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Europe as a Pharmaceutical Location

Strengthening Resilience and Competitiveness

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Abstract

The pharmaceutical industry in Europe guarantees innovative and high-quality pharmaceuticals and is characterised by its economic importance. At the same time, there are critical dependencies, particularly on certain generic drugs and active ingredients, above all from China, India, and various South-East Asian states.

In order to strengthen resilience, preference should be given to instruments of supply chain diversification, stockpiling as well as emergency production capacities rather than a reshore of production activities to Europe. The reason for this is to contain significant additional costs for European healthcare systems.

In lieu of industrial subsidies, the pharmaceutical industry ecosystem should be consolidated so as to strengthen competitiveness. This includes an excellent education system for skilled workers, a flourishing research and development landscape, an implementation of the European IPCEI Health in a way that promotes innovation, as well as the creation of a European Health Data Space.

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1. Introduction

Europe's pharmaceutical industry is both an innovative, economically important industry, and an essential part of public service provision in a fraught geo-economic era.

For instance, in 2020 the European[1] pharmaceutical industry exported goods at a value of some 510 billion Euro, imported goods worth 347 billion Euro and had over 835,000 employees.[2] While also being vital for the provision of drugs in Europe, and having confirmed its capacity to address urgent crises by means of innovative vaccine developments during the Covid-19 pandemic, for example. The prominence of Europe as a pharmaceutical and innovation location extends far beyond the continent.

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

Exported goods 2020

509.828 billion Euro

Imported goods 2020

347.124 billion Euro

Balance of trade 2020

162.704 billion Euro

In total
835,590 employees
in 2020

122,331 employees
in R&D in 2020

R&D expenditure

39.656 billion Euro in 2020

2017 to 2021
on average four per cent
growth per annum

Own representation
Source: EFPIA[3]

Bottlenecks[4] in important medication have occurred time and again for many years. At the start of the Covid-19 pandemic, there were major supply problems owing to the global "demand shock", but also due to widespread lockdowns in China and other key supplier countries in South-East Asia, for instance. Europe's dependence on these production sites in the medical and pharmaceutical sector, particularly in the generic segment and for PPE materials[5] ,only became known to many as a result of the pandemic. If unpredictable crises are exacerbated by production problems, then interdependencies with the Far East inevitably have repercussions – in the short-term at least – on global supply chains and thus on medical supplies within Europe. To make matters worse, during the pandemic India imposed[6] an export ban on 26 pharmaceuticals, primarily antibiotics and drug components. These developments have caused deep concern both among the public and politicians about a potential lack of medical products and asymmetric interdependencies in global pharmaceutical supply chains, and have spurred new initiatives.

That is why a two-pronged approach needs to be adopted in strengthening the European pharmaceutical industry: strengthening competitiveness and resilience regarding the security of healthcare provision. Both goals complement one another, but need to be separated when it comes to the approach and choice of instruments. For example, a general reshore of large swathes of pharmaceutical production to Europe would lead to high costs both for pharmaceutical manufacturers and the healthcare system, and thus inevitably for citizens. This would not strengthen competitiveness. Rather, a surgically precise intervention is imperative, which, at first, specifically defines certain dependencies on particular products and active pharmaceutical ingredients. And even in this case, a reshore of production is not the first method of choice owing to the enormous costs. Initially, it is necessary to examine a greater diversification of supply chains and strategic emergency capacity including emergency production capacity.

In order to strengthen competitiveness, flat-rate subsidies under the guise of strengthening resilience should be avoided. Subsidies distort the effectiveness of the market and give rise to less competition and declining competitiveness over the medium- to long-term. Instead, a supportive regulatory framework should be created so as to reinforce the pharmaceutical industry ecosystem. This includes an excellent education system for skilled workers, a flourishing research and development landscape, an implementation of the European IPCEI Health in a way that promotes innovation, as well as the establishment of a European Health Data Space. This framework ought to provide individual companies, from corporate groups to start-ups, with the best conditions for developing their own competitiveness.

The following chapter will deal with strengthening resilience alongside illustrating target-oriented instruments. The chapter elaborates on the listed areas for strengthening competitiveness and will outline ways to comprehensively support the pharmaceutical industry ecosystem.

2. Strengthening Resilience

Considerations for strengthening Europe's resilience, focus[7] on "the development of a future-proof strategy for shaping security of supply over the long-term" and for "strengthening pharmaceutical production" versus reducing dependency on a few countries and production sites. On the other hand, calls for a general reshore of pharmaceutical production to Europe are primarily preventative in nature and cannot rectify short-term bottlenecks. A more differentiated approach is also taken by the newly created EU Health Emergency Preparedness and Response Authority (HERA), whose work is divided into "preparedness" and "crisis response". Specifically in the area of "preparedness", tasks are referred to as "overcoming market challenges and strengthening open strategic autonomy" as well as "ensuring the provision of medical countermeasures". The latter sets itself the goal of procuring, stockpiling, and distributing medical goods within the EU and to identify delivery bottlenecks before they become supply shortfalls.[8]

After all, as formulated by the European Parliament (EP) in its Resolution 2020, "[p]ublic health has become a geostrategic weapon that can bring a continent to its knees". According to data by the European Medicines Agency (EMA), the number of pharmaceutical supply shortages increased by 20-fold between 2000 and 2018, and by twelvefold since 2008; this can primarily be attributed to vulnerable supply chains associated with a limited number of chemical manufacturers in China[9].

Within the framework of the European Health Union, the mandate of the EMA has been extended and now applies to the monitoring of supply bottlenecks to a greater extent than before. An authority known as the "Executive Steering Group on Shortages and Safety of Medicinal Products" (MSSG) is being established within the EMA, which is responsible for creating a list of critical pharmaceuticals. Recommendations for avoiding bottlenecks are also being drawn up[10] by the EMA. Within the emerging EU Health Union, the emergency authority HERA and the EMA will therefore closely cooperate and join forces to ensure an improved early warning system for potential pharmaceutical shortages.

In light of this, it is imperative that Europe's resilience in the supply of pharmaceuticals is strengthened across the board. First and foremost, this involves reducing the import of critical active pharmaceutical ingredients from China, India and various South-East Asian countries. For those products and basic materials deemed to be particularly critical and relevant for supply to EU citizens and which are produced in non-EU countries, thought should be given to a diversification of supply chains, the formation of emergency reserves and emergency capacities, right through to a complete reshore to Europe in absolutely exceptional cases. Here, a decisive criterion may be how often a pharmaceutical has been classified as a delivery or even a supply shortfall over the past years; considerations[11] should also incorporate the existing number of production sites

(manufacturer concentration) for certain medication. The WHO list of drugs particularly relevant for supply provides an initial approach. A so-called "positive list of vital pharmaceuticals" is, however, not always easy to implement, as observed by Karl Broich, President of the Federal Institute for Drugs and Medical Devices (BfArM). He is of the opinion that various expert associations in Germany have cited what they believe to be the most important and indispensable drugs, resulting in a long and thus impractical list.[12]

In its document on *Structured Dialogue on Security of Medicines Supply*, the EU Commission proposes the identification of critical drugs based on their therapeutic indication and the availability of suitable alternatives.[13] The next step is to disclose strategic dependencies and EU manufacturing capacities for the identified drugs. The Swedish EU Council Presidency that began on 1 January 2023, accords priority to the subject of pharmaceuticals, as cited in its programme.[14] Accordingly, the EU Commission's comprehensive pharmaceutical package, already dated for December 2022, should be presented as soon as possible. Changes to pharmaceutical legislation are scheduled to take place in late March, according to the EU Health Commissioner Stella Kyriakides. As per the EMA, supply bottlenecks in antibiotics were recently registered in 26 EU countries. Earlier and mandatory notifications of impending supply shortfalls in pharmaceuticals are to be introduced according to the Commission's plans.[15]

The above-mentioned measures may have a complementary effect and reinforce one another. This is reflected in the announcement by Federal Minister of Health Karl Lauterbach (SPD); namely a reform of the existing practice of awarding rebate contracts according to the logic of the cheapest manufacturer price in Germany, and an integration of location considerations into rebate contract tenders in the future. It means that health insurances will be obliged to purchase from manufacturers whose production uses more expensive active ingredients. In addition to the price, tenders of the rebate contracts will include the award criterion or lot "share of active ingredient production in the EU"[16]. Currently, health insurances conclude contracts with the cheapest manufacturers (in some cases exclusive rebate contracts). Pharmacies may only dispense these drugs. In the future, manufacturers producing in Europe are to be taken into account, which, in turn, aims to boost production in Europe and ensure better availability of pharmaceuticals.[17] Although this step is welcomed by the industry, it is highly doubtful whether supply bottlenecks can be entirely avoided this way. What is more likely, is to require more than just a reform of existing rebate contracts – albeit only Germany is referred to here – to further enhance location conditions in Europe for pharmaceutical companies and bring about long-term improvements to supply security. Strengthening resilience within the meaning of supply security must therefore be thought about in European terms.

Remuneration of production in Europe or at a minimum part of the production steps of active ingredients critical for supply in Europe, would at least represent a pricing in of the "geopolitical risk", and increase the supply or planning security. Having said that, European production cannot respond to demand shocks in the short-term.[18] Yet it is true that a partial European production of basic materials would mean better environmental and occupational safety standards. The significant additional costs for national health systems are put aside for now.

The key points from the Federal Ministry for Health (BMG), which have now been incorporated into a draft bill on the "Act on Combating Supply Bottlenecks for Off-Patent Pharmaceuticals and for Improving the Supply of Paediatric Medicine" (ALBVVG), are also likely to fuel the debate on the automatic substitution of biosimilars, which was decided in the Act on Greater Security in the Supply of Pharmaceuticals (GSAV) and deferred at short notice by one year.[19]

Here it is about pharmacies' obligation, in the case of biological pharmaceuticals (biologics), to

dispense a pharmaceutical preparation that is as cheap as possible, unless indicated differently by the physician. The hoped-for competition aims to reduce costs for biopharmaceutical drugs. The fear that similar conditions could emerge in the biological pharmaceuticals sector to that in the generic one (dependencies, manufacturer concentrations, supply bottlenecks), is being voiced by the industry.[20] These considerations also need to be taken into account in the downstream question of preserving and expanding competitiveness.

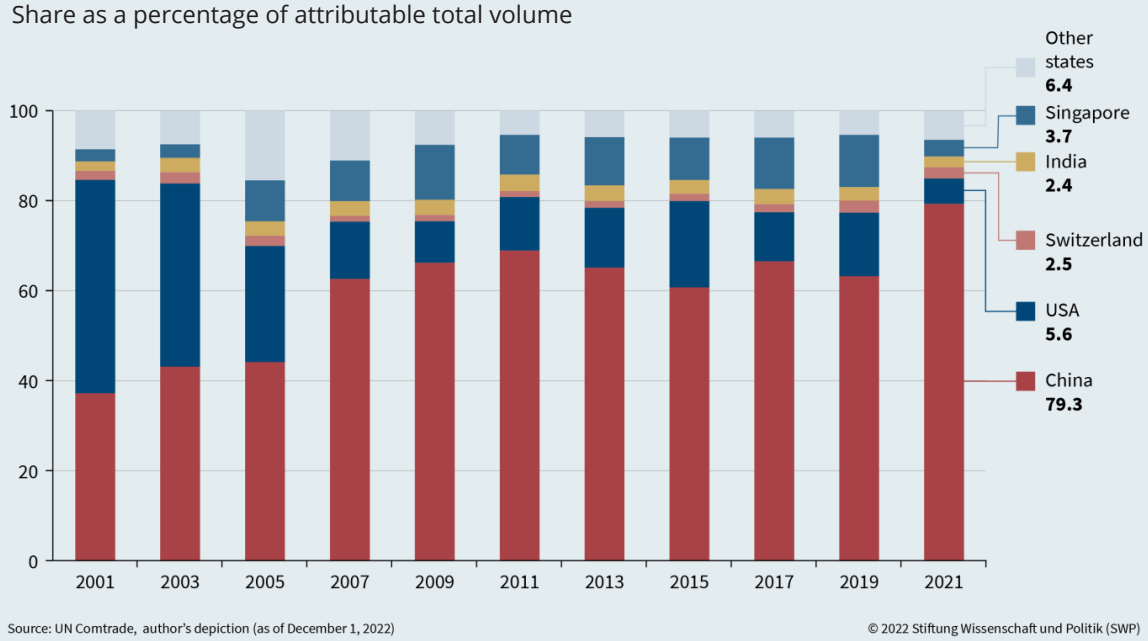
The declared goal is to strengthen Europe as a pharmaceutical location as well as to diversify supply chains. After all, diversification increases supply security. If one site fails, even its own in Europe, another can compensate for this. It is important to have an overview of available suppliers and better transparency of supply and delivery structures, so as to prevent several manufacturers from unknowingly purchasing goods from the same production site. This also incorporates industry consultation, for instance as part of pharmaceutical dialogue or in the advisory board on supply bottlenecks with several players at the Federal Institute for Drugs and Medical Devices (BfArM), as in the example of Germany. In the course of the draft bill on the ALBVVG, the Federal Institute for Drugs and Medical Devices is to experience an expanded legal framework of action by establishing an early warning system for detecting impending supply shortfalls.[21]

Dependencies on Active Pharmaceutical Ingredients

Europe purchases the majority of its active pharmaceutical ingredients from China and India. Already in 2020, a European Parliament Resolution drew attention to the geopolitical dimension of drug imports; according to which 60 to 80 per cent of all APIs come from China and India.[22] In turn, India itself receives (as of 2020) 70 per cent of its active pharmaceutical ingredients from China, and generic drugs for the European and global market are produced locally. Although China and India are often mentioned in the same breath as the pharmaceutical heavyweights in Asia, China plays a superior role in the global supply chain owing to its production capacities of chemical intermediates and APIs.[23] Nonetheless, India stands out as the world's largest supplier of generic drugs, and manufactures 20 per cent of global demand.[24] This nexus illustrates the dominance of China in active pharmaceutical ingredients (APIs). There is currently no place else where such large volumes of underlying active ingredients for pharmaceuticals can be produced so cheaply.[25] Overall, 68 per cent of production sites for active ingredients intended for Europe are located in Asia, and predominantly in India and China.[26]

If we look at the specific area of antibiotics, for instance, it can be concluded that China provides 80 to 90 per cent of global active pharmaceutical ingredient (API) quantities for antibiotics, as well as globally exporting 42.4 per cent of all finished antibiotics (finished pharmaceutical products).[27] The EU purchases seven per cent of its finished antibiotics from China.[28] In his analysis on the "EU's open strategic autonomy in pharmaceuticals", Michael Bayerlein, from the Stiftung Wissenschaft und Politik, proposes a specific focus on antibiotic APIs when reflecting on dependencies. Since only the distinction between finished pharmaceutical products and chemical intermediates, the active ingredients needed for further use and manufacture, reveals a more targeted determination of dependencies in the field of antibiotics.[29] What is more, antibiotics play an important role for the broad supply to the public and for medical treatments. As the diagram indicates, there is a strong import concentration as a share of the attributable total volume of antibiotic API in the EU.

Import of antibiotics (API) to the EU.
Share as a percentage of attributable total volume



Source: Stiftung Wissenschaft und Politik[30]

Although the monetary value of these inputs is very low on the whole, it does not necessarily have to apply to the imported volumes. With the result that strategic dependencies cannot be ruled out for individual generic drugs such as antibiotics (for example penicillin) and their underlying active ingredients, above all.[31] By way of comparison: At almost 80 per cent of the daily required drug doses, generic drugs in particular represent the lion's share of prescription-only medicines dispensed in Germany; whereas generic drugs only make up 9.3 per cent of pharmaceutical costs.[32] These generic drugs include, for example, widely distributed antibiotics such as amoxicillin and painkillers such as aspirin and paracetamol. According to a report by the University of Minnesota's Center for Infectious Disease Research and Policy, almost 100 per cent of the active ingredients for medication such as penicillin G, levodopa and paracetamol and more than two-thirds of active ingredients for other important drugs such as antidiabetics, antihypertensives, antiretrovirals and other antibiotics come from China. Dependencies in the manufacture of active ingredient components and APIs, which, in turn, are used to produce generic drugs, not only affects Germany and Europe, but is a global phenomenon, too.[33]

Due to considerable pressure on costs for generic drugs, that is, patent-free pharmaceuticals, and basic chemicals, production has been gradually shifted away from Europe in recent decades.[34] Even though diversified production and supply chains with spare capacity proved particularly effective during the pandemic, dependencies were clear to see especially on low-priced products.[35] As an immediate measure, production and supply chains should therefore be diversified where possible, so as to increase supply security and minimise strategic dependencies on a few suppliers. It is true that Chinese manufacturers are virtually unrivalled in price, yet, as indicated below, there are measures to support a diversification of supply chains. Here, for instance, the European Union's market power through joint purchasing is advantageous.

The complete reshore of production or production steps of active ingredients or drugs relevant for supply to Germany or other European countries appears to be an "uncertain, time-consuming and, above all, costly undertaking at this present stage"[36]. It is also unclear how production reshoring to China is to be prevented in the future, if currently innovative pharmaceuticals lose their patent protection.[37] Potential input on this is provided by a feasibility study drawn up by the consultancy Roland Berger on behalf of the generic drugs industry: *Versorgungssicherheit mit Antibiotika: Wege zur Produktion von Antibiotikawirkstoffen in Deutschland beziehungsweise der EU* [Supply Security with Antibiotics: Ways to Produce Antibiotic Active Ingredients in Germany and the EU].[38] Using the example of cephalosporins (a group of broad-spectrum antibiotics often used in clinical practice), it examines three models on how active pharmaceutical ingredient production could be intensified in Europe again. However, all three scenarios, which assume a reshoring of antibiotic agent production at various production levels, would not be economically viable. The reasons for this are clear: higher personnel and investment costs in Germany and Europe alongside generally higher standards.

The authors' draft solutions refer to government support programmes. At first with i) state interventions in the price, ii) via subsidies (production cost subsidy and investment grants to reduce the depreciation amount), for the purpose of keeping local production competitive, and iii) through funding manufacturers that provide extra capacities for production.[39] Subsidies to support innovations and for establishing a European API supply chain could be necessary: However, as is so often the case with subsidies, they must not be spread too thinly, but rather only in relevant or critical areas such as for APIs. Excessively generous subsidies in production processes (or example via a subsidy on manufacturing costs to reduce fixed and/or variable costs or personnel and energy costs), hamper innovation.[40]

Another instrument are so-called differential cost contracts by the state: a European agency (joint public procurement) such as HERA, for instance, tenders out the supply of several tonnes of antibiotics or antibiotic APIs with non-Chinese suppliers and reimburses the difference between the higher production price and the global market price at Chinese level. The tender would enable the EU to select the world's best supplier, the global market would continue to function – but simply circumventing China.[41] This instrument could be swiftly applied, especially in the purchase of APIs in partner countries. Remuneration via an extra lot in the rebate contracts with regard to location consideration, takes account of this logic, too. Having said that, this approach would not conform with the WTO; albeit there would be no formal grounds to counter this owing to the non-functional mechanism for settling disputes.

A strategic reserve of medical equipment and medication has also been developed in the framework of the joint rescEU reserve on stockpiling and distribution among the EU Member States.[42] In addition to a joint public tender, commitments to purchase from a specific production company can also be taken into account for the cited product categories – a rather risk-free undertaking.

According to a survey conducted by the IQVIA, 52 major pharmaceutical companies, or 71 per cent, would be prepared to invest in the European API supply chain if "economic barriers" (price, existing manufacturing capacities) could be overcome. European suppliers particularly stand out by virtue of their reliability and conformity.[43] In the US, a lot of money has already been invested so as to reshore the production of basic chemicals to their own country, to name one example. And within Europe, too, we can observe tendencies to reduce the dependency on Chinese pharmaceuticals. In Austria, there is already specific government support for antibiotics production.[44]

The settlement of research and production sites in Europe therefore largely depends on reliable industrial policy and regulatory framework conditions, which will be addressed in the “Strengthening Competitiveness” chapter. In order to promote this, a positive incentive policy is needed as opposed to companies being coerced to relocate. Politicians are thus responsible for this issue.

It should, however, be noted that until Europe can be strengthened as a pharmaceutical location, there needs to be short- and medium-term bridging measures (for example active diversification of supply chains, development of a pharmaceutical rescEU reserve and stockpiling of raw materials and active pharmaceutical ingredients). Be that as it may, the financial burdens on statutory and private health insurance providers are likely to increase because of higher drug prices in Germany and the EU resulting from considerations on the diversification of supply chains, for instance, through extra payments for a European API supply chain, or a partial reshore of production sites. Here, in Germany, this would lead to health funds requiring further state subsidies in order to stabilise the additional contribution to health insurance to some extent. In the light of multiple crises, high inflation and cash-strapped public coffers, convincing patients and citizens about a further increase in health insurance contributions or additional payments for pharmaceuticals is unlikely to be easy.

3. Strengthening Competitiveness

Research and Development

The strengths of Europe as a pharmaceutical location do not lie in active pharmaceutical ingredients and mass-produced pharmaceutical products, but instead in high-quality products based on intensive research and development. To ensure that Europe remains at the forefront in global pharmaceutical competition over the long-term, research and development need to be promoted for new and high-quality pharmaceuticals.

Besides the automotive industry, the pharmaceutical industry constitutes one of the most innovative sectors in Europe. In 2020, there were 122,000 jobs in R&D in the pharmaceutical industry, and 39.7 billion Euro were invested in research and development.[45]

In the European Union, that is, without the strong pharmaceutical profile of European countries such as Switzerland and the UK, 22.1 billion Euro were invested in the development of new drugs in 2019. This is more than Japan, China, and India combined,[46] and bears testimony to the innovative strength of the European pharmaceutical industry. There is little room for complacency, though. The difference between the EU and the United States, as the strongest pharmaceutical location worldwide, is enormous: In 2019, 58.0 billion Euro were invested in developing new drugs in the US, which is more than twice as much as investments in the EU.[47] What is more, the transfer of research and development in favour of the United States continues. The shortfall in the European Union is growing.

Another aspect warns against neglecting R&D efforts in the EU: there is a rapid increase in pharmaceutical research in China and other emerging countries; the gap with the EU and the US is narrowing. In the period between 2017 and 2020, R&D expenditure for pharmaceuticals in China grew on average by 12.9 per cent each year; whereas it was only by 8.5 per cent in the US and as low as by 4 per cent in Europe.[48] Of the 95 substances newly introduced onto the global drug market in 2021, 35 come from the US, 19 from Europe and as much as 18 from China. This means China will not only continue to be an important supplier of basic pharmaceutical products and low-cost drugs in the future, but also a serious competitor in the pharmaceutical high-tech segment with a growing R&D capability and effective translation into new products.[49]

Pharmaceutical research and development in Europe benefits from good research infrastructure and a high-performance science and university system that releases excellently trained scientists onto the labour market, and is available as a cooperation partner for research companies. With regard to the pharmaceutical industry, there is a division of labour between publicly funded research at universities and non-university research institutions and companies. Publicly funded institutes mainly carry out basic research, for example identifying basic substances, whose

pharmaceutical effect could be useful. The pharmaceutical industry often addresses these results from basic research, further develops them and, in positive cases, enables them to be incorporated into clinical research. New regulations[50] with the introduction of the Clinical Trials Information System (CTIS)[51] are improving the clinical testing of new drugs.[52]

Research cooperation and the division of responsibility between industry and publicly funded institutions are designed in a flexible way. It is linked particularly closely with regard to biotechnology and genetic engineering, which are becoming increasingly important for the production of new pharmaceuticals (biopharmaceuticals); here, basic research and application-oriented research are virtually one and indivisible. This is indicated by a flourishing biotechnology start-up scene, particularly in the US, but also in many European countries, which is primarily fed through outsourcing of publicly funded research institutions.

Owing to basic research at universities and non-university research institutions that is relevant for pharmaceuticals, the public sector is closely involved in pharmaceutical innovation. Moreover, thanks to research funding programmes, it can directly support the research-based pharmaceutical industry. And finally, by removing bureaucratic over-regulation,[53] such as with the approval of new production sites or the testing and approval of new drugs, by introducing research-friendly framework conditions, and swiftly approving new drugs, it has a direct impact on Europe's innovative power as a pharmaceutical location.[54]

In the framework programme for research and innovation, "Horizon 2020", 2347 research projects are listed in the field of pharmacology and pharmacy, which have been carried out over the last few years.[55] The new funding programme, "Horizon Europe", also provides intensive support to health-related research. A total of 8.2 billion Euro have been earmarked for this.[56]

The urgent need for research into diagnostics, vaccines, antibiotics, and pharmaceuticals is emphasised.[57]

The Pharmaceutical Strategy for Europe also focuses on promoting research and development of "high-quality, safe, effective, and more environmentally friendly medicines"[58]. Many other funding programmes, such as on cancer[59] or Corona research[60] or the European Health Data Space (EHDS),[61] make the research location of Europe interesting for the pharmaceutical industry. The European Medicines Agency (EMA)[62] undertakes key tasks at the interface between R&D and economic use. Further harmonising the approval of new pharmaceuticals, for instance with orphan drugs, would make Europe even more attractive as a pharmaceutical location. In view of future pandemic situations, the European Health Emergency Preparedness and Response Authority (HERA) is also developing research activities that benefit the pharmaceutical location.[63]

In sum, it is clear that the pharmaceutical industry in Europe has great potential for innovation. With strong research and development, it can assert itself on the global stage in the knowledge-intensive and high-cost pharmaceutical sector. The main competitors are pharmaceutical companies in the US and increasingly in China. In order to maintain the competitiveness of Europe as a pharmaceutical location, the following tasks arise concerning R&D: 1. Faster procedures and less bureaucracy for research projects, particularly in the clinical phase, and for the Europe-wide approval of new pharmaceuticals. 2. Further tax relief for research and development. 3. Expansion of the science and higher education system, especially in the specialist fields of life sciences, health sciences, and most notably biotechnology and genetic engineering, as well as the promotion of cooperation between state funded-research and research companies. 4. Close integration of the R&D-strong pharmaceutical locations Switzerland and the United Kingdom into the European Union's research network.

IPCEI Health

Important Projects of Common European Interest (IPCEI) describe transnational cooperation for which an exception in EU state aid law applies. The foundation for this is Article 107 (3b) of the Treaty on the Functioning of the European Union (TFEU).[64] Former IPCEI initiatives encompass hydrogen, battery cells, chips, and the Cloud.[65] On 3 March 2022, under the French Council Presidency, 16 Member States[66] announced the creation of an IPCEI Health.[67] Only at the end of the year did Germany decide in favour of a – minor – contribution despite the initiative having been largely taken by the Federal Chancellor Angela Merkel and the French President Emmanuel Macron at the third Franco-German Technology Dialogue in May 2021.[68] France is likely to participate with a budget of 1.5 billion Euro, whereas Germany will probably contribute only 185 million Euro.[69] The IPCEI Health aims to fund important projects in the biotechnology and pharmaceutical industry through state grants, loans, and guarantees. The pharmaceutical industry also expressly supported German's participation in the IPCEI.[70] According to the manifesto[71] of the 16 founding states dated March 2022, IPCEI Health pursues the following three goals:

(1) To make an important contribution to the European Health Union and the New Industrial Strategy for Europe.

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

(3) To develop new products and services with a high share of research and innovation.

Joint projects of IPCEI Health may include innovative and sustainable production processes, innovation for the treatment of antibiotics resistance, and rare diseases alongside the development of gene and cell therapies.[72]

Since state aid represents a significant intervention in the European internal market, funding needs to be rigorously justified. According to up-to-date criteria of the Commission,[73] IPCEI must contribute toward common European objectives, such as the Green Deal or the Digital Strategy (Clause 4). A distinction is made between three types of projects: i) Projects in the field of research, development, and innovation (Clause 22); ii) projects with an initial industrial use (Clause 23); iii) and infrastructure projects (Clause 25). To receive funding, companies and research institutes must raise a "considerable co-financing amount" (Clause 19) and prove that the project has a financial shortfall (Clause 33).

In its current draft, IPCEI Health addresses this financial shortfall for research and development and the associated innovations. This makes it possible to internalise positive externalities through innovation, including for healthcare. The requirement for high levels of innovation is a recurrent theme in the official criteria catalogue for IPCEI. For instance, research and development projects need to be "highly innovative" (Clause 22) and projects on industrial use must not entail the optimisation of pre-existing products (Clause 24). It is therefore important to ensure during implementation that these criteria are adhered to and that IPCEI Health brings about "positive spill-over effects on the internal market" (Clause 2). Subsidisation of existing industries without an innovative character, on the other hand, would be inefficient and would curtail Europe's competitiveness over the medium-term. As a result, IPCEI Health would no longer be an instrument for closing a financial shortfall for innovation, but merely a state subsidy for selected industries. The integration of small- and medium-sized enterprises (SMEs) must also be further improved compared to the 2014 criteria,[74] despite the Commission's updated criteria. Larger companies can more easily manage the IPCEI application process as they regard personnel and funding. The innovative added-value of IPCEI Health thus largely depends on its specific implementation.

The European Health Data Space

Europe as a pharmaceutical and innovation location is also to be enhanced with the planned European Health Data Space (EHDS) within the framework of the European Health Union. The European Health Union, initiated by Commission President Ursula von der Leyen in September 2020, aims to address deficits resulting from experiences of the Corona pandemic and "improve protection, prevention, preparedness, and response to human health hazards at EU level"[75]. The European Health Data Space can play an important role here, as recently confirmed by representatives at the Konrad-Adenauer-Stiftung's EU Data Summit.[76]

Access to research data (secondary healthcare data) for the industrial healthcare industry in Germany and Europe is currently poor, even though research data for the study of tumorous diseases, rare diseases, personalised healthcare, clinical trials, new drug therapies, and generally for R&D reveals enormous potential.[77] Here in Germany, this is due to research companies' ineligibility to apply to the research data centre established for this purpose on the one hand, and to a still inadequate digitalisation of the public healthcare system (ePA, ePrescription), on the other.[78] With the planned Health Data Utilisation Act in Germany, the pharmaceutical industry will now receive comprehensive access to health data; while the European Health Data Space also provides for this. From a German perspective, this will at least lay the foundation for a connection to the EHDS. What is doubtful, though, is whether the EHDS will become operational from 2025 as planned by the EU Commission. It is more likely to be a learning system that is gradually improved.

The healthcare systems of the Member States already generate, process, and store a large volume of data. Yet, access to health data (digital patient record, e-medication plan) is still not guaranteed for many EU citizens. Even for research in the second step, after health-related data has been anonymised or pseudonymised, it is difficult to harness 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."[80]

According to the Commission, the new legal framework would enable stakeholders such as researchers, decision-makers, and member states to access electronic health data so as to promote better diagnosis, treatment, and patient well-being, as well as attaining an optimised and well-defined policy. What is more, the EHDS aims to drive the harmonisation of provisions on an internal market for digital health products and services, thus increasing the efficiency of healthcare systems. In this context, there is much talk about the often called for European digital sovereignty, which entails consulting anonymised and pseudonymised data of EU citizens to develop new innovative approaches in the pharmaceutical sector. This, in turn, means that data or AI-based solutions from China or the US could be renounced.

A positive example of this are interactions with the European Plan to Combat Cancer, in particular, or support for efforts of the EU-wide "Beyond 1 Million Genomes" project.[81] The development and expansion of data registers (tumour register, spine register, prostate cancer) is promoted, too.[82] Data usage could, for example, improve understanding as well as early detection, diagnosis, treatment, and monitoring of cancer by enabling health service providers in the EU to access and share health data across borders. The more high-quality data can be used, the greater the benefit for research and development as well as diagnosis.[83] This would appear logical since data from as many patients as possible, such as for a therapy or for tolerability of drugs in trials, provide a more comprehensive view of the advantages and disadvantages.

The establishment of the EHDS is vital for strengthening Europe as a pharmaceutical location. As already mentioned, although the active ingredients

and research for innovative biopharmaceuticals, such as for cancer treatments, are still being primarily produced in Europe and North America, this sector is also undergoing developments in China.[84] To this end, the European Chamber of Commerce in China writes: "China finds itself at a critical juncture, as the country is currently transforming from a generic drugs manufacturer to a supplier of primary drugs."[85] Strengthening the industrial healthcare sector and Europe's competitiveness as a scientific and research location, thus largely depends on access to research data as part of the EHDS.

For this reason, it is necessary to establish quality-assured databases, such as for patient data including genomic data. This requires adequate funding and standardisation, as well as statutory regulations for data protection compliant access which is research- and application-friendly at the same time.

4. Summary

The pharmaceutical industry in Europe represents both an economically important sector and a component of public service provision. That is why both competitiveness and resilience must be taken into account if Europe is to be strengthened as a pharmaceutical location. For both goals, independent strategies should be taken as regards to their approach and selection of instruments. A sweeping reshore of pharmaceutical production would give rise to high costs for the healthcare system and undermine competitiveness, however. The strength of the European pharmaceutical industry does not therefore lie in active pharmaceutical ingredients and mass products, but rather in high-quality R&D-intensive products.

To strengthen resilience, precise interventions should be made in products for which there are critical dependencies. A dependency on China is to be viewed critically for active pharmaceutical ingredients (APIs) in the field of antibiotics, in particular. However, prior to considering a reshore, other measures should be taken such as a diversification of supply chains alongside the maintenance of strategic emergency capacities and emergency production capacities.

In order to strengthen competitiveness, a supportive regulatory framework should be created and expanded in place of subsidies. This includes an excellent education system for skilled workers, a flourishing research and development landscape, an implementation of the European IPCEI Health in a way that promotes innovation, as well as the establishment of a European Health Data Space. This business- and innovation-friendly climate would strengthen Europe as a pharmaceutical location for future investment decisions, too.

1 The data refers to the EU-27, Norway, Switzerland, the United Kingdom, Serbia, Turkey, and Russia.
2 European Federation of Pharmaceutical Industries and Associations (EFPIA) (2022): The Pharmaceutical Industry in Figures – Key Data 2022. https://www.efpia.eu/media/637143/the-pharmaceutical-industry-in-figures-2022.pdf (last accessed on 13/02/2023).
3 Ibid.
4 It should also be noted that, for pharmaceuticals in Germany, a distinction is made between delivery and supply bottlenecks. More information on this: Veröffentlichte Lieferengpassmeldungen. In: *Pharmanet.bund.de* (without date). https://anwendungen.pharmnet-bund.de/lieferengpassmeldungen/faces/public/meldungen.xhtml;jsessionid=5F339EC8F3F6AFC99D990EDB741BD0BD?jfwid=5F339EC8F3F6AFC99D990EDB741BD0BD%3A0.
5 Personal Protective Equipment (PPE).
6 Ellis-Petersen, Hannah (2020): India limits medicine exports after supplies hit by coronavirus. In: *Theguardian.com* dated 04/03/2020. https://www.theguardian.com/world/2020/mar/04/india-limits-medicine-exports-coronavirus-paracetamol-antibiotics (last accessed on 13/02/2023).
7 Bethkenhagen, Dana (2022b): Lehren aus dem Stresstest Pandemie. In: *Tagesspiegel.de* dated 16/05/2022, updated on 19/01/2023. https://background.tagesspiegel.de/gesundheit/lehren-aus-dem-stresstest-pandemie (last accessed on 13/02/2023).
8 European Commission (2021a): Introducing HERA, the European Health Emergency Preparedness Response Authority, the next step towards completing the European Health Union, 16/09/2021. https://health.ec.europa.eu/system/files/2021-09/hera_2021_comm_en_0.pdf (last accessed on 13/02/2023) and European Commission (2021): EU-Behörde für die Krisenvorsorge und -reaktion bei gesundheitlichen Notlagen (HERA): Vorkehrungen für künftige Notlagen im Gesundheitsbereich (EU Health Emergency Preparedness and Response (HERA): precautions for future emergencies in the healthcare sector) (press release 16/09/2021). https://ec.europa.eu/commission/presscorner/detail/de/ip_21_4672 (last accessed on 13/02/2023).
9 European Parliament (2020): Report on the shortage of medicine – how to address an emerging problem. https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.pdf (last accessed on 13/02/2023).
10 Europäische Gesundheitsunion (2022): Schutz der Gesundheit der Europäer/innen und gemeinsame Reaktion auf grenzüberschreitende Gesundheitskrisen. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_de (last accessed on 13/02/2023).
11 Haarhoff, Heike (2022): Unkluge Abhängigkeiten. In: *Tagesspiegel.de* dated 20/04/2022. https://background.tagesspiegel.de/gesundheit/unkluge-abhaengigkeiten (last accessed on 13/02/2023).
12 Haarhoff, Heike (2023): Schlechte Prognose. In: *Tagesspiegel.de* dated 10/01/2023. https://background.tagesspiegel.de/gesundheit/schlechte-prognosen (last accessed on 13/02/2023).
13 European Commission (2022): Vulnerabilities of the global supply chains in medicine. Structured Dialogue on the security of medicines supply. https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_swd_en.pdf (last accessed on 13/02/2023).
14 Swedish Presidency of the Council of the European Union (2023). https://swedish-presidency.consilium.europa.eu/media/lltm2xh3/the-swedish-presidency-programme.pdf (last accessed on 13/02/2023).
15 Europäische Union will Medikamentenmangel bekämpfen (2023). In: Spiegel.de dated 17/01/2023 https://www.spiegel.de/wirtschaft/medikamenten-mangel-europaeische-union-will-regeln-verschaerfen-a-77d7a3cf-79cf-458a-adce-f71dbfe2eae5 (last accessed on 13/02/2023).
16 Haarhoff, Heike (2022): Gute Eckpunkte, schlechte Eckpunkte. In: *Tagesspiegel.de* dated 21/12/2022. https://background.tagesspiegel.de/gesundheit/gute-eckpunkte-schlechte-eckpunkte#:~:text=Knappe%20Fiebers%C3%A4fte%20f%C3%BCr%20Kinder%2C%20fehlende,Versorgung%20mit%20Arzneimitteln%20verbessern%20will (last accessed on 13/02/2023).
17 Ein „Geschenk für Pharmaunternehmen"? In: *Tagesschau.de* dated 20/12/2022. https://www.tagesschau.de/inland/lauterbach-kindermedikamente-preise-103.html (last accessed on 13/02/2023).
18 Bethkenhagen, Dana (2022a): Unabhängigkeit hat ihren Preis. In: *Tagesspiegel.de* dated 24/11/2022. https://background.tagesspiegel.de/gesundheit/unabhaengigkeit-hat-ihren-preis (last accessed on 13/02/2023).
19 The draft bill that has now been submitted specifies the key points initially presented. This envisages an "obligation to stockpile over several months" for discounted pharmaceuticals, to name one example. Further proposals include: "increased stockpiling obligations" for hospital pharmacies. The following passage can be found on the rebate contracts "when concluding rebate contracts, account should be taken of the highest possible percentage of active ingredient production in the European Union or a contracting state to the European Economic Community" (at least half of the specialist lots shall be awarded). Measures on supply chain diversification indicated in the draft only apply to oncological drugs and antibiotics, however.
20 Bethkenhagen, Dana (2023): Begeht Lauterbach einen Wiederholungsfehler? In: *Tagesspiegel.de* dated 16/01/2023. https://background.tagesspiegel.de/gesundheit/begeht-lauterbach-einen-wiederholungsfehler (last accessed on 13/02/2023).
21 Federal Ministry of Health (2023): Draft law to combat supply bottlenecks for patent-free drugs and to improve the supply of paediatric pharmaceuticals. 14 February 2023. https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/A/ALBVVG_RefE_bf.pdf (last accessed on 21/02/2023).
22 European Parliament (2020): Report on the shortage of medicines: how to address an emerging problem (2020/2071(INI)). https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.pdf (last accessed on 20/02/2023).
23 Martuscelli, Carlo (2021). Made-in-China pills come with unwanted side effects for the EU. In: Politico.eu dated 15/04/2021. https://www.politico.eu/article/europe-china-medicines-drug-imports-health/ (last accessed on 13/02/2023).
24 Indian pharmaceuticals – a formula for success (without date). In: Invest India. https://www.investindia.gov.in/sector/pharmaceuticals (last accessed on 13/02/2023).

25 Horner, Rory (2020): The world needs pharmaceuticals from China and India to beat coronavirus. In: *Theconversation.com* dated 25/05/2020. https://theconversation.com/the-world-needs-pharmaceuticals-from-china-and-india-to-beat-coronavirus-138388 and https://www.euractiv.com/section/health-consumers/news/europes-dependence-on-medicine-imports/ (last accessed on 13/02/2023).

26 Pharmabranche warnt vor Abhängigkeit von Fernost – EU will mit neuer Arzneistrategie reagieren. In: *Handelsblatt.com* dated 20/05/2022. https://www.handelsblatt.com/unternehmen/industrie/arzneimittel-pharmabranche-warnt-vor-abhaengigkeit-von-fernost-eu-will-mit-neuer-arzneistrategie-reagieren/28363374.html (last accessed on 13/02/2023).

27 Sicking, Marzena (2022): China dominiert den Markt für Antibiotika. In: *Arzt-wirtschaft.de* dated 05/07/2022. https://www.arzt-wirtschaft.de/vermischtes/china-dominiert-den-markt-fuer-antibiotika/ und Schulz, Florence (2022): Europe's dependence on medicine imports. In: *Euractiv.com* dated 16/03/2020. https://www.euractiv.com/section/health-consumers/news/europes-dependence-on-medicine-imports/ (both last accessed on 13/02/2023).

28 European Centre for International Political Economy (2020): Key Trade Date Points on the EU27 Pharmaceutical Supply Chain. https://www.efpia.eu/media/554792/key-trade-data-points-on-the-eu27-pharmaceutical-supply-chain.pdf (last accessed on 13/02/2023).

29 Bayerlein, Michael (2022): Offene strategische Autonomie der EU im Bereich Arzneimittel. In: *SWP-Aktuell/A 75*. https://www.swp-berlin.org/publikation/offene-strategische-autonomie-der-eu-im-bereich-arzneimittel (last accessed on 13/02/2023).

30 Ibid.

31 Pharmaunternehmen weniger abhängig von China als gedacht. In: *Iwd.de* dated 09/03/2022. https://www.iwd.de/artikel/pharmaunternehmen-weniger-abhaengig-von-china-als-gedacht-537069/ (last accessed on 13/02/2023).

32 Pro Generika (2018): Generika in Zahlen. http://www.progenerika.de/app/uploads/2020/09/Generika-in-Zahlen_2018.pdf (last accessed on 21/02/2023).

33 Beusekom, Mary Van (2023): Experts detail progress made, next steps to fortify US drug supply chain. In: *Cidrap* dated 02/02/2023. https://www.cidrap.umn.edu/resilient-drug-supply (last accessed on 13/02/2023) and Martuscelli, Carlo (2021).

34 European Commission (2022): Vulnerabilities of the global supply chains of medicines. https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_swd_en.pdf (last accessed on 13/02/2023).

35 Bathmann, Thorsten (2022): Resilienz pharmazeutischer Lieferketten. Study for the Verband Forschender Arzneimittelhersteller e. V. (vfa). Institut der deutschen Wirtschaft e. V. https://www.vfa.de/download/studie-resilienz-pharmazeutischer-lieferketten.pdf (last accessed on 13/02/2023) und Michaela Hempel (2021): Strategie für die industrielle Gesundheitswirtschaft: Anker in Krisenzeiten und Wachstumstreiber der Zukunft. In: Bundesverband der Deutschen Industrie. https://bdi.eu/publikation/news/strategie-fuer-die-industrielle-gesundheitswirtschaft/ (last accessed on 20/02/2023)

36 Pharmaunternehmen weniger abhängig von China als gedacht (2022). https://www.iwd.de/artikel/pharmaunternehmen-weniger-abhaengig-von-china-als-gedacht-537069/ (last accessed on 13/02/2023).

37 Ibid.

38 Studie zur Versorgungssicherheit mit Antibiotika: Wege zur Produktion von Antibiotikawirkstoffen in Deutschland bzw. der EU. Roland Berger, 2018. https://progenerika.de/app/uploads/2020/09/20181115_ProGenerika_Antibiotika studie2018_final-2.pdf (last accessed on 13/02/2023).

39 Richter-Kuhlmann, Eva (2018): Antibiotika: Riskante Abhängigkeit vom Ausland. In: *Deutsches Ärzteblatt 2018/115(49)*. https://www.aerzteblatt.de/archiv/203739/Antibiotika-Riskante-Abhaengigkeit-vom-Ausland (last accessed on 13/02/2023).

40 Cernicky, Jan (2022): Energiewende und Protektionismus: Wie gehen wir pragmatisch mit China um. In: Konrad-Adenauer-Stiftung e. V., Analysen & Argumente, No. 491. https://www.kas.de/documents/252038/16166715/Energiewende+und+Protektionismus+%E2%80%93+Wie+gehen+wir+pragmatisch+mit+China+um.pdf/442ba770-d504-43cc-25f1-eaf7d970dfc1?version=1.3&t=1665588334715 (last accessed on 13/02/2023).

41 Ibid.

42 COVID-19: Kommission beschließt erstmals Einrichtung eines Vorrats an medizinischen Ausrüstungen im Rahmen von rescEU (Commission decides for the first time to establish a stockpile of medical equipment within the framework of rescEU), press release dated 19/03/2020. https://ec.europa.eu/commission/presscorner/detail/de/ip_20_476 and Martuscelli, Carlo/Collis, Helen (2021): EU efforts to ‚reshore' drug production trip over subsidy rules. https://www.politico.eu/article/pharma-industry-drug-production-eu-subsidy-european-commission/ (both last accessed on 13/02/2023).

43 Badwy, Ammar (2021). How dependent is the European pharma supply chain on China? In: *Pharmaoffer.com*. https://pharmaoffer.com/blog/european-api-dependency/ and Martuscelli, Carlo/Collis, Helen (2021): EU efforts to ‚reshore' drug production trip over subsidy rules. https://www.politico.eu/article/pharma-industry-drug-production-eu-subsidy-european-commission/ (last accessed on 13/02/2023).

44 Bethkenhagen, Dana (2022a): Unabhängigkeit hat ihren Preis. https://background.tagesspiegel.de/gesundheit/unabhaengigkeit-hat-ihren-preis (last accessed on 13/02/2023).

45 European Federation of Pharmaceutical Industries and Associations (EFPIA) (2022): The Pharmaceutical Industry in Figures – Key Data 2022, https://www.efpia.eu/media/637143/the-pharmaceutical-industry-in-figures-2022.pdf (last accessed on 13/02/2023).

46 Europa ist gut? In: *vfa* (without date). https://www.vfa.de/de/wirtschaft-politik/darum-europa/europa-ist-gut (last accessed on 13/02/2023).

47 Ibid.

48 Pharmazeutische Forschung und Entwicklung in Europa oder anderswo? In: *Pharmafakten.de* dated 10/08/2022. https://pharma-fakten.de/grafiken/pharmazeutische-forschung-und-entwicklung-in-europa-oder-anderswo/ (last accessed on 13/02/2023).

49 Ibid.

50 (EU) Regulation No. 536/2014 of the European Parliament and Council dated 16 April 2014 on Clinical Trials with Human Medicines and repealing Directive 2001/20/EC https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32014R0536&from=EN (last accessed on 13/02/2023).

51 Cinical Trials Information System. In: *European Medicines Agency* dated 31/01/2022. https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system (last accessed on 13/02/2023).

52 New regulations such as the introduction of the Clinical Trials Information System (CTIS) aim to improve the clinical trial of new drugs, even though there were still great difficulties in submitting applications and uploading data at the start of the mandatory system (31/01/2023).

53 Cf. for biopharmaceuticals: Gabrielczyk, Thomas (2021): Biotechbranche in Deutschland. Potenzialanalyse und Handlungsempfehlungen. Konrad-Adenauer-Stiftung e. V., Analysen & Argumente, No. 466. https://www.kas.de/documents/252038/11055681/Biotechbranche+in+Deutschland.pdf/c61a0a29-3f60-23ef-5133-3f5e82263abe?version=1.0&t=1639054425654 (last accessed on 13/02/2023), pp. 6-7.

54 Research Services of the German Bundestag (2008). Independent Pharmaceuticals Research https://www.bundestag.de/resource/blob/417788/7b2e38f8064b0bcf354cfde8569ced80/WD-8-046-08-pdf-data.pdf (last accessed on 13/02/2023), p. 4.

55 Cordis EU research results, https://cordis.europa.eu/search?q=%2Fproject%2Frelations%2Fcategories%2FeuroSciVoc%2Fcode%3D%27%2F21%2F35%2F159%27&p=1&num=10&srt=/project/contentUpdateDate:decreasing (last accessed on 13/02/2023).

56 European Commission (2021b): Horizon Europe – the most ambitious EU research & innovation programme ever. https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/3c6ffd74-8ac3-11eb-b85c-01aa75ed71a1 (last accessed on 13/02/2023).

57 Ibid, p. 35.

58 European Commission (2020): A Pharmaceutical Strategy for Europe. https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_de (last accessed on 13/02/2023).

59 EU Mission: Cancer (subject overview): https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en (last accessed on 13/02/2023).

60 European Commission (without date): Coronavirus research innovation https://research-and-innovation.ec.europa.eu/research-area/health/coronavirus_en, First „ERAvsCorona" Action Plan. Short-termed coordinated Research & innovation actions (2020). https://research-and-innovation.ec.europa.eu/system/files/2020-04/ec_rtd_era-vs-corona.pdf (last accessed on 13/02/2023).

61 European Commission (2022): Questions and answers – EU Health: European Health Data Space (EHDS). https://ec.europa.eu/commission/presscorner/detail/en/ qanda_22_2712 (last accessed on 13/02/2023).

62 European Medicines Agency (without date.). https://www.ema.europa.eu/en (last accessed on 13/02/2023).

63 European Commission (2021a): Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union, COM(2021) 576 https://health.ec.europa.eu/system/files/2021-09/hera_2021_comm_en_0.pdf (last accessed on 20/02/2023).

64 Treaty on the Functioning of the European Union (2021). https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:de:PDF (last accessed on 13/02/2023).

65 Olk, Julian (2022): Warum Deutschland beim großangelegten EU-Projekt für Gesundheit nicht mitmacht. In: *Handelsblatt.com* dated 03/05/2022 https://www.handelsblatt.com/technik/thespark/industriepolitik-warum-deutschland-beim-grossangelegten-eu-projekt-fuer-gesundheit-nicht-mitmacht/28297276.html (last accessed on 13/02/2023).

66 The 16 Member States are Austria, Belgium, Denmark, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Romania, Slovenia, Spain.

67 Results of French Presidency of the Council of the European Union (2022). https://presidence-francaise.consilium.europa.eu/en/news/press-conference-launch-of-an-ipcei-on-health-announced-during-the-ministerial-conference-towards-an-independent-competitive-and-innovative-european-healthcare-sector/ (last accessed on 13/02/2023).

68 3. Deutscher Technologiedialog – Stärkung der Widerstandsfähigkeit der europäischen Medizin- und Pharmaindustrie (Third German Technology Dialogue – strengthening the resilience of the European medicine and pharmaceutical industry) (press release 185, dated 31/05/2022). https://www.bundesregierung.de/breg-de/aktuelles/pressemitteilungen/3-deutsch-franzoesischer-technologiedialog-staerkung- der-widerstandsfaehigkeit-der-europaeischen-medizin-und-pharmaindustrie-1919764# (last accessed on 13/02/2023).

69 Trappe, Thomas (2022): Mehr pandemiebedingte Ausgaben geplant. In: Tagesspiegel.de dated 10/11/2022. https://background.tagesspiegel.de/gesundheit/mehr-pandemiebedingte-ausgaben-geplant (last accessed on 13/02/2023).

70 Ibid.

71 Manifest towards a health IPCEI (2022). https://www.entreprises.gouv.fr/files/files/secteurs-d-activite/industrie/industries-de-sante/manifesto_towards_a_health_ipcei.pdf (last accessed on 13/02/2023).

72 Ibid.

73 European Union (2021): Criteria for appraising the compatibility of state aid to promote important projects of joint European interest with the internal market. https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52021XC1230(02)&from=EN (last accessed on 13/02/2023).

74 European Commission (2014): Communication of the bodies, institutions and other agencies of the European Union. https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52014XC0620(01)&from=EN (last accessed on 13/02/2023).

75 European Commission (without date): European Health Union Protecting the health of Europeans and joint reaction to cross-border health crises. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_de (last accessed on 13/02/2023).

76 European Data Summit (2022): Sustainable Competition, Day 3. In: *YouTube* dated 02/12/2022. https://www.youtube.com/watch?v=D66dDropRuE (from minute 1:20:27 – key note: The EHDS Proposal)

77 European Medicine Agency (2020): The General Data Protection Regulation. Secondary Use for Medicines and Public Health Purposes. https://www.encepp.eu/events/documents/Discussionpaper.pdf and Open Data Institute (2021): Secondary use of health data in Europe. https://theodi2022.wpengine.com/wp-content/uploads/2021/09/Secondary-use-of-Health-Data-In-Europe-ODI-Roche-Report-2021-5.pdf as well as Horgan, Dennis et al. (2022): European Health Data Space – An Opportunity Now to Grasp the Future of Data-Drive Healthcare. https://www.mdpi.com/2227-9032/10/9/1629 (last accessed on 13/02/2023 in each case).

78 The research data centre facilitates access to account data of all people with statutory health insurance in Germany.

79 Great divergence is also clear in the digitalisation of health systems between EU Member States – this is also repeatedly stipulated in the legislative proposal on the EU Health Data Space. https://prod.ucwe.capgemini.com/wp-content/uploads/2022/07/eGovernment-Benchmark-2022-1.-Insight-Report.pdf (last accessed on 13/02/2023).

80 European Commission (without date): European Health Union Protecting the health of Europeans and joint reaction to cross-border health crises. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_de (last accessed on 13/02/2023).

81 Beyond 1 Million Genomes (without date): https://b1mg-project.eu/ see also Arnold, Norbert (2019): Gene und Genome. In: *Die politische Meinung*, edition 559 dated 11/12/2021. Konrad-Adenauer-Stiftung e. V. https://www.kas.de/de/ web/die-politische-meinung/artikel/detail/-/content/gene-und-genome-1 as well as Ders. (2019): Medizinische Genomsequenzierung. Bedeutung für Krankenversorgung und Genomforschung. Konrad-Adenauer-Stiftung e V. https://www.kas.de/de/einzeltitel/-/content/genomsequenzierung (last accessed on 13/02/2023 in each case).

82 Michaela Hempel (2021): Strategie für die industrielle Gesundheitswirtschaft: Anker in Krisenzeiten und Wachstumstreiber der Zukunft. In: Bundesverband der Deutschen Industrie.

83 Ibid. und Künstliche Intelligenz als Entwicklungshelfer? In: Tagesschau.de dated 17/01/2023. https://www.tagesschau.de/wissen/forschung/medikamentenentwicklung-101.html

84 Pharmabranche warnt vor Abhängigkeit von Fernost – EU will mit neuer Arzneistrategie reagieren. In: Handelsblatt.com dated 20/05/2022. https://www.handelsblatt.com/unternehmen/industrie/arzneimittel-pharmabranche-warnt-vor-abhaengigkeit-von-fernost-eu-will-mit-neuer-arzneistrategie-reagieren/28363374.html (last accessed on 13/02/2023) – patent-free cancer drugs, generic drugs such as (tamoxifen, nab-paclitaxel) are also experiencing supply shortages.

85 Schulz, Florence (2022): Europe's dependence on medicine imports. In: Euractiv.com dated 16/03/2020. https://www.euractiv.com/section/health-consumers/news/europes-dependence-on-medicine-imports/ und Pharmabranche warnt vor Abhängigkeit von Fernost – EU will mit neuer Arzneistrategie reagieren. In: Handelsblatt.com dated 20/05/2022. https://www.handelsblatt.com/unternehmen/industrie/arzneimittel-pharmabranche-warnt-vor-abhaengigkeit-von-fernost-eu-will-mit-neuer-arzneistrategie-reagieren/28363374.html (last accessed on 13/02/2023 in each case).

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