German State Aid for Covid-19 Medicinal Products: A Risk for Solidarity in the European Union

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Abstract

To respond to the need for a vaccine against and a treatment for Covid-19, the German Federal Government used various economic incentives to promote pharmaceutical and biotechnological research and development (R&D) as well as manufacturing. More specifically, it decided to subsidise several German companies working in this field. Such domestic measures might, however, present a challenge to European state aid law. It is against this backdrop that this article discusses the compatibility of the payments made with the new ‘crisis-born’ European legal framework for state aid. Furthermore, the article offers some critical comments on the aid’s effects on solidarity and cohesion in the European Union (EU) and the proposals put forward for expanding the EU’s health policy competencies.

Keywords

medicinal products – Covid-19 – state aid – temporary framework – solidarity – EU Health Union

1 Introducing the Problem

The Covid-19 pandemic, with its dramatic consequences for health, work, and everyday life, has illustrated the importance of an adequate and high-quality supply of medicinal products on a global scale. It here is important to note that pharmaceutical supply during a health crisis does not only require the establishment and maintenance of resilient supply chains for existing essential
medicines – a challenge that was apparent long before the pandemic struck –, but that it was now also of the utmost importance to ensure R&D and the subsequent (mass) production of novel vaccines against SARS-CoV-2. Further, effective medication was and is still needed for those who fall ill without or despite vaccination. Hence, with high-ranking decision-makers like the then German finance minister Olaf Scholz and others declaring they would do ‘whatever it takes’ to successfully manage the crisis,¹ the German government, like many others, started to finance pharmaceutical companies. Partly, this was done in the context of international cooperation,² but mainly within the framework of national initiatives. In total, the various governments spent several billion in US dollars. In doing so, they expanded the approach to crisis management that Mario Draghi had set out quite boldly as head of the European Central Bank to assist troubled businesses and industries and simply extended support to the economically untroubled pharmaceutical sector; it seems that states considered public aid a panacea.

From an EU state aid law perspective, payments made by Member States to domestic firms can pose a threat to the internal market as it may distort competition (cf., Article 107(1) Treaty on the Functioning of the European Union (TFEU)).³ Whether facing a pandemic or not, the EU Commission (Commission) has to limit the negative consequences distorted competition may have on the level playing field of the internal market.⁴ However, the financial market crisis of 2007–2008 first showed that large-scale crisis situations can lead to a temporary relaxation of the Commission’s position on state aid. In the same line, the Commission has, over the last year and a half, starting in March 2020, created and repeatedly amended a Temporary Framework for State Aid Measures to Support the Economy in the Current Covid-19 Outbreak.

¹ A. Funk, ‘Scholz’ persönlicher “Whatever it takes”-Moment’, Der Tagesspiegel (13 March 2020), available online at https://www.tagesspiegel.de/politik/wie-die-bundesregierung-die-wirtschaft-stuetzen-will-scholz-persoenlicher-whatever-it-takes-moment/25642184.html (accessed 29 November 2021).
² Cf., Coalition for Epidemic Preparedness Innovations (CEPI), ‘CEPI gets EUR140 million funding boost from Germany while expanding coronavirus vaccine search’, CEPI (13 March 2020), https://cepi.net/news_cepi/cepi-gets-e140-million-funding-boost-from-germany-while-expanding-coronavirus-vaccine-search/ (accessed 29 November 2021).
³ EU state aid law is also relevant for the European Economic Area (EEA). In the following, Iceland, Liechtenstein and Norway, respectively members of the EEA, are therefore also considered when discussing the ‘Member States’ in the context of state aid law.
⁴ Commission, ‘Coordinated economic response to the Covid-19 Outbreak’, 13 March 2020, COM (2020) 112 final, p. 9: ‘[The Member States] make sure that State aid is effective in reaching those companies in need and that harmful subsidy races are avoided, where Member States with deeper pockets can outspend neighbours to the detriment of cohesion within the EU.’
Framework). On this legal basis, the state aid extended by France, Germany, Ireland, and Italy for Covid-19 medicinal products has not been legally challenged, as can be seen so far.

The point is that these payments raise various issues for European health policy. In other words, the current European legal framework cannot solve certain fundamental problems; in fact, it might even reinforce them. The reason for this lies in the distribution of competencies between the Member States and the EU as regards health policy; in the main they lie with the Member States. It follows that it is, at least at the moment, mainly Member States with a higher GDP and with developed pharmaceutical and biotech industries which drive ‘game-changing’ pharmaceutical innovations as a result of financial grants. The pharmaceutical oligopolies not only provide these Member States with a strong political influence on the European health policy, possibly to the detriment of other Member States, but could also result in a preferential, if not exclusive supply of medicinal products to these Member States, especially if their production was combined with protectionist measures, such as intra-European export restrictions.

Be that as is may, such fragmentation in health protection between Member States endangers solidarity and cohesion within the EU, which is already facing increasing internal discord. This solidarity is a fundamental legal principle of EU law, though, and encompasses such diverse specifications as the principle of loyal cooperation (Article 4(3) Treaty on European Union (TEU)). Moreover, solidarity between Member States is a functional requirement of the EU. Consequently, the legal policy question arises whether the EU, to address the challenges at hand, should be granted more responsibility to govern pharmaceutical R&D and manufacturing, and to thus be able to better control

5 Commission, ‘Temporary Framework for State aid measures to support the economy in the current Covid-19 outbreak’, OJ C 91 I, 20 March 2020, 1–9.
6 Commission Decision SA.57367.
7 More in Section 3.
8 Commission Decision SA.57453.
9 Commission Decisions SA.62576 and SA.65774.
10 Cf., L. van Middelaar, Das europäische Pandämonium (Berlin: Suhrkamp, 2021) p. 100 ff.
11 W. Berg and S. Augsberg, ‘Article 168 AEUV’, in: U. Becker, A. Hartje, J. Schoo and J. Schwarze (eds.), EU-Kommentar, 4th edn. (Baden-Baden: Nomos, 2019) pp. 2295–2311, para. 16.
12 Supra note 10.
13 A. von Bogdandy, ‘Europäische Prinzipienlehre’, in: A. von Bogdandy (ed.), Europäisches Verfassungsrecht (Berlin: Springer, 2003) pp. 149–203 and pp. 182 ff.
14 M. Lais, Das Solidaritätsprinzip im europäischen Verfassungsverbund (Baden-Baden: Nomos, 2007) p. 360.
the management of the pandemic. In a survey conducted by the European Parliament, 69% of the public wanted this at least.\textsuperscript{15}

German aid for Covid-19 medicinal products is a good case in point. After all, Germany is one of the Member States with a higher GDP and a developed pharmaceutical and biotech industry.\textsuperscript{16} During the current pandemic, the success of the vaccine Comirnaty, developed by the subsidised German biotech company BioNTech SE, together with its American partner Pfizer Inc., has had a marked influence on the management of the crisis in the EU. Germany here is reported to have successfully championed the interests of industry, and that of its own industry in particular. Indeed, in the EU negotiations on joint vaccine procurement Germany negotiated in such a way that BioNTech SE was able to achieve comparatively high prices per dose whilst also becoming the main supplier to the EU.\textsuperscript{17} This was ultimately done to the detriment of some of the other Member States who, for various reasons, did not want to spend so much money on vaccine supply.\textsuperscript{18}

It is against this background that the article first sets out the new legal yardstick for EU state aid law (2). To provide the reader with a better understanding of the ‘big picture’ of pharmaceutical-relevant EU crisis policy, other related Communications are also discussed. The article then outlines the aid the German government has made available to domestic pharmaceutical companies and explains its legal compatibility with the Temporary Framework (3). The ensuing discussion reviews the aid’s effects on solidarity (4) and considers, in the face of a pandemic, EU proposals for new health measures (5). Finally, the paper draws a conclusion and offers an outlook for future research and discussion (6).

\textsuperscript{15} European Parliament, ‘Uncertainty/EU/Hope. Public opinion in times of Covid-19’, June 2020, p. 30.

\textsuperscript{16} Cf., Statista, ‘Top Pharmaunternehmen in Europa nach Umsatz und Ausgaben für Forschung und Entwicklung im Jahr 2020’, Statista (2021), available online at https://de.statista.com/statistik/daten/studie/448918/umfrage/top-10-pharmaunternehmen-in-europa-umsatz-und-forschungsausgaben/ (accessed 29 November 2021).

\textsuperscript{17} M. Peigné, ‘EU’s “secret” vaccine negotiators: Who’s dealing with Big Pharma?’, EU Observer (4 November 2021), available online at https://euobserver.com/coronavirus/153412 (accessed 29 November 2021).

\textsuperscript{18} Cf., W. Mussler, ‘EU will mehr Impfdosen – und zahlt nun wohl auch mehr dafür’, Frankfurter Allgemeine Zeitung (19 April 2021), available online at https://www.faz.net/aktuell/politik/ausland/ue-zahlt-wohl-mehr-fuer-corona-impfdosen-von-biontech-und-pfizer-17301708.html (accessed 29 November 2021).
The EU’s Crisis-Born Pharmaceutical Policy

2.1 Announcing a Coordinated Economic Crisis Response
As the pandemic first hit Europe at the beginning of March 2020, the European economy went into recession. It was at this time that the Commission issued its first Coordinated Economic Response to the Covid-19 Outbreak on 13 March 2020, outlining in general terms the (immediate) measures the EU would take to contain the economic fallout from the crisis.19 At the same time, the Commission recognised the potential impact the crisis response measures adopted by the individual Member States could have on the EU as a whole and, consequently, placed emphasis on the importance of the internal market, which, as an instrument of solidarity, was to balance the different interests.20 Regarding Member State aid in particular, the Commission, as the body responsible for state aid control, faced a balancing act: On the one hand, it had to ensure that no harmful race for subsidies would emerge, that, in the end, would jeopardise cohesion within the EU;21 on the other hand, in view of the limited EU budget, it had to encourage Member States to make financial resources available to jointly manage the crisis.22

2.2 The Temporary Framework for State Aid and Its Amendments
These considerations led the Commission to adopt the Temporary Framework on 19 March 2020. It was no legislative act, but a Communication (followed by a possible self-binding) in which the Commission set out in detail how it intended to interpret the relevant law, should a Member State notify an aid.23 As during the financial crisis of 2007, the Temporary Framework was based on Article 107(3)(b) TFEU, since this exemption from the general ban on state aid in Article 107(1) TFEU enables Member States to set up large-scale funding and guarantee schemes.24 It should be pointed out though that other existing exemptions, such as Article 107(2)(b) TFEU, continued to apply alongside the Temporary Framework and completed it.25 Yet, this first version of the

19 Supra note 4.
20 Ibid., p. 3 ff.
21 Ibid., p. 10.
22 Ibid.
23 C. Seitz and A.S. Berne, ‘Die Panazee gegen Covid-19: Das EU-Beihilfenrecht, Staatliche Unterstützungsmaßnahmen und der Befristete Beihilfenrahmen der EU-Kommission’, Europäische Zeitschrift für Wirtschaftsrecht 31(14) (2020) 591–598.
24 J.L. Buendía and A. Dovalo, ‘State Aid Versus Covid-19. The Commission Adopts a Temporary Framework’, European State Aid Law Quarterly 19(1) (2020) 3–7.
25 Cf., ibid.
Temporary Framework did not yet refer to the need for a (co-)financing of effective vaccines and medicines.

A first amendment to the Temporary Framework on 3 April 2020 introduced five new forms of aid, three of which targeted products being developed to fight Covid-19. The first allowed Member States to subsidise coronavirus-related and other relevant antiviral R&D, which included vaccines, medicinal products and treatments, and process innovations for an efficient production of the required products (para. 35 and footnote 31 Temporary Framework). The second concerned the construction or upscaling of the infrastructure needed to develop and test products intended to fight Covid-19, up to first industrial development before mass production. These products included Covid-19 relevant medicinal products (including vaccines) and treatments, their intermediates, active pharmaceutical ingredients, and raw materials (para. 37(a) Temporary Framework). Lastly, the third allowed investment aid to be made available for the production of ‘Covid-19 relevant products’ (para. 38 Temporary Framework).

This usage of ‘Covid-19 relevant products’ and ‘relevant medicinal products’, confuses, though, both regarding the respective meaning and the possible differentiation of the two terms. On the one hand, the Commission may have wanted to include all products relevant for the treatment of Covid-19 and may have simply forgotten to add the term ‘Covid-19’ before ‘relevant medicinal products’. On the other hand, the sentence could be interpreted as if only certain types of medicinal products relevant for the treatment of Covid-19 should be covered. Indeed, at least the German translation implies this, by distinguishing between ‘Covid-19 betreffenden Produkten’ and ‘relevanten Arzneimitteln’. If the latter were true, uncertainty would arise for Member States as to which specific products they could promote in accordance with the third measure. One way or another, the wording is fraught with legal uncertainty. All in all, the Commission having already set out under which conditions it would consider aid measures to be compatible with Article 107(3)(c) TFEU, it thus further extended the funding opportunities that already existed on the basis of the Temporary Framework (paras. 34, 36, 38).

26 Commission, First Amendment to the Temporary Framework to support the economy in the context of the coronavirus outbreak, OJ C 112, 4 April 2020, 1–9.

27 Medical devices, disinfectants, etc. also fall under this category, of course. In this article, however, only the regulations relevant for medicinal products are considered and explained.
Concerning the extension of aid for R&D, which arguably constituted the most marked change, the Temporary Framework as amended envisaged simplifications and expansions, but also stricter obligations compared to the pre-existing Framework for State Aid for Research and Development and Innovation (R&D&I Framework). For one thing, it now was possible for all sizes of enterprises to cover 80% of the costs of industrial research and experimental development (para. 35(d) Temporary Framework), which was significantly more than before (cf. Appendix II to the R&D&I Framework). Also, the Temporary Framework assumed the aid to have, under Paragraph 35(b), an incentive effect under certain circumstances, whereas the incentive had to be proven under Paragraph 66 R&D&I Framework, at least regarding individual aid. In contrast, the Commission enshrined within Paragraph 35(g) Temporary Framework that the aid beneficiary undertakes to grant non-exclusive licenses to third parties in the EEA on non-discriminatory market terms, whereas in the R&D&I Framework there is no such provision. This should guarantee an even, simultaneous supply of Covid-19 products to all Member States.

On 13 October 2020, as part of the fourth amendment to the Temporary Framework (the other amendments have no bearing on pharmaceuticals), its application was extended until 30 June 2021. The fifth amendment of

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28 F. Bostoen, N. Colpaert, W. Devroe, J. Gruyters, L. Michaux and L. Van Acker, ‘Corona and EU Economic Law: Competition and Free Movement in Times of Crisis’, European Competition and Regulatory Law Review 4(2) (2020) 72–95.
29 Commission, ‘Framework for State aid for research and development and innovation’, OJ C 198, 27 June 2014, 1–29.
30 Selection of the three examples adopted from supra, note 28.
31 Commission, ‘State aid: Commission extends Temporary Framework to enable Member States to accelerate research, testing and production of coronavirus relevant products, to protect jobs and to further support the economy in the coronavirus outbreak’, European Commission (3 April 2020), available online at https://ec.europa.eu/commission/presscorner/detail/en/ip_20_570 (accessed 29 November 2021).
32 Commission, 4th Amendment to the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak and amendment to the Annex to the Communication from the Commission to the Member States on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to short-term export-credit insurance, OJ C 3401, 13 October 2020, 1–10.
28 January 2021 prolonged the application until 31 December 202133 and a sixth amendment dated 18 November 2021 prolonged it to 30 June 2022.34

2.3 Striving for a Joint Supply of Covid-19 Medicinal Products

Beyond the new framework for state aid, the Commission adopted two more Communications, this time specifically targeting Covid-19 medicinal products. These Communications did not relate to a single area of law or policy (like state aid), but rather encompassed many different approaches from different areas, some of which were within the sovereignty of the EU institutions, but most of which were in the hands of the Member States. On 17 June 2020, the EU Strategy for Covid-19 vaccines once again emphasised the importance of equitable access to vaccines for all Member States.35 Accordingly, the Commission appealed to the Member States to cooperate, arguing that a joint procurement approach would increase the EU’s leverage when negotiating with pharmaceutical industry representatives. At the same time, the Commission underlined that such an approach would nonetheless respect the competencies in health policy harboured primarily in the Member States.36 It is for this reason that the Commission also clarified that, the Advance Purchase Agreements (APAs) should be concluded on behalf of and in the name of the participating Member States, despite being negotiated by the Commission and being financed through the Emergency Support Instrument.37 What is more, on 6 May 2021, the EU Strategy on Covid-19 therapeutics came into force.38 Building on the experience gained with the EU Strategy for Covid-19 vaccines, the Commission proposed an EU approach to R&D, authorisation, manufacturing, and the procurement

33 Commission, Fifth Amendment to the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak and amendment to the Annex to the Communication from the Commission to the Member States on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to short-term export-credit insurance, OJ C 34, 1 February 2021, 6–15.

34 Commission, Sixth Amendment to the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak and amendment to the Annex to the Communication from the Commission to the Member States on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to short-term export-credit insurance, OJ C 473, 24 November 2021, 1–15.

35 Commission, ‘EU Strategy for Covid-19 vaccines’, 17 June 2020, COM (2020) 245 final, especially 2f.

36 Ibid., 3.

37 For a fundamental criticism of APAs see A. von Bogdandy and P.A. Villarreal, ‘The Role of International Law in Vaccinating Against Covid-19: Appraising the COVAX Initiative’ MPIL Research Paper Series No. 2020–46 (Heidelberg: Max Planck Institute for Comparative Public Law and International Law, 2020), 5f.

38 Commission, ‘EU Strategy on Covid-19 Therapeutics’, 6 May 2021, COM (2021) 355 final.
of therapeutics. This included, inter alia, joint procurement contracts based on the *Joint Procurement Agreement for medical countermeasures* according to Article 5 of Decision 1082/2013/EU,\(^39\) APAS, and even emergency stockpiling within the framework of the amended *EU Civil Protection Mechanism*.\(^40\)

### 2.4 Fighting Foreign Threats to the Supply of Covid-19 Medicinal Products

With the ‘race for a vaccine’ allegedly seeing US investors trying to buy up stakes in the German CureVac AG to secure priority access,\(^41\) the rise of the pandemic gave handling (state-controlled) foreign direct investments (FDI) in pharmaceutical companies a new dimension and urgency.\(^42\) Consequently, on 26 March 2020, the Commission issued a Guidance to the Member States, in which it expressed its concern that FDI in the health care and pharmaceuticals sector would endanger the EU’s capacity to provide for the health needs of its citizens.\(^43\) As a result, the Commission called on the Member States to make full use of their screening mechanisms to protect their respective health infrastructures, or, where such a mechanism was not in place as yet, or where the mechanism did not capture such transactions, to set up a comprehensive screening mechanism and, in the meantime, ‘to use all other available options’.\(^44\) These very serious concerns about foreign threats to the security of supply in the EU even prompted the Commission to call upon Member States to participate in and thus protect their domestic enterprises.\(^45\) Although

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\(^39\) European Parliament and the Council, ‘Decision on serious cross-border threats to health and repealing Decision No 2119/98/EC’, OJ L 293, 5 November 2013, 1–15.

\(^40\) In 2019, the rescEU-element of the *EU Civil Protection Mechanism* established, inter alia, a new European reserve of resources. As regards the response to Covid-19, a rescEU medical reserve and distribution mechanism was set up by the Commission, with stockpiles in nine Member States.

\(^41\) J. Dams, ‘Donald Trump greift nach deutscher Impfstoff-Firma’, *Welt* (15 March 2020), available online at https://www.welt.de/wirtschaft/article206553143/Corona-USA-will-Zugriff-auf-deutsche-Impfstoff-Firma.html (accessed 29 November 2021).

\(^42\) For more details on FDI screening in the pharmaceutical sector, see K. Plank, ‘Medicinal Products and the Screening of Foreign Direct Investment’, *European Pharmaceutical Law Review* 5 (3) (2021) 123–128.

\(^43\) Commission, Guidance to the Member States concerning foreign direct investment and free movement of capital from third countries, and the protection of Europe’s strategic assets, ahead of the application of Regulation (EU) 2019/452 (FDI Screening Regulation), 1–5.

\(^44\) *Ibid.*, 2.

\(^45\) Cf., J. Espinoza, ‘Vestager urges stakebuilding to block Chinese takeover’, *Financial Times* (12 April 2020), available online at https://www.ft.com/content/e14f24c7-e47a-4c22-8cf3-f629da62b0a7 (accessed 29 November 2021), quoting European Commissioner for
these external common commercial policy initiatives had no direct link to intra-European state aid policy, they quite possibly had a tangible effect, specifically as regards the later changes concerning aid for pharmaceutical R&D and manufacturing in the first amendment to the Temporary Framework and, more generally, on the willingness of the EU and the Member States to finance pharmaceutical companies.

3 German State Aid for Covid-19 Medicinal Products

3.1 Legal Policy Background of the Individual Aid Measures

Without a vaccine against Covid-19 being available all through 2020, the German government, like other governments, had to base the core of its infection control policy on severe restrictions in all areas of public and private life, demanding strong efforts and sacrifices from its citizens. Hence, the German government could call it a very happy coincidence that several domestic biotech companies were ambitious enough to start R&D of potential vaccine candidates right at the beginning of the pandemic, some of them even before the pandemic reached Europe. One of them, the biotech company IDT Biologika GmbH, cooperating with several German universities, began to develop a vector vaccine, for example, based on an older product against smallpox. In contrast, the biotech companies BioNTech SE and CureVac AG aimed to develop a novel mRNA-based vaccine. The government’s participation in the funding of these projects constituted the first pillar of German state aid for Covid-19 medicinal projects, and expressed confidence in future infection control.

Accordingly, in a first step, the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, in short BMBF) together with the Federal Ministry for Health (Bundesministerium für Gesundheit, in short BMG) issued a Directive for a Special Programme to Accelerate Research and Development of Urgently Needed Vaccines against SARS-CoV-2 (Vaccines Directive) in June 2020.\footnote{BMBF, ‘Richtlinie für ein Sonderprogramm zur Beschleunigung von Forschung und Entwicklung dringend benötigter Impfstoffe gegen SARS-CoV-2’, Bundesanzeiger (BAnz) AT 18.06.2020 B6.} In addition to its commitment to the Coalition for Epidemic Preparedness Innovations (CEPI), the German government pursued with this funding directive the aim of ensuring the earliest possible and most comprehensive supply of an effective and safe vaccine for the German population.

Competition Margrethe Vestager: ‘We don’t have any issues of states acting as market participants if need be – if they provide shares in a company, if they want to prevent a takeover of this kind’.

\cite{BMBF, Richtlinie für ein Sonderprogramm zur Beschleunigung von Forschung und Entwicklung dringend benötigter Impfstoffe gegen SARS-CoV-2, Bundesanzeiger (BAnz) AT 18.06.2020 B6.}
population. The specific purpose of the initiative was to promote clinical trials, to expand study capacities, and to increase production capacities for vaccine candidates. This included the express support of different technological approaches to increase the chances of success. Remarkably, Section 4 of the Vaccines Directive contained a passage according to which the government expected ‘that an appropriate share of the production of an approved vaccine will also be made available for needs-based supply in Germany’.\footnote{The original German phrase reads: ‘dass auch ein angemessener Anteil der Produktion eines zugelassenen Impfstoffes für die bedarfsgerechte Versorgung in Deutschland zugänglich gemacht wird’.} Since 1 August 2020, BMBF and BMG have awarded subsidies amounting to approximately EUR 740 million to the three domestic vaccine developers BioNTech SE,\footnote{EUR 375,002,291, cf. Funding references 01 KI 20700 and 01 KI 207001. Besides, it here is worth noting that BioNTech SE’s vaccine is based on basic research conducted and funded with public money since the late 1990’s; see Gemeinsame Wissenschaftskonferenz, ‘Pakt für Forschung und Innovation. Monitoring-Bericht 2021’, Vol. III, p. 15.} CureVac AG,\footnote{EUR 252,612,248, cf., Funding reference 01KI 20703.} and IDT Biologika GmbH\footnote{EUR 113,702,976, cf., Funding reference 01KI 20702.} to achieve the objective of the Vaccines Directive.\footnote{For two of the companies this meant that the funding they had already received from February onwards was approved retrospectively, cf. BMBF, Sonderprogramm zur Beschleunigung von Forschung und Entwicklung dringend benötigter Impfstoffe gegen SARS-CoV-2, available online at https://www.gesundheitsforschung-bmbf.de/de/sonder-programm-zur-beschleunigung-von-forschung-und-entwicklung-dringend-benotigter-impfstoffe-gegen-sars-cov-2 (accessed 29 November 2021).}

At the same time and as elsewhere, the search for effective pharmaceutical treatments began in 2020, albeit involving less prominent pharmaceutical and biotech companies and attracting less public attention than the development of a vaccine against Covid-19. However, therapeutic drug development has taken and continues to take longer than vaccine development. Fortunately, in some cases, researchers were able to further develop already existing medicines. The German Merck KGaA, for instance, was able to successfully repurpose the active ingredient dexamethasone, a substance widely used for other conditions for decades.\footnote{Verband Forschender Arzneimittelhersteller, ‘Covid-19: zugelassene und zur Zulassung eingereichte Medikamente’, VFA (24 November 2021), available online at https://www.vfa.de/de/arzneimittel-forschung/coronavirus/zugelassene-zur-zulassung-eingereichte-medikamente-covid-19 (accessed 29 November 2021).} The German government’s participation in the funding of the R&D and manufacturing of therapeutics complemented its aid for vaccines and thus formed the second pillar of the German state aid policy for Covid-19 medicinal projects.
Consequently, after BioNTech SE’s vaccine had received market approval by the Commission in December 2020, BMBF and BMG issued their first Directive to Promote Research and Development of Urgently Needed Therapeutics against SARS-CoV-2 (First Therapeutics Directive) in January 2021.\(^{53}\) It addressed the early clinical development of therapeutic approaches against Covid-19 in Germany, so that preclinically successful candidates could be made available for patient care as quickly as possible (para. 1.1 First Therapeutics Directive). The specific purpose of the grant was to support the clinical development of products directed against SARS-CoV-2, on the one hand, and of new therapeutic approaches intended for the treatment of severe courses of Covid-19, on the other. Regarding the latter category, studies focusing on the repurposing of existing products were, in exceptional cases, also eligible for aid (para. 2 First Therapeutics Directive). In the same way as the Vaccines Directive, this directive also set out the express support of different technological approaches to increase the chances of success. As a result, first projects started to be promoted at the beginning of 2021. In June 2021, however, BMBF and BMG found that the First Therapeutics Directive was not sufficient to meet the consistently high demand for new effective therapeutics. As a result, a second Directive to Promote Research and Development of Urgently Needed Therapeutics against SARS-CoV-2 (Second Therapeutics Directive) was implemented. Based on these second and third steps, the German government began to subsidise eight projects of mostly small and medium-sized German biotech companies, some of them collaborating with German universities, to the tune of EUR 46.31 million, all aimed at the early clinical development of urgently needed therapeutics against Covid-19.\(^{54}\)

Around the same time, in May 2021, BMBF and BMG issued the Directive for the Promotion of Clinical Development of Supply-related Covid-19 Medicinal Products and their Manufacturing Capacities (Directive Supply-related Covid-19 Medicinal Products).\(^{55}\) Complementing the First Therapeutics Directive, this directive was first and foremost intended to support the later stages of the clinical development of pharmaceutical candidates (para. 1.1 Directive Supply-related Covid-19 Medicinal Products). In addition, the directive was to facilitate the inclusion of products already approved for other conditions in the

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\(^{53}\) BMBF, Richtlinie zur Förderung von Forschung und Entwicklung dringend benötigter Therapeutika gegen SARS-CoV-2, BAnz AT 06.01.2021 B3, available online at https://www.gesundheitsforschung-bmbf.de/de/forschung-und-entwicklung-dringend-benotigter-therapeutika-gegen-sars-cov-2-13455.php (accessed 29 November 2021).

\(^{54}\) Ibid.

\(^{55}\) BMG and BMBF, Richtlinie zur Förderung der klinischen Entwicklung von versorgungsna- hen COVID-19-Arzneimitteln und deren Herstellungskapazitäten, BAnz AT 14.05.2021 B3.
treatment of Covid-19. In other words, the main purpose of the grant was to advance the clinical development of pharmaceutical candidates directed against the virus and of therapeutic approaches intended for the treatment of Covid-19, whether novel or repurposed. Again, the use of different technological approaches was encouraged to increase the chances of success. Furthermore, manufacturing capacity could be subsidised. Remarkably, and in contrast to the other directives, BMBF and BMG highlighted the importance of public funding, both for the progress of the specific projects and for Germany as a location for biotech R&D, in the context of the Directive Supply-related Covid-19 Medicinal Products (see para. 1.1). So, in September 2021, in a fourth and so far last step, the German government, based on the Directive Supply-related Covid-19 Medicinal Products, promised further subsidies – a total of approximately EUR 150 million – to six small and medium-sized German biotech companies, intended to support the later stages of clinical development and to expand the manufacturing capacity of Covid-19 treatments.56

3.2 The Aid Scheme and Its Compatibility with the Temporary Framework

After the Commission had generally approved the extension of aid for pharmaceutical R&D and manufacturing in the first amendment to the Temporary Framework, the German government remained unsure about the type and amount of aid it was to grant to domestic pharmaceutical companies. It is for this reason that BMBF and BMG first created a Scheme for the Temporary Granting of Aid within the Scope of the Federal Republic of Germany in Connection with the Outbreak of Covid-19 (Aid Scheme) in April 2020.57 Under this scheme, it was to be possible, if approved by the Commission, to grant specific individual aid to companies at a later stage.

The Commission concluded that the scheme constituted state aid under the meaning of Article 107(1) TFEU, and that BMBF and BMG had met the formal requirement of Article 108(3) TFEU of notifying the scheme to the Commission before putting it into effect on 24 April 2020.58 The scheme’s compatibility

56 See BMBF, ‘Spahn/Karliczek: Weiterer Schub zur Entwicklung und Herstellung von versorgungsnahen Arzneimitteln gegen Covid-19’, BMBF (6 September 2021), available online at https://www.bmbf.de/bmbf/sharedocs/pressemitteilungen/de/2021/09/060921-Arzeneimittel.html?view=renderNewsletterHtml (accessed 29 November 2021).

57 BMBF and BMG, Bekanntmachung der Regelung zur vorübergehenden Gewährung von Beihilfen im Geltungsbereich der Bundesrepublik Deutschland im Zusammenhang mit dem Ausbruch von Covid-19 (Bundesregelung Forschungs-, Entwicklungs- und Investitionssubventionen), BAnz AT 14.05.2020 B7.

58 Commission Decision, 28 April 2020, COM (2020) 2871 final.
subsequently depended on whether it could be approved by way of exception pursuant to Article 107(3)(c) TFEU and the conditions set out in the Temporary Framework, especially Sections 3.6, 3.7 and 3.8.

On this account, the Aid Scheme comprised three areas of aid. Firstly, it targeted aid for R&D as pertinent to the coronavirus and, if relevant to Covid-19, other viral diseases (para. 1 Aid Scheme). This also provided that the aid beneficiaries committed to granting non-exclusive licenses under market conditions to third parties within the EEA (para. 1(6) Aid Scheme). Secondly, the scheme contained investment aid to enable the construction or upscaling of infrastructure necessary to develop, test, and scale up Covid-19 relevant products, right up to first commercial use before mass production (para. 2 Aid Scheme). Thirdly, the scheme included investment aids to produce Covid-19 relevant products (para. 3 Aid Scheme). Having been specifically designed to meet the requirements of the three pharmaceutical-relevant measures of the Temporary Framework, the scope of eligible R&D and products was identical in wording with the Temporary Framework. The only exception is Section 3 Aid Scheme, which, in deviating from Section 3.8 Paragraph 38 of the Temporary Framework, encompassed ‘Covid-19 relevant medicinal products.’

In any case, the Commission, found the scheme to comply with the Temporary Framework and that it contributed to the achievement of a common objective of crucial importance, i.e. was both appropriate and necessary to fighting the pandemic. Therefore, the Commission approved the aid scheme by deciding not to raise any objections, declaring it compatible with Article 107(3)(c) TFEU on 28 April 2020. As a result, the Aid Scheme entered into force on the day of its approval.

Taking Sections 3.6, 3.7 and 3.8 of the Temporary Framework as amended as a basis, Sections 1, 2 and 3 of the Aid Scheme subsequently constituted the legal basis for state aid for all later individual aids in Germany. Conversely, to clarify, the Vaccines Directive of June 2020 only served the purpose of implementing the legal basis for state aid at the administrative level within the German legal framework. This meant that the Vaccines Directive did not further elaborate the Aid Scheme. In November 2020, BMBF and BMG thus prolonged the Aid Scheme, which was approved by the Commission as conforming with the fourth amendment to the Temporary Framework.

The First Therapeutics Directive of January 2021 then administratively implemented the Aid Scheme as prolonged. Next, in February 2021, the Commission approved another
extension to the Aid Scheme up until 31 December 2021 as consistent with the fifth amendment to the Temporary Framework. The Directive Supply-related Covid-19 Medicinal Products of May 2021 and the Second Therapeutics Directive of June 2021 thereupon implemented the Aid Scheme in the same way as the other directives had done before.

As far as can be seen, the aid granted to the 17 German companies has not been legally challenged by the Commission pursuant to Article 108(1), (2) TFEU.

4 Effects and Competence Background of the Current EU Pharmaceutical Policy

4.1 State Aid for Covid-19 Medicinal Products as a Risk for Solidarity

Given the pressure of the pandemic, it is easy to understand why the Commission adopted a policy that ultimately allowed Germany to benefit from state aid, yet its impact on solidarity has been negative.

In a general sense, the concept of solidarity encompasses the insight that the realisation of one’s own goals is linked to the realisation of communal goals. This connection creates a ‘qualified bond’ between the respective parties involved and expresses itself in a de facto relationship of dependence, or even a sense of belonging. In the case of the EU, this idea of solidarity is at the heart of the European project. Regardless of its significance, solidarity has neither been defined within the Treaties nor been used in a coherent form, however. Although it is generally acknowledged as a principle of EU law, opinions regarding its specific legal function diverge and cannot be discussed in detail here. This article argues that the legal principle of solidarity enshrines

62 Commission Decision, 12 February 2021, COM (2021) 1066 final.
63 Supra note 14, p. 45.
64 T. Kingreen, Das Sozialstaatsprinzip im europäischen Verfassungsverbund, (Tübingen: Mohr Siebeck, 2003), p. 244: ‘qualifizierte Verbundenheit’.
65 Supra note 14, p. 45.
66 Cf. Advocate General Sharpston, C 715/17, C 718/17, C 719/17, ECLI:EU:C:2019:917, para. 253: ‘Solidarity is the lifeblood of the European project’; A. Bartenstein, The Concept of Solidarity, (Baden-Baden: Nomos, 2021), p. 118: ‘Solidarity is running through the EU’s bloodlines’.
67 A. Bartenstein, supra note 66, p. 126; cf. also P. Van Cleynenbreugel, Market Supervision in the European Union: Integrated Administration in Constitutional Context, (Leiden: Brill / Nijhoff, 2014), p. 13.
68 Nettesheim, for example, argues that the principle cannot create specific obligations but can only serve as an orientation when balancing different values and interests. See M. Nettesheim, ‘Konzeptionen und Dimensionen von Solidarität im Recht der Europäischen
in the Treaties the political ambition of the Member States to achieve common
goals and tasks in the interest of the EU.69 It follows that, for the most part, this
legal principle of solidarity refers to a solidarity between the Member States
with regard to the objectives and tasks of the EU.70 In this respect, the Member
States have a mutual responsibility with regard to the objectives laid down in
the law.71 This mutual responsibility really is at the core of the principle of
solidarity.72 Therefore, the obligation is, first and foremost, a procedural one,
constituting solidarity through procedures, and finds its origin in the principle
of loyal cooperation in Article 4(3) TEU, which expresses the common interest
with regard to the EU objectives set out in Article 3 TEU by creating mutual
obligations.73 These may involve disadvantages for the individual Member
States, but they are to be accepted with regard to the common interest.74

What follows is that the aid provided by the German government poses a
threat to the EU legal principle of solidarity regarding the EU’s objective of
health protection (cf. Article 3(3) TEU). This is not to say that the aid itself
violates loyal cooperation regarding health protection, but that it may result
and serve as justification for further practices which ultimately violate or will
violate loyal cooperation. From a different point of view, regarding the legal
quality of the principle of solidarity, the practices could at least jeopardise
political solidarity. The first reason for this, as already indicated above, is that
the German government was able to exert particular pressure on the EU’s
pharmaceutical policy to the detriment of other Member States because of its
subsidies to BioNTech SE.

The second reason for the aid to have disregarded loyal cooperation is that
the initiative was used as an argument to torpedo a common EU approach
for the joint procurement of medicinal products. The background to this was
that the Commission could only ‘appeal’ for the joint procurement of Covid-19
medicinal products within the EU Strategy for Covid-19 vaccines and the EU

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69 C. Calliess, Öffentliche Güter im Recht der Europäischen Union (8 January 2021), available online at https://www.bertelsmann-stiftung.de/fileadmin/files/BSt/Publikationen/GrauePublikationen/OEffentli-che_Gueter_im_Rech_der_EU_FINAL.pdf (accessed 29 November 2021), p. 15.
70 U. Volkmann, ‘Solidarität in einem vereinten Europa’, Staatswissenschaften und Staatspraxis 9 (1998) 17–44; C. Calliess, ‘Europa als Wertegemeinschaft – Integration und Identität durch europäisches Verfassungsrecht?’, Juristenzeitung 59(21) (2004) 1033–1045.
71 Supra note 66, p. 16.
72 Ibid.
73 Ibid.
74 Supra note 14, p. 88; supra note 69, p. 16.
Strategy on Covid-19 therapeutics, which made the voluntary participants a mere ‘coalition of the willing’. In spite of the fact that Germany was part of this coalition, it did not prevent the German government from simultaneously concluding bilateral agreements with the three domestic vaccine developers which earlier had been granted aid. In response, believing themselves to be in the right, German politicians referred to the expectations outlined in the Vaccines Directive, according to which Germany was to be granted shares in the production in return for investments. As a result, the previous consensus not to undermine the Commission’s efforts turned out to be ineffective. What is without doubt is that this approach caused a political outcry in other Member States, damaging both dependence and belonging. Furthermore, Germany did not take account of and express due political responsibility in its approach towards other Member States; whereas Germany can drive pharmaceutical innovation and subsequently can supply its population with pioneering medicinal products, other Member States cannot and therefore depend on Germany.

The third reason is that these public investments in individual companies have, moreover, (co-)boosted the entire German biotech sector well beyond the current Covid-19 crisis. The resulting industrial lead will, in the event of a future health emergency, enable Germany to exert influence on EU health policy again, or to even be given preference in the supply of medicines. Evidence for the likelihood of such preferential supply can be found in reports on planned APAs that the German government has concluded with domestic pharmaceutical companies, under which public payments would be linked to

75 See Section 2.3.
76 Quoted by M. Becker, ‘Ärger um deutsche Impfstoff-Alleingänge’, Spiegel (8 August 2021), available online at https://www.spiegel.de/politik/deutschland/corona-impfstoff-eu-aerger-um-deutsche-impfstoff-alleingaenge-a-acc65399-23ac-49a5-afee-b388 31c822e9 (accessed 29 November 2021), in which the German legal scholar Alexander Thiele indicates a suspected breach of the law. The EU Commission has not taken any legal action against this behaviour though.
77 Bundesregierung (German Government), ‘Antwort der Bundesregierung auf die Kleine Anfrage des Abgeordneten Stefan Keuter und der Fraktion der AfD’, Bundestagsdrucksache 19/27666, 18 March 2021, p. 2.
78 Cf., for example, the comments of Italian Prime Minister Guiseppe Conte, as reported by T. Piller, ‘Zum Jahresende noch ein Deutschland-Bashing’, Frankfurter Allgemeine Zeitung (21 December 2020), available online at https://www.faz.net/aktuell/wirtschaft/italiens-regierung-kritisiert-deutschen-impfstoff-kauf-17125878.html (accessed 29 November 2021).
79 Cf., A. John, ‘Boost für die deutsche Biotech-Branche?’, Tagesschau (5 November 2021), available online at https://www.tagesschau.de/wirtschaft/unternehmen/biotech-branche-startups-biontech-101.html (accessed 29 November 2021).
a ‘right of the federal government to advance supply’ and the obligation of establishing ‘production sites in Germany’, whereas ‘transferability to the EU’ would only be ‘possible if needed’. The restriction does not specify, of course, what an EU need means, nor what would happen if Germany and other Member States were to clash over demand in the case of a shortage. However, voices have recently been raised in Germany criticising the rationing of the popular Comirnaty while donating millions of doses of the same to the COVAX initiative. Against this background, future leaders will most likely be more reluctant to export medicines produced in Germany. Similar to the bilateral procurement, such protectionism would again prevent the EU from achieving its health goals. Also, Germany would again fail to live up to the special responsibility it has towards the other Member States, damaging their trust in the existence of a special ‘bond’ among Member States, and, moreover, their sense of belonging and allegiance to the EU.

4.2 Limited EU Competencies in Public Health Policy

The fact that the EU did not itself take comprehensive measures to limit the risks that the grants posed to solidarity or, rather, why it was deemed necessary for the Commission to allow such aid in the first place, needs to be placed in a wider context: namely, the discrepancy in the area of health policy between EU objectives and tasks, on the one hand, and actual powers (and funding) to act, on the other.

The horizontal clause of Article 168(1)(1) TFEU establishes a substantive legal obligation to take health protection into account when exercising other competencies, which is equally stated in the general clause of Article 9 TFEU. In contrast, the remaining provisions of Article 168 TFEU establish the vertical relationship between the EU and the Member States: Article 168(1) Subparagraphs (2) and (3) TFEU describe task areas whereas Article 168(2) to (7) TFEU contain measures to fulfil them. However, these measures are only to a certain extent accompanied by the EU’s own powers to adopt

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80 All quotations from supra, note 17.
81 G. Ismar, ‘Das steckt hinter Spahns Biontech-Rationierung’, Der Tagesspiegel (20 November 2021), available online at https://www.tagesspiegel.de/politik/vollbremsung-auf-gerader-strecke-das-steckt-hinter-spaahns-biontech-rationierung/27818692.html (accessed 29 November 2021).
82 Supra note 11, paras 8ff.
83 R. Rebhan, ‘Art 9 AEUV’ in U. Becker, A. Hartje, J. Schoo and J. Schwarze (eds.), EU-Kommentar, 4th edn. (Baden-Baden: Nomos, 2019) pp. 465–468, paras 1ff.
84 T. Kingreen, ‘Article 168 AUV’ in: C. Calliess and M. Ruffert (eds.), EUV/AEUV-Kommentar, 5th edn. (Munich: C.H. Beck, 2016) pp. 1804–1817, paras 2 and 13–25.
supranational measures.\textsuperscript{85} As Article 6 Sentence 2(a) TFEU and Article 2(5) TFEU already imply, the EU’s competencies in the field of health are limited to supporting, coordinating, and supplementing the measures adopted by the respective Member States.\textsuperscript{86} The right of access to preventive health care and medical treatment under Article 35 Charter of Fundamental Rights of the EU (CFR) also does not change this allocation, (cf., Article 51(1) sentence 2, (2) CFR\textsuperscript{87}). This implies that if the EU acts within the framework of Article 168 TFEU, the provisions are not binding on the Member States, so that the formal competencies remain in the hands of the Member States. Article 168(5) TFEU, additionally, stipulates that EU legislative measures may not provide for any harmonisation of the legislation of the Member States. While this prohibition only applies to the measures mentioned in Paragraph 5, including the ones intended to combat serious cross-border threats to health, however, other provisions of primary law may not be used to circumvent it.\textsuperscript{88}

Even internal market regulations do not change this fundamental allocation of competencies. Rather, the EU can only take a limited influence on the health policies of the Member States – either by way of positive integration, via the general clause of Article 114 TFEU, or by way of negative integration, via the guarantees of the four freedoms (with state aid control constituting a special form of negative integration).\textsuperscript{89} Regarding state aid, the EU does have legal competence for the supervision of all of its kinds, including subject areas in which it has no competence of its own. It is also true that the Commission can take health policy considerations into account when assessing individual subsidies, but it cannot pursue its own positive policy by way of state aid control.\textsuperscript{90} This explains why the Commission cannot prohibit some Member States’ aid on the grounds of others being unwilling or unable to extend the same (always assuming, of course, that the aid is considered compatible with the Internal Market). It is for the same reason of limited influence that it was legally possible for Member States such as the Czech Republic, France, and Germany to erect intra-European export restrictions and to impose bans on face masks, medical protective equipment and pharmaceuticals, despite of

\textsuperscript{85} D. Thym and J. Bornemann, ‘Binnenmarktrechtliche Grundlagen des Infektions- und Gesundheitsschutzrechts’ in S. Huster and T. Kingreen (eds.), \textit{Handbuch Infektions- schutzrecht}, (Munich: C.H. Beck, 2021) pp. 65–90, paras 5ff.

\textsuperscript{86} Cf., supra note 11, para. 15 and supra note 84, para. 4.

\textsuperscript{87} T. Kingreen, ‘Article 51 GRCh’ in C. Calliess and M. Ruffert (eds.), \textit{EUV/AEUV-Kommentar} (5th ed., Munich: C.H. Beck, 2016) pp. 2949–2964, para. 6.

\textsuperscript{88} \textit{ECJ C-426/13 P (R)}, \textit{eCLI:EU:C:2013:848}, para. 75 (Commission v. Germany).

\textsuperscript{89} Supra note 85, paras 8ff and 57f.

\textsuperscript{90} R. Streinz, \textit{Europarecht}, 11th edn. (Heidelberg: C.F. Müller, 2019) p. 463, para. 1126.
these protectionist measures reintroducing internal borders and, thus, endangering the availability of medicines throughout the EU. Such interference with the free movement of goods in the internal market is, after all, in principle lawful – whether based, for example, on a factual restriction under Article 35 for the ‘protection of public health’, or a justification within the meaning of Article 36 TFEU in accordance with the protection of human health and life.91 In this respect, the Commission’s repeated emphasis on the importance of the internal market as an instrument of solidarity may seem politically opportune at a time of unequal access to medical goods, but is neither legally required nor particularly compelling.92

Only the legislative measures of Article 168(4)(a) to (c) TFEU referring to product safety in the field of public health shall give rise to an original EU competence. Admittedly, this competence is shared with the Member States. Still, if the EU adopts measures, they have a blocking effect quite unlike the support and coordination measures (cf., Article 2(2) sentences 2, 3 TFEU).93 Nevertheless, it follows that Member States are only bound by European provisions within this narrow subject area, such as the centralised marketing authorisation of Covid-19 medicinal products carried out by the Commission and based on scientific assessments by the European Medicines Agency. All in all, it can be concluded that the EU’s hands were largely tied regarding binding health policy measures during the Covid-19 crisis and that further action at the EU level will only be achievable on the basis of consensus. Consequently, the question has arisen whether the EU itself should obtain more competencies in health policy in the future.

5 Establishing an EU Health Union as a Remedy?

In view of this the Commission has, since autumn 2020, compiled a comprehensive draft framework for a new, so-called EU Health Union (Health Union), which extends the EU’s health policy measures, as based on existing competencies. More precisely, the proposal consists of three interlinked key initiatives, each with its own set of sub-initiatives: firstly, there is the aim to improve Crisis Preparedness and Response; secondly, there is the intention to

91 For more details, cf., J. Bäumler and J.P. Terhechte, ‘Handelsbeschränkungen und Patentschutz für Impfstoffe’, Neue Juristische Wochenschrift 73(48) (2020) 3481–3487.
92 Cf., supra note 85, para. 14.
93 Supra note 84, para. 5.
develop a *Pharmaceutical Strategy for Europe* (Pharmaceutical Strategy);\(^{94}\) and thirdly, there is the aspiration to launch *Europe's beating cancer plan*.\(^ {95}\) Since it is beyond the scope of this article to discuss all three initiatives in detail, only a very small selection of the contents relevant to the supply of medicines during a crisis is examined further here.

5.1 **Presenting the Expansions**

The backbone of the new Health Union is the Commission’s proposal for a *Regulation on serious cross-border threats to health and repealing of Decision No. 1082/2013/EU* (Draft Regulation) of 11 November 2020, which constitutes part of the initiative for *Crisis Preparedness and Response*.\(^ {96}\) Since the planned regulation aims to combat serious cross-border health threats, it is based on Article 168(5) **TFEU**. In justifying the elaboration of the Draft Regulation, the Commission points to the risks of Member State competing over health measures and, thus, the importance and benefits of such competition being coordinated at EU level (cf. in particular Recital 15).

As a starting point, Article 3(8) Draft Regulation defines the term ‘medical countermeasures’ as ‘medicinal products for human use [...] as defined in Directive 2001/83/EC of the European Parliament and of the Council [...] or other goods or services for the purpose of preparedness and response to a serious cross-border threat to health’. A ‘serious cross-border threat to health’, in turn, ‘is understood as a life-threatening or otherwise serious hazard to health [...] which spreads [...] across the national borders of Member States [...]’ pursuant to Article 3(7) Draft Regulation. In this respect, it can be assumed that only a certain, albeit unspecified group of medicinal products, deemed important in connection with the aforementioned threat, is to be covered by the provisions referred to as medical countermeasures. In contrast to this, drugs against non-infectious diseases, such as hereditary diseases, are most likely excluded.

Article 12 Draft Regulation then contains a provision which allows the joint purchase of medical countermeasures for serious cross-border threats to health. This will be open to the Commission and ‘any Member States which so desire’ (Article 12(1) Draft Regulation), but also to the states of the European Free Trade Association and EU candidate countries. However, this voluntary

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\(^{94}\) Commission, ‘Pharmaceutical Strategy for Europe’, 25 November 2020, [COM (2020) 761 final.](https://eur-lex.europa.eu/eli/reg/2021/334/oj)

\(^{95}\) Commission, ‘Europe’s Beating Cancer Plan’, 3 February 2021, [COM (2021) 44 final.](https://eur-lex.europa.eu/eli/reg/2021/334/oj)

\(^{96}\) Commission, ‘Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU’, 11 November 2020, [COM (2020) 727 final; amended by the European Parliament on 14 September 2021, as part of the first reading, P9_TA(2021) 0377.](https://eur-lex.europa.eu/eli/reg/2021/334/oj)
obligation is subject to several conditions (Article 12(2) Draft Regulation). On the one hand, the rights and obligations of countries not participating in the joint procurement must be respected, in particular when the rights and obligations relate to the protection and improvement of human health (subsection b). Furthermore, the budgets of the non-participating countries shall not be directly affected by the procurement (subsection e). Also, the joint procurement shall not affect the internal market, nor constitute discrimination or a restriction on trade, and shall not distort competition (subsection d). On the other hand, the participating countries shall procure the medicines in question exclusively through the joint procedure and shall not negotiate in parallel for the same products (c). The approach prescribed here obviously reflects the negative experiences gained when procuring Covid-19 vaccines earlier in the crisis, an experience whose repetition should be avoided at all costs. Furthermore, a formal recognition of a public health emergency at Union level by the Commission (Article 23 Draft Regulation) shall allow for the introduction of ‘measures, which are applicable during the period of public health emergencies, related to medicinal products […]’ (Article 25(1)(a) Draft Regulation) and ‘mechanisms to monitor shortages of, develop, procure, manage and deploy medical countermeasures’ (Article 25(1)(b) Draft Regulation).

Beyond the Draft Regulation, and driven to improve Crisis Preparedness and Response, the Commission has already established a new service by decision of 16 September 2021 (Decision), called the European Health Emergency Preparedness and Response Agency (HERA). Similar to the Draft Regulation, HERA’s tasks also include, inter alia, ‘medical countermeasures’. Unlike the Draft Regulation, however, the HERA framework only includes products (and not services) considered useful for diagnosing, preventing, and protecting from or treating conditions associated with serious health threats as medical countermeasures; more specifically, this includes vaccines and therapeutics (cf., Recital 6 Decision and the explanations within the communication accompanying the establishment of HERA). Under Article 2 Decision, HERA will be responsible – albeit in close cooperation with the Member States – for promoting advanced R&D of medical countermeasures and related technologies (subsection b), addressing market challenges and boosting the EU’s open strategic autonomy in medical countermeasures production (subsection c), the swift procurement and distribution of medical countermeasures (subsection d), and

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97 Commission Decision, 16 September 2021, COM (2021) 6712 final.
98 Commission, ‘Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union’, 16 September 2021, COM(2021) 576 final, p. 1.
increasing the stockpiling capacity of critical products (e). To fulfil its tasks, HERA will be provided with EUR6 billion from the EU budget over a period of six years.

Finally, the Pharmaceutical Strategy of 25 November 2020 takes a comprehensive approach, not immediately driven by the crisis, to addressing a wide range of problems in the provision of medicines. Based on Articles 114 and 168 TFEU, individual measures consist of legislative projects, such as a fundamental review of the basic European pharmaceutical legislation (p. 17), of non-legislative measures, and of EU investments, e.g. for pharmaceutical R&D and procurement (cf., pp. 13 ff.: p. 26).

5.2 ... and Criticising Them

While the initiatives contain somewise lessons learnt from the coronavirus crisis, they, unfortunately, also seem to suffer from some of the shortcomings that have dominated EU Covid-19 management since the beginning of the pandemic.99

Admittedly, it is a very good approach to make more EU funding for pharmaceutical R&D and manufacturing available through HERA, as it strengthens innovative power, especially in, but not limited to fields that would otherwise be neglected by private enterprises. In addition, the planned mechanisms to develop and manage medicinal products (Article 25(1)(b) Draft Regulation) will be a first step towards ensuring that there will be a certain (minimum) supply of medicines available throughout the EU, while promoting pharmaceutical care in those Member States which currently have no strong industry of their own and reducing financial expenditure on imports. What is more, the planned joint procurement (Article 12, 25(1)(b) Draft Regulation) will give participants greater bargaining power vis-à-vis pharmaceutical companies, as they will be stronger negotiating together than all by – and potentially against – themselves. The safeguard against disloyal behaviour by participants (Article 12(2)(c) Draft Regulation) will ensure that this market power is not undermined by some Member States.

Nonetheless, it is to be feared that the ideas sound more effective than they might actually be in the face of an emergency. The main reason for this is that the important joint procurement relies on the voluntary participation of the Member States. Those with a strong pharmaceutical economy, such as Germany, might not agree to have their sovereign right to act on national health policy (like concluding procurement contracts) being curtailed, nor are

99 Similarly, A. Alemanno, ‘Towards a European Health Union: Time to Level Up’, European Journal of Risk Regulation 11(4) (2020) 721–725.
they willing to see their pharmaceutical industries being placed at a possible disadvantage. Indeed, it is because of feared disadvantages for its pharmaceutical industry and future (cancer) research that Germany has refused to release the patents for the mRNA vaccines to date.\textsuperscript{100} The other participating Member States, in turn, would, with the Draft Regulation, have the legal prerequisites, but, without corresponding undisturbed access to a strong and innovative pharmaceutical industry, not the factual prerequisites for a strong and effective joint management of health crises. Further, other measures like \textsc{hera} promoting pharmaceutical R&D and manufacturing can still only be regarded as supportive, cooperative, and complementary actions. The EUR 6 billion that \textsc{hera} will have at its disposal over six years will arguably not be enough, especially when compared to Germany, which all by itself will be spending almost EUR 1 billion over a period less than half of that of \textsc{hera}. This means that in the event of a crisis \textsc{hera}’s funds could only be a supplement to Member State funding. What follows is that these European funds can perhaps alleviate, but certainly not prevent a renewed \textsc{eu} policy of lowering state aid control, all with its undesirable consequences for solidarity within the \textsc{eu}.

Overall, the \textsc{eu} cannot effectively preclude a situation in which the motto ‘every man for himself’ once again poses a challenge to solidarity and cohesion between the Member States. Therefore, the Health Union will most likely be an initiative that can mitigate fragmentation, but not – to stay in the language of pharmaceuticals – a real ‘blockbuster’.\textsuperscript{101}

6 Conclusion and Outlook

What has become apparent from looking at the liberalisation of state aid control and events in the field of \textsc{fdi}, with the coronavirus pandemic only acting

\textsuperscript{100} For a position in favour of a patent release see M. Fratzscher, ‘Was für eine Freigabe der Impfstoff-Patente spricht’, Welt (10 May 2021), available online at https://www.welt.de/debatte/kommentare/article231026345/Marcel-Fratzscher-Was-fuer-Freigabe-der-Impfstoff-Patente-spricht.html (accessed 29 November 2021). For a position against a patent release see R. Hilty, ‘Wer am Patentschutz rüttelt, spielt mit dem Feuer’, interview by M. Hutterer \textit{Max-Planck-Gesellschaft} (8 March 2021), available online at https://www.mpg.de/16557172/patentschutz-corona-impfung (accessed 29 November 2021).

\textsuperscript{101} As reported by B. Stüer, ‘Staat und Gesellschaft in der Pandemie. Sondertagung der Vereinigung der Deutschen Staatsrechtslehrer in Wien’, \textit{Deutsches Verwaltungsblatt} 136(13) (2021) 851–856. A. Müller holds a similar opinion; \textit{cf.}, \textit{also} (but as of December 2020), I. Kickbusch and A. de Ruijter, ‘How a European health union can strengthen global health’, \textit{The Lancet Regional Health – Europe} (1) (2021) 100025.
as a catalyst for pre-existing policy developments,\textsuperscript{102} is that the Commission has markedly changed its stance on otherwise more critically eyed governmental intervention in the ‘open market economy with free competition’ as set out in Article 119(1) TFEU.\textsuperscript{103} This policy allowed Member States to distribute large amounts of aid to domestic pharmaceutical and biotech companies in an effort to combat the Covid-19 health crisis. The success of a German company’s vaccine, made possible in part by this aid, provided the German government with opportunities to influence EU health policy and, at the same time, to gain preferential access to a scarce and urgently needed commodity. Since such payments were not equally possible for all Member States, they jeopardised solidarity and cohesion within the EU. The reason why the EU has not taken similar measures for the benefit of all Member States lies in the distribution of competencies in the field of public health: most of the critical powers rest with the respective Member States. It is against this background that the Commission has made, based on existing competencies, proposals to expand EU public health policy in the framework of a new Health Union. Unfortunately, however, these proposals are not far-reaching enough for the EU to be comprehensively better prepared for future crises, nor are they likely to be strong enough to be able to ensure solidarity among the Member States at a time of crisis.

Naturally, the Member States could always, as an expression of solidarity,\textsuperscript{104} transfer new health competencies to the EU by way of treaty amendment. To this end, the German legal scholar Christian Calliess has suggested to add the fight against cross-border pandemics to the European legislative competencies of Article 168(4) TFEU.\textsuperscript{105} Applying the criteria of the principle of subsidiarity by analogy, he argues that measures at the EU level to combat such dangers would be of decisive importance.\textsuperscript{106} As a further concession to subsidiarity, the expansion would have to reserve the right for Member States to strengthen

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\footnotetext[102]{Cf., P. Callol ‘Protectionist trends in cross-border mergers and acquisitions in Europe: national interest, FDI and other ingredients of the growing regulatory maze’, European Competition Law Review 42(3) (2021) 117–129, with further proof.}
\footnotetext[103]{A criticism of the danger posed by both possible state control of pharmaceutical production and foreign trade defence to the fundamentals of the economic regulatory system of free markets in Europe has also been echoed by P.-C. Müller Graff in ‘Pandemiedruck im Binnenmarktrecht’, Zeitschrift für das gesamte Handels- und Wirtschaftsrecht 185(4) (2021) 461–473.}
\footnotetext[104]{Cf., supra note 69, p. 18.}
\footnotetext[105]{C. Calliess, ‘Braucht die Europäische Union eine Kompetenz zur (Corona-)Pandemiebekämpfung?’, Neue Zeitschrift für Verwaltungsrecht 49(5) (2021) 505–511.}
\footnotetext[106]{Ibid. Generally on the balance between solidarity and subsidiarity, see C. Calliess, ‘Subsidiaritäts- und Solidaritätsprinzip in der Europäischen Union’, 2nd edn. (Baden-Baden: Nomos, 1999) pp. 185 ff.}
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protection at the EU level through additional national measures.\textsuperscript{107} As a result of these considerations, Calliess proposes a new Article 168(4)(d) TFEU:

Measures for the early notification, monitoring and control of serious cross-border health threats, in particular in the event of pandemics. These measures shall not prevent Member States from maintaining or adopting enhanced protective measures where these are imperative.\textsuperscript{108}

Even if detailed analysis must be left to future research, this proposal seems, at least at first sight, to offer a very balanced and arguably more effective approach to the management of health crises at the EU level than that set out in the context of the Health Union. It allows for compulsory provisions within a narrowly defined subject area, generating an equal level of health protection throughout the EU in case of emergency. The discussion of a certain minimum level of health protection would, moreover and quite rightfully, spark debate of an old taboo topic, namely what level of minimum health care each Member State would have to provide for the EU to be able to successfully combat cross-border health threats.\textsuperscript{109} A new Article 168(4)(d) TFEU would enable Member States to pursue additional health goals as well. Despite these obvious benefits, such an extension of the TFEU would have to follow the legislative procedure of Article 48(2), (3) TEU requiring the consent of all Member States (Article 48(4) TEU).\textsuperscript{110} In the absence of consensus—which is not unlikely\textsuperscript{111}–a ‘coalition of the willing’ could be considered.\textsuperscript{112} Alas, this would most likely have disadvantages similar to the Health Union proposals. Either way, Member States will have to decide which way to go for the future.

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\item \textsuperscript{107} Supra note 105.
\item \textsuperscript{108} Ibid. (original in German).
\item \textsuperscript{109} Cf. supra note 99.
\item \textsuperscript{110} Supra note 105.
\item \textsuperscript{111} Cf. supra note 15.
\item \textsuperscript{112} Cf. M. Ruffert, ‘Article 20 EUV’, in: C. Calliess and M. Ruffert (eds.), EUV/AEUV-Kommentar, 5th edn. (München: C.H. Beck, 2016) pp. 330–338 paras 1ff.
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