Pharmaceutical Industry

Perfect combination of tradition, innovation, and attractive costs

Germany is the best international location for the research, production, and distribution of pharmaceuticals at an exceptionally high level. Direct access to internationally renowned scientists, outstanding research units, and major pharmaceutical markets make Germany a unique business location. The development of the world’s population structure is creating new challenges and is leading to increased demand for pharmaceuticals. This, together with significant advancements in medical biotechnology research, is giving the pharmaceutical industry new impetus worldwide.

Covid-19 Fuels Debate over API Production Locations

The effects of the corona crisis on global drug supply chains has reignited debates about international trade and potential shortage of drugs and generics.

Widespread concern over import dependency

Germany’s Federal Minister of Health, Jens Spahn, announced his intent in March to initiate consultations with EU partners about the possibility to relocate the production of certain active pharmaceutical ingredients (APIs) back to Germany.

He is not the only one worried about pharma supply chains: Earlier this year, the Bavarian Minister of Health, Melanie Huml, advocated the need for a European effort to ensure “that European social and environmental standards are complied with in pharmaceutical production.”

Another prominent health politician and professor of health economics and epidemiology, Karl Lauterbach, has proposed prioritizing discount contracts with suppliers that manufacture their pharmaceuticals in Europe. Five of the 16 German federal states have publicly voiced their support for initiatives along these lines. What is behind the common wish of German politicians to rely more on their country’s proven capabilities in drug manufacturing?

Covid-19 impact on global manufacturing and trade

The effect of the Covid-19 pandemic on global supply chains provided new fuel for the debate about international trade with drugs, particularly with respect to generics. Large quantities of these medicines – the patents for which have expired – are imported from Asia.

Around 60 percent of APIs worldwide are manufactured in India or China. India alone accounts for 18 percent of global generic drug manufacturing, most of which is exported. China is also not only a major manufacturing location itself, but produces 70 percent of the APIs for India’s generics industry. This situation makes these two countries major players in the global market for generic medicines.

According to WHO estimates, China accounts for 20 percent of global API manufacturing. Its production capacities were hit hard by the strict measures put in place by authorities to stop the infection, resulting in a decrease in manufacturing output.

Response to disruptions

As the virus spread globally, India temporarily placed an export curb on 26 drugs and APIs – which account for 10 percent of the country’s pharmaceutical exports – in order to avoid domestic shortages. Similarly, the UK banned the parallel export of 82 drugs in order to prevent re-routing of drug supply to countries with higher prices for pharmaceutical products.
Concerns about the security of drug supply in Europe are not new. However, the sharp increase in shortage risk for essential drugs such as antibiotics and narcotics for surgery has reinvigorated the discussion about possible measures. In Germany, six new cases were added to the drug supply shortage database in 2020 (as of April 7, 2020). A survey of German pharmacists indicates that 90 percent of them experienced supply issues in the previous three months.

### Balancing safety and cost

Germany’s Federal Association of Pharmaceutical Manufacturers (BAH) has said in a statement that "[one] should think about incentives to strengthen the European Union as a location for the pharmaceutical industry and bring the production of APIs and pharmaceuticals back to the European Union."

Discussions about the security of pharma supply in Germany often involve the topic of discount contracts that designate pharma companies as the sole providers of a drug in exchange for a discount. These were introduced in 2003 to make the procurement of pharmaceuticals more predictable for suppliers and less costly for health insurance companies. A side effect of this instrument has been the reduction of potential suppliers for drugs in the lower price segment. This has made supply chains more vulnerable to disturbances – such as the Covid-19 pandemic – because the number of alternate procurement options was significantly decreased.

The urge to contain healthcare system costs has increased import dependency levels. Drug production in India, for example, is estimated to be 50 percent cheaper than in Europe according to a 2016 study. Initiatives to encourage an expansion of generic manufacturing in Europe must accordingly reconcile the need for robust supply chains with the requirement for healthcare cost containment - a task which can only be accomplished by keeping the dynamics of the pharmaceutical industry in mind.

### Latest Publications

**Industry Overview - The Pharmaceutical Industry in Germany**

Germany offers the perfect location for the development, production and sale of world-class pharmaceuticals.

**Livestream Webinar**: The German Consumer Healthcare (OTC) Market
The Industry in Numbers

- The German pharmaceutical market is the largest in Europe and the fourth largest in the world. The annual sales of medicinal products total more than EUR 41.5 (2017) and this figure continues to experience sustained growth (+5% in 2017 vs. previous year).
- 1170 pharmaceutical and biotechnology companies with more than 128,000 workers (2015) operate in Germany. In addition to globally successful enterprises, the industry composed of more than 800 medium-sized businesses and young biotech companies.
- German companies invest EUR 6.2 billion (2016) annually in research and development.
- Top 10 of the most important indications on the statutory health insurance market in terms of sales (2016):

<table>
<thead>
<tr>
<th>Indication areas (ATC-3)</th>
<th>EURO in mil.</th>
<th>% vs. previous year</th>
<th>% share of total sales</th>
<th>% share of total quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>38,676.60</td>
<td>3.13</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>L04B Anti-TNF products</td>
<td>2,127.5</td>
<td>8.15</td>
<td>5.50</td>
<td>0.07</td>
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<tr>
<td>N07A Multiple sclerosis Product</td>
<td>1,730.90</td>
<td>-0.91</td>
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<tr>
<td>A10C Human insulin and analogues</td>
<td>1,394.70</td>
<td>1.15</td>
<td>3.61</td>
<td>1.76</td>
</tr>
<tr>
<td>L01H Antineoplastic protein kinase inhibitors</td>
<td>1,385.20</td>
<td>15.61</td>
<td>3.58</td>
<td>0.04</td>
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<td>B01F Direct factor-Xa inhibitors</td>
<td>1,070.90</td>
<td>32.09</td>
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<td>0.65</td>
</tr>
<tr>
<td>N02A Analgesics, Anaesthetic agents</td>
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<td>3.18</td>
<td>2.75</td>
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<tr>
<td>J05B Virostatic agents, not for HIV</td>
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<td>2.49</td>
<td>0.16</td>
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<tr>
<td>J05C Virostatic agents for HIV</td>
<td>961.50</td>
<td>3.68</td>
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<tr>
<td>L04X Other immunosuppressants</td>
<td>899.00</td>
<td>11.90</td>
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<td>T02D Diabetes tests</td>
<td>833.50</td>
<td>-1.97</td>
<td>2.15</td>
<td>3.66</td>
</tr>
</tbody>
</table>

Source: BPI 2017

Self-medication Market
Within Europe, Germany is the leading market for non-prescription medicines, so-called OTC (over-the-counter) products. OTC refers to medicinal products which may be sold only in pharmacies but for which no prescription is required.

The annual sales of non-prescription medicinal products total more than EUR 8.7 billion (2017, with growth of +3.7% vs. previous year). The largest share of self-medication products is accounted for by pharmacies with 69% (EUR 7.2 billion), followed by drug stores, supermarkets, and mail-order pharmacies. The three best-selling product groups include cold remedies, analgesics, and skin products.

### Over-the-Counter (OTC) Medicine

**Sales of OTC medicinal and health products by pharmacies increased by 3.7% from 2016 to 2017**

OTC sales of medicinal products and health products in Germany by source of financing 2013 - 2017 (in EUR million)

![Bar chart showing OTC sales by source of financing from 2013 to 2017](chart)

**Note:** Sales figures are based on sales by pharmacies, including mail-order pharmacies.

**Source:** IMS Health 2018

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### Pharmaceutical Production

The pharmaceutical industry in Germany manufactures pharmaceutical products worth over EUR 29 billion annually (2016).

### Infrastructural Benefits

In addition to its central location in the heart of Europe, Germany offers an excellent, well-developed, nationwide infrastructure. The most modern transportation networks work in coordination with a high-quality communication and energy infrastructure. Hundreds of thousands of highly qualified workers from the areas of medical technology, pharmaceutical technology, and mechanical engineering enable companies to implement efficient and complex production processes. Pharmaceutical companies in Germany also benefit from the close proximity to leading machine and plant
manufacturers. This ensures continuous production processes and reduces downtime. Germany accounts for approxi-
mately 37 % of the total production of machinery and plants in Europe.

Research and Development

Germany has become one of the world’s most important countries for clinical studies. Germany is the leader in indus-
try-initiated clinical studies in Europe and second worldwide. The dense network of universities and faculties as well
as a variety of research institutions not affiliated to universities speak in favor of Germany as a business location.

References

Dr. Hagen Pfundner, CEO Roche Pharma AG and Managing Director Roche Deutschland Holding GmbH

“The availability of a highly trained labor force, a secure legal framework, the company's own long tradition in Ger-
many, and a proven record in biopharmaceutical production were determining factors for the site expansion.”

Associations

The pharmaceutical industry is represented by several associations:

**German Association of Research-based Pharmaceutical Companies (vfa):** The vfa represents the interests of 44
global leaders in research-based pharmaceutical companies and more than 100 subsidiaries and affiliated companies in
healthcare, research, and economic policy.

- [Official Homepage - vfa](#)

**German Association for the Pharmaceutical Industry (BPI):** The BPI represents approx. 240 companies. This in-
cludes traditional pharmaceutical companies, pharmaceutical service providers, and companies in the fields of biotech-
nology, herbal medicine and homeopathy/anthroposophy.

- [Official Homepage - BPI (only in German)](#)
German Association of Pharmaceutical Producers (BAH): With more than 450 members, the BAH has the most members among the pharmaceutical industry associations in Germany. Its members are primarily pharmaceutical producers, but also pharmacists, lawyers, publishers, agencies, as well as market and opinion research institutes in the healthcare field.

- Official Homepage - BAH

Pro Generika: Pro Generika is the association of companies that manufacture generic and biosimilar products in Germany. Pro Generika has 16 member companies in Germany. Companies manufacturing generic and biosimilar products together cover over 75 percent of the medicinal drugs required by the statutory health insurance funds.

- Official Homepage - Pro Generika (only in German)