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pharmaceutical site Europe

Strengthening resilience and competitiveness

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At a glance

The pharmaceutical industry in Europe is a guarantee for innovative and high-quality medicines and impresses with its economic importance. At the same time, there are critical dependencies, especially with certain generics and active ingredients
from China, India and various Southeast Asian countries.

In order to strengthen resilience, supply chain diversification instruments, stockpiling and emergency production capacities should be preferred to relocating production to Europe in order to keep the considerable additional costs for the European healthcare systems within limits.

To strengthen competitiveness, the pharmaceutical industry ecosystem should be strengthened instead of industrial subsidies.
This includes, among other things, an excellent education system for specialists, a flourishing research and development landscape, an innovation-promoting implementation of the European IPCEI Health and the establishment of a European health data space.

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1 Introduction

Europe's pharmaceutical industry is both an innovative, economically important sector and an essential part of services of general interest in geo-economically tense times.

In 2020 , the European1 pharmaceutical industry exported goods worth around 510 billion euros, imported goods in Value of 347 billion euros and counted over 835,000 employees.2 At the same time, it is essential for the supply of medicines in Europe and underpinned its ability to react to crises, for example through innovative vaccine developments in the Covid-19 pandemic. The charisma of Europe as a location for pharmaceuticals and innovation goes far beyond the continent.

Europe's pharmaceutical industry in figures - appreciation for added value

Exported goods 2020

509.828 billion euros

Imported goods 2020

347.124 billion euros

Trade Balance 2020

162.704 billion euros

A total of 835,590 employees in 2020

122,331 employees in R&D in 2020

R&D expenditure

39.656 billion euros in 2020

2017-2021

an average of 4% pa growth

Own representation

Source: EFPIA3

Bottlenecks4 in important medicines have been occurring again and again for many years. At the beginning of the Covid-19 pandemic, there were massive Delivery problems due to the global "demand shock", but also, for example, due to the comprehensive lockdowns in China and others important supplier countries in Southeast Asia. Many people only became aware of Europe's dependence on these production sites in the medical and pharmaceutical sector, especially in the generic segment and for PPE materials,5 with the pandemic. If production problems are added to unforeseen crises, the interdependencies with the Far East will inevitably have an impact – at least in the short term – on global supply chains and thus on drug sales care within Europe. A further aggravating factor during the pandemic was that India imposed an export ban on 26 medicines, primarily antibiotics and drug components.6 These developments have caused great concern among the general public and politicians about a possible shortage of medicines and asymmetric interdependencies in the global pharmaceutical supply chains and launched new initiatives.

Therefore, in strengthening the European Pharmaceutical industry two things to be considered: the Strengthening competitiveness and resilience with regard to health care security. Both goals complement each other, but in the approach and the choice of instruments must be to be separated from each other. For example, a general relocation of large parts of the pharmaceutical production to Europe would lead to high costs for both the pharmaceutical manufacturer and the consumer for the healthcare system and thus inevitably for the citizens. the bet competitiveness would not be strengthened as a result. A surgically precise intervention is much more necessary, which first precisely defines certain dependencies for certain products and preliminary products. And even with these is a return storage of the production is not the first choice because of the enormous costs. First should Among other things, greater diversification of supply chains and strategic emergency capacities including emergency production capacities should be examined.

In order to strengthen competitiveness, flat-rate subsidies under the guise of strengthening resilience should be avoided. Subsidies distort the effectiveness of the market tes and lead to less competition and an overall decline in competitiveness in the medium to long term. Rather, a supportive regulatory framework should be created to strengthen the pharmaceutical industry ecosystem. This includes, among other things, an excellent Education system for professionals, a thriving research and development landscape, an innovation-promoting implementation of the European IPCEI Health and the development of a euro European health data room. Within this framework, individual companies, from corporations to start-ups, should find the best conditions for developing their own competitiveness.

In the following chapter, the strengthening of resilience will first be discussed and target-oriented instruments will be explained. In the following chapter, the areas listed for strengthening competitiveness are explained in more detail and ways to comprehensively support the ecosystem of the pharmaceutical industry are shown.

2. Strengthening of resilience

When thinking about strengthening Europe's resilience, the focus is on the "development of a viable strategy for creating long-term security of supply" and on "strengthening pharmaceutical production" versus reducing dependency on a few countries and production sites.7 On the other hand, the demand for a blanket relocation of pharmaceutical production to Europe is primarily preventive and cannot resolve short-term bottlenecks. The newly created EU authority for crisis prevention and response to health emergencies (HERA), whose work is divided into "precaution" and "crisis response", also takes a more differentiated approach. Especially in the area of "precaution" the tasks "overcoming the market challenges and strengthening the open strategic autonomy" as well as "securing the provision of medical countermeasures" are mentioned.

The latter has set itself the goal of procuring, storing and distributing medical goods within the EU and wants to identify delivery bottlenecks before they become supply bottlenecks.8

Because, as the European Parliament (EP) put it in its Resolution 2020, "Public health has become a geostrategic weapon that can bring a continent to its knees". According to the European Medicines Agency (EMA), the number of drug supply shortages has increased 20-fold between 2000 and 2018 and since increased 12-fold in 2008, primarily due to vulnerable supply chains linked to a limited number of chemical manufacturers in China.9 The EMA

The mandate was expanded as part of the European Health Union, which now affects the monitoring of delivery bottlenecks more than before. An authority, the so-called "Executive Steering Group on Shores and Safety of Medicinal Products" (MSSG), is set up within the EMA, which is responsible for compiling a list of critical medicinal products. Further recommendations for avoiding bottlenecks are being drawn up by the EMA.10 In the EU health union that is currently being established, who The emergency authority HERA and the EMA therefore work closely together and in tandem ensure an improved early warning system in the event of possible drug shortages.

Considering this is an overall strength to improve Europe's resilience in the supply of medicines. First and foremost, this includes reducing the import of critical primary products from China, India and various Southeast Asian countries. For those products and raw materials that are considered to be particularly critical and supply-relevant for the supply of citizens in the EU and that are produced in non-EU countries, there should be a diversification of the supply chains, the establishment of emergency reserves and emergency capacities up to A complete relocation to Europe should be considered in exceptional cases. A decisive criterion can be how often a drug has been classified as a delivery or even supply bottleneck in the past few years; the existing number of production sites (manufacturer concentration) for certain drugs should also be included

considerations.11 The WHO list of medicines that are particularly relevant to medical care provides a first approach. However, a so-called "positive list of essential medicinal products" is not always easy to implement, as Karl Broich, President of the Federal Institute for Drugs and Medical Devices (BfArM), notes.
In his opinion, various specialist societies in Germany have named what they consider to be the most important and indispensable drugs, which leads to a long and therefore useless list.12

In its document on the *Structured Dialogue on the Safety of Drug Supply ,* the EU Commission proposes identifying critical drugs based on their therapeutic indication and the availability of suitable alternatives.13 In a next step, for the

identified drugs strategic dependencies and EU manufacturing capacities are disclosed. The Swedish EU Council Presidency, which began on January 1, 2023, gives priority to the topic of pharmaceuticals, as stated in its program.14 Accordingly, the EU Commission's extensive pharmaceutical package, which was already dated for December 2022, should be presented as soon as possible. According to EU Health Commissioner Stella

Kyriakides take place at the end of March. According to the EMA, delivery bottlenecks for antibiotics were recently registered in 26 EU countries. According to the Commission's plans, earlier and obligatory notifications of imminent supply bottlenecks for medicinal products are to be introduced.15

The above measures can have a complementary effect and reinforce each other. This fits in with the announcement by Federal Minister of Health Karl Lauterbach (SPD) that he will reform the existing practice when awarding discount contracts based on the logic of the lowest manufacturer price in Germany and will in future integrate location considerations into discount contract tenders. For example, health insurance companies are to be obliged to buy from manufacturers who produce with more expensive active ingredients. In the tenders the discount

contracts, the award criterion or lottery "share of active substance production in the EU" is awarded in addition to the price.16 The health insurance funds are currently concluding contracts with the cheapest manufacturers (in some cases exclusive discount contracts). Pharmacies are only allowed to dispense these medicines. In the future, manufacturers who produce in Europe are to be taken into account, which in turn is intended to boost production in Europe and ensure better availability of medicines.17 Although this step is welcomed by the industry, it is more than questionable whether supply bottlenecks will be completely reversed as a result avoid. Also it should be more than just that Reform of the existing discount agreements - mind you here only related to Germany - need to further improve the location conditions in Europe for pharmaceutical companies and bring about long-term improvements in the security of supply. Strengthening resilience in terms of security of supply must therefore be thought of in European terms.

A reward for production in Europe or at least parts of the production steps of ver
supply-critical active ingredients in Europe would at least represent a pricing in of the "geopolitical risk" and increase supply and planning security, whereby European production would not be able to react to demand shocks in the short term.18 However, partial European production of starting materials would certainly have better environmental and Include occupational health and safety standards. The considerable more
costs for the national health systems are initially excluded here.

The cornerstones from the Federal Ministry of Health (BMG), which have now been combined into one draft bill for the "Act to combat supply bottlenecks in off-patent medicines and to improve the supply of medicines for children" (ALBVVG) are also likely to fuel the debate about the automatic substitution of biosimilars, which in the law for more safety in medicines

funds supply (GSAV) decided and pushed back by one year at short notice

19 This refers to the obligation on the part of the pharmacist to dispense a preparation that is as inexpensive as possible for biological medicinal products (biologicals), unless this has been indicated otherwise by a doctor. The hoped-for competition should reduce the costs for biopharmaceutical drugs. The fear that conditions similar to those in the generic area (dependencies, manufacturer concentrations, supply bottlenecks) could arise in the biological drug area is raised by industry, for example.20 These considerations also apply to the subsequent question of maintaining and expanding competitiveness take into account.

The declared goal is to strengthen Europe as a pharmaceutical location and to diversify the supply chains. Because diversification increases security of supply. If one location fails, including our own in Europe, another can compensate for this. What is important is an overview of the existing suppliers and better transparency of the supply and delivery structures so that several manufacturers do not unknowingly purchase goods from the same production site. In addition
also includes querying the industry, for example in a pharmaceutical dialogue or in the advisory board Delivery and supply bottlenecks with several
Actors at the Federal Institute for Drugs and
Medical devices (BfArM) such as Germany. In the course of the draft of the ALBVVG, the BfArM is to experience an expansion of the legal framework for action by setting up an early warning system to identify impending supply bottlenecks.21

Drug dependencies

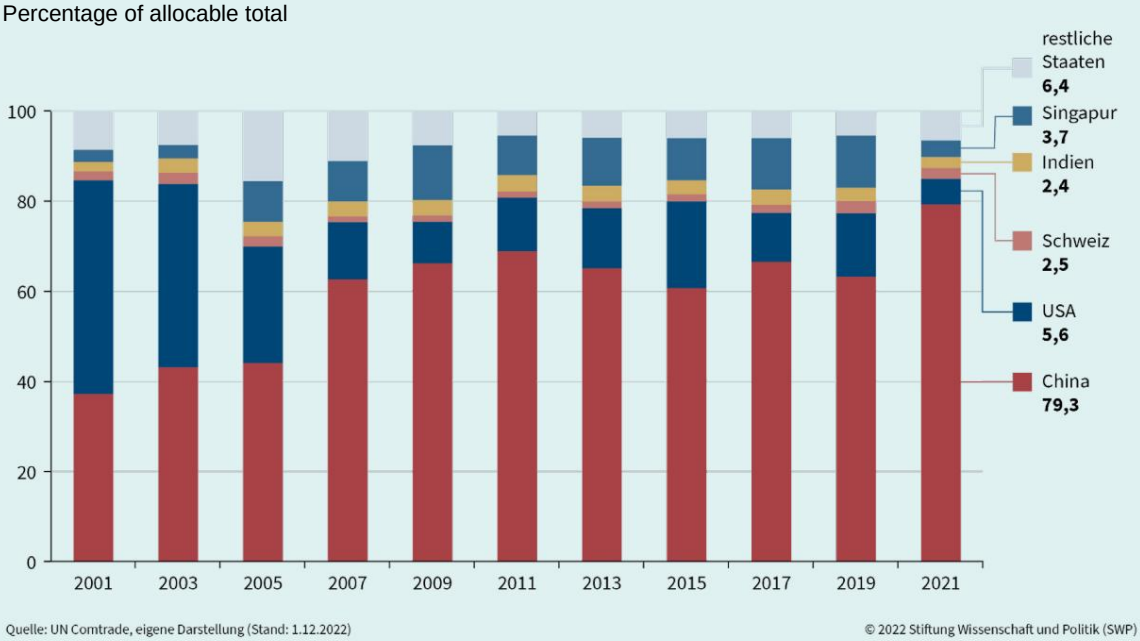
preliminary products

Europe obtains a large part of its pharmaceutical precursors (active pharmaceutical ingredients, API) from China and India. As early as 2020, the European Parliament made a resolution on the geopolitical dimension of the
Drug imports carefully, after which 60 to
80 percent of all API from China and India stam
men.22 India itself (as of 2020) receives 70 percent of its active pharmaceutical ingredients from China, and generics are then manufactured locally for the European and global markets. Although China and India are often mentioned in the same breath as the pharmaceutical heavyweights in Asia, China plays a major role in the global supply chains due to its production capacities of chemical precursors and APIs.23 Nonetheless, India stands out as the world's largest supplier of generic drugs and is 20 percent of world demand.24 This Ver
chaining underscores China's dominance in active ingredients (APIs). Nowhere else can such large quantities of the active ingredients for medicines be produced so cheaply.25 Overall, 68 percent of the production sites for active ingredients destined for Europe are in Asia, primarily in India and China.26

If one considers the specific area of antibiotics, for example, it can be stated that China provides 80 to 90 percent of the global active ingredient (API) for antibiotics and exports 42.4 percent of all finished antibiotics (finis hed pharmaceutical products) worldwide.27 The The EU obtains 7.0 percent of its finished antibiotics from China.28 In its analysis of the "EU's open strategic autonomy in the field of pharmaceuticals"
Michael Bayerlein from the German Science and Politics Foundation suggests placing a special focus on antibiotic APIs when considering dependencies. Because only the distinction between finished pharmaceutical products and the chemical precursors, the active ingredients that are needed for further use and manufacture, makes a more targeted determination of dependencies in the field of antibiotics visible.29 In addition, antibiotics play a role in the broad supply of the population and medical treatments play an important role.

As the graph shows, there is a strong concentration of imports as a proportion of the total attributable quantity of antibiotics APIs into the EU.

Import of antibiotics (API) into the EU
Percentage of allocable total



Source: Stiftung Wissenschaft und Politik30

Although the monetary value of these advance payments is very low overall, it does not necessarily apply to the imported quantities, so that strategic dependencies for individual generics such as antibiotics (e.g. penecillin) and above all their underlying active ingredients cannot be ruled out.31 For comparison : With a share of almost 80 percent of the daily required drug doses, generics in particular represent the majority of the prescription drugs dispensed in Germany, although generics account for only 9.3 percent of drug costs.32 These

For example, generic drugs include common antibiotics such as amoxicillin, pain relievers such as aspirin, and acetaminophen. According to a report by the Centers for Infectious Disease Research and

University of Minnesota policy come close
100 percent of the active ingredient for drugs such as

Penicillin G, levodopa and paracetamol and more than two-thirds of the active ingredient gave way to others

Current drugs such as antidiabetics, antihypertensives, antiretroviral drugs and others

Antibiotics from China. The dependency in the production of active ingredient components and API, which in turn are used to manufacture generics, does not only affect Germany and Europe, but is a global phenomenon.33

Due to the considerable cost pressure for generic, i.e. patent-free medicines, and basic chemicals, production has been gradually relocated away from Europe in recent decades.34 It is true that the pandemic has primarily diversified production and supply

Chains with capacity reserves proved successful, but dependencies were nevertheless found , particularly for low-priced products.35 As an immediate measure, production and supply chains should therefore be diversified as far as possible in order to increase security of supply and reduce strategic dependencies on a few suppliers. Although Chinese manufacturers are almost unrivaled in their low prices, there are measures, as described below, that allow for a diversification of supply

support chains. Here, for example, the market power of the European Union through joint purchases is an advantage.

The production or production steps of supply-relevant active ingredients or Medicines to Germany or to others reclaiming all European countries appears at the current stage to be an “uncertain, time-consuming and, above all, expensive project”36. It is also unclear how relocations of production to China are to be prevented in the future if innovative medicines are currently losing their patent protection.37 The feasibility study on supply security with antibiotics provides possible input : *Ways to produce antibiotic active ingredients in Germany or the EU,* prepared on behalf of the company the generic drug industry from the company

beratung Roland Berger.38 Using the example of cephalosporins (a group of broad-spectrum antibiotics that are frequently used in clinical practice), she is investigating three models of how active ingredient production (API) could be intensified again in Europe. All three scenarios assume that the production of active antibiotic substances is shifted back at different levels

going out of volume production, however, would not be economical. The reasons for this are open obvious: higher personnel and investment costs in Germany and Europe as well as generally higher standards.

The authors refer in their Solution sketch on state support programs. Firstly with i) state intervention in price, ii) subsidies (subsidies for production costs and investment subsidies to reduce the amount of depreciation) to keep local production competitive, and iii) by supporting manufacturers who provide extra capacities for production.39 Subsidies to support innovations and to set up a European API supply chain could be necessary: However, as is so often the case, subsidies must not be distributed indiscriminately, but only used in relevant or critical areas such as APIs become. Too generous

Subsidies applied to production processes (e.g. via a subsidy towards production costs in order to reduce fixed and/or variable costs or personnel and energy costs) also have an inhibiting effect on innovation.40

Another instrument are so-called Government contracts for differential costs: a European agency (joint public procurement) such as HERA, for example, puts out to tender the delivery of several tons of antibiotics or antibiotics APIs from a non-Chinese supplier and reimburses them

difference between the higher production price and the Chinese level are the world market price. The tender would put the EU in a position to select the world's best provider, the world market would continue to function - only bypassing China.41 This instrument could be used before

especially when purchasing APIs in partner countries find application quickly. This logic is also taken into account by rewarding an extra ticket in the discount agreements with regard to location considerations. However, this approach would not be WTO-compliant, although the dispute settlement mechanism does not function properly, so there is no formal way of taking action against it.

A strategic reserve of medical equipment and medicines has also been created as part of the joint rescEU reserve for stockpiling and distribution among the EU member states.42 In addition to a

In a joint public tender, purchase guarantees from a specific production company for the product categories mentioned can also be considered – a fairly risk-free undertaking.

According to a survey conducted by the company IQVIA, 52 larger pharmaceutical companies, or 71 percent of them, would be willing to invest in the European API supply chain if the “economic barriers” (price, existing manufacturing capacities) could be overcome. European suppliers are particularly impressive when it comes to reliability

laxity and conformity.43 A lot of money has already been invested in the USA in order, among other things, to bring the production of basic chemicals back into the country. And within Europe, too, there are tendencies to reduce dependence on Chinese medicines. In Austria, there is already special state funding for the production of antibiotics.44

The settlement of research and production facilities in Europe therefore depends to a large extent on reliable industrial policy and regulatory framework conditions, which are addressed in the chapter “Strengthening competitiveness”. In order to promote this, a positive incentive policy is needed and companies are not forced to relocate. Politicians are therefore responsible for this question – it should be noted, however, that there are also short and medium-term bridging measures (e.g. active

designed diversification of supply chains, establishment of a drug reserve rescEU reserve and storage of raw materials and active pharmaceutical ingredients). In any case, as a result of considerations for a diversification of the supply chains, for example via the extra remuneration of a European API supply chain or a partial reversal storage of production sites, the financial burdens on statutory and private health insurance companies are increasing due to higher drug prices in Germany and the EU. In this country, the health fund would need further state subsidies in order to keep the additional contribution to health insurance reasonably constant. In view of multiple crises, high inflation and tight public coffers, the patients

Patients or citizens may find it difficult to explain a further increase in health insurance contributions or co-payments for medicines.

3. Strengthening of competitiveness

3.1 Research and Development

The strengths of Europe as a pharmaceutical location do not lie in pharmaceutical primary and mass products, but in high-quality R&D-intensive products. Research and development for new and high-quality pharmaceuticals must be promoted in order for Europe to maintain a leading position in global pharmaceutical competition.

The pharmaceutical industry belongs next to the automotive industry among the most innovative industries in Europe. In 2020 there were 122,000 R&D jobs in the pharmaceutical industry and 39.7 billion euros were invested in research and development.45

In the European Union – i.e. excluding European countries with a strong pharmaceutical focus such as Switzerland and the United Kingdom – 22.1 billion euros were invested in the development of new drugs in 2019; that is more than in Japan, China and India combined.46 This proves the innovative strength of the European pharmaceutical industry. Nevertheless, there is no reason to sound the all-clear. The difference between the EU and the United States as the world's strongest pharmaceutical location is enormous: In the USA, invested 58.0 billion euros in the development of new drugs in 2019, more than twice as much as in the EU.47 In addition, the shift of research and development in favor of the United States continues. The European Union is lagging behind.

Another aspect is a warning not to neglect R&D efforts in the EU: pharmaceutical research in China and other emerging countries is increasing rapidly; the distance to the EU and the USA is narrowing. In the period 2017 to 2020, R&D expenditure for pharmaceuticals in China increased by an average of 12.9 percent per year, in the USA by only 8.5 percent and in Europe by only 4 percent.48 The 95 substances newly introduced in the global drug market in 2021 come from them 35 from the USA, 19 from Europe and at least 18 from China. As a result, China will not only continue to be an important not a major supplier of pharmaceutical raw materials and cheap medicines, but a serious competitor in the pharmaceutical high-tech segment with a growing R&D output and effective translation into new products.49

Pharmaceutical research and development in Europe benefits from a good research infrastructure and an efficient science and university system that releases excellently trained scientists onto the job market and that is available as a cooperation partner for research-based companies. With regard to the pharmaceutical industry, there is a division of labor between publicly funded research at universities and non-university research institutions and companies. In publicly funded institutes, basic research is mainly carried out, such as identifying basic substances that could develop a useful pharmaceutical effect. The pharmaceutical industry

often picks up these results from basic research and develops them further and, if positive, incorporates them into clinical research. With the introduction of the Clinical Trials Information System (CTIS)51, new regulations50 improve the clinical testing of new medicinal products.52

Research cooperation and the division of tasks between industry and publicly funded institutions are not rigid, but rather flexible. It is particularly closely interlinked with regard to biotechnology and genetic engineering, which are becoming increasingly important for the manufacture of new pharmaceuticals (biopharmaceuticals); here, basic research and application-oriented research can hardly be separated.

This is supported by the flourishing biotech start-up scene, especially in the USA, but also in many European countries, which is mainly fed by spin-offs from publicly funded research institutions.

Due to the pharmaceutically relevant basic research at universities and non-university research institutions, the public sector is closely involved in pharmaceutical innovation. In addition, it can directly support the research-based pharmaceutical industry through research funding programs. And finally, through the reduction of bureaucratic over-regulation,53 as it occurs, for example, in the approval of new production sites or the testing and approval of new drugs, through the introduction of research-friendly framework conditions and the speedy approval of new drugs, it has a direct influence on the innovativeness of pharmaceutical location Europe.54

The “Horizon 2020” framework program for research and innovation lists 2,347 research projects in the field of pharmacology and pharmacy that have been carried out in recent years.55 The new “Horizon Europe” funding program also provides intensive support for health-related research. A total of 8.2 billion euros is planned.56 The urgent need for research into diagnostics, vaccines, antibiotics and pharmaceuticals is emphasized.57

The Medicines Strategy for Europe also puts a focus on promoting research and development of “high quality, safer, more effective and more environmentally friendly medicines”58. Many other funding programs, such as for cancer 59 or corona research60 or the European Health Data Space (EHDS)61, make Europe an interesting research location for the pharmaceutical industry. At the interface between R&D and

The European Medicines Agency (EMA)62 assumes central tasks for economic use. Further harmonization of the approval of new pharmaceuticals, for example in the case of orphan drugs, would make Europe even more attractive as a pharmaceutical location. With a view to future pandemic situations, the European Health Emergency Preparedness and Response Authority (HERA) is also developing research activities that will benefit the pharmaceutical location.63

In summary, it is clear that the pharmaceutical industry in Europe has high potential for innovation. With strong research and development, it can assert itself globally in the knowledge-intensive and high-priced pharmaceutical segment. The main competitors are pharmaceutical companies in the USA and increasingly in China. In order to keep Europe as a pharmaceutical location competitive, the following tasks arise with regard to R&D: 1. Faster processes and less bureaucracy for research projects, especially in the clinical phase, and for the Europe-wide approval of new pharmaceuticals. 2. Additional tax breaks for research and development. 3. Expansion of the scientific and university system, especially in the fields of life sciences, health sciences and, above all, biosciences and genetics technology and promotion of cooperation between state-funded research and research-based companies. 4. Close involvement of the R&D strong pharmaceutical locations Switzerland and United Kingdom into the European Union research network.

3.2 IPCEI Health

Important projects of common European interest (IPCEI) describe transnational cooperation for which an exception in EU state aid law applies. The basis is Article 107 (3b) of the Treaty on the Functioning of the European Union (TFEU).64 Previous IPCEI initiatives cover the areas of hydrogen, battery cells, chips and the cloud.65 On March 3, 2022, 16 member states66 under French Council Presidency announced the creation of an IPCEI Health.67 Germany only decided to participate – marginally – towards the end of the year, although the initiative was largely initiated by Chancellor Angela Merkel and French President Emmanuel

Macron on the third Franco-German

Technology Dialogue was launched in May 2021.68 France is expected to participate with a budget of 1.5 billion euros, while Germany will probably only contribute 185 million euros.69 With the IPCEI Health

important projects in the biotechnology and pharmaceutical industry are to be supported by government grants, loans and guarantees. The pharmaceutical industry also expressly supported Germany's accession to IPCEI.70 Laut

Manifesto71 of the 16 founding states of March 2022

IPCEI Health pursues three goals:

(1) An important contribution to the European Health Union and New Industry strategy for Europe.

(2) Promote the first industrial application of innovative and sustainable production processes.

(3) New products and services with to develop a high proportion of research and innovation.

Joint projects of the IPCEI Health can, among other things, be innovative and

sustainable production processes, innovation for treatment of antibiotic resistance and rare diseases, and the development of gene and cell therapies.72

Because state aid is a significant

encroachment on the European internal market, support must be strictly justified.
According to the Commission's updated criteria73

IPCEI must make a contribution to common European goals such as the Green Deal or the digital strategy (item 4). A distinction is made between three types of projects: (i) projects in the field of research, development and innovation (item 22), (ii) projects with initial industrial use (item 23), (iii) infrastructure projects (item 25). For funding, companies and research institutes must make a “significant co-financing contribution” (item 19) and show that the project has a funding gap (item 33).

In its current form, IPCEI Health addresses this funding gap for research and development and the resulting innovations. positive externality

The effects of innovations, including for health care, can be internalized in this way. The demand for high innovativeness runs like a red thread through the official

Catalog of criteria for IPCEI. For example, research and development projects must be “very innovative” (item 22) and projects for industrial use must not include any optimization of existing products (item 24).

It is therefore important to ensure during implementation that these criteria are met and that IPCEI Health causes “positive spill-over effects on the internal market” (item 2). Subsidizing existing industries without inno

On the other hand, a vative character would be inefficient and, in the medium term, would lead to lower competitiveness in Europe. This would mean that IPCEI Health would no longer be an instrument for closure

ing a financing gap for innovations, but merely a government subsidy instrument for selected sectors. Also the involvement of small and medium-sized children

take (SMEs) must despite the update of
Criteria further improved by the Commission compared to the 201474 criteria
the. Larger companies can more easily manage the application process for IPCEI in terms of personnel and finances. The innovative added value of IPCEI Health thus depends largely on its concrete implementation.

3.3 The European Health Data space

The pharmaceutical and innovation location Euro
pas is also to be upgraded with the planned European Health Data Space (EHDS) as part of the European Health Union. The European Health Union, which was initiated by Commission President Ursula von der Leyen in September 2020, is intended to address the deficits resulting from the experience of the corona pandemic and to “protect, prevent, prepare for and respond to threats to human health in the EU -level ver

mend”75. The European Health Data Space can play an important role here, as representatives at the EU Data Summit of the Konrad Adenauer Foundation recently confirmed.76

The current issue is access to research data (secondary healthcare data) for the industrial healthcare industry in German
The country and Europe are in poor shape, although research data for research into tumor diseases, rare diseases, personalized medicine, clinical studies, new drug therapies and R&D in general reveal enormous potential The research data center set up for this purpose, but fundamentally also the still inadequate digitized public health system (ePA, ePrescription).78 With the planned Health Data Utilization Act in Germany, the pharmaceutical industry should now have comprehensive access to health data and also the European Healthy

heitsdatenraum provides for this. That's over
From a German point of view, at least the basis for connection to the EHDS has been laid. However, it is questionable whether the EHDS will be operational from 2025 as planned by the EU Commission. Rather, a “learning system” is to be assumed, which is gradually being improved.

Member States' healthcare systems already generate, process and store a large amount of data. Nevertheless, access to their health data (digital patient file, e-medication plan) is not yet guaranteed for many EU citizens. Even for research in the second step, after the health-related data has been anonymized or pseudonymized, it is difficult to use this data to improve diagnosis and treatment.79 The EU Commission describes this fact in its

Legislative proposal as follows: "EU health sector is rich in data, but poor in making it work for people and science."

With the new legal framework, according to the Commission, stakeholders (researchers, policy makers, Member States) should have access to eHealth Data to improve diagnosis, treatment and patient well-being

To encourage patients and to better and
arrive at well-founded policies. The EHDS is also intended to promote the harmonization of regulations for a single market for digital health products and services, thereby increasing the efficiency of health systems. In this context, there is often talk of the frequently demanded European digital sovereignty, in which the anonymized and pseudonymised data of EU citizens is used to develop new, innovative approaches in the pharmaceuticals sector.

This in turn means not having to resort to data or AI-based solutions from China or the USA.

As a positive example, in particular
Interactions with the European
Called plan to fight cancer or else

Efforts of the EU-wide “Beyond 1 Million Genomes” project are supported.80 The development and expansion of data registers (tumour register, spinal column register, prostate cancer) is also being funded.81 The use of data can, for example, improve understanding and early detection, diagnosis , treatment and surveillance of cancer can be improved by enabling healthcare providers in the EU to access and share health data across borders. The more high-quality data that can be used, the greater the benefit for research and development and diagnosis.82 This seems logical, because data from as many patients as possible, for example in a therapy or on the tolerability of drugs in studies, is provided a fuller picture of the pros and cons.

The establishment of the EHDS is essential for strengthening Europe as a pharmaceutical location. As mentioned, the active ingredients and research for innovative biopharmaceuticals, for example for cancer therapies, are still primarily produced in Europe and North America, but this sector is also developing in China.83 In this regard writes the European Chamber of Commerce in China: "China is in a critical stage, because the country is currently changing from a manufacturer of generics to a supplier of original medicines."84 The strengthening of the industrial health economy and the competition

The ability of Europe as a location for science and research therefore depends to a large extent on access to research data within the framework of the EHDS. This requires the establishment of quality-assured databases, for example for patient data including genomic data.

This requires sufficient funding and standardization as well as legal rules for data protection-compliant and at the same time research and user-friendly access.

4. Conclusion

The pharmaceutical industry in Europe is both an economically important branch as well as part of the services of general interest. Competitiveness and resilience must therefore be considered in order to strengthen Europe as a pharmaceutical location. For both goals should be in the approach and the choice of instruments independent strategies can be chosen. On the other hand, a blanket outsourcing of pharmaceutical production would incur high costs for the healthcare system and damage competitiveness. The strength of the European pharmaceutical industry does not lie in pharmaceutical primary and mass products, but in high-quality R&D-intensive products.

To strengthen resilience, precise interventions should be made on the products with critical dependencies. Dependence on China is critical, especially in the case of pharmaceutical precursors (active pharmaceutical ingredients, API) in the field of antibiotics. However, before reshoring is considered, other measures should be taken, such as diversifying supply chains and maintaining strategic contingency and contingency production capacities.

To enhance competitiveness, instead of subsidies, a supportive regulatory framework to be created and expanded. This includes, among other things, an excellent th education system for specialists, a flourishing research and development landscape, an innovation-promoting implementation of the European IPCEI Health and the development of a European health data space. With this business and innovation friendly Climate would also strengthen Europe as a pharmaceutical location for future investment decisions.

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