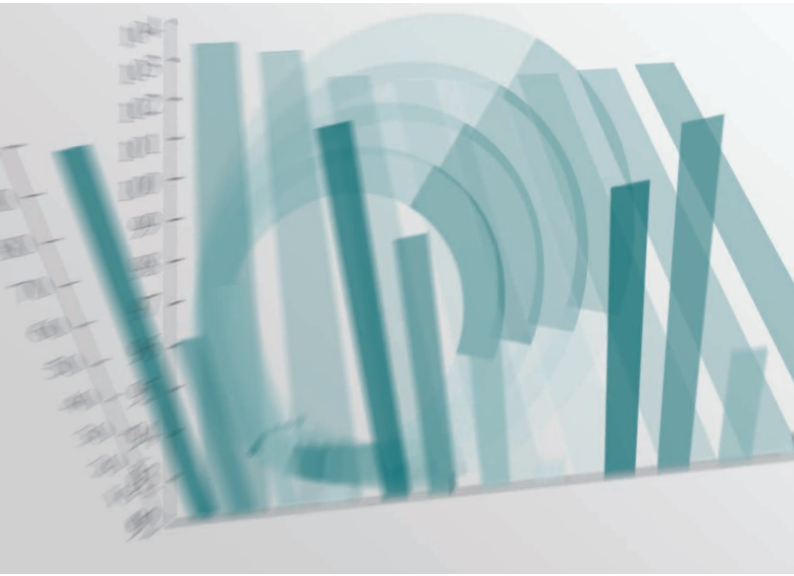
Pharma-Data 2011

BPI German Pharmaceutical Industry Association



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Preface

Facts can be very uncomfortable, as they often contradict well-loved prejudices and fallacies. In observing the discussions surrounding the pharmaceutical industry in Germany, one finds that these dominated by a distorted picture of the industry, which is not founded on facts.

Pharmaceutical drugs are always viewed as cost drivers in the political arena. The debates often focus on cost reduction measures or price negotiations for innovative medicinal products. But pharmaceuticals are much more: they are the most important tool for physicians used in the treatment of diseases. Without pharmaceutical drugs, the medical advances of the past decades would not have been possible. Neither would the health care sector have been such a crisis-resistant part of the German economy. With its innovations and competitiveness, the pharmaceutical industry contributes a great deal to the German economy.

Also, this industrial sector employs tens of thousands of highly qualified individuals. In doing so, the pharmaceutical industry must navigate the often conflicting agendas of health care policy, social policy and economic policy.

In spite of its undisputed successes, the public and particularly the media often perceive the pharmaceutical industry as a monolithic bloc with negative connotations. The most frequent accusation leveled at the industry is that it profits from illness. It often seems impossible to clarify that the pharmaceutical industry is very heterogeneous and that the profits of today are the research and development investments of tomorrow.

These facets are often intentionally ignored, as they undermine the old black-and-white view of the German health care sector. These tendencies were also seen in the discussions in 2010. The cost control measures were the usual measures adopted in misguided health policy, including mandatory rebates and a price moratorium, which avoided addressing the issue of a sustainable cost structure for the health care sector. In addition, the debate surrounding the early benefit assessments and the subsequent price negotiations for innovative drugs has shown that health policy makers may preach support for competitiveness, but reality is much different. Core structural issues are inhibiting competition among the health insurance providers.

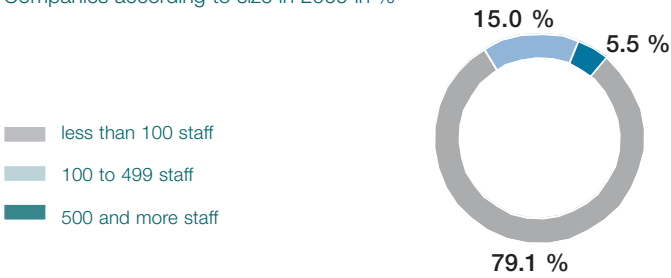
Another contribution of the pharmaceutical industry which is frequently ignored is the stabilisation of insurance premiums for statutory health insurance (SHI). Through mandatory rebates pharmaceutical companies have financed roughly 6 billion Euros since 2005. In 2010 alone, this sum was at a record high of 1.5 billion Euros. The fact that the SHI system currently has a billion-Euro surplus is in large part due to the contribution of the pharmaceutical industry.

In general, the goal must be to shift to a more fact-oriented discussion and to throw old prejudices overboard in order to constructively work toward a sustainable health care sector in Germany. For one thing is clear: we still have the best system for comprehensive health insurance worldwide. This 41st edition of "Pharma Data" provides facts and background information on the pharmaceutical market with the aim of contributing to a more factual debate in the health care sector.

Sector structure

According to the trade register at the Federal Office for Statistics, a total of 903 pharmaceutical companies* are registered in Germany. Over the course of the last few 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 methodological 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 recorded at the Federal Office for Statistics.

Companies according to size in 2009 in %



Source: Calculation of the BPI, based on data of the VCI and of the Federal Office for Statistics 2011.

* In the "cost structure statistics", the Federal Office for Statistics shows 238 companies (reporting category 20+). There are an additional 495 companies with less than 20 staff. 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 903 companies mentioned above. It is still true that around 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.

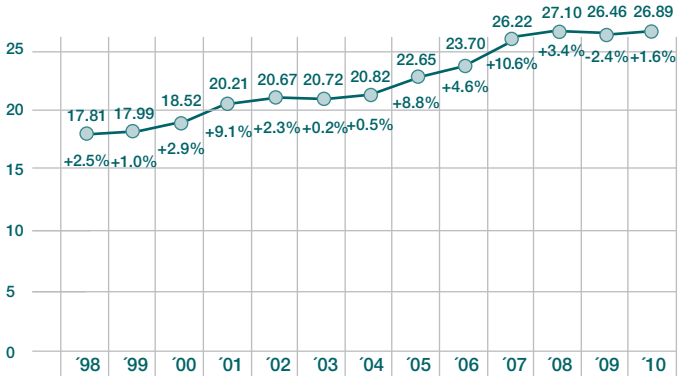
Almost two-thirds of the BPI membership are owner-managed companies. Approximately 90 % of the companies act on a national as well as international level. Although the proportion of export business is constantly growing, many companies generate the greater proportion of their turnover on the German market. The future of these companies focusing on Germany as a business location is heavily influenced by the political health care framework in Germany.

Production

In 2010, the pharmaceutical industry in Germany produced pharmaceuticals valued at 26.9 billion Euros. This represents an increase of 1.6 % compared to the year 2009. Domestic production significantly depends on pricing, pharmaceutical drugs imports as well as export demand.

Pharmaceutical Production* from 1998 – 2010**

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



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

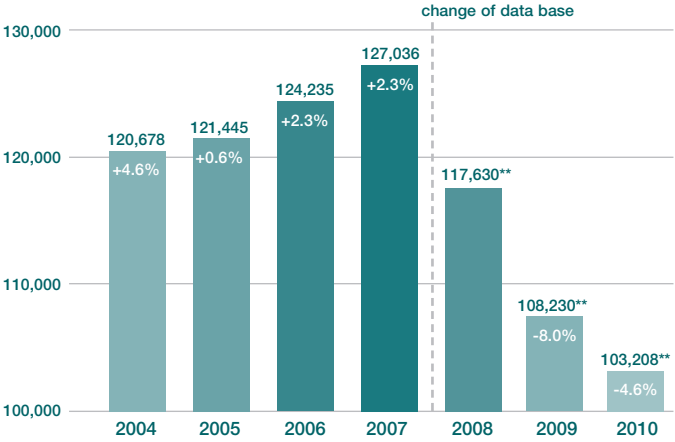
** Since 2009 the GP 21 (pharmaceutical and similar goods) has replaced the GP 244.This new statistical classification prevents a direct comparison with values from previous years.

Source: Illustration of the BPI, based on data of the VCI 2011 and the Federal Office for Statistics 2011.

In 2010, 103,208 employees were employed by companies producing pharmaceutical goods.

Employees

Development of staff numbers* in companies pertaining to the pharmaceutical industry 2004 – 2010 (changes compared 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, please note the change of the economic 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 2011 and the Federal Office for Statistics 2011.

Foreign trade

In 2010, pharmaceuticals valued at 51.1 billion Euros were exported from the Federal Republic of Germany. This corresponds to an increase of 8.0 % compared to the previous year 2009. At the same time, pharmaceuticals valued at 38.0 billion Euros were imported into the Federal Republic of Germany in 2010. This constitutes an increase of 6.9 % compared to 2009. The main supplier of pharmaceuticals to Germany is Ireland, followed by the USA, Switzerland and Great Britain. France comes in 5th place, followed by the Netherlands.

Import and export of pharmaceutical drugs*
(in million Euros, changes compared to the previous year in %)

Year	Import		Export**	
	million Euros	+/- %	million Euros	+/- %
2000	10,353.47	+25.9	15,177.47	+5.9
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

* 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 and the Federal Office for Statistics 2011.

Main suppliers of pharmaceutical drugs* to Germany (in Million Euros)

	2005	2006	2007	2008	2009	2010
Ireland**	7,388.86	8,283.95	8,626.71	8,985.03	7,934.95	6,751.54
USA	4,857.61	5,027.26	5,931.85	6,501.50	7,193.86	6,253.57
Switzerland	2,153.74	2,729.90	4,502.61	4,333.46	4,845.13	5,463.70
Great Britain	1,786.18	1,815.59	1,847.81	1,682.74	2,299.63	2,569.65
Spain	668.87	829.72	990.18	1,038.00	1,205.72	2,479.95
France	1,804.79	2,034.73	1,897.93	1,842.35	1,741.96	2,331.83
Netherlands	951.24	952.55	1,369.03	1,224.94	1,182.51	1,954.97
Italy	1,180.83	1,193.98	1,367.09	1,415.20	1,546.32	1,702.05
Belgium	1,081.82	1,027.49	1,204.81	1,318.56	1,292.36	1,487.63
Sweden	908.04	998.17	990.65	1,029.17	1,106.91	1,217.70
Others	2,803.19	3,473.39	3,978.17	4,692.22	5,203.30	5,798.67
Total	**25,585.17**	**28,366.72**	**32,705.83**	**34,063.16**	**35,552.63**	**38,011.25**

* 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 and the Federal Office for Statistics 2011.

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

	2005	2006	2007	2008	2009	2010
Belgium**	9,092.61	10,076.72	11,070.24	11,616.23	10,918.27	10,495.80
Netherlands	1,755.23	2,497.69	3,526.56	4,367.44	4,423.55	6,553.10
USA	3,742.55	4,222.33	4,330.88	5,752.41	5,861.38	4,979.74
Switzerland	1,917.03	2,320.16	2,488.89	2,419.29	2,865.12	2,818.90
Great Britain	1,528.72	1,806.50	2,229.93	2,443.45	2,440.71	2,770.38
France	1,520.30	1,576.24	1,903.22	2,249.68	2,255.97	2,525.98
Italy	1,579.71	1,687.55	1,991.34	2,045.26	2,192.60	2,465.54
Austria	966.12	955.55	1,069.27	1,161.28	1,252.11	1,458.74
Russ. Federat.	573.48	798.62	840.00	1,099.05	984.30	1,390.49
Spain	930.57	1,013.97	1,196.50	1,207.85	1,254.42	1,375.34
Others	8,152.53	9,519.19	11,261.24	13,187.40	12,917.56	14,299.24
Total	**31,758.85**	**36,474.52**	**41,908.34**	**47,549.32**	**47,365.99**	**51,133.24**

* 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).

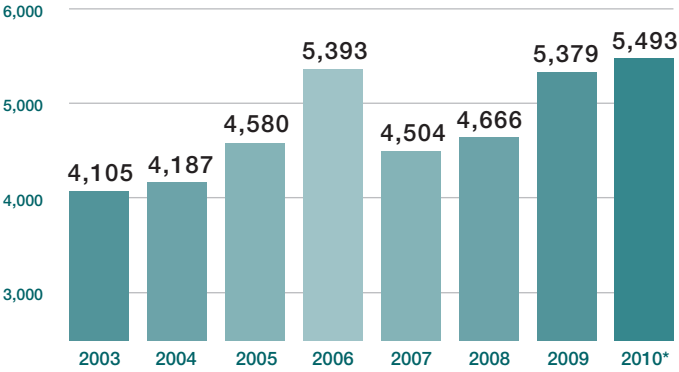
** The remarkably high export rate is explained by the VCI as due to special circumstances.

Source: Illustration of the BPI based on data of the VCI and the Federal Office for Statistics 2011.

Research and Development

In 2010, the pharmaceutical industry in Germany invested a total of roughly 5.5 billion Euros in research and development (R&D). This investment level was slightly higher as compared to the previous year (5.4 billion Euros).

Investments in research and development by the pharmaceutical industry 2003 - 2010 (in Million Euros)



* projected data

Source: Illustration of the BPI based on data of the Stifterverband Wirtschaftsstatistik 2011.

Hence, the R&D expenditures of the pharmaceutical industry constitute around 9.4 % of the overall R&D investments in the German economy (58.4 billion Euros). With this investment volume, the pharmaceutical industry is in third place behind the automobile industry and the electronics industry.

The high investment level demonstrates that the pharmaceutical industry continued to focus on innovation despite the economic crisis. In 2008, the total R&D expenditures were at 8.1 %. While the overall R&D investment level of the German economy decreased in 2009 in response to the economic crisis, the pharmaceutical industry continued to increase its investments in R&D.

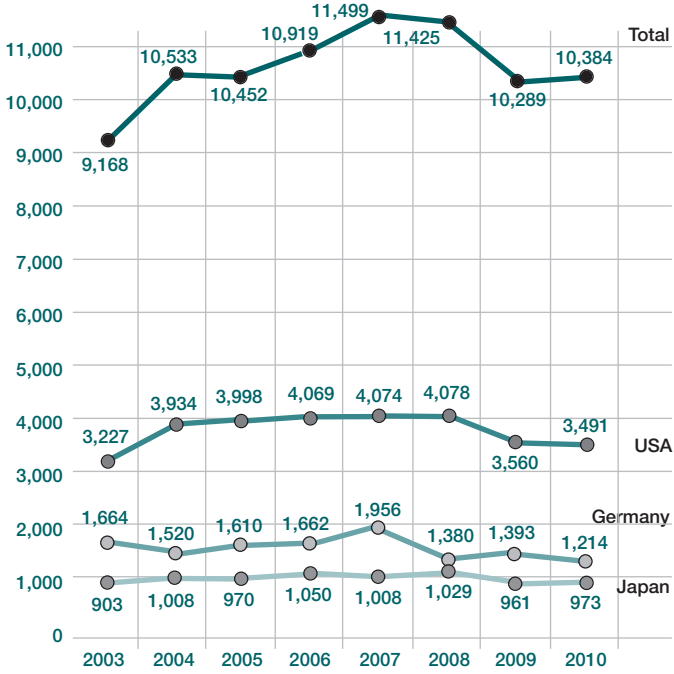
The data are based on available data at editorial deadline of the German Stifterverband Wissenschaftsstatistik, which are still based on projected data for previous years. In the Pharma Data 2010 issue, this projected data was used as a basis for projecting R&D expenditures in 2009 of 4.6 billion Euro. In light of the preliminary data off current statistics, this projected data for R&D in 2009 must now be corrected upwards to 5.4 billion Euro. This development shows that the pharmaceutical industry increased its R&D spending in 2009, despite originally planning lower expenditure levels. Similar increases are expected for 2010 and 2011.

Relatively speaking, the pharmaceutical industry is one of the most research-intense sectors, with a share of the R&D costs versus turnover amounting to about 15%, thus securing future jobs in Germany. In its 2010 report, the expert commission on research and innovation of the federal government has reported the pharmaceutical industry as the industry with top expenditures in R&D in 2007. 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 2009 increased to 20,240 compared to 15,516 in the year 2001. With this, the number of staff in this sector increased by around 30% in the period from 2001 to 2009, while it stagnated in the whole chemical industry during the same period of time. Data were not available for the year 2010 at editorial deadline.

Patents

Patents are an incentive for innovations, guaranteeing the patent holder marketing exclusivity for a certain time period in return for a risky development. This applies equally to all economic areas. Patents have a special impact on the pharmaceutical industry because the time it takes to develop new active substances (NCE / NBE = New Chemical Entities / New Biological Entities) is 8 to 12 years, a relatively long period, and the costs for development are especially high.

Published patent applications and patents granted concerning pharmaceutical drugs effective in Germany

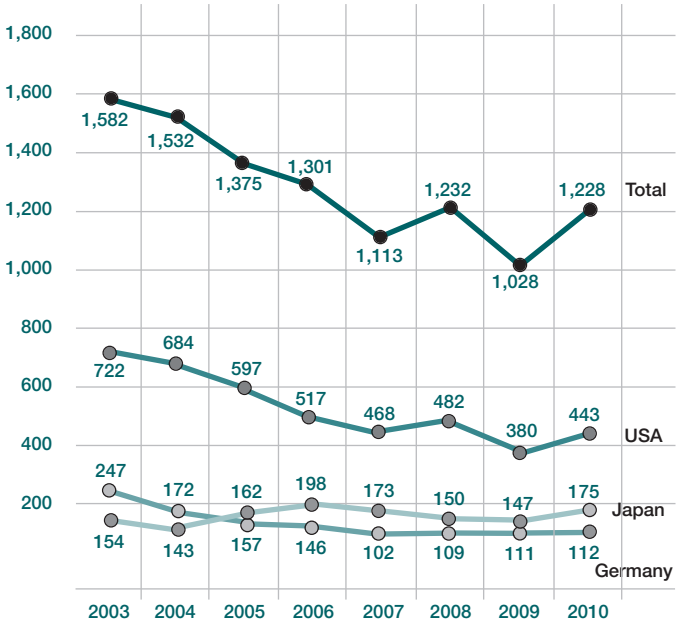


Data are based on the database PATDPA with the patent applications and/or patent grants published in the respective year. Patent applications and/or patent approvals were counted at the German and European Patent Office. Duplicates are not counted.

Source: Illustration of the BPI based on data of the German Patent and Trademark Office, 2011

10,384 patent applications for pharmaceutical drugs were published in Germany in the year 2009, which represents a slight increase of 1 % compared to the previous year. The most important patent applicant is still the USA, holding approximately 34 % of all patent applications. Germany comes second with 11.7 % (compared to 13.5 % in the previous year). While patent applications from Germany decreased by almost 30% from 2007 to 2008, the number remained relatively constant in 2009 and 2010.

Patent applications in the sector of pharmaceutical drugs with biotechnological reference



Data are based on the database PATDPA with the patent applications and/or patent grants published in the respective year. Patent applications and/or patent approvals were counted at the German and European Patent Office. Duplicates are not counted.

Source: Illustration of the BPI based on data of the German Patent and Trademark Office 2011.

The number of patent applications for pharmaceutical drugs with biotechnological reference increased to 1,228 in 2010 compared to 1,028 patent applications in 2009. Applicants from Germany are in third place with 112 patent applications, following the USA (443 patent applications) and Japan (175 patent applications). Compared to the year 2003, the number of patent applications decreased by about 22 % in this sector.

Research and development of pharmaceutical drugs

Innovations are a driving force for successful growth of pharmaceutical companies. New active substances, formulations and production processes secure jobs 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 treatment options and close existing therapeutic gaps. Innovations in the pharmaceutical industry take place in several areas:

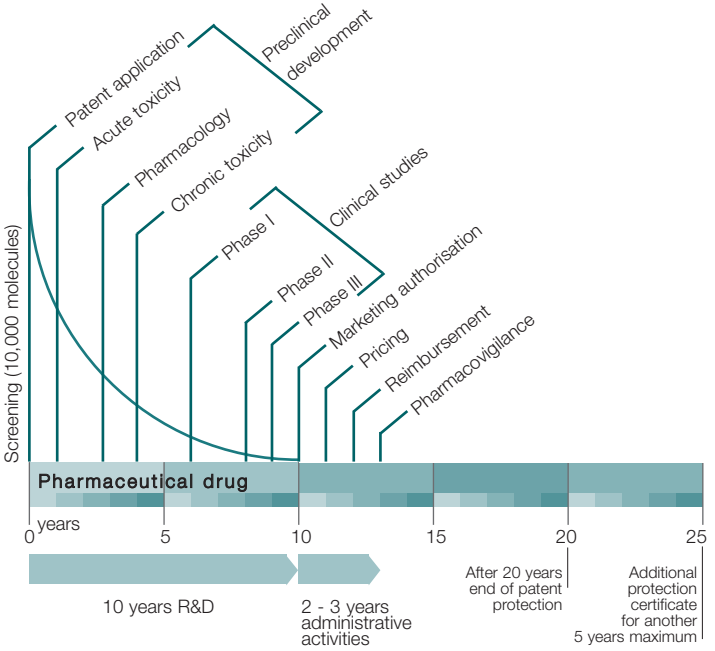
- -> New active substances
  Chemically defined active substances, defined natural substances, phytopharmaceuticals, biopharmaceuticals, "me-too" substances (molecular variants of known active substances with a similar chemical structure)
- -> New pharmaceutical forms and new specifically active combinations 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 effort in R&D, testing and authorisation 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 or increased availability in the body.

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.

New technologies contribute to manufacturing and availability of goods in greater quantities, improved quality or at reduced costs. Especially in therapies which are very expensive due to a complex manufacturing technology, these innovations can improve availability for patients and reduce the burden for the health care system at the same time.

Stages of pharmaceutical drug research and development in the EU

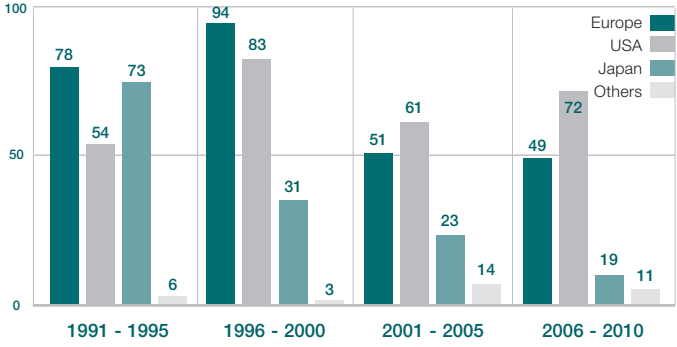


Source: Illustration of the BPI based on the European Federation of Pharmaceutical Industries and Associations (EFPIA) 2011.

The pharmaceutical companies often have less than 10 years to market a new product and to recoup 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 market launches, favouring 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 billion Euros between 1980 and 2008 (forecast) – the number of newly introduced active substances decreased markedly.

New active substances (new chemical or biological entities – NCE/NBE) 1991 – 2010 sorted by invention countries worldwide



Source: Illustration of the BPI based on data of the EFPIA 2011.

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 controlled centrally, the reimbursement policies are controlled 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 proven by 22 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 programme 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 for restructuring the drug market (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.

In the context of the current discussion surrounding health care spending, the topic of the costs of developing a new active substance, which were 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. 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 many 100 millions of Euros. Apart from the discussion surrounding the appropriate methodology for this calculation, the key point is 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. In this context 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 pharmaceutical formulations or the research into new indications or new patient populations.

Many current therapy 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 for restructuring the drug market (AMNOG), which focuses on medicinal products, whose effect is not well-known to the medical community at the time of first authorisation. The situation for improving medicinal products with established active substances has not improved with the AMNOG. The search for new pharmaceuticals on the basis of 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 all competent partners is essential. Cooperation between 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. 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 a higher benefit for patients can be proven does the innovation offer a true therapeutic improvement. 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 life sciences. New methods and findings in the complex metabolic 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. 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 over 200 medicines approved on a biotechnological basis in Germany. These represented approximately 17 % of the turnover in the pharmacy market in 2010. Biotechnology therefore ceased to be a futuristic vision a long time ago, and day by day provides concrete benefit for the patient. Insulins constitute the main share of the global market, followed by immunomodulators, and EPO, 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 in the medium and 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, no new biotechnological new chemical entities were authorized in Germany in 2010.

Including the non-clinical development stage, there were 344 active substances in the development pipeline in 2010. This is an increase of 2.4 % compared to the previous year. In 2009, this increase versus 2008 was higher at 8 %. This continued increase is an unexpectedly positive signal in view of the economic crisis and the subsequent reduction in R&D expenditures. The development progress is visible in the 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, which had decreased for the first time to 43 biopharmaceuticals in 2009, now increased again in 2010 to 46. In phase II and III there was an increase to 90 (7%) active substances and to 15 active substances, respectively.

The long periods for pharmaceutical drug development and the reasons for them were already discussed in sections „Patents“ (p. 15) and “Research and development of pharmaceutical drugs” (p.18). In this context it is not surprising that in terms of development of ready-to-market products with marketing authorisation, the German biotech companies are lagging behind compared to the USA, where the biotechnology sector developed much earlier.

The developments in the field of biotechnological pharmaceutical drugs and therapies are still in the early stages. 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 examinations.

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 2007, the marketing authorisation of the active substance EPO, which was developed in Germany, represented a milestone in this sector, as EPO

was the first biotechnologically produced biosimilar with a truly big potential market volume.

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 development 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, generated a turnover of over one billion Euros (1.059 million Euros) in 2010, which is an increase of 7 % relative to 2009.

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

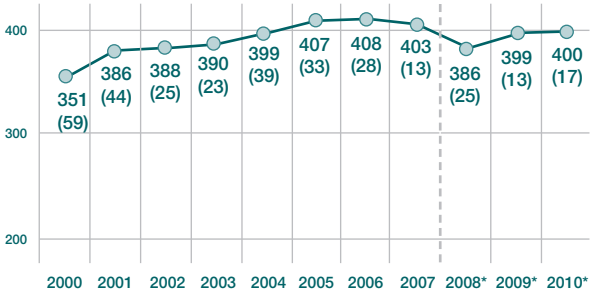
The biotechnology sector in Germany 2010
(in million Euros, changes compared to the previous year in %)

	2009	2010	
Number of companies			
Core segment	399	400	< 1 %
Extended segment	531	550	4 %
Number of staff			
Core segment	9,809	10,043	2 %
Extended segment	14,950	15,500	4 %
Turnover			
Core segment	992	1.059	7 %
Extended segment	2,180	2,400	10 %
R&D expenditures			
Core segment	777	809	4 %
Extended segment	1,050	1,000	- 5 %

Source: Illustration of the BPI based on data of Ernst & Young 2011.

The number of biotechnology companies remained stable in 2010 compared to the previous year: based on data of the German Biotechnology Report 2011 by Ernst & Young there were 400 companies compared to 399 in the previous year. The biotech sector has managed to weather the economic crisis very well. In this context it needs to be considered that the different sources these data are based on 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. In its 2010 report, Ernst & Young first included an extended segment of biotechnology companies, which is consistent with the data collection of "biotechnologie.de" authorised by the Federal Ministry of Research and Education (BMBF) and therefore allows comparability of both data sets. The data collection of "biotechnologie.de" is based on a definition that includes the fields of industrial and green biotechnology, which counted 538 companies. 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 (13 companies in 2009): Ernst & Young reports 17 start-ups, biotechnologie.de reports eight. While Ernst & Young reported 17 new start-ups, the report also showed that 16 firms had disappeared: six due to insolvency, eight due to acquisitions and mergers, two due to "inactivity or other reasons".

Number of biotech companies (start-ups in brackets)



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

Source: Illustration of the BPI based on data of Ernst & Young 2011.

Mergers and acquisitions (M&A) 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 has continued in 2010, with eleven M&A-transactions in 2009. In general, however, the activity levels are still lower than the previous years (e.g. 16 in 2006). It will need to be seen if M&A activity will pick up as the world economy recovers.

In general, there are excellent future prospects for medical bioengineering considering the products already launched on the market, the products in advanced development as well as the products constantly moving up from fundamentals research. A requirement for this is a predictable and stable health care system. This especially applies to reimbursement policies, because the fundamental for decisions made on investments in R&D are the refinancing conditions, i.e. reimbursement policies in the pharma market. The Act for restructuring the drug market (AMNOG) with its fundamental changes of the reimbursement policies in Germany is therefore of great significance for whole biotech sector in Germany.

Continuous monitoring of the safety of pharmaceutical drug safety / pharmacovigilance

Pharmacovigilance is an umbrella term that encompasses all activities intended to recognize side effects of pharmaceutical drug therapy and to avoid misuse of pharmaceutical drugs.

In general, each effective pharmaceutical drug can also induce undesired effects. However, they usually only occur in one of 100,000 patients or even less.

The risk assessment of a pharmaceutical drug in the whole population is the subject of pharmacoepidemiology. It is generally considered to be the basic science of the safety of pharmaceutical drugs. The purpose is to identify the causal relationships between exposure and efficacy, if possible to prophylactically prevent undesired adverse effects and to increase the therapeutic benefit.

The Paul-Ehrlich-Institute (PEI) is the responsible national competent authority for vaccines, blood preparations and sera; for all other medicines, it 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.

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 concurrent medications, are 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.

Pharmaceutical companies are legally obliged to actively collect, evaluate and report cases of adverse reactions or interactions, contraindications and quality issues related to their drugs. The reports must be submitted to the respective competent authority. Reports of serious adverse reactions must also be reported in an expedited fashion to the national authorities of the EU member states and the EMA in London. This reporting requirement pertains to all reports involving the drug of interest arising nationally or in another EU member state, but also in countries outside of Europe. The BPI is also integrally involved in the continuous exchange of information between the pharmaceutical industry and the regulatory authorities.

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 Stufenplanbeauftragter). 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.

Should further measures for the protection of patient welfare be deemed necessary, these measures are immediately implemented. For the most part, these measures are implemented by the pharmaceutical company in question, but in some cases they are the result of special requirements set forth by the national or EU regulatory authorities. The "Stufenplanverfahren" described in the German Medicines Act regulates which measures must be taken by a pharmaceutical company in order to increase patient safety, including such measures as changing the patient information leaflet or withdrawing the drug from the market. Many drug safety procedures, called "Referrals", are increasingly being coordinated not on a national level, but by the EMA on an EU-wide level.

Reports of side effects

According to the BfArM, the authority received around 52.500 individual case reports of adverse reactions originating in Germany in 2010. The majority of these reports were submitted by the pharmaceutical industry. An increase in the number of literature reports was noted, which is due to well-established systems for literature screening in pharmaceutical companies. The large majority of the reports concerns events that occurred outside of Germany, in particular outside of the EU. This is due to the current regulatory reporting requirements as per § 63b of the German Medicines Act.

Almost 50 % of the reports submitted to the Paul-Ehrlich-Institute (PEI), which consistently receives fewer reports than the BfArM, were related to monoclonal antibodies. A little more than a third of the reports are related to vaccination complications. These cases are reported in compliance with the infection protection law (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen – IfSG; law for the prevention and fighting of infectious disease in humans). About 10 % concern cellular blood products.

The overall increase in reports may be traced back to improved methods for reporting, including electronic reporting via the internet.

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 closely cooperate with the local state authorities and with those of other European nations. There are also close contacts with authorities of states outside 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 profession communications concerning information on newly identified, significant risks concerning the use and administration of pharmaceutical drugs and measures for risk mitigation.

The Pharma Codices of the pharmaceutical industry associations BPI and VFA (AKG – "Arzneimittel und Kooperation im Gesundheitswesen" [pharmaceuticals and cooperation in the health care sector] and FSA – "Freiwillige Selbstkontrolle Arzneimittelindustrie" [voluntary self-monitoring of the pharmaceutical industry]) oblige their members to send out important information concerning pharmaceutical drug safety, in coordination with the national competent authorities, to health professional circles, i.e. to physicians and to the Drug Commissions of the German Medical Association and the German Pharmacists.

The members of the 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 concerning newly identified, severe side effects, recalls of faulty batches or other information that needs to reach the physician and/or pharmacist in the fastest possible way in order to secure patient safety.

This is to ensure that important information will not be overlooked in the daily mail.

The global pharmaceutical market

In 2010, the global turnover of pharmaceutical drugs totaled 634 billion Euro (861 billion US-Dollars), an increase of 5.4 % compared to the previous year.

Development of the global pharmaceutical market

	2006	2007	2008	2009	2010
Total market (billion Euro)*	477.5	528.4	577.5	599.7	633.9
Total market (billion US-Dollars)	648.7	717.9	784.6	814.7	861.2
Change compared to previous year (in %)		10,7%	9,3%	3,8%	5,7%

* 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: 0.736)

Source: Illustration of the BPI based on data of IMS World Review 2011.

Nearly 80 % of the total turnover of the global pharmaceutical market is generated by North America, Europe and Japan. The turnover in North America increased by 4.0 % to 244.6 billion Euros Dollars, which represents 39 % of the global pharmaceutical turnover in 2010. At the same time, the European pharmaceutical market shrank by 0.3 % to 173.6 billion Euros, while Latin America increased its pharmaceutical turnover significantly by 21 % to almost 33 billion Euros.

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

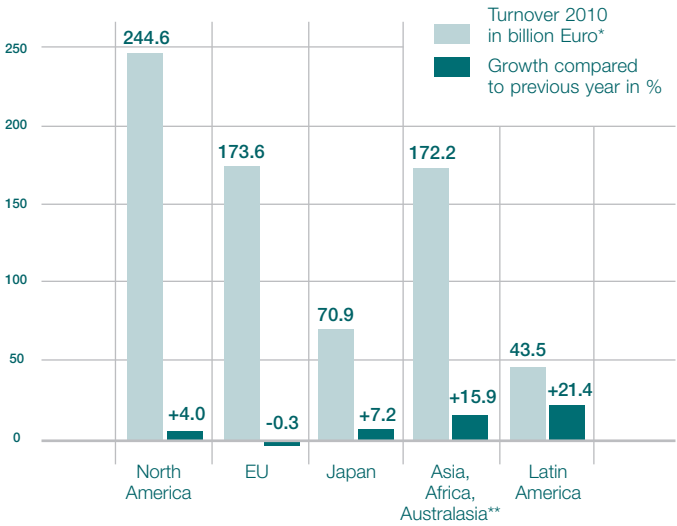
Country	Turnover 2010 (million US-Dollars)	Growth to LCD 2010 (%)*	Turnover 2010 (million Euro)**
USA	310,725	3	228,721
Japan	96,355	0	70,926
China	41,045	22	30,213
Germany	40,544	3	29,844
France	38,943	1	28,665
Italy	26,514	3	19,517
Brasil	22,788	18	16,774
Spain	22,203	3	16,343
Canada	21,631	3	15,922
Great Britain	20,299	4	14,942

* 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: 0.736)

Source: Illustration of the BPI based on data of IMS World Review 2011.

Global pharmaceutical market by region 2010



* 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: 0.736)

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

Source: Illustration of the BPI based on data of IMS World Review 2011.

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 Pharmaceuti-cal market

Upon closer analysis, these pharmaceutical markets are heterogeneous with regards to market size, yet all show continuous growth. Pharmaceutical pricing and reimbursement are regulated in different ways in the 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 2010 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, the United Kingdom is first, followed by Belgium, Germany, Italy and Spain.

Pharmaceutical markets of the EU-15

EU-member state	Turnover* for 2010 (Million USD)	Growth*** to LCD 2010 (%)	Turnover* for 2010 (Million Euro)
Germany**	40,544	3	29,844
France**	38,943	1	28,665
Italy**	26,514	3	19,517
Spain**	22,203	3	16,343
Great Britain**	20,299	4	14,942
Belgium**	6,067	3	4,466
Greece	6,005	-13	4,420
The Netherlands	5,024	-2	3,698
Portugal	4,961	-2	3,652
Sweden**	4,041	1	2,974
Austria**	4,011	1	2,952
Denmark**	2,573	1	1,894
Finland**	2,454	-2	1,806
Ireland**	2,416	-1	1,778
Luxembourg	229	-1	168
Total	186,284	-0.1	137,120

* 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: 0.736)

Source: Illustration of the BPI based on data of IMS Health World Review 2011.

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* 2010

Turnover in million Euro**

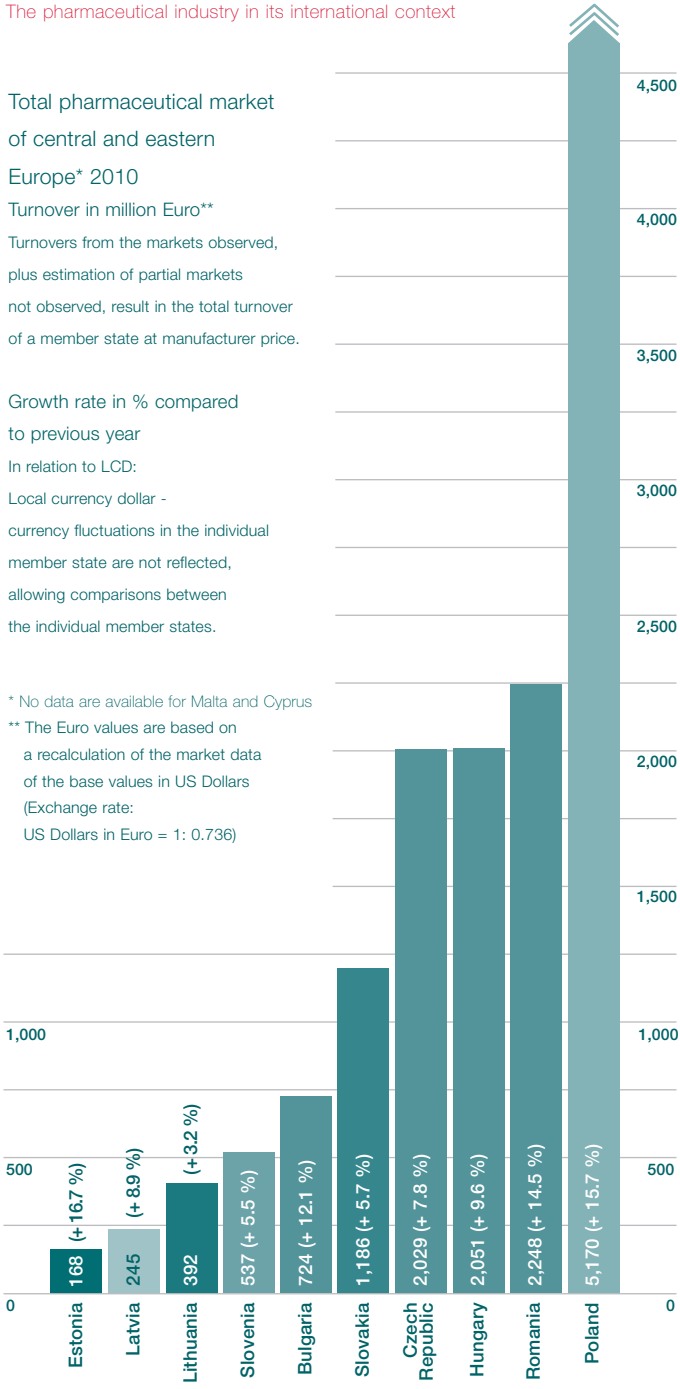
Turnovers from the markets observed, plus estimation of partial markets not observed, result in the total turnover of a member state at manufacturer price.

Growth rate 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: 0.736)



Source: Illustration of the BPI based on data of IMS World Review 2011.

Over the next five years, IMS Health is expecting an average growth rate of 2.2 % in the EU member states. By comparison, a growth rate of 4.8 % is predicted for non-EU member states. The five most important EU markets are expected to grow by 1.9 %.

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

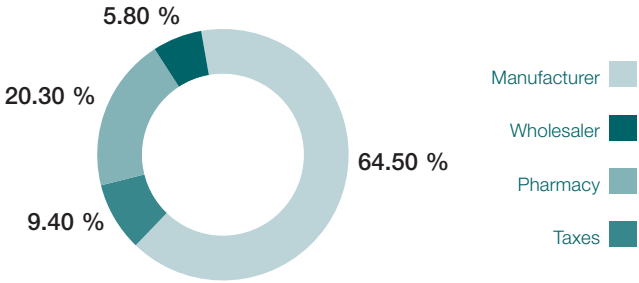
Europa	2010 – 2015
EU top five member states	1.9 %
EU member states	2.2 %
Non-EU member states	5.3 %
Global market	5.0 %

Source: Illustration of the BPI based on data of IMS Market Prognosis Global 2011.

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 a sufficient market share. 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 (2009)
- Based on pharmacy retail price



The values constitute a non-weighted mean value for Europe.

Source: Illustration of the BPI based on EFPIA 2011.

The graph of the pharmaceutical price structure in Europe 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 January 2011)

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 | 5.5	2.1 | 5.5
Greece	23.0	6.5	6.5
Great Britain[2]	20.0	0.0	20.0
Ireland[3]	21.0	0.0 | 21.0	0.0 | 21.0
Iceland	25.5	25.5	25.5
Italy	20.0	10.0	10.0
Croatia	23.0	0.0	23.0
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	8.0	8.0
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
Slovak Republic	20.0	10.0	10.0
Slovenia	20.0	8.5	8.5
Spain	18.0	4.0	4.0
Czech Republic	20.0	10.0	10.0
Hungary	25.0	5.0	5.0
Cyprus	15.0	5.0	5.0

[1] Pharmaceutical drugs subject to reimbursement: 2.1%; Pharmaceutical drugs not subject to reimbursement: 5.5%

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

[3] pharmaceutical drugs for oral administration: 0%, others: 21.0%

[4] Prescription drugs 5 %, Non-prescription drugs 21.0 %.

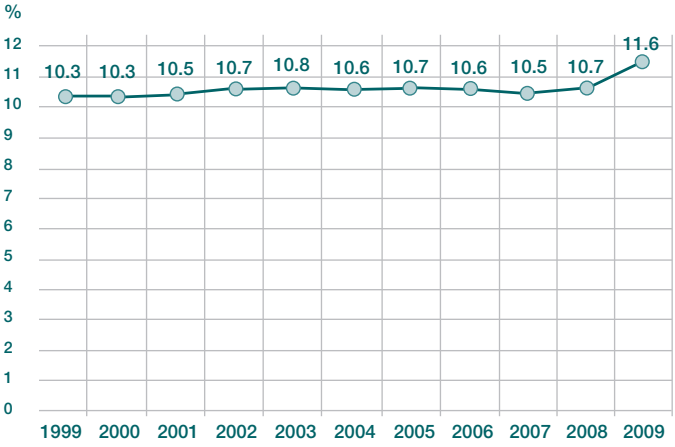
Source: Illustration of the BPI based on ABDA 2011.

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 that note that a conclusive evaluation is not possible based only on these figures. 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.

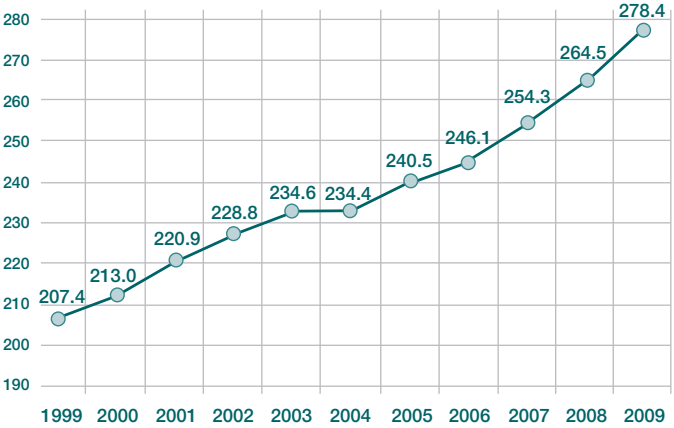
Development of health care expenditures - share of the GDP in %



Source: Illustration of the BPI based on data of the Federal Statistical Office 2011.

The share of health care expenditures of the GDP has remained stable in Germany over the course of the years: between 1999 and 2008, this percentage has been between 10.3 % and 10.7 %. The relative increase in 2009 to 11.6 % is partially due to a statistical effect resulting from a decrease in the GDP as a consequence of the financial crisis in 2009.

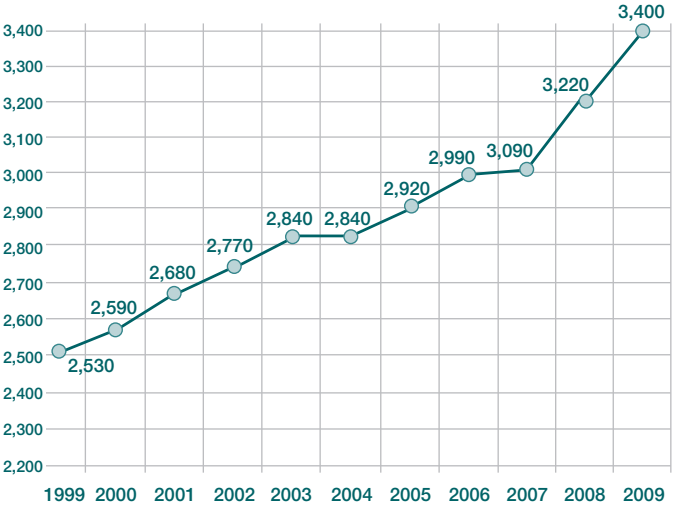
Development of nominal health care expenditures (in billion Euros)



Source: Illustration of the BPI based on data of the Federal Statistical Office 2011.

Nominal health care expenditures in Germany have been continually on the rise since 1999 and, by 2009, were at 278.4 billion Euros. This constitutes an increase of 5.3 % compared to 2008. In the same period, health costs per inhabitant rose by 5.6 %, from 3,220 Euros in 2008 to 3,400 Euros in 2009.

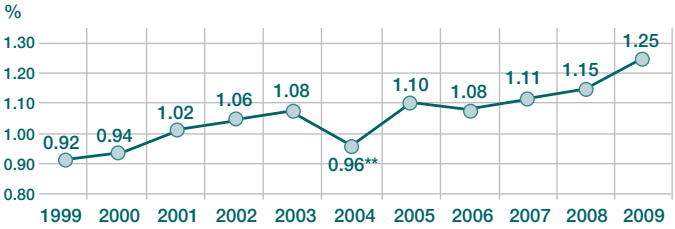
Development of health care expenditures per inhabitant (in Euros)



Source: Illustration of the BPI based on data of the Federal Statistical Office 2011.

In 2009, the share of the SHI expenditures for pharmaceutical drugs, expressed as a percentage of GDP, increased by 0.1 % to 1.25 %.

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 2011.

According to current data for the crisis year 2009 from the Federal Statistical Office, 4.7 million people (every ninth employee) were employed in the German health care sector. The number of jobs in the health care sector rose by 2.2 % in 2009 as compared to 2008. The primary cause of this is an increase in the health service professions (e. g. physicians and other health professionals) and social professions (e.g. geriatric care givers). In 2009, the largest number of staff was employed in outpatient, inpatient and day-patient care health care facilities.

In an ageing society such as Germany´s, with a structural shift toward older, multi-morbid people, and increasing chronic diseases 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.

Due to continually rising contributions to the Statutory Health Insurance (SHI), the development of SHI expenditures is of great interest each year. For many years, the SHI expenditures have been around 7.0 % of GDP (2009: 7.1 %), while the SHI expenditures for drugs are consistently around 1.25 % (2008: 1.15 %) of GDP. Therefore, in the context of the effects of the financial crisis, the drug expenditures of the SHI did not increase beyond the general economic growth rate. 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 influenced by structural problems, i.e. changes in both the revenues as well as the expenditures.

When it comes to revenues, the following factors may have a negative impact:

- -> Increase in the number of so-called mini-jobs (marginal employment)
- -> Loss of incomes 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

On the expenditures side, changes are needed because of

- -> medical and technological progress in combination with an ageing population
- -> increases in chronic diseases
- -> Remuneration increases for physicians in outpatient care
- -> Hospital tariff contracts
- -> Expansion of SHI benefits, e.g. palliative care
- -> Value Added Tax (VAT) increase of 19%
- -> Implementation of the European legislation on working hours

The reforms of 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), introduced in 2006, mainly focused on cost reduction for drug expenditures, 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) and the Act for restructuring the drug market (AMNOG) resulted in further regulatory measures in certain areas, in particular the drug supply. The Statutory Health Insurance Restructuring Act is another measure focused purely on cost reduction. From the perspective of the pharmaceutical industry, the increase in the mandatory discounts (max. 16 %) and the heretofore longest price moratorium for two and a half years are of particular importance. The burden placed on pharmaceutical companies by mandatory discounts was 1.5 billion Euro in 2010 and is forecast at 2 billion Euro in 2011. The AMNOG represents a significant paradigm shift in pricing for pharmaceuticals in Germany. In the future, the price fixed 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 newly implemented early benefit assessment. The first results of these assessments are expected for end of 2011 / beginning of 2012, at the earliest.

In the course of further reforms, the increasing trend toward standardizing of therapies needs to be stopped. At a time when 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.

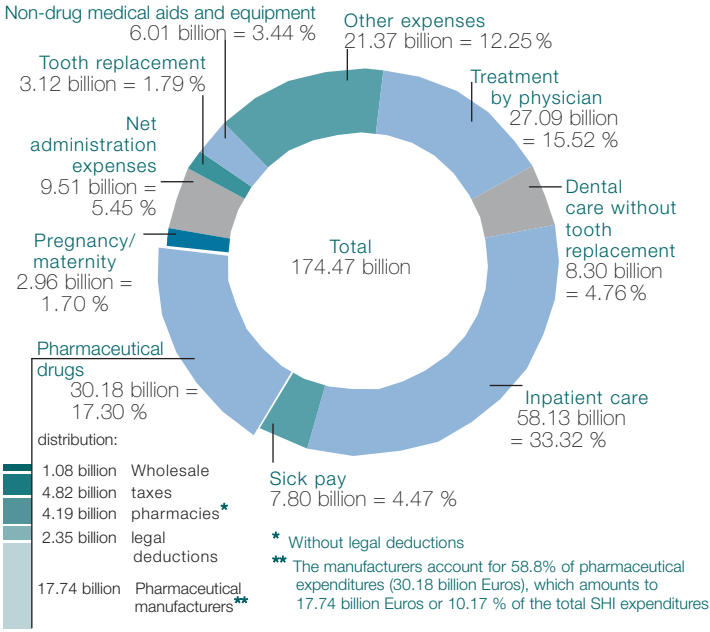
From the perspective of the pharmaceutical industry, a first step toward a financially sustainable reform of the SHI system would be freezing the employer's contribution and uncapping the upper limit of the supplemental premiums. On the one hand, this would break the current link between health care costs and labor expenditures, while on the other hand the use supplemental premiums can be used as a means of regulating the SHI market. The insured persons are better able to make decisions in choosing his or her SHI provider.

Future health care reforms must 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 expenditures and the services financed by them" (expert opinion in 2003).

Cost structure of the Statutory Health Insurance (SHI) 2010
(in billion Euros and as % of all SHI-expenditures)



* Without legal deductions

** The manufacturers account for 58.8% of pharmaceutical expenditures (30.18 billion Euros), which amounts to 17.74 billion Euros or 10.17 % of the total SHI expenditures.

Source: Illustration of the BPI based on KJ1 2011; Drug prescription report 2010.

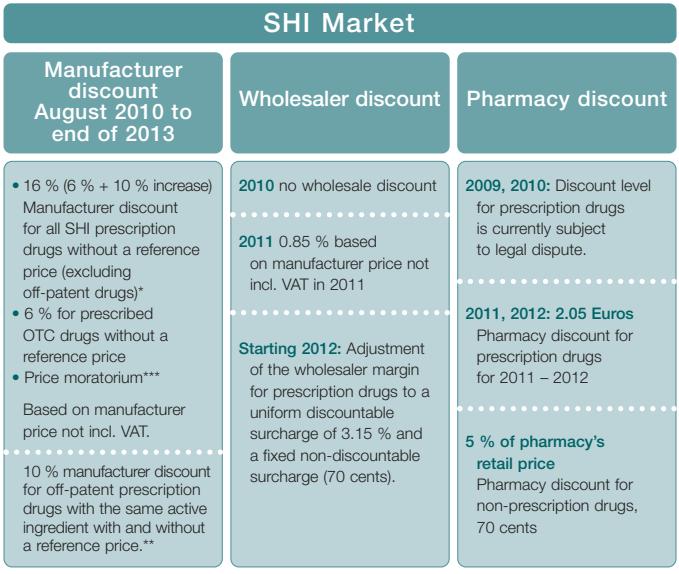
Inpatient care, at 58.13 billion Euros in 2010, is the most cost-intensive sector of the SHI system. The combined expenditures for pharmaceutical drugs (30.18 billion Euros) and for medical treatment (27.09 billion Euros) amount to 57.27 billion Euros, which accounts for nearly the total expenditures of the inpatient care sector. The share of drug expenditures alone was at 17.3 % of the total SHI expenditures.

When analyzing the SHI drug 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 on a 6 % wholesaler margin, 3 % plus 8.10 Euros for the pharmacy margin, as well as 19 % Value Added Tax. The retail price would total just about 11 Euros.

Irrespective of this, rising drug 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, as shown below.

SHI obligatory discounts***



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

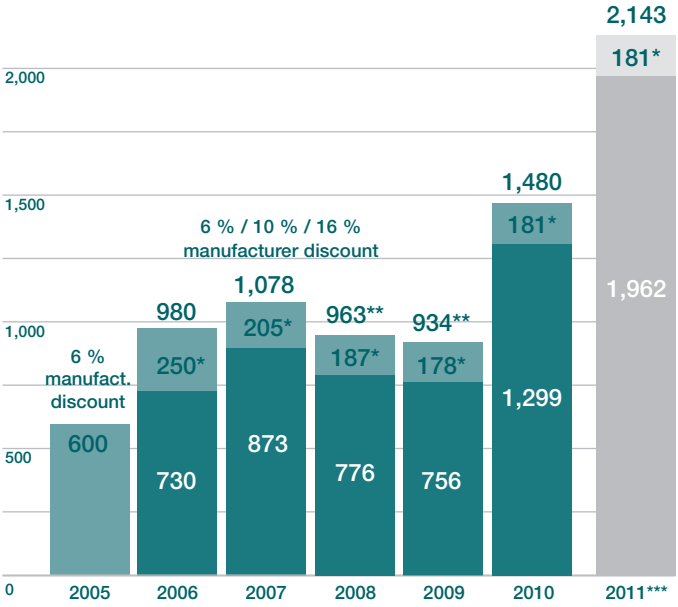
** If at least 30% less than the respective reference price, then a) the 10% discount is automatically dropped. With products with a reference price, the discount is determined based on the reference price. If the price of the product is below the reference price, the discount is based on the lower price.

*** 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 2011.

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. 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 2005–2010 (in million Euros), manufacturer price in SHI market



* So-called "discount for generics"

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

*** Estimates for 2011; the mandatory discounts for the private health insurance sector are not included.

Source: IMS analyses based on PharmaScope® 2011.

In 2010, the cost burden of the pharmaceutical industry due to the obligatory discounts was more than 1.5 billion Euros. IMS has forecast the cost burden of the pharmaceutical industry in 2011 to be more than 2 billion Euros. 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 German Act on reinforcing SHI competition (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 German Law to enhance organizational structures of SHI (GKV-OrgWG) passed. This law, which went into force end of 2008, provides that when entering into contracts as per German Social Code V § 130a sect. 8, procurement law is applicable “provided the pre-requisites mentioned therein are fulfilled”.

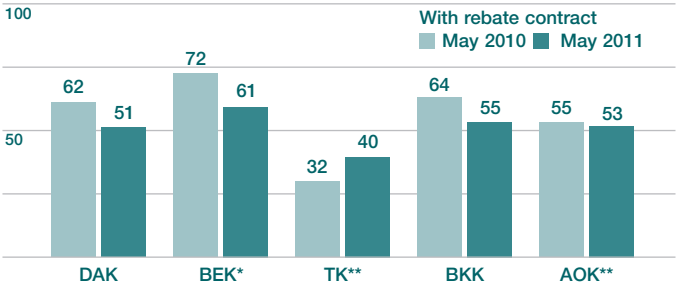
The Act for the Modernization of Procurement Law of 24 April 2009 is also of great importance. This regulation requires the calls for tender to be divided into partial and/ or specialist lots, something that can be helpful to small- and medium-sized enterprises. But the act also contains important regulations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

While the applicability of Procurement Law to rebate contracts concerning generic drugs may be considered a given, a final legal decision on the issue concerning discount contracts patented drugs is still pending.

An essential aspect here is whether Statutory Health Insurance providers, when signing a rebate contract concerning patented drugs, are actually making a selection decision for the insured persons. This pre-selection would be an important characteristic of a public service contract as applied to procurement law, since patented drugs cannot be substituted with discounted equivalents at the pharmacies.

Meanwhile, the number drugs subject to rebate contracts is consistently high for all SHI providers. In May 2011, 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 %)



* Barmer Ersatzkasse merged with Gmünder Ersatzkasse in 2010

** At the time the data was collected, many rebate contracts had expired.

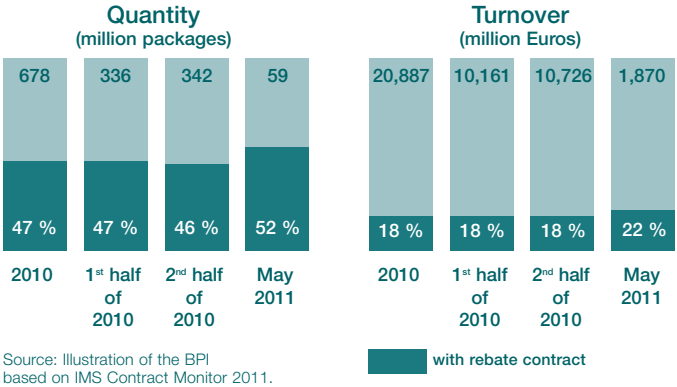
Source: Illustration of the BPI based on IMS Contract Monitor 2011.

According to IMS Health, almost half of the dispensed medications in the SHI market were subject to rebate contracts as of May 2011. In June 2010, 157 health insurance providers had 8,425 rebate contracts in place with 134 pharmaceutical companies covering 27,024 pharmaceuticals. In April 2011, IMS Health reported that 156 health insurance providers had contracts with 178 manufacturers. There were 10.568 contracts in place covering more than 27,218 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 2011.

Regarding the applicability of cartel laws, changes in this direction were implemented pursuant to the coming into force of the German Act for Restructuring the Drug Market (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 cartel law that will be available to the Bundeskartellamt (bureau in charge of regulating competition) for enforcement purposes. 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 German Pharmacy Market

The developments in the German pharmacy market present a very heterogeneous picture. Compared to 2009, the total turnover in the pharmacy market assessed at manufacturer prices rose in 2010 by 3.8 % to a total of 25.6 billion Euros. For prescription drugs, there was an increase in turnover of 5.0 %. On the other hand, turnover with OTC medications decreased by 5.3 %.

Looking at the volume trends in the overall market reveals that there was a slight decrease in 2010. The largest decline of 8.1% compared to the previous year is found within the "drugs and chemicals" sector.

Turnover developments in the pharmacy market 2007 – 2010

(in million Euros)

	2007	2008	2009	2010	Change vs. previous year in %
Total	22,799.3	23,796.2	24,677.4	25,613.4	3.8
Prescription only	17,718.9	18,611.5	19,425.1	20,402.8	5.0
OTC (in pharmacies)	2,927.7	2,974.9	2,918.5	2,823.7	- 3.3
Non-drugs	1,260.7	1,291.6	1,355.5	1,393.1	2.8
Narcotics	686.3	717.2	789.5	814.8	3.2
Non-pharmacy OTC	200.8	195.8	183.5	173.9	- 5.3
Drugs and Chemicals	5.0	5.3	5.2	5.2	0.3

Source: Illustration of the BPI based on data of Insight Health 2011.

Sales trends in the pharmacy market 2007 – 2010

(packages in millions)

	2007	2008	2009	2010	Change vs. previous year in %
Total	1,586.9	1,610.0	1,602.0	1,554.4	- 3.0
Prescription only	691.5	723.1	728.6	709.1	- 2.7
OTC (in pharmacies)	699.3	694.5	678.8	650.2	- 4.2
Non-drugs	138.2	135.1	136.2	139.1	2.1
Non-pharmacy OTC	48.8	47.4	48.2	45.4	3.5
Narcotics	8.6	9.2	9.7	10.0	- 5.7
Drugs and Chemicals	0.6	0.6	0.6	0.6	- 8.1

Source: Illustration of the BPI based on data of Insight Health 2011.

[1] 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 2010 according to sub-categories, the largest growth in comparison to the previous year was found in biopharmaceuticals (12.4 %). Pharmaceutical drugs increased by 2.7 %.

Turnover development of pharmaceutical drug segments according to sub-categories 2007 – 2010 (in million Euros)

	2007	2008	2009	2010	Change vs. previous year in %
Total	22,799.3	23,796.2	24,677.4	25,613.4	3.8
Pharmaceutical drugs	17,331.4	17,982.3	18,678.1	19,177.5	2.7
Biopharmaceuticals	3,075.6	3,351.4	3,484.6	3,915.8	12.4
Phytopharmaceuticals	715.7	732.3	771.6	793.0	2.8
Other*	800.8	828.2	805.5	778.8	- 3.3
Diagnostics	593.6	606.0	632.0	646.3	2.3
Homeopathic medicines	243.9	252.2	258.5	252.8	- 2.2
Anthroposophic medicines	38.4	43.8	47.1	49.3	4.6

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

Source: Illustration of the BPI based on data of Insight Health 2011.

In terms of volume, only anthroposophical medicines and diagnostics increased in 2010 (7.1 % and 2.6 %, respectively). The sales volumes of pharmaceutical drugs increased by 3.4 %.

Sales volumes of pharmaceutical drug segments according to sub-categories 2007 – 2010 (in million packages)

	2007	2008	2009	2010	Change vs. previous year in %
Total	1,586.9	1,610.0	1,602.0	1,554.4	- 3.0
Pharmaceutical drugs	1,235.6	1,259.5	1,251.1	1,209.1	- 3.4
Phytopharmaceuticals	130.8	132.0	129.5	126.2	- 2.6
Other*	119.7	114.9	116.2	115.6	- 0.5
Homeopathic medicines	49.8	51.5	52.4	49.4	- 5.8
Diagnostics	26.9	27.5	28.3	29.1	2.6
Biopharmaceuticals	17.6	17.6	16.8	16.8	- 0.2
Anthroposophic medicines	6.5	6.9	7.6	8.1	7.1

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

Source: Illustration of the BPI based on data of Insight Health 2011.

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 slightly decreasing trend in sales volumes. Compared to the previous year, the largest growth (5.83 %) was in the field of anti-platelet treatments, followed by topical anti-rheumatics and analgesics (1.82 %).

Top 10 leading indication areas (ATC-3) in the pharmacy market 2010 by sales volumes

Indication areas (ATC-3)	Packages in thousands	% to previous year	Share of total turnover in %	Share of total sales in %
Total	1,554,361.9	- 2.97	100.00	100.00
N02B other analgesics	144,201.3	- 5.59	1.95	9.28
R01A nasal preparations, topical	73,756.0	0.75	0.65	4.75
R05C expectorants without anti-infectants	60,932.1	- 8.69	0.89	3.92
V03X other therapeutic preparations	47,831.2	- 8.00	0.83	3.08
A02B ulcer treatments	42,531.4	- 7.80	2.25	2.74
M01A anti-phlogistic/anti-rheumat., non-steroid.	41,729.7	- 4.99	0.76	2.68
C07A beta-blockers	37,581.1	0.50	0.77	2.42
M02A anti-rheumatics and analgesics, topical	30,534.5	1.82	0.55	1.96
N05B hypnotics and sedatives	26,963.6	0.60	0.46	1.73
B01C Anti-platelet treatments	25,908.1	5.83	1.53	1.67

Source: Illustration of the BPI based on data of Insight Health 2011.

The turnover developments in the Top 10 indications according to ATC-3 show the highest increases (as compared to the previous year) in the areas of "other antineoplastic agents" and anti-TNF preparations. The share of these two groups in the total turnover in the pharmacy market was 6.79 % in 2010.

Top 10 leading indication areas (ATC-3) in the pharmacy market 2010 by turnover

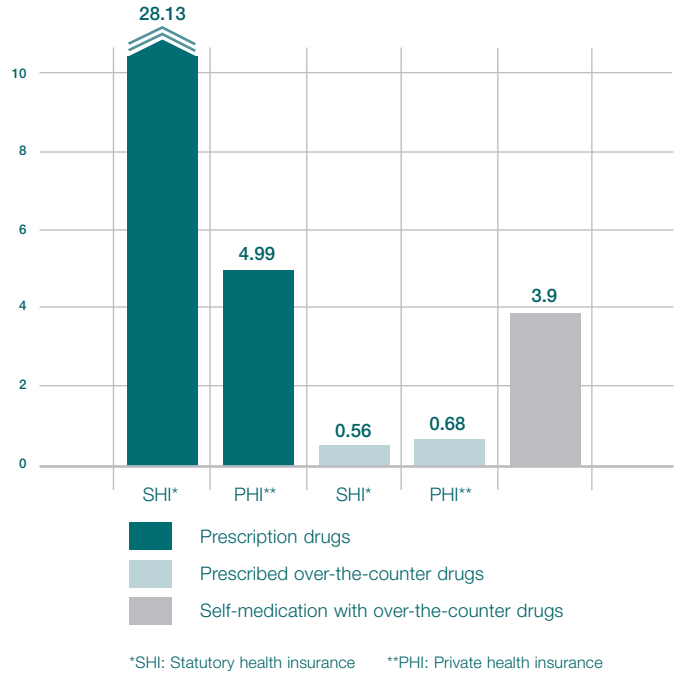
Indication areas (ATC-3)	In thousands Euros	% to previous year	Share of total turnover in %	Share of total sales in %
Total	25,613,370.3	3.79	100.00	100.00
L01X Other antineoplastic agents	873,859.7	33.15	3.41	0.07
A10C Human insulin and analogs	869,697.9	1.80	3.40	0.82
L04B Anti-TNF preparations	866,911.4	25.84	3.38	0.02
N05A Antipsychotics	817,329.0	4.38	3.19	0.86
N02A Analgesics, narcotics	717,611.0	4.70	2.80	0.45
L03B Interferons	650,897.5	6.53	2.54	0.02
C09D Angiotensin II antagonists	650,613.5	8.71	2.54	0.59
N03A Antiepileptics	609,659.2	8.57	2.38	0.71
J07A Vaccines, monovalent	594,563.4	- 16.45	2.32	0.38
T02D Diabetes tests	589,650.7	2.43	2.30	1.65

Source: Illustration of the BPI based on data of Insight Health 2011.

The German pharmaceutical market

The illustrations below show the different segments of the pharmaceutical market in pharmacies. For prescription drugs assessed with the pharmacy's retail price, IMS Health determined a total turnover of 33.12 billion Euros in 2010. Of this turnover, ca. 28.13 billion Euros (84.9 %) was disbursed by the SHI providers. The turnover of over-the-counter medicines showed a total of 5.12 billion Euros for 627 million packages.

2010 turnover of pharmaceuticals in pharmacies at pharmacy retail price (in billion Euros)

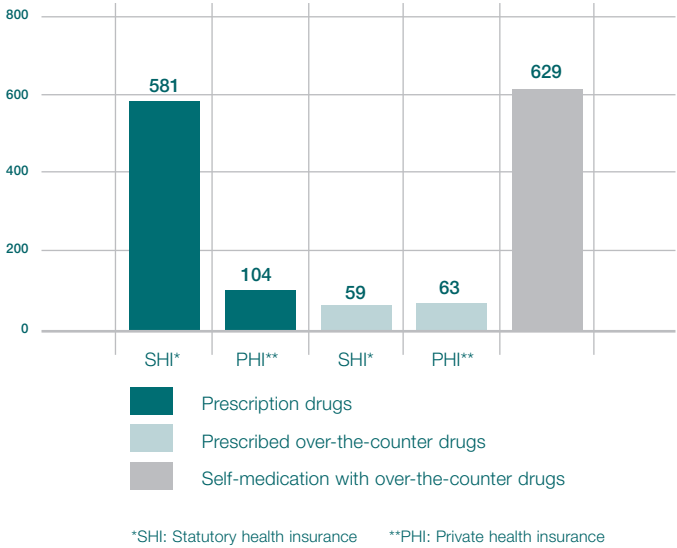


*SHI: Statutory health insurance **PHI: Private health insurance

Source: Illustration of the BPI based on data of IMS Health 2011.

In 2010, 59 million package units of over-the-counter drugs were reimbursed by the SHI providers, while 506 million units were purchased for self-medication.

Sales volumes of pharmaceuticals in pharmacies 2010
(in million package units – PU)



*SHI: Statutory health insurance **PHI: Private health insurance

Source: Illustration of the BPI based on data of IMS Health 2011.

The differences between turnover and sales volumes are due to the price level of the relevant pharmaceutical drugs. At 48.35 Euros per package, the average pharmacy retail price of a prescription drug is significantly higher than the average price of over-the-counter drugs (6.98 Euros).

The price differences between over-the-counter and prescription drugs are an expression of the different competitive situation of these products. Over-the-counter drugs are established products that have been on the market for quite some time, and that are frequently subject to competition from generics. There are also many phytopharmaceuticals in this segment of highly effective pharmaceutical drugs. The group of prescription drugs includes many innovative medicinal products, which are partly still protected by patent and whose higher price is intended to cover the high R&D costs.

The OTC Market

The turnover developments in the German pharmacy market in 2010 with pharmacy-only drugs, non-pharmacy-only drugs and health products (GMS, Gesundheitsmittel)* is still dominated by pharmacy-only drugs at 79 % (sales volumes: 78 %). However, for the past years, the share of health products in the pharmacy market has been increasing (share in turnover 2005: 12.2 %, in 2010: 16.4 %). In the last two years the turnover in health products has increased by 2.2 %. 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 2005: 15.7 %; in 2010: 16.8 %).

In comparison to the previous year, the OTC market in 2010 showed slight decreases (sales volumes: -3.3 %; turnover: -2.1 %) to levels below those in 2004, the year the health care modernization act eliminated, with a few exceptions, reimbursement of non-prescription drugs.

Development of turnover in the German OTC pharmacy market

Turnover in thousand Euros at pharmacy retail price

	2005	2006	2007	2008	2009	2010
Pharmaceutical drugs						
- Pharmacy-only	5,529,331	5,294,711	5,285,794	5,108,196	4,978,771	4,822,819
- OTC	350,075	334,815	328,635	316,233	298,569	283,469
GMS pharmacy	820,650	845,954	833,337	899,387	961,019	999,495
Total	6,700,056	6,475,480	6,447,766	6,323,816	6,238,359	6,105,783

Market share in %	2005	2006	2007	2008	2009	2010
Pharmaceutical drugs						
- Pharmacy-only	82.6	81.8	82.0	80.8	79.8	79.0
- OTC	5.2	5.2	5.1	5.0	4.8	4.6
GMS pharmacy	12.2	13.0	12.9	14.2	15.4	16.4
Total	100	100	100	100	100	100

Source: Illustration of the BPI based on data of IMS OTCGMS Report 2011.

*GMS: Defined as products competing with pharmaceutical drugs.

Development of sales volumes in the German OTC pharmacy market

Volume in thousands of package units

Packages	2005	2006	2007	2008	2009	2010
Pharmaceutical drugs						
- Pharmacy-only	686,585	653,090	641,636	619,023	607,719	585,504
- OTCs	51,202	48,958	46,965	45,093	44,204	41,508
GMS pharmacy	137,866	127,207	123,271	122,142	126,733	126,309
Total	875,653	829,255	811,872	786,258	778,656	753,321

Market share in %	2005	2006	2007	2008	2009	2010
Pharmaceutical drugs						
- Pharmacy-only	78.4	78.8	79.0	78.7	78.0	77.7
- OTCs	5.9	5.9	5.8	5.8	5.7	5.5
GMS pharmacy	15.7	15.3	15.2	15.5	16.3	16.8
Total	100	100	100	100	100	100

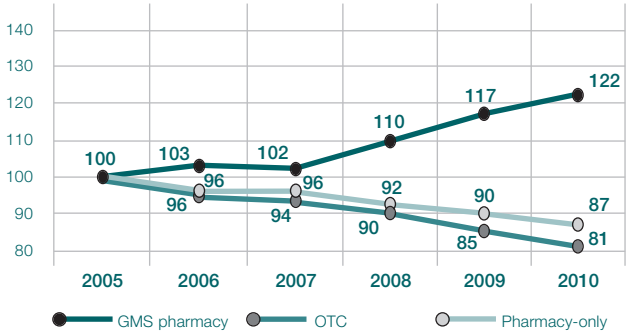
Source: Illustration of the BPI based on data of IMS OTCGMS Report 2011.

As in the past, the mail-order distribution channel has continued to show dynamic developments. However, determining the exact turnover and sales volumes in the mail-order business continues to be difficult due to unvalidated numbers. However, it is clear that there is a shift from in-pharmacy dispensing of pharmaceuticals to mail-order distribution. In 2010, the turnover of the mail-order business with OTC drugs and health products has increased by 7.9 % and has a 10 % share in the OTC market. Strong brands and large package sizes often have a far greater share, perhaps up to 30 %. Only very few companies are able to compensate their losses in turnover in the pharmacy-dispensed pharmaceuticals with turnover increases in the mail-order business.

Every fifth non-prescription product sold in pharmacies is also a non-pharmacy-only product (share in sales volumes: 22 %; share in turnover: 20 %). As demonstrated in the following graph, this trend has been observed since 2004.

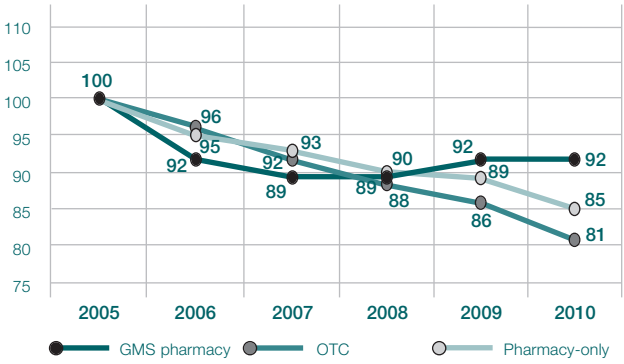
Indexed illustrations of turnover and sales development of over-the-counter drugs in the German pharmacy market (index comparison, based on turnover (pharmacy retail price) 2005 = 100; based on sales volumes: units 2005 = 100)

Developments in turnover (index)



Source: Illustration of the BPI based on data of IMS OTCGMS Report 2011.

Developments in sales volumes (index)



Source: Illustration of the BPI based on data of IMS OTCGMS Report 2011.

In the category of non-drugs, higher quality products are increasingly on offer. For instance, the average price of a non-drug health care product sold in pharmacies rose from 5.95 Euros in 2005 to 7.91 Euros in 2010.

In 2009, the average pharmacy retail price of a product in the German pharmacy market was 8.11 Euros. The average price in the category with the highest sales volumes for pharmacy-only drugs was 8.24 Euros in 2010, which slightly higher than the average price in 2009 and is also 2 % higher than the average pharmacy retail price in 2005. Over the next years, further developments in the German pharmacy market such as the growth of the mail-order business, expansion of franchising and cooperation amongst pharmacies will exert a strong influence on price development.

Average pharmacy retail price for OTCs in the pharmacy market

Prices in Euro	2005	2006	2007	2008	2009	2010
Pharmaceutical drugs						
- Pharmacy-only OTCs	8.05	8.11	8.24	8.25	8.19	8.24
- Non-pharmacy OTCs	6.84	6.84	7.00	7.01	6.75	6.83
GMS* pharmacy	5.95	6.65	6.76	7.12	7.58	7.91
Mean value** (weighted by sales volumes)	7.65	7.81	7.94	8.04	8.01	8.11

* 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 2011.

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 2008 – 2010

Subcategory	2008	2009	2010
Total	667,058,109	676,948,339	676,541,694
Pharmaceuticals*	629,429,360	638,818,316	638,698,236
Diagnostics	21,697,438	22,769,452	23,929,569
Other**	6,299,770	6,257,367	5,871,339
Phytopharmaceuticals	6,055,594	5,859,070	5,285,243
Homeopathics	2,700,022	2,396,542	1,949,924
Anthroposophic medicines	875,925	847,592	807,383

* Including biopharmaceuticals

** Hygiene products, injection equipment, disinfectants, sideline products, DROGEN, diet products, medical devices, chemicals, nutritional supplements

Source: Illustration of the BPI based on data of Insight Health 2011.

In 2010, an overall volume of 677 million prescriptions were financed through the SHI system. The share of pharmaceuticals in the total prescription volume is around 94.4 %. Looking at the development of the volume of prescriptions, it becomes clear that the volume of prescribed diagnostics has continuously increased, currently making up 3.5 % of the total volume of prescriptions. Phytopharmaceuticals are prescribed in 0.8 % of cases, homeopathic medicines in 0.3 % of cases.

Turnover financed by the SHI system 2008 – 2010, pharmacy retail price in Euros

Subcategory	2008	2009	2010
Total	29,541,970,141	30,880,290,845	31,922,998,297
Pharmaceuticals*	28,406,306,189	29,671,778,579	30,689,841,365
Diagnostics	837,273,042	903,715,628	945,558,363
Other**	169,533,746	177,029,282	166,160,834
Phytopharmaceuticals	81,395,760	81,393,463	79,905,763
Anthroposophic medicines	22,319,616	23,678,175	22,622,640
Homeopathics	25,141,788	22,695,718	18,909,332

* Including biopharmaceuticals

** Hygiene products, injection equipment, disinfectants, sideline products, DROGEN, diet products, medical devices, chemicals, nutritional supplements

Source: Illustration of the BPI based on data of Insight Health 2011.

Development of market shares as financed by the SHI system 2008 – 2010 in %

	Prescription volumes			Turnover		
Subcategory	2008	2009	2010	2008	2009	2010
Total	100.00	100.00	100.00	100.00	100.00	100.00
Pharmaceuticals*	94.36	94.37	94.41	96.15	96.09	96.14
Diagnostics	3.25	3.36	3.54	2.83	2.93	2.96
Other**	0.94	0.92	0.86	0.57	0.57	0.52
Phytopharmaceuticals	0.91	0.87	0.78	0.28	0.26	0.25
Anthroposophic medicines	0.13	0.13	0.12	0.08	0.08	0.07
Homeopathics	0.40	0.35	0.29	0.09	0.07	0.06

* Including biopharmaceuticals

** Hygiene products, injection equipment, disinfectants, sideline products, DROGEN, diet products, medical devices, chemicals, nutritional supplements

Source: Illustration of the BPI based on data of Insight Health 2011.

In looking at turnover, it is clear than the turnover in pharmaceuticals 2010 was 29.7 billion Euros or 4.5 % above the levels in the previous year. The market share of pharmaceuticals is 96 %. The relatively small share of phytopharmaceuticals (0.3 %) in SHI spending is primarily due to the lower average price for such products. The same is true for homeopathics, which account for 18.9 million Euros or a mere 0.06 % in SHI expenditures.

Top 10 leading indications (ATC-3) in the SHI market 2010 by sales volumes

Indications (ATC-3)	Prescriptions	% to previous year	%-share of total volume	%-share of total turnover
Total	676,541,694	- 0.06	100.00	100.00
M01A antiphlog. / antirheum., non-steroid	35,966,283	0.96	5.32	1.81
N02B other analgesics	35,528,601	- 3.87	5.25	1.94
C07A beta-blockers	34,381,332	3.40	5.08	1.74
A02B ulcer treatments	27,851,300	3.55	4.12	2.88
C09A ACE inhibitors	24,706,450	2.86	3.65	1.07
T02D diabetes tests	23,410,593	5.36	3.46	2.81
C03A diuretics	21,609,202	1.06	3.19	1.23
H03A thyroid preparations	20,427,188	5.31	3.02	1.02
N06A antidepressants / mood stabilizers	19,382,759	6.88	2.86	2.55
C08A calcium antagonists	18,145,192	1.04	2.68	0.95

Source: Illustration of the BPI based on data of Insight Health 2011.

When looking at sales volume in 2010, the “antidepressants / mood stabilizers”, followed by “diabetes tests” and “thyroid preparations”, showed the highest growth rates. This group corresponds to 6.38 % of the total turnover.

Top 10 leading indications (ATC-3) in the SHI market 2010 according to turnover

Indication areas (ATC-3)	In million Euros	% to previous year	%-share of total volume	%-share of total turnover
Total	31,923.0	3.38	100.00	100.00
A10C human insulin and analogs	1,193.7	1.72	1.77	3.74
N05A antipsychotics	1,149.3	6.74	1.76	3.60
L04B Anti-TNF preparations	1,097.7	20.73	0.04	3.44
N02A analgesics, narcotics	925.0	4.80	0.92	2.90
A02B ulcer treatments	917.8	- 12.37	4.12	2.88
T02D diabetes tests	896.8	4.79	3.46	2.81
N03A antiepileptics	819.2	9.30	1.36	2.57
N06A antidepressants / mood stabilizers	812.7	7.17	2.86	2.55
L03B interferons	795.2	3.76	0.05	2.49
C09D angiotensin-II antagonists, combinations	782.8	8.50	1.14	2.45

Source: Illustration of the BPI based on data of Insight Health 2011.

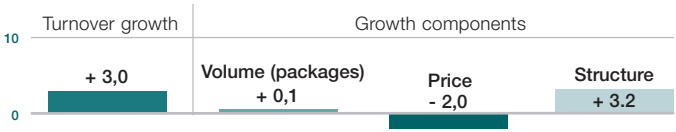
With respect to turnover in 2010, the “anti-TNF preparations” had the highest growth rate in comparison to the previous year. The highest declines were seen for ulcer treatments (12.37 %).

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.

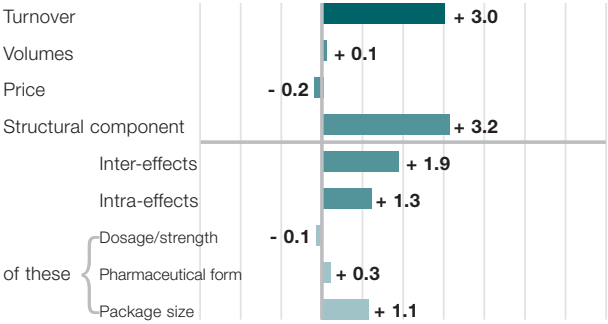
As a quantitative instrument of market research and health care policy, the SHI structure component study of IMS HEALTH shows the individual components (price, volume and structure) of changes in turnover.

SHI - structural component, growth rates, 2010
(changes to previous year in %)



Source: Illustration of the BPI based on data of the IMS® SHI-Structural component study 2011.

Growth components in 2010 as a cause of the turnover developments in the SHI market, divided into sub-groups (in %), pharmacy retail price



Source: Illustration of the BPI based on data of the IMS® SHI-Structural component study 2011.

In 2010, the IMS structural component was 3.2 %. In the past, this component has ranged between 5 % and 8 %. The price level in the SHI pharmaceutical market decreased slightly by 0.2 %, while the volumes increased by 0.1 %.

By simple addition, one can generate the individual components (e.g. the structural component "package size") for the individual forms of administration, the preparation 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.

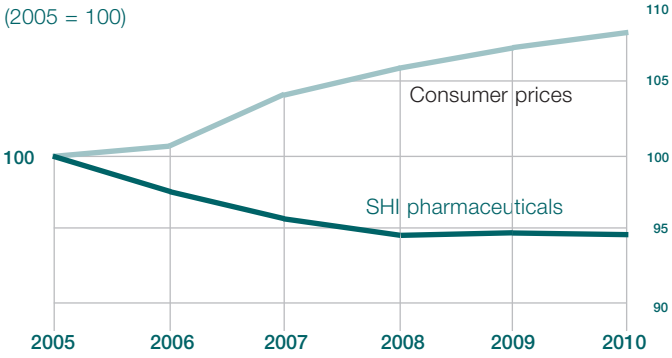
The “Pharmaceutical Atlas” published by the Institut für Gesundheits- und Sozialforschung (IGES) uses the ATC classification, similar to the IMS structure component analysis. The IMS structure component analysis examines all ATC groups (ATC 1 to ATC 4) and thus allows for indication-oriented analysis 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 2010, especially when compared with the development of consumer prices.

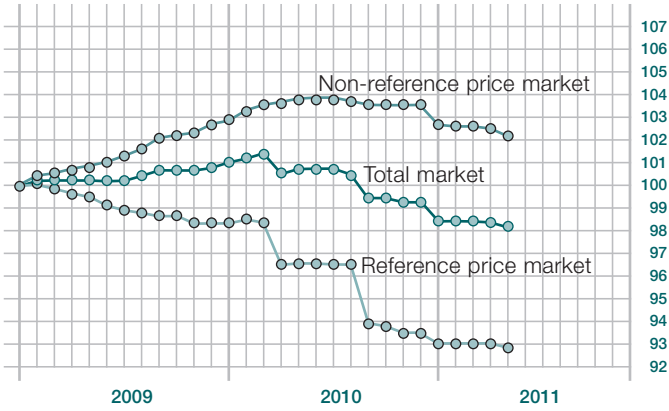
Price development for pharmaceuticals -
Price indices in comparison
(2005 = 100)



Sources: Illustration of the BPI based on data of the Federal Statistical Office 2011.

As part of the German Act on SHI Modernization (GMG), a new pharmaceutical drug price ordinance has been in effect since 1 January 2004, which – for the prescription-only segment – has led to decreasing distribution costs for high-priced pharmaceuticals, while those for low-cost pharmaceuticals have increased. Furthermore, since 2006, the significant effects of the German Act on Economic Optimization of Pharmaceutical Care (AVWG) have become evident. Prices, especially for pharmaceutical drugs under reference pricing, are continuously decreasing.

Price development according to market segments between January 2009 – May 2011 (January 2009 = 100)



Source: Illustration of the BPI based on data of the Wissenschaftliches Institut der AOK (WidO) 2011.

The number of pharmaceutical drugs in Germany

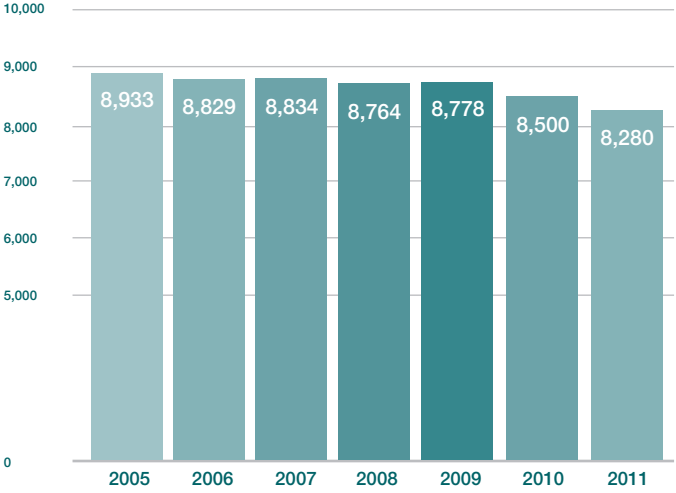
One focus of criticism is the relatively high number of pharmaceutical drugs on the German market in international comparison. However, a more differentiated approach is required in this matter, as the method for tallying the number of drugs differs internationally.

As of 17 June 2011, the BfArM reported marketing authorisations or registrations for 60,237 pharmaceutical drugs in all indications. The “Rote Liste®” for 2011, the comprehensive drug registry for Germany, only includes 8,280 preparations, with a total of 33,737 prices (pharmaceuticals are almost always marketed at different prices for different package sizes).

This difference between nearly 60,000 authorised pharmaceuticals on the one hand and only roughly 10,000 drug entries in the “Rote Liste®” can be explained by the different tallying methods and the only partial listing of self-medication drugs in the “Rote Liste®”.

In Germany, a separate marketing authorisation is required for each strength and each pharmaceutical form of a single active substance. This means there is a separate authorisation for each cream, unction 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 authorisation.

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



Source: Illustration of the BPI based on data of the “Rote Liste®" 2011.

Also, the number of drugs reported by the BfArM is simply 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 authorisation of a pharmaceutical drug does not necessarily require that drug to also be marketed. It is not unusual for marketing authorisation holders to only market a part of the authorized products in the company portfolio. However, the marketing authorisation of an unmarketed drug 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 have 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 companies (so-called OTC-reimbursement list). Also, the “Rote Liste®” is also a reference for other health professionals such as pharmacists.

In short, 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 says more about the supply amplitude and supply depth of the market than about a possible over-saturation of the market, since the number of drugs gives no information on the actual use of the drugs.

Interventions in the pharmaceutical market - future prospects

The continuous governmental interventions in the pharmaceutical sector previously described here have continued in 2010. These governmental interventions have increased in frequency, both in the area of drug law and civil law. Since 1989, changes to pharmaceutical legislation have been made nearly every year, leading to fundamental changes in the pharmaceutical market. In 2010, several laws modifying civil law and affecting the pharmaceutical industry: the German Social Code Book V was changed in a second legislative act before the previous change was formally completed. These changes have required continuous adjustment and adaptation on the part of pharmaceutical companies.

Policymakers primarily focus on the expenditures of the Statutory Health Insurance system. The fundamental problem of achieving sustainability in the SHI system in Germany can only be solved if policymakers also address the revenue side of this equation. Germany's population is getting older and should benefit from medical advances. However, this will only be sustainable if society accepts that this will also require an increase in expenditures. The Christian Democratic-Free Democratic coalition government has reverted to interventionist centralist measures for cost-containment, with a special focus on the pharmaceutical market. By implementing higher mandatory manufacturer discounts, the government can generate short-term savings which would be much more difficult to extract from hospitals and SHI-registered physicians. However, it should be emphasized that the pharmaceutical market is not the primary cost driver in this instance: it only contributes 17 % to the SHI system budget and increases at a rate of 0.6 %.

In defining the process for early benefit assessments, the Act for restructuring the drug market (AMNOG) established a regulatory instrument intended to assess the added benefit of innovative drugs and to determine their reimbursement levels. For drugs with new chemical entities subject to data exclusivity, pharmaceutical companies must submit a dossier to the Federal Joint Committee (G-BA), at the latest at the time of first market launch in Germany. The result of this assessment provides the basis for reimbursement level negotiations between the pharmaceutical company and the Federal Association of Statutory Health Insurance Funds. The reimbursement level is negotiated as a rebate or discount on the manufacturer's price. If no agreement is reached, an arbitration body decides. In publishing its paper "Dezentral vor Zentral [Decentralised before Centralised]", the German Pharmaceutical Industry Association was the

first German industry association to submit its ideas for a system for negotiating reimbursement levels. Policymakers used many of the ideas presented in this paper, but finally decided on a centralized negotiation procedure, while the decentralized negotiations are secondary.

Because the time required for the development of pharmaceuticals is so long, a transparent and predictable health care policy is of great importance for the pharmaceutical industry. Yet transparency and planning reliability are increasingly threatened by short-term interventions such as mandatory rebates, pricing moratoria and other measures that continue to exist irrespective of the procedure for negotiating reimbursement levels. The concentration process in the pharmaceutical industry is exacerbated. Small and medium sized enterprises are particularly threatened by this development. This tendency is augmented by policymakers' refusal to honor the effort invested in R & D, especially in the areas of new indications for established drugs or new pharmaceutical forms (e. g. for children or geriatric patients), by not including them in the reimbursement programs. Attempts to prevent the formation of oligopolies in other industries are completely contradicted in the pharmaceutical industry, where the formation of these oligopolies is encouraged.

A policy focused purely on cost-containment in the pharmaceutical market fails to do justice to the contribution of the pharmaceutical industry towards the treatment of diseases and the perception of Germany as a highly competitive industrial powerhouse. The German Pharmaceutical Industry Association will work to counteract these effects by publically calling attention to the successes achieved with the use of pharmaceutical for the prevention and treatment of diseases (e.g. in the areas of HIV treatment and oncology).

Future growth potential is predicted for novel therapies in biomedicine, genetic medicine and tissue engineering. Even though these therapeutic approaches are only at the start of their development, the German Pharmaceutical Industry Association focused on this area early on. Drugs in this segment are sometimes able to cure conditions for which there were previously only symptomatic treatments. The legal framework for their approval at the EU level via the centralized authorisation procedure involves significant hurdles, which affects the costs of the medicinal products. Policymakers wish to regulate the market penetration of these innovative – and therefore usually more expensive – medicinal products through regulatory measures in reimbursement policy. The availability of innovative pharmaceuticals on the German market will be in large part influenced by how the process of early benefit assessment is conducted and how responsibly the stakeholders deal with negotiations over reimbursement levels. This will require a willingness to engage in constructive dialog, instead of confrontational disputes as witness in the past.

In 2011, the „Gesetz zur Verbesserung der Versorgungsstrukturen in der Gesetzlichen Krankenversicherung“ (Act to improve the health care service delivery by the SHI) will implement significant changes. The German Pharmaceutical Industry Association was the first German industry association to submit a concept for improving the transparency and democratic legitimization of the Joint Federal Committee (G-BA). Other aspects of this draft legislation, such as the upgrading and new structure of specialist physician care, offer interesting possibilities for patients with rare diseases.

2011 will also see the start of a significant amendment of the German Drug Act (AMG). Changes pertaining to pharmacovigilance made at the EU level will result in significant changes to the German Drug Act and the organization of pharmacovigilance practices in the industry and competent authorities. Of particular relevance for the pharmaceutical industry are the Directive 2011/62/EU on the prevention of counterfeit medications and the Directive 2010/84/EU and Regulation (EU) No. 1235/2010 in the area of pharmacovigilance. In this pharmaceutical package, initiated in 2008, the European Commission has addressed significant regulatory topics. However, these regulations will need to be further specified by the European Commission with co-called delegated acts.

The focus of the legislation to prevent counterfeit drugs from entering the legal supply chain is the implementation of security features on drug packaging. The aforementioned delegated acts will contain specifications for the unique identifier system, but not for the so-called tamper proof evidence. In addition, the delegated acts will also address topics such as Good Manufacturing Practice for active substances and import requirements. Details on which medicinal products will be required to have security features and which will not, will also be discussed in the delegated acts.

Regarding the new legislation on pharmacovigilance, the particular form of the public hear-ings, access to the European EudraVigilance Da-tabase and its contents, as well as the requirements for post-authorisation efficacy studies will be of particular interest.

Many of the anti-counterfeiting measures as well as the phar-macovigilance regulations are expected to be addressed in the 16th Amendment of the German Drug Act. The German Pharmaceutical Industry Association will focus on ensuring that the implementation of these measures in Germany will not exceed the requirements stipulated by EU law and that adequate solutions are found to manage the resulting issues.

With its 60 years of experience in the pharmaceutical market and through its network of experts in its Berlin office, Brussels office and the European association EUCOPE, the German Pharmaceutical Industry Association is in a good position to master the future challenges.

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Acronyms

AKG	Arzneimittel und Kooperation im Gesundheitswesen (Pharmaceuticals and Cooperation in the Health Care Sector)
AMG	Azneimittelgesetz (German Medicines Act)
AMNOG	Arzneimittelmarktneuordnungsgesetz (Act for restructuring the drug market)
AOK	Allgemeine Ortskrankenkasse (a German public health insurance company)
ATC Code	Anatomic Therapeutic Chemical Classification
AVP	Apothekenverkaufspreis (pharmacy retail price)
AVWG	Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz (Economic Optimization of Pharmaceutical Care Act)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
BIP	GDP
BMBF	Bundesministerium für Bildung und Forschung (Federal Ministry of Research and Education)
BMG	Bundesministerium für Gesundheit (Federal Ministry of Health)
BPI	Bundesverband der Pharmazeutischen Industrie e. V. (German Association for Pharmaceutical Industry)
DDD	Defined Daily Dose
DRGs	Diagnosis Related Groups
EFPIA	European Federation of Pharmaceutical Industry and Associations
EMA	European Medicines Agency
EU	European Union
F&E	R & D (Research and development)

FSA	Freiwillige Selbstkontrolle Arzneimittelindustrie (Voluntary Self-regulation for the Pharmaceutical Industry)
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
GKV	Gesetzliche Krankenversicherung (Statutory Health Insurance; SHI)
GKV-OrgWG	Gesetz zur Weiterentwicklung der Organisationsstrukturen in der Gesetzlichen Krankenversicherung (Act to enhance the organizational Structures of Statutory Health Insurance)
GKV-WSG	GKV-Wettbewerbsstärkungsgesetz (Act to Reinforce Competition between the German Statutory Health Insurance)
GMG	GKV-Modernisierungsgesetz (SHI System Modernization Act)
GMS	Gesundheitsmittelstudie (health product study)
GWB	Gesetz gegen Wettbewerbsbeschränkungen (Act against Restraints of Competition)
HAP	Herstellerabgabepreis (manufacturer price)
IGES	Institut für Gesundheits- und Sozialforschung (a research institute for health and healthcare)
IMS	IMS HEALTH GmbH & Co. OHG
Insight Health	INSIGHT Health Management GmbH
LCD	Local Currency Dollar
MwSt.	VAT
NCE / NBE	New Chemical or New Biological Entities
OTC	Over-the-counter / Self-medication
OR	Outcomes Research

Acronyms

PE	Packungseinheit (package unit; PU)
PEI	Paul-Ehrlich-Institute
Phytos	Phytopharmaceuticals
PKV	Private Krankenversicherung (Private health insurance)
SGB V	Sozialgesetzbuch V (Code of Social Law V)
SGG	Sozialgerichtsgesetz (Social Court Code)
UAW	Unerwünschte Arzneimittelwirkung (adverse drug reaction)
WHO	World Health Organisation
WidO	Wissenschaftliches Institut der Ortskrankenkassen (Scientific institute of the AOKs)

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