Filling the Competence Gap in the Health Policy of the European Union (EU) by a New Article 168 (4) d) TFEU

– Lessons Learned from the Covid-19 Pandemic –

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Abstract

This article deals with the capabilities and limitations of the European Union in adopting measures in the fight against pandemics on the basis of legal and economic evaluative criteria. The Covid-19 pandemic has directed the spotlight on the EU's seemingly fumbling response in handling pandemics. The reason for this appearance of ineffectiveness lies in the lack of material competence of the EU in this area, which currently is limited to only a 'coordination competence' for health policy. The EU is thus dependent on the consensus and cooperation of all Member States in adopting measures such as the rules on vaccine procurement and on the vaccination passport. At the same time, given that pandemics do not stop at national borders, the European idea is dependent on a successful European response to pandemics, as only a common strategy can avoid border controls and ensure effective measures. Accordingly, the treaties include the goal of combating health hazards. However, the discrepancy between the European goal and the lack of necessary competences for its efficient accomplishment endangers the European idea as well as the Union's legitimacy. This must be resolved through an addition to the competence, while taking into account the criteria of the subsidiarity principle. This article proposes an amendment to add a subsection (subsection 'd)') to Article 168(4) of the Treaty on the Functioning of the European Union (TFEU) to supplement the EU's competence and to enable the EU to adequately react to future pandemics.

Keywords

European Health Union – European health competence – European public good – Corona pandemic – harmonisation and coordination of national health policies – European Medicines Agency

I. Introduction

In some policy areas, the European Union (EU) suffers from a gap between promise and delivery: The political actors at the European level tend to promise ambitious policies to uphold the goals enshrined in the European Treaties, which the European institutions fail to 'deliver' due to insufficient competences. For example, the EU treaties envisage a stable euro area (Article 119(2) TFEU), but as evidenced by the events following the 2008 global financial crisis and the resultant sovereign debt crisis, the fulfilment of this promise cannot be guaranteed due to a lack of economic and fiscal policy competences (see Article 121 TFEU). Similarly, the EU treaties promise to EU citizens the freedom of movement without border controls in an 'area of freedom, security and justice' (Article 67 TFEU). However, with the temporary reappearance of border controls in the wake of the migration crisis and the security situation following the terrorist attacks in Paris, the institutions in Brussels and Berlin have made it clear that there are no practical guarantees in this regard.[1] A similar predicament exists in the field of health policy. 'The EU' promises a European health policy to its citizens (Article 168 TFEU with Article 35 Charter of Fundamental Rights of the EU), but in the throes of a pandemic with Europe-wide as well as global effects, the EU's role appears limited to that of mere coordination between the Member States. In all of these examples, the EU treaties include more ambitious goals than the EU can deliver on the basis of the competences assigned to it by the Member States.[2]

This problem was well-illustrated by the debate on the European Commission's handling of the joint procurement of vaccines for its twenty-seven Member States.[3] While the Commission appeared to be in charge, in reality, it could only *coordinate* the decision-making among Member States by consensus – a fact often overlooked by the public. A steering committee, comprising representatives from all twenty-seven Member States, as well as a joint negotiating team comprising representatives from the Commission, Germany, Spain, Poland, Italy, France, Sweden, and the Netherlands, seem-

1 For details on this and on the eurozone generally, see Christian Calliess, *Öffentliche Güter im Recht der EU*, (Bertelsmann Stiftung 2021), 19 et seq. and 45 et seq., doi: 10.11586/2020072.

2 Also using this at the outset and as a starting point of their analysis, Corina Andone and Florin Coman-Kund, 'Persuasive Rather than "Binding" EU Soft Law? An Argumentative Perspective on the European Commission's Soft Law Instruments in Times of Crisis', The Theory and Practice of Legislation 10 (2022), 22-47 (29-30).

3 Marie Gontariuk et al., 'The European Union and Public Health Emergencies: Expert Opinions on the Management of the First Wave of the COVID-19 Pandemic and Suggestions for Future Emergencies', in: Front. Public Health, 20 August 2021, doi: 10.3389/fpubh.2021.698995.

ingly handled the negotiations with the vaccine manufacturers. However, according to publicly available information, the individual Member States had decided for themselves which manufacturer to pre-order from and how many vaccine doses to purchase. One might conjecture from this that the economically less prosperous Member States, also influencing the steering committee's decision, pushed for larger quotas of the cheaper vaccines to be ordered. Therefore, a costly spread of orders, as in the case of the US orders, was averted. Consequently, an insufficient amount of vaccines were ordered.

At the same time, due to the lack of a common European strategy, there were no coordinated controls on entry into the EU from third countries that were binding on all Member States. Among other consequences, this led to the (re-)introduction of national controls at the internal borders between Member States. In the first weeks of the pandemic, almost all borders in the Schengen area were subject to strict border controls, with some notable exceptions such as the German-Dutch border in the federal state of North Rhine-Westphalia.[4] This reaction to the pandemic impaired the free movement of persons within the internal market, infringing upon a core right of EU citizens (Article 21 TFEU) in the 'area of freedom, security and justice', the so-called Schengen area. In the wake of this fragmentation, there is a risk that the protective measures that make sense in and of themselves will be neither coherent, nor efficient, nor proportionate in light of the pandemic's cross-border dimension.[5]

Considering the difficulties experienced in the first months of the Covid-19 pandemic, the European Commission presented a proposal for the construction of a 'European Health Union' in November 2020. This proposal bundles various measures for more effective combating of cross-border health risks, including comprehensive precautionary strategies, institutional reforms, and binding obligations for Member States and compa-

4 Matthias Eckardt, Kalle Kappner and Nikolaus Wolf, 'Covid-19 Across European Regions. The Role of Border Controls', in: Charles Wyplosz (ed.), Covid Economics 42, 19 August 2020, 94-111 (97 et seq.).

5 In particular on the coherence requirement, see Matthias Ruffert, 'Article 7 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 2 et seq. as well as Christian Calliess, 'Article 13 TEU)' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), para. 2; with regard to the restriction of fundamental freedoms: ECJ, *Stoß et al. v. Wetteraukreis et al.*, judgment of 8 September 2010, ECLI:EU:C:2010:504; André Lippert, 'Das Kohärenzerfordernis des EuGH. Eine Darstellung am Beispiel der Rechtsprechung zum deutschen Glücksspielmonopol', Europarecht 47 (2012), 90-99; Bernd Hartmann, Kohärenz im Glücksspielrecht: vertikal – horizontal – intersektoral?, EuZW 25 (2014), 814-819.

nies.[6] By 2025, the EU has transformed many of its proposals into legislation, pushing the European Health Union to the boundaries of what is possible in terms of competence in the area of health policy.

This article argues that this current framework is still insufficient to ensure the fulfilment of the objectives set out in the EU Ttreaties. It has become necessary to add a legislative competence regarding pandemic protection in the field of health policy. To this end, relying on legal and economic arguments, this article aims to develop criteria for transferring competences to the EU. In essence, the article argues that competences should be transferred when there is a gap between European public goods 'promised' in the objectives of the Treaties and the competences of the EU is entitled in this respect (II.). The analysis of the normative framework in the area of public health and the issues encountered by the EU during the Coronavirus pandemic show that these criteria are met (III.). Further, the internal market competences cannot remedy the lack of competence in the field of public health (IV.). Thus, to truly fulfil the objectives in the field of public health and safeguard the achievements of European integration, it is necessary to adapt the Treaties to include more expansive competences for health policy. Hence, this article closes with a plea to amend the treaties, in order to equip the EU with the necessary competence to combat any future pandemics (V.).

II. General Criteria for a Transfer of Competence to the EU

The transfer of competence to the EU is primarily a political, rather than a legal, decision. However, one can make a political argument for such a transfer on the basis of criteria developed in legal science and economics. Turning to the law, the legal standard governing the question of competences is the principle of subsidiarity. Directly, it applies only to the interpretation of existing competences, but it can – by analogy – also guide the question of the transfer of competences (1.). The same holds true for the criterion of 'European added value' provided by economic theory (2.). On this basis, in

[6] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Building a European Health Union, Strengthening the EU's resilience to cross-border health threats, COM/2020/724; European Commission, Proposal for a Regulation of the European Parliament and of the Council. On an enhanced role for the European Medicines Agency in crisis preparedness and management in relation to medicines and medical devices, COM/2020/725; European Commission, Proposal for a Regulation of the European Parliament and of the Council. Establishing a European Centre for Disease Prevention and Control, COM/2020/726 and European Commission, Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health, COM/2020/727.

legal reasoning and economic theory, the political argument can be made that competences should be transferred from Member States to the EU, where the Treaties outline a common good that Member States cannot realise on their own due to its cross-border context (3.).

1. Objectives of the EU and the Principle of Subsidiarity

States are historically tasked with attaining goals pertaining to the realisation of common goods,[7] or public goods, as referred to in economics.[8] Article 3 of the Treaty on European Union (TEU) transfers some of these goals and tasks from the Member States to the EU under the premise that these are carried out adequately, and especially, to safeguard the public goods having a cross-border dimension: If the Member States are left to their own devices, they would be overburdened with solving the problems peculiar to the cross-border context.[9]

This overload can generally be substantiated based on the principle of subsidiarity. In this respect, the following two sets of questions must be distinguished:

On the one hand, there is the question of whether and how a competence transferred to the EU should be *exercised* to achieve a goal. This essentially means, whether the EU can and should *act at all*, and if so, to what extent. To answer these questions, the principles of subsidiarity and proportionality (Article 5 TEU) must be observed.[10] Article 5(3) TEU formulates, first, a 'negative criterion' according to which the EU may act in cases where an action by the Member States alone may not be sufficient to solve a problem. In addition to this according to a 'positive criterion', the EU must be able to

7 Christian Calliess, 'Gemeinwohl in der Europäischen Union – Über den Staaten- und Verfassungsverbund zum Gemeinwohlverbund', in: Winfried Brugger, Stephan Kirste and Michael Anderheiden (eds), *Gemeinwohl in Deutschland, Europa und der Welt* (Nomos 2002), 173-214.

8 For an overview, see Armin Steinbach and Anne van Aaken, *Ökonomische Analyse des Völker- und Europarechts* (Mohr Siebeck 2019), 49 et seq. with a general application of economic methods of analysis to European law reference areas on 147 et seq.

9 Thomas Dietz, Elinor Ostrom and Paul C. Stern, 'The Struggle to Govern the Commons', Science 302 (2003), 1907-1912; Inge Kaul, Donald Blondin and Neva Nahtigal, 'Introduction: Understanding Global Public Goods' in: Inge Kaul (ed.), *Global Public Goods* (Edward Elgar 2016), xiii-xcii; in addition, in overview Steinbach and van Aaken (n. 8), 49 et seq.

10 See European Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. The principles of subsidiarity and proportionality – strengthening their role in EU policy-making, COM/2018/703 final, 23 October 2018.

act more adequately than the Member States, a fact to be evidenced by an evaluative comparison.[11]

On the other hand, the question as to whether the competence to attain an objective should be transferred to the EU in the first place is a *political decision* and legally carried out by way of a treaty amendment through the procedures specified under Article 48 TEU. Within this framework of competences conferred by such an amendment, the criteria of the principle of subsidiarity can only be applied by analogy. This means that a competence should be transferred where Member States alone cannot act sufficiently, and the EU is more suitably equipped to realise a goal specified in the treaties.

2. European Added Value in Economic Theory

Moreover, the criteria used within the framework of economic theory for the provision of the so-called '(European) public goods' confirms the above legal and political findings.[12] From this point of view, European action should be possible in those areas in which the Member States alone cannot act 'sufficiently' concerning the provision and realisation of a European public good due to 'policy spill overs', i. e. the States are overburdened, and in which the European level has more suitable and effective means at its disposal than the Member State level ('economies of scale'), i. e. the EU can act 'better' in comparison. Within this framework, it is important to identify those areas in which an action at the EU level brings 'European added value'[13] and thus (in the language of politics[14]) strengthens European sovereignty or autonomy. In other words, wherever the sum of all Member States makes a difference and thus, at the same time, an added value can be achieved in a global context through joint European action (the so-called 'Brussels effect'),[15] there is a European public good towards which the EU should be able to function and act. It is not by mere chance that these criteria, to a certain extent, coincide

11 Christian Calliess, *Subsidiaritäts- und Solidaritätsprinzip in der Europäischen Union* (2nd edn, Nomos 1999), 65 et seq. including a test grid on p. 271 et seq. with further references; most recently Calliess (n. 1), 22 et seq.

12 See Clemens Fuest and Jean Pisani-Ferry, 'A Primer on Developing European Public Goods', EconPol Policy Report 16 (2019), 1-42 (7 et seq.).

13 See Fuest and Pisani-Ferry (n. 12), 7 et seq.

14 See Press and Information Office of the Federal Government, 'Meseberg Declaration. Renewing Europe's Promise for Security and Prosperity', 19 June 2018, press release 214.

15 Anu Bradford, 'The Brussels Effect', Nw. U. L. Rev. 107 (2012), 1-68; Benjamin Hartmann and Sofia Lucas Areizaga, Kommission: Die Herausforderungen für die Zukunft der Europäischen Union, in: Gregor Kirchhof, Mario Keller and Reiner Schmidt (eds), Europa: In Vielfalt geeint!, Munich 2020, 101-116.

with the criteria under the principle of subsidiarity, as outlined in Article 5 TEU.[16]

3. The Necessity of Competence Transfers Where European Tasks Exceed the EU's Capacity to Act

At this point, it is important to clarify that the objectives of the EU are not necessarily congruent with its competences, and therefore its capacity to act. Some objectives aim higher by specifying contents beyond the competences currently conferred upon the EU in the Treaties. This leads to the generally problematic discrepancy between the European promise and its delivery: The current European order of competences does not enable the EU to deliver on the promised European goals. Illustrative of such a deficit are the fields of European social policy (see Article 3 para. 3 TEU and Article 151 on the one hand, and Article 153 TFEU on the other), economic policy (see Article 119 on the one hand, and Article 121 TFEU on the other), and European health policy. This discrepancy between promise and potential delivery can prove detrimental to the EU's legitimacy and further lead to practical problems, as the tasks included in the treaties are usually aimed at addressing issues with a cross-border dimension. Thus, competence should be transferred where there is such a disparity between tasks and competences that undermines the Union's capacity to act.

III. The Covid-19 Pandemic and the Limits of EU Competence in the Field of Health Policy

A significant disparity between the specified tasks and assigned competences can be found in the field of public health policy, particularly in the response to the Covid pandemic (1.). While the EU has moved forward with the establishment of the European Health Union during the Covid-19 pandemic, a lack of legislative competence in this field has significantly constrained this development (2.).

1. Disparity Between Tasks and Competences in the Field of Health Policy

The challenges described above are exacerbated by the Covid-19 pandemic, which has made us aware of the fact that the competences conferred

16 In depth analysis Calliess (n. 1), 22 et seq.

upon the EU in the area of public health, unlike those in environmental and consumer protection policy, are insufficient. While the European Court of Justice (ECJ) recognises a 'general principle' that health 'must undoubtedly be given priority',[17] particularly in relation to economic considerations, the Member States remain the 'masters of health policy'.[18] According to Article 168(1) TFEU, the EU's competence is generally restricted to activities that complement, promote, or coordinate the health policies of the Member States.[19] This limited competence of the EU remains unaltered by Article 35 of the Charter of Fundamental Rights of the EU, which postulates a 'right of access to preventive healthcare and the right to benefit from medical treatment'. Although arguments for a protective dimension of European fundamental rights ('duty to protect') have been advanced in case law and literature,[20] Article 51(1) sentence 2 and (2) of the Charter clarify that the rights listed therein may not lead to an expansion of the EU's competences.[21]

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17 ECJ, *Artegodan GmbH*, judgment of 19 april 2012, case no. C-221/10 P, ECLI:EU:2012:216, para. 99.

18 Markus Kotzur, 'Article 168 TFEU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), *European Union Treaties* (C. H. Beck and Hart 2015), para. 7; Werner Berg and Steffen Augsberg, 'Article 168 TFEU' in: Ulrich Becker, Armin Hatje, Johann Schoo and Jürgen Schwarze (eds), *EU-Kommentar* (4th edn, Nomos / facultas / Helbing Lichtenhahn 2019), para. 16; Rudolf Mögele, 'Die EU und COVID-19: Befugnisse und Initiativen', EuZW 31 (2020), 297-344.

19 Thorsten Kingreen, 'Article 168 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 3 et seq. and 13 et seq.; Daniel Thym and Jonas Bornemann, 'Binnenmarktrechtliche Grundlagen des Infektions- und Gesundheitsschutzrechts', in: Stefan Huster and Thorsten Kingreen (eds), *Handbuch Infektionsschutzrecht* (2nd edn, C. H. Beck 2022), ch. 2, paras 49 et seq.; differentiating Astrid Wallrabenstein, 'Gesundheitspolitik' in: Bernhard W. Wegener, Armin Hatje, Peter-Christian Müller-Graff and Jörg Philipp Terhechte (eds), *Enzyklopädie Europarecht, Europäische Querschnittpolitiken*, vol. 8 (Nomos 2014), paras 65 et seq.; from a legal practitioner's point of view: Tobias Maass and Florian Schmidt, Die Entwicklung des EU-Gesundheitsrechts seit 2012, EuZW 26 (2015), 85-92.

20 Christian Calliess, 'Dimensions of Fundamental Rights – Duty to Respect versus Duty to Protect' in: Hermann Pünder and Christian Waldhoff (eds), *Debates in German Public Law* (Hart Publishing 2014), 27-42; also Gerald Sander, 'Europäischer Gesundheitsschutz als primärrechtliche Aufgabe und grundrechtliche Gewährleistung', ZEuS 8 (2005), 253-272; with a current overview and comparative analysis to positive obligations under the European Convention of Human Rights Niklas Täuber, 'Positive Obligations within the European Fundamental Rights Protection System: The Unleashing of a Beast or Realization of 21st Century Fundamental Rights Protection', Berliner Online-Beiträge no. 149, 19 September 2023, available at <https://www.jura.fu-berlin.de/forschung/europarecht/bob/berliner_online_beitraege/Paper149-Taeuber/BOB149_Positive-Obligations-within-the-European-Fundamental-Rights-Protection-System.pdf>, last access 12 November 2025.

21 'Article 52 CFREU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), *European Union Treaties* (C. H. Beck and Hart 2015).

According to Article 168(2) TFEU, the Commission may,

> 'in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation'.

In the exercise of such coordination by the EU, the competence of the Member States remains unaltered; that is, it is not – as in the case of binding legislation – *europeanised* or even limited (see Article 2 para. 2 TFEU). In this sense, within the paradigms of public health competence, the EU can merely facilitate coordination among Member States that make decisions themselves by unanimity. This shows that the real power remains in national hands (Article 2 para. 3 and 5 TFEU).[22] How this unfolds in practice is illustrated, for instance, by the recent attempt of the EU to address the Covid-19 pandemic by 'inviting'[23] manufacturers of masks and respirators to 'immediately increase production'. As such, pursuant to Article 168(2) TFEU, the Commission cannot bind or commit the Member States to any such joint procurement without their consent. It follows that this requires a voluntary agreement on the joint procurement of medical equipment via public tenders. Accordingly, it appeared on the outside that the Commission had carried out the procurement procedures; however, in fact, its acts were contingent on the consent of the Member States, which formally remained the purchasers of the products.[24] In this way – similar to the procurement of vaccines[25] – while ostensibly the EU appears to act, the real mandate remains with the Member States which decide by unanimity. Consequently, responsibility and competence diverge: The EU might be held responsible for all the failures that could occur during the procurement process, even though the European level never could or did act on its own accord due to its lack of competence.

This legal situation is underpinned by the exclusion of any European harmonisation of national laws of the Member States (Article 168(5) TFEU). This prohibition also covers measures

> '[…] designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health […]'.

22 Christian Calliess, 'Article 6 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 5 and 12 et seq. and Christian Calliess, 'Article 2 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 19 et seq.

23 Communication from the Commission COM/2020/112 final, 13 March 2020, 4.

24 Thym and Bornemann (n. 19), ch. 2, para. 16 with further references.

25 See Commission Communication, COM/2020/245 final, 7 June 2020.

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An exception to this prohibition on European harmonisation only applies in the case of narrowly defined areas explicitly listed in Article 168(4) TFEU, which are as follows:

> 'a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;
>
> (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
>
> (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.'

Currently, only the above-listed measures can qualify as '*common safety concerns in public health matters*' as defined under Article 4(2)k) TFEU, where the EU may have full (shared) legislative competence. Not surprisingly, the list reflects competences transferred to the EU level in the course of past political experience with crises (such as HIV blood products, BSE, EHEC).[26] Consequently, Member States can only be bound by the European requirements within the scope of application of Article 168(4) TFEU.

2. EU Practice in the Covid-19 Pandemic: Moving Forward, but with the Handbrake on

In comparison to the European legal framework in the field of public health prior to the Covid-19 pandemic (a.), the EU has taken significant steps forward with the adoption of its Health Union framework. However, it has repeatedly come up against the restrictive boundaries of the coordination competence (b.).

a) EU Secondary Law and Administrative Framework Before the Covid-19 Pandemic

While the EU has widely exercised its competences under Article 168(4) TFEU,[27] the existing legislation to combat pandemics was very limited, given the prohibition on harmonisation under Article 168(5) TFEU. The frame-

26 Sander (n. 20), 253 et seq.; Kingreen (n. 19), paras 18 et seq.; Birgit Schmidt am Busch, *Die europäische Gesundheitssicherung im Mehrebenensystem* (Mohr Siebeck 2007).

27 With an overview Kotzur, 'Article 168 TFEU' (n. 18), paras 13 et seq.

work essentially came down to Decision 1082/2013/EU on improving cooperation and coordination, which enabled epidemiological surveillance and monitoring, early detection and control of diseases, through close coordination between the Union and the Member States. Central to this coordination were the establishment and maintenance of an early warning and response system, as well as the work of a 'Health Security Committee' comprising representatives from national health authorities working in close coordination with the Commission.[28]

Other pre-existing parts of the framework are the two EU agencies: the well-known European Medicines Agency (EMA) and importantly, the Stockholm-based European Centre for Disease Prevention and Control (ECDC), which was established in 2004.[29] The independent agency collects information, identifies and assesses hazards on this basis, and can provide expert opinions. In 2013, the aforementioned Decision 1082/2013/EU entrusted the ECDC with the task of operating and coordinating a transnational network comprising the Agency, the Commission, and the Member States for the epidemiological surveillance of communicable diseases. Furthermore, the ECDC also operates an early warning and response system.[30]

b) Making Full Use of Limited Competences – More but Still Not Enough

As outlined above, the Covid-19 pandemic called on the European Union to take action, especially given the cross-border dimension combined with the specific goal of the Union to ensure a high level of health protection for its citizens. However, despite the limited competences in the area of health, the EU was able to strengthen the existing structures and expand them to form a network of measures, procedures and institutions, which also serve to protect human health in the event of an infectious risk.[31]

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28 See 1 and 8 et seq. of Decision 1082/2013/EU of 22 October 2013 of the European Parliament and of the Council on Serious Health Procedures, Official Journal of the EU, no. L 293 of 5 November 2013.

29 Regulation 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Official Journal of the EU, no. L 136 of 30 April 2004; on this Andreas Orator, *Möglichkeit und Grenzen der Einrichtung von Unionsagenturen* (Mohr Siebeck 2017), 142 et seq.

30 See Article 4 et seq. Regulation 51/2004/EC of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control, Official Journal of the EU, no. L 142 of 30 April 2004; Orator (n. 29), 131-132.

31 See the overview in Thym and Bornemann (n. 19), ch. 2, paras 44 et seq. and 68 et seq.

aa) Limited Strengthening of the Existing Framework

Additionally, in the course of the Covid-19 pandemic, the EU relied on this existing framework and – in 2022 – decided to facilitate and expand this existing network to protect EU citizens' health against infectious risk.

(1) Substantial Rules

The above-mentioned Decision 1082/2013/EU was repealed by Regulation 2022/2371/EU dated 23 November 2022. The change in the nature of the legal strategy – issuing a Regulation instead of an updated decision – already indicates a more expansive approach of the Union in this regard. The Regulation aims to broaden the Union's powers to react to cross-border health threats. The framework is – due to Article 168(5) TFEU – scaled back to the coordinating functions of the Union. This includes *inter alia* more substantive rules for the Union's coordination of Member States' prevention, preparedness, and response-planning to such cross-border health threats and their review (Article 5 et seq.) as compared to the former framework under Decision 1082/2013. These efforts are still coordinated by the Health Security Committee, now set up under Article 4 of the Regulation.[32]

(2) Expanding Mandates of EMA and ECDC

Additionally, the EU further broadened the mandate of the pre-existing institutions, the EMA and ECDC, throughout the pandemic. On the basis of Article 168(4)(c) TFEU, the role of the EMA was strengthened through Regulation 2022/123/EU. Its mandate now includes the following under Article 1:

> '(a) preparing for, preventing, coordinating and managing the impact of public health emergencies on medicinal products and on medical devices and the impact of major events on medicinal products and on medical devices at Union level;
>
> (b) monitoring, preventing, and reporting on shortages of medicinal products and on shortages of medical devices;
>
> (c) setting up an interoperable information technology (IT) platform at Union level to monitor and report on shortages of medicinal products;
>
> (d) providing advice on medicinal products that have the potential to address public health emergencies
>
> (e) providing support for the expert panels provided for in Article 106(1) of Regulation (EU) 2017/745.'

32 Providing an analysis of the Regulation Daniel Alin Olimid and Anca Parmena Olimid, 'Accuracy of Information, Data and Health Resilience: An Analytical Study of the Regulation (EU) 2022/2371', Revue des Sciences Politiques 77 (2023), 49-61.

As the competence basis for this is Article 168(4)(c), the competence limit of Article 168(5) TFEU does not apply. Hence, this has facilitated the possibility of more detailed substantive rules, which are now available in the restricted area of medicinal products.

Additionally, EMA is now involved in the Union's assessment of public health risks, as per Article 20 of Regulation 2022/2371/EU.

The role of ECDC in responding to the pandemic remains crucial: In the early days of the Covid-19 pandemic, it was able to provide conclusive data on the spread of the virus.[33] Subsequently, the ECDC was significantly strengthened through Regulations 2022/2370/EU and 2022/2371/EU. Regulation 2022/2370/EU extended its mandate to include protection from cross-border health-threats, still encompassing well-functioning procedures as the aforementioned early warning and response system (now in Article 8). The same applies for Regulation 2022/2371/EU, according to which the ECDC plays a central role in the coordination of the pandemic prevention efforts by the Member States. Its central task here is to assess risks for current and future pandemics, as well as to assess the prevention, preparedness, and response-planning by the Member States every three years as per Article 8 of Regulation 2022/2371/EU, which enables it to issue recommendations to the Member States to adapt their planning.[34]

(3) Vaccine Procurement

Deficits are also been identified with regard to attempts by the EU to increase the production of protective equipment such as masks and respirators. In this respect, the European Commission 'requests'[35] the suppliers to 'increase production without delay'. Only such a non-binding request is possible within the framework of Article 168(2) TFEU, so that nothing more (but also nothing less) than a voluntary agreement on the joint procurement

33 Providing a detailed overview of the involvement of ECDC in the first months of the pandemic Dionyssis G. Dimitrakopoulos and Georgette Lalis, 'The EU's Initial Response to the COVID-19 Pandemic. Disintegration or 'Failing Forward'?, Journal of European Public Policy 29 (2021), 1395-1413 (1399-1400).

34 Maria an der Heiden, Julia Schilling and Ute Rexroth, 'Pandemic Preparedness im Rahmen der Internationalen Gesundheitsvorschriften (IGV): Die Rolle des ÖGD', Public Health Forum 31 (2023), 332-335 (333); with a summary (while still referencing the proposal) Elenor Brooks, Anniek de Ruijter, Scott L. Greer and Sarah Rozenblum, 'EU Health Policy in the Aftermath of COVID-19: Neofunctionalism and Crisis-Driven Integration', Journal of European Public Policy 30 (2023), 721-739 (729).

35 European Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup. The coordinated economic response to the COVID 19 pandemic, COM/2020/112 final, 5.

of medical equipment via public tenders was launched. In this context, although the Commission could take over the implementation of the procurement procedures, the EU acted on behalf of the Member States, which formally remained the purchasers of the products.[36] In this way, as in the case of vaccine procurement,[37] externally, it is the EU that appears to act, but internally, it is the Member States that decide by consensus, and retain control over the entire process. Once again, responsibility and competence diverge here. This means that from the outset there was a danger that the EU could be held responsible for all mistakes, although internally, it was fully dependent on the involvement and agreement of the Member States; i. e. it could not act independently.

bb) Adding a Financial Framework Through EU4Health

With Regulation 2021/522/EU, the Union has used its coordination competence under Article 168(5) TFEU to support Member States in order to improve human health. In this regulation, the initial tension between the Union's goals and competence becomes apparent in the regulation's preliminary considerations. The Regulation considers:

> '(1) According to Article 3(1) of the Treaty on European Union (TEU), among the aims of the Union is the promotion of the well-being of its peoples.
>
> (2) According to Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.'

Then, rather underwhelmingly, the Regulation is compelled to admit its limited possibilities:

> '(3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of Member States for the definition of their health policies and for the organisation, management and delivery of health services and medical care.'

However, the Regulation provides a framework for such coordination, and, more importantly, from its budget of 5.1 billion euros, provides Member States with significant funds.[38] Thus, while following a coordinative ap-

36 Thym and Bornemann (n. 19), ch. 2, para. 16 with further references.

37 See European Commission, Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank. EU Strategy for COVID-19 Vaccines, COM/2020/245.

38 Brooks, de Ruijter, Greer and Rozenblum (n. 34), 734.

proach, the Union might have a significant impact on the quality of health of its citizens by the provision of these funds.[39]

cc) Installation of HERA

In addition, the European Health Emergency Preparedness and Response Authority (HERA) has been added to the network and has been fully operational since 2022, building on the experience of the Covid-19 pandemic. HERA is another 'indispensable centrepiece of a strong Health Union' and is intended to provide preparedness for cross-border crises – such as pandemics – in the future, and to take immediate action when such a crisis occurs. This includes, in particular, ensuring the production and supply of medical protective equipment and vaccines. HERA is also intended to ensure better coordination in the event of a crisis by acting as a joint resource control centre for the Member States and EU institutions.[40] Putting this into practice, the EU was able to secure the procurement of vaccines within a very limited timeframe after an Mpox outbreak in 2022.[41] However, as far as binding and harmonising measures are concerned, the proposals continue to be pitted against the competence limit of Article 168(5) TFEU.[42]

dd) Further Crisis Response in the Aftermath of the Covid-19 Pandemic Outside the Scope of Article 168 TFEU

However limited the Union's competences under Article 168(5) TFEU, the EU has put forward a variety of further responses to the Covid-19 pandemic. Considering the findings so far, it does not surprise that major legislation brought forward by the EU lies outside the strict limits of Article 168. The most prominent example of this, of course, is the EU's recovery plan NextGenerationEU based on Articles 162, 175 ff., and 136 TFEU, with the aim of combatting the economic impacts of the Covid-19 pandemic.[43]

39 Further on the economic response to the Covid-19 pandemic Vincent Delhomme and Tamara Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order, YBEL 41 (2022), 48-82 (54 et seq.); Chih-Mei Luo, 'The COVID-19 Crisis: The EU Recovery Fund and Its Implications for European Integration – a Paradigm Shift', European Review 30 (2021), 374-392.

40 For more details, see Commission Communication, COM/2021/576 final.

41 European Commission, Achievements of the von der Leyen Commission. Overcoming the Covid-19 Pandemic Together and Building a Health Union, 8 March 2024, 2; on the installation of HERA Delhomme and Hervey (n. 39), 58 et seq.

42 As to the reluctance to add additional powers of the Member States Brooks, de Ruijter, Greer and Rozenblum (n. 34), 732.

43 See Christian Calliess, 'Erweiterung und Reform der Europäischen Union', EuZW 34 (2023), 781-788 (783).

Another example of a yet-to-be-adopted measure tackles the issue of digitalisation and healthcare: The Commission has put forward a proposal for a Regulation on the 'European Health Data Space', aiming to simplify the circulation of health data between the Member States.[44] The Commission bases its proposal on the internal market competence in Article 114 TFEU.

For a full overview of the detailed measures, the Commission has recently published an overview as to the successes of the Health Union until this point.[45]

c) Interim Result

It is clear from the foregoing examples that both the network outlined in the area of European health protection and the proposal for its further development within the framework of the 'European Health Union', must build on the non-binding measures typical for a coordination competence.[46] A ban on harmonisation under Article 168(5), in turn, leaves the Union at the mercy of the voluntariness and consensus between the Member States. From a health policy perspective, the same applies to the proposal for a European vaccination passport. While overall, these developments demonstrate some progress, any further developments are blocked by the competence limit set by Article 168 (5) TFEU. The EU made the best out of the tools available – within the ambit of Article 168 TFEU and without.[47] More detailed and, most importantly, binding action by the EU will require a change in the EU treaties. Following this, a crucial lesson to be learnt from the Covid-19 pandemic is that the ECDC should be strengthened and developed into a 'real' EU health agency, possibly with executive powers, and entrusted by the Member States with the responsibility for crisis preparedness and response. As part of this, the ECDC will be equipped with the ability to provide practical support to Member States in situations such as the Covid-19 pandemic.[48]

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44 European Commission, Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final.

45 European Commission, Achievements of the von der Leyen Commission. Overcoming the Covid-19 pandemic together and building a Health Union (November 2024, available online).

46 In this regard Christopher Schoenfleisch, *Integration durch Koordinierung?* (Mohr Siebeck 2018), 7 et seq. and 109 et seq.

47 With the same conclusion Martin Rhodes, '"Failing Forward": a Critique in Light of Covid-19', Journal of European Public Policy 28 (2021), 1537-1554 (1544 et seq.).

48 See European Commission, Building a European Health Union: Strengthening the EU's resilience to cross-border health threats, COM/2020/724 final, 5 and 17 et seq. and in detail European Commission, Establishing a European Centre for Disease Prevention and Control, COM/2020/726.

IV. Health Policy on the Basis of the Internal Market Competence?

The lack of a genuine competence for health policy can also not sufficiently be compensated for through a more expansive use of the EU's internal market competence. The establishment of a common market or 'internal market'[49] has been a core objective of the European Economic Community since it was founded in 1957 and continues to be one of the central objectives of the EU today according to Article 3(3) TEU. Article 26(2) TFEU defines the internal market as 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty'. As such, the idea behind an internal market is about the merging of national markets into a single market in which goods and persons can circulate without border controls or other restrictions as freely as possible. The realisation of the internal market is based on two – ideally complementary – strategies, namely 'positive' and 'negative' integration.[50]

1. Positive Integration

Within the framework of positive integration, the European legislator realises the freedom of movement within the internal market through harmonisation. In this respect, the Article 114 TFEU provides the general competence basis for internal market measures. Additionally, there are also specific competences pertaining to free movement of persons (e. g. Article 21 para. 2, Articles 46, 50, 53 TFEU) which allow the EU to harmonise Member States' legislation which may affect the smooth functioning of the internal market.[51] Such legislation includes those aimed at the protection of health during pandemics. In particular Art. 114 TFEU might provide for a potential basis to supplement the limited competence of the EU under Article 168 TFEU. This is because there are respective provisions for the internal market, like

49 This was preceded by the Commission's White Paper on 'Completing the Single Market' of 14 June 1985 (COM/85/310); on this and on the conceptual delimitation Markus Kotzur, 'Article 26 TFEU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), European Union Treaties (C. H. Beck and Hart 2015), paras 1 et seq.

50 See Fritz W. Scharpf, 'Negative and Positive Integration in the Political Economy of European Welfare States', in: Gary Marks, Fritz W. Scharpf, Philippe C. Schmitter and Wolfgang Streeck, *Governance in the European Union* (Sage 1996), 15-39; Stefan Korte, 'Article 26 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 10 et seq. and 26 et seq.

51 For more details, see the study by Markus Ludwigs, *Rechtsangleichung nach Article 94, 95 EG-Vertrag* (Nomos 2004).

Article 9 TFEU coupled with Article 168(1) TFEU, which provide for measures on protecting health, like Article 11 TFEU does concerning environmental policy,[52] Article 12 TFEU on consumer protection policy, and Article 147(2) TFEU on employment policy. These cross-cutting tasks must therefore always be considered for all EU measures in other areas, including in the context of internal market-related legal harmonisation pursuant to Article 114(1) TFEU. This is underlined not the least by Article 114(3) TFEU, which directs the Commission to assume a high level of protection in its proposals for legislative harmonisation with regard to some of these policy areas, such as health protection.

Article 114(1) TFEU in its wording appears to provide a *carte blanche* to the EU to enact 'measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market'. However, it is precisely this wording which leads to recurrent questions about understanding this seemingly no-holds-barred cross-sectional competence vis-a-vis other specific substantive competences conferred upon the EU by the Member States: This is necessary to ensure that alongside the smooth functioning of the internal market, public welfare too can be protected. This is to be done through policies in the areas such as environmental, consumer, and health protection. Also debated is the question of where the 'limitation' on EU competence of health protection under Article 168 TFEU stops, and where the general harmonisation power under Article 114 TFEU begins.

a) Leading Decision on the Tobacco Advertising Ban

The case law of the ECJ on the European tobacco advertising ban throws light on the question about which health related measures can be based on Article 114 TFEU.[53] While the regulation of tobacco and its advertising continues, to this day, to be the subject of inconsequential follow-up judg-

52 Christian Calliess, 'Die neue Querschnittsklausel des Article 6 ex 3 c EGV als Instrument zur Umsetzung des Grundsatzes der nachhaltigen Entwicklung', DVBl 1998, 559-568.

53 ECJ, *Germany v. Council and Parliament*, case no. C-376/98 [2000] ECR I-2247; see also the contributions in Doris König and Dirk Uwer (eds), *Grenzen europäischer Normgebung* (Bucerius Law School Press 2015), 13 et seq.; critically Devika Khana, 'The Defeat of the European Tobacco Advertising Directive: A Blow for Health', YBEL 20 (2001), 113-138; Walter Frenz and Christian Ehlenz, 'Rechtsangleichung über Art. 114 AEUV und Grenzen gem. Art. 5 EUV nach Lissabon', EuZW 22 (2011), 623-626; Sacha Prechal, Sybe de Vries and Hanneke van Eijken, 'The Principle of Attributed Powers and the "Scope of EU Law"' in: Leonard Besselink, Frans Pennings and Sacha Prechal (eds), *The Eclipse of the Legality Principle in the European Union* (Wolters Kluwer 2011), 213-248 (236 et seq., 245).

ments by the ECJ[54] as well as numerous debates and disagreements in legal scholarship,[55] the first tobacco advertising ban ruling gives a clear and coherent answer to the question of delimitation between the internal market and health policy competence, and should thus be the basis of any further discussion. The decision provides in clear albeit terse terms that other ancillary articles of the TEU may not be used as a legal basis to circumvent the express exclusion of any harmonisation provided under Article 168(5) TFEU. At the same time, however, the ECJ points out that this is not to say that the harmonisation measures adopted on the basis of Article 114(1) TFEU may not incidentally impact the protection of human health. As such, under certain circumstances, health protection may even play a 'decisive role' in the context of the intended measure. The ECJ arrived at this conclusion based on a joint reading of Article 114(3) TEU and the corresponding cross-cutting health policy clause of Article 168(1) TFEU, which obliges the Union institutions to also strive to achieve a high level of health protection in the pursuit of other Treaty objectives. The latter, however, was only deemed to be a 'secondary objective', or incidental, to the main regulation.[56] Against this background, the ECJ then examined the following about the measure in question supposedly based on the internal market competence under Article 114 TFEU:

1. First, whether the measure actually serves to eliminate obstacles to the free movement of goods and the freedom to provide services;[57] and
2. Secondly, whether it actually contributes to the elimination of distortions of competition.[58] Within the framework of this objective of Article 114 TFEU, the ECJ specifically examines whether the distortions of competition which the act seeks to eliminate are justified. If this condition were not met, there would be practically no limits to the competence of the Community legislator.[59]

The ECJ considers this requirement of actually serving to eliminate trade barriers and noticeable distortions of competition in the internal market to be mandatory and therein clarifies that Article 114(1) TFEU contains a general, but not unrestricted, competence to enact harmonisation measures. Any measure that does not fulfil this requirement – as emphasised by the ECJ –

54 Latest addition ECJ, *Poland v. Parliament and Council*, case no. C-358/14, ECLI:EU:C:2016:323, para. 26, 32 et seq. (); also see ECJ, *Ireland v. Parliament and Council*, case no. C-301/06, ECLI:EU:C:2009:68.

55 Critical of recent case law Martin Nettesheim, 'Die Tabak-Urteile des EuGH: Lifestyle-Regulierung im Binnenmarkt', EuZW 27 (2016), 578-581 (580).

56 Werner Berg, *Gesundheitsschutz als Aufgabe der EU* (Nomos 1997), 463 et seq.

57 ECJ, *Germany v. Council and Parliament* (n. 53), paras 95-102.

58 ECJ, *Germany v. Council and Parliament* (n. 53), paras 106-114.

59 ECJ, *Germany v. Council and Parliament* (n. 53), paras 106 et seq.

must be regarded as a circumvention of Article 168(5) TFEU, which prohibits harmonisation of areas outside the scope of those listed in Article 168(4) TFEU.[60] This leads to the conclusion that the measures intending to combat pandemics such as Coronavirus cannot be based on the internal market competence of Article 114(1) TFEU just because it allows the possibility of harmonisation to the European legislator.

The clear wording of Article 168(5) TFEU and the accompanying conclusions must also apply *mutatis mutandis* to the specific free movement competences under Article 21(2) as well as Articles 46, 50, 53 TFEU. This is illustrated by, for example, Recommendation (EU) 2020/1475 of 13 October 2020, which, pursuant to Article 288(5) TFEU, is non-binding and is explicitly 'only' intended to ensure a coordinated approach or enhanced coordination in case a Member State wishes to take measures to restrict freedom of movement on public health grounds. Concerning the risk of cross-border infection chains, this was in turn supplemented by another Recommendation (EU) 2021/119 dated 1 February 2021.[61]

Thus, with the law on the internal market and the free movement of persons, the EU at best only has an indirect regulatory access to the health and infection control law of its Member States. If, for example, it lays down secondary legislation for the authorisation and distribution of medicinal products or vaccines, it primarily regulates the free movement of goods in the internal market, but at the same time ensures uniform (minimum) standards for the European public good of health protection for the citizens of the Union. In this respect, the aforementioned European Medicines Agency (EMA)[62] is also a supranational regulatory agency that facilitates the EU-wide testing and authorisation of medicines and vaccines and thus establishes common standards.

b) European Vaccination Certificate

Contrary to what has been discussed above, the Commission has relied on Article 21(2) TFEU as legal basis in its proposal submitted on 17 March 2021 for a European vaccination passport (so-called 'digital green passport'). This proposal is likely to encounter a similar objection to the one which was the subject of the ECJ decision on the tobacco advertising ban. On the flip side,

60 Torsten Stein, 'Die Querschnittsklausel zwischen Maastricht und Karlsruhe, in: Ole Due, Marcus Lutter and Jürgen Schwarze (eds), *Festschrift für Ulrich Everling*, vol. II (Nomos 1995), 1439-1453 (1441 et seq.); Kotzur, 'Article 168 TFEU' (n. 18), para. 10.

61 OJ EU L 337, 14.10.2020, p. 3 and OJ EU L 36 I, 2.2.2021, p. 1 respectively.

62 Regulation 726/2004/EC of 31 March 2004 establishing a European Medicines Agency, Official Journal of the EU, no. L 136 of 30 April 2004; on this Orator (n. 29), 142 et seq.

one could argue that this measure serves to advance the freedom of movement, as its focus is on safe travel during a pandemic, and that health protection is only incidentally affected. Indeed, the Regulation proposes that the results of receiving a COVID-19 vaccination, recovering from a COVID-19 illness, or testing negative should be recorded in a forgery-proof certificate based on uniform criteria. In concrete terms, this certificate can be converted into a QR code that can be presented on paper or a smartphone, just like a train ticket. Overall, it remains unclear whether Article 21(2) TFEU can hold up as competence basis for the vaccination passport.

As an alternative, the vaccination passport could have also been based on the EU's coordination competence under Article 168 TFEU. Indeed, the development of a technical platform that enables the vaccination card databases of the Member States to exchange information with one another, as well as to verify and mutually recognise the 'certificates', can be achieved in this manner. In this respect, the expectation is that Member States will set up national databases and require the testing and vaccination centres, as well as doctors, to upload all relevant data on vaccinations administered, negative test results, and recoveries from the illness. Above all, Member States should remain free to decide for themselves which concrete benefits they might wish to link to the green certificate. On the other hand, if they continue to require travellers holding these certificates to quarantine or undergo additional testing, they will have to notify the Commission, as well as all other Member States, and justify why such additional requirements are necessary.[63]

The fact remains that, despite proposing a Regulation on the legal basis of Article 21 TFEU, the Commission has willingly limited itself to the role of a coordinator/mediator, which is rather in accordance with the coordination competence of Article 168 TFEU. Having acted in this manner, the Commission has cautiously taken into account the potential limitations to its competence and skilfully avoided a potential rebuke by the ECJ similar to the first decision on the ban on tobacco advertising.

c) Interim Result

As a result, the EU's role in the area of health and infection control can at best be described as that of having indirect regulatory access over the health

63 See in detail the proposal for a Regulation on a framework for the issuance, verification and acceptance of interoperable certificates for vaccination, testing and recovery with the objective of facilitating free movement during the COVID 19 pandemic (digital green passport), see COM/2021/130 final.

and infection control law of the Member States via its competences pertaining to the internal market and freedom of movement.

2. Negative Integration

Where positive integration through European harmonisation cannot take place, the EU may resort to negative integration, which is defined by the fundamental freedoms that characterise the internal market. Here, the role of health protection will be limited to that of a justification for national measures such as export restrictions or border controls.[64]

In its *Cassis de Dijon* ruling[65] on the fundamental freedom of free movement of goods, the ECJ established the principle of mutual recognition. According to this principle, any product lawfully manufactured and marketed in one Member State may also be imported into other Member States, where it must, as a rule, be freely marketable. In this way, it has in effect formulated a sort of presumption as to a country-of-origin principle for goods in the internal market, according to which the legal and technical regulations of one Member State are, in principle, to be considered equivalent to those of another. However, the country of destination can rebut this presumption by defending its national legislation on the basis of written and/or unwritten grounds of justification (e. g. according to Article 36 TFEU as well as beyond this, by way of so-called imperative requirements of public interest). If the justification is found valid, i. e. the country of destination justification outweighs the country of origin principle, the said presumption is deemed to be rebutted, with the consequence that there is no mutual recognition, i. e. the internal market remains fragmented.[66] In this matrix of internal market regulation, *national health protection* is one such possible justification in the public interest that can be legitimataly raised and must always be balanced against the European fundamental freedoms, namely, the free movement of goods, services, and persons, bearing in mind the principle of proportionality.[67] This means that the national border controls may be

64 Thym and Bornemann (n. 19), ch. 2, paras. 13 et seq. and 22 et seq. with further references.

65 ECJ, *Cassis de Dijon*, judgment of 20 February 1979, case no. C-120/78 (1979) ECR 649, ECLI:EU:C:1979:42, para. 14.

66 In detail Christian Calliess, 'Europäischer Binnenmarkt und europäische Demokratie: Von der Dienstleistungsfreiheit zur Dienstleistungsrichtlinie – und wieder Retour?', in: DVBl 2007, 336-346.

67 For further details, see Thorsten Kingreen, 'Article 34-36 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, Munich 2022), paras 89 et seq. and 198 et seq.; Markus Kotzur, 'Article 36 TFEU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), *European Union Treaties* (C. H. Beck and Hart 2015), paras 1 et seq.

rightfully justified as a measure to curtail the spread of a pandemic. Similarly, export bans imposed by a Member State with the aim of securing its own needs for medical products may also be legitimate, even though these bans interfere with the principle of the free movement of goods (Article 35 TFEU). In this respect, the ECJ has confirmed that '*the need to ensure the regular supply of the country for essential medical purposes may justify an obstacle to intra-Community trade*', provided that the specific measure is proportionate.[68] Within the framework of this balance, the national public good of health protection seen from the lens of the European internal market, mediated via the justification test, acquires the character of a European public good in certain aspects. At the same time however, the internal market remains fragmented as a uniform area without border controls. In the wake of the Covid-19 pandemic, the European Commission has emphasised that 'essential goods needed to contain health risks can reach all those in need'.[69] It could be the case that such an approach to ensuring the availability of protective equipment across Member States through a coordinated strategy, rather than through harmonisation, was done with a view to avoid political interference.[70] However, making the functioning of the internal market contingent upon solidarity or unanimity is neither legally necessary nor compelling.[71]

3. Interim Result

This analysis has demonstrated that the lack of competence for health policy cannot be remedied by the rules on the internal market to achieve proper pandemic protection at the EU level. From the perspective of positive integration, the use of the internal market competence through Article 114 TFEU is clearly limited and subject to the ban on harmonisation under Article 168(5). From the perspective of negative integration, the fundamental freedoms put the need of justification on Member States that impose border controls. However, many of these measures can be justified on the basis of a public health emergency. The overall possibilities of the EU to introduce countermeasures to pandemics are thus extremely limited.

68 ECJ, *The Queen v. Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd.*, judgment of 28 March 1995, case no. C-324/93, ECLI:EU:C:1995:84, para. 37.

69 Communication from the Commission COM/2020/112 final, 13 March 2020, 3.

70 See European Commission/European Council, Common European Roadmap for the Repeal of COVID-19 containment measures, 11.

71 Thym and Bornemann (n. 19), ch. 2 para. 14 with further references.

V. Filling the Gap Between Promise and Delivery in the Field of Pandemic Protection

As outlined above, a treaty amendment is politically necessary if a discrepancy between treaty objectives and the competences conferred upon the EU is to be resolved. This is the case if there is a gap between European public goods 'promised' in the objectives of the Treaties (and thus recognised by all Member States when signing them) and the corresponding competences to which the EU is entitled, in the course of which the EU either cannot act at all, or cannot act sufficiently.

1. Pandemic Protection as a European Public Good

Considering the above-mentioned shortcomings in European health policy on the one hand, and the criteria applicable in the context of economic theory for the provision of (European) public goods[72] on the other, certain avenues of action at the EU level emerge: While keeping the criteria of subsidiarity in mind, it follows that in policy fields wherein Member States alone cannot act 'sufficiently' to provide for and realise a European public good because of 'policy spill overs', the EU is better equipped to act ('economies of scale').[73] When employed correctly, in these fields EU measures add value[74] and thus (in the language of politics[75]) strengthen European sovereignty or autonomy. Put simply, this advantage is achieved by strength in numbers (of Member States) as well as through joint European action (the so-called 'Brussels effect').[76]

Taking these criteria as a basis, it becomes clear that cross-border pandemic control is a European public good that cannot be sufficiently provided for by a purely coordinating competence alone. This is particularly evident in the lack of a cross-border strategy in the fight against the pandemic: In the course of this shortcoming, the introduction of national controls at the internal borders between the Member States may affect the free movement of persons in the internal market, and thus infringe upon a core right of the EU citizens

72 See Fuest and Pisani-Ferry (n. 12), 7 et seq.
73 Calliess, *Öffentliche Güter* (n. 11), 22 et seq.
74 See Fuest and Pisani-Ferry (n. 12), 7 et seq.
75 See Meseberg Declaration (n. 14).
76 On this, from a legal perspective, Christian Calliess, 'Finanzkrisen als Herausforderung der internationalen, europäischen und nationalen Rechtsetzung', VVDStRL 71 (2012), 113-182 (esp. 175 et seq.); in depth Bradford (n. 15); on this in context: Hartmann and Areizaga (n. 15), 101 et seq.

(Article 21 TFEU) within the Schengen area. At the same time, however, there are no coordinated controls on entry into the EU from third countries. In light of this fragmentation, which is rooted in the lack of material competence of the Union, there is a real and significant risk of deploying protective measures that lack coherence, efficiency, or proportionality, given the cross-border dimension of the pandemic.[77]

2. Possible Gap Filling in the Field of Pandemic Protection

Based on the foregoing, according to the current allocation of competences in the Treaties, the EU is not sufficiently equipped to take on the fight against pandemics, primarily because the European legislative competences in the area of public health policy are limited under Article 168(4) TFEU. In this respect, there is an evident discrepancy between the goals and tasks of the EU on the one hand, and the actual competences of the EU on the other. While according to Article 168(5) TFEU, the EU should, on the one hand, be able to act to '*combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health*', on the other hand, it may only do so by way of coordinating support measures and not by way of enacting harmonising legislation. As shown above, such coordination competence falls short of ensuring effective cross-border pandemic control and avoiding the collateral damage to European citizens and the European idea as a whole caused by border controls mentioned above.

If one also looks (by way of a systematic interpretation) at the catalogue of EU competences, it becomes clear that the European strategies and measures to combat pandemics such as the Coronavirus can certainly be classified as '*common safety concerns in public health matters*' under Article 4(2)k) TFEU.

It should therefore be noted that to realise the European public good of health protection, there is an *evident discrepancy* between what has been promised in the Treaties versus the actual possibilities of achieving those promises. More specifically, the possibilities for action by the EU legislator are insufficient due to the limits on the form of competences. Based on the foregoing, in order to realise European public goods, Article 168(4) TFEU on its

77 In particular on the coherence requirement in the EU, see Matthias Ruffert, 'Article 7 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C.H. Beck 2022), paras 2 et seq. as well as Christian Calliess, 'Article 13 TEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C.H. Beck 2022), para. 2; with regard to the restriction of fundamental freedoms: ECJ, Stoß et al. (n. 5); Lippert (n. 5); Hartmann (n. 5).

own would be insufficient, and therefore, would have to be supplemented by an additional European legislative competence for combating cross-border pandemics.[78]

The above definition of European public goods and the application of the standards of the principle of subsidiarity outlined above (here, in the context of an amendment of the Treaty, 'only' as a political guideline), support the argument in favour of a specific European competence in fighting pandemics. Since a pandemic does not stop at borders and spreads across Europe as it does globally, the fact that a common European response will provide added value with regard to prevention and control is decisive. At the same time, this would ensure that the reimposition of national border controls, which restricts the functioning of the internal market and the Schengen area, would no longer be necessary and could only be justified in extreme or exceptional cases, such as, in the face of complete inaction on the part of the EU or an obviously ineffective European strategy. However, in order not to prevent the Member States from doing 'more', in the sense of achieving the right balance between the principles of solidarity and subsidiarity,[79] and attaining cooperation based on the division of labour, the possibility of strengthening protection by way of national action would have to be granted in the Treaty. This would allow decentralised action above and beyond what can be achieved through European harmonisation.

Against this background, in April 2021, I had proposed an amendment to the European health competence of Article 168(4) TFEU by a new letter d), which ran as follows:[80]

> '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 reinforced protective measures where these are necessary.'

As already illustrated above, due to the systematic position of Article 168 (4), the prohibition of harmonisation for the field of pandemic protection in

78 Considering but disregarding the necessity of a treaty change Delhomme and Hervey (n. 39), 59; also promoting the necessity of a treaty change to add competences in the field of pandemic control Juuso Järviniemi, Robert Scholz and Kalojan Hoffmeister, 'From COVID-19 Towards a European Health Union: Proposals for Treaty Reform on Health', 2022, available at: <https://jef.eu/wp-content/uploads/2022/06/From-COVID-19-towards-a-European-Health-Union-Proposals-for-Treaty-reform-on-health.pdf>, last access 12 November 2025.

79 Calliess (n. 11), 'Subsidiaritäts- und Solidaritätsprinzip', 185 et seq. with further references.

80 First published in Christian Calliess, 'Braucht die Europäische Union eine Kompetenz zur (Corona-) Pandemiebekämpfung', NVwZ 40 (2021), 505-511 (511).

Article 168 (5) would no longer apply so that the EU would gain a genuine legislative competence in the field of pandemic protection.

Very similar to this is the wording proposed in the draft report on proposals of the European Parliament for the amendment of the Treaties (2022/2051 (INL)) submitted by the Committee on Constitutional Affairs on 22 August 2023:

> 'Measures for the early notification, monitoring and management of serious cross-border threats to health, in particular in the event of pandemics. These measures shall not prevent Member States from maintaining or adopting reinforced protective measures where these are imperative.'

The draft report was adopted by a narrow majority on 22 November 2023. The European Council must now decide whether to open the Constitutional Convention according to Article 48 TEU. In its conclusions of 15 December 2023 (EUCO 20/23), the Council emphasised that it will address the issue of internal reforms at its next meetings, with a view to adopting conclusions in the summer of 2024.

Such an addition to the competences would – as has been shown above – not least also be necessary for the realisation of an effective 'European Health Union' as well as the accompanying legal, financial, and personnel strengthening of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). This is because, according to the principle of conferral, agencies can only be established within the scope of the Treaties (Article 5(2) TEU) and, have clearly defined executive powers that are subject to the control of the ECJ.[81] Their work could, moreover, be complemented by the establishment of a new agency modelled on the US Agency for Advanced Biomedical Research and Development (BARDA).

3. Ways of Closing Gaps in the Area of Pandemic Protection

Under certain conditions, the simplified Treaty Amendment Procedure (Article 48(6) TEU) can be deployed to supplement competences. In the past, this is how a new paragraph 3 was added to Article 136 TFEU to legitimise the European Stability Mechanism (ESM) in the context of the rules of Economic and Monetary Union.[82] However, since the proposed amendment

81 ECJ, *United Kingdom v. European Parliament and Council*, case no. C-270/12, ECLI:EU:C:2014:18; in detail Orator (n. 29), 185 et seq. and 459 et seq.

82 On this, Christian Calliess, 'Perspektiven des Euro zwischen Solidarität und Recht – Eine rechtliche Analyse der Griechenlandhilfe und des Rettungsschirms, Zeitschrift für europarechtliche Studien, ZEuS 14 (2011), 213-282. ZEuS 2011, 213 (275 et seq.); Christian Calliess, *Die neue Europäische Union nach dem Vertrag von Lissabon*, 2010, 90 et seq.

would extend the EU's competences, the ordinary Treaty Amendment Procedure pursuant to Article 48 (2) and (3) TEU without setting up a convention may have to be resorted to. Every Ttreaty amendment requires the consent of all Member States (see Article 48 para. 4 and para. 6 TEU).[83]

If such a consensus cannot be achieved, then the mechanism of enhanced cooperation (Article 20 TEU, 326 et seq. TFEU) – often referred to as 'coalition of the willing' – can be considered as a strategy to equip the EU with more expansive possibilities in the field of pandemic protection at least in the participating Member States.[84]

If neither of these mechanisms are successful, a specific treaty under international law between the willing Member States – as was done for example with the European Fiscal Treaty of 2012[85] – may be considered as the last resort.

VI. Conclusion

The Covid-19 pandemic made it painfully obvious that the EU only possesses a coordinating competence in the area of health policy and is therefore dependent on the consensus and cooperation of all Member States in deploying its measures. At the same time, only a common European strategy can avoid border controls and ensure effective measures in dealing with the pandemic. Against this background, there are important factual and legal arguments in favour of changing the wording of Article 168(4) TFEU, as proposed above, to include the combatting of pandemics, and thus introduce a genuine legislative competence of the EU. The systematic position of such an amendment in Article 168(4), in turn, would mean that the prohibition of harmonisation according to Article 168(5) TFEU would no longer apply. The wording proposed above in compliance with the ideal of subsidiarity attempts to find a balance between binding European measures and Member State flexibility: On the one hand, it can resolve the obvious discrepancy between European task and competence, as described above, by enabling a common European strategy through which the reimposition of national

83 Jean-Claude Piris, The Future of Europe (Cambridge University Press 2012), 106 et seq.

84 Matthias Ruffert, 'Article 20 EUV' in: Christian Calliess and Matthias Ruffert (eds): *EUV/AEUV* (6th edn, C. H. Beck 2022, paras 1 et seq.; in the context of a reform of the EU: Christian Calliess, 'Szenarien für die EU der Zukunft' in: Gregor Kirchhof, Mario Keller and Reiner Schmidt (eds), *Europa in Vielfalt geeint!, 30 Perspektiven zur Rettung Europas vor sich selbst* (C. H. Beck 2020), 263-296 (281 et seq.).

85 For further details see Christian Calliess, 'From Fiscal Compact to Fiscal Union? New Rules for the Eurozone' in: Cambridge Yearbook of European Legal Studies 14 (2012), 101-117.

border controls may be avoided while ensuring effective measures for attaining the European public good of health during a pandemic. At the same time, such a strategy should be deployed – in accordance with the principles of subsidiarity and proportionality – in an open manner that leaves room for the necessary flexibility and gives leeway to the Member States, should they wish to go beyond the common European measures.

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