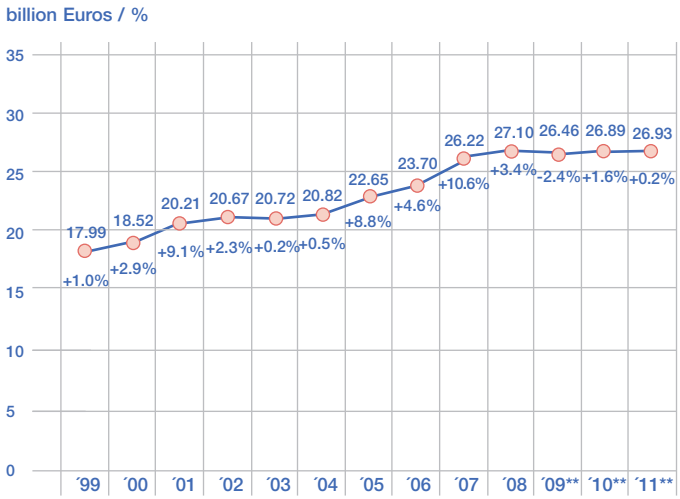
Production

In 2011, the pharmaceutical industry in Germany produced pharmaceuticals valued at 26.9 billion Euros.

This represents an increase of 0.2 % compared to the year 2010. Domestic production is highly dependent on pricing, pharmaceutical drug imports as well as export demand.

Pharmaceutical Production* from 1999 – 2011**

(Production value in billion Euros, changes relative to the previous year in %)



* Index of goods for statistics of production (GP 21), Production of pharmaceutical and similar goods.

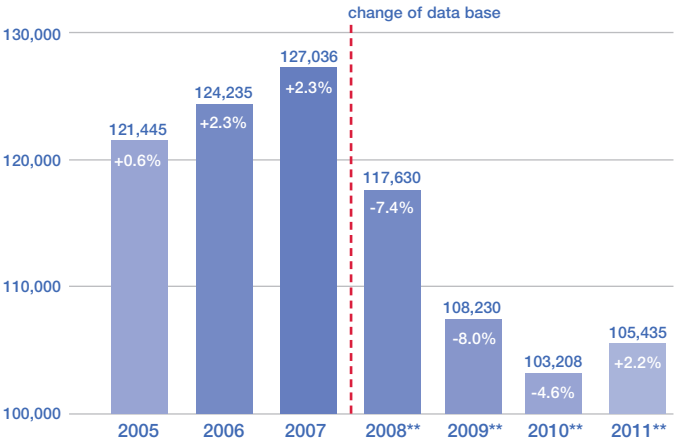
** Since 2009 the GP 21 (pharmaceutical and similar goods) has replaced the GP 244.This new statistical classification prevents a direct comparison with values from previous years.

Source: Illustration of the BPI, based on data of the VCI 2012 and the Federal Office for Statistics 2012.

Employees

In 2011, 105,435 staff were employed by companies producing pharmaceutical goods. The good economic climate has led to a record high in employment in 2011 in Germany. An annual average of 41 million people were employed. According to the Federal Office for Statistics, this was the highest employment rate since reunification. In comparison to 2010, ca. 535,000 people more were employed in 2011, which corresponds to an increase of ca. 1.3 %.

Development of staff numbers* in the pharmaceutical industry 2005 – 2011 (changes relative to the previous year in %)



* The data refer to companies (reporting category 20+). Compared to the information provided in the Pharma Data up to 2007, there has been a transfer of the specialist operating sectors to the level of "companies", because the reporting category 20+ for specialist operating sectors was removed in the course of the bureaucracy reduction law of the Federal Office for Statistics.

** For data from the year 2008 onwards attention should be paid to the change of the economy sector from WZ 24.4 to WZ 21. This new statistical classification prevents a direct comparison with data from previous years

Source: Illustration of the BPI based on data obtained of the VCI 2012 and the Federal Office for Statistics 2012.

Foreign trade

In 2011, pharmaceuticals valued at 50.4 billion Euros were exported from the Federal Republic of Germany. This corresponds to a decrease of 1.4 % compared to 2010. At the same time, pharmaceuticals valued at 37.6 billion Euros were imported into the Federal Republic of Germany. This constitutes a decrease of 1.0 % compared to 2010. The main supplier of pharmaceuticals to Germany is Switzerland, followed by the USA, Ireland, the Netherlands and Great Britain.

Import and export of pharmaceutical drugs*

(in million Euros, changes relative to the previous year in %)

Year	Import		Export**	
	million Euros	+/- %	million Euros	+/- %
2001	12,051.17	+16.4	20,478.36	+34.9
2002	19,284.83	+60.0	18,835.18	-8.0
2003	19,327.83	+0.2	22,230.11	+18.0
2004	22,221.42	+15.0	28,681.63	+29.0
2005	25,585.17	+15.1	31,758.85	+10.7
2006	28,366.72	+10.9	36,474.52	+14.8
2007	32,706.83	+15.3	41,908.34	+14.9
2008	34,063.16	+4.1	47,549.32	+13.5
2009	35,552.63	+4.4	47,365.96	-0.4
2010	38,011.25	+6.9	51,133.24	+8.0
2011	37,618.32	-1.0	50,421.52	-1.4

* Business branch 21, Production of pharmaceutical goods. A new statistical classification was introduced in 2008. The production of pharmaceutical goods is now to be found in WZ 21 (previously WZ 24.4).

** Because of statistical peculiarities and different surveys, the production statistics and external trade statistics cannot be compared with each other.

Source: Illustration of the BPI based on data of the VCI 2012 and the Federal Office for Statistics 2012.

Main suppliers of pharmaceuticals* to Germany (in million Euros)

	2006	2007	2008	2009	2010	2011
Switzerland	2,729.90	4,502.61	4,333.46	4,845.13	5,463.70	6,376.50
USA	5,027.26	5,931.85	6,501.50	7,193.86	6,253.57	5,728.23
Ireland**	8,283.95	8,626.71	8,985.03	7,934.95	6,751.54	4,653.31
Netherlands	952.55	1,369.03	1,224.94	1,182.51	1,954.97	4,127.49
Great Britain	1,815.59	1,847.81	1,682.74	2,299.63	2,569.65	3,313.73
Belgium	1,027.49	1,204.81	1,318.56	1,292.36	1,487.63	1,822.54
Italy	1,193.98	1,367.09	1,415.20	1,546.32	1,702.05	1,792.42
France	2,034.73	1,897.93	1,842.35	1,741.96	2,331.83	1,754.11
Sweden	998.17	990.65	1,029.17	1,106.91	1,217.70	1,035.44
Spain	829.72	990.18	1,038.00	1,205.72	2,479.95	1,023.40
Others	3,473.39	3,872.57	4,692.22	5,203.30	5,798.67	5,991.15
Total	**28,366.72**	**32,601.23**	**34,063.16**	**35,552.63**	**38,011.25**	**37,618.31**

* Business branch 21, Production of pharmaceutical goods. A new statistical classification was introduced in 2008. The production of pharmaceutical goods is now to be found in WZ 21 (previously WZ 24.4).

** Because of generous EU subsidies the economy in Ireland has developed very well in the last years. Many chemical companies also use the good conditions governing the location Ireland to produce a significant share of their preliminary products (especially pharmaceutical products) and then export them for further processing. Due to this division of labor the export trade with Ireland has increased tremendously.

Source: Illustration of the BPI based on data of the VCI 2012 and the Federal Office for Statistics 2012.

Main importers of pharmaceutical drugs* from Germany (in million Euros)

	2006	2007	2008	2009	2010	2011
Belgium**	10,076.72	11,070.24	11,616.23	10,918.27	10,495.80	7,531.28
Netherlands	2,497.69	3,526.56	4,367.44	4,423.55	6,553.10	6,676.76
USA	4,222.33	4,330.88	5,752.41	5,861.38	4,979.74	5,665.32
Switzerland	2,320.16	2,488.89	2,419.29	2,865.12	2,818.90	3,221.24
France	1,576.24	1,903.22	2,249.68	2,255.97	2,525.98	2,752.75
Italy	1,687.55	1,991.34	2,045.26	2,192.60	2,465.54	2,483.99
Great Britain	1,806.50	2,229.93	2,443.45	2,440.71	2,770.38	2,421.35
Russian Fed.	798.62	840.00	1,099.05	984.30	1,390.49	1,626.93
Austria	955.55	1,069.27	1,161.28	1,252.11	1,458.74	1,551.06
Spain	1,013.97	1,196.50	1,207.85	1,254.42	1,375.34	1,448.99
Others	9,519.19	11,261.24	13,187.40	12,917.56	14,299.24	15,041.85
Total	**36,474.52**	**41,908.34**	**47,549.32**	**47,365.99**	**51,133.24**	**50,421.52**

* Business branch 21, Production of pharmaceutical goods. A new statistical classification was introduced in 2008. The production of pharmaceutical goods is now to be found in WZ 21 (previously WZ 24.4).

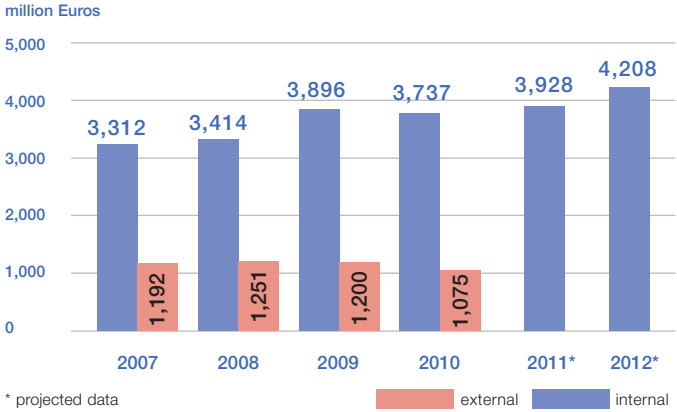
** The remarkably high export rate is explained by the VCI as due to special circumstances.

Source: Illustration of the BPI based on data of the VCI 2012 and the Federal Office for Statistics 2012.

Research and Development

In 2011, the pharmaceutical industry in Germany planned to invest roughly 3.9 billion Euros in research and development (R&D). This value is reflects only the companies' own outlays for R&D and does not include expenses of outsourcing to contract research organizations, as reported in the R&D survey of the Stifterverband. This planned investment level was higher relative to the previous year (3.7 billion Euros).

Investments in research and development by the pharmaceutical industry 2007 – 2012 (in Million Euros), actual data up to 2010, projected data for 2011 and 2012



The external R&D-expenditures for 2011 and 2012 cannot be shown here.

Source: Illustration of the BPI based on data of the Stifterverband Wirtschaftsstatistik 2012.

The internal R&D expenditures of the pharmaceutical industry in 2011 constitute around 7.9 % of the overall internal R&D investments in the German economy (49.3 billion Euros). In terms of absolute investment volume, the pharmaceutical industry is in fourth place behind the automobile industry, the electronics industry and mechanical engineering industry.

The high investment level demonstrates that the pharmaceutical industry continued to focus on innovation despite the economic crisis. The chronological dynamic of this development is particularly interesting: while the overall internal R&D investment level of the German economy decreased by 1.7 % in 2009 (relative to 2008) in response to the economic crisis, the pharmaceutical industry did not scale back its R&D investments until the following year 2010, when R&D investments decreased by 4.1 % relative to 2009. In 2010, under the impression of projected deficits in the statutory health insurance (SHI) system, a price moratorium on non-generic drugs and increased mandatory rebates (from 6 to 16 %) were instituted. It is likely that the decrease in R&D expenditures reflects an industry effort to compensate for the reduction in turnover resulting from these measures. In 2011 and 2012, the pharmaceutical industry is planning higher R&D investments, despite unprecedented surpluses in the SHI system and the continuation of the above-mentioned cost-control measures through 2013.

The data are based on available data at editorial deadline of the German Stifterverband Wissenschaftsstatistik, which are still based on projected data for the most recent years. In the Pharma Data 2011 issue, this projected data was used as a basis for projecting R&D expenditures in 2010 of 5.5 billion Euro. This projected data for R&D in 2009 must now be corrected downwards to 4.8 billion Euro. This development clearly demonstrates the negative impact of legislative restrictions on the pharma industry's turnover in respect to R&D investments.

Relatively speaking, the pharmaceutical industry is one of the most research-intense sectors, with R&D costs of ca. 9 % versus turnover (electrical engineering industry 6.8%, vehicle manufacturing 5.5 %, mechanical engineering industry 3.9 %), thus securing highly qualified jobs in Germany. This trend in the development of the R&D costs is also reflected in the development of employment figures: the number of staff employed in R&D

in 2010 increased to 19,300 compared to 15,500 in the year 2001. With this, the number of staff in this sector increased by around 20 % in the period from 2001 to 2010, while it stagnated in the overall chemical industry during the same period of time. Data were not available for the year 2011 at editorial deadline.

Research and development of pharmaceutical drugs

Innovations are a driving force for improvements in patient care, but also for growth of pharmaceutical companies. New active substances, formulations and production processes ensure improved therapeutic options as well as securing employment and tax revenue in Germany.

The purpose of research and development (R&D) in the pharmaceutical sector is to improve diagnostic methods, symptomatic or causal treatments or the preventive treatments, as well as to increase available options and close existing therapeutic gaps. Innovations in the pharmaceutical industry are achieved in manifold areas:

-> New active substances
Chemically defined active substances, defined natural substances, phytopharmaceuticals, biopharmaceuticals, "me-too" substances (molecular variants of known active substances with a similar chemical structure)

-> New pharmaceutical forms and new specifically active combinations of active substances

-> Extension of the indications of known active substances

-> Specific improvements of active substances, new application forms

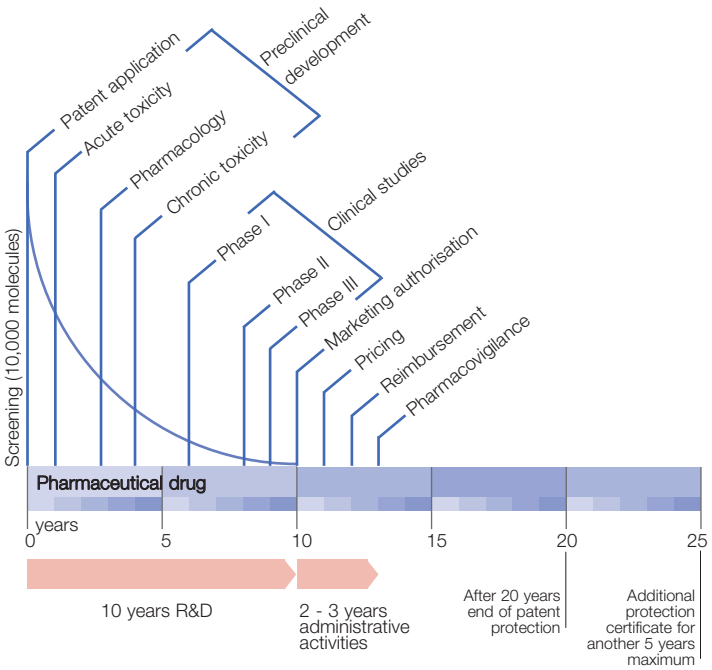
-> Other new treatment options

-> Improved or new manufacturing technologies of active substances

For all forms of innovation, a high level of investment in R&D, testing and approval is required. Even a minimal change of the molecular structure of a substance can result in the reduction of side effects, enhanced efficacy with a reduced dose, increased bioavailability in the body or new beneficial effects. Improvements of the pharmaceutical form can increase benefit, make application easier or improve the dosing regimen. Therefore, incremental improvements based on established active substances are an essential part of progress in the pharmaceutical industry, as in other economic sectors (such as the automobile and computer industries).

New technologies contribute to manufacturing and availability of goods in greater quantities, improved quality or at reduced costs. Biotechnology is only one such example, which has allowed the recombinant microbial production of insulin to replace pancreatic tissue from animals as a source of this vital hormone. This not only avoided supply shortages, but also reduced side effects. Especially in therapies which are very expensive due to a complex manufacturing technology, these innovations can improve the safety of a drug, its availability for patients and reduce the burden for the health care system at the same time.

Phases of pharmaceutical drug research and development in the EU

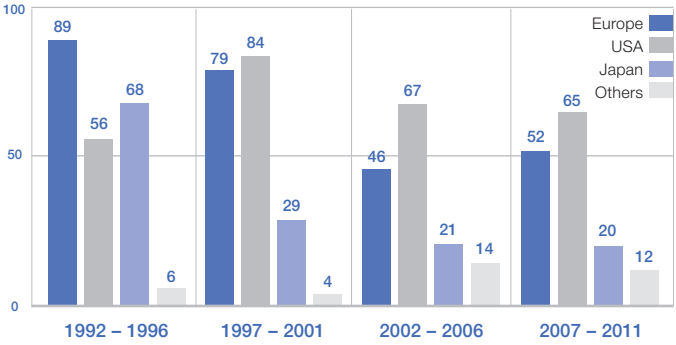


Source: Illustration of the BPI based on the European Federation of Pharmaceutical Industries and Associations (EFPIA) 2012.

Pharmaceutical companies often have less than 10 years to market a new product and to earn back the start-up costs, generate profit for investment into R&D and to compensate for losses in the development process. The high development costs in relation to the short period of market exclusivity forces global product launches, favoring big multinational enterprises with the necessary financial capacity. These have increased in number in the past years through numerous mergers and acquisitions; this process is still ongoing.

Despite this trend and rising costs for development for pharmaceutical companies in Europe - the European Federation of Pharmaceutical Industry and Associations (EFPIA) reports an increase of 2.3 billion Euros to 27.5 billion Euros between 1980 and 2011 - the number of newly introduced active substances decreased markedly.

New active substances (new chemical or biological entities – NCE/NBE) 1991 – 2011 sorted by originator countries worldwide



Source: Illustration of the BPI based on data of the EFPIA 2012.

In order to accurately calculate the development costs for pharmaceutical drugs, the regulatory framework - especially the reimbursement policies - within which the pharmaceutical industry operates must be reliable. While regulatory requirements are mainly regulated centrally, reimbursement policies are regulated by each country on a national level. The ability to plan costs is an essential basis for investment decisions in the R&D sector. Unfortunately, the situation in Germany has not improved in the last years, as demonstrated by the passage and implementation of 23 legislative reform acts in the health care sector since 1989. If this trend continues it is hardly predictable what the situation concerning reimbursements and the market environment for a development program initiated now will look like in 8 to 12 years when the product will be ready for launch. As such, the economic

basis required for innovations – the ability to plan costs – is missing for companies which mainly generate their turnover in Germany. The Act on the Reform of the Market for Medicinal Products (AMNOG) and the SHI System Modification Act passed in 2010 are a case in point: the SHI Modification Act is a cost-cutting measure which put in a place a particularly long price moratorium until end of 2013 as well as an increase of the mandatory discounts by 10 %, especially for innovative medicinal products. The AMNOG is associated with especially drastic changes for pharmaceutical companies. The early benefit assessment in particular sets a completely new course for the reimbursement policy regarding new pharmaceutical drugs in Germany and also raises complex questions regarding methodology and implementation. Through the international reference pricing system, by which over 80 countries worldwide reference German pharmaceutical drug prices, this development has global implications. The Act to improve the health care service delivery by the SHI funds (2011) and the 16th Amendment of the German Medicines Act (2012) have also changed the regulatory framework, even if the scope of these changes was relatively small.

In the context of the current discussion surrounding health care spending, the topic of the costs for the development of a new active substance, which was estimated to be 900 million USD in 2003 and up to 1.3 billion USD in 2006, is brought up again and again. These evaluations were based on a record of the overall development costs for new chemical or biological substances in relation to the actual number of newly authorised pharmaceutical drugs. Therefore, the costs for failed development programs and so-called opportunity costs, i.e. the profit that could have been generated with the capital used during the development period, are included in these estimates. These costs are not abstract; instead, they reflect the realistic expectations of the investors regarding returns on investment during drug development.

Only an estimated one or two out of 5,000 to 10,000 substances screened during pharmaceutical drug development will eventually achieve marketing authorisation status, and not every marketed product is economically successful. It should also be noted that there is much public controversy regarding these figures. If the pure out of pocket expenses are considered, the expenditures are still in the range of 540 million USD. Even critics estimate the costs for the development of new active substances within the range of several 100 millions of Euros. Apart from the discussion surrounding the appropriate methodology for this calculation, the key point is therefore still the same: the development of innovative pharmaceutical drugs is a very complex, risky and tedious process.

The high costs are interpreted in a way that smaller companies do not have a stake in the innovation process, as the required expenditures cannot be financed with turnovers of less than several billion. However, this does not take into account that smaller companies, especially from the life sciences field, are often the starting point for new innovations which are then sold to larger companies during the development process. Therefore, companies of all sizes function as elements of an innovation system. In addition, one must not overlook that significant innovations are also possible with considerably lower financial expenditures, especially when it is possible to access previously published data. Among other things , this concerns the improvement of well-established pharmaceutical drugs with new formulations or research on new indications or new target patient populations.

Many current treatment standards were developed on the basis of these incremental improvements. Despite this, such innovations are not appreciated as such by the public or by

decision makers in politics and management. Therefore, they are not considered in the framework definitions, as is clearly seen in the Act on the Reform of the Market for Medicinal Products (AMNOG), which focuses on medicinal products whose effects are not well-known to the medical community at the time of first authorisation. The framework for improving medicinal products with established active substances has not improved with the AMNOG. Research on new pharmaceuticals based on well-established active substances and the improvement of the corresponding legal framework is of great importance, especially for location-bound, mainly medium-sized companies, as they only have limited resources available for investment into research and development.

In order to make optimal use of opportunities for therapeutic progress, interdisciplinary work, cooperation and networking between competent partners is essential. Cooperation between the scientific community and companies of all sizes is therefore an important factor for the development of pharmaceutical drug innovations.

Therapeutic progress in this context is what offers advantages for patients in comparison to existing therapies, e.g. active substances for thus far untreatable illnesses, improved efficacy, fewer side effects or improved usability. One impressive example of the latter type of innovation is found in HIV treatments. Since its introduction in 1996, the number of daily tablets required in highly active anti-retroviral therapy (HAART) was reduced from more than 20 to only one! This not only significantly improved the quality of life of patients, but also helped avoid medication errors.

At the time of marketing authorisation, which is based on quality, efficacy and safety criteria, it is hardly possible to make a valid statement on whether or not a new product is better than an existing therapy because available data from clinical studies is often insufficient. Only when advantages are achieved in diagnostics or therapy in medical practice and an increased benefit for patients can be proven does the innovation represent true therapeutic progress. The patient's benefit as well as other clinical, economical and humanitarian results of health-related measures in the individual or the population is the subject of the field of Outcomes Research (OR).

Bio-engineering and genetic engineering

The innovation process in pharmaceutical drug development is mainly driven by progress in the life sciences. New methods and findings in the complex metabolism processes of living cells, cell compounds, organs and living beings make it increasingly possible to understand the development of diseases in detail on a molecular level and to develop targeted therapies and medicines. The active substances can either be small synthetic molecules or biological molecules. Biological molecules are either chemically similar to or even identical with endogenous substances. They are therefore suitable for treating diseases caused by a deficiency of endogenous substances, e.g. the administration of insulin in diabetics, administration of erythropoetin (EPO) in renal disease or cancer or the use of the growth hormone somatotropin in growth deficiency. In the past, these substances had to be isolated from body parts of humans or animals in a complex procedure and could hardly be obtained in sufficient quantities. Furthermore, the transmission of diseases in the manufacturing process of could not always be avoided.

These restrictions were overcome by modern biotechnology and genetic engineering. Today there are already nearly 200 medicines approved on a biotechnological basis in Germany, 150 of these are products of genetic engineering. These represented approximately 17 % of the turnover in the pharmacy market in 2010. Biotechnology has therefore ceased to be a futuristic vision, and instead provides real everyday benefits for patients. Insulins constitute the main share of the global market, followed by immunomodulators, and erythropoietin, as well as vaccines and other hormones.

Other molecules are monoclonal antibodies – whose significance keeps growing in the therapy of cancer-, receptor molecules, enzymes and receptor antagonists. Meanwhile, the first products based on DNA or RNA are also available. There are numerous new therapy approaches, which will lead to the development of completely new products medium or long term. Further areas with dynamic development are gene therapy, tissue engineering and regenerative medicine. Subsequent to new developments in genetic analysis, personalized medicine is also on the rise.

After the authorisation of the trifunctional antibody Removab (Catumaxomab, Fresenius Biotech GmbH, developed in Germany in cooperation with TRION Pharma GmbH) in 2009 for the treatment of malignant ascites, one new authorisation was granted to the German biotech company Biofrontera in 2011 for a new active substance (Arneluz) for the treatment of actinic keratosis.

According to the 2012 Biotechnology Report of Ernst & Young, there were 301 active substances in the development pipeline in 2011, including the non-clinical development stage, which represents stagnation. The number of active substances decreased by 1% versus the previous year (304 active substances). This shows a trend toward cost-saving measures as a result of the difficult financing situation: while 15 development projects were discontinued in 2010, 27 such projects were discontinued in 2011. The plateau in the number of new active substances is also linked to a shift in the number of active substances in the different stages of clinical studies (phase I-III): the number of active substances in phase I increased significantly from 47 to 53, relative to 2011. The number of active substances in phase II development decreased from 82 to 75, while the number of actives in phase III remained constant at 14. The decrease in phase II is linked to the discontinuation of 11 development projects which did not reach the required “proof of concept” milestones in human subjects.

The long timeframes for pharmaceutical drug development and their reasons were already discussed the section “Research and development of pharmaceutical drugs” (p.14). In this context it is not surprising that in terms of development of ready-to-market products with marketing authorisation, the German biotech companies continue to lag behind in comparison to the USA, where the biotechnology sector developed much earlier. In Europe, Great Britain leads in this field with 218 clinical development programs in progress, followed by Germany (142), Denmark (125) and Switzerland.

The development of biotechnological pharmaceutical drugs and therapies still has enormous potential. With the decoding of the human genome, increasing understanding of the function of proteins and peptides, and their extremely complex interactions due

to systems biology, the knowledge base keeps growing. With the aid of bioinformatics, new techniques are developed in order to extract essential and required information from the enormous data volumes available. Integrating the different fields of knowledge will result in the development of new active substances, completely new mechanisms of action and therapy approaches.

Nowadays the individualization of therapies is already noticeable, as well as testing of individual drug effects or side effects of pharmaceutical drugs due to the use of pharmacogenomic or metabolomic testing in the context of "stratified medicine", which analyses differences between patient groups and bases different therapeutic approaches on these findings.

Besides this, new perspectives in the field of "biosimilars" are opening up. This term is used to describe biologically active substances marketed as a generic preparation after the patent protection of the original pharmaceutical drug has expired. They are called biosimilars because biological molecules show minor differences and therefore are not completely identical. For this reason, the effort for testing and authorisation of biosimilars is significantly higher than for other generics and the expected price drop is not as significant as it is for other pharmaceutical drugs. The European Medicines Agency (EMA) granted the first marketing authorisations for biosimilars for the European market in 2006.

In the long run, a better understanding of pathomechanisms and treatment options developed on this basis will result in therapies for currently untreatable diseases. Aside from this primary goal, there is also the expectation that new revolutionary treatment approaches (e.g. by preventing the manifestation of a disease or by treating the disease's root cause instead of its symptoms) will result in lower treatment costs.

In Germany - especially since the mid-nineties and due to public financial support - a biotechnological industry has developed on the basis of start-up and spin-off companies, which, according to data provided by Ernst & Young, achieved a turnover of over one billion Euros (1.091 million Euros) in 2011, which is an increase of 10 % relative to 2010.

The majority of these companies developed diagnostics, pharmaceutical drugs, therapies and associated technologies and methods.

The biotechnology sector in 2010 (in million Euros, changes compared to the previous year in %)

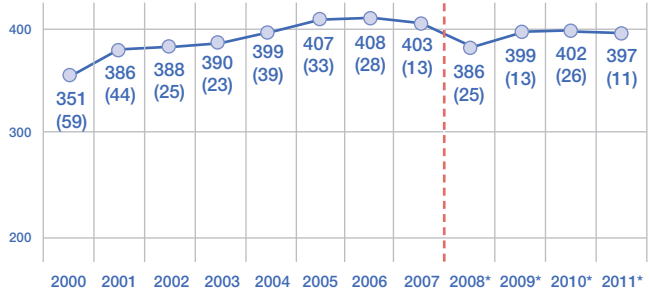
	2010	2011	
Turnover (in mill.)	989	1,091	10 %
R&D expenditures (in mill.)	752	783	4 %
Number of companies	402	397	- 1 %
Number of employees	9,650	10,053	4 %

Source: Illustration of the BPI based on data of Ernst & Young 2012.

The number of biotechnology companies decreased slightly in 2011 compared to the previous year: based on data of the German Biotechnology Report 2012 by Ernst & Young there were 397 companies compared to 402 in the previous year. In this context it needs to be considered that the different sources these data are based on used different definitions for counting biotechnology companies. The core segment defined by Ernst & Young focused on pure biotechnology companies. Big enterprises and companies that are not solely involved in biotechnology are not included. The data collection of “biotechnologie.de”

is based on a definition that includes the fields of industrial and green biotechnology, which counted 552 companies in 2011 (538 in 2010). The number of companies comprising the core segment has remained constant in the past years at around 400 firms. The number of start-up companies has stagnated at the level of an all-time low: Ernst & Young reports 11 start-ups, biotechnologie.de reports ten (previous year: eight). While Ernst & Young reported 11 new start-ups, the report also showed that 17 firms had disappeared: 13 due to insolvency / disbanding, four due to acquisitions and mergers. When making these comparisons it is important to keep in mind that tracking the number of start-ups is difficult and that sometimes new information received in the following years requires an upward adjustment of the numbers.

Number of biotech companies (start-ups in brackets)



* new statistical classification prevents a direct comparison of values from previous years.

Source: Illustration of the BPI based on data of Ernst & Young 2012.

Mergers and acquisitions of firms have gained great significance in the biotech field, leading to a slight decline in the number of companies, but also larger and more powerful structures, retaining assets and jobs in Germany.

This trend continued in 2010 with ten M&A-transactions, but has decreased to four M&A in 2011. This is a result of the negative impact of the decreased availability of financing options in the life sciences sector. The statistics of the past years show how volatile this environment is. The capital inflow fell from 257 million euro in 2008 to 153 million Euro in 2009, then rebounded to 441 million Euro in 2010. An all-time low of 130 million Euro was reached in 2011.

Despite the difficult financing situation, there are excellent future prospects for medical bioengineering considering the products already launched on the market, the products advanced in development as well as the products constantly moving up from fundamental research. A requirement for this is a predictable and stable health care system. This especially applies to reimbursement policies, because the basis for decisions made on investments in R&D are the refinancing conditions, i.e. reimbursement policies in the pharma market. The Act on the Reform of the Market for Medicinal Products (AMNOG) with its fundamental changes of the reimbursement policies in Germany is therefore of great significance for whole biotech sector, affecting not just mature companies, but also start-ups, since investors will make their decisions in the context of projected returns and risks resulting from the AMNOG.

Continuous monitoring of pharmaceutical drug safety / pharmacovigilance

The WHO defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

The legal requirement for a pharmaceutical company to maintain an adequate pharmacovigilance system is defined in the German Medicines Act (AMG), which reflects the national implementation of the EU Directive 2001/83/EC (as amended with the Directive 2010/84/EU in the context of the "pharma package"). For example, this law requires all marketing authorisation holders in Germany to to report all cases involving serious adverse reactions occurring in Germany to the relevant national authority within 15 days (see §63c "Zweites Gesetz zur Änderung arzneimittelrechtlicher und anderer Vorschriften").

The Paul-Ehrlich-Institute (PEI) is the responsible national competent authority for vaccines, blood preparations and sera; for all other medicines, this is the Federal Institute for Drugs and Medical Devices (BfArM). The European Medicines Agency (EMA) is responsible for process implementation on the European level, and issues recommendations, which are then implemented in all member states through decisions of the European Commission in a legally-binding manner.

In order to comply with these reporting requirements, pharmaceutical companies are required to appoint a responsible person for pharmacovigilance (or, according to German law, the so-called Stufenplanbeauftrager). This person is responsible for collecting and evaluating safety information and for coordinating necessary measures to be taken. This person is personally liable for his or her activities. On a national (German) level, the so-called "Stufenplan" per § 63 German Medicines Act serves to monitor, collect and evaluate risks associated with pharmaceutical drugs.

When safety measures are deemed necessary to protect patients, these measures are implemented immediately. Usually, these measures are implemented by the pharmaceuctical company, but sometimes they result from direct requirements imposed by the competent national or European authorities. The graduated plan described in the AMG regulates which measures should be implemented by the pharmaceutical company to improve patient safety. These measures include changing the patient information leaflet or even taking the drug off the market. Many pharmcovigilance procedures (so-called referrals) are primarily triggered on a European level and coordinated by the EMA and run as Urgent Union Procedures (Regulation (EC) 726/2004 as amended by Regulation (EU) 1235/2010 in context of pharma package).

Identification of side effects in clinical trials

The data collected on side effects in clinical trials (i.e. under ideal controlled conditions) is not representative for the use of the drug in daily practice. On the one hand, the pre-defined inclusion and exclusion criteria for clinical trials narrow down the target population to such an extent, that extrapolating from this population to the general public is not always valid. On the other hand, the frequencies of adverse drug effects in these relatively small patient collectives is often lower than the frequencies reported later in the general population.

As a result, certain side effects, for example those occurring with specific underlying conditions or with certain concomitant medications, are often not identified in the clinical trials.

The monitoring of drugs under the conditions of everyday practice, i.e. after market authorisation, is of the highest importance for furthering drug safety and so for quality management of treatments.

Reports of side effects

According to the BfArM, the authority received around 49,866 individual case reports of adverse reactions originating in Germany in 2011, including both initial reports and reports with follow-up information on the same case. The majority of these reports were submitted by the pharmaceutical industry (85%). The total number of reports originating in Germany remained

nearly constant relative to the previous year's reporting volume, whereas the number of reports originating outside the EU has continued to increase.

According to the PEI, 16,553 adverse reaction reports were received in 2011. Two-thirds of these were spontaneous reports, one third originated from clinical trials, mostly with monocolonal antibodies. The number of reports related to monoclonal antibodies has continued to increase, along with the number of reports transmitted by pharmaceutical companies. In 35 % of the reported cases, the patient made a full recovery. In 34 % of the cases, no follow-up information was available on the cases, despite attempts made to acquire this information.

EU-wide exchange of safety data

In the field of drug safety (pharmacovigilance), the swift exchange of information between the individual competent authorities of the EU member states is of great significance. For that reason, the EU has created graduated information systems where, depending on urgency, the respective required procedures are applied. A so-called Rapid Alert System concerning pharmacovigilance is used whenever one of the member states identifies a suspected change of the benefit-risk ratio of a given pharmaceutical drug which might require changes to the approval status.

Both German national competent authorities cooperate closely with the local state authorities, and with those of other European nations. There are also close contacts with authorities of countries outside of Europe, the World Health

Organization (WHO), the pharmaceutical drug commissions of the health care professions, as well as with pharmacovigilance centers that collect reports of adverse drug effects.

“Rote Hand Brief” as a direct health professional communication

The “Rote Hand Brief” is an instrument for direct health professional communications concerning information on newly identified, significant risks concerning the use and administration of pharmaceutical drugs and measures for risk mitigation.

The statutes and codices of the pharmaceutical industry associations BPI and VFA oblige their members to communicate important information concerning pharmaceutical drug safety, in consultation with the national competent authorities, to health professional circles. This may include information on new serious side effects, recalls of defective lots, and other information that needs to reach the attending physicians directly to ensure patient safety. The members of the pharma associations are required to use the symbol of a red hand with the wording “Important information concerning a pharmaceutical drug” on envelopes as well as on letters. In particularly urgent instances, it is necessary to also communicate this information verbally, via fax or through the public media (press, radio, television).

The global pharmaceutical market

In 2011, the global turnover of pharmaceutical drugs totaled 684 billion Euro (953 billion US-Dollars), an increase of 8.3 % compared to the previous year.

Development of the global pharmaceutical market

	2007	2008	2009	2010	2011
Total market (billion Euro)*	521.6	571.6	594.8	631.4	684.2
Total market (billion US-Dollars)	726.4	796.1	828.4	879.4	952.9
Change compared to previous year (in %)		9.6	4.1	6.1	8.4

* The Euro values are based on a recalculation of the market data of the base values in US Dollars (Exchange rate: US Dollars in Euro = 1: 0.718)

Source: Illustration of the BPI based on data of IMS World Review 2012.

More than 75 % of the total turnover of the global pharmaceutical market is generated by North America, Europe and Japan. The turnover in North America increased by 3.3 % to 247.4 billion Euros Dollars, which represents 36 % of the global pharmaceutical turnover in 2011. At the same time, the European pharmaceutical market increased by 6.5 % to 189.3 billion Euros, while Latin America increased its pharmaceutical turnover significantly in 2011 by 11.7 % to almost 48.8 billion Euros.

Top 10 pharmaceutical markets worldwide and growth to LCD* (in %)

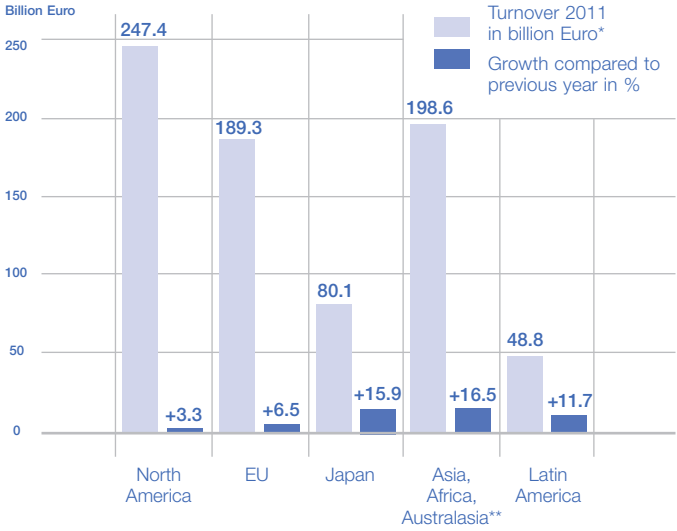
Country	Turnover 2011 (million US -Dollars)	Growth to LCD 2011 (%)*	Turnover 2011 (million Euro)**
USA	322,290	3	231,404
Japan	111,642	5	80,159
China	66,805	16	47,966
Germany	44,916	2	32,250
France	41,197	1	29,579
Brazil	28,465	17	20,437
Italy	28,357	2	20,360
Spain	22,679	- 2	16,284
Canada	22,294	- 1	16,007
Great Britain	21,564	2	15,483

* LCD: Local currency dollar – currency fluctuations in the country are not considered, so the growth rate in the various countries is comparable.

** The Euro values are based on a recalculation of the market data of the base values in US Dollars (Exchange rate: US Dollars in Euro = 1: 0.718)

Source: Illustration of the BPI based on data of IMS World Review 2012.

Global pharmaceutical market by region 2011



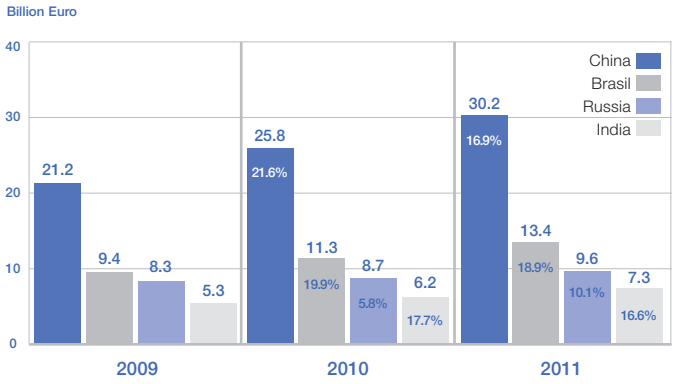
* The Euro values are based on a recalculation of the market data of the base values in US Dollars (Exchange rate: US Dollars in Euro = 1: 0.718)

** The Region "Asia, Africa, Australasia" includes Japan.

Source: Illustration of the BPI based on data of IMS World Review 2012.

The economic influence of the three emerging markets Brazil, Russia, India and China (summarized under the expression "BRIC") has increased significantly in the last years. This development also includes the pharmaceutical sector. The turnover with pharmaceuticals in 2011 in these countries totaled ca. 60.5 billion Euros, which constitutes an increase of 16.1 % versus the previous year (ca. 52.0 billion Euros). The pharmaceutical turnover has increased continuously in all four markets over the past three years. In contrast to the more pessimistic prognoses for other pharmaceutical markets worldwide, the outlook for the BRIC countries' pharmaceutical markets foresees continued growth in turnover. The significance of these markets for the pharmaceutical industry will continue to increase in the next years.

Turnover* in BRIC countries 2009 – 2011
(Changes relative to previous year in %)



* The Euro values are based on a recalculation of the market data of the base values in US Dollars (Exchange rate: US Dollars in Euro = 1: 0.718)

Source: Illustration of the BPI based on data of IMS World Review 2012.

Overall, the health care market is a growing market with considerable employment potential. To date, many diseases are still untreatable, while increasing life expectancy and changing consumer interest, as well as the search for a higher quality of life, have increased the demand for health-related services and products. In addition, advances in the fields of medicine and pharmacy, particularly in molecular and cellular biology, generate novel innovation incentives. Furthermore, a trend toward personalized medicine in the form of individualized diagnostics and treatments is evident.

The European Pharmaceutical Market

Upon closer analysis, these pharmaceutical markets are heterogeneous with regards to market size and market development.

Pharmaceutical markets of the EU-15

EU member state	Turnover* for 2011 (Million USD)	Growth*** to LCD 2011 (%)	Turnover* for 2011 (Million Euro)****
Germany**	44,916	2	32,250
France**	41,197	1	29,579
Italy**	28,357	2	20,360
Spain**	22,679	-2	16,284
Great Britain**	21,564	2	15,483
Belgium**	6,513	2	4,676
Greece	6,133	-2	4,404
The Netherlands	5,313	0	3,815
Sweden**	4,523	2	3,248
Portugal	4,486	-7	3,221
Austria**	4,310	2	3,095
Denmark**	2,734	-1	1,963
Finland**	2,595	1	1,863
Ireland**	2,442	-4	1,753
Luxembourg	243	1	174
Total	198,005	0,7*****	142,168

* Turnovers from the markets observed, plus estimation of partial markets not observed, result in the total turnover of a member state at manufacturer price.

** Pharmacy market and hospital market data were available for these markets.

*** LCD: Local currency dollar - currency fluctuations in the individual member state are not reflected, allowing comparisons between the individual member states.

**** The Euro values are based on a recalculation of the market data of the base values in US Dollars (Exchange rate: US Dollars in Euro = 1: 0.718)

***** The total growth in LCD 2011 of 0.7% is a weighted value (unweighted: -1.5%)

Source: Illustration of the BPI based on data of IMS Health World Review 2012.

Pharmaceutical pricing and reimbursement are regulated in different ways in different countries. However, a common feature of these markets in an increasing competition in the generics sector.

The analysis of the annual turnover in the EU-15 in 2011 shows that, in absolute volume, Germany, France, Italy, followed by Spain represent the largest pharmaceutical markets. In terms of growth rates compared to the previous year, however, Germany, Italy, Great Britain, Belgium, Sweden and Austria outstrip the other countries with a weak growth rate of around 2%.

In the following, selected eastern and central European member states with special economic relationships will be looked at in more detail.

Total pharmaceutical market of central and eastern Europe* 2011

Turnover in million Euro**

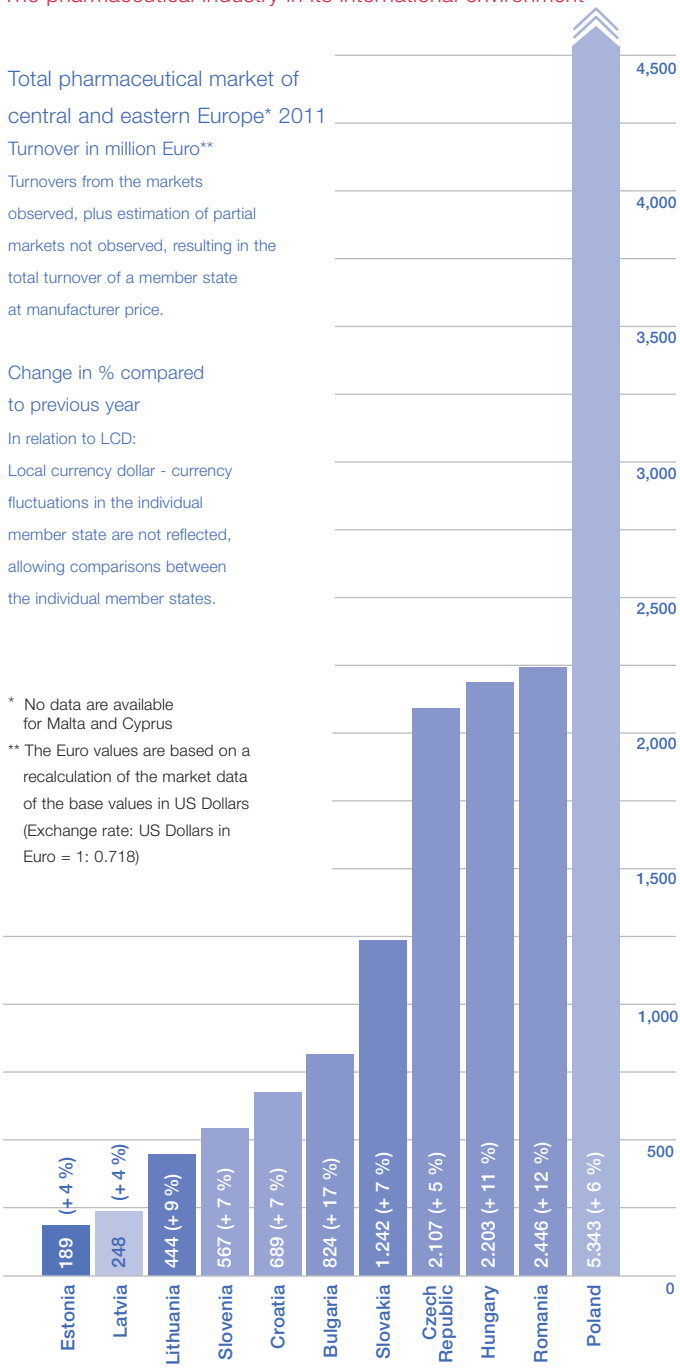
Turnovers from the markets observed, plus estimation of partial markets not observed, resulting in the total turnover of a member state at manufacturer price.

Change in % compared to previous year

In relation to LCD:
Local currency dollar - currency fluctuations in the individual member state are not reflected, allowing comparisons between the individual member states.

* No data are available for Malta and Cyprus

** The Euro values are based on a recalculation of the market data of the base values in US Dollars (Exchange rate: US Dollars in Euro = 1: 0.718)



Source: Illustration of the BPI based on data of IMS World Review 2012.

Over the next five years, IMS Health is 0.7 % is predicted for non-EU member states. The five most important EU markets are expected to grow by 0.6 %.

Market prognosis using constant exchange rates, growth in %, manufacturer price.

Europe	2010 – 2015
EU top five member states	0.6 %
EU member states	-0.8 %
Non-EU member states	0.7 %
Global market	4.5 %

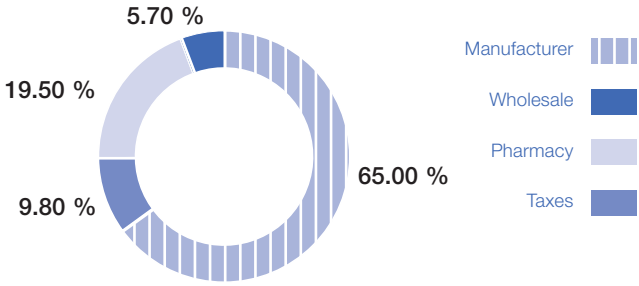
Source: Illustration of the BPI based on data of IMS Market Prognosis Global 2012.

International Comparison of Pharmaceutical Drug Prices

A pharmaceutical product varies in price from country to country for various reasons, including simple factors such as different VAT. In addition, direct governmental intervention often regulates the profit margins allowed to different trade levels (e.g. pharmacies, wholesalers). These factors account for the pricing variance across Europe. When conducting international comparisons of pharmaceutical drug prices, it is important to note that this is only possible based on individual trade levels. For example, when selecting the dominant trade level in Germany, it is necessary to verify if this trade level is also dominant in other countries or at least has sufficient market relevance. Also, the data based on the manufacturer price is not available for all countries, so that the prices may need to be recalculated. Political influences on

pricing and reimbursement, as well as national prescribing and treatment habits also impact on drug pricing. When conducting overall market comparisons, volume adjustments are necessary.

Pharmaceutical price structure in Europe (2010)
– Based on pharmacy retail price



The values constitute a unweighted mean value for Europe.

Source: Illustration of the BPI based on EFPIA 2012.

The graph of the pharmaceutical price structure shows the share of each individual trade level in the pharmaceutical drug prices in Europe. This clearly illustrates that the drug manufacturers are not the only group influencing drug prices, as the pharmacy retail price also contains components contributed by other factors such as distribution and VAT.

Value Added Tax (VAT) rates in Europe (as of 1 September 2012)

Country	Standard VAT rate (%)	VAT rates applied to drugs Prescription (%)	OTC (%)
Belgium	21.0	6.0	6.0
Bulgaria	20.0	20.0	20.0
Denmark	25.0	25.0	25.0
Germany	19.0	19.0	19.0
Estonia	20.0	9.0	9.0
Finland	23.0	9.0	9.0
France[1]	19.6	2.1	7.0
Greece	23.0	6.5	6.5
Great Britain[2]	20.0	0.0	20.0
Ireland[3]	23.0	0.0 - 23.0	0.0 - 23.0
Iceland	25.5	25.5	25.5
Italy	21.0	10.0	10.0
Croatia	25.0	0.0	25.0
Latvia	22.0	12.0	12.0
Lithuania[4]	21.0	5.0	21.0
Luxembourg	15.0	3.0	3.0
Malta	18.0	0.0	0.0
The Netherlands	19.0	6.0	6.0
Norway	25.0	25.0	25.0
Austria	20.0	10.0	10.0
Poland	23.0	6.0	6.0
Portugal	23.0	6.0	6.0
Romania	24.0	9.0	24.0
Sweden	25.0	0.0	25.0
Switzerland	8.0	2.5	2.5
Slovakia	20.0	10.0	10.0
Slovenia	20.0	8.5	8.5
Spain	18.0	4.0	4.0
Czech Republic	20.0	14.0	14.0
Hungary	27.0	5.0	5.0
Cyprus	15.0	5.0	5.0

[1] Pharmaceutical drugs eligible for reimbursement: 2.1%; Pharmaceutical drugs not eligforible reimbursement: 7.0 %

[2] Non-prescription drugs: 20.0 %, pharmaceutical drugs prescribed by NHS: 0 %

[3] pharmaceutical drugs for oral administration: 0%, others: 23.0%

[4] Pharmaceutical drugs eligible for reimbursement 5.0 %; Pharmaceutical drugs not eligible for reimbursement: 21.0 %.

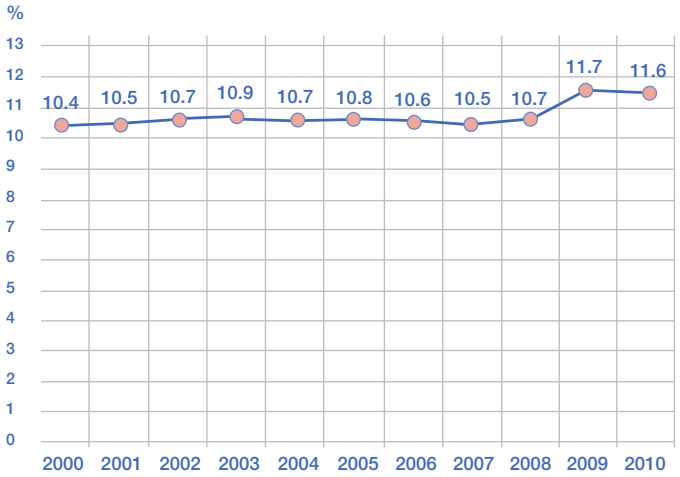
Source: Illustration of the BPI based on ABDA 2012.

When comparing the VAT rates applied to pharmaceuticals, it may be noted that only Bulgaria, Denmark, Germany, Iceland and Norway apply the full standard VAT rate.

The Health Care Market in Germany

When analyzing expenditures, it is important to note that a conclusive evaluation based solely on these figures is not possible, especially when comparing health systems internationally. This requires a more detailed and in-depth analysis of, for example, organizational structures or social circumstances and frameworks. However, the percentage of the GDP that a society dedicates to its health care system reflects the importance that society places on the health care system. Therefore, a high percentage of GDP dedicated to health care does not necessarily constitute wasteful spending.

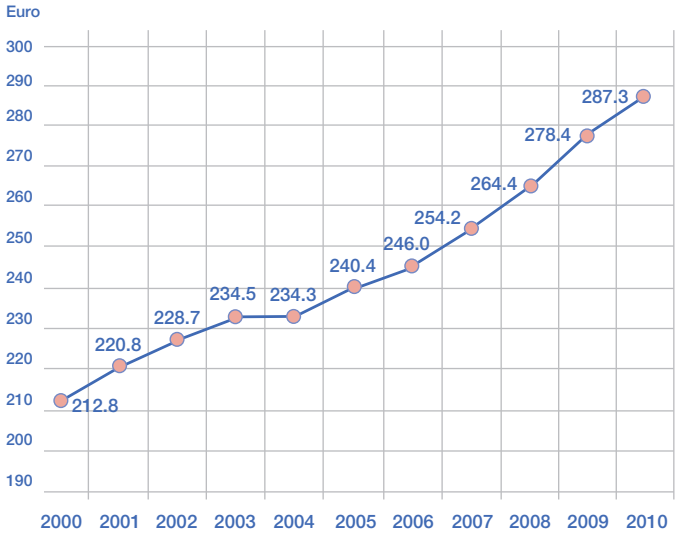
Development of health care expenditures – share of the GDP in %



Source: Illustration of the BPI based on data of the Federal Statistical Office 2012.

The share of health care expenditures of the GDP has remained relatively stable in Germany over the course of the years: between 2000 and 2008, this percentage has been between 10.4 % and 10.7 %. The relative increase to be seen in 2009 and 2010 is partially due to a statistical effect resulting from a decrease in the GDP during these two crisis years.

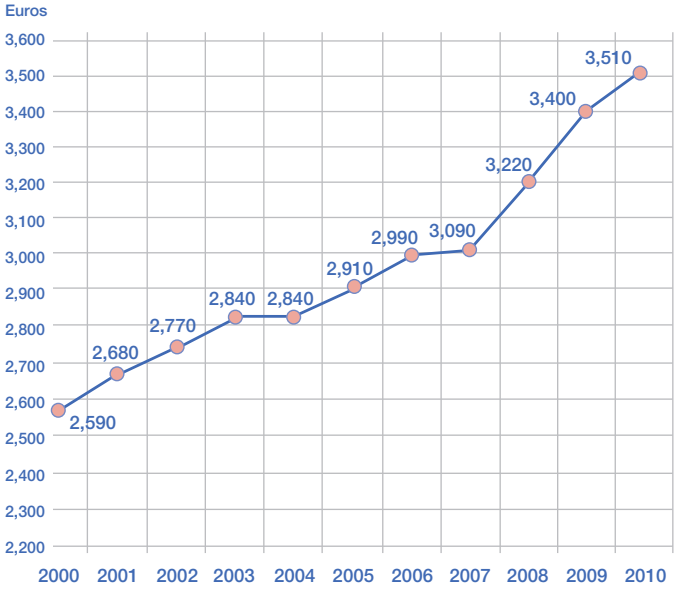
Development of nominal health care expenditures (in billion Euros)



Source: Illustration of the BPI based on data of the Federal Statistical Office 2012.

The nominal health care expenditures in Germany have been on the rise continuously since 1999 and, by 2010, were at 287.3 billion Euros. This constitutes an increase of 3.2 % compared to 2009. In the same period, health expenditures per inhabitant increased by 3.2 %, from 3,400 Euros in 2009 to 3,510 Euros in 2010.

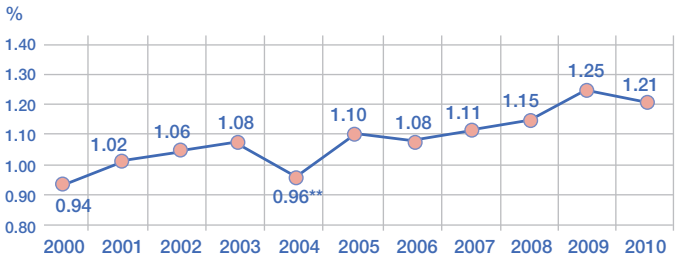
Development of health care expenditures per inhabitant (in Euros)



Source: Illustration of the BPI based on data of the Federal Statistical Office 2012.

In 2010, the share of the SHI expenditures for pharmaceutical drugs, expressed as a percentage of GDP, decreased by 0.04 % to 1.21 %.

Development of pharmaceutical drug expenditures of the SHI providers – Percentage of GDP



* Pharmaceutical drug defined according to health care expenditures calculation of Federal Statistical Office.

** OTC-drugs excluded from reimbursement by SHI

Source: Illustration of the BPI based on data of the Federal Statistical Office 2012.

According to current data for the crisis year 2010 from the Federal Statistical Office, more than 4.8 million people, i.e. ca. every ninth employee, were working in the German health care sector. The number of jobs in the health care sector rose by 1.9 % in 2010 compared to 2009. The primary cause of this rise is an increase of health professions (e. g. physicians and other medical staff) and social professions (e.g. geriatric care). In 2009, the largest number of staff was employed in outpatient, inpatient and day-patient care health care facilities.

Because of the ageing society in Germany with a structural shift towards older, multi-morbid people and increasing disease chronification owing to lifestyle and nutritional habits, the health care policy must find sustainable solutions. To do this, the potential of a strong, innovative, job-intensive health care sector must be strengthened, not weakened.

Health care policy interventions over the last years display a tendency toward encouraging competition between stakeholders, and toward integrative health care solutions. However, a financially sustainable health care system in Germany still seems to be a distant prospect.

The development of SHI expenditures is subject of health care political discussions on a regular basis. For many years, the SHI expenditures have been around 7.0 % of GDP (2010: 7.1 %). The SHI expenditures for drugs have been consistently around 1.21 % (2009: 1.25 %) of GDP and therefore show a slight decrease in 2010. The SHI expenditures for drugs did not increase faster compared to the general economic growth rate when taking the effects of the financial crisis into account. In view of this development, there is no evidence of a “cost explosion” in the health care sector.

The financial situation of the SHI is particularly influenced by structural problems on both the revenue and expenditure side.

The following factors may have a negative impact on the revenue side:

-> Increase in the number of mini-jobs
-> Loss of income subject to social insurance deductions
-> Stagnating earned income
-> Salary receipt with simultaneous increases in other sources of income
-> Decreasing pension payments with an increasing number of pensioners
-> Shift toward private health insurance
-> Short time work

Need for action on the expenditures side develops due to:

-> Medical and technological progress in combination with a shift in the ageing structure
-> Increase of chronic diseases
-> Remuneration increase for physicians working in outpatient care
-> Hospital tariff contracts
-> Expansion of the SHI services, e.g. palliative care
-> burden due to Value Added Tax (VAT) of 19 %
-> Implementation of the European legislation on working hours

The reforms during the past years have not led to a sustainable stabilization and restructuring of the financial situation of the SHI.

While the German Economic Optimization of Pharmaceutical Care Act (Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz, AVWG), introduced in 2006, mainly focused on cost reduction only of the expenditures for pharmaceutical drugs, the German Act to Reinforce Competition between the German Statutory Health Insurance providers (GKV- Wettbewerbsstärkungsgesetz) in 2007 aimed to foster competition in the health care sector. The Statutory Health Insurance Restructuring Act (GKV-ÄndG 2011) as well as the Act for restructuring the drug market (AMNOG) resulted in further regulatory measures in certain areas, in particular the supply of pharmaceutical drugs. The Statutory Health Insurance Restructuring Act constitutes a measure purely for cost reduction. From the perspective of the pharmaceutical industry, the increase in the mandatory discounts of a maximum of 16 % and the heretofore longest price moratorium lasting two and a half years are of particular importance. The burden placed on pharmaceutical companies by mandatory discounts amounted to 2.5 billion Euro in 2011 and is estimated to come to 2.5 billion Euro in 2012 as well. However, the AMNOG represents a significant paradigm shift in view of price formation for pharmaceuticals in Germany. In the future, the price determined by the manufacturer for an innovative pharmaceutical drug will only be reimbursed for the first year after market launch. The level of reimbursement after this first year will be largely determined by the results of the newly implemented early benefit assessment.

In the course of further reforms, the increasing trend toward standardization of therapies needs to be stopped. At a time where the pharmaceutical industry is ever more capable of developing individualized treatment options and applying them in medical practice, the manifold therapy options must not be restricted solely for the purpose of cost reduction, e.g. through treatment guidelines or exclusions published by the self-government of SHI providers.

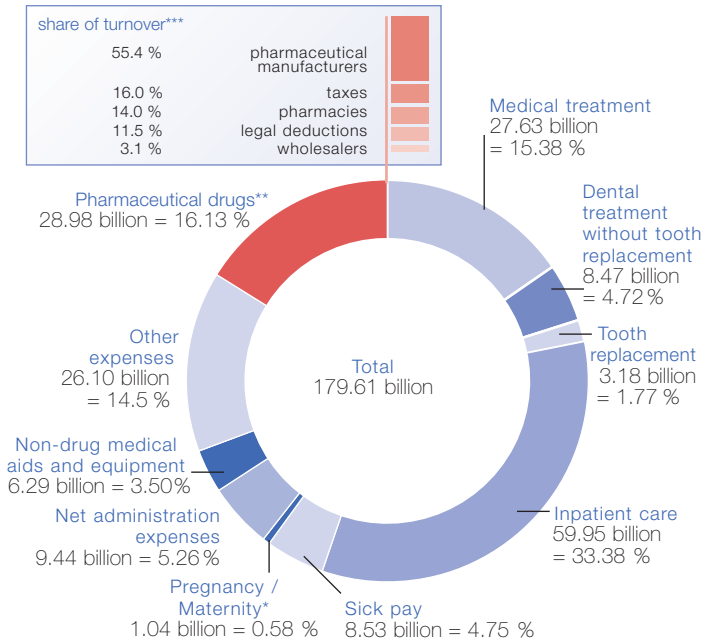
A first step toward a financially sustainable reform of the SHI system was performed with freezing the employer's contribution and uncapping the upper limit of the supplemental premiums. This way it was possible to partly decouple the health care costs and labor costs. Furthermore the supplemental premiums can be used as regulating measure of the SHI market. The insured persons are better able to make decisions in choosing his or her SHI provider.

In general, health care reforms should contribute significantly to deregulation and streamlining of administration in favor of increased personal responsibility and entrepreneurial freedom for the stakeholders concerned. The goal should be to allow the service providers in the health care sector to concentrate the greatest share of their energy on providing the best possible care to patients.

Cost Structure of the Statutory Health Insurance (SHI) System

According to the view of the national expert panel, the goal of cost limitation is always a "tightrope walk between withdrawal effects that cause increasing premiums, primarily outside the health sector, for consumers and investors, and the positive effects that are generated by health costs and the services financed by them" (expert opinion in 2003).

Cost structure of the Statutory Health Insurance (SHI) 2012
(in billion Euros and as % of all SHI-expenditures)



* without inpatient delivery

** including VAT. Legal obligatory discounts for pharmaceutical manufacturers and for pharmacies as well as savings due to voluntary rebate contracts of the pharmaceutical industry are accounted for.

*** including VAT. Legal obligatory discounts for pharmaceutical manufacturers and for pharmacies as well as savings due to voluntary rebate contracts of the pharmaceutical industry are not accounted for.

Source: Illustration of the BPI based on KJ1 2011; Drug prescription report 2012.

Inpatient care, at 59.95 billion Euros in 2011, is the most cost-intensive sector of the SHI system. The combined expenditures for pharmaceutical drugs (28.98 billion Euros) and for medical treatment (27.63 billion Euros) amount to 56.61 billion Euros, which accounts for nearly the total expenditures of the inpatient care sector. The share of pharmaceuticals expenditures alone was at 16.1 % of the total SHI expenditures.

When analyzing the SHI pharmaceuticals expenditures, the amounts the different trade levels contribute to these costs are often neglected, i.e. the proportion of the wholesalers' and pharmacies' margins, and the Value Added Tax. If a given pharmaceutical drug at manufacturer price costs one Euro, on average, one needs to add the wholesaler margin, the pharmacy margin as well as 19 % Value Added Tax. The retail price would total just about 12 Euros.

Irrespective of this, rising pharmaceutical expenditures, as well as falling point values of medical treatment, are predominantly caused by the increase of outpatient therapy options, as well as a shift from inpatient to outpatient care. The Diagnosis Related Groups (DRGs) and the resulting shorter inpatient stays are going to reinforce this tendency even more in the years to come. As in the past, the shift in services has not been followed by the required funding.

The broader public too often does not realize that manufacturers as well as pharmacists are required to grant an obligatory discount for the stabilization of the SHI expenditures.

SHI obligatory discounts***

SHI Market

Manufacturer discount August 2010 to end of 2013	Wholesaler discount	Pharmacy discount
• 16 % (65 + 10 % increase) Manufacturer discount for all SHI prescription drugs without a reference price (excluding off-patent drugs)* • 6 % for prescribed OTC drugs without a reference price • Price moratorium*** Based on manufacturer price not incl. VAT	**2010:** no wholesale discount **2011:** 0.85 % based on manufacturer price not incl. VAT in 2011 **Starting 2012:** Adjustment of the wholesaler margin for prescription drugs to a uniform discountable surcharge of 3.15 % and a fixed non-discountable surcharge (70 cents).	**2009, 2010:** Discount level for prescription drugs is currently subject to legal dispute. **2011, 2012: 2.05 Euros** Pharmacy discount for prescription drugs for 2011-2012 **5% of pharmacy's retail price:** Pharmacy discount for non-prescription drugs, 70 cents
10 % manufacturer discount for off-patent prescription drugs with the same active ingredient with and without a reference price**		

Private health insurance market: Manufacturer- and wholesaler discounts and price moratorium for prescription drugs.

* 6 % plus 10 % pursuant to § 130a Section 3b (capped at 16 %)

** If at least 30 % less than the respective reference price, then a) the 10 % discount is automatically dropped. With products with a reference price, the discount is determined based on the reference price. If the price of the product is below the reference price, the discount is based on the lower price.

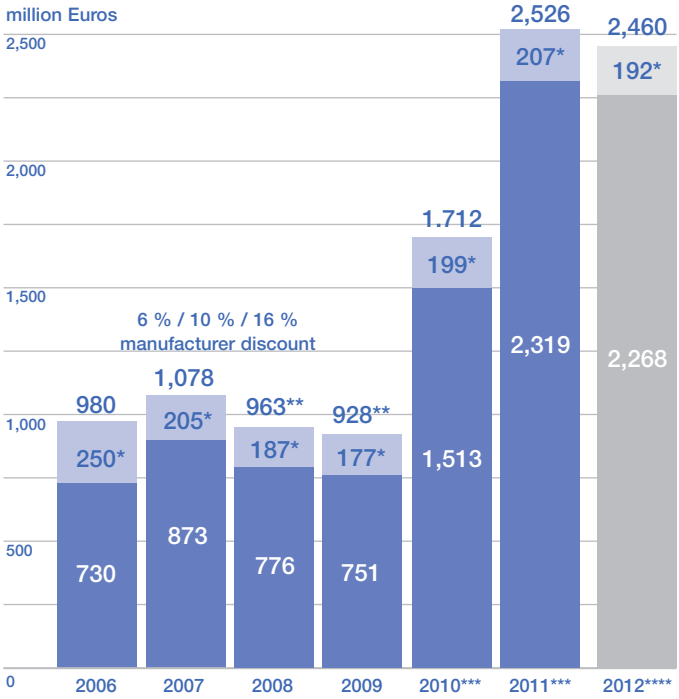
*** The price moratorium is in force from 1 August 2010 to 31 December 2013 at the pricing level of 1 August 2009.

Source: Illustration of the BPI analogous to IMS Health 2012.

The obligatory discounts have been mandatory since the solidarity tax was instituted in 2002 (200 million Euros), and they have been adapted several times. On 1 August 2010, the 6 % obligatory discount, which had been reduced in the beginning of 2005, was increased and capped at 16 %. The 16 % obligatory discount for off-patent drugs with the same active substance (as defined in the German Economic Optimization of Pharmaceutical Care Act) was kept in place, but capped at 16 %. Therefore, for drugs without a reference price, a mandatory discount of 16 % must be

paid on the manufacturer price since 1 August 2010. In addition, a price increase moratorium (versus the price levels of 1 August 2009) is in force from 1 August 2010 to 31 December 2013.

Cost burden of the pharmaceutical industry due to obligatory discounts 2006–2012 (in million Euros), manufacturer price in SHI market



* so-called "generics discount"

** Discount decrease due to (among other factors) the price moratorium ending in April 2008

*** price moratorium discount is included

**** Estimates for 2012; based on data for half of the year 2012, the mandatory discounts for the private health insurance (applicable since 2011) sector are not included

Source:: Illustration of the BPI based on IMS Health PharmaScope® 2012.

In 2011, the cost burden for the pharmaceutical industry due to the obligatory discounts amounted to approximately 2.5 billion Euros. In 2012 the cost burden is estimated to come to 2.5 billion Euro as well. The small- and medium-sized enterprises

are particularly hard hit by these additional costs because they are unable to cross-subsidize the expenditures from other parts of their product palette. Such political interventions contradict the official commitment to supporting small- and medium-sized enterprises. State interventions accelerate the consolidation of the market in favor of larger pharmaceutical companies or companies with very diverse product portfolios.

Discount / Rebate Contracts in the SHI System

Since 2003, the SHI providers have had the legal option (§ 130a sect. 8 German Social Code V) to negotiate individual rebate / discount contracts with pharmaceutical companies. In the first few years, this regulation had nearly no practical significance. However, with the Act to Reinforce Competition between the German Statutory Health Insurance (GKV-WSG) effective as of 2007, this instrument has rapidly gained momentum as a result of auxiliary measures, such as its relevance for the performance audits for doctors, reduced co-payments for patients and the legal requirement of preferential dispensing of rebated drugs in the pharmacies. Only after lengthy legal disputes about the application of distribution, competition and cartel laws and after involvement of the EU Commission was the Act to enhance the organizational Structures of Statutory Health Insurance passed. This law provides that when entering into contracts as per German Social Code V § 130a sect. 8, procurement law is applicable.

The Act for the Modernization of Procurement Law of 24 April 2009 is also of great importance. This regulation requires the calls for tender to be divided into partial and/ or specialist lots, something that can be helpful to small- and medium-sized enterprises. But the act also contains important regulations for legal protection of the stakeholders, in particular regarding the

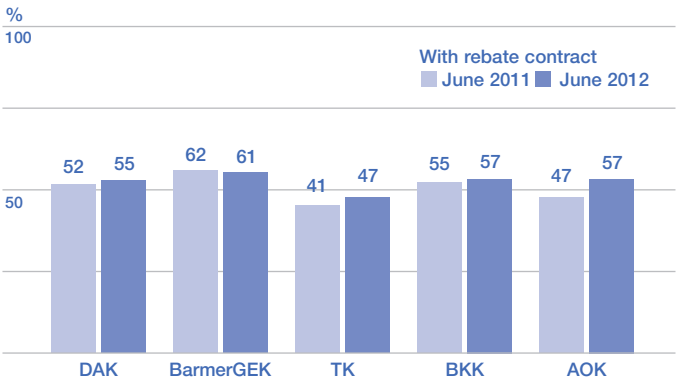
invalidity of illegal de facto procurement (§ 101b sect. 1 GWB). However, this invalidation only applies if a complaint is submitted to the procurement chamber within 30 days of obtaining knowledge of the contract or no longer than six months after the contract is signed (§101 b sect. 2 GWB).

With the coming into force of the Second Act amending the German Medicines Act and other regulations on 26 October 2012, the rule of public procurement law for old discount contracts that have been unlawfully signed, was abolished by lawful stipulation that such contracts become ineffective six months after the delivery month.

This could make legal questions not yet clarified, e.g. the obligation for call for tenders for rebate contracts for drugs under patent protection become virulent.

Meanwhile, the number drugs subject to rebate contracts is on a consistently high level for all SHI providers. In June 2012, the BEK (Barmer Ersatzkasse) had the highest market share of rebated drugs (61 %) in the generics segment.

Share of discounted drugs in different Statutory Health Insurance providers (market share in %)



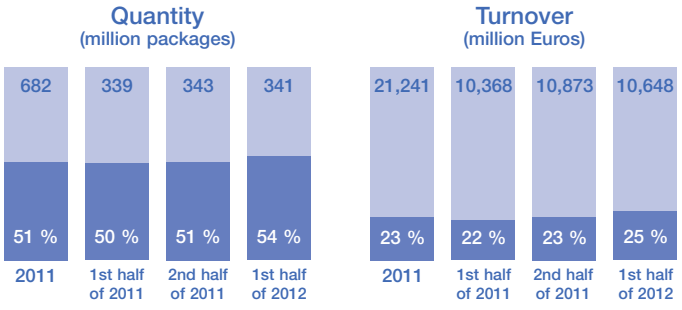
Source: Illustration of the BPI based on IMS Contract Monitor 2012.

According to IMS Health, more than half of the dispensed medications in the SHI market were subject to rebate contracts as of June 2012. In December 2010, 157 health insurance providers had 8,425 rebate contracts in place with 134 pharmaceutical companies covering 27,024 pharmaceuticals. In December 2011, 152 health insurance providers had contracts with 178 manufacturers according to IMS Health. There were 11,256 contracts in place covering more than 31,581 pharmaceuticals.

Being excluded from a rebate contract has the same effects as a partial exclusion from the market since the contractually set time period (usually two years) stipulates the preferred distribution of the discounted pharmaceuticals.

It is necessary to level the competitive playing field for all stakeholders in the health care market: all contractual arrangements between SHI providers and care givers and pharmaceutical companies need to be subject to cartel and competition regulations (GWB and UWG, respectively). As more and more SHI providers merge, the market leverage of the SHI providers is growing steadily.

SHI-market and pharmaceutical drugs subject to rebate contracts



Source: Illustration of the BPI based on IMS Contract Monitor 2012.

Regarding the applicability of cartel laws, changes in this direction were implemented pursuant to the coming into force of the Act on the Reform of the Market for Medicinal Products (Arzneimittelmarktneuordnungsgesetz – AMNOG), effective as of 1 January 2011. These changes particularly affect the regulations concerning formation of cartels (§§ 1-3 GWB) and the regulatory tools and sanctions allowed by the Federal Cartel Authority (Bundeskartellamt). In addition, the legislation changed the previously dual legal procedure for disputes arising with the SHI providers to a single procedure under solely civil jurisdiction.

In general, selective contracting between manufacturers and SHI providers is undertaken within a highly regulated system characterized by massive market interventions, as well as the monopolistic position of the SHI providers. The "regulation jungle" – including reference pricing and co-payment waivers – needs to be reviewed.

The Act on the Reform of the Market for Medicinal Products (AMNOG)

With the AMNOG coming into force on 1 January 2011, the procedure of the early benefit assessment was implemented as a tool in order to allow the assessment of the early benefit in relation to an adequate comparative therapy and to allow the negotiation of reimbursement for costs of innovative pharmaceutical drugs. For pharmaceutical drugs with new active substances under patent protection the pharmaceutical companies have to submit a dossier at the latest when the product is first placed on the market in Germany. This dossier is subject to an assessment of the Federal Joint Committee (G-BA). The result of the assessment serves as the basis for the Federal Association of Statutory Health Insurance Funds. The reimbursement sum is negotiated

as a discount on the manufacturer price. Without an agreement an arbitrative board has to make the decision on the reimbursement discount. The BPI with its paper position paper „Dezentral vor zentral“ was the first pharmaceutical industry association contributing to the discussion on a system for negotiation of reimbursement sums. The legislative body has considered many of the ideas, but made the decision for centralized negotiations at the end, which can only be complemented with decentralizjaed negotiations in the second place.

Until the beginning of October 2012 the G-BA has completed 27 assessment procedures. In three cases the obligation to submit a dossier was waived. This is only possible when the product is expected to only cause negligible expenses for the SHI. The assessment of negligibility is based on the data provided to the SHI about the expected costs and the expected turnover of the drug with the SHI. As long as the expenses for outpatient care do not exceed 1 million Euros within 12 calendar months they are regarded as negligible. However the applicant has to prove in practice that the turnover will remain below this limit also in the long run.

The previous decisions of the G-BA show that no product has yet achieved the highest possible category of additional benefit. A substantial additional benefit taking all assessed patient populations into account was only achieved six times. However, in nineteen cases, no additional benefit was determined. One reason for this is the balancing of benefit and risk on the endpoint level. This interim result of additional benefit assessment is disillusioning. Several products for which an assessment of the G-BA is available, were assessed by experts to be leap innovations, before the early benefit assessment was made.

The manufacturer of the drug Linagliptin applied for a repeated benefit assessment. According to the G-BA the manufacturer did not submit sufficient data for an additional benefit assessment versus the comparative therapy chosen by the G-BA. Therefore the G-BA did not certify an additional benefit for formal reasons. As a consequence, the drug would have had a reimbursement sum on the price level of the comparative therapy of the generic drug. The manufacturer therefore decided not to market the drug in Germany. To allow a speedy reassessment in such a situations, the § 35a SGB V was changed by the 16th Amendment of the German Medicines Act in such a way that the submission of a dossier is possible within one year, when the additional benefit was not proven in accordance with § 35a Abs. 1 Satz 5 SGB V. This allows access to a repeat benefit assessment and also the submission of complete documentation.

Up until 1 September 2012 there were three more cases besides Linagliptin, where the manufacturer decided not to market the product in Germany as a result of the benefit assessment. The decision was based on the fact that due to changes of the comparative therapy chosen by the G-BA no additional benefit was proven according to the G-BA.

Although the faster repeat submission of a dossier is possible now, one has to keep in mind that because of the benefit assessment the drug is not available to patients from the time of marketing authorisation. The AMNOG states that an additional medical benefit for Orphan Drugs is already evident through the marketing authorisation. This is consistent because an additional benefit for these drugs was already certified by the European Commission by granting the marketing authorisation. This confirms that with this drug a satisfactory therapy option is available for the first time or where another therapy is available the new drug proved to have a substantial benefit.

At first, the G-BA decided to delegate the assessment of the dossiers to the Institute for Quality and Efficiency in Healthcare (IQWiG; Institut für Qualität und Wirtschaftlichkeit). In the further course of the process the G-BA revised this approach and decided to perform the assessment procedure for orphan drugs below the turnover threshold of 500 Mio Euro as well. This change serves as an example for the further development of the procedure as a whole, which must be seen as a learning system.

* Assessed by Professor Hartmut Morck in the assessments of new drugs in the Pharmaceutical Journal.

The German Pharmacy Market

The developments in the German pharmacy market present a very heterogeneous picture. Compared to 2010, the total turnover in the pharmacy market assessed at manufacturer prices rose in 2011 by 2.1 % to a total of 26.2 billion Euros. For prescription drugs, there was an increase in turnover of 1.7 %. The turnover with OTC medications increased by 5.3 %.

Looking at the volume trends in the overall market reveals that there was a slight increase in 2011. The highest increase of 4.1 % compared to the previous year is found in the "controlled drugs" sector.

Turnover developments in the pharmacy market 2008–2011 (in million Euros)

	2008	2009	2010	2011	Change vs. previous year in %
Total	23,799.2	24,687.1	25,628.7	26,178.3	2.14
Prescription only	18,611.9	19,425.6	20,403.3	20,750.5	1.70
Pharmacy only	2,974.9	2,918.5	2,823.7	2,903.3	2.82
Non-drugs	1,294.2	1,364.8	1,407.8	1,500.4	6.57
Controlled drugs	717.2	789.5	814.8	835.9	2.59
GSL medicines	195.8	183.5	173.9	183.0	5.26
Drugs and Chemicals	5.3	5.2	5.2	5.2	- 0.41

Source: Illustration of the BPI based on data of Insight Health 2012.

Sales trends in the pharmacy market 2008–2011 (packages in millions)

	2008	2009	2010	2011	Change vs. previous year in %
Total	1,610.1	1,603.0	1,555.8	1,604.2	3.11
Prescription only	723.1	728.6	709.1	723.8	2.09
Pharmacy only	694.5	678.8	650.2	676.7	4.07
Non-drugs	135.1	137.1	140.5	146.1	3.99
Controlled drugs	47.4	48.2	45.4	46.5	2.52
GSL medicines	9.2	9.7	10.0	10.5	4.14
Drugs and Chemicals	0.6	0.6	0.6	0.5	- 4.90

Source: Illustration of the BPI based on data of Insight Health 2012.

* For this survey, the wholesale turnovers and the direct sales of manufacturers to pharmacies was recorded. Afterwards, these were re-assessed using the manufacturer price. Turnovers of manufacturers with hospitals are not included.

When comparing the development of the pharmaceutical drug segments in 2011 according to sub-categories, the largest growth in comparison to the previous year was found in the category "other products". This segment comprises products for body hygiene and dental care, injection equipment, disinfectants, sideline products, drugs, medical devices, chemicals, veterinary products and nutritional supplements.

Turnover development of pharmaceutical drug segments according to sub-categories 2008–2011 (in million Euros)

	2008	2009	2010	2011	Change vs. previous year in %
Total	23,799.2	24,687.1	25,628.7	26,178.3	2.14
Pharma. drugs for humans	17,982.7	18,678.6	19,180.9	19,383.1	1.05
Biopharmaceuticals	3,351.4	3,484.6	3,915.8	4,184.4	6.86
Phytopharmaceuticals	734.9	780.8	807.7	882.2	9.22
Other*	828.2	805.5	775.9	755.3	- 2.66
Diagnostics	606.0	632.0	646.3	667.1	3.22
Homeopathic medicines	252.2	258.5	252.8	253.3	0.22
Anthroposophic medicines	43.8	47.1	49.3	52.8	7.16

* Hygiene products, injection equipment, disinfectants, sideline products, drugs, medical devices, chemicals, veterinary medicines, nutritional supplements, dietary products

Source: Illustration of the BPI based on data of Insight Health 2012.

In terms of volume, only anthroposophic medicines and diagnostics increased in 2011 (5.6 % and 4.3 %, respectively). The sales volumes homeopathic medicines decreased by 1.5 % compared to the previous year.

Sales volumes of pharmaceutical drug segments according to sub-categories 2008–2011 (in million packages)

	2008	2009	2010	2011	Change vs. previous year in %
Total	1,610.1	1,603.0	1,555.8	1,604.2	3.11
Pharma. drugs for humans	1,259.5	1,251.1	1,209.2	1,252.3	3.57
Biopharmaceuticals	132.0	129.5	126.2	125.5	- 0.51
Phytopharmaceuticals	115.1	117.2	117.1	122.1	4.31
Other*	51.5	52.4	49.4	48.7	- 1.53
Diagnostics	27.5	28.3	29.1	30.3	4.32
Homeopathic medicines	17.6	16.8	16.8	16.7	- 0.44
Anthroposophic medicines	6.9	7.6	8.1	8.5	5.61

* Hygiene products, injection equipment, disinfectants, sideline products, drugs, medical devices, chemicals, veterinary medicines, nutritional supplements, dietary products

Source: Illustration of the BPI based on data of Insight Health 2012.

In Germany, over 100 pharmaceutical companies with highly qualified staff are engaged in producing anthroposophic and homeopathic medicines. Germany is the market leader in the fields of phytopharmaceuticals, anthroposophic and homeopathic medicines. The medicines are used all across the European Union. In Germany alone, there are some 60,000 physicians who regularly prescribe homeopathic and anthroposophic medicines. Outside of Europe, the homeopathic field enjoys global popularity, especially in the USA, Central and South America, Asia, India, and South Africa. Anthroposophic medicine is especially popular in North and South America, as well as in Australia and New Zealand.

An analysis of the Top 10 indications according to the Anatomical Therapeutic Chemical Classification (ATC-3) shows an overall increasing trend in sales volumes. Compared to the previous year, the largest growth (9.7 %) was in the field of anti-platelet treatments, followed by analgesics (7.9 %).

Top 10 leading indication areas (ATC-3)
in the pharmacy market 2011 by sales volumes

Indication areas (ATC - 3)	Packages in thousands	% to prev. year	share of total turnover in %	share of total sales in %
Total	1,604,210.8	3.11	100.00	100.00
N02B other analgesics	155,530.5	7.90	9.70	2.04
R01A nasal preparations, topical	78,581.2	6.54	4.90	0.67
R05C expectorants without anti-infectants	66,355.0	3.52	4.14	0.99
V03X other therapeutic preparations	43,562.1	- 2.47	2.72	0.73
M01A anti-phlog. /anti-rheumat., non-steroid.	42,678.0	2.27	2.66	0.75
A02B ulcer treatments	41,918.9	- 1.44	2.61	1.84
C07A beta-blockers, pure	39,881.4	6.12	2.49	0.73
M02A anti-rheumat. and analgesics, topical	33,011.3	5.50	2.06	0.61
B01C anti-platelet treatments	28,426.6	9.72	1.77	1.20
N05B hypnotics and sedatives	27,962.2	4.12	1.74	0.47

Source: Illustration of the BPI based on data of Insight Health 2012.

The turnover developments in the Top 10 indications according to ATC-3 show the highest increases (as compared to the previous year) in anti-TNF preparations and “other immunosuppressants”. The share of these two groups in the total turnover in the pharmacy market was 6.1 % in 2010.

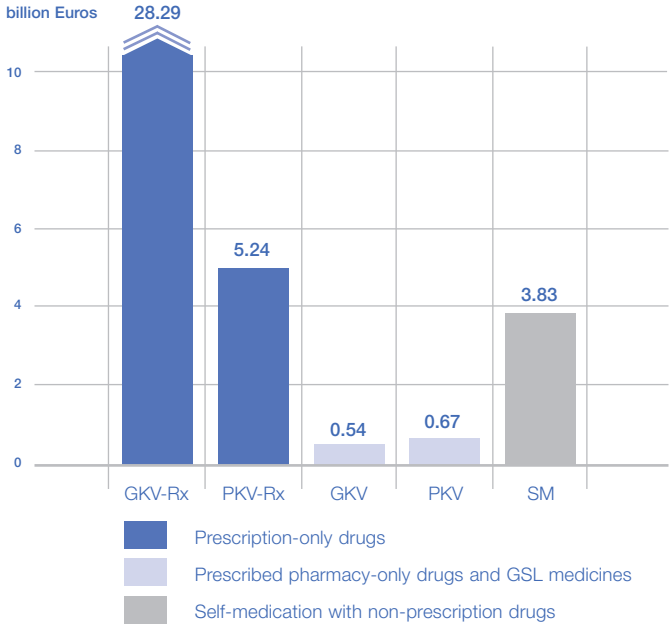
Top 10 leading indication areas (ATC-3)
in the pharmacy market 2011 by turnover

Indication areas (ATC - 3)	in thousand Euro	% to prev. year	share of total turnover in %	share of total sales in %
Total	26.178.271,4	2,14	100,00	100,00
L04B Anti-TNF preparations	995.620,4	14,85	3,80	0,02
A10C Human insulin and analogs	890.129,4	2,35	3,40	0,78
L01X Other antineoplastic agents	888.954,5	1,73	3,40	0,06
N05A Antipsychotics	848.608,2	3,83	3,24	0,85
N02A Analgesics, narcotics	740.201,1	3,15	2,83	0,45
C09D Angiotensin II antagonists	679.230,5	4,40	2,59	0,62
L03B Interferons	677.711,8	4,12	2,59	0,02
N03A Antiepileptics	650.126,9	6,64	2,48	0,71
T02D Diabetes tests	609.461,7	3,36	2,33	1,67
Lo4X Other immunosuppressants	586.874,6	14,67	2,24	0,12

Source: Illustration of the BPI based on data of Insight Health 2012.

The following illustrations show different segments of the drug market in pharmacies. For prescription-only drugs IMS Health determined a total turnover of 33.53 billion Euro (pharmacy retail price) for the year 2011. The share of turnover on the expenses of the SHI was 28.29 billion Euros (84.4 %) in 2011. The turnover with prescribed OTC drugs on SHI expenses and private health insurance was 0.54 billion Euros and 0.67 billion Euros, respectively. Self medication with OTC drugs came to approximately 3.83 billion Euros.

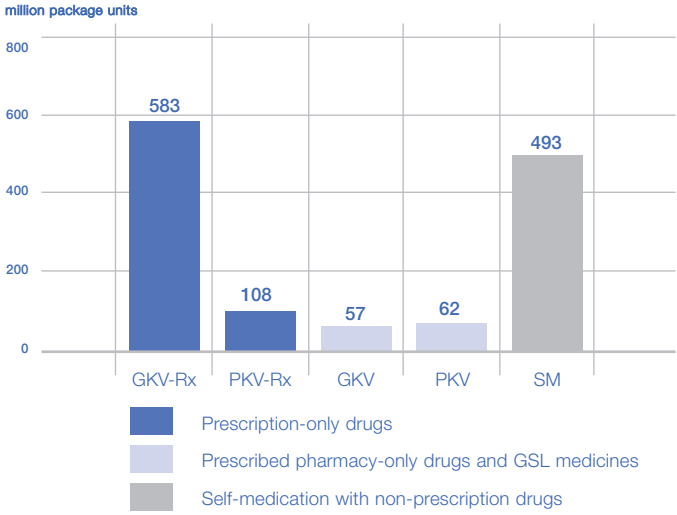
Turnover of pharmaceutical drugs in pharmacies 2011 at pharmacy retail prices (in billion Euros)



Source: Illustration of the BPI based on data of Insight Health 2012.

57 million package units of OTC drugs were reimbursed by the SHI in 2011, while 493 million package units were bought for self medication.

Sales volumes of the drug market in pharmacies 2011
(in million package units- PE)



Source: Illustration of the BPI based on data of Insight Health 2012.

The reason for the differences between turnover and sales volumes can mainly be seen in the different pricing levels of the drugs under review. The average pharmacy retail price of a prescription-only drug dispensed on prescription was approximately 48.35 Euros per package, which is clearly above the average price of 6.98 Euros of a non-prescription drug.

The price difference between prescription-only drugs and drugs available without a prescription reflect the different competitive environments of these products. Non-prescription drugs are well-established, have been on the market for some time and often have generic competitors. This segment of highly active products also contains many phytopharmaceuticals. The segment of prescription-only drugs contains many newly developed products, some of them still under patent protection and whose higher price contributes to covering the high costs of research and development.

The SHI pharmaceutical market

The SHI pharmaceutical market gives an overview of prescriptions as well as turnover financed by the SHI system. Turnovers are calculated on the basis of the pharmacy retail prices; therefore, they include the respective wholesaler and pharmacy margins, as well as VAT.

Number of prescriptions paid for by the SHI system 2009 – 2011

Subcategory	2009	2010	2011
Total	676,958,920	676,552,490	679,628,159
Pharmaceuticals*	638,823,909	638,734,304	642,102,799
Diagnostics	22,770,938	23,930,917	24,283,575
Other**	6,260,798	5,874,304	5,662,074
Phytopharmaceuticals	5,859,069	5,255,591	5,033,748
Homeopathic medicines	2,396,609	1,949,986	1,764,349
Anthroposophic medicines	847,597	807,388	781,614

* including biopharmaceuticals

** Hygiene products, injection equipment, disinfectants, sideline products, drugs, medical devices, chemicals, veterinary products, nutritional supplements, dietary products

Source: Illustration of the BPI based on data of Insight Health 2012.

In 2011, an overall volume of 680 million prescriptions were financed through the SHI system. The share of pharmaceuticals in the total prescription volume is around 94.5 %. Looking at the development of the volume of prescriptions, it becomes clear that the volume of prescribed diagnostics has continuously increased, currently making up 3.6 % of the total volume of prescriptions. Phytopharmaceuticals are prescribed in 0.7 % of cases, homeopathic medicines in 0.3 % of cases.

Turnover financed by the SHI system 2009 – 2011, pharmacy retail price in Euros

	2009	2010	2011
Total	30,880,287,408	31,922,997,011	32,146,568,910
Pharmaceuticals*	29,671,775,178	30,692,702,100	30,921,324,085
Diagnostics	903,715,628	945,558,363	954,985,504
Other**	177,029,258	166,160,834	156,614,034
Phytopharmaceuticals	81,393,450	77,043,742	75,467,060
Anthroposophic medicines	23,678,175	22,622,640	20,671,800
Homeopathic medicines	22,695,718	18,909,332	17,506,426

* including biopharmaceuticals

** Hygiene products, injection equipment, disinfectants, sideline products, drugs, medical devices, chemicals, veterinary products, nutritional supplements, dietary products

Source: Illustration of the BPI based on data of Insight Health 2012.

Development of market shares as financed by the SHI system 2009 – 2011 in %

	Prescription volumes			Turnover		
	2009	2010	2011	2009	2010	2011
Total	100.00	100.00	100.00	100.00	100.00	100.00
Pharmaceuticals*	94.37	94.40	94.48	96.09	96.15	96.20
Diagnostics	3.36	3.54	3.57	2.93	2.96	2.97
Other**	0.92	0.87	0.83	0.57	0.52	0.49
Phytopharmaceuticals	0.87	0.78	0.74	0.26	0.24	0.23
Anthroposophic medicines	0.13	0.12	0.12	0.08	0.07	0.06
Homeopathic medicines	0.35	0.29	0.26	0.07	0.06	0.05

* including biopharmaceuticals

** Hygiene products, injection equipment, disinfectants, sideline products, drugs, medical devices, chemicals, veterinary products, nutritional supplements, dietary products

Source: Illustration of the BPI based on data of Insight Health 2012.

In looking at turnover, it is clear than the turnover in pharmaceuticals 2011 was 32.2 billion Euros or 0.7 % above the levels in the previous year. The market share of pharmaceuticals is 96 %. The relatively small share of phytopharmaceuticals (0.2 %) in SHI spending is primarily due to the lower average price for such products. The same applies to homeopathic medicines, which account for 17.5 million Euros or a mere 0.56 % in SHI expenditures.

Top 10 leading indications (ATC-3) in the SHI market 2011 by sales volumes

Indications (ATC -3)	Prescriptions	% to prev. year	% share of total volume	% share of total turnover
Total	679,628,159	0.45	100.00	100.00
N02B other analgesics	36,656,504	3.17	5.39	1.98
M01A anti-phlog. / antirheumat., non-steroid	36,119,241	0.43	5.31	1.80
C07A beta-blockers	35,278,702	2.61	5.19	1.71
A02B ulcer treatments	29,042,774	4.28	4.27	2.51
C09A ACE inhibitors, pure	25,072,461	1.48	3.69	1.01
T02D diabetes tests	23,775,606	1.56	3.50	2.81
C03A diuretics	21,549,841	- 0.27	3.17	1.22
H03A thyroid preparations	21,474,589	5.13	3.16	1.04
N06A antidepressants / mood stabilizers	20,181,103	4.10	2.97	2.43
C08A calcium antagonists, pure	18,087,251	- 0.32	2.66	0.90

Source: Illustration of the BPI based on data of Insight Health 2012.

When looking at sales volume in 2011, the “thyroid preparations” and “ulcer treatments”, followed by “antidepressants / mood stabilizers”, showed the highest growth rates. This group corresponds to 10.4 % of the total turnover.

Top 10 leading indications (ATC-3) in the SHI market 2011 according to turnover

Indication areas (ATC-3)	In million Euros	% to previous year	% share of total volume	% share of total turnover
Total	32,146.6	0.70	100.00	100.00
L04B Anti-TNF preparations	1,244.9	13.40	3.87	0.05
A10C human insulin and analogs	1,216.0	1.87	3.78	1.75
N05A antipsychotics	1,187.9	3.36	3.70	1.78
N02A analgesics, narcotics	951.4	2.85	2.96	0.96
T02D diabetes tests	902.9	0.68	2.81	3.50
N03A antiepileptics	869.0	6.08	2.70	1.39
C09D angiotensin-II antagonists, combinations	819.2	4.65	2.55	1.22
L03B interferons	813.8	2.33	2.53	0.05
L01X other antineoplastic agents	813.1	4.45	2.53	0.08
A02B ulcer treatments	806.3	- 12.15	2.51	4.27

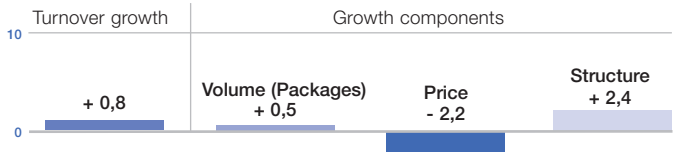
Source: Illustration of the BPI based on data of Insight Health 2012.

With respect to turnover in 2011, the “anti-TNF preparations” followed by “antiepileptics” had the highest growth rate in comparison to the previous year. The highest decline was seen for ulcer treatments (12.15 %).

The SHI structural component

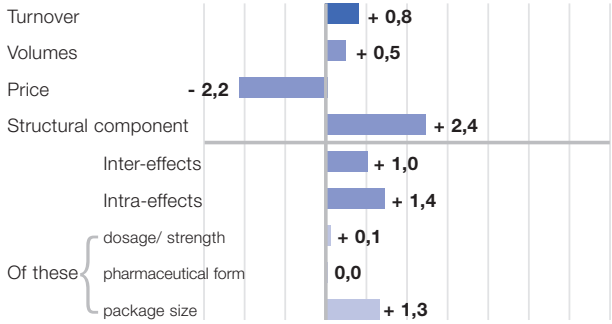
The structural component allows a detailed analysis of trends in factors affecting SHI pharmaceutical expenditures. It is possible to identify to what extent there has been a trend toward the prescription of innovative and patented pharmaceutical drugs. The structural effect comprises different effects attached to a specific product (package size, dosage/ strength and pharmaceutical form) and effects within and/or among pharmaceutical segments as well as indication groups. The SHI structure component study of IMS HEALTH, as a quantitative instrument of market research and health care policy, shows the individual components (price, volume and structure) of changes in turnover.

Growth components in the SHI pharmaceutical market, 2011
(changes to previous year in %)



Source: Illustration of the BPI based on data of the IMS® SHI-Structural component study 2012.

Growth components in 2011 as a cause of the turnover developments in the SHI market, divided into sub-groups (in %), pharmacy retail price



Price basis: pharmacy retail price including VAT, without rebates
Source: Illustration of the BPI based on data of the IMS® SHI-Structural component study 2012.

In 2011, the IMS structural component was 2.4 %. In the past, this component has ranged between 5 % and 8 %. While the price level in the SHI pharmaceutical market decreased by 2.2 %, the volumes increased by 0.5 %.

By simple addition, one can generate the individual components - e.g. the structural component “package size”- for the individual dosage forms, the product in general, as well as at the hierarchy levels above. The SHI market is described based on the pharmacy retail prices, including VAT. The structural component study shows changes for four different segments.

The “Pharmaceutical Atlas” published by the Institut für Gesundheits- und Sozialforschung (IGES) uses the ATC classification, similar to the IMS structure component analysis. The IMS structure component analysis examines all ATC groups (ATC 1 to ATC 4) and thus allows for indication-oriented analysis of the individual growth factors at all levels.

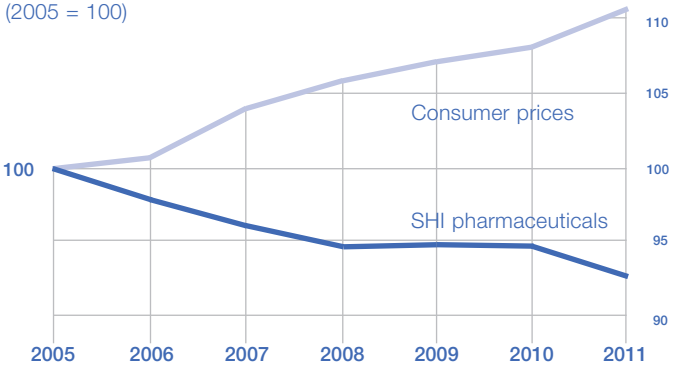
The “Pharmaceutical Atlas” of the IGES takes a different approach. The essential difference to IMS is in the different definition of the components. When it comes to structure of the turnover components, the IGES looks at consumption, treatment approach, generics, dosage/package size, manufacturer and pricing components. There are detailed analyses for the 30 indications with the most prescriptions. The quantitative unit of measure used in the Atlas refers to the Defined Daily Dose (DDD). The IMS HEALTH structure component analysis is based on quantitative units such as packages units or tally units.

It has been shown that changes in pricing, volumes and quality all have an influence on expenditures. Innovative pharmaceuticals, which generate high costs in development, naturally have a higher price level, but they also contribute significantly to the treatment of previously untreatable or insufficiently

treatable diseases, offering a significant benefit to the affected patients. At the same time, many well-established (often generic) drugs are available for the treatment of less severe diseases. These drugs' price levels have been trending downward since 2006, though the actual price level is obscured by rebate contracts.

The SHI-Pharmaceuticals Index, which is based on a slightly different calculation method compared to the figures of the IMS structural analysis, also confirms this decline in drug prices in the SHI system for 2011, especially when compared with the development of consumer prices.

Price development for pharmaceuticals
Price indices in comparison
(2005 = 100)



Sources: Illustration of the BPI based on data of the WidO and the Federal Statistical Office 2012.

The consequences of the major interventions into the german pharmaceutical market due to the Statutory Health Insurance Restructuring Act (GKV-ÄndG) and the Act on the Reform of the Market for Medicinal Product (AMNOG) are displayed in the illustration below. The prices in the reference price market as well as the non-reference price market are continuously decreasing.

Price development according to market segments
between January 2010 – July 2012 (January 2010 = 100)

Source: Illustration of the BPI based on data of the WidO 2012.

The OTC Market

The turnover developments in the German pharmacy market in 2011 with pharmacy-only drugs, non-pharmacy-only drugs and health products (GMS, Gesundheitsmittel)* is still dominated by pharmacy-only drugs at 78 % (sales volumes: 77.5 %), while health products and non-pharmacy-only drugs have a share of 17.2 % and 4.8 %, respectively. However, for the past years, the share of health products in the pharmacy market has been increasing (share in turnover 2006: 13 %, in 2011: 17.2 %). When one looks at the corresponding sales volumes, however, it is clear that there were significant price increases, while the increases in sales volumes were relatively moderate (share in sales volumes 2006: 15.3 %; in 2011: 16.9 %).

In comparison to the previous year, the OTC market in 2011 showed slight decreases (sales volumes: -2.2 %; turnover: -0.7 %) to levels below those in 2004, the year the health care modernization act eliminated, with a few exceptions, reimbursement of non-prescription drugs.

* GMS: Defined as products competing with pharmaceutical drugs.

Development of turnover in the German OTC pharmacy market

Turnover in thousand Euros at pharmacy retail price

	2006	2007	2008	2009	2010	2011
Pharmaceutical drugs						
- Pharmacy-only	5,294,711	5,285,794	5,108,196	4,978,771	4,822,819	4,729,806
- OTCs	334,815	328,635	316,233	298,569	283,469	290,286
GMS pharmacy	845,954	833,337	899,387	961,019	999,495	1,045,569
Total	6,475,480	6,447,766	6,323,816	6,238,359	6,105,783	6,065,661

Market share in %	2006	2007	2008	2009	2010	2011
Pharmaceutical drugs						
- Pharmacy-only	81.8	82.0	80.8	79.8	79.0	78.0
- OTCs	5.2	5.1	5.0	4.8	4.6	4.8
GMS pharmacy	13.0	12.9	14.2	15.4	16.4	17.2
Total	100	100	100	100	100	100

Source: Illustration of the BPI based on data of IMS Health 2012.

However, if one takes into account the pharmacy mail-order business the turnover from this business compensates for the decreasing turnovers.

Development of sales volumes in the German OTC pharmacy market

Volume in thousands of package units

Packages	2006	2007	2008	2009	2010	2011
Pharmaceutical drugs						
- Pharmacy-only	653,090	641,636	619,023	607,719	585,504	571,376
- OTCs	48,958	46,965	45,093	44,204	41,508	41,204
GMS pharmacy	127,207	123,271	122,142	126,733	126,309	124,388
Total	829,255	811,872	786,258	778,656	753,321	736,968

Market share in %	2006	2007	2008	2009	2010	2011
Pharmaceutical drugs						
- Pharmacy-only	78.8	79.0	78.7	78.0	77.7	77.5
- OTCs	5.9	5.8	5.8	5.7	5.5	5.6
GMS pharmacy	15.3	15.2	15.5	16.3	16.8	16.9
Total	100	100	100	100	100	100

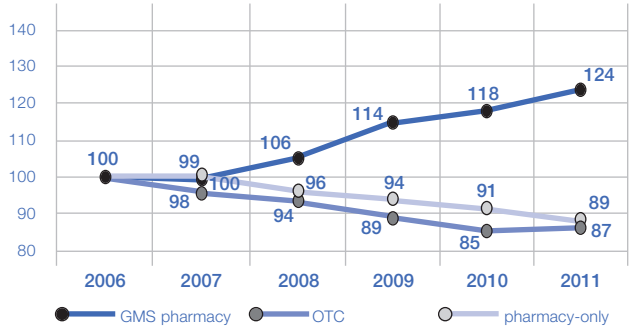
Source: Illustration of the BPI based on data of IMS Health 2012.

Meanwhile the mail-order distribution channel has reached a market share of 11 %. However, a decrease of the previously two-digit growth rates is to be seen. Within the previous year, the pharmacy mail-order business grew by 8 % in turnover with OTC drugs and health products (sales volumes +9 %). Still, as the available data for the mail-order business remain inaccurate it is difficult to conclusively assess this distribution channel and its development. Especially strong brands and large package sizes often have a far greater share, sometimes up to 30 %.

Every fifth non-prescription product sold in pharmacies is also a non-pharmacy-only product (share in sales volumes: 22.5 %; share in turnover: 22 %) and 3/4 of these products are not even drugs. As shown in the following images, the development of health products in terms of sales volumes is relatively stable, while turnover / sales volumes of pharmacy-only and OTC drugs show a downward trend.

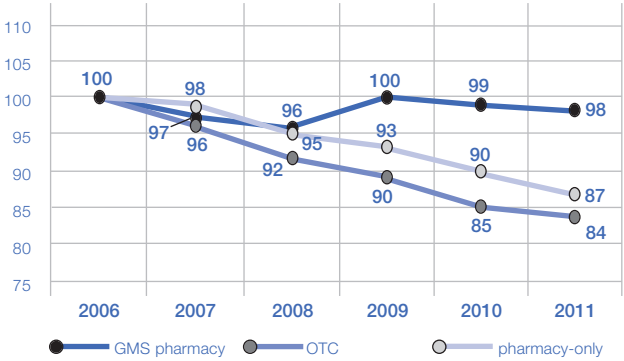
Indexed illustrations of turnover and sales development of over-the-counter drugs in the German pharmacy market (index comparison, based on turnover (pharmacy retail price) 2006 = 100; based on sales volumes: units 2006 = 100)

Developments in turnover (index)



Source: Illustration of the BPI based on data of IMS Health 2012.

Developments in sales volumes (index)



Source: Illustration of the BPI based on data of IMS Health 2012.

In the category of non-drugs, higher quality products are increasingly on offer. As an example, the average price of a non-drug health product sold in pharmacies increased from 6.65 Euros in 2006 to 8.41 Euros in 2011.

In 2011, the average pharmacy retail price of a product on the German pharmacy market was 8.23 Euros. The average price in the category with the highest sales volumes (pharmacy-only drugs) was 8.28 Euros in 2011, and is therefore slightly higher than the average price in 2010 and is also 2.1 % higher than the average pharmacy retail price in 2006. Therewith, the price of high quality -, OTC – and pharmacy-only drugs remained stable over years and they secure the drug supply for self medication.

Average pharmacy retail price for OTCs in the pharmacy market

Prices in Euros	2006	2007	2008	2009	2010	2011
Pharmaceutical drugs						
- Pharmacy-only OTCs	8.11	8.24	8.25	8.19	8.24	8.28
- Non-pharmacy OTCs	6.84	7.00	7.01	6.75	6.83	7.05
GMS* pharmacy	6.65	6.76	7.12	7.58	7.91	8.41
Mean value **	7.81	7.94	8.04	8.01	8.11	8.23

* GMS: Defined as products competing with pharmaceutical drugs.

** Mean value (weighted by sales volumes in each category)

Source: Illustration of the BPI based on data of IMS OTCGMS Report 2012.

The number of pharmaceutical drugs in Germany

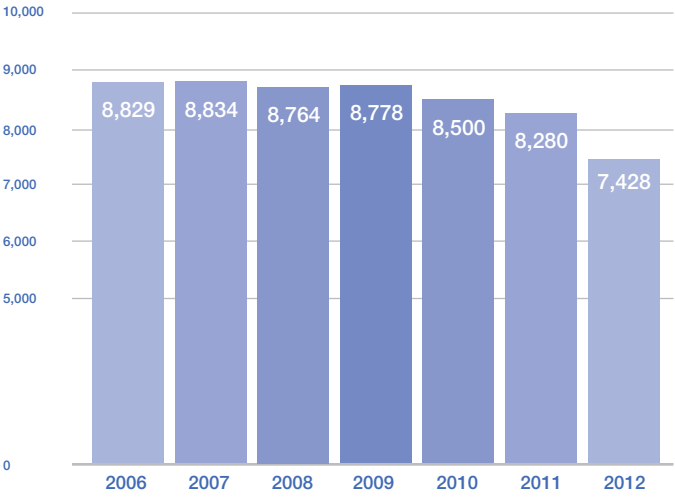
One focus of criticism is the relatively high number of pharmaceutical drugs on the German market in an international comparison. However, a more differentiated approach is required in this matter, as the method for tallying the number of drugs differs internationally.

As of 15 October 2011, there were about 90,000 marketing authorizations or registrations for pharmaceutical drugs in all indications according to statistics of the BfArM. The “Rote Liste®”, the comprehensive drug registry for Germany, in its current version of 2012, lists only 7,428 products with a total of 29,241 prices (pharmaceuticals are almost always marketed at different prices for different package sizes).

This difference between approximately 90,000 authorized or registered pharmaceuticals on the one hand and only not even 7500 entries for products in the "Rote Liste®" on the other hand can be explained by the different tallying methods and the only partial consideration of self-medication drugs in the "Rote Liste®".

In Germany, a separate marketing authorization is required for each pharmaceutical strength and each pharmaceutical form of a single active substance. This means there is a separate marketing authorization for each cream, ointment or salve of the same active substance. This is a German phenomenon. In other countries, as well as the European Medicines Agency, preparations with the same strength, but different pharmaceutical forms, are still counted as one single marketing authorization.

Number of pharmaceutical drugs listed in the "Rote Liste®"



Source: Illustration of the BPI based on data of the "Rote Liste®" 2012.

Furthermore, the statistics of the BfArM simply represent the maximum number of preparations that may be marketed in Germany. This does not necessarily mean that all of these products are indeed marketed at all times. The granting of marketing authorization does not necessarily imply the necessity to market the drug. It is not unusual for marketing authorization holders to only place part of the authorized products in the company portfolio on the market. However, the marketing authorization of a drug that is not placed on the market will expire after three years (Sunset Clause).

The "Rote Liste®" is open to all suppliers of pharmaceutical drugs. This registry is particularly popular with physicians, so that most pharmaceutical companies wishing to have their products prescribed by physicians have a vested interest in having their products listed. Drugs intended primarily for self-medication are not listed as extensively as prescription drugs.

However, a listing of these self-medication drugs is still relevant, as even non-prescription medications may be covered by the SHI in the context of drug guidelines (the so-called OTC-reimbursement list). The "Rote Liste®" is also a reference for other health professionals such as pharmacists.

The number of pharmaceutical drugs available on the German market cannot be determined with absolute certainty. In general, the number of drugs available on a single market is a measure for supply amplitude and supply depth of the market and says little about a possible over-saturation of the market, since the sole number of drugs does not give information on the actual use of the drugs.

Interventions in the pharmaceutical drug market – future prospects

This year's Pharma Data make clear that the fundamental problems of the pharmaceutical industry in Germany remain the same as in the previous years.

Far from it: the situation is getting worse!

Since 1989, changes to pharmaceutical legislation have been made nearly every year, leading to fundamental changes in the pharmaceutical market and affecting the pharmaceutical companies. Drastic measures like the price decree and the increased mandatory manufacturer discounts have been a permanent part of the repertoire of each goverment. In general they are implemented in the beginning of the legislation. This time however, the duration and the length of the mandated cost-control measures is unique. At that time the burden was imposed on the pharmaceutical industry to make a contribution in economically difficult times and unburden the SHI. This is what the pharmaceutical industry did. But why do the cost-control measures continue, while at the same time the German economy is booming and the SHI has build billions of savings – thanks to the insured persons but also thanks to the pharmaceutical industry? The politics still owe the answer. The cost-control measures must be stopped, because a poor economic environment is not a reason anymore. The drastic governmental interventions constrain the competitiveness of Germany as a location for pharmaceutical industry.

This year's Pharma Data show: what became evident since the coming into force of the AMNOG in 2010 continued in 2011: a complete change of the pharma market. Companies have to accept that innovative pharmaceuticals they want to place on

the market are subject to an additional benefit assessment followed by central price negotiations, which constitute new challenges in establishing a product on the market. Assessment procedures are common in the European context. However, the German procedure of the early benefit assessment poses a challenge for the pharmaceutical industry in particular.

The problems of the early benefit assessment already become obvious during the first negotiations and decisions, especially when it is about the choice of an appropriate comparative therapy for new drugs. This importantly sets the course for pharmaceutical manufacturers. Furthermore the decision is made here whether a product can refinance its development costs and also whether the product can enter a fair competition with an adequate therapy. That this is not always the case is shown in market withdrawal of some products. This becomes most evident when taking a drug as an example, which because of the choice of comparative therapy was not certified an additional benefit, but at the same time was imported from abroad by the biggest kind of health insurer in order to supply the drug to its patients. No one would do this if the drug did not have an additional benefit!

It will be essential for the future whether the early benefit assessment and the reimbursement negotiations will be used to achieve what the legislative body intended: adequate and fair prices for novel drugs. Also a clear guidance, when an additional benefit is evident in comparison to the currently used therapy. They are ready to demonstrate the additional benefit of their products and to negotiate a rebate on the manufacturer price. However this has to happen under fair conditions, otherwise this will harm Germany as a location for pharmaceutical industry. It must be clear to everyone that a company will not let a decision made in Germany jeopardise its worldwide market. In the long run Germany will have to be able to compete in

marketing the best possible drugs - this has to be clear to political decision makers as well as self-government. Everyone has to pull in the same direction.

Besides current challenges due to the AMNOG, the pharmaceutical companies in Germany have to face numerous different controlling tools, which are mainly pure cost reduction tools. These comprise for example obligatory discounts, the price decree, the lowering of the reference price and the SHI rebate contracts. Due to the immense cost pressure, especially in the generic segment, the manufacturing of drugs in Germany became increasingly difficult. No wonder that companies relocate. However, manufacturing in Asia or India causes the problems of dependence on the one hand and much longer supply chains on the other hand. Who does not want that, has to make sure that companies located in Germany can live and work successfully. It is also essential that SHI rebate contracts in the generic segment give the pharmaceutical companies space to breathe. Otherwise the situation for companies in Germany as a location for pharmaeutical industry will get worse. The decreasing SHI expenses for drugs shall prompt looking from pure price regulation tools to intelligent management tools.

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Acronyms

AKG	Arzneimittel und Kooperation im Gesundheitswesen
AMG	Arzneimittelgesetz
AMNOG	Arzneimittelmarktneuordnungsgesetz
AOK	Allgemeine Ortskrankenkasse
ApU	Abgabepreis pharmazeutischer Unternehmen
ATC Code	Anatomisch-Therapeutisch-Chemische (ATC) Klassifikation
AVP	Apothekenverkaufspreis
AVWG	Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
BIP	Bruttoinlandsprodukt
BMBF	Bundesministerium für Bildung und Forschung
BMG	Bundesministerium für Gesundheit
BPI	Bundesverband der Pharmazeutischen Industrie e. V.
DDD	Defined Daily Dosis (definierte Tagesdosis)
DRGs	Diagnosis Related Groups
EFPIA	European Federation of Pharmaceutical Industry and Associations
EMA	European Medicines Agency
EU	Europäische Union
F&E	Forschung & Entwicklung
FSA	Freiwillige Selbstkontrolle Arzneimittelindustrie
G-BA	Gemeinsamer Bundesausschuss
GKV	Gesetzliche Krankenversicherung

GKV-OrgWG	Gesetz zur Weiterentwicklung der Organisationsstrukturen in der Gesetzlichen Krankenversicherung
GKV-WSG	GKV-Wettbewerbsstärkungsgesetz
GMG	GKV-Modernisierungsgesetz
GMS	Gesundheitsmittelstudie
GWB	Gesetz gegen Wettbewerbsbeschränkungen
HAP	Herstellerabgabepreis
IGES	Institut für Gesundheits- und Sozialforschung
IMS	IMS HEALTH GmbH & Co. OHG
Insight Health	INSIGHT Health Management GmbH
LCD	Local Currency Dollar
Mio.	Millionen
Mrd.	Milliarden
MwSt.	Mehrwertsteuer
NCE / NBE	New Chemical or New Biological Entities
OTC	Over-the-counter / Selbstmedikation
OR	Outcomes Research
PE	Packungseinheit
PEI	Paul-Ehrlich-Institut
Phytos	Herbal Medicinal Products / Pflanzliche Arzneimittel
PKV	Private Krankenversicherung
SGB V	Sozialgesetzbuch V
SGG	Sozialgerichtsgesetz
UAW	Unerwünschte Arzneimittelwirkung
WHO	World Health Organisation
WidO	Wissenschaftliches Institut der Ortskrankenkassen

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**German Association for
Pharmaceutical Industry (BPI e.V.)**

Friedrichstraße 148
10117 Berlin
Germany
Phone: +49 30 2 79 09 - 0
Fax: +49 30 2 79 09 - 3 61
E-Mail: info@bpi.de
Internet: www.bpi.de

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