DGAPanalyse

Nr. 6 / September 2018

A New Strategy for European Health Policy

Anna-Lena Kirch with research assistance from Daniela Braun

DGAP

Contents

A New Strategy for European Health Policy

Anna-Lena Kirch with research assistance from Daniela Braun

3 **Executive Summary**

5 **1. Introduction**

7 **2. Challenges and Demands for European Health Policy**

8 **3. Conflict Lines in EU Health Policy**

9 **4. Legal Framework for European Health Policy**

11 **5. Status Quo of European Health Policy**

13 **6. A New Agenda for European Health Policy**

20 **7. Recommendations for German Health Policy**

23 Notes

A New Strategy for European Health Policy

Anna-Lena Kirch with research assistance from Daniela Braun

Executive Summary

As the EU's largest country and a leading European power, Germany has traditionally considered the cohesion of the EU to be one of its major responsibilities; it has utilized its influence to hold the other member states together in the face of Brexit and the countless other crises the Union has recently weathered. In the area of European health policy, however – which is not only an essential part of the EU's social dimension, but is also being discussed in the context of its security and development positioning – the situation is different: Rather than shaping the discussion about the future direction of European health policy, Germany often seems hesitant to even participate.

German policymakers cite two factors to explain the country's reluctance:

1. The EU's legal competencies in the area of health policy are limited. According to Art. 168 TFEU, the EU is meant to primarily play a coordinating role; the organization of national health systems is still the responsibility of the individual member states.
2. The complex structure of Germany's self-governance in health care, as well as the diverse interests of its national medical associations, health insurers, businesses, and other stakeholders, make it more difficult for the country to engage in a discussion of EU-level health policy or adopt a unified position on European health policy questions.

The EU is not yet making use of existing opportunities for political cooperation, nor is it taking advantage of all of the tools at its disposal. Health policy is a cross-cutting issue, and is shaped indirectly by several other EU policy areas and instruments, among them legislation governing the single market and the European Semester. Further Europeanization is still possible, as is deeper voluntary cooperation between member states.

At the same time, there is a profound need for more German engagement. There are four areas in which the EU needs to establish a strategy for the future:

- Whether and how the EU should address growing inequality in health questions, for example with regard to access to medication;
- How the EU can address the challenges posed by demographic change, rising health costs, and limited resources in the short- and medium-terms;
- How the employment, innovation, and economic growth opportunities created by the health sector and the healthcare economy can be optimally utilized; and
- How the EU can become a more capable and effective actor in global health policy.

The differing positions of the various member states on the role the EU should take in the area of health policy can be simplified to a conflict between large and small member states. Large member states like Germany, the United Kingdom, Poland, Spain, and, with a few caveats, France and Italy, tend to see stronger cooperation and coordination, as well as policy harmonization, less as opportunities to take advantage of economies of scale and more as undesirable, risky intrusions into national structures. They generally already have sufficient human and financial resources, as well as their own assessment and quality management frameworks. In addition, they have to take into consideration complex constellations of interests at both the national and regional levels. At the same time, they already have strong negotiating positions; their national markets are large and attractive enough to not require additional leverage from EU structures and joint approaches.

Among the large member states, however, there are different levels of receptivity to European approaches to health policy. Germany leads the camp of skeptics, which also includes countries like Great Britain and Poland; France, Italy, and Spain, on the other hand, are generally more open to more European cooperation, as well as voluntary collaboration between member states, for example in the field of pharmaceuticals.

For small and medium-sized states, Europeanized structures and deeper cooperation offer the potential for positive scaling effects. This is particularly the case when it comes to accreditation processes, the benefit assessment of medical devices, the availability of expertise and research, early warning mechanisms, personnel allocation, and price negotiations. States like Malta, Belgium,

Ireland, Luxembourg, Slovenia, Estonia, Croatia, Greece, and Portugal are among the particularly pro-European states in this area. Other small states, including the Czech Republic, Bulgaria, and Denmark, are more skeptical of any Europeanization of health policy, and bring concerns regarding national sovereignty to the debate.

There are several variables that influence the positions of the individual member states, for example the organization of existing national health systems (i.e., whether they are more centralized or more federal), their financial structures (whether health systems are state-run or administered by social insurance companies), and the existence or absence of a robust national health care industry. The effects of the recent European financial and economic crises on national economies and employment rates also play a role. The upcoming end of the Juncker Commission's term in 2019 and the ongoing negotiations concerning the next Multiannual Financial Framework trigger further questions, among them how health policy related instruments and projects within the EU should be organized and financed in the future. The future trajectory of the EU Directorate-General for Health and Food Safety (DG SANTE) and the EU Health Action Program – currently a separate budgetary item – is uncertain.

Germany should push for a European health policy that strengthens European cohesion and socioeconomic convergence, supporting countries like Greece and Romania that cannot currently provide a sufficient standard of care. At the same time, potential innovations – such as advances in the areas of e-health and research – should be developed further, with the long-term support of networks and research projects.

Aside from these steps, the EU's ability to combat cross-border health risks should be built up, and it should play a stronger role in global health issues to both compensate for the withdrawal of the United States from health and development policy and compete more credibly against illiberal actors. Germany should proactively develop and communicate its own priorities and improve domestic political coordination to better contribute to a new agenda for European health policy. Existing partnerships, like those with France, Austria, and the Benelux states, should be strengthened. With the Brexit vote Germany has lost its most important partner in EU health questions, rendering it even more essential that it establishes new partnerships within the EU. A systematic strengthening of its exchange and broadening of cooperation formats with the Nordic and Baltic states could be particularly promising; these countries are already close to Germany's position in many areas, and could alleviate the loss of Great Britain both within the single market and in global health questions.

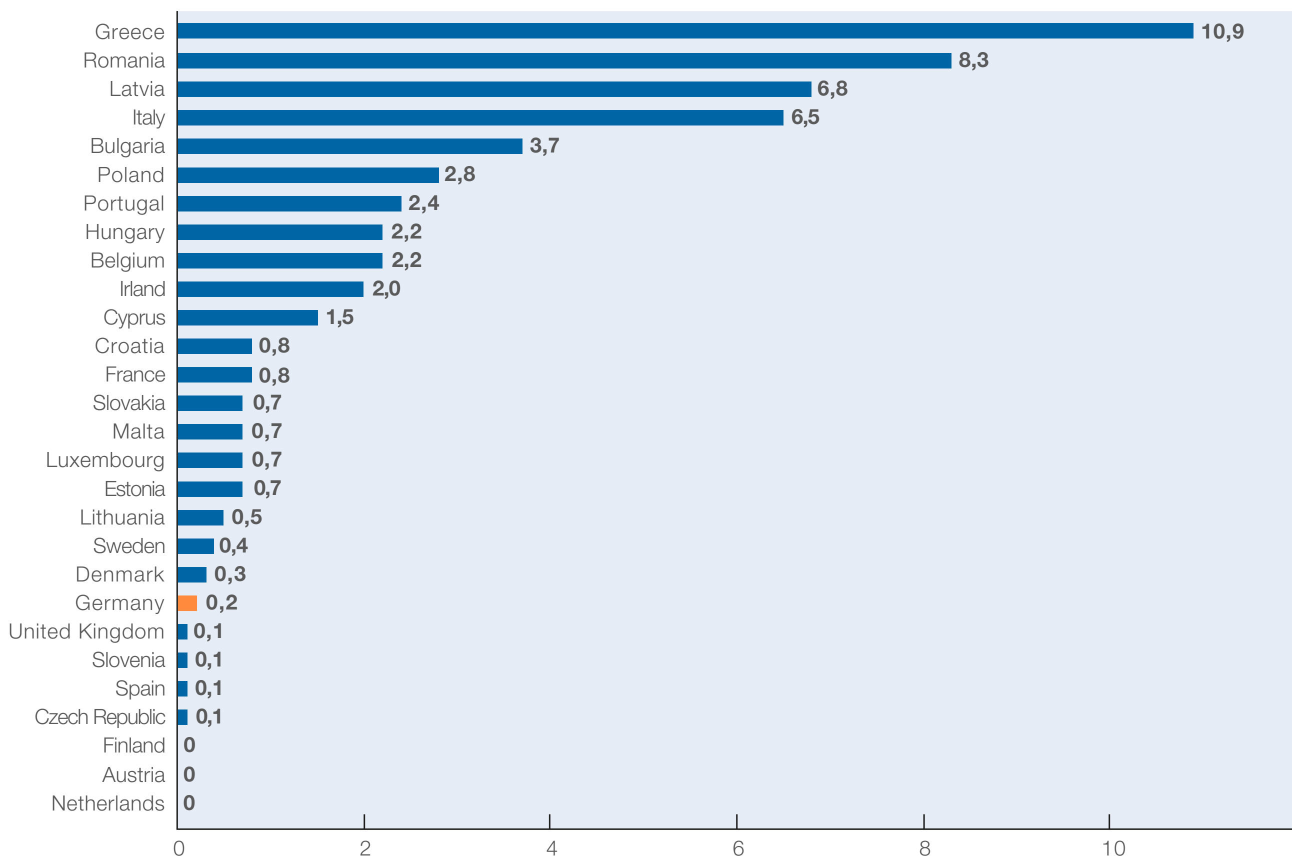
1. Introduction

Both the European Commission and the EU member states are eager to see how German engagement in the debate over the future of the EU will look under its new government. One of the largest structural challenges the EU will soon have to confront is the growing economic and social divergence within the Union. Simply put, this conflict runs between the Northern and Western states on the one hand and the Southern and Southeastern states on the other. In the aftermath of the European financial and sovereign debt crises, which deepened existing inequalities between member states, there are significant divergences along many indicators, from employment to national debt. The North-South/Southeast division is particularly stark in the area of health, especially when it comes to access to high-quality and affordable healthcare – a policy area that can have explosive social and political repercussions (see figure 1).

The September 2016 EU Bratislava summit made Europe's social dimension an explicit priority of the Union's future agenda in recognition of the divisive potential of these internal divergences; this focus was further underpinned by a reflection paper released following the publication of President of the European Commission Jean-Claude Juncker's white paper. At the Gothenburg social summit on November 20, 2017, the European Commission, European Parliament, and Council proclaimed social rights one of the pillars of the European Union, including 20 fundamental principles formulated to strengthen the social dimension of Europe, whose implementation would be supported by a social "scorecard". The right to timely, high-value, and affordable health care and medical treatment was explicitly included.[1]

The current German government's emphasis on European integration was sufficient to claim the title of its coalition agreement ("A New Beginning for Europe"), and it has already delivered initiatives for deeper cooperation in the areas of defense, migration, and the eurozone; nevertheless, it has taken no pro-active steps thus far to shape a European health policy.[2] That makes the German political agenda seem inconsistent: On the one hand, it explicitly claims to encourage European solidarity and cooperation; on the other, it has done nothing to address the area of health policy, or urgent challenges like the

Figure 1: Percent of population whose healthcare needs are not being met for cost reasons (2015)



Source: https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_benchmarking_healthcareaccess_en.pdf, p. 44

inequality of opportunities afforded to European patients in different member states.[3]

From the German point of view, this gap can be explained on the basis of Art. 168, par. 7 TFEU, which does not foresee any EU-level competencies regarding the institutional structure or the financing system of national health systems. In recent years, the German government has expressed the opinion that further Europeanization of this policy area would not be legally permissible. Several German jurists, however, question whether this conclusion is entirely valid, arguing[4] that the law is more nuanced, and that there is in fact leeway for more cooperation even without any change to existing treaties. This is especially true given the cross-cutting nature of health policy and the Union target of doing more to safeguard the protection of human health.

Thus far, Germany has taken a passive stance, preferring a fundamentally limited European health policy, citing the legal barrier imposed by Art. 168 par. 7 TFEU. The smaller member states, on the other hand – including Belgium, Luxembourg, Ireland, Malta, Estonia, Slovenia, and Greece – would welcome a stronger EU role in health policy. The initiatives under discussion include stronger cooperation in the procurement of pharmaceuticals, e-health, benefit assessment exercises, the exchange of expertise and best practices, horizon scanning, and personnel planning. While some of the other larger member states, including France, Spain, and Italy, have expressed an interest in deeper EU-level cooperation in these areas, Germany has not; in the Council Working Party on Public Health, its stance has ranged from reluctant to openly skeptical, even regarding cooperation approaches that would not necessarily require German participation. The logic of Germany's self-governance – which comprises domestic health insurers and physicians and dentists unions – as well as Germany's federal structure contribute significantly to this resistance. Compared to nationalized, centrally organized health systems, the complex structure of Germany's self-governance in the area of health renders political compromises and systemic reforms more difficult, even at the domestic level.

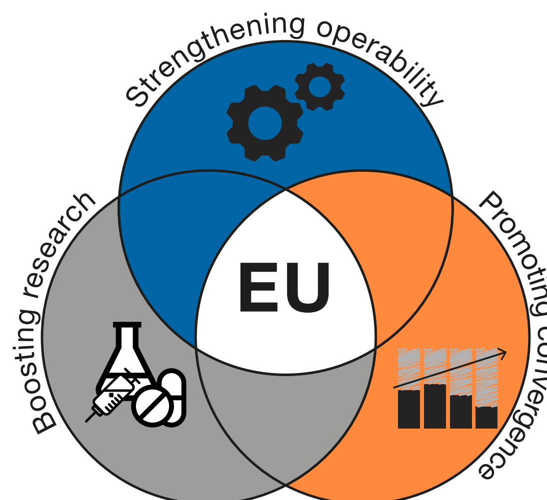
With its passive – even defensive – stance towards European cooperation initiatives suggested by both the European Commission and the smaller member states, Germany invites the accusation that it is standing in the way of further Europeanization, especially compared to the other member states, along with the criticism that it is displaying a lack of solidarity with the smaller member states and those most affected by the financial and debt crises. The list of proactive German initiatives in the area of European health policy is short, and restricted to areas that have not focused on the creation of new legislation – for example the government's engagement in the 2014 Ebola crisis, when Germany provided one of three planes used for the emergency evacuation of international humanitarian assistants and (together with France) deployed epidemic control teams (the EU "white helmet initiative"), which were eventually implemented within the framework of the European Medical Corps.

This passivity is difficult to reconcile with Germany's self-image as an inclusive and reliable European leader, and endangers intra-European cohesion. Moreover, it would be in the country's interest to actively engage in the negotiation of the next Multiannual Financial Framework (MFF), and to develop a more proactive, constructive agenda for European health policy in light of the upcoming German Council presidency in 2020.

German approaches to a European agenda should fall into three overarching priority areas, as part of a broad strategy that addresses various aspects of European sustainability and EU cohesion:

(1) The promotion of social and economic convergence, with short- and medium-term guarantees of broad access to affordable and high-quality health care;
(2) Boosting innovation and research; and
(3) Strengthening European capacities, both external and internal.

Figure 2: Three target dimensions for Germany in European health policy



These three target dimensions are closely interwoven, and all essential for successful EU cooperation and integration in other policy areas. For example, greater equality in the area of health would have a positive impact on innovation potential and economic performance. It would

reduce collective good problems, and thus facilitate the Union's ability to act externally; greater convergence would allow for more equal contributions of financial and human resources in the event of a global health crisis. At the same time, these dimensions are also a precondition for a stable and resilient monetary union, a functioning internal market, and a functioning European neighborhood policy.

In specific terms, the German government should contribute more strongly and proactively than it has thus far to ongoing debates on patient mobility, e-health, and quality management. It should also strengthen the commitments it has already made in areas like research cooperation and international health management, and use the expertise it has already established during its G7 and G20 presidencies to draw up long-term plans for global health promotion. Germany could also expand cross-border partnerships, for example with France, Austria, the Benelux countries, and Poland, and open up issues of pan-European capacity-building to voluntary cooperation formats.

2. Challenges and Demands for European Health Policy

The list of short-, medium-, and long-term challenges facing the EU in the area of health policy is long:

Demographic Change

Ongoing demographic change poses one key challenge. The average age of the EU population rose by almost six years between 1996 and 2016, and life expectancy is still rising. At the same time, between 2011 and 2016 annual population growth was negligible, remaining between 0.2 percent and 0.4 percent.[5] This trend poses significant challenges for European health systems.

Rising Health Expenditures and Innovation Pressures

The increasing life expectancy of the population and the increasing occurrence of chronic diseases have both driven up the costs of health care and overall expenditures on national health systems.[6] The average health expenditure of EU member states amounts to about ten percent of their gross domestic product (GDP),[7] and will climb further as innovations in the pharmaceutical and medical technology industries drive up costs.[8]

Skilled Labor Shortages and Gaps in Supply

At the same time, declining employment levels and skill shortages in the healthcare sector in many EU member states are leading to shortages of healthcare personnel, particularly in rural and underdeveloped areas.[9] The so-called "brain drain" contributes further to this problem, particularly in countries in Southern and Central Eastern Europe. Some EU countries are better at compensating for these supply gaps and cost increases than others, which in turn reinforces existing social and economic divergences within the EU.

Public and Private Debt

Healthcare cost increases are leading to uneven development across Europe, especially when combined with existing public deficits: In many countries of Southern and Southeastern Europe these costs are likely to lead to substantial budget cuts and service reductions, even more so than in many of the more financially strong Northwestern member states. The case of Greece demonstrates the long-term impact of the European financial and debt crisis. As a result of high public debt, declining tax revenue, and austerity measures implemented as conditions of EU support, funding for the health system has come under enormous pressure. Significant gaps in health care provision have arisen, especially in rural areas. As a result, private co-payments for health care – which were high to begin with – have continued to rise, a trend that has further increased existing inequalities in access to medical care.[10]

Declining Commitments in Global Health

There is also a need for action in many areas of global health. Brexit poses one set of short and medium-term challenges, as the UK has been a key EU player in global health. The increasing withdrawal of the United States from development policy poses another: US President Donald Trump has called the financial stability of several multilateral organizations into question.

Declining financial support for health-related projects at the global level does more than endanger the EU's ability to take action in acute crises; it also reduces its ability to compete in geostrategic and ideological terms with third countries like Russia and China, which are increasingly positioning themselves as development actors and expanding their influence in Africa and countries within the European neighborhood, challenging the EU's potential and credibility as a serious global actor.

Innovation and Growth Potential

In part because of these risks, the area of health offers huge potential for growth, competitiveness, innovation, and employment. The European pharmaceutical industry alone has a market value of more than 200 billion euros, and invests more than 35 billion euros annually in research and development.[11] The medical device industry is also an important economic sector, with a market value of more than 100 billion euros and average growth rates of around 4.4 percent since 2008. It includes approximately 27,000 companies in the European Economic Area, 95 percent of which are small and medium-sized enterprises (SMEs), and accounts for the highest proportion of European patent applications at around seven percent.[12] There is particularly high potential for innovation and growth in the e-health sector.[13]

Positive Influence on Employment

In addition to its importance for Europe's economic power and its innovation potential, the health economy plays a prominent role in the European labor market. Over 1.8 million doctors, 3.4 million nurses, and 3.2 million health care assistants work in the EU.[14] The research-focused pharmaceutical industry has about 740,000 direct employees, and more than 675,000 people are employed in the medical technology industry throughout Europe.[15]

3. Conflict Lines in EU Health Policy

Given the range of challenges and opportunities outlined above, some states within the EU – especially smaller member states – along with many European stakeholder organizations and large sections of the EU population are in favor of strengthening the EU's role in health and social security. They see a need for action, especially given the growing inequality of European patients' access to medical treatments and new and/or expensive medicines. Large EU member states, on the other hand, are more reluctant, and even defensive of their domestic systems. In summary, the following lines of conflict within the EU can be outlined:[16]

1. **German reluctance and its veto position:** Germany has taken the initiative in only a few cases, such as the Ebola crisis management and surveillance of communicable diseases. At the same time, it tends to block discussions of deepening European health policy more systematically than the other member states, referring to the limited EU competencies in the policy area. Countries like the UK, Poland, the Czech Republic, and Bulgaria often support Germany's position. Germany has also been especially critical of voluntary cooperation formats negotiated by other member states, both within and outside EU structures. Germany was therefore often perceived as a hindrance to further cooperation and reform. Two major factors contribute to German positioning: On the one hand, Germany's attitude is shaped by its system of self-governance in the health sector and the existence of strong interest groups at both the national and regional levels, which make decision-making and compromise within the EU more difficult. German medical representatives, for example, view Europeanization trends critically, as they tend to add additional layers of bureaucracy to the work processes of German physicians. On the other hand, due to its political influence, strong domestic employment rates, and a healthy economy, Germany is not dependent on European cooperation and health support.
2. **Small vs. large member states:** Smaller EU member states tend to cooperate more than large member states. This trend is mainly due to the smaller states' limited financial, human, and administrative resources, their limited bargaining power compared to that of large countries, and their less attractive national markets. They also call for a stronger EU role in standard-setting, benefit assessment, personnel planning, information exchange, and drug-related negotiations. Smaller health systems usually also mean greater adaptability and readiness to innovate and restructure. For smaller member states, the prospect of positive economies of scale is an important motivating factor. This is especially true for more prosperous countries, such as Malta, Ireland, Luxembourg, the Netherlands, and Belgium. In contrast, small, poorer member states in South and Southeastern Europe – such as Romania, Bulgaria, Hungary, and Portugal – focus more on European solidarity and financial support, without necessarily seeking to further Europeanize structures and processes. The more Commission-critical small member states, including the Czech Republic, Lithuania, and Bulgaria, focus on the principles of subsidiarity and national sovereignty, as do the United Kingdom, Spain, and Poland. Large member states like Germany, France, Spain, Italy, the United Kingdom, and Poland are less interested in Europeanization of processes, which could interfere with national structures and procedures, than many smaller countries. Large member states are more likely to have sufficient resources, along with the necessary administrative capacity and

expertise. Their markets are also large and attractive enough for pharmaceutical companies and the healthcare industry as a whole, so they do not rely on EU leverage or economies of scale in price negotiations. The attractiveness of a European health policy is also diminished in member states with strong decentralized structures, strong traditions of self-government, and dominant corporate interests.

3. **North vs. South:** The European financial and debt crisis has tended to hit North-Western health systems less hard than Southern European and South-East European ones. At the same time, the research-based pharmaceutical and medical technology industry is stronger in the Northwest than in Southern and Southeastern Europe. Southern European EU member states are therefore more willing to regulate and harmonize than North-Western European EU member states.
4. **European institutions/stakeholder organizations/ European populations vs. EU member states:** In general, European advocacy organizations such as the European Patients' Forum, the European Public Health Alliance (EPHA), and the European Hospital and Healthcare Federation (HOPE) are more open to a stronger European health policy than national actors. The same applies to EU institutions such as the European Commission and the European Parliament. This can easily be explained by the logic of interdependency, path dependency, and institutional loyalties. That being said, according to the 2016 Eurobarometer Survey 63 percent of Europeans support greater EU engagement in health issues.[17]

4. Legal Framework for European Health Policy

While some EU member states and European stakeholder organizations emphasize the political and economic need for a pro-active European health policy, the competencies of the EU, and the European Commission in particular, are at first sight very limited.[18] Only Art. 168 TFEU is dedicated entirely to health, regulating as it does the area of public health protection. According to this framework, it is the EU's responsibility to improve the general level of public health through prevention efforts and the provision of health information; the EU is also meant to play a role in the fight against serious, widespread diseases and cross-border health threats. These latter responsibilities include combating tobacco use and alcohol abuse, as well as monitoring, reporting on, and responding to pandemics and other cross-border health crises.

Paragraph 1 states, in particular, that the design and implementation of other EU policies must also ensure a high level of health protection. Paragraph 2 also addresses the goal of improving the complementarity of health systems in border areas and ensuring that they are not structured in ways that reduce interoperability. Paragraph 4 lit. a) - c) lists the areas where the EU has regulatory competence under primary law, in line with the ordinary legislative procedure; these include measures to establish quality and safety standards for organs, "substances of human origin," blood, and blood derivatives (a), measures to protect public health in plant and veterinary fields (b), and measures to establish high quality and safety standards for pharmaceuticals and medical devices (c).

That being said, Article 168 TFEU does not establish EU competencies in the organization of national health systems. Article 168 TFEU, paragraph 7 reads as follows: "The activities of the Union shall respect the responsibility of the member states for the definition of their health policies and for the organization of health services and medical care. The responsibilities of the member states include the management of health services and medical care, as well as the allocation of resources allocated to them."[19]

On the basis of this article, therefore, the EU is primarily empowered to promote, assist, and, where necessary, complement member state cooperation. In practical terms, this implies that the role of the European Commission is to promote cooperation, and in particular the exchange of best practices, with the aim of sustainably improving the level of health in the EU and protecting EU citizens from health risks.

However, Article 168 TFEU cannot be considered or interpreted in isolation. It is embedded in a complex primary law structure , and buttressed by a wealth of secondary legal acts. The health policy area in a broader sense is also directly and indirectly influenced by numerous other policy fields and instruments. These include, first and foremost, internal market rules (Article 114 TFEU), macro-economic coordination instruments (Regulation (EU) 1175/2011 based on Article 121 (6) TFEU), and the Charter of Fundamental Rights, along with occupational safety and health (Article 153 para. 1 lit.a) and consumer protection (Article 169 TFEU) regulations.[20]

The impact of the European single market on national health policies has been evident for several decades. The establishment of the single market has resulted in numerous legislative acts, so that "single market health policy" can be seen as in fact the oldest dimension of (indirect) European health policy.

While certain areas of domestic health policy enjoy special legislative protection and are thus excluded from common market rules and logic, many other areas are shaped by the interplay of domestic legislation and EU internal market rules. Over the years, several "spill-over" effects of internal market rules have been observed in national social and health policies, including measures guaranteeing equal treatment, transparency, and the EU's four fundamental freedoms, in particular the mobility of patients, healthcare professionals, and services.[21] One crucial driving force in the Europeanization of health policy have been rulings by the European Court of Justice (ECJ), as in the case of the Patient Mobility Directive 2011/24 / EU (see, for example, the Kohll/Decker case-law).[22] At this point, the process of internal market-driven integration and harmonization is considered to be largely complete.

In the academic debate, the position is often expressed that national legislation has not been disproportionately influenced or limited by single market legislation. In the case of the German health care system, for example, European financial support regulations take Federal German Law of Hospital Financing into account, and when in doubt, cross-border access to hospital treatment depends on national authorization.[23]

The influence of macro-economic instruments and coordination mechanisms on the design of national health care structures, on the other hand, has increased over time, especially in the wake of the European economic and financial crisis. The European Commission reacted to the crisis by reforming Europe's budgetary supervision competencies on the basis of Article 121 (6) TFEU in order to better anticipate and respond to macroeconomic imbalances within the EU in the future; these reforms included the European Semester, and revisions of the Stability and Growth Pact.

Under normal circumstances, EU member states that are not subject to European Stability Mechanism (ESM) programs or excessive deficit procedures cannot be forced to implement country-specific recommendations of the European Commission; they must provide accounts of their reform processes, but are not sanctioned for recommendations they do not implement.

Countries that are receiving assistance from these programs, on the other hand, have to accept more EU influence on their domestic policies. Social and health policies are generally the largest national expenditure items, accounting for around 29.5 percent of GDP on average across the EU, meaning they are also the largest targets for budgetary recommendations.[24] Under the terms of Greece's MoU, for example, the country was committed to far-reaching structural reforms in the areas of pharmaceutical markets, hospital care, and health insurance organization, which are supported and monitored by the European Commission, the European Central Bank (ECB) and the International Monetary Fund (IMF). The country was obligated to reduce its number of doctors, and to introduce additional payment requirements for treatments and medications. Similar conditions were applied to Portugal and Cyprus.[25]

As part of the European Semester, country-specific recommendations were issued in 2017 for twelve EU member states calling for reforms to increase the efficiency of their national health systems. The European Commission also plans to integrate a socio-political "scorecard" into the European Semester that would grade the implementation of the European Pillar of Social Rights, with the aim of strengthening the EU's social dimension and making it more visible.[26] It is therefore foreseeable that the European Semester will increasingly be linked to social policy indicators, rather than just economic indicators, to prevent and reduce social imbalances within the Union.

The example of budgetary control, however, shows the inherent problem with any framework that would attempt to firmly divide social and economic competencies without taking into account the interplay between the two policy areas. While Article 168 (7) TFEU establishes the organization of national health systems as a matter for the member states, this national sovereignty is limited by the budgetary dimensions of health policy. A holistic approach is therefore essential. Closely related to this argument, it is worth noting that the ECJ has thus far only sanctioned incidents where EU competencies were fundamentally exceeded.[27] Furthermore, the EU's Charter of Fundamental Rights and the social dimension of European citizenship presuppose a right to a "high level of human health protection," in particular access to "preventive health care" and the right to "benefit from medical treatment"[28]; that being said, art. 6 par. 1 TFEU establishes that the rights grounded in the charter do not extend the competencies of the Union as defined by the relevant treaties.

Overall, Article 168 TFEU cannot be considered an absolute legal barrier to a progressive Europeanization of health policy.[29] While the regulatory competence of the EU to harmonize national legislation is very limited, the EU has a wide range of tools at its disposal under Article 168 (5) TFEU. There is therefore room for more in-depth EU cooperation in the future, whether it involves all 27 member states or smaller coalitions within the Union.

The Patient Mobility Directive 2011/24 / EU, for example, cited the cross-cutting objecting of ensuring a high level of health protection to launch various voluntary initiatives promoting member state cooperation, including the European Reference Networks (ERNs), the Joint Health Technology Assessment (HTA), and the eHealth Network.

5. Status Quo of European Health Policy

Instruments and Incentives

As described in the previous section, EU regulatory competence in the field of health is very limited under ordinary legislative procedure. The EU's legislative powers mainly cover the area of pharmaceutical policy, which is overseen by DG SANTE, and ensuring quality standards for medical devices and technologies, which are the responsibility of the Directorate-General for Internal Market, Industry, Entrepreneurship, and SMEs (DG GROW). However, in most other areas and sub-dimensions of European health policy, the EU has other tools and incentives at its disposal. These include coordination and best practice exchange, networking, and research funding. These allow the Commission to indirectly set standards for cooperation and prioritize different research areas by structuring tenders and setting eligibility criteria.

The European Commission presented its most recent European health policy strategy in a white paper it released in 2007.[30] The objectives of the current European health policy are formulated in the Third Health Action Program 2014-2020, and can be summarized under four pillars:

(1) health promotion, disease prevention, and promotion of healthy lifestyles,
(2) the protection of citizens from cross-border threats to health,
(3) the contribution to innovative, efficient, and sustainable health systems, and
(4) access to better health care.[31]

Annual work plans to implement the above objectives have been adopted within the larger framework of the multi-year plan. However, the program's budget is limited – and it is moreover the only item within the current EU budget that is explicitly and exclusively dedicated to the promotion of public health.

The total program budget amounts to 449.39 million euros, just 0.04 percent of the EU's Multiannual Financial Framework.[32] Implementation of these goals relies – among other things – on co-financed Joint Actions to promote voluntary cooperation between member states.[33] Past and current joint actions have included the implementation of best practices in chronic disease management, e-health network support, forecasting and demand planning for the provision of vaccines, and an analysis and policy development package to address unequal health opportunities.[34]

Overall, the Juncker Commission has launched fewer legislative acts focused on health than previous European Commissions; DG SANTE, for example, has only submitted a legislative proposal for increased cooperation on health technology assessment (HTA).[35] That being said, the other Directorates-General, such as DG MARKT, have occasionally submitted legislative proposals related to health; one such proposal has called for a new directive requiring proportionality tests prior to the adoption of new regulations concerning professions.[36] Representatives of the Commission argue that further legislation and harmonization efforts are currently not necessary, and that future initiatives should come from the member states themselves.

Health in the Context of the Better Regulation Agenda

The current stance of the European Commission must be seen in the context of the broader debate on the EU's future. It can be considered a response to ongoing discussions about limiting the EU's engagement to "big questions" where it can have noticeable added value for the whole of the EU. The overarching "Better Regulation Agenda" was spurred by – among other things – debates in the UK and the Netherlands about possible shifts of EU competencies back to the national level. As a result, the Council working party on health has rarely been meeting. The perceived inactivity of the EU has been frustrating actors who would prefer the EU take a stronger role in this area, including member states like Belgium, Malta, and Luxembourg, along with other European stakeholder organizations.

Given the current uncertainty about the future of the EU in general, there is a possibility that DG SANTE will continue reducing its activity; particularly in the context of ongoing EU budget negotiations, leaving fewer member states to finance a larger number of priorities and projects in the future. The ultimate question may be whether there will be a new health program beyond 2020, and whether DG SANTE will continue to exist at all in the wake of a possible restructuring under the next European Commission. Critics of this trajectory, both in the various member states and in stakeholder organizations, warn that the loss of DG SANTE within the European Commis-

sion could shift the health narrative too much towards the interests of the health industry as DG GROW gains importance,[37] potentially marginalizing the issue of public health. The elimination of DG SANTE would also mean the absence of any central body coordinating EU health policy activities, which would be detrimental to the "health in all policies" approach to cross-sector promotion of health protection within the EU.

At the same time, the implementation of the current EU health program has been criticized. In particular, there are complaints that Joint Actions are not designed to be sustainable enough, and that stakeholders are included too late and with little systematic involvement. Similarly, there is a lack of data to evaluate the efficiency and actual added value of these measures. Another fundamental point of criticism concerns the question of whether the EU should continue to finance expert activities and NGO projects. This criticism is particularly strong in those member states that are not interested in a stronger European dimension in the health sector and are in a position to finance and produce research themselves – or are simply unwilling to increase their contributions to the EU budget.

The Uncertain Future of European Health Policy

Overall, the Council and the Commission agree that no additional transfers of competencies requiring treaty changes are currently necessary, or even desirable, to strengthen the EU's role in the health field. Instead, in line with the different scenarios outlined in the white paper on the future of the EU, ideas are being discussed concerning how to make the best possible use of existing tools and instruments. Potential instruments and procedures include greater cooperation at the supranational EU level (such as HTAs), as well as voluntary cooperation formats that would include smaller constellations of member states. Specific considerations and collaborative efforts focus on issues such as the exchange of information and expertise, common early detection mechanisms ("Horizon Scanning"), joint HTA, joint price negotiations, joint drug procurement, and the consequences of brain drain and skill shortages. Further initiatives are centered around classic public health topics such as prevention and health promotion.

Since 2014, several EU Council presidencies – most notably the Greek, Italian (2014), and Dutch Council presidencies (2016) – have focused on options and instruments of voluntary cooperation on drug price negotiation, occasioned by the approval of the high-priced hepatitis C drug Sovaldi. The Dutch Council presidency concluded, for example, that, while new medicines have a high potential for innovation and can meaningfully contribute to improved public health, they also put a strain on national health systems as more resources are allocated to price determination and benefit assessment. This has effectively already resulted in market failures in some EU countries, preventing patients from accessing the medications they need at affordable prices.

Against this background, Council conclusions stated that the "pharmaceutical system in the EU and its Member States, which is characterized by a division of competencies between Member States and the EU level, can benefit from dialogue and a more holistic approach regarding pharmaceutical policy, by enhancing voluntary cooperation between Member States aimed at greater transparency, to safeguard common interests, ensuring access of patients to safe, effective and affordable medicinal products as well as the sustainability of national health systems."[38] The conclusions of the Maltese Council presidency in the first half of 2017 were even more ambitious and comprehensive, calling for broader and more active voluntary European cooperation on health systems in general. This document also addressed the need for improved access to medical technologies and medicines, while suggesting other possible areas of cooperation, such as common responses to brain drain and skill shortages in various EU countries. It also proposed more intensive, voluntary cooperation in human resource planning, the development and application of ethical criteria in the appointment of health professionals, and the development of the ERNs into specialized medical centers with differentiated functions.[39] In comparison, the agenda of the Bulgarian Council presidency in the first half of 2018 was less ambitious regarding voluntary cooperation. It identified affordable pharmaceuticals and public health – and more specifically children's nutrition – as priorities.[40]

Overall, a look at the Council conclusions issued in recent years shows a consistent sense of necessary steps to be taken on the EU level, as well as the underlying analysis of problems and challenges. However, promising, sustainable solutions have yet to emerge – and many member states mention the absence of German leadership as a central obstacle.

Trend Towards Greater Sub-Regionalism

Since there is no consensus on health policy objectives at the EU level beyond general intentions, more member states and stakeholders are adopting intergovernmental, sub-regional approaches of their own. These include the Valletta Declaration, a predominantly Southern Euro-

pean coalition to jointly negotiate drug prices;[41] cooperation initiatives undertaken by the Nordic countries; the BeneluxA initiative, which includes Belgium, the Netherlands, Luxembourg and Austria;[42] and cooperative arrangements among the Visegrád countries (Poland, Hungary, Slovakia, and Czech Republic). Both the Valletta Declaration and BeneluxA focus on the pharmaceutical and health technology sectors. The Visegrád states (V4), on the other hand, are focusing on joint initiatives to promote innovation in the health sector, and digitization strategies in a broader sense – in its 2017/2018 program, for example, the Hungarian V4 presidency specifically mentioned medical and nanorobotic innovation. Over the longer term, the coalition will also be examining potential cooperation on e-health and price negotiations.[43]

Sub-regional cooperation formats will likely continue to gain in importance, especially if EU engagement continues to decline. If Germany continues to not participate in these sub-regional initiatives, German actors will not have the opportunity to directly influence intra-European developments. This would render Germany a passive observer, or "policy taker", in the event that sub-regional policies trigger spillover effects affecting Germany or the EU as a whole. This would be conceivable, for example, in the case of common standards, which are gradually being promulgated within the EU. If these sub-regional policies achieve critical mass, Germany itself could come under pressure to adopt them; conversely, if they fail to achieve widespread adoption, they could create divergent standards in different parts of the Union, rendering later supranational EU approaches nearly impossible. Cross-border cooperation initiatives, on the other hand, which respond to specific sub-regional challenges, carry little risk of negative repercussions, either for Germany or the EU.

So far, however, these sub-regional initiatives have failed to deliver sustainable results, primarily due to a lack of strategic and specific objectives and process targets.[44] That being said, individual pilot projects in the area of pharmaceuticals – for example in the generics sector – are already in progress.

These cooperation approaches comprise voluntary associations of states. They often include formalized structures, but lack the kind of supranational elements like sanctioning mechanisms and resource facilities that EU structures have at their disposal. Some of these groups, like BeneluxA and the Valletta Coalition, are open to outside membership; others, like the Visegrád group and the Nordic Council, are not. These groups are generally dominated by small- and medium-sized states; Germany and France are not actively involved in any cooperation format, and neither Italy nor Spain holds a leadership role, although they were among the original signatories to the Valletta Declaration in June 2017. This restricts the groups' chances of success when it comes to price negotiations with the pharmaceutical industry.

It is therefore in the interest of proactive smaller countries like Malta and Belgium to involve the Commission in so-called "coalition of the willing" initiatives, and to discuss ideas in Council working parties – however, this approach has earned the criticism of Germany, and several other larger member states, who fear that groups of member states could work in concert with the Commission to extend EU competencies through the back door. There is also the concern that the Council's agenda is already overburdened and dominated by pharmaceutical policy, crowding out discussions concerning other areas of European added value. Therefore, Germany, Spain, and Sweden prefer that voluntary cooperation take place outside of the EU institutions, for example through the BeneluxA and V4 initiatives.

Germany has also been anxious to prevent these voluntary cooperation formats from having unintended consequences for the German health care system. These could include interference with national price setting for health services, or definitions of reimbursement rules, and possible threats to other structural principles of traditional German self-governance. Accordingly, Germany agreed with the Maltese Council conclusions only after the German delegation was allowed to contribute an addendum stating that "the design of voluntary cooperation at each stage is the sole responsibility of the Member States that voluntarily organize. [...] There is no overall coordination of activities, in particular not by the Commission. Agreements that are made within this cooperation, and the results of the discussions, will only have an effect on the internal mechanisms of the Member States that voluntarily join. There is no involvement of European structures outside the competencies foreseen in the European treaties. "[45]

6. A New Agenda for European Health Policy

As has been shown, the future agenda of European health policy should target three overarching areas: (1) social and economic convergence, (2) innovation and research, and (3) the EU's internal and external capacity to act. In the following subchapters, selected sub-areas of European health policy are outlined to present the status quo,

current challenges, and possible next steps, taking into account these overarching targets.

6.1 Patient Mobility

The field of patient mobility is regulated by secondary legislation at the EU level. The Patient Mobility Directive was adopted as a result of a number of ECJ rulings in which the ECJ ruled in favor of patient plaintiffs who had been denied reimbursement by their countries of origin for treatment or medical device purchases in other EU countries. The directive regulates the provision of patient mobility by guaranteeing transparent, non-discriminatory procedures that specify the conditions under which patients have access to treatments, therapies, and medicines in other EU countries, and the conditions under which costs will be reimbursed. The aim of the directive is not to encourage patients to make greater use of their right to mobility, but rather to provide clear information and legal certainty; furthermore, the directive emphasizes that it in no way restricts the right of member states to independently determine their own catalogues of national health care services and national health care financing mechanisms.[46] The need for greater cooperation between health systems is justified by the objective of guaranteeing access to safe and high-quality healthcare to patients, especially in border regions. The ERNs and the e-health network are specified as concrete projects the EU should focus on.

In the pan-European context, patient mobility plays only a limited role; because of both language and trust barriers – as well as simple logistics – patients usually prefer treatment near their places of residence. Patients are also often uncertain about the processes and prospects of reimbursement of costs in other member states, as well as the quality of treatment. According to a 2014 Eurobarometer survey, only five percent of respondents in the EU have used medical services in another EU country over the past 12 months, and only two percent of respondents planned for treatment in other EU countries. Respondents who had considered treatment in other EU countries cited serious illnesses, such as cancer, as reasons. The impact of the Patient Mobility Directive on routine healthcare is therefore low.[47]

However, a different picture emerges in popular holiday regions and densely populated border regions – for example at the German-French border, the German-Polish border, in the Benelux sub-region, and the Ireland-Northern Ireland border. Higher patient mobility is observed in these regions compared to the rest of the EU. To facilitate mobility in border regions, EU-coordinated initiatives are therefore complemented by a wealth of cross-border, often bilateral, initiatives.[48] These cooperations are often organized between regions or municipalities.

In Germany's case, there are also a few agreements between German health insurance and service providers in neighboring European countries, as well as agreements between hospitals meant to pool expertise. Examples include the cooperation of cardiology stations in the Saarland and the French département of Moselle, a trauma network in the SaarLorLux region, and a German-Polish neonatal screening initiative. The focus of many of these cooperation projects is on knowledge exchange; they are only rarely associated with significant cross-border investment.

The challenges facing such cooperation projects are manifold, and in many ways mirror the causes of limited patient mobility: Language barriers, trust gaps, unclear legal and health insurance issues, and ignorance of the organization and function of health systems in other countries all play significant roles. There are also cross-border differences in medical standards and financing systems, as well as cost pressures, exacerbated by the uncertainty of long-term project financing.

While some of these problems and difficulties are geographically specific, there are others that span the entire EU. The EU should therefore continue initiatives that weigh the various approaches being used, along with their prospects of success, to arrive at a set of best practices.

The main responsibility for stabilizing cross-border cooperation, however, lies with the member states. Cross-border cooperation should therefore be embedded in national and bilateral strategies, and be based on framework agreements. It will also require financial and personnel support to meet the requirements of the respective nations' health care systems. For Germany in particular, cross-border cooperation with France, Poland, Austria, and the Benelux countries could be a lever to establish important networks and strengthen health cooperation with these strategically important partners – on the EU level as well.

6.2 Mobility of Health Care Professionals

While patient mobility is more of a niche topic at the EU level, the mobility of health care professionals is fraught with challenges, opportunities, and risks – and it is a topic that has already engendered a great deal of controversy among EU member states. Southeast European member states are suffering comparatively more from a shortage

of skilled workers and brain drain as young, specialized professionals leave their countries of origin to work in Northern and Western Europe.[49] Ireland, the United Kingdom, Sweden, and Finland in particular benefit from the intra-European mobility of doctors, while countries such as Greece, Portugal, Romania, Hungary, and Poland, as well as the Baltic States, are particularly negatively affected.[50]

This creates various challenges and problems. One urgent problem is the difficulties this entails for national planning; a related problem stems from the different educational capacities of the different countries, and the high costs that a state incurs in funding medical degrees. Some member states are training too few young medical professionals to meet their own needs, while others incur the costs of providing expensive medical training but cannot benefit from the labor of their graduates, who prefer to work in other European countries that offer better conditions.

There are already several initiatives at the European level to address this structural asymmetry and the challenges of general Europe-wide demand planning. In 2012 the European Commission presented an Action Plan addressing the need for a sustainable EU health workforce, which identified the potential for action in four areas:

(1) requirement forecasts for the personnel composition of national health sectors,
(2) early detection mechanisms to predict future needs for specific qualifications and health care specializations,
(3) a best practice exchange to develop recruitment and retention strategies, and
(4) "ethical employment" processes.[51]

In the context of the Joint Action SEPEN in effect from 2013 to 2016, a network for cooperation and health care personnel planning was created; the Joint Action was later extended until 2018.[52] In addition, the Maltese Council presidency prioritized cooperation on European health professional planning in its Council conclusions, and proposed stronger cooperation on needs planning, joint training, and information exchange. The Hungarian government submitted further proposals during its presidency, including a call for more consistent adherence to "ethical hiring" rules[53] specified by the World Health Organization (WHO). It also discussed the introduction of compensation mechanisms for EU countries that are disproportionately affected by intra-EU brain drain.

However, there is no serious discussion at the EU level about taking action beyond joint horizon scanning and voluntary best practice exchange. Proposals such as compensation payments and other redistributive mechanisms are seen as excessive interventions in the organization of national health systems. Instead, the responsibility for reforms that would create more attractive working conditions is primarily seen as lying with the member states. The absence of a European discussion in this area can be partially attributed to the fact that large EU member states like Germany, Great Britain, and Spain are more likely to benefit from intra-EU mobility in the health sector – or at least are not negatively affected – and therefore see little need for European action in this area. The prevailing assessment is that brain drain and skill shortages have to be considered in the context of wider systemic transformation as part of the process of working towards greater social and economic convergence. In order to counteract economic and social divergence, the scope for EU activities and voluntary cooperation in this area, both at the EU level and bilaterally, should be further explored.

6.3 Digitization and E-Health

As in many other areas of European policy, digitization is set to play a significant role in the health sector.

Within the EU, different digitization measures and proposals are coordinated and financed by different bodies. A voluntary e-health network has been established on the basis of the Patient Mobility Directive to facilitate cooperation and exchange between member states and maximize the interoperability of different health systems; this network is the main decision-making body on e-health at the EU level, and national decision-making bodies working on e-health issues are organized within this network. Within the network, which includes representatives from all EU member states, a broad range of topics is discussed, summarized in Health Action Plan 2012-2020. The concrete projects included range from the systematic provision of health-related data and the creation of various databases to telemedicine and the widespread introduction and interoperability of electronic medical records to the introduction of electronic prescriptions.[54] Within the European discourse, it is emphasized that these measures could increase efficiency, reduce costs in the long run, promote the mobility of patients and professionals, close gaps in care, facilitate targeted research and early detection, and foster innovation.[55]

To advance the digitization of health at the EU level in all its facets, the European Commission held a public consultation on transforming healthcare in the digital single market in the second half of 2017, and published a Communication on Digital Transformation in April 2018.[56] The Estonian Council presidency also devoted itself to

the European e-health agenda in the second half of 2017, and organized a three-day conference on “Health in the Digital Society. Digital Society for Health”. At the end of its presidency, the Council also made specific mention of e-health for the first time, setting out two specific priorities: (1) the empowerment of patients through electronic access to health data, and (2) the provision of data-driven health research and innovation.[57] To further develop and implement the e-health network, a new Joint Action (eHAction) was launched in March 2018. The Connecting Europe Facility (CEF) also works to provide a “Digital Services Infrastructure for eHealth” by 2020 at the EU level to help member states exchange data and establish interoperability.[58]

The EU member states therefore agree in principle that the development of e-health and the further digitization of European health data are essential steps. On the other hand, there are clear differences on questions of details and practical implementation. These differences arise from the member states’ national discourses and attitudes, as well as their available resources and processes and existing domestic structures. This can be seen, for example, in the availability of broadband networks, and the degree to which various stakeholders in domestic health systems already exchange electronic data.

Smaller member states – especially in Northern Europe, but also in other parts of the EU like Belgium, Slovakia, and Austria – often push the e-health agenda more actively than the larger member states, and often have less pronounced concerns about privacy issues and cyber-security risks. At the same time, the population in Northern Europe is already more familiar with elements of e-health than populations in Central and Southern Europe; according to a special Eurobarometer survey conducted in 2017, for example, more than 40 percent of respondents in Estonia, Finland, and Denmark used e-health services over the previous 12 months, compared with less than 10 percent in Malta, Germany, and Hungary.[59]

This gap is correlated with strong divergences in existing infrastructure, as well as varying levels of digitization and e-governance. While the Nordic and Baltic countries are already leaders in this area, many Southwestern European countries still have a lot of catching up to do. Another factor is the organization of existing health systems and the degree of their centralization. In smaller, centrally organized countries, it is easier and requires less resources to create uniform, state-of-the-art structures than in large, decentralized health systems with a high degree of regional self-governance.

Against this background, the main task of the European Commission and the individual member states is to align standards in data processing, data transmission, and data security, and create interoperable structures. This is particularly important as the EU works to get and remain ahead of external competitors. Common standards and structures will make it easier to exploit eHealth in the medium and long term to achieve more in the areas of health prevention, innovation, and research, and make the early detection of crises and other health policy developments possible.

In the short term, cooperation in best practice exchange and the further education of health care workers on topics such as data security should be a priority. As in other health-related cross-cutting areas, it will also be essential to ensure that individual countries and regions within the EU do not disproportionately lag behind others; this would run counter to the overall objective of promoting broad protection of public health and maximum patient safety. In order to avoid such a negative scenario, existing support instruments should be used, and the Commission should work to ensure a sustainable exchange between member states.

6.4 Quality and Safety Standards

Ensuring quality and safety standards for medicines and medical devices is the key health policy area where the EU has explicit regulatory competence. The European Medicines Agency (EMA), for example, is responsible for the marketing authorization of medicines at the EU level, in cooperation with the member states.

Reforms to medical device legislation bring the potential for significant innovation in ensuring quality and safety standards.[60] A package of new regulations governing medical devices (VO (EU) 2017/745) and in vitro diagnostics (VO (EU) 2017/746) was adopted in April 2017; after a transition period, the new regulations will be effective in April 2020 and 2022, respectively. The regulatory review of medical devices has been reexamined, particularly in response to scandals like the 2010 case of French company Poly Implant Prothèse, which made low quality breast implants. The newly introduced innovations include, among other elements, stronger EU involvement in product classifications, revised definitions of medical devices, the addition of cosmetic product groups with non-medical purposes (e.g. contact lenses and implants), and the creation of a European database. However, member states have criticized the transitional period, arguing that it provides inadequate time to adjust.

Under the auspices of DG SANTE, a proposal for more intensive European cooperation on Health Technology Assessment was presented in February 2018, including HTAs that would be legally binding for all member states. The Commission is thus building on existing voluntary cooperation in the context of a Joint Action between the member states, specifically national HTA authorities. In the Commission's view, greater European cooperation in the assessment of medicines and other forms of therapy brings numerous benefits: With increasingly complex HTAs due to ever more complex innovation, the Commission anticipates general cost savings and efficiency gains through the increased Europeanization of HTAs. It also foresees an increase in transparency, the convergence of quality standards, and better access to medicines for smaller member states, such as Luxembourg, which do not have their own HTA authorities.[61] It also anticipates benefits for the industry, which until now has had to conduct 25 separate price negotiations, and has therefore focused primarily on the markets of the large member states.

The HTA initiative is currently supported by segments of the medical device industry, large parts of the pharmaceutical industry, the European Parliament, and many smaller member states, including the Baltic States, the Netherlands, Croatia, Slovakia, and Hungary. In contrast, criticism has come mainly from larger member states – including Germany, Spain, France, and Poland, but also Bulgaria, Romania, the Czech Republic, and Greece.[62] The opponents of the proposal, often states with their own HTA authorities and well-organized associations of doctors and pharmacists, accuse the Commission of exceeding its competence with the initiative. They also complain about unnecessary bureaucracy growth and the danger of sinking national quality standards. In the case of smaller member states such as Romania and Bulgaria, criticism is based more on their very limited resources; it is feared that national systems and administrations will be overburdened by the requirements set out in the Commission proposal.

Immediate challenges in the pharmaceutical and medical device sector have also arisen through Brexit. This applies to marketing authorization of medicines , but also other assessment procedures – for example, British experts are currently responsible for over 20 percent of the EMA's work.[63] In addition to the loss of UK expertise and labor in marketing authorization of medicines, it is expected that the logistical implications of the EMA move will also contribute to delays in the application process during the transition period. As the largest EU member state, Germany could help make the transition as easy as possible by providing financial and human resources; Germany could also proactively work towards a compromise solution for the HTA dossier that relieves smaller EU states and stimulates the exchange of expertise.

6.5 EU Funding Instruments, Network Building, and Research Support

Research funding and networking support are at the center of the EU's health-related activities. In addition to the health program set up through DG SANTE, other programs to promote health objectives also contribute given the cross-cutting nature of health policy.[64] For example, the Cohesion Fund within the European Structural and Investment Funds (ESIF), touches on health through projects focusing on information and communication technology (ICT), SMEs, social inclusion, and employment. The European Regional Development Fund (ERDF) can also be used to promote health-related infrastructure, e-health, and SMEs. The European Social Fund (ESF), meanwhile, finances initiatives that focus on health promotion, demographic change, and health inequalities, among other areas. Health-related projects are funded under the EU's Horizon 2020 research program, and the European Investment Bank (EIB) is promoting projects to increase access to healthcare and social and economic cohesion in the EU, including through the European Fund for Strategic Investments, launched in 2015.

In the area of network building, the Patient Mobility Directive set important milestones in 2011, particularly the creation of the ERNs. The ERN initiative aims to bring together existing EU-wide expertise by linking centers of expertise and healthcare providers, with a specific focus on improving diagnosis and treatment strategies for rare diseases. The Commission primarily provides operational support, and is responsible for funding basic coordination work. Member states' participation in ERNs is voluntary. Following the first call for ERNs, a total of 24 reference networks were set up in March 2017, involving more than 300 hospitals in 25 EU member states plus Norway.[65] Greece and Malta are seeking to participate with the next round of calls. The ERNs have great potential for further development in the short and medium term if they succeed in consolidating the newly created networks.

The participating EU member states should also work to use the data obtained (taking into account the necessary data security requirements) for further research, epidemiological surveillance, and the development of guidelines for successful treatment and quality standards. In addition to the potential for gathering diagnostic and

scientific knowledge, the comprehensive networking of physicians and experts carries an additional value for individual patients, who benefit from the pooling of expertise regarding their treatment options, and physicians, who can exchange their expertise more easily and regularly in areas with few domestic experts.

ERNs also help build trust between relevant actors. Many health care providers want to use ERNs to support new treatments and provide insight into more common diseases. One of the biggest challenges is integrating ERNs into national health systems, meaning the sustainability of this cooperation initiative depends substantially on the sustained commitment of the member states themselves. The decisive factor will be their desire to promote the necessary coordination for the harmonization and interoperability of standards and procedures – for example, reimbursement of costs and ICT systems.

The potential and added value of European support measures – especially in networking and research funding – should be obvious. However, representatives of the EU member states at national, regional, and local levels, as well as numerous non-governmental stakeholders at various levels, criticize the procedures and structures of European funding and networking strategies, citing in particular the complexity of EU procedures and the tendency not to sufficiently involve stakeholders at an early stage, along with their extensive bureaucracy, limited lifetimes, and the lack of empirical data concerning the sustainability and long-term effects of individual projects.

In addition, as in many other policy areas, Brexit poses key challenges in the health sector, including maintaining the quality of existing research networks and providing a comparable level of financial and human resources in the future. In order to bridge the Brexit transition phase as easily as possible, the EU-27, and Germany in particular, should further increase their involvement in research funding and research cooperation in the short and medium term. This does not only apply to existing structures and networks; Germany and the EU-27 should also provide financial resources for future EU research projects that promise European added value.

Certain member states and groups of member states could also take on specific responsibilities in areas where they have particular expertise or see particular added value. In the same way, they could take leading roles in the continuation and development of existing projects. The creating of such open and flexible clusters of expertise would increase the sense of ownership on the part of the member states, and thus strengthen the sustainability of structures. Moreover, such a structure would complement the Commission's work, and relieve it of a certain degree of its responsibility for implementation. Of course, this cannot result in individual countries being excluded from networks or research projects. The structure of the ERNs, which are organized with the help of network coordinators connected to hospitals and research institutes, could serve as a model. Great Britain and the Netherlands, as well as Germany and France, are already visibly represented within the ERNs; Germany, for example, provides four of the 24 network coordinators. In principle, efforts should be made to create collaborations and networks that are as inclusive as possible. The European Commission should therefore stick to the structure of Horizon 2020, the third pillar of which supports collaborative research projects.

Germany should also participate in the negotiations concerning the next Multiannual Financial Framework to ensure that health is maintained as a separate budget item to avoid reductions in the funding aimed at harmonizing health levels within the EU. In terms of specific content, the EU should aim to maintain a balance between economic and socio-political innovation with regard to research cooperation and funding of Joint Actions. The focus should be on issues with pan-European added value, such as the consequences of demographic change, global and cross-border health risks, patient safety, antibiotic resistance, digitization, and the management of rare diseases; in order to avoid duplication, there should be some level of coordination governing which priorities should be promoted at the EU level and which could be better addressed by the WHO or the UN. Global trends should also be taken into account and anticipated in order to predict how they might affect the performance of health-related multilateral organizations. For example, if the US gradually withdraws from the WHO – and other countries respond by modifying their priorities commensurately – the EU should become more involved in certain areas.

6.6 Global Health

Global health is a policy that addresses the health challenges of an increasingly globalized world. It includes development policy issues, the fight against cross-border health threats, and governance issues. The Commission defines global health as the "worldwide improvement of health, reduction of disparities, and protection against global health threats."[66] The EU's ability to act externally is directly related to its ability to act internally; weakening liberal regulatory structures have a negative impact

on global health, as the UN and WHO are central arenas of global health policy.

In this context, the US' reductions to its commitments to global health are immediately visible. It has already planned budget cuts for the Centers for Disease Control and Prevention (CDC), and re-introduced the "Global Gag Rule", which states that the US will not provide financial assistance to NGOs offering or advising on abortions.[67]

The EU is increasingly active in foreign policy in the field of global health, in particular in the wake of health crises such as BSE and the H1N1 pandemic in 2009.[68] Measures already initiated and implemented include, for example, the Medical Corps, which can be deployed to worldwide health crises, the epidemiological training programs of the European Centers for Disease Control and Prevention (ECDC), and the financing of the SHIPSAN and AIRSAN projects to improve airborne and maritime disease control. The EU also supports the Universal Health Coverage Partnership, which seeks to improve health coverage in 35 partner countries by strengthening political dialogue, health care capacity, and financial resources.[69]

Despite these initiatives, the EU's commitment to global health is not consistent. As with other EU health activities, this is partly due to the cross-cutting nature and fragmentation of the policy area, as well as a lack of coordination. The EU is a "patchwork actor"[70], with its competencies dispersed among different organizations and grounded in various legal texts. Overall, the EU's legal competencies in the area of health remain limited; the individual member states themselves are instead the key players in global health.

In addition to Germany, countries such as Great Britain – which has had its own global health strategy since 2014 – along with France, the Netherlands, Belgium, Spain, Finland, Denmark, and Sweden are very active in global health, though with different understandings of what that entails. While Spain, Denmark, and Belgium in particular emphasize global justice as their main reference framework in global health, the Netherlands, the United Kingdom, France, and Germany also emphasize security and investment aspects.[71] As a result of these different priorities, the EU has so far failed to exploit its potential collective influence. This is evidenced by the fact that the EU has not yet effectively translated its weight into political influence, even though its member states hold a not inconsiderable share of the vote weight in the UN institutions and are among the largest donors to development projects. This applies equally to the WHO, where the EU is also not seen as an effective actor despite holding observer status.

A new, proactive global health strategy for the EU

The EU set the strategic basis for its current global health policy in the 2010 Commission Communication on Global Health Policy and the subsequent Council conclusions. The Council agrees with the four priorities set by the Commission, which include: improving global governance, advancing universal health coverage, increasing coherence within the EU, and promoting expertise that is accessible to all.[72] So far, however, these priorities have not developed sustainable momentum, and seem to have generally been forgotten – the EU Global Strategy 2016, for example, does not even mention global health. It is thus difficult to say that the EU has any consistent strategic orientation regarding its role in global health.

In light of this problem and the challenges outlined above, a new, pro-active global health strategy should be developed. The EU should use it to outline its future role in global health, and prioritize and coherently align its policies. To ensure that the priorities developed are not forgotten once again, the European Council and the European Parliament should be closely involved in the development of this strategy. Similarly, a variety of academic and civil society stakeholders should be involved to give the strategy momentum and broad acceptance. The Global Health Policy Forum, which the Commission organizes four times a year to stimulate exchanges between different health stakeholders, could offer an appropriate format. A new European Global Health Strategy should be multisectoral and multidisciplinary, linking the internal and external dimensions of health issues. In order to enhance its international credibility, the EU should also take action to improve the level of health care within the European Neighborhood.

In its new global health strategy, the EU should also continue to pursue its value-based approach. To this end, it should promote better global health care in its development policy, as well as in international organizations, sustainably strengthening health systems and framing them as part of a human rights-based approach. At the same time, the EU should use its economic power to establish standards and norms in global competition, for example by enshrining high health standards in multilateral trade agreements. The environmental dimension of health, including protection against environmental risks that are harmful to human health, should also be further integrated into its future strategy. Here the EU could assume a global leadership role, filling the vacuum that has arisen

with the US withdrawal from the Paris Climate Agreement. In addition, given current geopolitical changes, a concrete roadmap for strengthening cooperation with international multilateral organizations – in particular the UN – is needed to develop a sustainable vision for global governance, including in the area of health.

The impetus for the development of a new global health strategy should come primarily from the EU member states in order to strengthen the initiative. As the largest and economically strongest member state, Germany could play a leading role in agenda setting at the EU level, for example in the context of the German Council presidency in 2020. Berlin has shown a strong commitment to global health in recent years – especially in the context of its G7 and G20 presidencies. Moreover, the coalition agreement announced the government's intention to develop a national strategy for global health. Synergies within this process could also be useful at the EU level.

The EU should continue to improve the coordination and coherence of its existing actions, and consider setting up a Global Health Coordination Center, which could be located within the European External Action Service. The coordinating body could focus on EU action in the field of global health, and when necessary coordinate and review its focus and the priorities it has set. It would work closely with the various Directorates-General and EU agencies, and serve as a point of contact to disseminate information internally and externally, bringing together different actors in the field of global health. Such a coordinating body would also have the advantage of occupying the issue of global health at the EU level, without requiring any new transfer of competence.

The EU should also prepare for emergencies by promoting efforts to combat impending health crises. Antibiotic resistance, the growing global burden of disease from noncommunicable diseases, and the risk of the rapid spread of infectious diseases in an increasingly interconnected world are challenges that should be urgently addressed in its global health strategy. The European Commission has already taken important steps in its action plan against antibiotic resistant disease, which it adopted in 2017. The UK, Sweden, and the Netherlands were among the initiative's leading supporters, and Germany and France have intensified their commitments. Regarding noncommunicable diseases, which are an increasingly large global health problem, the EU should strengthen its preventive measures and become a best practice region.

With the Ebola outbreak in West Africa and the recent Zika crisis, the potential danger of rapidly spreading infectious disease has attracted more and more attention among political decision-makers. The EU's response to Ebola has often been criticized as being too uncoordinated and too slow compared to the US government's financially strong and professionally coordinated response.[73] In order for the EU to be more effective in the future, the mandate and funding of the European Center for Disease Control and Management should be expanded, especially when it comes to the prevention and monitoring of health crises; this is increasingly urgent as the US cuts funding for its own Centers for Disease Control and Prevention, not least so the EU can protect its own people.

7. Recommendations for German Health Policy

In the area of health policy, the EU is under considerable pressure for the social, political and economic reasons outlined above. At the same time, the future orientation of the policy field is uncertain and lacks an overall strategy. Member states have thus far failed to agree on a future direction for an EU health agenda. As noted above, many smaller states are promoting more Europeanization in the area of health policy, and support further solidarity in the form of financial support, either to achieve greater economies of scale – as in Belgium, Ireland, Malta, Luxembourg, Estonia, and the Netherlands – or to combat pressing systemic challenges like brain drain and health inequality in countries like Romania, Hungary, Portugal, and Greece. Larger member states, in particular those with strong traditions of self-governance in health policy or strong regions and decentralized health policymaking, are more skeptical about stronger cooperation. For this reason, sub-regional and voluntary cooperation formats that include only smaller groups of EU countries are increasingly prevalent.

Due to its size and its system of self-governance in the area of health policy, Germany is among the skeptical member states. However, citing limited EU competencies, Germany has abstained more fundamentally from any discussions about stronger future EU cooperation than the other EU member states, regardless of their size, business structure, and financial strength.

In addition to the EU's internal policy-related disagreements, Brexit and various other crises and challenges are forcing the EU to confront the question of how limited resources can be used to finance and implement an increasing number of priorities. This has led to controversy over the sustainability, proportionality and efficiency of existing European health initiatives and instruments. It is uncertain whether DG SANTE or the Union's health pro-

gram will continue to exist in their current forms under the next European Commission.

In light of existing uncertainties concerning the institutional form, resources, and direction developing EU health policy should take, Germany should bring its position more into line with its aspiration to play a leadership role in Europe, and play a more active role in formulating, implementing, and supporting a European health agenda. The German Council presidency in 2020 offers the ideal opportunity for this: Germany should be involved in shaping a forward-looking policy that allows the EU to act in solidarity and promote convergence on health-related issues. In doing so, it should make a positive contribution to innovation and competitiveness in the health care sectors, and help make the EU more effective, both internally and externally.

Specifically, the German government might consider the following policy recommendations.

(A) Short-Term Recommendations

1. **Develop a pan-European, pro-active strategy:** In the context of the Multiannual Financial Framework 2021-2027 negotiations, the German government should adopt a less restrictive approach to EU health policy that is compatible with its overarching European policy approach. Health policy should not be considered in isolation; German positioning should instead reflect the cross-cutting nature of the policy area. This requires stronger internal German coordination: (1) within the Federal Ministry of Health, (2) between the various Federal Ministries, (3) between the Federal Government and the Bundesländer, (4) and between government bodies, bodies of self-governance, and relevant stakeholders.
2. **Establish its reliability as an EU partner:** So far, the German government has not adequately outlined its approach to EU health policy issues and has not been part of pro-active coalitions, and was therefore often perceived as a stumbling block. In order to overcome this reputation, it should therefore visibly and transparently communicate whether and where Germany sees room for a stronger EU dimension and more European cooperation. Since Article 168 (7) TFEU does not provide an absolute legal barrier to the Europeanization of health policy, the German position and its underlying reasoning should go beyond references to EU competencies and include political arguments. For the negotiations concerning the next MFF, Germany should identify core areas to be strengthened or maintained at the EU level, such as ERNs and other networks for information exchange and coordination, along with global health and e-health.
3. **Demonstrate solidarity:** For many member states, especially the smaller ones with limited resources, the Commission is seen as an important partner for gaining visibility at the EU level and promoting their own initiatives. In order to prevent unwanted interference in its health sector – even interference "through the back door" – Germany should think about ways to preemptively integrate these countries in inclusive health policy approaches. Germany should therefore more pro-actively engaged in voluntary cooperation initiatives, dealing with strategic health related topics and engaging in the MFF negotiations on sustainable health-related financial instruments that benefit structurally disadvantaged member states.
4. **Build and maintain partnerships:** The German government should strengthen and explore options for more in-depth cooperation with established partners - especially in the context of Brexit, as Germany will lose its most important health policy partner in the EU. This applies in particular to cooperation with France and the Benelux and Nordic countries; but areas of potential cooperation should also be explored with strategically important countries like Poland, even as the countries struggle to cooperate in other policy areas. Possible areas of cooperation could include digitization, innovation promotion, prevention, and research cooperation.
5. **Keep Brexit in mind:** As in all other policies, European health policy must prioritize mitigating the negative consequences of Brexit. The UK's exit will have a significant impact on mobility, research cooperation, ERNs, marketing authorization of medicines, and European engagement in global health. For Germany, aside from increasing spending and the provision of expertise and other human resources, this means that efforts to maintain intra-European cohesion and solidarity-based European policies must be reiterated.

(B) Middle- and Long-Term Recommendations

1. **Stronger coordination and use of data:** Germany should work together with other EU actors to strengthen the coordination of health-related activities in the different areas – meaning health policy, but also internal market policy, research policy, and economic governance. Spill-over effects can only be anticipated, and potential economies of scale exploited, if the cross-cutting nature of health is taken into account. Increased coordination is needed both within the Com-

mission and between member states and emerging sub-regions. This is connected to the need to build and maintain a sustainable database in order to be able to better assess the medium- to long-term effectiveness of European funding and initiatives like Joint Actions.

2. **Strengthen social and economic convergence:** Germany should continue to work with its EU partners to respond to the growing economic and social divergences that threaten the EU's political legitimacy and the cohesion of the Union. If conditions between member states continue to diverge, it will pose a significant political threat, and jeopardize the fundamental continuity of the economic and monetary union and the EU-27 in the medium and long term. In concrete terms, these divergences include access to affordable, good health care, poverty-related health risks, and the systematic brain drain of healthcare professionals. Declining social and economic convergence would also severely affect the credibility of the EU in the enlargement process, as well as within multilateral organizations and in negotiations with third countries. The EU should continue to think about the social dimension of the economic and monetary union, and complement coordination processes within the European Semester with targeted support measures based on Article 168 (5) TFEU, which aims at reducing health inequalities in the EU.
3. **Extend and consolidate existing networks:** The ERNs, which are considered both useful and expandable by a majority of health care stakeholders, should be preserved and utilized to their full potential. In addition to providing the necessary resources, the EU should continue to support their evaluation processes, with the goal of identifying opportunities for interoperability and standardization and responding to them efficiently. In doing so an inclusive approach should be pursued, involving European, national, and regional stakeholders from an early stage.
4. **Understand health system differences as opportunities:** Tools for health system comparison – as with similar instruments used in the Economic Governance context – should be seen as an opportunity, not a threat. The creation of appropriate, comparable indicators in connection with Horizon Scanning efforts to detect challenges to national health systems should not be misconstrued as harmonization efforts; rather, they provide valuable input for European initiatives (for example in the area of standardization and interoperability) and national reforms. Eurobarometer surveys, as well as the results of policy background discussions, show that a better understanding of how different health systems function and how national conditions diverge within the EU is urgently needed in the health sector.
5. **Strengthen health foreign policy and communication:** Against the background of a shifting global balance of power and increasing global connectivity, the EU should strengthen its external health policy and formulate a new global health strategy. To ensure that the priorities developed are not forgotten, the process should be as inclusive as possible, and involve the EU institutions and relevant stakeholders from an early stage. Germany should play a leading role in this process, building on the profile it developed during its G7 and G20 presidencies. This includes the optimization of EU communication structures in order to make contributions to crisis management and European neighborhood development more visible and transparent. An improved image of EU efficacy will make member states more willing to coordinate and devote the resources necessary to further enhance its role.

Notes:

1 European Commission, The European Pillar of Social Rights in 20 principles, <https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights/european-pillar-social-rights-20-principles_de> (accessed on 09.04.2018).

2 German government, coalition agreement between CDU, CSU, and SPD, 19th legislative period, 14.03.2018, < https://www.bundesregierung.de/Content/DE/_Anlagen/2018/03/2018-03-14-koalitionsvertrag.pdf?__blob=publicationFile&v=2>, (accessed on 09.04.2018), pp. 96-103.

3 Ibid, p. 6; German government, government statement, <https://www.bundesregierung.de/Content/DE/Artikel/2018/03/2018-03-21-reg-erkl-kanzlerin.html> (abgerufen am 09.04.2018).

4 See for example Mary Guy und Wolf Sauter, The History and Scope of EU Health Law and Policy, CCP Working Paper 16-02, 2016, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2718045 (accessed on 14.08.2018); Thorsten Kingreen, Eine neue Strategie für eine europäische Gesundheitspolitik (A New Stategy for a European Health Policy): Discussion paper for the German Council on Foreign Relations, 2017, Edition 1; Winfried Kluth, Workshop discussion paper: Eine neue Strategie für europäische Gesundheitspolitik (A New Strategy for a European Health Policy), 2017, Edition 2, S. 13-17.

5 Eurostat, People in the EU – Statistics on Demographic Changes, data from July 2017, <http://ec.europa.eu/eurostat/statistics-explained/index.php/People_in_the_EU_–_statistics_on_demographic_changes> (accessed on 09.04.2018).

6 European Commission, Report, Seminar on "Strategic investments for the future of healthcare", 27.02.2017, <https://ec.europa.eu/health/sites/health/files/investment_plan/docs/ev_20170227_mi_en.pdf>, (accessed on 09.04.2018); OECD / European Commission, Health at a Glance: Europe 2016 - State of Health in the EU Cycle 2016, in: OECD Publishing, 23.11.2016, <https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe-2016_9789264265592-en> (accessed on 09.04.2018), S.116.

7 Ibid, S.10.

8 OECD, Healthcare costs unsustainable in advanced economies without reform, 24.09.2015, <http://www.oecd.org/health/healthcarecostsunsustainableinadvancedeconomieswithoutreform.htm> (accessed on 09.04.2018).

9 Bank for social economy, Shortage of skilled workers in health care: Recruitment of foreign caregivers, Brussels July 2015, <https://www.eufis.eu/fileadmin/Dokumente/EU-Politik/2015_07_Fachkräfte_im_Gesundheitswesen.pdf> (accessed on 09.04.2018).

10 European Commission, State of Health in the EU – Companion Report 2017, 2017, <https://ec.europa.eu/health/sites/health/files/state/docs/2017_companion_en.pdf> (accessed on 12.04.2018), p. 53.

11 European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry in Figures: Key Data, 2017, < https://www.efpia.eu/media/219735/efpia-pharmafigures2017_statisticbroch_v04-final.pdf (accessed on 09.04.2018), p. 4.

12 MedTech Europe, The European Medical Technology Industry - in figures / 2018, <http://www.medtecheurope.org/sites/default/files/resource_items/files/MedTech%20Europe_FactsFigures2018_FINAL_0.pdf> (accessed on 09.04.2018), p. 19.

13 Verzijl, Dervojeda, Probst & Frideres / European Commission, The Internet of Things: Smart Health, Business Innovation Observatory, Case Study 46, February 2015, <https://ec.europa.eu/eip/ageing/sites/eipaha/files/library/553de49941f48_Business%20Innovation%20Observatory%20-%20Smart%20Health.pdf> (accessed on 09.04.2018).

14 Eurostat, Health Personnel Statistics – physicians, Datenauszug vom September 2017, <http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_personnel_statistics_-_physicians> (accessed on 09.04.2018).

15 European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry in Figures (see note 11), p.4; MedTech Europe, The European Medical Technology Industry - in figures / 2018 (see note 12), p. 15.

16 This sketch concerning the intra-EU lines of conflict is based primarily on workshops and background discussions conducted in the framework of the DGAP project "A new strategy for European health policy" conducted from September 2017 to April 2018 in Berlin and Brussels. Discussion partners included representatives of the Federal Ministry of Health, health attachés and ministry representatives of other EU member states, representatives of the European Commission from various directorates-general, European business and civil society stakeholders, and academics. A complete, detailed analysis of different positions of EU member states, stakeholders, and EU institutions cannot be included here; for this purpose, additional scientific research would be required.

17 Eurobarometer, Perceptions and expectations, fight against terrorism and radicalization (QA), Special Euroba-rometer of the European Parliament 85.1, 2016, <http://www.europarl.europa.eu/pdf/eurobarometre/2016/attentes/eb85_1_synthesis_perceptions_wishes_terrorism_en.pdf> (accessed on 16.04.2018).

18 Martin Schölkopf and Holger Pressel, Das Gesundheitswesen im internationalen Vergleich: Gesundheitssystemvergleich, Länderberichte und europäische Gesundheitspolitik (An international comparison of health services: Health system comparisons, country reports, and European health policy), 3rd edition, Medizinisch Wissenschaftliche Verlagsgesellschaft, 2017, p. 257.

19 Kingreen, Eine neue Strategie für eine europäische Gesundheitspolitik (A new strategy for a European health policy) (see note 4).

20 Schölkopf and Pressel, Das Gesundheitswesen im internationalen Vergleich (An international comparison of health services), (see note 18), pp. 257-258.

21 Kingreen, Eine neue Strategie für eine europäische Gesundheitspolitik (A new strategy for a European health policy)(see note 4), p. 12-21.

22 InfoCuria, Decker Urteil des Gerichtshofes (Decker ruling), 28 April 1998, <http://curia.europa.eu/juris/showPdf.jsf;jsessionid=9ea7d0f130defefbbee642ec4d538138cde43348bebc.e34KaxiLc3eQc40LaxqMbN4Pb38Pe0?docid=43791&pageIndex=0&doclang=DE&mode=req&dir=&occ=first&part=1&cid=352624> (accessed on 10.04.2018); Frank Schulz-Nieswandt, Gesundheitspolitik (Health policy), in: Europa von A bis Z: Taschenbuch der europäischen Integration, Nomos Verlag, 2014, pp. 277-279.

23 Kingreen, Eine neue Strategie für eine europäische Gesundheitspolitik (A new strategy for a European health policy) (see note 4), pp. 18-20.

24 Ibid.

25 Schölkopf and Pressel, Das Gesundheitswesen im internationalen Vergleich (An international comparison of health services), (see note 18), pp. 257-258.

26 European Commission, Working documents of the Commission: Social scoreboard accompanying documents, communication from the commission to the European Parliament, Council, European Economic and Social Committee, and the Committee of Regions, Brussels 26.04.2017, <http://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52017SC0200&from=DE> (accessed on 09.04.2018); European Commission, headlines: European Semester – Winter package, 07.03.2018, <http://ec.europa.eu/social/main.jsp?langId=de&catId=89&newsId=9063&furtherNews=yes> (accessed on 09.04.2018).

27 Kingreen, Eine neue Strategie für eine europäische Gesundheitspolitik (A new strategy for a European health policy) (see note 4), p. 27.

28 Schulz-Nieswandt, Gesundheitspolitik (Health policy), (see note 22), pp. 277-279.

29 Matthias Pechstein, Diskussionspapier zur Skizzierung des europarechtlichen Spielraums bei der Europäisierung von Gesundheitspolitik (Discussion paper sketching out European options for the Europeanization of health policy), third edition, 2017, p. 16.

30 European Commission, white paper, Together for Health: A Strategic Approach for the EU 2008-2013, Brüssel 23.10.2007, <https://ec.europa.eu/health/sites/health/files/policies/docs/whitepaper_en_0.pdf>, (accessed on 09.04.2018).

31 European Commission, press release, Q&A on the third Health Programme 2014-2020, Brüssel 26.02.2014, <http://europa.eu/rapid/press-release_MEMO-14-139_en.htm>, (accessed on 09.04.2018).

32 European parliament, Briefing Health and Social Security, 2016, <http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/583865/EPRS_BRI(2016)583865_EN.pdf> (accessed on 12.04.2018).

33 European Commission, Factsheet, Funding under the 3rd Health Programme 2014-2020, <http://ec.europa.eu/chafea/documents/health/hp-factsheets/joint-actions/factsheets-hp-ja_en.pdf>, (accessed on 09.04.2018).

34 European Commission, Webinar, Joint Action – Annual Work Programme 2017, Luxembourg 30.03.2018, <http://ec.europa.eu/chafea/documents/health/ja-awp-2017-303103_en.pdf> (accessed on 09.04.2018); EuroHealthNet, Joint Actions, <https://eurohealthnet.eu/hpe/joint-actions>(accessed on 09.04.2018).

35 Timo Clemens, Kristine Sørensen, Nicole Rosenkötter, Kai Michelsen, and Helmut Brand, The Directorate-General for Health and Consumers 1999–2014: An assessment of its functional capacities, in: Health Policy 121, 2017, <http://www.healthpolicyjrnl.com/article/S0168-8510(17)30093-3/pdf> (accessed on 10.04.2018), pp. 594-603.

36 European Commission, Vorschlag für eine Richtlinie des Europäischen Parlaments und des Rates über eine Verhältnismäßigkeitsprüfung vor Erlass neuer Berufsreglementierungen (Proposal for the European Parliament and Council regarding propriety guidelines for new occupational regulations), COM(2016) 822 final, Brussels 10.01.2017, <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52016PC0822&from=DE> (accessed on 21.08.2018).

37 The points of criticism included here came up in workshops and confidential background discussions with representatives of various EU member states.

38 Council of the European Union, Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, 17.06.2016, <http://www.consilium.europa.eu/de/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/> (accessed on 09.04.2018).

39 Council of the European Union, Draft of council conclusions on strengthening cooperation initiatives between member state health systems, Brussels 09.06.2017, (Adopted 16.06 2017), <http://data.consilium.europa.eu/doc/document/ST-9978-2017-REV-1/de/pdf> (accessed on 09.04.2018).

40 Programme of the Republic of Bulgaria for the Presidency of The Council of the European Union, 2018, <https://eu2018bg.bg/en/programme> (accessed on 10.04.2018), pp. 29-30.

41 The members of the Valetta Coalition are Malta, Cyprus, Greece, Italy, Spain, Portugal, Romania, Ireland, Croatia, and Slovenia. France has observer status. See: Sarantis Michalopoulos, EU southern alliance on drug pricing expands, 01.02.2018, <https://www.euractiv.com/section/health-consumers/news/eu-southern-alliance-on-drug-pricing-expands/> (accessed on 10.04.2018).

42 The BeNeLuxA Initiative – Collaboration on pharmaceutical policy, Terms of Reference, Annahme am 01.03.2017, <http://www.beneluxa.org/sites/beneluxa.org/files/2017-07/BeneluxA_Terms_of_References_final_0.pdf> (accessed on 09.04.2018).

43 Hungarian Presidency of the Visegrad Group, V4 Connects, Presidency Program, 2017, <http://www.visegradgroup.eu/documents/2017-2018-hungarian/20172018-hungarian> (accessed on 10.04.2018), pp. 13, 23-24.

44 Emma Eatwell, Voluntary cooperation between health systems: are we getting the balance right?, 03.01.2018, <https://www.hanovercomms.com/2018/01/03/voluntary-cooperation-health-systems-getting-balance-right/> (accessed on 10.04.2018).

45 Council of the European Union, Draft of minutes, edition: 3548. Daily meeting of the Council of the European Union (Employment, social policy, health, and consumer protection), annex, German edition, 29.06.2017 (from 15/16 June 2017 in Luxembourg), <http://data.consilium.europa.eu/doc/document/ST-10375-2017-INIT/de/pdf>, (accessed on 09.04.2018), p. 11.

46 Official Journal of the European Union, Directive 2011/24 / EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, adopted on 9.03.2011, <http://eur-lex.europa.eu/LexUriServ/LexUServ.do?uri=OJ:L:2011:088:0045:0065:de:PDF> (accessed on 10.04.2018).

47 Eurobarometer, Patient rights in cross-border healthcare in the European Union, Special Eurobarometer 425, 2015, <http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_425_sum_de.pdf> (accessed on 09.04.2018), pp. 5, 9-17.

48 For a summary, see for example: European Commission, European Cross-Border Cooperation on Health: Theory and Practice, 2017, <http://ec.europa.eu/regional_policy/en/information/publications/brochures/2017/european-cross-border-cooperation-on-health-theory-and-practice> (accessed on 09.04.2018) or: European Commission, Study on Cross-Border Cooperation: Capitalising on existing initiatives for cooperation in cross-border regions, 2018, <https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2018_crossbordercooperation_exe_en.pdf> (accessed on 09.04.2018).

49 OECD / European Commission, Health at a Glance (see note 6).

50 Irene A Glinos, Matthias Wismar, James Buchan und Ivo Rakovac, How can countries address the efficiency and equity implications of health professional mobility in Europe?, Policy Brief 18, 2015, <http://www.euro.who.int/__data/assets/pdf_file/0008/287666/OBS_PB18_How-can-countries-address-the-efficiency-and-equity-implications-of-health-professional-mobility-in-Europe.pdf?ua=1> (accessed on 09.04.2018); Tim Ball and Ginger Hervey, The EU exodus: When doctors and nurses follow the money, in: POLITICO, 27.09.2017, <https://www.politico.eu/article/doctors-nurses-migration-health-care-crisis-workers-follow-the-money-european-commission-data/> (accessed on 09.04.2018).

51 European Commission, Commission Staff Working Document on an Action Plan for the EU Health Workforce, 2012, <https://ec.europa.eu/health/sites/health/files/workforce/docs/staff_working_doc_healthcare_workforce_en.pdf> (accessed on 10.04.2018).

52 Health Work Force, <http://healthworkforce.eu/> (accessed on 10.04.2018); Maria Kroezen, Michel Van Hoegardaen, The Joint Action on Health Workforce Planning and Forecasting: Results of a European programme to improve health workforce policies, in: Health Policy, February 2018, Vol. 122, Nr. 2, pp. 87-93.

53 World Health Organisation, WHO Global Code of Practice on the International Recruitment of Health Personnel, <http://www.who.int/hrh/migration/code/WHO_global_code_of_practice_EN.pdf> (accessed on 10.04.2018).

54 eHealth Network, Guideline on the electronic exchange of health data under Cross- Border Directive 2011/24/EU: ePrescriptions and eDispensations, accepted on 21.11.2016 in Brussels,<https://ec.eropa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf> (accessed on 10.04.2018).

55 European Parliament, Briefing eHealth – Technology for health, 12.03.2015, <http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_BRI(2015)551324> (accessed on 10.04.2018).

56 European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 25.04.2018, <https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering> (accessed on 14.08.2018); European Commission, Synopsis Report, Consultation: Transformation Health and Care in the Digital Single Market, 2018, <https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_consultation_dsm_en.pdf> (accessed on 10.04.2018).

57 Council of the European Union, Social Policy, Health and Consumer Affairs Council meeting on 8 December 2017, Draft Council conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health, accepted on 08.12.2017 in Brussels, <http://data.consilium.europa.eu/doc/document/ST-14078-2017-INIT/en/pdf> (accessed on 10.04.2018).

58 European Commission, eHealth, <https://ec.europa.eu/cefdigital/wiki/display/CEF-DIGITAL/2017/05/30/eHealth> (accessed on 10.04.2018).

59 Eurobarometer, Attitudes towards the impact of digitisation and automation on daily life, Special Eurobarometer 460, 2017, <http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2160> (accessed on 10.04.2018).

60 Sarah-Lena Böning and Remi Maier-Rigaud, Gesundheits- und Verbraucherpolitik (Health and Consumer Policy), in: Jahrbuch der Europäischen Integration (Yearbook of European Integration), Nomos Verlag, Baden-Baden, 2017, pp. 265-268.

61 Ibid.

62 Sarantis Michalopoulos, Commission reassures 'worried' member states on Health Technology Assessment, in: Euroactiv, 10.01.2018, <https://www.euractiv.com/section/health-consumers/news/commission-reassures-worried-member-states-on-health-technology-assessment/> (accessed on 10.04.2018).

63 Paul Dallison and Sanya Khetani-Shah, POLITICO Brexit Files: Repeal Bill timetable — Drug diplomacy — Merkel's warning, in: Politico, 07.04.2017, < https://www.politico.eu/newsletter/brexit-files/politico-brexit-files-repeal-bill-timetable-drug-diplomacy-merkels-warning/> (accessed on 16.04.2018).

64 European Parliament, Briefing Health and Social Security, (see note 32).

65 European Commission, ERNs, 2017, https://ec.europa.eu/health/sites/health/files/ern/docs/2017_brochure_en.pdf (accessed on 10 April 2018).

66 European Commission, GD Gesundheit und Lebensmittelsicherheit, Globale Gesundheitspolitik (General Directorate, Health and Food Safety, Global Health Policy), <https://ec.europa.eu/health/international_cooperation/global_health_de> (accessed on 27. 03.2017).

67 Daniela Braun, US Retreats From Its Lead on Epidemic Preparedness, June 2017, <https://yaleglobal.yale.edu/content/us-retreats-its-lead-epidemic-preparedness> (accessed on 10 April 2018).

68 Thea Emmerling and Andrzej Rys, The Development of EU Health Policy: Treaty Basis, Health Acquis and History, in: Thea Emmerling, Ilona Kickbusch und Michaela Told (Hrsg.), The European Union as a Global Health Actor, World Scientific Publishing Co. Pte. Ltd., Singapur 2016, pp. 21-91.

69 Universal Health Coverage: http://uhcpartnership.net/about/ (accessed on 17.04.2018).

70 Emmerling and Rys, The Development of EU Health Policy: Treaty Basis, Health Acquis and History, in: Thea Emmerling, Ilona Kickbusch and Michaela Told (Hrsg.), The European Union as a Global Health Actor, World Scientific Publishing Co. Pte. Ltd., Singapur 2016, pp. 21-91.

71 Remco Van de Pas, Lies Steurs, Sarah Delputte and Jan Ordie, The Global Health Policies of the EU and its Member States: A Common Vision?, in: Odermatt und Van den Sanden (Hrsg.), The EU and its Member States in the World: Legal and Political Debates, Proceedings of the Interdisciplinary Doctoral Colloquium „The EU as a Global Actor", Working Paper No. 185, July 2017, pp. 10-23.

72 Council of the European Union: Council conclusions on the EU role in Global Health, 10 May 2010, http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/EN/foraff/114352.pdf (accessed on 17 April 2018); Europäische Kommission, GD Gesundheit und Lebensmittelsicherheit, Globale Gesundheitspolitik, <https://ec.europa.eu/health/international_cooperation/global_health_de> (accessed on 27. 03.2017).

73 Elizabeth Speakman, Martin McKee and Richard Coker, If not now, when? Time for the European Union to define a global health strategy, in: The Lancet, April 2017, Vol. 5, pp. 392-393.

Sources: Icons in Figure 2:
Cogwheel: Anastasya Bolshakova, Creative Commons (Attribution 3.0 Unported)
Link to her webite on Iconfinder: https://www.iconfinder.com/nastu_bol
Link to licence: https://creativecommons.org/licenses/by/3.0/

Erlenmeyer flask: Aleksandr Reva (https://www.iconfinder.com/Revicon)
Syringe/pills: Jenny Kate (https://www.iconfinder.com/JennyKate911)

DGAP**analyse** / Nr. 6 / September 2018

Dieses Werk ist lizenziert unter einer Creative Commons **Namensnennung – Nicht kommerziell – Keine Bearbeitungen** 4.0 International Lizenz.
This work is licensed under a Creative Commons ***Attribution – NonCommercial – NoDerivatives*** *4.0 International License.*

Deutsche Gesellschaft für Auswärtige Politik
German Council on Foreign Relations

The opinions expressed in this publication are those of the authors and do not necessarily reflect the views of the German Council on Foreign Relations (DGAP).

Rauchstraße 17 / 18 · 10787 Berlin
Tel. +49 (0)30 25 42 31 -0 / Fax -16
info@dgap.org · www.dgap.org

Publisher
Deutsche Gesellschaft für Auswärtige Politik e.V.

ISSN 1611-7034

Translation Josh Raisher
Edited by Eva-Maria McCormack
Layout Reiner Quirin
Design Concept Carolyn Steinbeck · Gestaltung