

# Political Briefing

September 2020

## Pharma is effective!



Corona brings unprecedented challenges for healthcare systems. Doctors, nursing staff and pharmacists have been doing superhuman work for months. The chemical-pharmaceutical industry contributes to this, so that we will hopefully soon and well master this exceptional situation.

Research on the new virus is just one example: There are already over 170 vaccine projects worldwide, eight of them with a focus here in Germany. Furthermore, our companies supply important components for vaccines that are being developed elsewhere. We also see many other aspects where contributions from the pharmaceutical industry are indispensable, especially in the current pandemic: From

life-saving drugs and disinfectants to inhalers and medical oxygen: Our products make medical care for already ill persons possible in the first place.

### Effective therapy for the pharmaceutical industry location

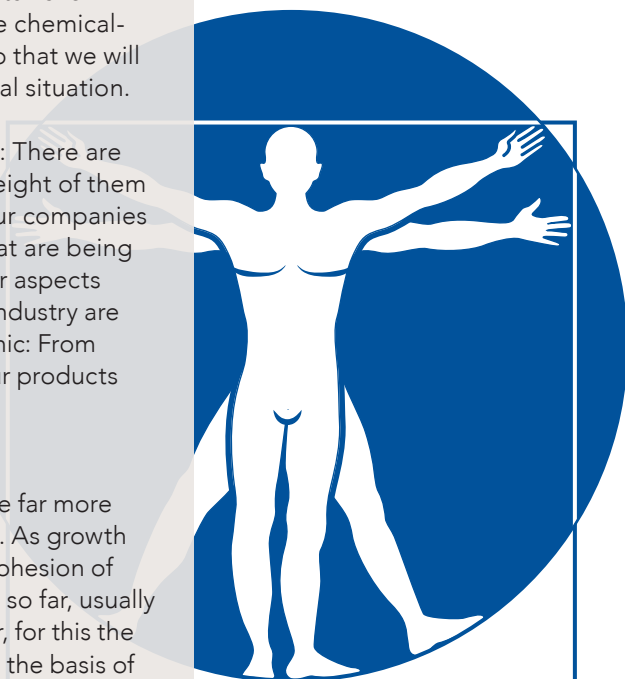
It is also becoming clear right now that the local pharma companies are far more than just reliable and responsible partners in acute crisis management. As growth drivers and attractive employers, they have a central function for the cohesion of society as a whole: At present, around 120,000 people have good and, so far, usually secure jobs in the pharmaceutical industry in Germany alone. However, for this the companies must be able to continue operating at the highest level, on the basis of competitive and innovation-friendly research and production conditions. Otherwise, competitors from Asia and the USA will outdo them in the medium term.

In the long run, competitiveness is only possible with sustainable structures, including a research allowance that meets international levels, cost-covering production conditions, reliable patent protection and regulated access to health data for private research facilities.

Let us work together to bring about such structures and, in this way, for a lastingly effective therapy for Germany as a pharmaceutical industry location.

### Werner Baumann

Vice-President of Verband der Chemischen Industrie



**Maintain domestic production**

# Supply security is most important

*The corona pandemic puts healthcare systems and supply chains to the test around the globe. The internationally networked pharmaceutical industry with its numerous research cooperations and production facilities worldwide ensures supply. This is particularly true in the current pandemic, as diversification increases supply security: If one location fails, others can stand in. All the same, corona also reveals dependencies on non-European production sites. Above all, this applies to off-patent drugs, especially generics.*

Why is this so? For years, health insurance funds have been exerting massive cost pressure on manufacturers through rebate contracts. The production of generics in Europe has long ceased to cover costs – and the number of raw material manufacturers in Germany alone dropped by around 10 percent to only 64 between 2010 and 2018. Meanwhile, China and India have become the largest manufacturers of

finished drugs and active substances. Sudden disruptions – such as quality defects, machine breakdowns or trade conflicts – can interrupt supplies for productions in Germany.

Generics production in Europe secures the supply and shortens transport and delivery routes. To prevent future supply shortages, four fields of action are essential:

■ **Strengthen value chains**

Stable trade agreements for pharmaceuticals can help stabilise supply chains. International division of labour can enhance both efficiency and resilience. In order to diversify supply relationships, research and production should increasingly be established in countries which have turned out reliable trading partners. The trade policy framework must be shaped in such a way that exchange is secured by agreements.

■ **Safeguard cost recovery**

Drug manufacture in Germany and Europe must be economically viable. This is the only way to stop the trend of local companies giving up the development of urgently needed medicines and forms of therapy. Therefore, health insurance funds should conclude rebate contracts with at least two, or better still, three manufacturers. Furthermore, pharma companies that can furnish proof of a European supply chain should be preferred in the future. Another important point: Alongside the price, also quality, high standards in production plants and loyalty to the location should be rewarded and taken into account in rebate contracts.

■ **Promote know-how**

To generate even more knowledge for the development of advanced therapies and new vaccines, a European research infrastructure should be created. Digitalisation in healthcare systems – a topic that has gained in importance as a result of the corona pandemic – must be further driven forward. This includes, in particular, making digital health data available for research purposes.

■ **Harmonise benefit assessment**

The introduction of a uniform Europe-wide benefit assessment for innovative drugs would avoid duplication of work, so that disputes about methods do not unnecessarily impair access to new medicines.



*The supply of medicines is secure in Germany. At least for the time being. Now it is important to keep up this security for the future.*

**Further strengthen research**

# Do not gamble away the future

*If we want to live healthier lives tomorrow, we need research today into future therapies and medicines, for example, for widespread cardiovascular diseases, diabetes and cancer. Pharma companies are working intensively on this. There are still diseases that are difficult or impossible to treat. This makes research and development even more important.*

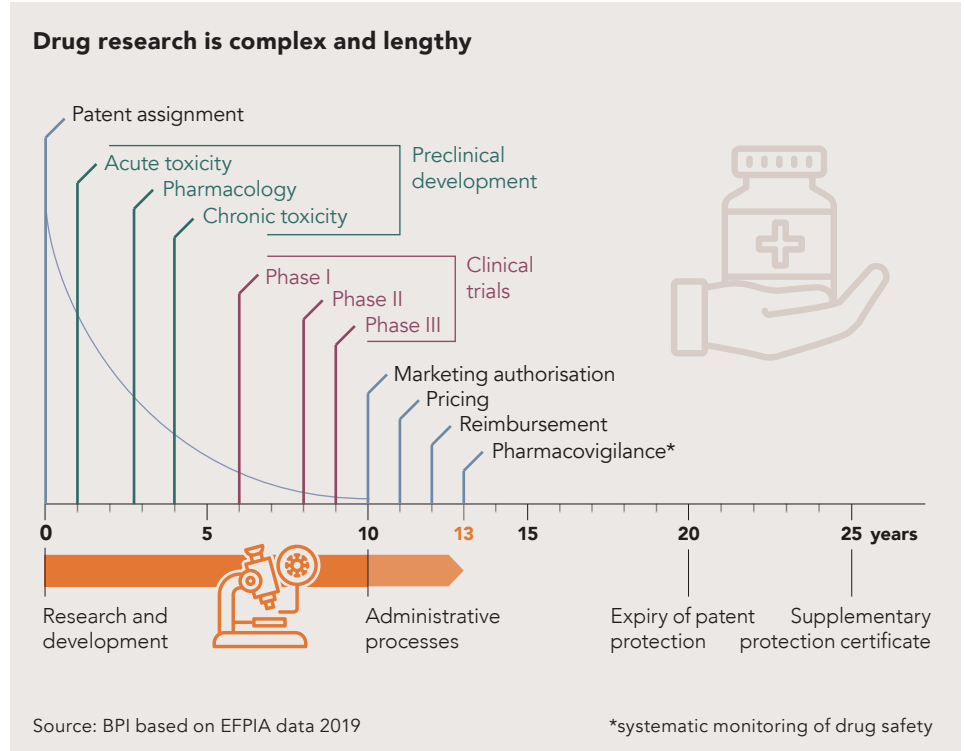
In 2019, the German pharmaceutical industry invested around 8.1 billion euros in research and development (R&D) for new therapeutic approaches and more effective drugs. This makes it one of the most innovative industries in Germany. However, the entrepreneurial risk is unusually high, because the development of new therapies and drugs is a complex and lengthy process. Therefore, framework conditions that facilitate cost-intensive projects are all the more important.

**Make research promotion a stable**

The German government once again doubled the important [research support through tax incentives](#) for all companies within the Pact for the Future up to 2025. This very instrument promotes investment in the future viability of Germany as an industry location. What is needed now is rapid implementation with low administrative costs, so that research does not fail due to a lack of staff – especially in small and medium-sized enterprises. Moreover, funding should be adjusted to an internationally competitive level, in order to strengthen Germany as an attractive location for research.

**Enable access to data**

Every day, large volumes of data are generated in hospitals, doctors' practices and medical research. This data can be used, for example, to form virtual control groups for clinical trials. The potential for validating research



*On average, it takes 13 years to bring a new drug to market. Over and again, promising projects fail even in the last clinical phase – substantial investments are lost and cannot be recouped.*

theses and models in this way is immense. Innovative therapies and more effective drugs could reach healthcare systems more quickly.

Access to health data – which patients have already released from the electronic patient file at the research data centre – has so far been limited to public research institutes. Research-based pharma companies, as important implementers of basic research into beneficial applications, are left out. The fact is ignored that they have been conducting for decades around 90 percent of clinical trials in patients in Germany that meet the highest data protection standards. For this reason, regulated access to data from the new research data centre should be made possible for private facilities too.

**Protect intellectual property**

At the latest 18 months after receipt of the application at patent offices, patents are publicly available. In return, applicants are given the right to use their invention exclusively: because only those who can rely on secure patent protection invest hundreds of millions of euros in research. With supplementary protection certificates and the connected patent term extension by up to five years, drug manufacturers can make up for the long development times of medicines. Therefore, the European legal framework for intellectual property protection should be quickly complemented by a supplementary protection certificate with a uniform EU-wide effect and a uniform granting procedure.

Staying competitive

# “Vitamin” for Germany

*It is a driver of growth and innovation, an attractive employer and safeguards good healthcare: the pharmaceutical industry in Germany. Speaking in metaphors, it is thus an essential vitamin for the future of Germany as a business location. This is particularly evident in the current situation.*

The corona pandemic emphasises the great importance of a strong and innovative pharmaceutical industry: The industry provides both proven and new active substances, optimises pharmaceutical forms and production processes and sees to better treatment options in this way.

► **Growth driver**

In 2019, the industry realised sales of more than 50 billion euros in Germany. Large and medium-sized pharma companies are an important economic factor for Germany as an export nation: They are crisis-proof, enhance structures and are loyal to the location. With sales of over 423,600 euros per employee, the industry holds a leading position in the German economy and is well above the industry average of ca. 301,600 euros. In the past ten years, production has grown by 2.5 percent annually – faster than in industry overall. Pharmaceutical products “made in Germany” are in strong demand worldwide and contribute significantly to successful exports of German industries.

► **Driver of innovation**

The pharmaceutical industry is the most research-intensive sector at the business location Germany. Most recently, research-based pharma and biotech companies spent around 8.1 billion euros on the development of new drugs. Strong innovation

capability is needed, because just a few substances make it to the target: From an average of 5,000 to 10,000 substances, only around five substances usually reach the decisive clinical phase II.

► **Attractive employer**

Roughly 120,000 staff work in around 360 companies. Domestic businesses and German subsidiaries of international groups offer highly qualified and well-paid jobs: The annual salary per employee is ca. 64,400 euros, as compared with ca. 51,100 euros in the manufacturing sector.

**More competitive pressure**

The pharmaceutical industry has been successful in Germany for decades. But this success story cannot be taken for granted. While Germany was once considered the “pharmacy of the world”, the domestic pharmaceutical sector is now coming under increasing pressure: The global competition of locations is getting ever fiercer.

The introduction of fiscal incentives for research and their recent doubling by 2025 are important first steps. However, anyone who wants future pharmaceutical productions to settle in Germany in addition to research and who wants to keep existing productions here must

**German pharmaceutical industry 2019**



Number of undertakings  
**358**



Staff  
**120,000**



Sales  
**€ 50.8 bn**



R&D expenditure  
**€ 8.1 bn**

continue to promote and strengthen the location in a sustainable manner – by way of the following:

- Adequate remuneration for active substance production and therapies
- Expansion of research promotion
- Driving forward digitalisation
- Improving patent protection

**Research against corona**

Research work connected with the new virus is immense:

- Out of over 170 vaccine projects against the pathogen worldwide, eight are being driven forward mainly in Germany. Two vaccines are being tested.
- Furthermore, some German companies supply components for vaccines that are being developed elsewhere.
- Germany has a similarly strong position in the development of new drugs against the virus, e.g. with agents based on genetically engineered antibodies.

**IMPRINT**

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