The Missing Keystone of the 'European Health Union'. Historic Development, *status quo* and Ideas *de lege ferenda*

Markus Frischhut*
Management Center Innsbruck, Innsbruck, Austria
markus.frischhut@mci.edu

'There is another concern that we must not neglect, and that is concern for people. If there is one domain where great efforts must be made, it is the domain of health. If there is one domain that seems to lend itself to agreement, it is the fight against disease. Epidemics and social problems know no borders.' (Robert Schuman)[1]

---

* Jean Monnet Professor, MCI | The Entrepreneurial School®, Innsbruck, Austria, and Adjunct Professor, *Alma Mater Studiorum – Università di Bologna*, Italy. The author would like to thank the organisers of this workshop 'The European Health Union. Set Up, Challenges and Global Outlook' held at 'Max Planck Institute for Comparative Public Law and International Law' in Heidelberg, as well as all the participants for fruitful discussions. A special thanks also goes to Mike Schwebag for valuable help in obtaining access to documents on the European Health Community, as well as to Katarina Weilert, the two anonymous reviewers and the editors for valuable feedback. The usual disclaimer applies. Parts of this contribution are based on Markus Frischhut, 'Eine Europäische Gesundheitsunion: Historische Ideen, aktuelle Pläne und Werte für einen resilienten Wiederaufbau', ZÖR 78 (2023), 177-201. This contribution was updated in mid-March 2025.

1 Maryse Cassan, *L'Europe Communautaire de la Santé: Préface de Louis Dubois* (Economica 1989), 229 (author's translation).

Abstract

The concept of a 'European Health Union' (EHU) is in the spotlight, but has not been defined so far. It is no International Organization, as the failed 'European Health Community' in the 1950s would have been. The EHU can be seen as an amalgam of already existing projects (Beating Cancer, etc.) and a reaction to the crisis of the pandemic. Quite some progress has been made in strengthening existing agencies (European Centre for Disease Prevention and Control [ECDC], European Medicines Agency [EMA]), creating a new authority Health Emergency Preparedness and Response Authority (HERA), updating cross-border health threats to a European Union (EU) regulation, and anchoring the 'One health'-approach (humans, animals, environment). However, a step that was announced by von der Leyen is still missing, an amendment of EU primary law; the keystone so to say. Another idea *de lege ferenda* is based on the case-law of the European Court of Justice (ECJ) on 'animal welfare' and suggests to see human health as an EU value.

Keywords

European Health Union – European Health Community – One Health – EU Values

I. Setting the Agenda

Ideally, the vertical distribution of competences between the supra-national European Union on the one hand and its Member States on the other ought to be based on considerations such as the effectiveness of performance of tasks at each level. According to the 'principle of conferral', the EU can only act 'within the limits of the competences conferred upon it by the Member States in the Treaties', and competences not conferred upon the EU remain with the Member States (Article 5(2) Treaty on European Union [TEU]).[2] The principle of subsidiarity embodies the idea of determining the most appropriate level of authority for specific tasks. According to the latter principle, the question is whether tasks cannot be sufficiently achieved by the Member States (at central, regional, or local level), and whether they can be better achieved at the Union level. However, this principle applies only to

2 Treaty on European Union, Consolidated version OJ 2016 C 202/13.

existing (non-exclusive) competences (Article 5(3) TEU). In other words, it is not a legally binding principle to decide on the allocation of competences, as according to the principle of conferral, Member States must take this decision. Nonetheless, it can be a source of inspiration, as ideally the competences should be legally[3] located where they generate added value, as also expressed by the initial quotation of *Robert Schuman*.

However, the field of health is an illustrative example of Member States' reluctance to transfer more competences to the EU level. In a nutshell, Member States have been willing to transfer additional competences to EU level if they recognise that they individually are not able to provide the necessary solutions for certain challenges. In this context, solutions can refer to the adoption of legal documents (hence, the question of legislation and the vertical distribution of competences), or simply to cooperation (working together) or coordination (align one's actions with each other). The latter field of collaboration (cooperation and coordination) on a voluntary level can be related to the 'Open Method of Coordination' (OMC)[4]. Although the OMC can make an important contribution in the field of public health, it is neither the main focus nor in the sole spotlight of this contribution.

Instead, this contribution seeks to address the question of how the EU has reacted to the SARS-COV-2 pandemic, considering the development of EU 'public health'[5] competences so far, the *status quo* (i. e., Article 168 Treaty on the

3 I. e. according to the principle of conferral.

4 In the field of quality standards and setting up 'European Reference Networks', the OMC has been described as 'acts of formalised informality' (author's translation); Stephan Rixen, 'Die Patientenrechte-Richtlinie als "Dienstleistungsrichtlinie des Gesundheitswesens"?', GPR 9 (2012), 45-50 (45, 48). Vassilis Hatzopoulos, *Regulating Services in the European Union* (Oxford University Press 2012), 311 has described the OMC as follows: 'The OMC can be analysed as a multi-level process of governance, comprising at least four stages. First, the European Council agrees on the general objectives to be achieved and offers general guidelines. Then, the Council of Ministers selects quantitative and/or qualitative indicators, for the evaluation of national practices. These indicators are following a proposal by the Commission or by other independent bodies or agencies. The third stage is the adoption of measures at the national or regional level (taking local particularities into consideration), aiming at the achievement of the set objectives, and in pursuit of the indicators chosen. These are usually referred to as the "National Action Plan" or NAPs. The process is complete by mutual evaluation and peer review between member states (occasionally alongside a system of naming and shaming/faming), at the Council level.'

5 'Public health' has more of a collective dimension, whereas 'access to healthcare' has an individual connotation. 'Public health' can be understood as 'the management of health risks and the prevention of disease', whereas 'healthcare' refers to the 'provision of health services and medical care'; Vincent Delhomme and Tamara K. 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. See also Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2019), 62.

Functioning of the European Union [TFEU][6]), and the question of possible future changes. In response to the pandemic, the EU has presented the concept of a 'European Health Union'. In this context, two issues must be addressed. First, what is the substance of this concept? Is it further determined or even clearly defined, and second, if this concept is located at the level of EU secondary or even primary law. The latter level is particularly interesting, given that in the past, the EU has had to restrict itself to focus on EU secondary law adopted by the EU institutions, due to the political infeasibility of the necessary unanimity among Member States to change EU primary law.

This contribution will examine the past examples (Section II.), briefly depict the *status quo* of the EU's competences in the field of public health (Section III.), and then showcase the European Health Union, covering the definition of this concept and the parts realised so far (Section IV.). This also includes the question of the significance of calling this construct a 'Union'. After depicting what has been achieved thus far (*de lege lata*), Section V. presents some ideas of what could be realised in the future (*de lege ferenda*). This contribution will focus on EU health law and, for reasons of space, mainly exclude more general questions on public health policy and governance. Hence, let us first turn to the past, before turning to the *status quo* and a possible future scenario.

II. Development and Early Ideas for EU Health Competences

1. The 1950s and the European Health Community Plan

At the beginning of European integration, a mention of 'health' could only be found in the Treaty establishing the European Coal and Steel Community (ECSC)[7] as a 'reason of justification' (e. g. Article 69(1)) within the internal market (i. e. the free movement of workers in the coal and steel industry). Hence, there were no substantive rules, but they only allowed for possible deviations from the free movement rules.

Among other initiatives[8], in September 1952, French Health Minister *Paul François Ribeyre* proposed a European Health Community (EHC), also

6 Treaty on the Functioning of the European Union, Consolidated version OJ 2016 C 202/47.

7 *Vertrag über die Gründung der Europäischen Gemeinschaft für Kohle und Stahl* of 18 April 1951, BGBl. 1952 II, 447. The ECSC Treaty had expired in 2002.

8 For further details, see Craig Parsons, *A Certain Idea of Europe* (Cornell University Press 2003); Frischhut, 'Eine Europäische Gesundheitsunion' (n. *).

 DOI 10.17104/0044-2348-2025-4-1011

referred to as the '*pool blanc*' (the 'white pool'[9]). Although this project has failed, it is worth examining what could have been possible. Following the 'Community-method',[10] this draft would have proposed a supra-national legal entity; hence, far more than simply a reason of justification. According to *Ribeyre*, the EHC should have been able to act and take decisions based on a delegation of part of the sovereignty of the participating states.[11] The objective of the EHC would have been to coordinate and improve health and social protection, as well as a *de facto* solidarity[12] to provide a foundation for that Community. Also noteworthy is the emphasis that was placed on a 'moral obligation to put people first'.[13]

The EHC would have created a 'common market' (for medicines and pharmaceutical products, dressing materials, medical-surgical equipment, climatic and thermal springs) and included both binding legal norms (e. g., anti-discrimination provisions) as well as fields of (mere) cooperation. Likewise, the EHC would have provided for the creation of an 'International Institute of Hygiene' and the possibility of mobile teams (composed of technicians and practitioners from the fields of medicine and epidemiology, respectively). These teams would have been able to conduct on-site surveys and strengthen local protection mechanisms in the event of a new epidemic outbreak. While epidemics and pandemics are not the only public health challenges, they have become the primary focus in light of the SARS-COV-2 pandemic.[14] A counterfactual discussion of 'what would have happened if' is inherently speculative and laden with uncertainty. However, the reality remains that this Community would have possessed more powers than the EU did at the time of the pandemic.

Title V (Health Measures) Chapter V (Combating Epidemics) of the proposal describes the following:[15] First, (1) the adaptation of common provisions relating to vaccination or notification, and (2) the early application of protective measures (this depending on the coordination of early detection measures). Furthermore, (3) the exchange of epidemiological information and

9 As opposed to the coal and steel 'black pool'.

10 See Walter Hallstein, *Die Europäische Gemeinschaft* (5th edn, Econ 1979).

11 Cassan (n. 1), 232 ff.

12 This idea is reminiscent of the speech of *Robert Schuman* (French Foreign Minister at the time) that led to the ECSC. On the question of solidarity, see also Section V. (at n. 215).

13 Cassan (n. 1), 222.

14 'An "epidemic" refers to a contagious, infectious, or viral illness that spreads to many people in a specific region, whereas a "pandemic" surpasses this region'; Wendy E. Parmet, Markus Frischhut, Amandine Garde and Brigit Toebes, 'Introduction to Public Health Law' in: Tamara K. Hervey and David Orentlicher (eds), *The Oxford Handbook of Comparative Health Law* (Oxford University Press 2021), 68-76 (69).

15 For these documents, see Cassan (n. 1).

applied research centres within the framework of the Community, (4) the organisation of the production of antigens and their distribution through the creation of a common market, as well as the standardisation of the composition of vaccines, their labelling, their dosage and the formation of safety stocks, or (5) in this area, the abolition of border controls. The creation of an 'International Health Police' has been considered.

Moreover, quite insightful from a contemporary pandemic perspective, Title VIII (pooling of resources) is of particular relevance. This would have provided for the gradual pooling of resources, the standardisation of production, the creation of stockpiles in the Member States in the event of an epidemic or other disaster, as well as the standardisation of product standards and the creation of a European pharmacopoeia (*pharmacopée européenne*).

In conclusion, this supra-national 'white pool' would have included many provisions that we find today in EU law (common market, non-discrimination, recognition of diplomas), but at the same time, it would have provided suggestions that could be pioneering in the light of the SARS-COV-2 pandemic. The latter field includes mobile teams for on-site surveys, international health police, and support for a country affected by a pandemic by means of resources through the EHC, as well as the gradual pooling of resources, etc.

As these plans could not be realised,[16] both in the 1951 ECSC and in the 1957 European Economic Community[17] (e. g. Article 36), health was only considered as a reason of justification within the internal market. The mention of 'health protection at work' only occurred in the context of the Commission promoting close cooperation between Member States (Article 118).

2. Development of Health Competences Since the 1950s

While the Treaties did not provide for hard competences, some progress[18] was evident in the fact that from 1984 onwards, the Health Ministers at least

16 With the departure of the father (*Ribeyre*) and the godfather (*Schuman*), the '*pool blanc*' became an orphan; see Alban Davesne and Sébastien Guigner, 'La Communauté européenne de la santé (1952-1954): Une redécouverte intergouvernementaliste du projet fonctionnaliste de "pool blanc"', Politique Européenne 41 (2013), 40-63 (55).

17 Vertrag zur Gründung der Europäischen Wirtschaftsgemeinschaft of 25 March 1957, BGBl. 1957 II, No 23, 753.

18 See also, for additional details, Anja Katarina Weilert, Ressortforschung: Forschung zur Erfüllung öffentlicher Aufgaben unter besonderer Berücksichtigung des Bereichs staatlicher und unionsrechtlicher Gesundheitsverantwortung (Mohr Siebeck 2022), 401-404.

had informal meetings.[19] This suggests that health issues were becoming increasingly important. Like the above-mentioned OMC, the influence of EU integration occurs not only through hard law but also through softer forms of coordination. The European Parliament (EP)'s 1984 '*Spinelli*-draft'[20] would have foreseen the Union's power to 'take action in the field of social and health policy' with regard to 'the coordination of mutual aid in the event of epidemics or disasters' (Article 56 'Social and health policy'). This idea did not become primary law and for reasons of space will not be explored further.

Against the background of Bovine Spongiform Encephalopathy (BSE) and Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS), the 1992 Maastricht Treaty[21] then enshrined 'public health' as a separate sectoral policy (in Article 129), hence more than just a reason of justification. Even before this Treaty, we can find examples of hard law based on other competences[22] as well as various soft law documents on cancer prevention[23], AIDS[24], or drug abuse[25].

The European Parliament's 1994 '*Herman*-draft'[26] did not strive to advance the European integration process in terms of 'public health' as a sectoral policy, but made two remarkable suggestions in terms of human rights and values. It would have enshrined a human right 'to benefit from measures for the good of their health'[27] and would have based EU membership on the values of 'freedom, equality, solidarity, human dignity, democracy, respect for human rights and the rule of law'[28]. Similar to the *Spinelli*-draft, these ideas were not implemented.

---

19 Brigitta Lurger, 'Art. 168 AEUV' in: Rudolf Streinz (ed.), *EUV/AEUV* (3rd edn, C.H. Beck 2018), 1671-1707 (1675), para. 7.

20 Draft Treaty Establishing the European Union of 14 February 1984, OJEC C77/33, 298-327.

21 Treaty on European Union, signed in Maastricht on 7 February 1992, OJEC C191/01, 1-110.

22 Lurger (n. 19), 1675, para. 7.

23 Commission, Proposal for a Council Resolution on a programme of action of the European Communities on cancer prevention, OJ 1985 C 336/11. For the EHU and cancer, see n. 52.

24 Resolution of the Representatives of the Governments of the Member States, meeting within the Council, of 29 May 1986 on AIDS, OJ 1986 OJ C 184/21.

25 Resolution of the Council and the Ministers for Health of the Member States meeting within the Council of 16 May 1989 concerning a European network of health data on drug abuse, OJ 1989 C 185/1.

26 Resolution on the Constitution of the European Union, OJ 1994 C 61/155.

27 Art. 13 of Title VIII: Human rights guaranteed by the Union, OJ 1994 C 61/155 (n. 26).

28 Recital 2 of the preamble, OJ 1994 C 61/155 (n. 26).

The 1997 Amsterdam Treaty[29] brought a slight strengthening of the quality and safety standards concerning organs, blood, etc.,[30] but at the same time emphasised the competence of the Member States for the organisation of healthcare and medical care. The 2001 Nice Treaty[31] brought no changes.[32] Finally, the 2007 Lisbon Treaty[33] essentially brought some clarifications (different types of competences, etc.) and additional competences in medicines and medical devices. As in the case of the two EP drafts (*Spinelli* and *Herman*), sometimes more interesting ideas can be found in those documents that did not enter into force. The 2004 Constitutional Treaty,[34] as is well known, did not enter into force. This would have provided for a strengthening in the 'monitoring, early warning of and combating serious cross-border threats to health', hence, a shared competence allowing for harmonisation (Article III-278 para. 4 lit. d). This provision would have provided, at least in theory, an opportunity to address the challenges raised by the pandemic.

In conclusion, although we can observe some progress, various plans would have been more ambitious (*Spinelli*, *Herman*). Let us now consider the legal *status quo* that was acceptable for the Member States as 'Masters of the Treaties'.

III. *Status quo* of the EU's Public Health Competences

As aptly mentioned in the literature, 'public health' is probably the EU competence that is most difficult to distinguish from shared competence, as the reality of EU health law and policy go beyond the wording of EU Treaties.[35] According to Article 168(1) TFEU, a 'high level' of human

29 Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signed at Amsterdam on 2 October 1997, OJ 1997 C 340/1.

30 See now Regulation 2024/1938/EU of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, OJ L 2024/1938, as corrected by OJ L 2024/90463.

31 Treaty of Nice amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signed at Nice on 26 February 2001, OJ 2001 C 80/1.

32 See also Lurger (n. 19), 1675.

33 Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon on 13 December 2007, OJ 2007 C 306/1.

34 Treaty establishing a Constitution for Europe, signed at Rome on 29 October 2004, OJ 2004 C 310/1.

35 See Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health', European Journal of Risk Regulation 11 (2020), 747-756 (750).

health protection[36] is required to be ensured in the definition and implementation of all Union policies and activities, as is also the case with other fields.[37]

In general, the EU only has a supportive[38] competence for the protection and improvement of human health, striving to prevent physical and mental illness and diseases, and obviating sources of danger to physical and mental health (Article 168(1) subparagraphs (2) and (3) TFEU). In the same way, the EU can only 'encourage' cooperation between the Member States (Article 168(2) TFEU) and not make it obligatory. Cooperation with third countries and the competent international organisations, both by the Union and by Member States, is also only encouraged ('to foster'), according to Article 168(3) TFEU. According to Article 168(5) TFEU, 'incentive [!] 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' can be taken. While these measures can be taken according to the ordinary 'legislative procedure', they can only include 'incentive measures', hence, 'excluding any harmonisation of the laws and regulations of the Member States'. In the same vein, according to Article 168(6) TFEU, the Council can adopt (non-binding) recommendations[39] and Article 168(7) TFEU emphasises the 'responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care'.

Article 168(4) TFEU, introduced by the Treaty of Amsterdam, constitutes a particularity in this context of health-related competences. In this context,

36 See also Art. 35 CFR. Consolidated version of the Charter of Fundamental Rights of the European Union, OJ 2016 C 202/389.

37 Art. 67 (3) TFEU (area of freedom, security and justice), Art. 147 TFEU and Art. 9 TEU (employment), Art. 169 (1) TFEU (consumer protection), Art. 191 (2) TFEU and Art. 3 (3) TEU (environment), respectively Art. 114 (3) TFEU (harmonisation of national law). Likewise, Art. 151 TFEU (social policy, respectively employment) refers to 'lasting high employment' and Art. 165 (1) TFEU (education) to 'quality education' (in German: '*qualitativ hoch stehenden Bildung*'); see also Art. 9 TFEU.

38 Art. 6 TFEU, competence to carry out actions to support, coordinate or supplement the actions of the Member States.

39 While they 'have no binding force' according to Art. 288 (5) TFEU, 'national courts are bound to take recommendations into consideration in order to decide disputes submitted to them, in particular where they cast light on the interpretation of national measures adopted in order to implement them or where they are designed to supplement binding Community provisions'; ECJ, *Grimaldi v. Fonds des maladies professionnelles*, judgment of 13 December 1989, case no. C-322/88, ECLI:EU:C:1989:646, para. 18.

the Union has a shared[40] competence for common safety[41] concerns in public health concerning organs and substances of human origin, as well as for blood and blood derivatives (lit. a), in the veterinary and phytosanitary fields (lit. b), as well as in medicinal products and devices for medical use (lit. c). Just for the sake of completeness, it should be mentioned that the EU does not only exert influence in the health sector through this apparent competence of Article 168 TFEU.

Besides these competences that can be attributed to the field of positive integration,[42] the European Court of Justice allowed individual patients to remove national barriers in the field of cross-border healthcare[43] by relying on the passive freedom of services[44] (negative integration).[45] These individual rights developed by the ECJ in a bottom-up manner have subsequently been codified in an EU directive that has been based not only (as often previously in similar cases) on Article 114 TFEU[46] but also on Article 168 TFEU.[47] Besides Article 114 TFEU and the more health-related fields, the EU has also exerted substantial influence in the field of health via the European Semester.[48]

40 Art. 4 (2) (k) TFEU.

41 On quality and safety standards, see Markus Frischhut, 'Standards on Quality and Safety in Cross-Border Healthcare' in: André den Exter (ed.), *Cross-Border Health Care and European Union Law* (Erasmus University Press 2017). See also Regulation 2024/1938/EU and Directives 2002/98/EC and 2004/23/EC, OJ L 2024/1938, as corrected by OJ L 2024/90463.

42 According to Carl Baudenbacher and Frank Bremer, 'European State Aid and Merger Control in the Financial Crisis: From Negative to Positive Integration', Journal of European Competition Law & Practice 1 (2010), 267-285 (267), the distinction between positive and negative integration 'was first made by the Dutch economist Jan Tinbergen, who called measures aiming at abolishing trade impediments between national economies with the goal of securing the proper operation of an integrated economic area "negative integration"'. 'Positive integration' 'was defined by Tinbergen as the "creation of new institutions and their instruments or the modification of existing instruments"'.

43 Besides these rights related to the (passive) freedom of services, social security rights are related to the free movement of workers; see Regulation 883/2004/EC of 29 April 2004 on the coordination of social security systems, OJ 2004 L 166/1, as amended by OJ 2019 L 186/21. See also Anja Katarina Weilert, 'Gesundheitsdienstleistungen im Binnenmarkt: Grundstrukturen und neue Entwicklungen', EuR 57 (2022), 731-754.

44 Art. 56 TFEU.

45 See Markus Frischhut and Hans Stein, *Patientenmobilität: Aktuelle Richtlinie und EuGH-Rechtsprechung* (Facultas.wuv 2011).

46 See case ECJ, *Germany v. Parliament and Council*, judgment of 12 December 2006, case no. C-380/03, ECLI:EU:C:2006:772, paras 39, 95.

47 Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ 2011 L 88/45, as amended by OJ 2025 L 2025/327 (Directive patient mobility).

48 See Natasha Azzopardi-Muscat, Timo Clemens, Deborah Stoner and Helmut Brand, 'EU Country Specific Recommendations for Health Systems in the European Semester Process: Trends, Discourse and Predictors', Health Policy 119 (2015), 375-383.

Based on the historic development and the *status quo* of EU health law, we now turn to the concept of the European Health Union and examine how it fits to the aforementioned developments.

IV. The Concept of a 'European Health Union'

1. A (Missing) Definition and Building Blocks

The European Commission has introduced the concept of the European Health Union, making it essential to first examine how the Commission defines and interprets this term. The European Commission addresses seven 'key initiatives' of the EHU.[49] The first two, crisis preparedness and the European Health Emergency Preparedness and Response Authority, can be seen as reactions to the pandemic. Four of them, the pharmaceutical strategy,[50] the European Health Data Space (EHDS),[51] Europe's Beating Cancer plan,[52] and the comprehensive approach to mental health,[53] are pre-existing issues that are placed under this 'umbrella term' of an EHU. In addition to this internal dimension, in the external sphere, this concept of the EHU is reinforced by the 'Global Health Strategy',[54] which was presented in November 2022 (i. e., two years after the presentation of the EHU concept; see below). Since its first usage by the European Commission, the understanding of the term has changed, and further elements have been added to it. Hence, the EHU can be seen as a shifting concept.[55]

---

49 European Commission, 'European Health Union: Protecting the Health of Europeans and Collectively Responding to Cross-Border Health Crises', <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en>, last access 29 October 2025.

50 Commission, 'Pharmaceutical Strategy for Europe' COM/2020/761 final. See also, in terms as a follow-up to this, COM/2023/192 and COM/2023/193 final. See also The EAHL Interest Group on Supranational Biolaw, 'Joint Statement "Health as a Fundamental Value.": Towards an Inclusive and Equitable Pharmaceutical Strategy for the European Union' (2022), <https://eahl.eu/eahl-interest-group-supranational-biolaw>, last access 29 October 2025.

51 Regulation 2025/327/EU of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU (Directive patient mobility) and Regulation 2024/2847/EU (Cyber Resilience Act), OJ 2025 L 2025/327 (Regulation EHDS).

52 Commission, 'Europe's Beating Cancer Plan', COM/2021/44 final.

53 Commission, 'On a Comprehensive Approach to Mental Health', COM/2023/298 final.

54 Commission, 'EU Global Health Strategy. Better Health for All in a Changing World', COM/2022/675 final.

55 See also the topics addressed in Commission, 'The European Health Union: Acting Together for People's Health', COM/2024/206 final.

The question arises as to the meaning of the term 'European Health Union', keeping in mind the ECJ's interpretation rules, as summarised in established case law.[56] A literal interpretation ('everyday language') of the EHU proves to be difficult, as there is no proper definition. At least these 'building blocks'[57] of the already existing initiatives and those adopted in the reaction to the crisis (see below) provide some clarification. Although the ECJ does not give strong weight to a historical interpretation,[58] the evolution of this concept should not be ignored. In our context, this approach refers to the Commission President's speech[59] (September 2020) and the Commission's key document (November 2020), presented shortly after the beginning of the pandemic (around January 2020).[60] This evolutionary background reveals the intention of the Commission to 'draw the lessons from the health crisis'.[61] Likewise, a teleological ('purposes of the rules') interpretation (i. e. the *effet utile*)[62], considering the purpose (*telos*) of the law, goes in a similar direction. This reveals the Commission's objective to 'strengthen [the] crisis preparedness and management of cross-border

56 According to 'settled case-law, the meaning and scope of terms for which EU law provides no definition must be determined by considering their usual meaning in everyday language, while also taking into account the context in which they occur and the purposes of the rules of which they are part'; ECJ, *Partena ASBL v. Les Tartes de Chaumont-Gistoux SA*, judgment of 27 September 2012, case no. C-137/11 ECLI:EU:C:2012:593, para. 56.

57 Commission, 'Building a European Health Union: Reinforcing the EU's Resilience for Cross-Border Health Threats' COM/2020/724 final 3.

58 ECJ, *CILFIT v. Ministero della Sanità*, judgment of 6 October 1982, case no. C-283/81, ECLI:EU:C:1982:335, para. 20.

59 Ursula von der Leyen, 'State of the Union Address by President von der Leyen at the European Parliament Plenary: SPEECH/20/1655' (16 September 2020), <https://ec.europa.eu/commission/presscorner/detail/ov/SPEECH_20_1655>, last access 29 October 2025.

60 Even before the pandemic, the term 'European healthcare union' could be found in the literature; Hans Vollaard and Dorte S. Martinsen, 'The Rise of a European Healthcare Union', Comparative European Politics 15 (2017), 337-351. In response to the pandemic, in May 2020, there was also a call by the European Socialists in the European Parliament to increase EU health competencies, as follows: on the one hand, to strengthen resilience in relation to the pandemic, and on the other hand, to address certain future issues in the health sector. Progressive Alliance of Socialists and Democrats, 'A European Health Union – Increasing EU Competence in Health – Coping with Covid-19 and Looking to the Future', 12 May 2020, <https://www.socialistsanddemocrats.eu/publications/european-health-union-increasing-eu-competence-health-coping-covid-19-and-looking>, last access 29 October 2025.

61 von der Leyen (n. 59), 3.

62 E. g. ECJ, *Andy Wightman and Others v. Secretary of State for Exitingthe European Union*, judgment of 10 December 2018, case no. C-621/18, ECLI:EU:C:2018:999, para. 40; *Poland v. Parliament and Council*, judgment of 16 February 2022, case no. C-157/21, ECLI:EU:C:2022:98, para. 92, 'useful effect' (EN), '*effet utile*' (FR).

health threats'.[63] From a more holistic or systematic perspective ('context in which they occur'), the Commission's November 2020 document highlights certain underlying ideas. The EHU strives for a less unilateral approach (and a more active role for the EU), focusing on vulnerable population, being based on solidarity, as well as the obligation to ensure a 'high level'[64] of human health protection.[65]

However, a systematic interpretation would eventually have to take into account the whole *acquis* (*communautaire*)[66] of EU law in this health-related context.[67] Since the entry into force of the Lisbon Treaty, EU values (both general ones[68] as well as health-related ones[69]) have to be envisaged together with human rights, especially Article 35 Charter of Fundamental Rights of the European Union (CFR).[70] This *acquis* also includes the principles developed by the ECJ (e. g., patient mobility) in the field of negative integration, and even the indirect EU impact via the European Semester.[71] This also includes all documents of positive integration, whether adopted based on economic competences and/or via Article 168 TFEU. In its last report on the Directive on patients' rights in cross-border healthcare[72] (based on both Article 114 TFEU and Article 168 TFEU), the Commission mentioned that '[m]aximising the potential of the Directive and strengthening cooperation between Member States in cross-border healthcare will be a further [!] step in

63 von der Leyen (n. 59), 3. See also European Commission (n. 49): 'a strong European Health Union, in which all EU countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer', referring to the better protection of EU citizens, the goal to 'equip the EU and its Member States to better prevent and address future pandemics', as well as to the improvement of the 'resilience of Europe's health systems'.

64 See n. 36-37.

65 Commission (n. 57), 1 f.

66 Given the changes brought about by the Lisbon Treaty (n. 33), it should nowadays read '*acquis de l'Union*' more precisely.

67 As mentioned above at the end of Section III.

68 Art. 2 TEU. See Markus Frischhut, The Ethical Spirit of EU Values: Status Quo of the Union of Values and Future Direction of Travel (Springer 2022).

69 Council Conclusions on Common values and principles in European Union Health Systems OJ 2006 C 146/1.

70 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.'

71 I. e. a system of economic monitoring and governance impacting national health systems via Country Specific Recommendations (CSRs); see Azzopardi-Muscat, Clemens, Stoner and Brand (n. 48).

72 See Directive 2011/24/EU.

building the European Health Union'[73]. This implies that there are more steps than just the three addressed by Commission president von der Leyen in her 2020 'State of the Union' speech.

In this speech, she had outlined her plan for an EHU consisting of three steps, as follows:[74] in the (1) first step, the EHU strives to 'reinforce and empower' two existing agencies (see below). The (2) second step attempts to 'build a European BARDA – an agency for biomedical advanced research and development'. While the first two steps are to be implemented at the level of EU secondary law, the (3) third step aims at amending EU primary law (see Section V.), referring to the necessity to 'discuss the question of health competences', also in the context of the 'Conference on the Future of Europe'.[75]

Meanwhile, the Commission's plans[76] (ad 1) have been implemented by the EU institutions. In January 2022, the EU strengthened the European Medicines Agency,[77] and in November 2022 the EU has upgraded Decision 1082[78] on serious cross-border health threats to an EU regulation[79] and strengthened the European Centre for Disease Prevention and Control.[80]

In addition to strengthening existing agencies as the first step mentioned by *von der Leyen*, she (ad 2) referred to a European 'Biomedical Advanced Research and Development Authority' (BARDA)[81] as a second step in her 2020 'State of the Union'-speech. With an acronym inspired by the wife of Zeus in Greek mythology, the Commission in mid-September 2021 proposed

73 Commission, 'Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare', COM/2022/210 final, 16.

74 von der Leyen (n. 59), 3.

75 See, for instance, Peter-Christian Müller-Graff, 'The Conference on the Future of Europe. The Future of Legal Europe – Will We Trust in It?', Journal of the Academy of European Law 22 (2021), 465-473.

76 All three corresponding proposals (Commission COM/2020/725, COM/2020/726 and COM/2020/727) were adopted on 11 November 2020, i. e., the same day as Commission, COM/2020/724 (n. 57).

77 Regulation 2022/123/EU of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ 2022 L 20/1, as amended by OJ 2024 L 2024/568 (Regulation EMA).

78 Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health […] OJ 2013 L 293/1, as repealed by OJ 2022 L 314/26.

79 Regulation 2022/2371/EU of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU OJ 2022 L 314/26, as completed by OJ 2024 L 2024/1232 (Regulation Cross-Border Health Threats).

80 Regulation 2022/2370/EU of 23 November 2022 amending Regulation 851/2004/EC establishing a European centre for disease prevention and control OJ 2022 L 314/1 (Regulation ECDC).

81 See Michael B. Kraft and Edward Marks, *U. S. Government Counterterrorism: A Guide to Who Does What* (CRC Press 2021).

the already-mentioned 'Health Emergency Preparedness and Response Authority' (HERA).[82] The title of this Commission document ('the next step towards completing the European Health Union') includes the idea that HERA can be seen as the second[83] step towards an EHU. HERA is not an agency[84] established by an EU regulation, but an 'authority' established by the Commission within its services,[85] to be supported by a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at the Union level.[86] The creation of another authority in the form of HERA alongside already existing (and even strengthened) agencies naturally brings with it the risk of overlap. The Commission apparently wanted to address this concern by providing an overview of the responsibilities of these three entities, which can be found in the annexe to one of the Commission's documents on HERA. In this annexe, the Commission generally distinguished between an initial 'preparedness phase' (marked in green in this annexe) and a possible subsequent 'crisis phase' (marked in red in this annexe).[87]

2. The Notion of a 'Union'

Since the EHU serves as a concept for responses to the pandemic on the one hand and already existing projects on the other, the question arises about the meaning of its designation as a 'union'. As the third step, changes to EU primary law, is still missing, the question of the institutional (or formal)

82 Commission, 'Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union', COM/2021/576 final. Commission, 'Decision establishing the Health Emergency Preparedness and Response Authority', C/2021/6712 final. In preparation for HERA, see also (from mid-February 2021): Commission, 'HERA Incubator: Anticipating together the threat of COVID-19 variants', COM/2021/78 final. See also the contribution of Bartłomiej Kurcz, 'Health Emergency Response at EU Level – Are There Legal Constraints, HJIL 85 (2025), 1195-1207.

83 The third step would be the discussion of an eventual changing of the existing vertical distribution of competencies (see Section V.).

84 See, for instance, Andreas Orator, *Möglichkeiten und Grenzen der Einrichtung von Unionsagenturen* (Mohr Siebeck 2017).

85 On 'DG Hera', including the four units 'policy and coordination', 'intelligence gathering, analysis and innovation', 'medical counter-measures' and the 'emergency office', see European Commission, 'HERA Organisational Chart', 16 February 2023, <https://health.ec.europa.eu/document/download/7cd9a972-de4a-467c-9c00-ca9671c2a73c_en?filename=organisational-chart_dg-hera_en.pdf>, last access 29 October 2025.

86 Council Regulation 2022/2372/EU of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level OJ 2022 L 314/64 (Regulation Medical Countermeasures).

87 Commission, COM/2021/576 final (n. 82).

qualification of a 'union' arises, in addition to the already addressed substance of this 'concept' (Section IV. 1.).

Within the EU, there are several 'unions', e. g. the Political Union,[88] the Customs Union,[89] the Economic and Monetary Union (EMU),[90] the Energy Union,[91] the Banking Union,[92] the Capital Markets Union (CMU),[93] the Innovation Union,[94] a European Defence Union,[95] and so on.[96] None of these examples can be qualified as an international organisation, as it would have been the case in the context of the finally not realised European Health Community (see Section II.). Three of these unions are more based on primary law (Customs Union, Political Union, and EMU); the Energy Union and the Banking Union (BU), however, are also largely based on secondary law. Finally, the 'Innovation Union' is merely one of seven flagship initiatives

88 Although the term does not appear in the EU treaties, since Maastricht, it has been used to refer to the political component of the EU and the Common Foreign and Security Policy (CFSP) created at that time.

89 Art. 3 (1) (a) TEU, Arts 28-32 TFEU.

90 Art. 3 (4) TEU, Arts 119-144 TFEU.

91 Commission, 'A Framework Strategy for a Resilient Energy Union with a Forward-Looking Climate Change Policy', COM/2015/80 final.

92 Regulation 1022/2013/EU of 22 October 2013 amending Regulation 1093/2010/EU establishing a European Supervisory Authority (European Banking Authority) as regards the conferral of specific tasks on the European Central Bank pursuant to Council Regulation 1024/2013/EU, OJ 2013 L 287/5. Council Regulation 1024/2013/EU of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions, OJ 2013 L 287/63. Regulation 806/2014/EU of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation 1093/2010/EU, OJ 2014 L 225/1, as amended by OJ 2025 L 2025/1.

93 See European Commission, 'Capital Markets Union: New Proposals on Clearing, Corporate Insolvency and Company Listing to Make EU Capital Markets More Attractive: IP/22/7348', 7 December 2022, <https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7348>, last access 29 October 2025.

94 Commission, 'EUROPE 2020. A strategy for smart, sustainable and inclusive growth', COM/2010/2020 final 5, 12, 32.

95 See European Commission and High Representative of the Union for Foreing Affairs and Security Policy, 'JOINT WHITE PAPER for European Defence Readiness 2030: JOIN (2025) 120 final', 19 March 2025, 22, <https://defence-industry-space.ec.europa.eu/eu-defence-industry/white-paper-future-european-defence-rearming-europe_en>, last access 29 October 2025.

96 Some argue that there are even more unions; see Vollaard and Martinsen (n. 60), 337-338. Recent European Council conclusions have addressed various unions (Energy Union; Capital Markets Union; Banking Union; Savings and Investments Union; Union of Skills): European Council, 'Conclusions: EUCO 1/25', 20 March 2025, <https://www.consilium.europa.eu/media/viyhc2m4/20250320-european-council-conclusions-en.pdf>, last access 29 October 2025.

in the context of 'Europe 2020',[97] and the notion of the Defence Union stems from the respective mission letter to Commissioner *Kubilius.*[98]

A parallel to the EHU can be found in the context of the Energy Union, where the Commission emphasises the fact of interdependence between the Member States, respectively a spill-over effect of a crisis,[99] resilience,[100] and sustainability, respectively, with the goal of putting the citizens[101] at the centre of the project.[102]

Likewise, the Banking Union and the EHU also have in common that both were conceived in response to a crisis,[103] and their objectives are comparable in this respect.[104] The similarity between the two crises (the sovereign debt crisis and the pandemic, respectively) is that in both cases, the inadequate response in one Member State can have a negative impact on other Member States.[105] As *Moloney* aptly pointed out, the Banking Union consists of several interrelated components. The heterogeneity of the legal sources is reflected in a mixture of international and Union law, in the latter a mixture of legally binding and soft law documents.[106] Some similarities also exist with

97 According to the Commission, 'the vision of Europe's social market economy for the 21st century'.

98 Ursula von der Leyen, 'Mission Letter to Andrius Kubilius, Commissioner-designate for Defence and Space', 17 September 2024, <https://commission.europa.eu/document/download/1f8ec030-d018-41a2-9759-c694d4d56d6c_en?filename=Mission%20letter%20-%20KUBILIUS.pdf>, last access 29 October 2025.

99 Also called a 'negative spill-over effect'. See Regulation 2021/241/EU of 12 February 2021 establishing the Recovery and Resilience Facility, OJ 2001 L 57/17, as amended by OJ 2024 L 2024/795 (Regulation Recovery and Resilience Facility), Recital 6: a 'lack of resilience can also lead to negative spill-over effects of shocks between Member States or within the Union as a whole'.

100 Emphasising resilience in the context of the EHU: Frank Vandenbroucke, 'A Health Union in Support of European and National Health Solidarity', The Lancet Regional Health – Europe 46 (2024), 101051.

101 Also emphasising the role of individuals in the context of the EHU, Clemens-Martin Auer, 'The Road Towards Developing a European Health Union: Milestones and the Debate of Common European Perspectives in Gastein', Eurohealth 28 (2022), 10-12 (12): 'A European Health Union that is formed in the interest of the citizen must guarantee the enforcement of the interests of the citizens as patients.'

102 Commission (n. 91), 2.

103 According to Delhomme and Hervey (n. 5), 2, a crisis can be defined as 'an unfolding circumstance which is generally understood as constituting an urgent and profound threat to core community values and the structures and institutions that support those values'.

104 Niamh Moloney, 'European Banking Union: Assessing Its Risks and Resilience', CML Rev 51 (2014), 1609-1670 (1629).

105 Oliver Bartlett, 'COVID-19, the European Health Union and the CJEU: Lessons from the Case Law on the Banking Union', European Journal of Risk Regulation 11 (2020), 781-789 (782).

106 Moloney (n. 104), 1625-1626. The EHU also comprises a mixture of EU secondary law, but not of international law.

regard to the question of the concrete applicability of Article 114 TFEU as a legal basis with reference to the tobacco advertising judgments[107], etc.[108]. In both cases, the ECJ played an essential role in exploring the jurisdictional and other legal boundaries before the transition to the respective Union.[109] According to *Bartlett*, it can be assumed that the ECJ would also constructively support the development of the EHU.[110]

To put it bluntly, one can conclude that the term 'Union' serves as a compensation for the inability to respond to a crisis through an amendment of EU primary law.[111] Some of these crises concern a situation of mutual dependence between the Member States and require more resilience.[112] In this context, different secondary law measures (some of which were enacted at different times) are bundled together by the concept of 'Union'. Some measures such as the pharmaceutical strategy, the European Health Data Space and the 'Global Health Strategy' are more obviously linked to (post-pandemic) crisis preparedness, while Europe's Beating Cancer plan is a topic that is only indirectly[113] linked to the pandemic. However, unlike the drafted European Health Community, the EHU does not constitute a Union in the sense of a legal entity. In a formal sense, these changes still qualify as a sectoral policy (i. e., part III TFEU). In a substantive sense, both the Banking Union and the EHU can be described in some sense as examples of an upgraded 'sectoral policy'.[114] The notion of a strengthened sectoral 'Union' within the EU therefore remains an elastic concept, reminiscent to some extent of the *Hallstein*-formula concerning 'association agreements' (trade agreements plus 1, or full EU membership minus 1).[115]

---

107 See ECJ, *Germany* (n. 46). On the Treaty establishing the European Stability Mechanism (ESM-Treaty), see ECJ, *Thomas Pringle v. Government of Ireland and Others*, judgment of 27 November 2012, case no. 370/12, ECLI:EU:C:2012:756.

108 Moloney (n. 104), 1653.

109 Concerning the Banking Union, see Moloney (n. 104), 1654.

110 Bartlett (n. 105), 784.

111 A preliminary question is obviously, if a change of EU Primary law is necessary (see also Section V.).

112 See now also Regulation 2024/2747/EU of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation 2679/98/EC (Internal Market Emergency and Resilience Act), OJ 2024 L 2024/2747.

113 A pandemic can also result in delays or interruptions in treatment for cancer patients.

114 See Frischhut, 'Eine Europäische Gesundheitsunion' (n. *).

115 Michael Schweitzer, Waldemar Hummer and Walter Obwexer, *Europarecht: Das Recht der Europäischen Union* (Manz 2007), 286-287.

3. A Selection of the Key Elements of the EHU

For reasons of space, only selected aspects of the key elements of the Union can be considered. This will include (1) some selected principles (such as, 'one health', a high-level of protection, solidarity, etc.), (2) stress tests, (3) joint procurement, (4) the EU Health Task Force, and (5) the situation of a 'public health emergency at Union level'.

The pandemic began because of a zoonotic disease. Against this background, climate change and the Commission's 'Green Deal'[116], it is not surprising that the EHU (ad 1) embraces[117] the 'one health'-approach.[118] According to Article 3(7) Regulation Cross-border Health Threats, '"One Health" means a multi-sectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions'. Besides this holistic approach (humans, animals, environment), the EHU also embraces[119] the well-known 'Health in All Policies'-approach,[120] and also repeats[121] the requirement to ensure a 'high level of human health protection'.[122] Another element of the underlying philosophy of the EHU, striving for more resilience and better preparedness, is (at least on paper[123]) solidarity[124]. Apart from the

116 Commission, 'The European Green Deal' COM/2019/640 final.

117 DG Santé section A is now entitled 'One Health'; see European Commission, 'DG Health and Food Safety – Organisation Chart', 12 March 2023, <https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-and-food-safety_en#leadership-and-organisation>, last access 29 October 2025.

118 See Jane Johnson and Chris Degeling, 'Does One Health Require a Novel Ethical Framework?', Journal of Medical Ethics 45 (2019), 239-243; Martin McKee, 'One Health Through the Lens of the Sustainable Development Goals', Eurohealth 28 (2022), 40-42.

119 Art. 1 (3) Regulation Cross-border Health Threats.

120 'Health *in* all policies' refers to considering health in other fields (that have to be willing to 'engage with health'), whereas 'health *for* all policies' strives to emphasise the 'mutual benefits of health and other sectors working together', hence, striving to create 'win-win solutions'. See Scott L. Greer et al., 'Making Health for All Policies: Harnessing the Co-Benefits of Health', POLICY BRIEF 50 (2023), 1-30 (5).

121 Art. 3 (1) Regulation Cross-border Health Threats; Art. 1 (3) and Art. 3 Regulation Medical Countermeasures, *et passim*.

122 See n. 36-37.

123 Criticising a lack of solidarity and risk-sharing between Member States, Anniek De Ruijter and Eleanor Brooks, 'The European Health Union: Strengthening the EU's Health Powers?', Eurohealth 28 (2022), 47-49 (48).

124 'The COVID-19 pandemic has revealed shortcomings in Union mechanisms for managing health threats, which call for a more structured Union-level approach, which is also built on the European value of solidarity, to future health crises'; Commission, 'Proposal for a Regulation Amending Regulation (EC) No 851/2004 Establishing a European Centre for Disease Prevention and Control', COM/2020/726 final 1. As aptly stated by Karin Henke, 'Der Aufbau der Europäischen Gesundheitsunion – Lernen aus der Corona-Krise', MedR 39 (2021), 890-896 (896), a EHU has to go beyond just the lessons learned out of the Covid-19 pandemic (see above n. 61).

'one health'-approach, these elements (health in all policies, high level of health protection) are not new. Solidarity is an EU value enshrined in Article 2 TEU since the entry into force of the Lisbon Treaty (1 December 2009), as well as a principle[125]. However, the pandemic has particularly highlighted the necessity for solidarity in the field of health.

After the key principles, we proceed to (ad 2) stress tests. Resilience can be achieved by preparedness. Preparedness must be tested during normal periods, before a crisis occurs. Depending on which entity oversees the relevant field, such a 'stress test' can be mandatory or recommended. In a Council recommendation[126] on the resilience of critical infrastructure, the Council simply encouraged Member States to conduct stress tests in sectors of cross-border relevance, (such as energy, digital infrastructure, etc.).[127] In contrast, the new EMA regulation foresees 'targeted stress tests' to avoid the shortage of both medicinal products and medical devices to be performed by the Commission, EMA, Member States or other relevant actors.[128] Likewise, the ECDC is tasked to develop such stress tests in close collaboration with the Member States and the Commission.[129]

Stress tests were suggested in May 2020;[130] hence, before the Commission's EHU plan from November 2020. So far, stress tests have already been carried out by the EU in the energy or banking sector, and according to these plans, they could be carried out in the health sector by the Member States according to the parameters established by the Commission. This should help Member States to detect areas that must require approval and, accordingly would allow the Commission to propose a 'Directive on minimum standards for quality healthcare',[131] based on the findings of these tests.[132] While respecting Member States' competence (see Article 168(7) TFEU), this would have introduced European minimum standards for quality healthcare and patient

125 Frischhut, *The Ethical Spirit of EU Values* (n. 68), 83-92.

126 Hence, a soft law document.

127 Council Recommendation of 8 December 2022 on a Union-wide coordinated approach to strengthen the resilience of critical infrastructure OJ 2023 C 20/1.

128 'Such stress tests entail a simulation of a public health emergency or major event in which some or all [!] segments of the processes and procedures laid down in this Regulation are tested'; Regulation EMA Recital 15. See also Regulation EMA on reinforced monitoring and mitigating shortages of critical medicinal products (Chapter II) and medical devices (Chapter IV).

129 Regulation ECDC Art. 5b (2) (e). See also Regulation Cross-Border Health Threats Art. 5 (5), addressing the Commission in this context.

130 Progressive Alliance of Socialists and Democrats (n. 60), 2.

131 This can currently conflict with Art. 168 (7) TFEU. Currently, according to Art. 4 (1) (b) Directive patient mobility, the Member State of treatment is responsible for 'standards and guidelines on quality and safety'.

132 Progressive Alliance of Socialists and Democrats (n. 60), 2.

safety.[133] Another possibility would be to amend EU primary law to provide for a shared competence in this field,[134] as then such stress tests could serve to monitor the correct implementation of EU law.

Although the Member States are responsible 'for the definition of their health policy and for the organisation and delivery of health services and medical care' (Article 168(7) TFEU), they can voluntarily cooperate, for instance, in the field of (ad 3) joint procurement, to achieve a better bargaining position. Joint procurement is not new and has already been an issue in the case of the 'swine flu' way back in 2009.[135] In this light, 'Regulation Cross-border Health Threats' strives to 'strengthen and extend' the current framework[136] for the joint procurement of medical countermeasures, and its Article 12 ('joint procurement of medical countermeasures') provides for the necessary details. An important question is whether a possible parallel procurement would be legal. According to Article 12(3)(c), it is only 'possible' to restrict parallel procurement and negotiation activities.[137]

In the context of 'support for international and field preparedness and response', ECDC shall establish (ad 4) an 'EU Health Task Force', i. e., outbreak assistance teams, with the aim to assist in local responses to outbreaks of communicable diseases and to collect field data, both in Member States and in third countries.[138] The EU Health Task Force shall have a permanent capacity as well as an enhanced emergency capacity and shall consist of ECDC staff and experts from Member States. Although the overall aim was to strengthen the ECDC's mandate, it is also emphasised that the new Regulation does 'not confer any regulatory powers on the Centre'.[139] Rather, the ECDC shall provide 'robust and independent scientific expertise'.[140]

---

133 Progressive Alliance of Socialists and Democrats (n. 60), 2. This directive should have comprised criteria to be reported to the Commission (relating to the parameters, such as hospital beds per capita, numbers of doctors, etc.), allowing the progress of healthcare systems to be tracked and being linked to the European Semester.

134 See Section V.

135 Anniek de Ruijter, 'A Silent Revolution: The Expansion of EU Power in the Field of Human Health: A Rights-Based Analysis of EU Health Law & Policy', (PhD thesis, fully internal, University of Amsterdam 2015), 205-212.

136 Regulation Cross-border Health Threats Recital 18, referring to the Joint Procurement Agreement for medical countermeasures, approved by the Commission on 10 April 2014.

137 On this 'exclusivity clause', see also Regulation Cross-Border Health Threats Recital 19.

138 Art. 11a Regulation ECDC (see also Recitals 23 and 24). On the EHC (and the possibility of mobile teams), see Section II.

139 Recital 29 Regulation ECDC.

140 Recital 8 Regulation ECDC.

A noteworthy innovation of the EHU is also the use of artificial intelligence (AI),[141] which shall be used for the digital platform for surveillance,[142] for updating the Early Warning and Response System (EWRS),[143] as well as by the EMA in the context of the 'European Health Data Space'[144] and the 'European shortages monitoring platform'.[145]

An important novelty for crisis preparedness is also the Commission's possibility to formally recognise (ad 5) a 'public health emergency at Union level', 'including pandemic situations where the serious cross-border threat to health in question endangers public health at Union level'.[146] So far, it has been up to the World Health Organisation (WHO) to declare a 'public health emergency of international concern' (PHEIC).[147] While the EU becomes more independent of the WHO, the Commission still has to 'liaise with the WHO in order to share [its] analysis of the situation of the outbreak'.[148] While this can be an advantage in terms of speedy reaction to a pandemic, this possibility may, of course, be challenging, as both the decision itself, as well as its timing, can certainly be the subject of heated political debate.[149] Following such a determination, the Council may, in accordance with 'Regulation Medical Countermeasures', activate an emergency framework. This framework allows for a variety of measures. These measures are 'medical countermeasures' (that is also why 'Regulation Cross-border Health Threats' has a broader scope) and shall ensure the supply of medical countermeasures

141 See Regulation 2024/1689/EU of 13 June 2024 laying down harmonised rules on artificial intelligence […] (Artificial Intelligence Act), OJ 2025 L 2024/1689.

142 Art. 14 (2) (a) Regulation Cross-Border Health Threats, 'for data validation, analysis and automated reporting, including statistical reporting'. See also Art. 3 (2) (a) and Recital 15 Regulation ECDC. This platform shall enable especially the automated collection and handling of surveillance and laboratory data.

143 Art. 18 (2) Regulation Cross-Border Health Threats. See also Art. 8 (4) and Recital 22 Regulation ECDC. The EWRS is a system 'enabling the notification at Union level of alerts related to serious cross-border threats to health', 'in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner', Recital 29.

144 Recital 45 Regulation EMA. On the EHDS, see n. 51.

145 Recital 58 Regulation EMA; i. e., an IT platform 'that is capable of processing information on the supply of and demand for critical medicinal products [especially] during public health emergencies or major events', Recital 20.

146 Art. 23 (1) Regulation Cross-Border Health Threats.

147 World Health Organization, *International Health Regulations (2005)* (2nd edn, World Health Organization 2008); Art. 1 defines a PHEIC, and Art. 12 provides for the procedure of determination of a PHEIC (see also Annexe 2); see also Art. 57 (3).

148 Art. 23 (3) Regulation Cross-Border Health Threats.

149 See also Eleanor 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.

that are crisis-relevant.[150] As this framework applies in the case of a 'public health emergency at Union level', this requires an activation through Council regulation, 'taking into account the need to ensure a high level of protection of human health'.[151] As this regulation is based on Article 122 TFEU (see below Section IV. 4.), the use of measures within the emergency framework is limited in time for a maximum period of six months (which can be prolonged).[152] Obviously, for reasons of time, HERA was set up as a Commission Directorate-General, and not as an agency. In the typical review-report of this regulation, the question of a possible upgrade of HERA to an agency shall also be addressed.[153]

4. Primary Law Dimension (*de lege lata*)

In the case of severe difficulties arising in the supply of certain products (notably in energy), Article 122(1) TFEU allows the Council to take appropriate measures 'in a spirit of solidarity between Member States'. The second paragraph refers to 'financial assistance' for a Member State experiencing difficulties or being seriously threatened with 'severe difficulties caused by natural disasters or exceptional occurrences beyond its control'. The European Parliament is side lined in this context and must only be informed according to the second (not in the case of the first) paragraph. So far,[154] sixteen documents[155] have been adopted based on Article 122 TFEU,[156]

150 These measures can include the following: a monitoring mechanisms (Art. 7); procurement, purchase and manufacturing of crisis-relevant medical countermeasures and raw materials (Art. 8); emergency research and innovation aspects of the preparedness and response plans, as well as the use of clinical trial networks and data-sharing platforms (Art. 9); an inventory of crisis-relevant medical countermeasure production (Art. 10) or raw materials (Art. 11); measures to ensure the availability and supply of crisis-relevant medical countermeasures (Art. 12); emergency funding (Art. 13).

151 Art. 3 Regulation Medical Countermeasures.

152 Art. 3 (4) Regulation Medical Countermeasures.

153 Art. 16 Regulation Medical Countermeasures. For a possible future development of HERA, see also Charlotte Godziewski and Simon Rushton, 'HERA-lding More Integration in Health? Examining the Discursive Legitimation of the European Commission's New Health Emergency Preparedness and Response Authority', Journal of Health Politics, Policy and Law 49 (2024), 831-854.

154 Valid as of mid-March 2025, all information retrieved from EUR-Lex. Four documents (in the field of energy and inflation) are no longer in force (see, for example, Regulation 2022/2578/EU of 22 December 2022 establishing a market correction mechanism to protect Union citizens and the economy against excessively high prices, OJ 2022 L 335/45, as amended by OJ 2023 L 2023/2920).

155 Mainly (twelve) Council regulations, two ECB decisions and two Council decisions.

156 Either the first (eight), the second (four) or both (four) paragraphs.

mainly in the fields of energy (5), finance (5), and pandemic (4),[157] as well as in the fields of the environment (1) and inflation (1).[158] It clearly seems as if Article 122 TFEU has replaced Article 352 TFEU (the 'flexibility clause') to avoid the latter's requirement of the Council deciding by unanimity. In the context of the ESM-Treaty, in *Pringle*, the ECJ has emphasised the EU's power under Article 122 TFEU to grant *ad hoc* (financial) assistance (under paragraph 2). However, according to the ECJ, Article 122(2) TFEU does not constitute an appropriate legal basis for a 'mechanism envisaged […] to be permanent'.[159] Simply put, this legal basis can be used for a short-term reaction to a particular difficulty, but not for long-term reforms.

Next Generation EU (NGEU) is a huge package intended to help Member States recover from the pandemic. The 'European Union Recovery Instrument',[160] based on Article 122 TFEU (see above), 'acts as the container instrument'[161] for NGEU and comprises EUR 750 000 million in total. In addition to other components (including an updated Decision on Own Resources[162], based on Article 311 TFEU), the key instrument is the 'Recovery and Resilience Facility' (RRF)[163], based on Article 175 TFEU (see above). As mentioned above, the increasing use of Article 122 TFEU can be seen as an example of 'creative legal engineering'. The German Constitutional Court (BVerfG) had to decide on the approval act of the German parliament concerning the 'Decision Own Resources'.[164] Indirectly, this could also have endangered NGEU, as an impor-

157 Besides Regulation Medical Countermeasures, also the following: Regulation 2020/2094/EU of 14 December 2020 establishing a European Union Recovery Instrument to support the recovery in the aftermath of the COVID-19 crisis, OJ 2020 L 433/23 (Regulation EU Recovery Instrument). Regulation 2020/672/EU of 19 May 2020 on the establishment of a European instrument for temporary support to mitigate unemployment risks in an emergency (SURE) following the COVID-19 outbreak, OJ 2020 L 159/1. Regulation 2020/521/EU of 14 April 2020 activating the emergency support under Regulation 2016/369/EU, and amending its provisions taking into account the COVID-19 outbreak, OJ 2020 L 117/3.

158 See Regulation 2022/2578/EU of 22 December 2022 establishing a market correction mechanism to protect Union citizens and the economy against excessively high prices, OJ 2022 L 335/45, as amended by OJ 2023 L 2023/2920 (hence, no longer in force).

159 *Pringle* (n. 107), para. 65.

160 Regulation EU Recovery Instrument.

161 Bruno De Witte, 'The European Union's COVID-19 Recovery Plan: The Legal Engineering of an Economic Policy Shift', CML Rev 58 (2021), 635-682 (636).

162 Council Decision 2020/2053/EU, Euratom of 14 December 2020 on the system of own resources of the European Union and repealing Decision 2014/335/EU, Euratom, OJ 2020 L 424/1 (Decision Own Resources); see also European Commission, Next Generation of EU Own Resources, IP/21/7025 (2021).

163 Regulation Recovery and Resilience Facility (n. 99).

164 BVerfG, *Verfassungsbeschwerden gegen Eigenmittelbeschluss-Ratifizierungsgesetz (NGEU) erfolglos*, judgment of 6 December 2022, case no. 2 BvR 547/21, 2 BvR 798/21, ECLI:DE:BVerfG:2022:rs20221206.2bvr054721.

tant 'financial dimension' of the European Health Union.[165] However, in the end, the two constitutional complaints were rejected. In particular, the statements with regard to Article 122 TFEU and its requirements[166] of a sufficient link between the pandemic and both the substance of the measures, as well as on a timeline (funds to be spent until 2026),[167] can make the 'creative legal engineering' (in terms of applying Article 122 TFEU) more challenging in the future.

In a sense, Article 122 TFEU can be seen to add up to the other legal bases that are complementing what has been called the 'web of health competence',[168] besides Article 168 TFEU. First and foremost, Article 114 TFEU (harmonisation of national law) should be mentioned here, which is often combined with Article 168 TFEU.[169] Further provisions to be mentioned are Article 153 TFEU (social policy),[170] Article 196 TFEU (civil protection),[171] Article 16 TFEU (data protection),[172] Article 173 TFEU (industry),[173] and Article 175 TFEU (economic, social and territorial cohesion).[174]

---

165 For further details (on number of Member States that can be supported; a sufficient link between the pandemic and the measures financed, etc.), see Thu Nguyen and Martijn van den Brink, 'An Early Christmas Gift from Karlsruhe?: The Bundesverfassungsgericht's NextGenerationEU Ruling', Völkerrechtsblog, 9 December 2022, doi: 10.17176/20221210-001631-0; Rudolf Mögele, 'EU-Wiederaufbaufonds: Deutschlands Beteiligung am Corona-Aufbaufonds verfassungskonform', Anmerkung zu BVerfG, Urteil v. 6.12.2022 – 2 BvR 547/21, 2 BvR 798/21, EuZW 34 (2023), 113-139 (137).

166 As interpreted by the BVerfG.

167 See BVerfG, *NGEU* (n. 164).

168 Kai P. Purnhagen et al., 'More Competences than You Knew?: The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak', European Journal of Risk Regulation 11 (2020), 297-306. This concept refers to a web that is 'stronger than its individual threads' (p. 303), where health takes precedence over mere economic considerations (ibid.) and where solidarity plays an important role (p. 304). On the precedence of health over economic considerations, see also Vlad Constantinesco, 'The ECJ as a Law-Maker: Praeter aut Contra Legem?' in: David O'Keeffe and Antonio Bavasso (eds), Judicial Review in European Union Law: Liber Amicorum in Honour of Lord Slynn of Hadley (Kluwer Law International 2000), 73-79.

169 Directive patient mobility; Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU [i.e., Directive patient mobility] [2021] OJ L458/1.

170 E. g., Directive 2022/431/EU of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, OJ 2022 L 88/1.

171 Regulation 2021/836/EU of 20 May 2021 amending Decision No. 1313/2013/EU on a Union Civil Protection Mechanism, OJ 2021 L 185/1, also based on Art. 322 TFEU (budget).

172 E. g., Regulation EHDS (n. 51).

173 Regulation 2021/523/EU of 24 March 2021 establishing the InvestEU Programme and amending Regulation 2015/1017/EU, OJ 2021 L 107/30, as amended by OJ 2024 L 2024/795 (Regulation InvestEU).

174 Likewise, Regulation InvestEU (n. 173); Regulation Recovery and Resilience Facility (n. 99).

In her 2020 'State of the Union'-speech, Commission president von der Leyen had referred to the third step of building an EHU, that is to say 'the question of health competences'.[175] This third step is still missing.[176] In the framework of the 'Conference on the Future of Europe',[177] the idea of making health and healthcare a competence shared between the EU and the EU Member States is mentioned,[178] however, without any concrete legal details concerning Article 168 TFEU.[179] In view of the obvious reluctance of the Member States to transfer further competences to the EU (not only in general, but also especially in the area of health), it will be interesting to see what lessons are actually drawn from the pandemic.[180] Nonetheless, the question remains about what needs to be done.

V. Suggestions (*de lege ferenda*): or the Missing 'Keystone'

1. Gradual Competence Creep?

The EU has often been accused of a 'competence creep', that is to say, a gradual extension of the powers of the EU to the disadvantage of the EU Member States and of national sovereignty.[181] The accusation of 'integration by stealth' goes in a similar direction; this refers to the fact of not following the aim 'to find the best feasible solution to a concrete problem', but to simply 'drive forward the integration process'.[182] Another accusation is 'crea-

175 von der Leyen (n. 59).

176 Valid as of mid-March 2025.

177 See Müller-Graff (n. 75).

178 Conference on the Future of Europe, 'Report on the Final Outcome', May 2022, 52, <https://www.europarl.europa.eu/news/en/press-room/20220509IPR29102/the-conference-on-the-future-of-europe-concludes-its-work>, last access 29 October 2025.

179 'Enhance the European Health Union Using the Full Potential of the Current Framework and Include Health and Healthcare Among the Shared Competencies Between the EU and the EU Member States by Amending Art. 4 TFEU'.

180 In view of new crises (war in Ukraine, inflation, etc.), the fear is justified that the 'window of opportunity' is already closed. On the window of opportunity and timing of health policy outputs, see Torben Fischer, Nicole Mauer and Florian Tille, 'A Framework for Studying EU Health Policy Through a Political Determinants of Health Lens: The Case of the European Health Union', Journal of Health Politics, Policy and Law 49 (2024), 691-720.

181 See, for instance, Sacha Garben, 'Competence Creep Revisited', JCMS 57 (2019), 205-222; Sacha Garben, 'From Sneaking to Striding: Combatting Competence Creep and Consolidating the EU Legislative Process', ELJ 26 (2020), 429-447; Stephen Weatherill, 'Competence Creep and Competence Control', YBEL 23 (2004), 1-55.

182 Giandomenico Majone, Dilemmas of European Integration: The Ambiguities and Pitfalls of Integration by Stealth (Oxford University Press 2005), 143-144.

tive legal engineering',[183] which has both a vertical ('stretching of the EU's competences in Article 122 and Article 175 TFEU') and a horizontal (between EU institutions) dimension.[184] This criticism, however, addresses less the EU than the Member States, which are the 'Masters of the Treaties'. However, if they do not provide the necessary tools to solve a crisis, EU institutions have to find creative solutions to respond to a crisis.[185] Besides this gap in necessary tools and actual challenges, Calliess has also identified a gap between objectives (Article 3 TEU) and actual competences; amongst others, also in the field of Article 168 TFEU.[186] This challenge of not providing the necessary tools in EU primary law also has to be seen in the context of the phenomenon of 'failing forward'. This has been described as follows: 'in an initial phase, lowest common denominator intergovernmental bargains led to the creation of incomplete institutions, which in turn sowed the seeds of future crises, which then propelled deeper integration through reformed but still incomplete institutions – thus setting the stage for the process to move integration forward'.[187] The following section analyses how this can be prevented.[188]

2. Shifting Healthcare Competences to the EU Level

In architecture, the 'keystone' is the stone on top of an arch, placed at the end, and holding together the whole construction. While there have been various improvements to the existing legal framework (Section IV. 3.), it is advisable to also add this last piece to the architecture of a true European Health Union. This missing keystone is the amendment of Article 168 TFEU.

183 De Witte (n. 161), 681.

184 See also, more recently, Andreas Eriksen and Michelle Everson, 'Health Policy: A Cautionary Tale of Constitutional Slippage and Polity Building Between Crisis and Nation Building' in: Diane Fromage, Adrienne Héritier and Paul Weismann (eds), *EU Regulatory Responses to Crises* (Oxford University Press 2025), 63-91.

185 This creativity obviously has to respect the boundaries of EU primary law and is subject to the legal control of the ECJ.

186 Christian Calliess, 'Braucht die Europäische Union eine Kompetenz zur (Corona-) Pandemiebekämpfung?: Zugleich ein Beitrag zu Prüfkriterien in der europäischen Kompetenzdebatte', NVwZ 40 (2021), 505-511 (506, 510). See also the contribution of Christian Calliess, 'Filling the Gap in the Health Policy of the European Union (EU) – Lessons Learned from the Covid-19 Pandemic –', HJIL 85 (2025), 1045-1074.

187 Erik Jones, R. Daniel Kelemen and Sophie Meunier, 'Failing Forward? Crises and Patterns of European Integration', Journal of European Public Policy 28 (2021), 1519-1536 (1519 f.); see also Erik Jones, R. Daniel Kelemen and Sophie Meunier, 'Failing Forward?: The Euro Crisis and the Incomplete Nature of European Integration', Comparative Political Studies 49 (2016), 1010-1034.

188 See Calliess, 'Pandemiebekämpfung' (n. 186); Calliess, 'Filling the Gap' (n. 186).

As the aim is an extension of the EU's competences to dispose of the necessary tools,[189] this would have to be implemented via the 'ordinary revision procedure' of Article 48(2)-(5) TEU, not according to the 'simplified procedure' of Article 48(6) TEU.[190] While there have been various proposals of how to amend Article 168 TFEU,[191] only a few are presented here.

The Constitutional Treaty[192] proposed upgrading 'measures concerning monitoring, early warning of and combating serious cross-border threats to health' to a shared[193] competence. Hence, allowing for harmonisation in this field in addition to other already existing safety concerns (blood, medical products, medical devices, etc.). While these existing shared competences of Article 168(4) TFEU are aimed at individual 'products', 'cross-border threats to health' target the preparedness of health systems, therefore, narrowing the scope of the Member States' competence of Article 168(7) TFEU with regard 'the definition of their health policy and for the organisation and delivery of health services and medical care'.

Based on Article 2(1) Regulation Cross-border Health Threats, 'communicable diseases'[194] are just one example of 'serious cross-border threats to health'. Hence, the proposal of Seitz to have a shared competence in the field of 'measures to prevent, control and combat communicable diseases with pandemic potential'[195] is narrower. This proposal is based on Calliess, who

189 Likewise, critical to refer to a EHU without changing EU primary law, Constanze Janda, 'Die Europäische Gesundheitsunion – Vorschläge der EU-Kommission' in: Indra Spiecker Döhmann (ed.), *Mehrebenensystem im Gesundheitswesen: Ein Jahr Corona: welche Lehren können wir ziehen?* (Peter Lang 2022), 9-39 (39).

190 See also, Calliess, 'Pandemiebekämpfung' (n. 186), 511; Andreas T. Müller, 'Europa und die Pandemie: Zuständigkeitsdefizite und Kooperationszwänge' in: Christian Walter (ed.), *Staat und Gesellschaft in der Pandemie: Berichte und Diskussionen auf der Sondertagung der Vereinigung der Deutschen Staatsrechtslehrer in Wien am 9. April 2021*, VVDStRl 80 (2021), 105-124 (114). Art. 46(7) TEU concerns another simplified procedure (qualified majority instead of unanimity).

191 See Frischhut, 'Eine Europäische Gesundheitsunion' (n. *).

192 Art. III-278(4)(d).

193 See also Art. 2(2) TFEU.

194 See Markus Frischhut and Scott L. Greer, 'EU Public Health Law and Policy – Communicable Diseases' in: Tamara K. Hervey, Calum Young and Louise E. Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017); Markus Frischhut, 'Communicable and Other Infectious Diseases: The EU Perspective' in: Tamara K. Hervey and David Orentlicher (eds), *The Oxford Handbook of Comparative Health Law* (Oxford University Press 2021).

195 Claudia Seitz, 'The European Health Union and the Protection of Public Health in the European Union: Is the European Union Prepared for Future Crossborder Health Threats?', ERA Forum 24 (2023), 543-566 (562). See also, Claudia Seitz, 'Schutz der Gesundheit in der Europäischen Gesundheitsunion: Ist die Europäische Union auf zukünftige grenzüberschreitende Gesundheitsgefahren vorbereitet?', EuZ 24 (2022), L1-L33.

has combined this upgrade with the possibility for Member States to 'maintain or adopt enhanced protection measures, where these are imperative'.[196] In the end, it will be a political question, if the broader (serious cross-border threats to health) or the more narrow (communicable diseases, especially pandemics) approach will be feasible.

In terms of the above-mentioned statement of *Schuman*,[197] (shared) competences for 'cross-border threats to health' (including a pandemic) should be located at the EU level, as the necessary tools have to be available where they actually make sense. This includes an integration of the already existing tool of stress tests, but not only concerning 'medicinal products' and 'medical devices' (EMA[198]), respectively only supporting or complementing Member States' measures (ECDC[199]). A shared competence including such stress tests in the context of preparedness for serious cross-border health threats[200] would provide the Union with the necessary tools, hence, taking the proposal of the Constitutional Treaty to the next level and avoiding a 'failing forward'.[201] While it could be seen as an additional step, ideally such a shared competence should also comprise minimum standards for quality healthcare in this context.[202]

Hence, the new *litera* (d) of Article 168(4), the (missing) keystone of the 'European Health Union', should be read as follows: 'measures concerning *preparedness (including stress tests)*, monitoring, early warning of and combating serious cross-border threats to health'.[203] On a parallel level,[204] this also requires an amendment to Article 35(2) CFR[205] and to extend the requirement

196 Calliess, 'Pandemiebekämpfung' (n. 186), 511 (translation), using not an identical, but a similar wording. The wording of *Calliess* is reminiscent of Art. III-278(4)(d). See also the contribution of Calliess, 'Filing the Gap' (n. 186).

197 See the quotation above Section I.

198 See Regulation EMA Recital 15 and Chapter II, IV (n. 128).

199 See Regulation ECDC Art. 5b(2)(e), Regulation Cross-Border Health Threats Art. 5(5) (n. 129).

200 Including, but not limited to, pandemics.

201 See Calliess, 'Pandemiebekämpfung' (n. 186); Calliess, 'Filling the Gap' (n. 186).

202 Progressive Alliance of Socialists and Democrats (n. 60), 2.

203 Emphasis indicating the new elements compared to Art. III-278(4)(d) Constitutional Treaty.

204 The parallelism of the amendment is required by Art. 51(2) GRC, as the 'Charter does not extend the field of application of Union law beyond the powers of the Union or establish any new power or task for the Union'.

205 Theoretically, one could also envisage the 'right of access to preventive health care and the right to benefit from medical treatment' of Art. 35(1) CFR. This has less practical impact and does not create an added value, as it refers to 'the conditions established by national laws and practices'. Deleting this latter part would be quite far reaching, as this would require a parallel amendment of Art. 168(7) TFEU itself, which is not realistic.

of a 'high level of human health protection' not only to all 'Union's policies and activities' but also to all the activities of the Member States. However, this approach does not require an amendment of Article 4(2)(k) TFEU, as this proposal falls within the existing wording of 'common safety concerns in public health matters, for the aspects defined in this Treaty'.

However, besides Article 168 TFEU and Article 35 CFR, another dimension must also be considered. As mentioned above, the 'one health'-approach can be seen as 'a multi-sectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions'.[206] Since 1957,[207] the free movement of goods can be restricted for 'the protection of health and life of humans, animals or plants'. Hence, we can find the three dimensions of humans, animals, and the environment (or at least plants) as 'reasons of justification'. As we have seen in Section II., 'public health' has also developed from a mere 'reason of justification' (ECSC) to a distinct 'sectoral policy' (Maastricht). Likewise, the 'one health'-approach enshrined in Article 36 TFEU (free movement of goods) can be further developed as follows.

3. Health as an Additional Value

In a remarkable ruling of mid-December 2020, the ECJ qualified 'animal welfare' as 'an EU value' in the context of ritual slaughter with reference to an EU regulation[208] on the protection of animals at the time of killing.[209] This is remarkable insofar as it is the first value outside Article 2 TEU and the addressees are not humans but animals. This statement from 2020 is also noteworthy insofar as the ECJ had previously refused[210] to judge animal welfare as a 'general principle of law' about 20 years earlier.[211] Although both the values of Article 2 TEU and the 'general principles of EU law' formally qualify as EU primary law, the values are to be seen as 'more' in terms of content.

206 Art. 3(7) Regulation Cross-Border Health Threats.

207 Treaty establishing the European Economic Community, from 25 March 1957; nowadays identical in Art. 36 TFEU.

208 Regulation 1099/2009/EU of 24 September 2009 on the protection of animals at the time of killing, OJ 2009 L 303/1, as amended by OJ 2018 L 122/11.

209 ECJ, *Centraal Israëlitisch Consistorie van België and Others*, judgment of 17 December 2020, case no. C-336/19, ECLI:EU:C:2020:1031, para. 41.

210 ECJ, *Jippes and Others v. Minister van Landbouw, Natuurbeheer en Visserij*, judgment of 12 July 2001, case no. C-189/01, ECLI:EU:C:2001:420, para. 74.

211 Takis Tridimas, *The General Principles of EU Law* (2nd edn, Oxford University Press 2006), 27.

Departing from animal welfare as a new value, one can argue (*argumentum a minori ad maius*) that human health is also a value in itself. This demand is of course formally[212] considered as a proposal *de lege ferenda* and would require either an EU primary law amendment by the 'Masters of the Treaties', or a corresponding further development of the law by the ECJ,[213] to be on the safe side. In the end, this approach could be seen as a complementary step in addition to the ECJ's case law[214] of giving precedence to health over mere economic considerations. However, no change of Article 2 TEU would be necessary by simply placing a stronger emphasis on the existing value of solidarity.[215]

In a holistic approach, the environment – as a human right[216] or value[217] – would also have to be considered. Both proposals, which show a certain connection against the background of the mention of human rights in Article 2 TEU, are, of course, also to be understood *de lege ferenda*. The connection of humans, animals, and the environment displayed in the 'one health'-approach would then also have a certain legal linking in the sense of three values, twice *de lege ferenda*, once already established by the ECJ. A certain parallelism would then also exist in the area of the vertical distribution of competences, if the EU would get more shared competences in health, as in the area of environment (Article 4(2)(e) TFEU). As is well known, environ-

212 This is to be understood as a cautious reading; in terms of content, the aforementioned conclusion '*argumentum a minori ad maius*' could already be sufficient at present to consider human health a value.

213 See for instance, Constantinesco (n. 168).

214 *Affish v. Rijksdienst voor de keuring van Vee en Vlees*, judgment of 17 July 1997, case no. C-183/, ECLI:EU:C:1997:373, para. 43; *P Artegodan v. Commission*, judgment of 19 April 2012, case no. C-221/10, ECLI:EU:C:2012:216, para. 99; *Swedish Match AB v. Secretary of State for* Health, judgment of 22 November 2008, case no. C-151/17, ECLI:EU:C:2018:938, para. 54.

215 In the past, for instance, patient mobility has been criticised of 'corroding solidarity'; Christopher Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity', CML Rev 43 (2006), 1645-1668. An idea to be further developed within the 'Horizon Europe' project 'Flexible Approaches to Support Health Through Financing (FLASH)'. Also emphasising solidarity in the context of the EHU: Vandenbroucke (n. 100); Council of the EU, 'Council Conclusions on the Future of the European Health Union: A Europe that Cares, Prepares and Protects: 9900/24', 21 June 2024, 3, <https://www.consilium.europa.eu/en/meetings/epsco/2024/06/21/>, last access 29 October 2025.

216 Ferdinand von Schirach, *Jeder Mensch* (Luchterhand 2021) 18: 'Artikel 1 – Umwelt', 'Jeder Mensch hat das Recht, in einer gesunden und geschützten Umwelt zu leben'.

217 Frischhut, *The Ethical Spirit of EU Values* (n. 68), 227-229. Also referring to the 'value of health [as] the cultural backbone of our European civilisation', Vytenis Andriukaitis and Gediminas Cerniauskas, 'Scenarios for the EHU's Evolution: Legislative Process, Resources, Narrative, and Political Will' in: Vytenis Andriukaitis and Gediminas Cerniauskas (eds), *A European Health Union: A Blueprint for Generations* (FEPS 2023), 273-312 (307).

mental and health policy are linked not least in that Article 191(1) TFEU also identifies 'protecting human health' as one of the objectives of environmental policy.

4. Conclusion: No 'Big Bang'

In conclusion, the EHU cannot thus be qualified as a 'big bang'.[218] To some extent, certain already existing legal possibilities for action have not been exhausted in the past.[219] Unlike in the context of previous crises, the response to the pandemic has taken place within EU law (and not outside, i. e., in international law).[220] It is intriguing that some elements of the EHU correspond to what had already been suggested in 1952, although not as a supra-national legal entity but as amendments to various documents of EU secondary law.

This contribution proposes the addition of the missing keystone (a new *litera* d for Article 168(4) TFEU) for the 'European Health Union'. At the moment, although consisting of valuable improvements, the EHU serves as an umbrella term[221] due to the lack of political will to change EU primary law. At the same time, it can be seen as a shifting concept that always incorporates current projects.

History consistently offers valuable lessons, and this holds true for the healthcare sector as well. It's fascinating to compare the idealistic vision behind the European Health Community – conceived freely on paper – with the more constrained, incremental development shaped subject to the limitations of the principle of conferral. While establishing a separate legal entity, such as a Health Community (in the sense of an international organisation), would neither add value nor align with the Lisbon Treaty,[222] the EU should

218 See also, Thibaud Deruelle, 'Covid-19 as a Catalyst for a European Health Union: Recent Developments in Health Threats Management' in: Bart Vanhercke and Slavina Spasova (eds), *Social Policy in the European Union: State of Play 2021: Re-Emerging Social Ambitions as the EU Recovers from the Pandemic* (ETUI Printshop 2022), 127-144; Müller (n. 190), 105, 129 and 131.

219 European Parliament Resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 (2020/2691(RSP)), OJ 2021 C 371/102 Recital I, referring to European Parliamentary Research Service, 'Unlocking the Potential of the EU Treaties: An Article-by-Article Analysis of the Scope for Action', May 2020, 29-30. Purnhagen et al. (n. 168), 306.

220 Müller (n. 190) 125; Delhomme and Hervey (n. 5), 34.

221 Mentioning that the 'European Health Union is to be more than the sum of its parts', Martin McKee and Anniek de Ruijter, 'The Path to a European Health Union', The Lancet Regional Health – Europe 36 (2024), 100794.

222 In the sense of abolishing the temple or three pillars construction, established by the Maastricht Treaty.

nonetheless be equipped with the necessary powers to address current and future health challenges. The original proposal for a European Health Community, which included ideas like mobile teams for on-site inspections and even an 'International Health Police', reflected a broader spirit of cooperation – such as resource pooling – that should continue to guide and inspire future reforms.

DOI 10.17104/0044-2348-2025-4-1011 ZaöRV 85 (2025)