HEALTH MADE IN GERMANY

The Pharmaceutical Sector
Germany is a major actor in the global healthcare sector and boasts a leading industry that develops, produces and distributes high-quality pharmaceutical products serving markets worldwide. The pharmaceutical sector benefits from cutting-edge research facilities, a long tradition in manufacturing and a highly diversified mix of large corporations as well as small and medium-sized enterprises (SMEs). Together, they form a strong base and provide the expertise necessary to meet the challenges of a changing global health market. This is best exemplified by increasing pharmaceutical export volumes, especially in Asia and Latin America. Germany is also among the world's top five pharmaceutical manufacturing services locations.

13% of annual revenues are invested in Research and Development

EUR 63.5 bn export sales generated by German pharmaceutical companies in 2016

660+ pharmaceutical companies are situated in Germany

594 clinical trials financed by pharmaceutical companies took place in Germany in 2016
Market Data

Global demand for high-quality drugs is constantly rising due to a growing global population, improved healthcare standards and strengthened economies in non-industrialized countries. According to IMS Health, global spending on medicine will reach USD 1.5 trillion by 2021. The sector is largely driven by innovation, a fact best demonstrated by the high numbers of newly approved drugs in Europe. More than 400 new pharmaceutical entities - on average 37 per year - have been authorized by the European Medicines Agency of the European Union since 2006.

The German pharmaceutical sector provides a broad range of high-quality products and services to address growing international demand. In 2016, German companies generated EUR 63.5 billion in export revenue. Today, international markets account for more than 66 percent of annual turnover in the German pharmaceutical sector. Between 2005 and 2016, export figures for German pharmaceutical companies recorded an annual growth rate of around 10 percent. German pharmaceutical products are particularly sought after in the USA and European countries. However, emerging markets, for example in Asia and Latin America, are also registering increased demand.

More than 660 pharmaceutical companies – of German origin and subsidiaries of multinational corporations – are based in Germany. These companies employed a workforce of around 114,000 in 2015 - mostly located around the cities of Hamburg, Berlin, Cologne, Frankfurt (Main), and Munich. The German pharmaceutical sector is dominated by SMEs, with about 400 companies having fewer than 20 members of staff.

Germany can look back on a long tradition as the "world’s pharmacy" and even today ranks among the world’s top five pharmaceutical production locations - being second only to the USA in terms of fermentation capacities. Major domestic pharmaceutical companies (including Bayer, BASF, Boehringer Ingelheim, and Merck) and numerous SMEs enjoy an excellent international reputation in all of the relevant pharmaceutical markets. This ranges from prescription to over-the-counter (OTC) drugs, from original drugs to generics, from small molecules to biopharmaceuticals. The sector also benefits from the internationally strong chemical companies that are domiciled in Germany, providing further manufacturing expertise and infrastructure.

One of the industry’s key success factors is its strong focus on research and development (R&D). Total R&D spending increased significantly to EUR 5.4 billion in 2015. This is equivalent to 13.2 percent of revenue, making it higher than in any other sector of industry in Germany. Most of the more than 300 drugs currently developed and set for approval in 2017 are targeting indications such as cancer (33 percent), inflammatory diseases (17 percent) and infectious diseases (12 percent).
Industry Trends

High-quality Products for International Markets
A steady increase in the quality of healthcare across the globe, the establishment of health insurance systems in developing countries, and new hospital infrastructures have all led to a growing global demand for conventional pharmaceutical products. German pharmaceutical companies are best known to deliver high-quality production volumes for many conventional pharmaceutical products such as antibiotics, hormones, vitamins, and radiopaque materials. This has allowed them to establish themselves as attractive export partners for many countries around the globe. The export revenues for German companies in Asia, for example, increased by 15 percent in 2015, reaching almost USD 6.8 billion. Here, the most attractive market is China, where, 22 percent of imported pharmaceutical products originate from German companies. Herbal medicines, original drugs and prescription drugs are in particularly high demand.

Digital Health for Better Patient Care
Technology-driven developments such as digitalization and Industry 4.0 are also revolutionizing the pharmaceutical sector and healthcare management. This offers great potential for more efficient research and development processes since computer-based, high-throughput approaches facilitate improved big data analyses. This increases the speed at which new therapies and diagnostics go from lab to market. German pharmaceutical companies are increasingly aware of new digital solutions and actively promote cooperation with start-ups and smaller companies from the biotechnology, medical technology and IT sectors. The aim is not only to improve R&D but also to provide new drug applications, enhance the effectiveness of treatment, and empower patients to actively manage therapies. Most of the large German corporations have founded special hubs and accelerators to build a platform for innovative IT-based healthcare solutions.

Other aspects of digitalization include the introduction of online and real-time monitoring in pharmaceutical production plants, connected manufacturing processes, and increased automation of industrial value chains in the sector. With its strong tradition of engineering and plant construction and its expertise in pharmaceutical chemistry, Germany offers the perfect infrastructure for combining cost-efficient, IT-based innovation with traditional high-quality manufacturing processes. For this reason, a wide variety of contract manufacturing service organizations (CMOs) have established themselves in Germany over the decades. This is particularly true for the biopharmaceutical sector which has experienced strong growth in recent years.

These CMOs profit from an ongoing outsourcing trend, making Germany the number two location worldwide in terms of fermentation capacities. The country also has a strong network of contract research organizations (CROs) that provide services relevant to drug development (target validation, lead optimization including delivery technologies, toxicological studies, bioanalytics and clinical trials management). The versatility and strength of the German CRO landscape, as it speeds up drug development, is a good reference point for international collaboration.

Personalized Medicine Focus
Innovation in the pharmaceutical sector is largely driven by technological advances made in molecular and cell biology. New technologies and research tools based on these findings pave the way for a better understanding of disorders and permit new strategies for combating not only symptoms but actual causes. Personalized medicine has also emerged as a new trend for targeted therapies. Biotechnology has developed as a major cornerstone in the development of new treatments in this context. German companies have played a substantial role in bringing these approaches from lab to market and into clinical practice. They can draw on a high level of expertise in clinically relevant biomarker R&D and a
strong diagnostics sector which offers companion diagnostics (CDx) for use in personalized medicine.

Furthermore, German biotech companies are particularly renowned for their expertise and innovation potential in targeted therapies for a broad range of indications from oncology to infectious, metabolic, neurological, and inflammatory diseases. In recent years, domestic and international pharmaceutical industry stakeholders have set up cooperation agreements and licensing deals with German biotech companies and start-ups to profit from this experience.

This is particularly true when it comes to new therapies for the treatment of cancer patients. German pharmaceutical companies are at the forefront of developing innovative approaches, for example, in the field of immunotherapies. Advances in biomedical research in recent decades have led to an increased understanding of the inner workings of the body’s defense system. New procedures based on bi- and multispecific antibodies, glycomodified antibodies, antibody-drug conjugates (ADCs), mRNA and DNA, oncolytic viruses, and cell therapies are well established in Germany. Based on this, many German companies are currently working on new preclinical and clinical drug candidates to fight cancer in a targeted manner (see “Spotlight on Oncology”).

High Level of Orphan Disease Expertise
The advancement of knowledge in understanding the molecular biology of diseases has also become the basis for developing targeted therapies for niche indications and rare diseases. As demonstrated by European Medicines Agency (EMA) and US Food and Drug Administration (FDA) statistics, the number of orphan drug designations has increased significantly over the past years. Facilitated approval processes for these drugs have further strengthened this trend. These favorable conditions have also paved the way for innovations developed by SMEs. According to the EMA, more than 70 percent of the medicines for rare disorders in the EU originate from the laboratories of SMEs, and German companies with their strong innovative capacities are increasingly active in this field. This is exemplified by growing approvals for orphan drugs in Germany. On average, one fifth of new drugs targeted orphan diseases, most of them for treatments in oncology (44 percent), metabolic diseases (21 percent), neurology (7 percent) and cardio-vascular diseases (6 percent). German companies have extensive experience in addressing specific groups of patients. Many of them, for instance, specialize in the development of therapies for children which is still one of the major challenges of modern medicine.

<table>
<thead>
<tr>
<th>Foreign Market</th>
<th>Export Volume (EUR million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>13,489</td>
</tr>
<tr>
<td>Netherlands</td>
<td>8,216</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>7,100</td>
</tr>
<tr>
<td>Switzerland</td>
<td>4,647</td>
</tr>
<tr>
<td>France</td>
<td>3,663</td>
</tr>
<tr>
<td>Italy</td>
<td>2,621</td>
</tr>
<tr>
<td>China</td>
<td>2,264</td>
</tr>
</tbody>
</table>

Source: BPI 2016
The German pharmaceutical sector is known for its far-reaching competencies in a number of business fields. This is reflected in the huge diversity of products and services offered. Companies actively focus their activities on:

- development, distribution and sale of original prescription drugs such as small molecules and biopharmaceuticals for the treatment of severe diseases
- manufacture, distribution and sale of generics and biosimilars
- development and manufacture of over the counter (OTC) drugs
- phytotherapy and homeopathic products
- manufacture and/or contract research for national and international clients

Many companies address several of these activity areas at the same time to broaden their client portfolio and to exploit synergies.

Pharmaceutical Innovation to Combat Common Diseases
The German pharmaceutical industry is world renowned for its commitment to innovation. This is reflected in high R&D spending levels, with companies able to provide extensive expertise in the treatment of numerous patient indications. Major activities relate to widespread common diseases, such as in the fields of oncology, metabolic diseases and immunology. The number of drugs already approved in Europe and newly developed drug candidates underline this high level of engagement. A glance at the pipeline of biopharmaceutical companies active in the Association of Research-Based Pharmaceutical Companies (vfa) demonstrates that these three disciplines alone account for more than 470 new agents currently under development from clinical phase I to III. A further analysis of vfa member companies highlights that the majority of drug projects with a chance of approval in 2017 focus in particular on treatments for cancer (33 percent), inflammatory (17 percent) and infectious diseases (12 percent).

Generics Expertise
Another major strength of the German pharmaceutical industry is its expertise in generics. This is reflected, among other things, in its activity on the German market as demonstrated by recent statistics published by the German Medicines Manufacturers’ Association (BAH) in 2017. The statutory health insurance companies in Germany paid a total of EUR 12 billion for generic products in 2016. Most of these drugs are produced by German companies with a reputation for high-quality manufacturing processes.

This also holds true for the growing biosimilars market. Due to the expiry of patent protection for many of the original biopharmaceutical drugs, generic companies and innovators are increasingly focusing on offering generic variants of biopharmaceuticals. With its considerable expertise in biopharmaceutical manufacturing, Germany provides excellent infrastructure for the production of biosimilars for the national and international market. From this perspective, due to a higher demand for cost-effectiveness in healthcare systems worldwide, German companies are also well-positioned in this area in the long term. According to the vfa, biosimilars accounted for 25 percent of all phase III candidates in the entire biopharmaceutical pipeline of German pharmaceutical companies in 2016.

High Quality Contract Manufacturing
Around 11 percent of German pharmaceutical companies are active in the contract manufacturing business. More than 300 companies offer a wide range of products, such as packaging services (58 percent), solid forms (29 percent), liquid forms (21 percent), specialized forms (20 percent), custom-made products (9 percent) and other services (50 percent).
percent. Most are located in North Rhine-Westphalia, Baden-Württemberg and Bavaria. There are three types of companies among the contract manufacturing organizations (CMOs):

- traditional CMOs focusing only on this business activity
- pharmaceutical companies that have merged with a CMO, now offering these services among other areas of business
- traditional pharmaceutical companies offering CMO services to operate at full capacity

Within the highly competitive CMO markets, German companies are well-known for their high degree of specialization, vertical integration and flexibility, the high quality of their process optimization and employee education, and excellent linkages with the German chemical industry. Today, these competencies are increasingly in demand because more than 80 percent of the innovation-driven pharmaceutical companies outsource their production to external organizations, particularly with regard to generic drugs.

**OTC Products Made in Germany**

Companies focusing on the development and distribution of over-the-counter (OTC) products are another expertise of the German pharmaceutical industry. In Germany alone, pharmaceutical companies achieved segment turnover of EUR 6.7 billion. Cold medicines, general pain treatments and therapies to combat muscle and limb pain count among the core competencies of German enterprises in this field. A large proportion of the products are sold on the domestic market. According to the BAH, this section of the industry contributed a gross value of around EUR 1.4 billion to the German economy in 2015. A growing number of companies also offer special therapies such as phytotherapies and homeopathy. One third of OTC product turnover is already generated in this segment, with experts forecasting further growth in the future. Germany’s strong domestic market makes OTC manufacturers attractive business partners for international clients. Plant-based, high-grade medicines “Made in Germany,” for example, are among the top pharmaceutical products sold in Asian countries.

**Top Indications of OTC Products according to Turnover in Germany in EUR million**

<table>
<thead>
<tr>
<th>Category</th>
<th>Turnover</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold Medicines and Drugs against Influenza Infection</td>
<td>704</td>
</tr>
<tr>
<td>General Pain Treatments</td>
<td>527</td>
</tr>
<tr>
<td>Muscle and Joint Pain Treatments</td>
<td>504</td>
</tr>
<tr>
<td>Antitussive Medicines</td>
<td>374</td>
</tr>
<tr>
<td>Gastrointestinal and Digestive Treatments</td>
<td>339</td>
</tr>
<tr>
<td>Mineral Nutrients</td>
<td>299</td>
</tr>
<tr>
<td>Products for other Respiratory Diseases</td>
<td>280</td>
</tr>
<tr>
<td>Abstergent Agents</td>
<td>249</td>
</tr>
<tr>
<td>Treatments against Skin Fungi</td>
<td>214</td>
</tr>
<tr>
<td>Tranquilizers and Sleep-Inducing Drugs</td>
<td>214</td>
</tr>
</tbody>
</table>

Source: BAH/IMS Health 2017

**Drug Candidates of German Companies with a Chance of Approval in 2017**

![Drug Candidates Chart]

- Cancer 33%
- Infectious Diseases 12%
- Cardiovascular Diseases 8%
- Diabetes Type 2 5%
- Mental Illnesses 5%
- Others 20%

Source: vfa 2017

Company Directory: Herbal, Homeopathic & Anthroposophic Medicines

[www.health-made-in-germany.de](http://www.health-made-in-germany.de)
The Pharmaceutical
Landscape in Germany

Innovation Leader Germany
Germany offers the ideal infrastructure for the
development and production of research-intensive,
high-grade products. It places a great value
on technology, backed by the country’s long his-
tory in the pharmaceutical and chemical industry,
as well as its particular strength in producing
complex products where containment and sterile
environments are critical. Hundreds of thousands
of highly skilled employees with backgrounds in
medical technology, pharmaceutical technology,
engineering, and processing make it possible for
German pharmaceutical companies to set up and
run high-quality processes.

R&D Excellence
The German pharmaceutical sector also works
very closely with non-university research insti-
tutes, universities, hospitals, and start-ups from
the biotechnology, medical technology and
chemical fields. In industry clusters and net-
works throughout the country they are aiming
to improve existing treatments and develop new
therapies. Over the past decades, some regions
have become established as Europe’s leading
R&D hubs and chemical parks, paving the way for
interdisciplinary collaboration.

The German pharmaceutical industry, integrated
into these networks as a valued partner, benefits
from the R&D excellence across the country and
is able to efficiently commercialize innovative
drugs. In 2016, the Federal Institute for Drugs and
Medical Products (BfArM) approved more than
1,500 advancements of existing agents relating,
for example, to new indications or with improved
delivery and formulation modes.

German Centers for Health Research
The German government has consistently sup-
ported excellence in health research. Since 2009,
the German Federal Ministry of Research and Edu-
cation (BMBF) and the federal states have phased
in new research structures, known as the German
Centers for Health Research, to more effectively
address major common diseases such as cancer,
diabetes, neurology, cardiovascular diseases,
infectious diseases, and lung diseases. There are
currently more than 90 locations and 120 cutting-
edge research institutes that are part of this huge
network. Many of them have launched several
projects involving national and international phar-
maceutical companies.

Strong Tradition in Infectious Diseases
The development of new treatments for infectious
diseases is a special area of German expertise.
Based on major scientific developments made by
German scientists such as Robert Koch and Emil
Behring at the end of the 18th century, the devel-
opment and production of vaccines has estab-
lished itself as a core pharmaceutical competence

### German Pharmaceutical Company R&D Expenditure in EUR billion

<table>
<thead>
<tr>
<th>Year</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>3.80</td>
</tr>
<tr>
<td>2005</td>
<td>4.16</td>
</tr>
<tr>
<td>2010</td>
<td>5.06</td>
</tr>
<tr>
<td>2015</td>
<td>5.46</td>
</tr>
</tbody>
</table>

Source: vfa, 2016

### German Pharmaceutical Industry Workforce Size

<table>
<thead>
<tr>
<th>Year</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>103,208</td>
</tr>
<tr>
<td>2011</td>
<td>105,435</td>
</tr>
<tr>
<td>2012</td>
<td>110,006</td>
</tr>
<tr>
<td>2013</td>
<td>110,036</td>
</tr>
<tr>
<td>2014</td>
<td>112,475</td>
</tr>
<tr>
<td>2015</td>
<td>114,069</td>
</tr>
</tbody>
</table>

Source: BPI, 2016
in Germany. This rich legacy has led a number of international corporations to construct large facilities there in recent decades. Around 25 new industry-driven clinical studies with promising vaccine candidates are established in Germany annually. Some German biotechnology companies, for instance, develop vaccination strategies based on natural messenger RNA as a data carrier instructing the human body to produce its own proteins to fight a wide range of infectious diseases. Other approaches have left the R&D phase and already entered the market: An innovative antiviral to treat human cytomegalovirus (HCMV) resulting from pioneering anti-infective research in a German biotech company reached the market in late 2017.

Germany also offers considerable expertise in the area of bacterial infections and the fight against multi-resistant pathogens. In the past two years, a growing number of German researchers have revealed new insights into promising antimicrobials in high-level peer-review publications to fight antibiotic-resistant strains. Besides new antibacterials, the class of bacteriophages is identified as an alternative treatment option. In 2017, a substantial number of German clinical researchers at hospitals, academic institutes and pharmaceutical companies founded the "National Forum Phages" research forum at the University of Hohenheim (Stuttgart) to further explore this potential. This offers plenty of new collaboration opportunities with partners worldwide in the long term.

**Strength in Clinical Trials**

Germany also offers attractive conditions for conducting clinical trials. Geographically located at the heart of Europe and close to other European countries, Germany makes it easy to integrate and manage study centers in the surrounding country markets and enjoys a reputation as a credible clinical study location for realizing high-quality data. Growing numbers of clinical studies are being conducted in German hospitals. The high level of expertise in clinical research is just one reason why a number of German pharmaceutical companies have entered into major strategic partnerships with German university hospitals to build up a new pipeline of promising new treatments. Around 20 university hospitals active in clinical research in Germany now work closely together within the “Koordinierungszentren für klinische Studien” (KKS - Coordination Centers for Clinical Studies) network to offer a one-stop-shop for companies and regulatory bodies. Germany’s attractiveness as a clinical trial location is confirmed by statistics available in the international registry of ClinicalTrials.gov. According to an analysis by vfa, a total of 594 trials financed by pharmaceutical companies took place in German hospitals in 2016. This puts Germany second behind only the USA and ahead of other European countries such as the United Kingdom (554), Spain (499), and France (454).
German Expertise

German pharmaceutical companies have extensive experience in bringing forward new drugs and therapies from lab to market. Whether it’s drug discovery, drug development or drug manufacturing in traditional markets or innovative areas, whether it’s large corporations or medium-sized companies, pharmaceutical products “Made in Germany” are highly appreciated all over the world. At the same time, international markets play an important role in the German pharmaceutical industry.

Here, the CEOs and Board members of three German pharmaceutical companies report on what makes their expertise so interesting for international partners and why global alliances and strategic partnerships are the key to successful business development.

InfectoPharm strives to improve children’s health. Since 1988, the medium-sized company is focusing on pharmaceuticals for children and difficult-to-treat infections. Today, InfectoPharm runs a highly diverse portfolio of more than 100 products and engages in about 30 strategic partnerships globally. 180 employees contribute to the annual growth of this family-owned company.

Dr Markus Rudolph
CEO, InfectoPharm Arzneimittel und Conislum GmbH, Heppenheim

What do international investors and partners appreciate most about your expertise?
InfectoPharm holds a leading market position in pediatrics. As well as around 30 outstanding products, we offer quick decision-making processes, customized collaboration models, and a solution-oriented mindset. A highly qualified team aims to establish long-term cooperation and provides thorough scientific product training. Our pediatric portfolio covers OTC and prescription-only pharmaceuticals for indications such as infectious and respiratory diseases, dermatology, and gastroenterology. The hospital anti-infective portfolio includes antibiotics for difficult-to-treat conditions like nosocomial infections and cystic fibrosis.

What do you believe is the basis for successful international cooperation and expansion?
Dedication to the product and the task at hand are crucial for any cooperation. Partners should share a mutual understanding of the expectations and challenges involved in international ventures and respect each other’s decisions.

Which export markets and international activities play a crucial role in your company development?
Over the last five years, InfectoPharm has registered mainly in Europe. We are now expanding into non-EU markets and exploring future opportunities. Attractive target regions have large pediatric populations and extensive needs for medical solutions which counter the serious issue of resistance. We are seeking business partners who have a proven track record in the commercialization of healthcare products in these regions.

Boehringer Ingelheim is a research-driven, family-owned large pharmaceutical company. Some 50,000 employees work in the three business areas of human pharmaceuticals, animal health and biopharmaceutical contract manufacturing. In 2016, Boehringer Ingelheim achieved net sales of around EUR 15.9 billion. Research and development expenditure runs at more than EUR 3 billion annually – equivalent to around 20 percent of company net sales.

Desitin Arzneimittel GmbH is a medium-sized pharmaceutical company. It operates internationally, with subsidiaries in Germany, Switzerland, Scandinavia, and Eastern Europe. At its Hamburg plant it produces medicines for the treatment of neurological and psychiatric illnesses, offering a large number of established and innovative products, especially for its core indications of epilepsy and Parkinson’s syndrome.

www.infectopharm.com
Alan Hillgrove
Member of the Board of Managing Directors with responsibility for the Human Pharma Business Unit, Boehringer Ingelheim, Biberach

What do international investors and partners appreciate most about your expertise?
We are recognized by our business partners from abroad for the high quality of our innovative products which we supply globally. Our international customers value our experience, the service level we offer and the clear solution orientation we demonstrate. They benefit from our process excellence, as well as the reliable and agile supply we guarantee.

What do you believe is the basis for successful international cooperation and expansion?
We believe that cooperating and expanding business on a global level can only be successful when those endeavors are clearly embedded in the vision of the corporation. This allows us to successfully address all topics that arise and to put the needed resources behind these activities. The success of an international cooperation requires strong partnerships, a clear understanding of joint interests and objectives, as well as respect and empathy for differences in culture and capabilities.

Which export markets and international activities play a crucial role in your company development?
Our international activities are at the core of everything we do. The global supply of our products at the high level of quality and service is only possible with a strong global network. Engaging in strategic international partnerships and further developing our company presence in the different countries allows us to be closer to our patients.

Dr Martin Zentgraf
CEO, Desitin Arzneimittel GmbH, Hamburg

What do international investors and partners appreciate most about your expertise?
Our international business partners and licensors highly appreciate our in-depth knowledge of the German and international markets in terms of medical and scientific aspects of CNS in general and market access specifically. Desitin has been committed to this therapeutic area for decades and has extremely well-established customer relations.

What do you believe is the basis for successful international cooperation and expansion?
Our international expansion concentrates on the northern European territories and selected eastern European countries. In most countries, the main focus of our activity is epilepsy. The development of new pharmaceutical dosage forms was essential within the context of establishing the critical mass in the relevant markets. Further CNS innovations were added on this basis.

Which export markets and international activities play a crucial role in your company development?
The most important markets are those where Desitin is represented with own subsidiaries – such as Norway, Sweden, and Denmark, as well as the United Kingdom, and Switzerland. Our subsidiaries in Eastern Europe – in the Czech Republic, Slovakia, and Romania – also play an important role.

www.boehringer-ingelheim.com
www.desitin.de
Spotlight on Cancer

High Medical Need for New Treatments
Cancer remains one of the major health threats in industrialized countries, being the second most frequent cause of death in Germany. Cancer treatment is currently composed of five pillars: surgery, radiation, chemotherapy, targeted therapies and, most recently, immuno-oncological therapies. The German pharmaceutical industry, including large corporations and small and medium-sized companies alike, has substantial activities in all of these five areas in joint collaboration with biotechnology companies.

Outstanding Research Infrastructure
With its globally renowned research centers and excellent clinical infrastructure, Germany offers outstanding opportunities for the research and development of new cancer drugs. The German Cancer Research Center (DKFZ) in Heidelberg ranks as one of the top locations worldwide in the field.

Understanding in oncology has increased significantly due to intensive research. This has helped to identify novel targets and biomarkers for improving the efficacy of existing cancer therapies and diagnostics as well as bringing totally new drugs to the market. Since the 1980s, a total of 29 biopharmaceuticals - three quarters of them monoclonal antibodies - have been approved in Europe and Germany with a first indication for the treatment of cancer. They are now a firmly established part of modern cancer therapy. In recent years, the sector has been particularly active with a total of ten new cancer drugs entering the European and German markets in 2015/16.

Targeted Therapies for Personalized Cancer Medicine
German pharmaceutical and biotech firms continue to invest intensively in oncology research, creating the basis for new personalized therapies. They often pursue completely new approaches, such as bi- or multispecific antibodies, glycomodified antibodies, antibody-drug conjugates (ADCs), mRNA- and DNA-based approaches, oncolytic viruses and cell therapies. They are not yet able to overcome cancer but can help patients diagnosed with cancer to live longer. Increasingly, cancer is becoming less a terminal illness and more a chronic one, with German companies playing a major role in further developing this trend. In 2016, there were 226 active compounds in the German pipeline for biopharmaceuticals against cancer - far more than in any other research field. Every year, more than a dozen German companies present their most recent results at the Annual Meeting of the American Society of Clinical Oncology in Chicago.

For pharmaceutical companies, oncology is also the most interesting indication for conducting clinical trials in Germany. According to an analysis in the international trials register of ClinicalTrials.gov, pharmaceutical companies financed a total of 146 trials for testing cancer drugs in German clinical research locations in 2016.

Expertise in Immunotherapies
Growing knowledge in immune biology and cancer research has enabled major advances, particularly in immuno-oncology. German immunologists and molecular biologists have uncovered a number of targets and signals within the immune system that serve as keys for mobilizing the immune response in the fight against cancer cells. Checkpoint inhibitors are currently the most well-known approach used in several cancer indications. Large pharmaceutical corporations and small and medium-sized biotechnology companies based in Germany have excellent, long-established expertise in developing novel immunotherapies that use different tools in the body’s own immune system to address cancer indications.

Clinical Trials in Germany according to Indications Financed by the Pharmaceutical Industry in 2016

<table>
<thead>
<tr>
<th>Indication</th>
<th>Trials Financed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology</td>
<td>146</td>
</tr>
<tr>
<td>Inflammatory Diseases</td>
<td>142</td>
</tr>
<tr>
<td>Cardiovascular Diseases</td>
<td>42</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>30</td>
</tr>
<tr>
<td>Diabetes Type 2 and its Effects</td>
<td>24</td>
</tr>
</tbody>
</table>

Source: vfa/clinicaltrials.gov
Industry Associations

The German pharmaceutical industry is represented by a number of industry associations that lobby for improvements for their member companies. HEALTH MADE IN GERMANY works closely together with them to provide support for international companies seeking collaboration and partnerships with German companies active in the pharmaceutical sector. To further enhance sector visibility, we facilitate the presence of German players at relevant industry events and provide a platform for connecting with international partners.

BPI – German Pharmaceutical Industry Association
Founded in 1951 and thus with 65 years of experience in drug research, development, authorization, manufacturing and marketing, BPI is the only national trade association which represents the pharmaceutical industry with all its variety. Our membership consists of 240 companies that cover classic pharmaceutical companies, businesses from biotechnology, phytopharmacy and homeopathy as well as companies with a small generic portfolio. The majority of our membership are family owned businesses and small and medium-sized enterprises that represent more than 11 percent of the pharmaceutical industry workforce in Europe. As an association representing the whole section of the pharmaceutical industry BPI’s goal is to ensure that patients receive the care and medicines they need. BPI is a political partner for decision-makers which contributes to the ongoing dialogue about the sustainability of healthcare systems.

www.bpi.de

VfA – Association of Research-Based Pharmaceutical Companies
The vfa, the Association of Research-Based Pharmaceutical Companies, is the trade organization of research based pharmaceutical companies in Germany. Forty-three leading research-based pharmaceutical companies are organized in the vfa. Together with their more than 100 subsidiaries and affiliated companies, they employ nearly 76,000 people in Germany. The vfa member companies are among the leading research-based pharmaceutical companies worldwide. They guarantee therapeutic progress in pharmaceuticals and ensure high-quality pharmaceutical therapy. In Germany more than 16,000 of their employees work in the field of research and development of pharmaceuticals. Here, the research-based pharmaceutical companies invest EUR 4 billion per year in pharmaceutical research. The Association of Research-Based Pharmaceutical Companies represents a German high-tech industry that is competitive in the international markets.

www.vfa.de/en

BAH – German Medicines Manufacturers’ Association
By company membership, the German Medicines Manufacturers’ Association (BAH) is the leading trade organization of the pharmaceutical industry in Germany. It represents the interests of more than 450 member companies, which create about 80,000 jobs in Germany. Globally operating medicines manufacturers are as involved in the manifold activities of the association as well as the broadly represented medium-sized businesses. BAH covers the entire range of the industrial landscape from self-medication medicines (OTC) through to prescription drugs (Rx) and medical devices. The association is a close contact partner for politicians, authorities and institutions within the healthcare sector, and provides a strong link between various interest groups.

BAH represents its members at European and international level through the Brussels-based AESGP and the Geneva-based WSMI.

www.bah-bonn.de/en
OUR SERVICES

HEALTH MADE IN GERMANY

Germany is one of the world’s most important providers and exporters of healthcare products and services. The country’s innovative medical products set international standards for quality, safety and reliability. German manufacturers and service providers in all health and life sciences segments attract overseas customers and partners and deliver leadership in healthcare innovation.

HEALTH MADE IN GERMANY is the export initiative for the German healthcare industry. It supports international companies and organizations that are interested in establishing contact with potential German partners and suppliers. Set up by the German Federal Ministry for Economic Affairs and Energy (BMWi), the initiative bundles expert market intelligence for easy industry access. One of the initiative’s main goals is to promote the German healthcare sector through international networking activities for the mutual benefit of international partners and German companies alike.

HEALTH MADE IN GERMANY does this by providing proactive support (including market and regulatory insight), introductory services, and networking platforms including trade events at home and abroad. The initiative serves four major industries active in the international medical market: pharmaceuticals, medical technology, medical biotechnology, and digital health care.

HEALTH MADE IN GERMANY also works closely with 16 major German industry associations and is part of the BMWi’s MITTELSTAND GLOBAL umbrella program for small and medium-sized enterprises. The initiative is ideally placed to provide access to German healthcare market information and to help overseas businesses identify potential German partners.

The HEALTH MADE IN GERMANY initiative is implemented by Germany Trade & Invest, the economic development agency of the Federal Republic of Germany, on behalf of the BMWi.

For more information:
www.health-made-in-germany.com

Our support for your business:

We publish market briefs and in-depth market studies of the German healthcare industry and its different sectors.

Our directories of German companies and research facilities with direct contact details help international businesses to identify contacts in Germany.

Our calendar is regularly updated with the latest industry events in Germany and overseas.

Visit www.health-made-in-germany.com for more information about the German healthcare industry and all HEALTH MADE IN GERMANY activities.

We take part in leading healthcare trade fairs all over the world, organize networking events and enjoy ongoing dialogue and exchange with international health policymakers.
Axel Lohse is the manager responsible for the medical biotechnology and pharmaceutical industries at HEALTH MADE IN GERMANY. He is your point of contact for expert advice in those fields and looks forward to receiving your inquiries and requests.

Get in touch with us to learn more about what HEALTH MADE IN GERMANY can do for you.

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About Us
Germany Trade & Invest (GTAI) is the economic development agency of the Federal Republic of Germany. The company helps create and secure extra employment opportunities, strengthening Germany as a business location. With more than 50 offices in Germany and abroad and its network of partners throughout the world, GTAI supports German companies setting up in foreign markets, promotes Germany as a business location and assists foreign companies setting up in Germany. All investment services and related publications are free of charge.

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