

### **Statistics 2013**

The Pharmaceutical Industry in Germany



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The vfa is the trade association of the research-based pharmaceutical companies in Germany. It represents the interests of 45 globally leading pharmaceutical companies and their more than 100 subsidiaries and affiliated companies in the areas of health, research, and economic policy. The vfa member companies make up about two thirds of the German pharmaceutical market and employ approximately 78,000 people in Germany. More than 18,000 are engaged in research and development.



#### Dear readers,

What at first glance seems to be a work of statistical analysis actually provides page after page of proof of the medical advances achieved for patients by pharmaceutical research companies. Thus, life-threatening illnesses, such as cancer, are a consistent research focus. A good third of all products brought onto the market in 2012 were drugs that make various types of cancer treatable (page 5), increasing the probability that more people will live longer and in better health.

Furthermore, pharmaceutical research companies are a stable and significant economic factor for Germany, both regionally and at the national level. They offer highly qualified jobs while strengthening the economy through exports. In hardly any other industry do employees provide more surplus value for the economy; likewise, the pharmaceutical industry has few rivals in terms of percentage of investment in Germany.

"Statistics 2013" offers readers some of the most important figures and facts collected by vfa over the last year. The report illustrates the accomplishments, developments, and potential of the pharmaceutical industry and its greater impact.

Considering the ongoing economic difficulties in Germany, these results are all the more remarkable. Increased mandatory discounts are lowering not only expenses for statutory health insurers, but also sales for our companies. Thus, the policy deprives an industry – which, perhaps more than any other, is focused on life-saving innovations – of capital that should be invested in research and development (R&D). Nevertheless, our companies' investment in R&D here in Germany reached record levels in 2012. Despite strong headwinds, we are proud to take responsibility for the advancement of medicine.

Germany shines not only as a center of research, but also of production: Medications "Made in Germany" are sought after the world over. An export ratio that has now reached 66 percent shows that companies earn less and less revenue in the domestic market and are focusing ever more intently on international competition in global markets.

Our industry has the potential to grow in Germany. Its development should be promoted, not hindered by shortsighted cost containment measures; after all, in the future, too, we want to be able to provide, from Germany and for Germany, benefit and surplus value for individuals as well as for the national economy.

Birgit Fischer CEO of vfa

Birgit Phiches

#### People

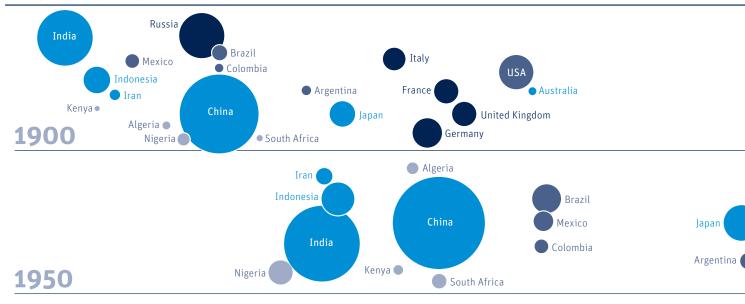
The population is getting older. Besides improved living conditions, medical progress plays a key role. Each year, we gain two to three months of extended life.

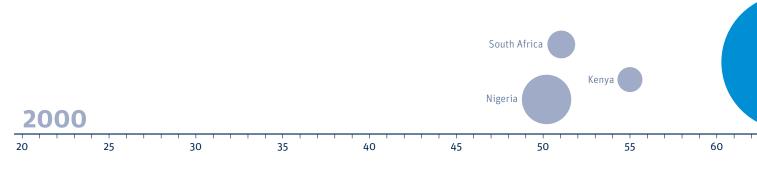
According to studies, new pharmaceuticals have provided 40 percent of these gains. Yet, only around a third of all illnesses known today are curable – or at least easily treatable. That's why the researched-based pharmaceutical companies are working flat out to conquer more and more diseases, or at least make it easier to treat them. Especially illnesses that prey primarily on the

elderly are the focus of the group's research: cancer, cardiovascular disease, Alzheimer's. Some of these diseases have already seen major progress, which has contributed significantly to the increase in overall life expectancy. For instance, the mortality rate from cardiovascular disease has declined by some 30 percent over the past 30 years! Innovative medications help patients suffering from diseases, such as rheumatoid arthritis, while improving their lives. Even the few people suffering from rare diseases have a growing range of new treatment possibilities to choose from.

#### 1900-2000: The century of longer life expectancy

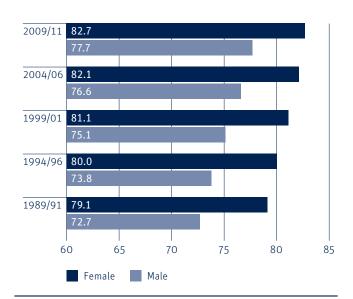
Life expectancy at birth in years worldwide





#### Life expectancy trends in Germany

in years



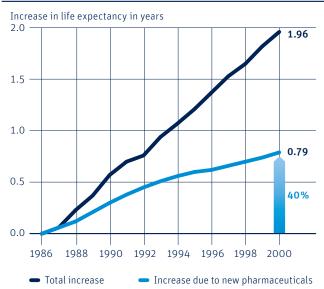
Source: destatis

65

70

Thanks in part to new pharmaceuticals, average life expectancy in Germany has increased by almost four years for women and five years for men over the past 20 years. For instance, several drugs specifically designed to target tumors have significantly extended, in part, the average lifespan for many patients diagnosed with cancer.

#### Changes in life expectancy and the part new medications have played

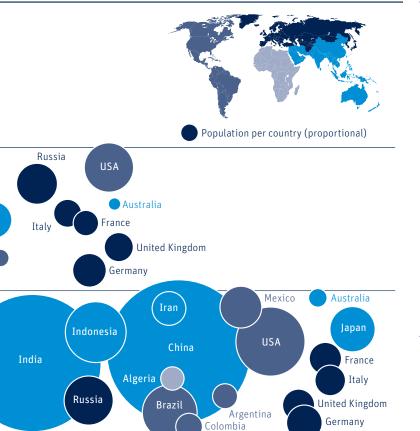


Source: The Impact of New Drug Launches on Longevity; Frank R. Lichtenberg; 2005

The innovations of the research-based pharmaceutical companies have made a decisive contribution to the increase in life expectancy. Some 40 percent of the years of life gained are due to the availability of innovative and better drugs.

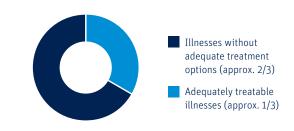
#### The challenge of disease

Some figures about medical needs



75

80



30,000 known illnesses worldwide

120,000

new cases of Alzheimer each year (in Germany, and rising)

175

new or reoccurring pathogens in the past 30 years

Source: vfa

85

#### People

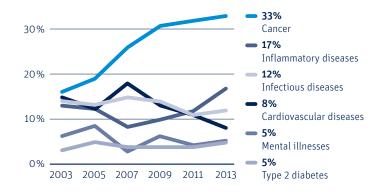
vfa companies are currently conducting research projects on over 110 diseases.

One-third of all projects are focused on improving cancer therapy. This reflects not only the frequency and severity of these diseases (there were approximately 220,000 deaths in Germany in 2010), but also the pay-off of intensive fundamental research into cancer since the late 1980s.

This research has yielded numerous cancertargeted drugs, which either shield tumors from growth hormone signaling or cut off their blood supply. Some have already been approved; many others will follow by 2017.

#### High importance of cancer therapy in vfa member projects

100% = All advanced-stage drug projects of vfa companies according to a vfa survey for the stated year. Only projects that could finish with approval within 4.5 years were included.



Source: vfa

# Cancer: new cases and deaths in Germany 550,000 450,000 350,000 250,000

2005

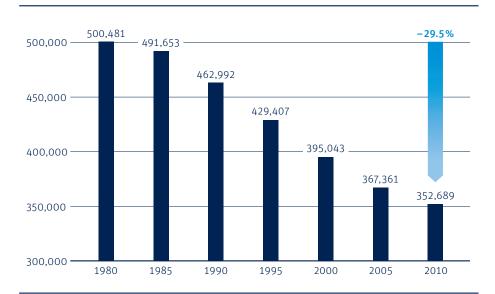
2010

1990 1995 2000

Source: RKI

150,000

#### **Deaths due to cardiovascular diseases** Number



With more than 350,000 deaths in 2010, cardiovascular diseases are still the leading cause of death in Germany. However, since 1980, the number of deaths due to cardiovascular diseases has decreased by around 30 percent. New, effective drugs for high blood pressure and stroke prophylaxis, among other diseases, are partly responsible.

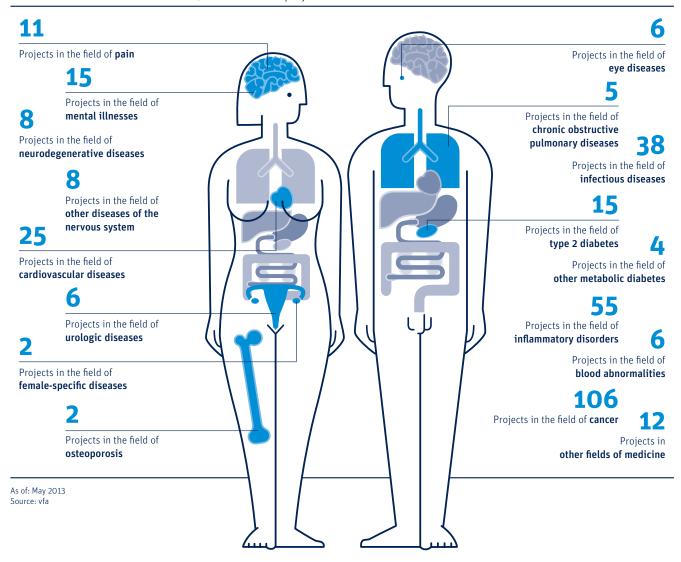
approx. 220,000

Deaths

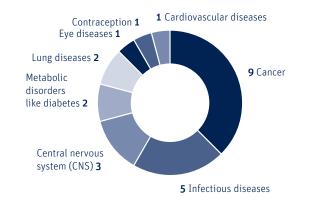
Source: vfa

#### Pharmaceutical projects of vfa companies promising approval by 2017

Distribution in various medical fields; total number of projects: 324



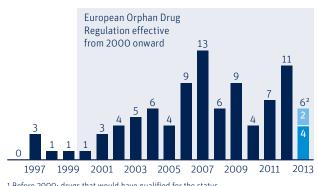
#### New molecular entities and their applications in 2012



Source: vfa

The 24 drugs with new molecular entities, which were launched on the market in 2012, are almost exclusively for serious diseases.

#### Marketing authorizations for medications with orphan drug status1 (number in the European Union)



- <sup>1</sup> Before 2000: drugs that would have qualified for the status
- <sup>2</sup> Expected authorizations (as of: August 2013)

Source: vfa

65 medications with orphan drug status are currently authorized (a continually updated list can be found at www.vfa.de/orphans).

#### Medicine

Since ancient times, humankind has tried to cure diseases with drugs. Whereas previously primarily active ingredients from nature (plants, minerals) were used, from the 19th century on, synthetic active ingredients started to make a major contri-

Since then the arsenal has expanded: Biopharmaceuticals occupy an increasingly important place in the fight against diseases. Another trend is the

development of personalized drugs, where a pretest determines whether the drug can most likely help the patient in question while creating no problematic side effects (stratification).

Equally important is the development of vaccines that ensure certain diseases never occur. Some diseases, such as polio or smallpox, have already been largely defeated.

#### From the medicinal plant to personalized medicine

From antiquity to the present





Since ancient times: Medicinal plants, minerals



(in addition):



Since the late 19th century

Synthetic active ingredients







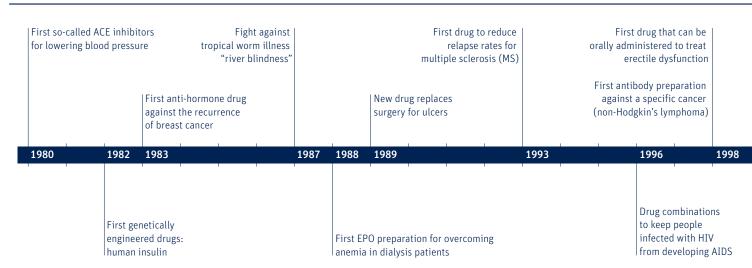




Since the 1980s: Personalized medicine (Drugs and pre-test)

Source: vfa

#### Milestones in pharmaceutical development



#### **Essential medicines**

Listed active ingredients

# 208 1st WHO Essential Drug List (1977) 17th WHO Essential Drug List (2011)

Source: WHO

Since 1977, the number of essential drugs has nearly doubled according to WHO.

#### Patented active ingredients (2011)

Medical prescriptions in Germany

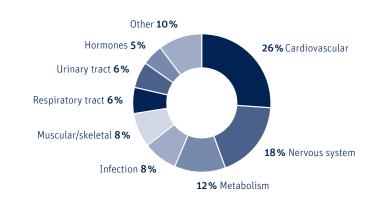


Source: vfa

Only six percent of medical prescriptions in Germany involve patented drugs.

#### Prescription drugs and their applications

packages sold in Germany 2012



Source: vfa

Excellent opportunity to cure difficult-to-treat First antibody therapy for breast cancer metastasis First drug to improve vision in the "wet" form Hepatitis C (virus subtype 1) using innovative of age-related macular antivirals Multi-drug resistant malaria conquered with a new combination of drugs degeneration New drugs offer extended life for sufferers Medication to significantly reduce the risk of Drugs with two new of metastatic malignant melanoma infection for children of HIV-positive mothers active principles against HIV infection 1999 2006 2000 2001 2007 2009 2011 2012 First drug that can transform chronic myelogenous leukemia into a chronic illness First drug for the rare First gene therapy approved in developed countries (for congenital Chance to cure Hepatitis C using hereditary condition First cervical a combination of drugs cancer vaccine phenylketonuria metabolic disease LPLD)

#### Research

By the time a drug is approved for patient use, it has already gone through a development phase of many years: From initial concept to approval, the process takes on average over 13 years. From an original 5,000 to 10,000 active substances under consideration, only one active ingredient achieves approval in the end. Strictly controlled studies, some with thousands of patients worldwide, are used to prove whether a drug works – and is truly safe. This is why pharmaceutical research is complex and expensive: Each drug launched on the market costs companies between USD 1 and 1.6 billion.

Despite the cost and effort, the supply of pharmaceuticals for treating patients grows each year by an average of 25 new drugs with new active ingredients.

In Germany alone, research-based pharmaceutical companies spend around EUR 5 billion annually on research and development – or almost EUR 14 million a day. One fifth of our employees work in research. Of the 20 companies worldwide with the highest research expenditures, eight are in the pharmaceutical industry.

#### How to invent and test a drug





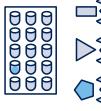
#### Focus on the disease

It all begins with a decision to develop a new drug for patients suffering from difficult-to-treat illnesses.



#### Look for a point of attack

Pharmaceutical researchers identify a suitable point of attack (target) in the pathological process. This is usually a molecule produced naturally in the body to which the active ingredient can attach itself in order to heal, alleviate or delay the progression of the illness.



#### Search for starting substances

Reference points are collected to ascertain what an active substance could look like. One possibility: screening. This means combining up to two million substances – one after the other – with the target molecules. Substances that bind to the target, and thus may have an effect, are called 'hits'.







#### Studies with a few healthy people: Phase I

The next step is to test the active ingredient on healthy volunteers: How does it travel through the body? At what dosage strength do side effects occur?



#### Development of the pharmaceutical form

A drug, tailored to the field of application, is developed from the active ingredient: e.g. a tablet, capsule, ointment, oral or injection solution, a spray, or drug patches.

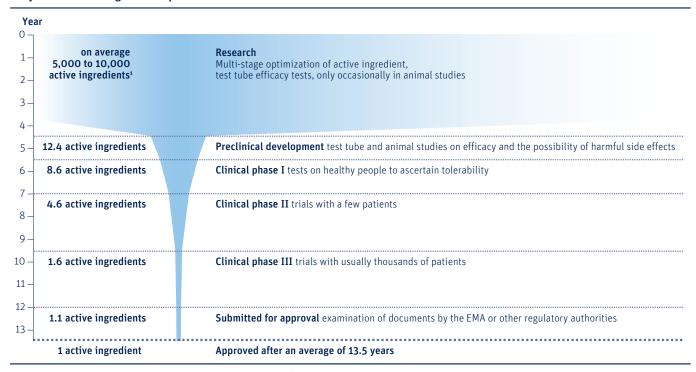




#### Studies with a few ill patients: Phase II

Typically, 100 to 500 patients, all volunteers, receive either the new drug or a comparable treatment. Doctors examine the efficacy, tolerability, and dosing.

#### Only a few active ingredients prove successful



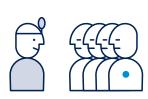
According to Paul, S.M., et al.: Nature Reviews Drug Discovery 9, 203–214 (2010)





#### From optimization to drug candidate

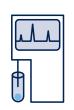
Initially, based on hit-substances, the appearance of a substance that binds well to the target can be determined. Such substances are then synthesized and tested extensively. The criteria are, among other things, solubility, target binding, and the tendency to not break down too quickly in the body.



#### Studies with many ill patients: Phase III

9

Doctors in numerous countries test the drug, usually with thousands of adult patients – similar to phase II. Less common side effects can also be determined during this phase.





In subsequent rounds, variations of the substances are produced using experience and computer simulations; these are also tested. This continues until a number of substances achieve test results good enough to be considered useful as active ingredients.



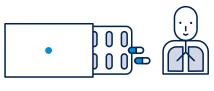
#### Review by regulatory authorities

Experts at regulatory authorities examine the results of all laboratory and animal tests and studies, including the technical quality (e.g. purity) of the drug. If the result of this review is positive, the drug is approved.



#### Tests for effects and tolerability

Promising substances are reviewed to determine whether they are truly safe and effective. This includes mandatory tests for toxicity and other adverse effects in cell cultures and animals. Only once a substance is proven safe and effective, may it be used as the active ingredient in a drug.





#### Application, monitoring, new studies

The drug can now be prescribed to patients. Doctors, manufacturers, and authorities monitor for any possible, rare side effects. The package insert is constantly updated. If the drug could help with other diseases, new clinical trials are begun.

<sup>&</sup>lt;sup>1</sup> These are newly synthesized during the research phase; vfa estimate.

#### Research

24 pharmaceuticals based on new NMEs (new substances known internationally as New Molecular Entities) were launched in the German market in 2012.

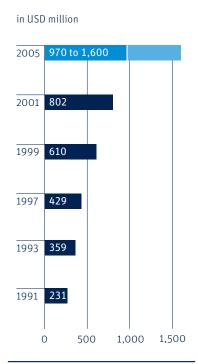
Due to the global nature of the research process, the number of such substances launched in Germany is closely connected to the international development of pharmaceuticals. Unless they are of merely regional importance, most new NMEs receive marketing authorization as soon as possible in all key countries. This is the only way to balance the costs for research and development of an NME, which globally amount to USD 1 to 1.6 billion on average, within its limited patent term.

More than half of the costs in 2005 were for clinical development, especially on logistically expensive, multinational phase III studies.

**Development costs** 

for a new pharmaceutical1

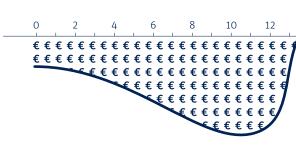
#### Market launches of new molecular entities in Germany



<sup>1</sup>Failures and costs of long-term capital commitment included Sources: Di Masi J.et al., Tufts University (1991); Office of Technology Assessment (1993); Myers

and Howe (1997); Office of Health Economics & Lehman Brothers (1999); Tufts University (2001); "The current state of innovation in the pharmaceutical industry" (Report for the European Commission, June 2008) Lifecycle of a drug

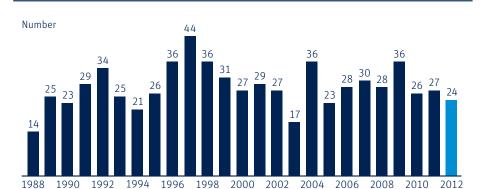




Research

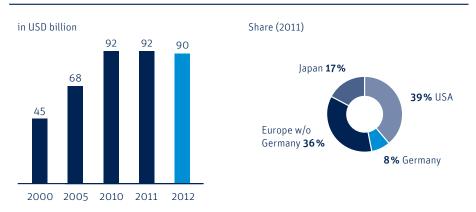
Patent protection (20 years)

Source: vfa

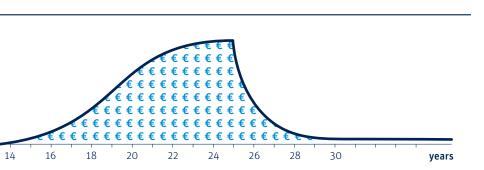


Source: vfa

#### R&D expenditures in Europe, Japan, and the USA



2012: Provisional data Sources: EFPIA, PhRMA, vfa



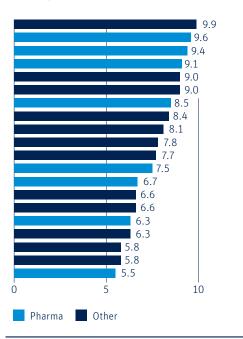
A drug that reaches the market after many years of development must be ready to compete at an early stage with other drugs that target the same indication. After a drug loses its patent protection, any manufacturer who is able to do so may copy the drug (producing a so-called generic), which results in enormous loss of revenue for the original manufacturer.

Competition from alternative treatments

Competition from generics

#### Ranking of the 20 companies with the highest expenditures in R&D

2011 expenditures in USD billion

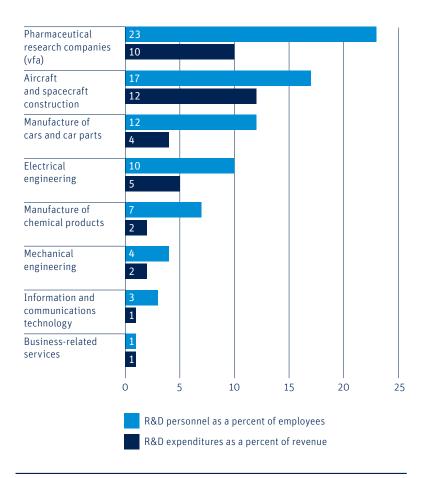


Source: Bloomberg, Booz & Company

Research expenditures of pharmaceutical manufacturers in Europe, Japan and the USA in 2012 were just under USD 90 billion. No fewer than eight pharmaceutical companies – all members of the vfa – are among the 20 companies with the world's highest research expenditures.

#### $\label{lem:conditional} \textbf{Germany's strongest industries in terms of research}$

Shares of R&D personnel and R&D expenditures



As of: 2011 Source: destatis, Stifterverband, vfa

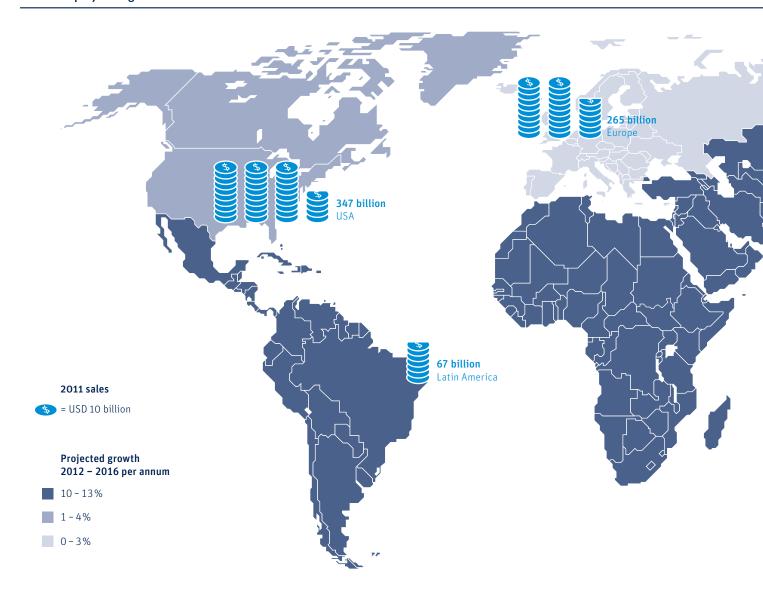
# The International Pharmaceutical Market

Until a few years ago, developed countries in particular, such as the USA, Japan, and those in Europe, were by far the most important markets for pharmaceuticals; yet the picture is increasingly changing: Thanks to the strengthening economies of Latin America, Eastern Europe, India, and China – as well as improved health care and the subsequent living conditions in other regions of the world – the outlook is shifting. While drug expenditures have stagnated or at best seen moderate increases in traditional indus-

trialized nations, some growth rates in other regions of the world have been well over 10 percent annually.

In Germany, expenditures on pharmaceuticals have been stagnating for several years – amounting to an approximate yet stable 1.7 percent of total gross domestic product. This places Germany in the middle of all surveyed OECD countries. In terms of total healthcare spending, Germany is actually ranked in the lower half of all countries compared.

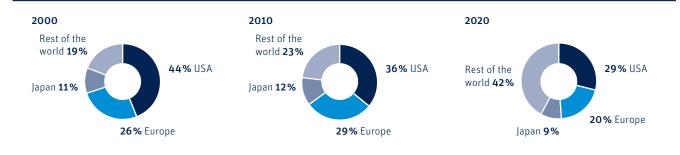
#### Sales and projected growth



Source: IMS Health, vfa

#### The rise of "pharmerging markets"

Share of sales

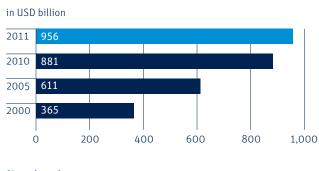


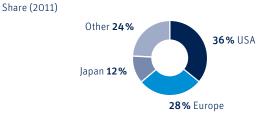
Source: vfa

The share of the "big three" – the USA, Europe, and Japan – will continue to decrease according to most experts. The rest of the world, which is currently about a quarter of sales, will grow in importance.

# 111 billion Japan 165 billion Africa, Asia, Australia

#### International pharmaceutical market





Sales at manufacturer prices in the pharmacy market; Source: IMS Health, vfa  $\,$ 

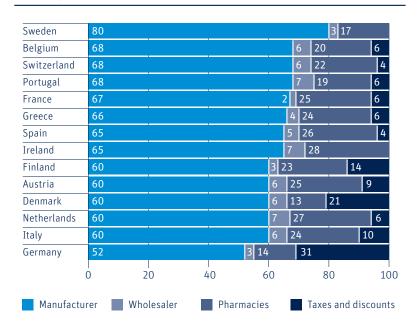
Global pharmaceutical sales have almost quadrupled since 1992. The USA, with around 36 percent, is still the world's largest single market, followed by Europe and Japan. However, the share of the "big three" has decreased. The rest of the world combined accounts for around onequarter of sales, perhaps even a bit more considering the unreliability of certain data in many countries. The Latin American and Asian markets are developing most strongly. In 2011, growth in these countries was between 13 and 18 percent, while the market in Europe shrunk by 1 percent.

# The International Pharmaceutical Market

With a manufacturer's share of 52 percent of the retail price, Germany is located in the bottom segment of a European ranking. Together with legally mandated manufacturer and pharmacy discounts, the tax rate in Germany amounts to 31 percent of the retail price, making it the highest in Europe. In most other European countries, the tax burden on pharmaceuticals is reduced or waived entirely.

#### Pricing structure in Europe

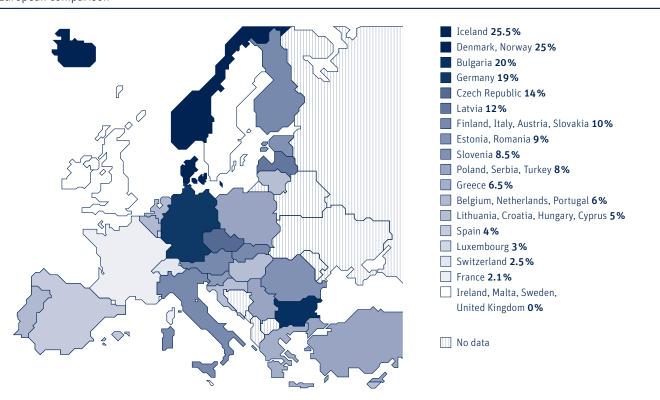
Share in percent



Prescribed or reimbursed pharmaceuticals; as of 2011 Sources: EFPIA, Pharmaceutical associations of European countries, vfa

#### Value added tax on pharmaceuticals

European comparison



#### Pharmaceutical expenditures

per capita in USD, adjusted for purchasing power as a percentage of gross domestic product as a percentage of total healthcare expenditures USA Hungary Hungary Canada 752 Slovakia 2.18 Slovakia 27.4 USA 2.07 Poland Japan 22.5 652 Ireland 648 Japan 1.94 Estonia 21.5 France 641 Canada 1.86 Japan 20.3 Germany 633 Portugal 1.83 Czech Rep. 20.0 Portugal Belgium 1.81 17.9 631 France Belgium Ireland 17.5 Hungary 564 1.63 Spain 536 Spain 1.62 Spain 17.4 Austria 533 Germany 1.60 Canada 16.6 Switzerland Ireland 531 1.56 Italy 16.2 Slovakia 525 Poland 1.54 France 15.6 Czech Rep. Iceland 508 1.50 Belgium 15.5 Italv 487 Italy 1.49 Iceland 15.4 Netherlands 479 Iceland Germany 1.39 14.1 Sweden 474 Estonia 1.27 Finland 13.2 469 12.1 Portugal Austria 1.26 Sweden Finland Finland 1.19 Austria 11.7 446 Czech Rep. Sweden 1.14 USA 11.7 Netherlands UК Norway 388 1.12 11.4 1.04 UK Switzerland Switzerland 375 9.4 Denmark UK Netherlands 9.4 333 1.02 Poland 326 Denmark 0.82 Denmark 7.4 Estonia 280 Norway 0.64 Norway 6.8

0

1

2

3

As of: 2011 Source: OECD 0

#### The largest pharmaceutical companies in 2012 Sales in USD billion

500

1.000

**Novartis** 50.8 Teva 24.8 Pfizer 46.9 **Abbott** 26.7 Johnson& Merck & Co. Johnson 27.9 AstraZeneca Sanofi 32.0 37.8 GlaxoSmithKline Roche 32.7 35.1

In an international comparison, Germany ranks in the middle-to-upper range for per-capita expenditures on pharmaceuticals. When taking into account economic performance (measured as gross domestic product) or other healthcare spending, Germany falls into the lower-to-middle range of the comparison scale.

10

20

40

30

0

#### Germany

Pharmaceutical products worth EUR 27.7 billion were produced in Germany in 2012, an increase of 2.8 percent compared with the previous year.

However, production growth in 2012 is not reflected in the companies' corresponding revenue statements. Government intervention (e.g. legally mandated discounts, price freezes) has

actually caused domestic manufacturing revenue to decrease by 0.6 percent.

With a net added value of over EUR 125,000 per employee in 2010, the pharmaceutical industry is one of the best performing and most productive industries in Germany.

#### Germany

#### 339 companies

with a commercial focus on the "manufacture of pharmaceutical products"

4%

share of the "manufacture of pharmaceutical products" industry sector of total net industrial production

10%

share of the "manufacture of pharmaceutical products" industry sector of total industrial R&D spending

Source: destatis, Stifterverband

While producer prices in the manufacturing industry have risen by 30 percent since 1990, the pharmaceutical industry has kept the price level almost stable through process innovations.

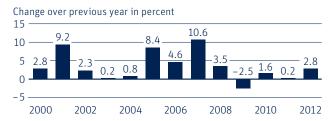
#### **Producer prices**

for pharmaceutical products



#### Production of pharmaceutical products in Germany



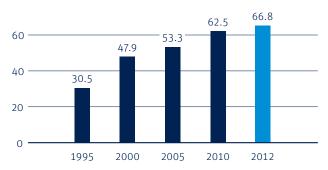


2012: provisional data Source: destatis, vfa

The export share of drugs produced in Germany has more than doubled over the last 15 years.

#### Export share of pharmaceutical manufacturers in Germany

Foreign sales as a percentage of total sales



#### **Capital spending**

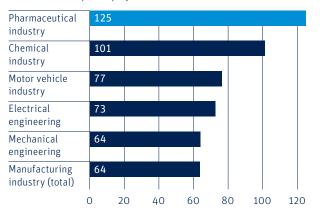
# Manufacture of DV equipment, electronic and optical products Pharmaceutical industry 3.3 Motor vehicle industry 3.1 Manufacturing industry (total) Mechanical engineering 0 1 2 3 4 5 6

As of: 2011 Source: destatis

With capital spending at a 3.3 percent share of sales, the pharmaceutical industry is one of the industries in Germany with aboveaverage capital spending. This triggers considerable additional production and employment in other industries, as was shown in a study by the German Institute for Economic Research. These indirect production and investment effects increase the industry's added value by roughly another 90 percent. In particular, industry sectors that provide higher added value and employment volume, such as research and development services, are pulled along by the pharmaceutical industry. Each job in one of our companies creates another job in another industry.

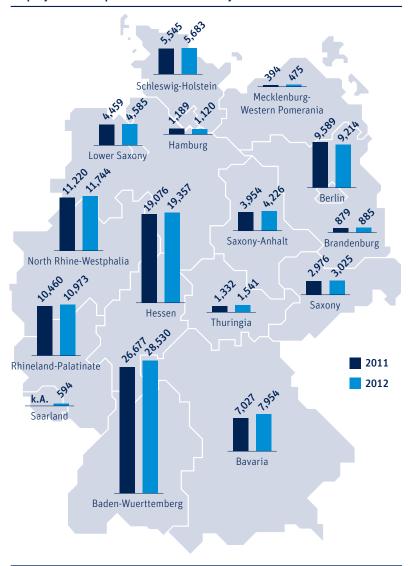
#### Added value

Net added value per employee in 2010 in EUR 1,000



Source: destatis

#### **Employees in the pharmaceutical industry**



# The German Pharmaceutical Market

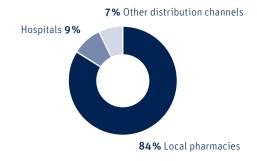
The work of pharmaceutical companies in Germany has been greatly hampered in recent years due to legislative measures. Several steps of tightening discount regulations have caused legally mandated manufacturer discounts to triple since 2005. In addition, discounts have increased substantially in recent years based on individual agreements. Overall, the manufacturer receives only about half of the selling price of a drug. While all other sectors of statutory health insurers reported increased

spending last year, expenditures for pharmaceuticals actually decreased.

The main driver behind spending on pharmaceuticals is not the price, which has actually been decreasing for years, but an increase in consumption resulting from an aging society and the availability of new, improved pharmaceutical treatments for severe and life-threatening diseases.

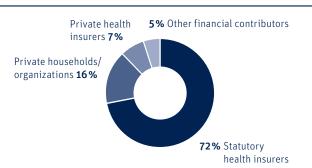
The local pharmacy is still the most important source for pharmaceuticals. On average, three-quarters of the cost is covered by statutory health insurers.

#### How do drugs reach the patients?



Source: destatis

#### Financing of pharmaceuticals



Source: destatis

#### How does a new drug enter the market?



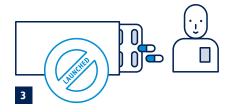
#### Testing

Drugs are tested for efficacy, safety, and technical quality before being submitted for approval. This includes required tests with cell cultures and animals, then on healthy individuals, and finally on patients.



#### **Approval**

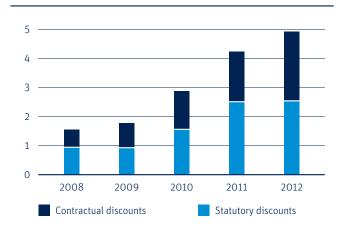
Experts at the relevant authorities examine the results of all laboratory tests, animal tests, and studies as well as the technical quality (e.g. purity) of the drug. If the result of their review is positive, the drug is approved.



#### Market launch

The drug enters the market and can be prescribed to patients. Doctors, manufacturers, and authorities monitor for any possible, rare side effects. The package insert is constantly updated.

#### **Discounts provided by pharmaceutical companies** in EUR billion

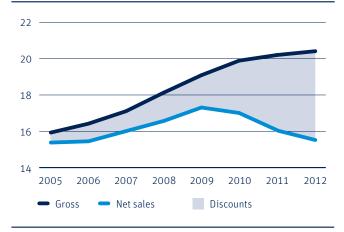


Legally mandated discounts have risen from nearly EUR 1 billion in 2008/2009 to over EUR 2.6 billion in 2012. These volumes are predicted to continue rising in 2013.

In 2012, additional, contractual discounts accounted for almost EUR 2.1 billion, marking an increase of around EUR 370 million over totals from the previous year. Discount agreements are also being concluded in increasing numbers for patented innovations.

Source: Federal Ministry of Health, IGES, vfa

#### Manufacturer sales in the SHI pharmaceutical market in EUR billion at pharmaceutical company prices



**Sales structure in the SHI pharmaceutical market in 2012**Percent shares of the retail price (list price) in pharmacies



Source: InsightHealth, Federal Ministry of Health, vfa

Source: InsightHealth, vfa



#### Benefit analysis

The scientific review describes the therapy-related medical benefits of a drug when applied to a particular therapeutic area for certain groups of patients.



#### Price setting

Within six months after receiving a decision in direct negotiations with the National Association of Statutory Health Insurance Funds, pharmaceutical companies must agree on a SHI refund as the discount on the pharmaceutical manufacturer price for drugs that have been deemed – through

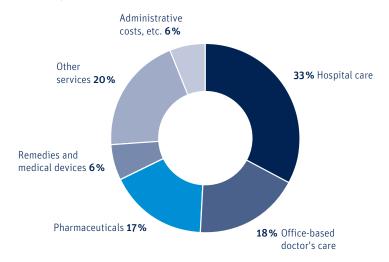
a benefit analysis by the Federal Joint Committee (G-BA) – to have an additional benefit as well as for drugs that have no additional benefits and cannot be assigned to any particular reference price group.

## The German Pharmaceutical Market

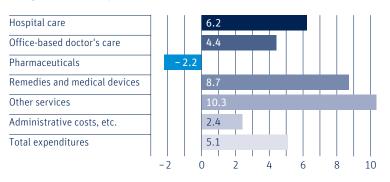
A third of SHI expenditures, EUR 62.5 billion of a total of EUR 190 billion, is spent on hospital treatment. Together, expenditures on care by doctors (EUR 34.5 billion; 18 percent) and for pharmaceuticals (EUR 31 billion; 17 percent) make up another third, with EUR 9.6 billion spent on administrative costs. Increases in mandatory manufacturer discounts resulted in a 2.2 percent decrease in expenditures for pharmaceuticals in 2012 compared to 2010.

#### Expenditures in the Statutory Health Insurance System in 2012

Shares in percent



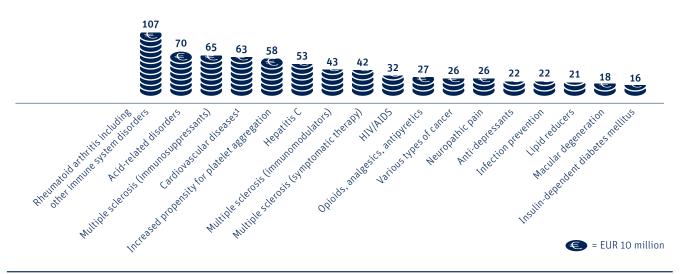
#### Changes since 2010 in percent

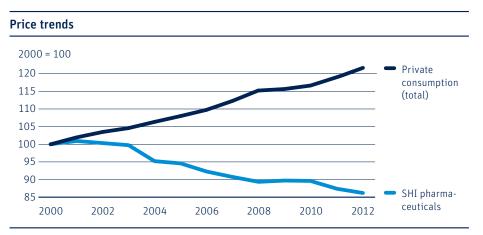


Provisional data; data includes additional payments by patients Source: BMG

#### Increase in consumption in 2012 based on health disorders

Changes in sales in EUR million



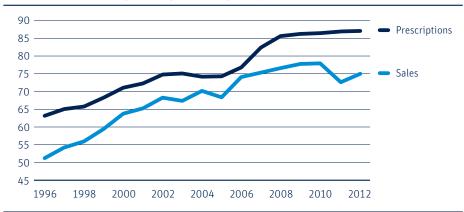


Up until 2003, prices for pharmaceuticals barely changed, after which they have significantly decreased. Pharmaceuticals are now more than 13.5 percent cheaper than they were in 2000. In contrast, overall prices for consumer goods and services have increased by almost 20 percent since 2000.

Source: destatis, WIdO

#### Generic drugs in the SHI market

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



When patents expire, the imitation products of other manufacturers (generic drugs) can be authorized for marketing alongside the original pharmaceuticals. In Germany, 80 percent of SHI prescriptions – almost half of total market sales – are generated in this so-called 'generics-eligible market'.

Over the past twelve years, Germany has evolved into the world's most generics-friendly country. Original products often lose almost their entire market share to generic drugs within a few months after a patent expires. An average of 87.2 percent of prescriptions and 75.3 percent of sales in the generics-eligible market were generated by imitation products in 2012.

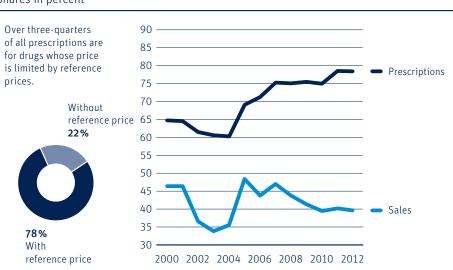
Source: Arzneiverordnungs-Report 2012 (up to 2011), SHI quick drug data 2012 (Jan-Oct)

In recent years, indirect price regulation based on reference prices has continued to expand significantly. In 2011 and 2012, around 78 percent of all pharmaceuticals prescribed in Germany were subject to this regulation. This share is the highest since reference prices were introduced. However, the share of pharmaceutical sales subject to reference prices has decreased overall due to the persistent reductions in reference prices.

On January 1, 2013, 4 new referenceprice groups were established for around 1,300 pharmaceutical products. A total of around 34,000 pharmaceutical products are now subject to regulations. As a result, the statutory health insurance funds saved around EUR 5.5 billion in 2012.

#### Reference prices in the SHI market

Shares in percent



Source: GKV, vfa

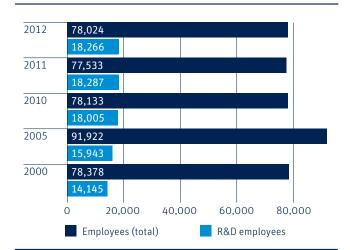
#### The vfa

The number of people employed at vfa companies increased slightly over the past year, as has the number of those employed in R&D. The R&D share (the number of R&D employees divided by the total number of employees) is 23.4 percent; almost one-quarter of all vfa employees work in this field.

Investment in research and development by the research-based pharmaceutical companies has risen again over the past year. With more than EUR 5 billion invested, the members are active in one of the most research-intensive sectors in Germany. Even investment in fixed assets showed a modest increase.

#### Employees of the vfa member companies

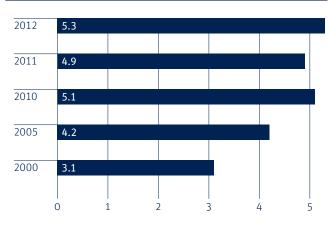
Number



From 2010: Only limited comparisons can be made with values from previous years (statistical adjustment); 2012: provisional data; Source: Stifterverband, vfa

#### R&D expenditures of vfa member companies

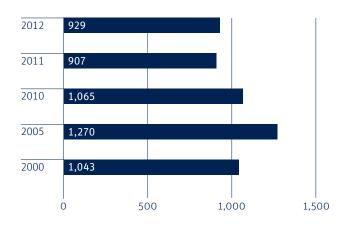
in EUR billion



From 2010: Only limited comparisons can be made with values from previous years (statistical adjustment); 2012: Provisional data; Source: Stifterverband, vfa

#### Capital spending of the vfa member companies

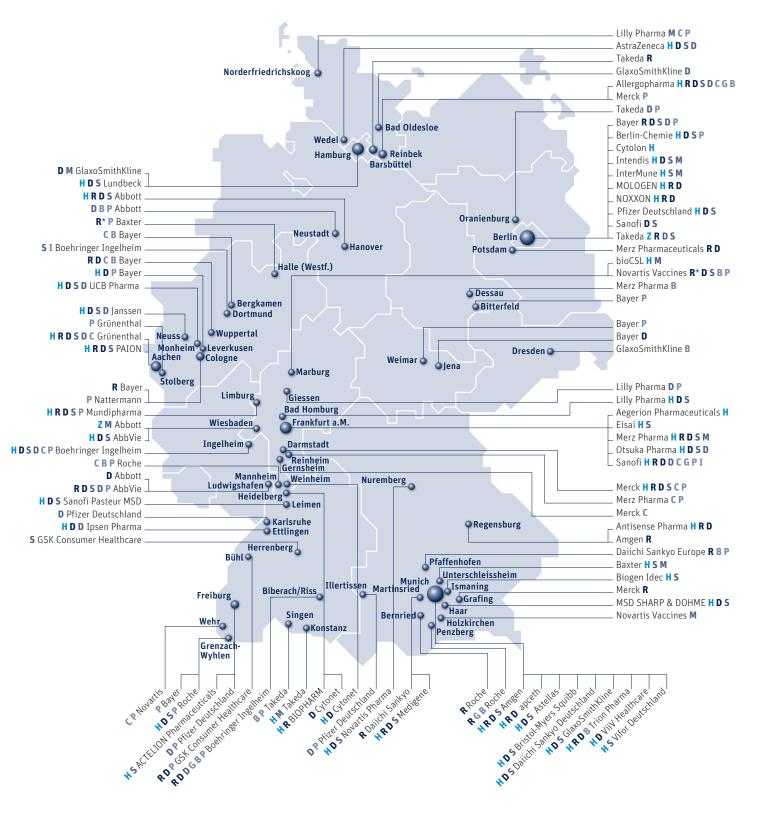
in EUR million



In 2012, investment in long-term fixed assets rose 2.4 percent to around EUR 930 million.

From 2010: Only limited comparisons can be made with values from previous years (statistical adjustment); 2012: provisional data; Source: vfa

#### vfa member sites and their subsidiaries



- **H** Company headquarters
- Second location
- Research/preclinical development
- R\* Only preclinical development
- D Clinical development
- S Sales & marketing
- D Distribution/shipping
- **M** Management
- C Chemical API production
- Genetic API production
- Biotechnology API without genetic engineering
- Production of finished pharmaceuticals
- Production of inhalers or injection devices

#### Member companies Associate members



























































































#### **Imprint**

#### **Published by**

Verband Forschender Arzneimittelhersteller e.V. (German Association of Research-based Pharmaceutical Companies) Hausvogteiplatz 13 10117 Berlin, Germany

#### Design

adlerschmidt kommunikationsdesign Berlin, Germany

#### **Photo credits**

Title: Getty Images P. 1: vfa

#### **Updated**

August 2013

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