European Journal of Risk Regulation (2025), 1–19
doi:10.1017/err.2025.10021

CAMBRIDGE UNIVERSITY PRESS

ARTICLE

Building the European Health Union (2019–2024): Successes, Limits and Future Perspectives

Vincent Delhomme and Carina van Os

European Union Law, Leiden University, Leiden, The Netherlands
Corresponding author: Vincent Delhomme; Email: v.n.delhomme@law.leidenuniv.nl

Abstract

The COVID-19 pandemic brought the EU health mandate under unprecedented scrutiny, providing a new impetus for action. The European Commission launched the 'European Health Union' (EHU), bringing a number of pre-existing and newer policy initiatives under a common umbrella. This contribution looks back at the recent developments in EU health law and policy, taking the 2019–2024 parliamentary term as a boundary. It offers an overview of what the EHU currently is, and what it could become. Despite its potential, the EHU is not yet a game changer. This can only happen if changes are brought to the EU's competence and budgetary frameworks. The contribution provides first a brief introduction to the EU's complex health competence framework and its general policy orientations in the field. We turn next to COVID-19, offering a condensed overview of the EU's response and of the subsequent changes brought to the legal framework applicable to health emergencies. We finish by casting a closer look at the EHU, examining the descriptive and normative aspects of this concept, and making recommendations to increase the clarity, quality and legitimacy of EU action in the field.

Keywords: COVID-19; EU Health Law; European Health Union

I. Introduction

When asked to reflect on the current state of EU health law and policy, COVID-19 looms large. The pandemic shook our societies to their core, leading to human losses and restrictions of civil liberties unseen in recent history. In spring 2020, only a couple of months into office, Ursula von der Leyen and her new Commission had to face this unprecedented challenge to the integrity and cohesiveness of the EU. The crisis came to define their mandate, the most visible consequence of which was the adoption of the Next Generation EU (NGEU) recovery package, a radical shift of the EU's economic and fiscal governance.[1] For EU health governance, however, the pandemic's legacy appears more elusive, two years after the WHO ceased to consider it as a "a global health emergency".[2] While COVID-19 brought the EU health mandate under unprecedented scrutiny – putting a definitive end, one would hope, to the "no competence in health" discourse – it fell short of

[1] P Dermine, "The EU's Response to the COVID-19 Crisis and the Trajectory of Fiscal Integration in Europe: Between Continuity and Rupture" (2020) 47 Legal Issues of Economic Integration 337; B De Witte, "The European Union's COVID-19 Recovery Plan: The Legal Engineering of an Economic Policy Shift" (2021) 58 Common Market Law Review 635.

[2] United Nations, "WHO Chief Declares End to COVID-19 as a Global Health Emergency" (2023) available at <https://news.un.org/en/story/2023/05/1136367> (last accessed 11 January 2025).

redefining the content and overall direction of EU health law and policy. The trumpeted "European Health Union", for all its potential, is not yet a game changer.

This contribution looks back at these recent developments in EU health law and policy, taking the 2019–2024 parliamentary term as a boundary, and offers a reflection on the present and future of the European Health Union. We provide first a brief introduction to the EU's complex health competence framework and its general policy orientations in the field (II). This is the necessary background to the analysis conducted in the rest of the paper. We turn next to COVID-19, offering a condensed overview of the EU's response and of the subsequent changes brought to the legal framework applicable to health emergencies (III). We finish by looking at the European Health Union, examining the descriptive and normative aspects of this concept. We argue that, while the current constitutional settlement allows the EU to do more and do better, a Treaty change is necessary to build a true Health Union. This is not needed, we believe, to grant substantially more powers to the EU, but to increase the clarity, quality and legitimacy of its action in the field (IV).

II. The complex patchwork of EU health powers and policies

EU health law and policy have previously been referred to as a "patchwork."[3] That term is still pertinent today. The EU is active in a vast domain relevant to health,[4] from disease prevention and treatment to healthcare (2). This comes despite a limited explicit mandate in the area. As we shall see, however, there is more than meets the eye when it comes to EU health competence (1).

1. The dynamic structure of the EU health competence

Health has a fragmented competence structure under the TFEU, weaving together direct and indirect powers of different nature, which have evolved over time.[5] Under its general competence for the "protection and improvement of human health," the EU may only carry out actions to support, coordinate or supplement that of the Member States.[6] This competence is further defined at Article 168 TFEU, the health specific legal basis contained in the Treaty. While the precise nature of EU supporting competence remains unclear,[7] a crucial aspect thereof is that no harmonisation measures may be adopted in the areas concerned.[8] This severely limits the ability for the EU to conduct a policy autonomous from that of the Member States. Under Article 168(5) TFEU, the EU may only adopt incentive measures, spending "small sums of money to promote European networks that connect people and organizations, put items on the agenda for the future, and [...]

[3] T Hervey and B Vanhercke, "Health Care and the EU: The Law and Policy Patchwork" in E Mossialos and Others (eds), *Health Systems Governance in Europe* (Cambridge, Cambridge University Press 2010), pp. 84–133.

[4] No authoritative legal text defines health under EU law. According to Anniek de Ruijter, "the concept of human health in the EU policy and legal context refers to the normal functioning of the (human) species and also to a more subjective expression of a (social) state of physical and mental well-being, depending on individual and social (national) backgrounds": A de Ruijter, *The Silent Revolution in EU Health Law and Policy* (Oxford, Oxford University Press) pp 57–8. It should be borne in mind that "public health" and "human health" have the same meaning under EU law and can be used interchangeably, both referring to the general concept of health. In this contribution, we use the term "public health" as opposed to "healthcare," see below n 14.

[5] For an historical overview of the evolution of EU health powers, one may usefully refer to Hervey and Vanhercke (*supra* n 3).

[6] Art 6(a) TFEU.

[7] See R Schütze, "Co-operative Federalism Constitutionalized: The Emergence of Complementary Competences in the EC Legal Order" (2006) 31 European Law Review 167.

[8] Art 2(5) TFEU.

produce research."[9] This is the role of the EU health programmes, adopted every five or six years, the latest of which covers the period 2021–2027.[10] This form of intervention, while not devoid of any influence on Member State policies, is nonetheless of limited impact.

As to the content of this general health competence, according to Article 168(1):

> Union action [. . .] shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.[11]

Union action is centred on "public health" issues, understood as the management of health risks and the prevention of disease, as opposed to "healthcare," the provision of health services and medical care,[12] an area which remains more firmly within the ambit of Member State competence.[13]

Along this supporting competence, the EU is granted a shared competence for a narrower set of matters, referred to as "common safety concerns in public health."[14] These safety concerns relate to (i) organs and substances of human origin, including blood; (ii) the veterinary and phytosanitary fields, including food safety; (iii) medicinal products and medical devices.[15] Unlike for its general health competence, the EU may adopt harmonisation measures in these areas,[16] allowing it to yield considerable influence.

Finally, and crucially, EU health law and policy has indirectly developed through a number of legal bases belonging to other policy areas and categories of competence. It is the case of Article 153 TFEU on social policy, which enables the EU to adopt harmonisation measures aimed at improving "the working environment to protect workers' health and safety,"[17] as well as Article 191 TFEU on the environment, which mentions health as a key objective.[18] One could also include Article 122 TFEU establishing a framework for EU action in situations of emergency (see Section II. below). The most important indirect health legal

[9] SL Greer, "The Three Faces of European Union Health Policy: Policy, Markets, and Austerity" (2014) 33 Policy and Society 13, 15.

[10] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ("EU4Health Programme") for the period 2021–2027, and repealing Regulation (EU) No 282/2014, OJ L 107/1.

[11] Union action shall also "complement the Member States' action in reducing drugs-related health damage, including information and prevention."

[12] For further elaboration on the difference between "public health" and "health-care," see Ruijter (*supra* n 5) 62–3.

[13] Under Art 168(7) TFEU:

> Union action shall respect 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. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.

[14] Art 4(2)(k) TFEU.

[15] Art 168(4) TFEU.

[16] Ibid.

[17] Art 153(1)(a) TFEU. Harmonisation powers are granted pursuant to Art 153(2)(b). See Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers a work, OJ L 183/1.

[18] Under Art 191 TFUE, "Union policy on the environment shall contribute to pursuit of the following objectives: preserving, protecting and improving the quality of the environment, protecting human health [. . .]."

basis, however, is Article 114 TFEU.[19] Under this article, the EU legislature may harmonise away the differences in Member States' legislation which give rise to obstacles to trade, hampering the proper functioning of the internal market.[20] Where these obstacles arise from discrepancies in health-related national provisions, the EU is legally competent to act and to set a common health standard. This practice was approved by the Court of Justice, which held in the landmark *Tobacco Advertising* ruling that "provided that the conditions for recourse to [Article 114 TFEU] are fulfilled, the [EU] legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made" by the legislature.[21]

This edifice, made of interwoven fields and legal bases, is far from being an ideal structure, as will be further discussed in Section IV. This complexity is rooted in the EU competence framework, based on a catalogue of policy fields which cannot account for the plurality of social phenomena and the plurality of goals that a given legal instrument often pursues.[22] This patchwork also reflects the all-encompassing nature of health. The health of a population impacts nearly every policy – think of security, education, employment. In return it is also impacted by nearly every policy.[23] That is why Article 9 TFEU requires the EU, '[i]n defining and implementing its policies and activities, [to] take into account requirements linked to the promotion of a high level of [. . .] human health', an obligation reiterated in Article 168(1) TFEU and Article 35 of the Charter of Fundamental Rights of the European Union. This "health in all policies" approach to policymaking recognises that factors beyond those traditionally addressed as "health" need to be addressed.[24]

2. A pivotal role in disease prevention and treatment, a limited role in healthcare *delivery*

Because of this complexity, EU health powers are generally underestimated.[25] So is the extent to which the EU regulates the field. This article is not the place to provide an exhaustive account of the state of EU health law and policy, including from a historical perspective.[26] Suffice it to say that EU involvement in health has dramatically increased since the 1990s, coinciding with the introduction of a devoted legal basis in the TFEU, then known as the EC Treaty, after the Maastricht revision.[27] Following the public health/healthcare dichotomy introduced earlier, the EU can be described as playing today a pivotal role in public health, i.e., the prevention and treatment of both communicable and non-communicable diseases at a population level, while exercising only a modest influence on the delivery of healthcare services and the organisation of health systems.

[19] This legal basis is often used in conjunction with Art 53(1) and 62 TFEU. See Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (Tobacco Advertising Directive), OJ L 2003 152/16.

[20] Art 114(1) TFEU. See Case C-376/98 *Germany v European Parliament and Council (Tobacco Advertising I)*, EU: C:2000:544.

[21] *Tobacco Advertising I*, para 88.

[22] See T Tridimas, "Competence after Lisbon: The Elusive Search for Bright Lines" in D Ashiagbor, I Lianos and N Countouris (eds), *The European Union after the Treaty of Lisbon* (Cambridge, Cambridge University Press 2012) pp. 47–77.

[23] SL Greer, "Introduction – What Is Public Health Policy?" in SL Greer and P Kurzer (eds), *European Union Public Health Policy: Regional and Global Trends* (Abingdon, Routledge 2016) p 1; see also de Ruijter (*supra* n 5) 52.

[24] O Bartlett and A Naumann, "Reinterpreting the Health in All Policies Obligation in Art 168 TFEU: The First Step towards Making Enforcement a Realistic Prospect" (2021) 16 Health Economics, Policy and Law 8.

[25] See T Hervey and A De Ruijter, "The Dynamic Potential of European Union Health Law" (2020) 11 European Journal of Risk Regulation 726.

[26] One may refer to the authoritative volume: TK Hervey and JV McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015).

[27] Art 129 EC.

Regarding disease prevention, the EU has acted in a wide range of public health matters. For communicable diseases, such as COVID-19, the informal group created in the 1990s to enhance common surveillance was turned into a broader framework.[28] The European Centre for Disease Prevention and Control (ECDC) plays a key role. It was established in 2004, following the breakout of several health crises, including the Severe Acute Respiratory Syndrome (SARS). It is tasked to coordinate the response of Member States against infectious diseases, through monitoring, research and scientific assistance.[29] Until COVID-19, the EU's response to serious cross-border threats to health, including biological or chemical agents and environmental events, was governed by Decision 1082/2013/EU, which contained rules on surveillance, early warning and the procurement of medical countermeasures.[30] The reforms brought that that legal framework are addressed in Section III.

Regarding non-communicable diseases, cancer in particular, the EU focuses on the root causes of ill-health,[31] targeting harmful lifestyles and the commercial determinants of health – i.e., the consumption of tobacco, alcohol and unhealthy foods.[32] Action is especially forceful for tobacco products, with measures prohibiting the advertising of tobacco in audiovisual and printed media and regulating the composition, packaging and labelling of products.[33] On food quality, EU intervention focuses on the provision of complete and reliable nutrition and health information to consumers.[34]

Going beyond the communicable/non-communicable dichotomy, the EU has set up a common framework to prevent the spread of health hazards through food, in which the European Food Safety Authority (EFSA) plays a pivotal role.[35] This followed the BSE or "mad cow disease" outbreak of the 1990s in the United Kingdom, a disease affecting cattle which subsequently spread to humans through meat consumption.[36] One may also

[28] See T Deruelle, "Bricolage or Entrepreneurship? Lessons from the Creation of the European Centre for Disease Prevention and Control" (2016) 2 European Policy Analysis 43, pp 52–3.

[29] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control ("ECDC Regulation"), OJ 2004 L 142/1; Deruelle (*supra* n 28) 56–59.

[30] Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No. 2119/98/EC, OJ 2013 L 293/1. This decision was repealed by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (SCBTH Regulation), OJ 2022 L 314/26.

[31] Communication from the Commission to the European Parliament and the Council, "Europe's Beating Cancer Plan", COM (2021) 44 final.

[32] A Alemanno and A Garde (eds), *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (Cambridge University Press 2015).

[33] Tobacco Advertising Directive; Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 2014 127/1.

[34] See, generally, Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ 2006 L 404/9; Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ 2011 L 304/18.

[35] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L 31/1. See also Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives OJ 2008 L 354/16.

[36] For an overview of the crisis, see C MacMaoláin, *Food Law: European, Domestic and International Frameworks* (Oxford and Portland, Oregon, Hart Publishing 2015) pp 124–32.

mention policy areas more closely related to environmental policy, where the EU has adopted measures: on chemicals,[37] against water pollution[38] or for better air quality.[39]

Regarding treatment, the EU has adopted measures on the safety of organs and substances of human origin, including blood, tissues and cells.[40] This is to ensure safe donations and transplantations throughout the EU. Blood transfusion raised on the top of the agenda with the HIV/AIDS outbreak of the late 1980s.[41] EU rules on medicines are similarly rooted in a crisis, the thalidomide scandal of the late 1950s, a medicine given to pregnant women to treat morning sickness which harmed the health of around 10,000 babies worldwide.[42] The EU has now extensive rules regulating medicines throughout their life cycle, from development, clinical trials, manufacturing, marketing, and post-marketing surveillance ("pharmacovigilance"), supported by the work of the European Medicines Agency (EMA).[43] Comparable rules apply to medical devices.[44]

EU action in healthcare is more limited. The EU has very little to say on the organisation of health and social security systems. The few binding measures that exist on healthcare focus on cross-border situations, addressing the rights of patients to seek treatment abroad,[45] the coordination of social security rights,[46] and the recognition of medical diplomas and qualifications.[47] This allows for the mobility of healthcare professionals and ensures that workers, students or tourists are adequately protected while being abroad. The EU nonetheless yields some influence in the area, through soft law and coordination measures aimed at promoting flexible convergence on general objectives concerning the sustainability and quality of care.[48] This has been done through the Open Method of

[37] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, OJ 2006 L 396/1.

[38] Council Directive of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources, OJ 1991 L 375/1.

[39] Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe, OJ 2008 L 152/1.

[40] Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation OJ 2010 L 207/14; Regulation (EU) 2024/1938 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.

[41] TK Hervey and JV McHale, *Health Law and the European Union* (Cambridge University Press 2004) pp 343–8.

[42] De Ruijter (*supra* n 5) 65–6.

[43] See Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ 2001 L121/34; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L311/67; Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L136/1.

[44] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, OJ 2017 L 117/1.

[45] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ 2011 L 88/45.

[46] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ 2004 L 166/1.

[47] Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, OJ 2005 L 255/22.

[48] S De La Rosa, "The OMC Processes in the Health Care Field: What Does Coordination Really Mean?" (2018) 3 European Papers – A Journal on Law and Integration 215234.

Coordination (OMC), a "means of spreading best practice and achieving greater convergence towards the main EU goals."[49] Another important process is the "European Semester," a cycle of coordination of the Member States's economic policies, where the Council discusses and adopts country-specific recommendations (CSRs).[50] These CSRs address the question of the sustainability of national healthcare systems,[51] and must be put into the broader context of the (austerity) measures adopted in response to the eurozone crisis.[52]

This brief overview reveals three important characteristics of EU health law and policy, which will guide our discussion in the next sections. First, EU intervention in the field is closely linked to cross-border health threats. These threats expose shortcomings in the current system and create a shared desire to fight them together, resulting in strengthening the EU framework.[53] Second, EU action, which extends to all fields of health, cannot reasonably be described as being only of a "supportive" nature anymore. The limits to the EU's mandate expressed in Article 168 TFEU are easily circumvented by the use of Article 114 TFEU, the legal basis underpinning most EU health instruments – it is widely used in the fields of food, tobacco, medicines and medical devices, as well as patient and healthcare professionals mobility. That being said, this is our third point, this does not mean that EU action is wired to favour market interests. If the market may be considered the predominant face of EU health law and policy,[54] this reflects the nature of the EU's powers and the fact that health and economic life are closely intertwined. Regulating health means regulating products and services. Some aspects of the EU *acquis* and the Court of Justice's case law may very well be criticised for their deregulatory effect, but this cannot hide the fact that the EU has largely re-regulated the field. The EU legislator is perfectly at liberty, and even required,[55] to use its internal market competence to pursue an ambitious health agenda. Any rigorous analysis of the various instruments surveyed can establish this point.

III. The COVID-19 pandemic: a tipping point?

To understand current developments in EU health law and policy, one needs to take a closer look at the COVID-19 pandemic and the EU's response to it (1). The crisis showed once more how much the EU can do under its current Treaties, while also exposing a number of weaknesses. This led to a reinforcement of the legal framework applicable to cross-border health threats (2).

1. The EU's forceful response to the crisis

On 11 March 2020, the WHO classified COVID-19 as a global pandemic.[56] By that time, the SARS-CoV-2 virus had already widely circulated in the EU. In the days that followed, most

[49] SL Greer and BVanhercke, "The Hard Politics of Soft Law: The Case of Health" in E Mossialos and Others (eds), *Health Systems Governance in Europe* (Cambridge University Press 2010) p 193. See also De La Rosa (*supra* n 48).

[50] Art 121 TFEU.

[51] N Azzopardi-Muscat and Others, "EU Country Specific Recommendations for Health Systems in the European Semester Process: Trends, Discourse and Predictors" (2015) 119 Health Policy 375; S De La Rosa, "Le Programme Santé de la Commission : Véritable Politique Européenne de Santé ou Simple Appui aux Politiques Nationales?" (2017) 4 Revue des Affaires Européennes 597.

[52] Greer (*supra* n 9).

[53] See also E Brooks and Others, "EU Health Policy in the Aftermath of COVID-19: Neofunctionalism and Crisis-Driven Integration" (2022) 30 Journal of European Public Policy 721.

[54] Greer (*supra* n 9).

[55] Art 114(3) TFEU.

[56] World Health Organisation, "WHO Director-General's Opening Remarks at the Media Briefing on COVID-19" (2020) available at <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020> (last accessed 11 January 2025).

Member States adopted drastic non-pharmaceutical interventions designed to stop the spread of the virus and safeguard their healthcare systems, in the form of stay-at-home orders, curfews and other shutdown measures. The pandemic, because of its scale, was not only a health crisis, but impacted all aspects of social and economic life. Accordingly, the EU's response to the virus was wide-ranging and multi-faceted, addressing both its health and economic consequences.

Regarding the former, the EU tried to preserve the integrity of the internal market while supporting economic recovery. In the early months of the pandemic, the Member States adopted various restrictive measures, with a total lack of coordination, severely hindering the free flow of goods, persons and services within the EU. These included border measures restricting individual mobility[57] and export bans or restrictions on goods like personal protection equipment or medicines.[58] The Commission reacted promptly, aiming to convince Member States to remove restrictions progressively as the situation improved. Its action unfolded along two main lines: (i) allowing the free movement of 'essential' goods, workers and economically active citizens,[59] and (ii) protecting intra-Union movement at the expense, if necessary, of extra-Union movement. As early as 16 March 2020, the Commission recommended the temporary restriction of non-essential travel from third countries into the Union for an initial period of 30 days.[60] The main step towards a coordinated lifting of internal restrictions was made through the "EU Digital Covid Certificate,"[61] whose provisions expired on 30 June 2023.

The most dramatic developments for the EU concerned its fiscal and economic governance. After they had adopted some smaller-scale financial assistance measures, through the REACT-EU fund[62] or the European Solidarity Fund,[63] the Commission and the Member States took the unprecedented step to issue a common debt to avert an economic

[57] For an overview of the measures adopted, see S Montaldo, "The COVID-19 Emergency and the Reintroduction of Internal Border Controls in the Schengen Area: Never Let a Serious Crisis Go to Waste" (2020) 5 European Papers 521.

[58] See European Commission, "Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup – Coordinated economic response to the COVID-19 Outbreak" COM (2020) 112 final, 3–4. For an overview of the measures adopted and a discussion of their legality, see B Pirker, "Rethinking Solidarity in View of the Wanting Internal and External EU Law Framework Concerning Trade Measures in the Context of the COVID-19 Crisis" (2020) 5 European Papers 573.

[59] See, e.g., European Commission, "Communication from the Commission Guidelines Concerning the Exercise of the Free Movement of Workers during COVID-19 Outbreak", OJ 2020 C102I/12; European Commission, "Covid-19 Guidelines for Border Management Measures to Protect Health and Ensure the Availability of Goods and Essential Services', OJ 2020 C 86I/1.

[60] European Commission, Communication to the European Parliament, the European Council and the Council, "COVID-19: Temporary Restriction on Non-Essential Travel to the EU in view of COVID-19", COM (2020) 115 final. The Commission gave further guidance on the implementation of the travel restrictions: European Commission, "Communication from the Commission COVID-19 Guidance on the Implementation of the Temporary Restriction on Non-Essential Travel to the EU, on the Facilitation of Transit Arrangements for the Repatriation of EU Citizens, and on the Effects on Visa Policy", OJ 2020 C 102I/3.

[61] The main instrument was Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ 2021 L 211/1.

[62] Regulation (EU) 2020/2221 of the European Parliament and of the Council of 23 December 2020 amending Regulation (EU) No 1303/2013 as regards additional resources and implementing arrangements to provide assistance for fostering crisis repair in the context of the COVID-19 pandemic and its social consequences and for preparing a green, digital and resilient recovery of the economy (REACT-EU), OJ 2020 L437/30.

[63] Regulation (EU) 2020/461 of the European Parliament and of the Council of 30 March 2020 amending Council Regulation (EC) No 2012/2002 in order to provide financial assistance to Member States and to countries negotiating their accession to the Union that are seriously affected by a major public health emergency, OJ 2020 L99/9.

meltdown and a potential new sovereign debt crisis. The NGEU recovery package is essentially a huge pot of money of 750 billion euro, made of grants and loans, distributed to the Member States to withstand the economic downturn and finance the long-term recovery and resilience of their economies.[64] Both the scale and the nature of the borrowings made – it is the first time that borrowings were used to finance spendings rather than loans – triggered debates as to the compliance of the NGEU package with the Treaties, with the principle of conferral in particular.[65]

The EU's *health* response to the crisis may be divided in three tiers: (i) the preventive aspect of limiting the spread of the virus through public health measures, such as social distancing or closure of premises; (ii) the organisation of the healthcare system, hospitals and intensive care units in particular, and the supply of necessary equipment to protect health professionals; (iii) the procurement of medical countermeasures, such as medicines or vaccines. The EU acted to different degrees in these three areas but, overall, the Member States remained mostly in charge. The EU did not order stay-at-home measures, deal with hospital planning or devise vaccine strategies, these issues touching upon the core of Member States' responsibilities in healthcare, public security and public policy.

On the first tier, preventive measures, the EU largely followed the framework instituted by Decision 1082/2013 on serious cross-border health threats. The Decision formally establishes a Health Security Committee, composed of representatives of the health ministries of the Member States, to coordinate national responses. This committee met several times a month and played a key role driving the EU's answer to the crisis.[66] Regarding containment measures the Commission published a 'Joint European Roadmap' in April 2020, trying to persuade Member States to follow scientific evidence as closely as possible and to revise their approach as the pandemic evolved.[67] The ECDC played a crucial role in this regard, as the body in charge of collecting, evaluating and disseminating relevant scientific data, providing scientific opinions and assistance, and exchanging information and best practices.[68] The ECDC released many technical reports providing guidance to Member States on health countermeasures, offering advice on, for instance, the isolation of infected individuals, the use of facemasks or testing.[69]

[64] NGEU is a complex legal construction based on three pillars: two new instruments, the European Union Recovery Instrument (EURI) and the Recovery and Resistance Facility (RRF), and a new Own Resources Decision (ORD), which is the text organising the system of own resources of the European Union. See Council Regulation (EU) 2020/2094 of 14 December 2020 establishing a European Union Recovery Instrument to support the recovery in the aftermath of the COVID-19 crisis (EURI Regulation), OJ 2020 433I/23; Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (RRF Regulation), OJ 2021 L 57/17; Council Decision (EU, Euratom) 2020/2053 of 14 December 2020 on the system of own resources of the European Union and repealing Decision 2014/335/EU, Euratom (ORD), OJ L 424/1. For more details, see De Witte (*supra* n 1).

[65] See Dermine (*supra* n 1); De Witte (*supra* n 1); M Ruffert and P Leino-Sandberg, "Next Generation EU and Its Constitutional Ramifications: A Critical Assessment" (2022) 59 Common Market Law Review 433.

[66] Decision 1082/2013, Art 17. The reports are available at <https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response/health-security-committee-hsc/health-security-committee-reports_en> (last accessed 11 January 2025).

[67] European Commission and European Council, "Joint European Roadmap towards lifting COVID-19 containment measures of 17 April 2020", OJ 2020 C 126/1.

[68] Regulation 851/2004, Art 3.

[69] See the extensive repository: available at <https://www.ecdc.europa.eu/en/publications-data/covid-19-guidelines-non-pharmaceutical-interventions> (last accessed 19 June 2024).

Regarding healthcare, the second tier, EU action was limited to coordinating the collaboration and mutual support of healthcare facilities, for the transfer of patients for instance, especially in border regions.[70] It was able to build on the long-standing "Euregios," in which health cooperation has been a strong dimension since the 1990s, such as the Germany–Netherlands–Belgium, Denmark–Sweden or Spain–Portugal border regions.[71] No guidance was given, even in the form of soft law, regarding the organisation of healthcare systems, especially hospitals, during the crisis.

On medical countermeasures, the last tier, the EU activated its joint procurement scheme under Decision 1082/2013. It used it for various goods: personal protective equipment ('PPE') – i.e. gloves, coveralls, masks, etc – laboratory equipment or medicinal products.[72] The European Medicines Agency (EMA) piloted the roll-out of COVID-19 treatments and vaccines,[73] ensuring that these were safe for human use. More controversially, Member States agreed that the Commission would centrally procure vaccines and coordinate a negotiation team that included experts from national administrations.[74] In this context, the Commission used the Emergency Support Instrument (ESI) to conclude Advance Purchasing Agreements with vaccine producers.[75] These agreements were entered into by the Commission on behalf of the Member States. However, the design of vaccination policies, such as the definition of priority groups, and the conduct of vaccination campaigns – who administers vaccines and where they are administered – stayed within the remit of the Member States.[76]

2. *A new legal framework against cross-border health threats*

Overall, the EU used its limited powers to the best it could in this crisis, even exceeding expectations. The lack of coordination at the beginning of the pandemic was not of the EU's due alone but reflected the sudden and unexpected nature of the crisis, and the fact that the EU was not in the driver's seat. Responsibility for a crisis response primarily lies at

[70] European Commission, "Communication from the Commission – Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare Related to the COVID-19 Crisis", OJ 2020 C 111I/1. See also European Commission, Communication from the Commission to the European Parliament, the Council the European Economic and Social Committee and the Committee of the Regions, "Short-Term EU Health Preparedness for COVID-19 Outbreaks" COM (2020) 318 final.

[71] See H Brand and Others, "Cross-Border Health Activities in the Euregios: Good Practice for Better Health" (2008) 86 Health Policy 245.

[72] Decision 1082/2013, Art 5. The various contracts may be retrieved via available at <https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/ensuring-availability-supplies-and-equipment_en#identifying-demands-and-matching-supplies-of-medical-equipment> (last accessed 05 June 2024).

[73] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L 136/1.

[74] European Commission, "Commission Decision of 18.6.2020 Approving the Agreement with Member States on Procuring Covid-19 Vaccines on Behalf of the Member States and Related Procedures", C(2020) 4192 final. See also European Commission, "Communication from the Commission 'EU Strategy for COVID-19 vaccines'", COM (2020) 245 final.

[75] Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, OJ 2016 L 70/1; Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak, OJ 2020 L 117/3. See E Schanze, "Best Efforts in the Taxonomy of Obligation – The Case of the EU Vaccine Contracts" (2021) 22 German Law Journal 1133.

[76] The Commission did provide some advice on "possible priority groups" for the initial phase of vaccine deployment: see European Commission, "Communication to the European Parliament and the Council – Preparedness for COVID-19 Vaccination Strategies and Vaccine Deployment", COM (2020) 680 final, 11–13.

national or sub-national level, depending on the structures and institutions that legitimate and inspire trust in public health systems.[77] Despite evident successes in the EU's support to the Member States, the most spectacular one being the NGEU package, COVID-19 nonetheless exposed some weaknesses in the framework for health crisis preparedness and response. The EU faced difficulties in ensuring the availability of the medical countermeasures needed to address Covid-19, among which medicinal products and medical devices. When the Commission published a call for tender to secure masks and medical protective equipment in February 2020, not a single company replied with an offer.[78] While a second public procurement procedure was published in March 2020 and did receive replies, the medical countermeasures could however not be delivered before mid-April, not promptly enough to fight a global pandemic of this magnitude.[79] As a consequence, France, Germany, Italy and the Netherlands decided to procure vaccines separately from the Commission.[80]

The EU brought a series of changes to its legal apparatus, designed to address these shortcomings by strengthening the Commission's powers and bringing more coherence to any future crisis response. The most visible of these changes was the creation in 2021 of a new Commission service, the Health Emergency Preparedness and Response Authority (HERA).[81] HERA is now primarily responsible for ensuring the availability of medical countermeasures in the event of a crisis and bears responsibility at all stages, from their development and production to their procurement and distribution.[82] The creation of HERA was complemented by new rules increasing the powers of the Commission to supply crisis-relevant medical countermeasures.[83] In addition, a new general framework on serious cross-border threats to health was introduced, in the form of a Regulation (SCBTH Regulation), replacing previous Decision 1082/2013.[84] The Regulation strengthens the analysis of and reporting on health systems indicators, to improve the surveillance and monitoring of health threats and to increase the cooperation between the different actors at the EU level, the Member States and the WHO.[85] The SCBTH Regulation recognises a new power to the Commission to declare a public health emergency at EU level,[86] in which case specific emergency measures become available, such as the possibility to activate HERA's emergency framework.[87] It also strengthens the rules for the joint procurement of medical countermeasures, introducing the possibility to agree upon an exclusivity clause to improve the EU's negotiation position.[88]

[77] AM Pacces and M Weimer, "From Diversity to Coordination: A European Approach to COVID-19" (2020) 11 European Journal of Risk Regulation 283, 286.

[78] L van Middelaar, *Een Europees pandemonium. Kwetsbaarheid en politieke kracht* (Groningen, Historische Uitgeverij 2021) p 72.

[79] Ibid.

[80] Ibid., pp 103–4.

[81] Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (HERA Decision), OJ 2021 C 393I/3. Initially conceived as a new agency, HERA was finally established as a new Commission Directorate General. The transformation of HERA into an agency will nonetheless be addressed in a future review by the Commission: Council Regulation (EU) 2022/2372 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 (Emergency Framework Regulation), OJ 2022 L314/64, Art 16.

[82] HERA Decision, Art 2.

[83] Emergency Framework Regulation.

[84] Regulation 2022/2371 (SCBTH Regulation).

[85] Ibid., Recital 2.

[86] Ibid., Art 23.

[87] Emergency Framework Regulation, Art 3(1).

[88] Ibid., Art 12 and Recitals 18–19.

The EMA was also given a greater role in the management of the necessary medicinal products and medical devices in case of crisis,[89] with the same goal to ensure availability of supply. A number of new structures were established to improve the monitoring and mitigation of shortages of medicines and medical devices, both in preparation for or during public health emergencies.[90] In particular, a new Emergency Task Force was created, providing scientific advice and recommendations on such products, contributing to the work of the relevant scientific committees and advising on various aspects related to clinical trials.[91] Finally, the mandate of ECDC was also reinforced. The new framework aims to improve the Centre's role in providing robust and independent scientific expertise and its overall activities related to serious cross-border health threats.[92] As part of its reinforced mandate, ECDC is able to provide recommendations and support related to the prevention and control of communicable diseases and related special health issues, and relevant coordinated action.[93] Other new tasks include the monitoring of national health systems capacity, the support of national monitoring of major diseases, and the identification of research priorities.[94] In addition, an EU Health Task Force within the ECDC was introduced, to assist in the preparedness for and response to health crises.[95]

Overall, these changes strengthen the coordination at EU level, filling the gaps and/or formalising the informal actions initiated during the Covid-19 response. Nevertheless, two issues may arise as regards the Commission's effectiveness in times of emergency. Van Kreij and De Vries identified the first, which concerns the lack of (enforcement) powers of HERA.[96] Since medical countermeasures are often produced by private actors, their cooperation is key to HERA. This is for instance the case where HERA request an inventory to be made, according to Articles 10 and 11 of the Emergency Framework. The authority has however no means to ensure that private actors provide the necessary information.[97] Similarly, private actors and Member States are not obliged to take measures where a risk of shortage exists, as laid down in Article 12 of the Emergency Framework. HERA's role is limited to facilitating relevant measures. A similar problem occurs with Article 7, where HERA needs information from Member States to carry out its monitoring task.[98] The Commission has other compliance tools at its disposal, such as the infringement procedure, but these methods may be too slow.[99] Thus, the lack of (enforcement) powers may make it difficult for the Authority to effectively ensure the availability of medical countermeasures in times of an emergency.

[89] Regulation (EU) 2022/123 of the European Parliament and of the Council 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.

[90] See the European Shortages Monitoring Platform (ESMP): Art 13 of Regulation 2022/123; the Medicine Shortages Steering Group (MSSG): Art 3; the Medical Device Shortages Steering Group (MDSSG): Art 21.

[91] Ibid., Art 15.

[92] Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022, OJ 2022 L 314/1.

[93] ECDC Regulation, Art 3(2)(c)(j), as amended by Regulation 2022/2370.

[94] Ibid., Art 3(2)(f)(h)(i), as amended by Regulation 2022/2370.

[95] Ibid., Art 11a, as amended by Regulation 2022/2370.

[96] L van Kreij and S de Vries, "HERA, de nieuwe EU-autoriteit voor de levering van schaarse medische producten ten tijde van gezondheidscrises", NtER 2021 nr. 9/10, pp 247–54, p 253.

[97] Ibid., p 251.

[98] Ibid., pp 249–50.

[99] Ibid., p 253.

A second issue concerns the new procurement regime. A joint EU procedure on an exclusive basis could strengthen the EU's bargaining power.[100] Both the SCBTH Regulation and the Emergency Framework refer to an exclusivity clause,[101] under which participating states cannot procure the medical countermeasure concerned via another route or run parallel procurement procedures to obtain it.[102] Such a clause is, however, optional.[103] Thus, when an emergency occurs, the adoption of an exclusive procurement procedure would depend on the willingness of the participating states, which, as it happened in the early stages of the Covid-19 pandemic, might put their own interests first.[104] This would diminish the EU's bargaining power, which could jeopardize the (timely) availability of medical countermeasures.[105]

IV. Strengthening the EU's health mandate

Beyond crisis preparedness and management, the COVID-19 pandemic highlighted the need for greater coordination and cooperation in health matters at the EU level. This also echoes citizens' concerns, as shown by the Conference on the Future of Europe, a unique participatory exercise concluded in 2022.[106] The Commission replied to these calls for action with the launch of the European Health Union, a new framework and vision for EU action in the field. Four years on, ambiguities remain as to the meaning of this new initiative and its added value for EU health law and policy (1). The European Health Union nonetheless provides a good springboard to reflect on what a renewed mandate for the EU in health could look like (2).

1. The European Health Union: what's in a name?

At the highest levels of EU policy making, the first reference to a European Health Union was found in Ursula von der Leyen's 2020 State of the Union address.[107] Thus doing, she, perhaps unknowingly, walked in the footsteps of former French Minister of Public Health Paul Ribeyre, who, in 1952, proposed to establish a European Health Community alongside the one for coal and steel (ECSC).[108] His proposal did not receive the necessary support, but many of his ideas, such as a coordinated approach to epidemics and the free movement of

[100] A de Ruijter and Others, "Give the EU More Power to Fight Epidemics" (*Politico Europe*, 26 March 2020) available at <https://www.politico.eu/article/coronavirus-eu-power-pandemic/>; Pacces and Weimer, (*supra* n 77), p 292.

[101] SCBTH Regulation, Recital 19; Emergency Framework, Recital 10.

[102] SCBTH Regulation, Recital 19.

[103] Art 8(2), Emergency Framework; see also Art 12(3)(c) SCBTH Regulation, this provision also applies to procurement procedures outside of emergency situations and does not have to be activated by the Council in the case of an emergency, see also Van Krij and De Vries, (*supra* n 96) p 250.

[104] See, e.g., Van Middelaar (*supra* n 78), pp 103–4; M Anderson, M Mckee and E Mossialos, "Covid-19 Exposes Weaknesses in European Response to Outbreaks" (2020) 368 BMJ 1075.

[105] Recital 2, Emergency Framework; A de Ruijter and Others, "Give the EU More Power to Fight Epidemics" (*Politico Europe*, 26 March 2020); Pacces and Weimer, (*supra* n 77), p 292.

[106] See European Commission, Communication, "Conference on the Future of Europe: Putting Vision into Concrete Action", COM (2022) 404 final.

[107] European Commission, "State of the Union Address by President von der Leyen at the European Parliament Plenary" (16 September 2020), available at <https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_1655>, (last accessed 14 January 2025).

[108] CVCE, "Statement by Paul Ribeyre on the Establishment of a European Health Community (September 1952)", University of Luxembourg, available at <https://www.cvce.eu/en/obj/statement_by_paul_ribeyre_on_the_establishment_of_a_european_health_community_september_1952-en-5350cea3-b096-47f5-9d4b-062dd139d934.html> (last accessed 14 January 2025).

medical professionals, are now part of the EU acquis.[109] Whether in the economic, monetary or energy domains, the "unionisation" of a given policy area has nowadays both a descriptive and prescriptive value. It signals that EU action has reached a certain level of maturity and coherence, as much as it sets the course for greater integration. That can be observed too with the European Health Union.

As in any other policy field, money is key. Increased funding might be the European Health Union's most tangible contribution to health in Europe. With a 5.3 billion euros budget, the 2021–2027 "EU4Health" programme constitutes a significant financial increase, to be compared with the 450 million euros envelope earmarked for the 2014–2020 programme.[110] To the "EU4Health" programme should be added the 43 billion euros worth of health-related measures contained in the national recovery and resilience plans adopted in the framework of the NGEU package.[111] While signalling greater investment in health, these sums must nonetheless be put into perspective. They are only a fraction of the total value of the EU's financial engagements for the period – the EU's 2021–2027 long-term budget and NGEU amount together to over 2 trillion euros[112] – and of the healthcare expenditure in the Member States – 432 billion euros for Germany alone in 2020.[113] Financially speaking, the EU remains a junior player in health matters.

While initially centred on cross-border health threats, the European Health Union came eventually to encompass the entire field of EU health law and policy.[114] A number of key initiatives from the Von der Leyen Commission may be singled out. On the legislative side, a key pillar of the European Health Union is the European Health Data Space (EHDS) Regulation, adopted in February 2025.[115] The EHDS creates a common data space in the field of health. Among other things, it will facilitate the exchange of data for the delivery of healthcare services across the EU (primary use of data), and allow for the reuse of health data for research and innovation purposes (secondary use of data). Another key pillar is the reform of the EU pharmaceutical legislation, put forward by the Commission in spring 2023.[116] Its overarching aim is to improve access to medicines for patients across the EU, enhance security of supply and address shortages. In conformity with the "One Health"

[109] A van der Mei and E Vos, "The State of the European Health Union – The Maastricht Contribution to EU Health Policy" in A van der Mei and M de Visser (eds), *The Treaty on European Union 1993–2013: Reflections from Maastricht* (Cambridge, Intersentia2013) pp 624–6.

[110] Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014–2020) and repealing Decision No 1350/2007/EC, OJ 2014 L 86/1, Art 5.

[111] V Lilyanova, "Health-Related Measures in the National Recovery and Resilience Plans" (2023) EPRS.

[112] European Commission, "The 2021–2027 EU Budget – What's New?" available at <https://commission.europa.eu/strategy-and-policy/eu-budget/long-term-eu-budget/2021-2027/whats-new_en#revision-of-the-eu-budget-2021-2027> (last accessed 14 January 2025).

[113] Eurostat, "Healthcare Expenditure Statistics" (2022), available at <https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics#Healthcare_expenditure> (last accessed 14 January 2025).

[114] European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "Health Union: acting together for people's health," COM (2024) 206 final.

[115] Regulation 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L 2025/327.

[116] European Commission, Proposal for a Directive on the Union code relating to medicinal products for human use, COM (2023) 192 final; European Commission, Proposal for a Regulation of the European Parliament and of Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, COM (2023) 193 final.

approach,[117] it aims to contribute to the fight against antimicrobial resistance (AMR).[118]

Two other important initiatives, this time in the form of Commission communications, should also be mentioned. The "Europe's Beating Cancer Plan" is the EU's renewed political commitment to fighting cancer,[119] a long-standing feature of EU health law and policy.[120] The plan focuses on the prevention, early detection and diagnosis and treatment of cancer, and the quality of life of (recovered) cancer patients. It will receive 4 billion euros of funding, including 1.25 billion from the EU4Health programme. As part of the plan, the Commission wishes to continue promoting healthier lifestyles and achieve a tobacco-free generation – i.e. ensuring that less than 5 per cent of the population uses tobacco by 2040.

The EU Global Health Strategy is part of the EU's external action and forms the external dimension of the European Health Union.[121] It aims to achieve three main objectives. The first two focus on improving disease prevention and treatment across people's life course, and improving health systems and healthcare coverage, thus broadly mirroring the two pillars of EU internal health policy. The third priority concerns the fight against pandemics and other health threats, also following a One Health approach – i.e. acknowledging the relationship between human health and animal health, the environment and climate. In that regard, the EU has been instrumental in the negotiation of a global WHO "Pandemic Agreement," a critical amendment to the 2005 International Health Regulations, aimed at improving the preparedness and response to future health threats at a global level.[122] The EU Global Health Strategy provides a good starting point, with a better conceptualisation of the EU's role on the world stage. In that area, the biggest challenge remains for Member States to speak in a united voice, in a particularly difficult geopolitical climate.[123]

Despite early calls to discuss "the question of health competences,"[124] there has been little appetite from Member States to open the Pandora's box of Treaty change. This is unlikely to change in the near future. As long as this is the case, the European Health Union will remain a political slogan, a "rebranding" of largely pre-existing initiatives rather than a fundamental change to the EU's health mandate and policy orientations.[125] This does not mean that the concept is devoid of interest. It has undoubtedly shed some light on the EU's

[117] One Health is defined by the WHO High Level Expert Panel as "an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems": WHO, available at <https://www.who.int/groups/one-health-high-level-expert-panel> (last accessed 14 January 2025). See also F Coli and H Schebesta, "One Health in the EU: The Next Future?" (2023) 2023 8 European Papers – A Journal on Law and Integration 301.

[118] See Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, OJ 2023 C220/1.

[119] European Commission, "Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan," COM (2021) 44 final.

[120] Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council of 7 July 1986, on a programme of action of the European Communities against cancer, OJ 1986 C 184/19.

[121] European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'EU Global Health Strategy – Better Health for All in a Changing World'," COM (2022) 675 final. See I Kickbusch and A de Ruijter, "How a European Health Union Can Strengthen Global Health" (2021) 1 The Lancet Regional Health – Europe 100025.

[122] WHO, "International Health Regulations (2005) – Third Edition" available at <https://www.who.int/publications/i/item/9789241580496> (last accessed 14 January 2025).

[123] Kickbusch and de Ruijter (*supra* n 121); M McKee and Others, "The EU Has a Global Health Strategy: The Challenge Will Be in the Implementation" (2023) 402 The Lancet 1025.

[124] European Commission, "State of the Union Address by President von der Leyen at the European Parliament Plenary" (*supra* n 107).

[125] See also M McKee and A de Ruijter, "The Path to a European Health Union" (2024) 36 The Lancet Regional Health – Europe 100794.

doings in health, bringing together different policy fields under one umbrella. It has created a certain momentum and given rise to expectations on which one may build to reflect upon the future of EU health law and policy.

2. Better clarity, improved quality, enhanced legitimacy

The emergence of the European Health Union has left the EU's formal position as a health actor largely unaltered. This is because, as argued throughout this paper, a form of health union has been, silently, years in the making. We believe that this form of "harmonisation by stealth,"[126] taking place under the veil of a limited formal competence, is no longer tenable. A Treaty change, as unlikely as it may be in the short-term, is needed to clarify the EU's responsibilities in health, improve decision- and law-making, and increase the democratic and political legitimacy of EU health law and policy.

Thinking about the European Health Union, one should first tackle the *what* – the need for a common European approach in health – before addressing the *how* – the legal/institutional changes necessary to give it shape. As should be clear to the reader by now, there is no field of health where the EU is prohibited to go. This is not only true for the *negative* reach of EU law, its scope of application,[127] but also in terms of *positive* legislative activity. This does not mean that the EU is omnipotent. Its action is limited by legal principles – conferral, subsidiarity and proportionality,[128] to name a few – and the political appetite of Member States for greater integration. In that regard, the current division of tasks between the EU and the national level appears broadly satisfactory, the former focusing on public health and product regulation, the latter retaining primary responsibility for the organisation and delivery of healthcare, as well as the management of health crises. Healthcare systems are at the core of modern Welfare States and express sensitive socio-fiscal choices. National or sub-national governments are better placed than the Union to respond to their population's needs and to build a crisis response that panders to different ethos and relationships to risk.

This is not a call for the status quo. The EU Health Union, as the EU in general, suffers in particular from one major deficit, the lack of fiscal integration and financial transfers between Member States, leaving some of the national healthcare systems chronically underfunded. A comparative exercise show how little the EU does to redress the fiscal imbalances between its richest and poorest regions,[129] if compared to other types of federal arrangements. Economic theory does recommend, however, to pool risk at the highest possible level in a federation, while leaving the concrete delivery of healthcare services to the sub-federal levels.[130] The EU is good at the latter, but does very little for the former. Worse, since the sovereign debt crisis of 2010, its fiscal and economic governance rules have been used to entrench fiscal rigour and limit social spending.[131] A change of course is therefore needed. Greater financial solidarity would also help evening out health

[126] S Garben, "Restating the Problem of Competence Creep, Tackling Harmonisation by Stealth and Reinstating the Legislator" in S Garben and I Govaere (eds), *The Division of Competences between the EU and the Member States: Reflections on the Past, the Present and the Future* (Hart Publishing 2017) pp. 300–335.

[127] According to the "retained power formula" of the Court of Justice, "the fact that a matter falls within the competence of the Member States does not alter the fact that, in situations covered by European Union law, the national rules concerned must have due regard to the latter": C-135/08, *Rottman*, EU:C:2010:104. See also B De Witte, "Exclusive Member State Competences – Is There Such a Thing?" in Garben and Govaere (*supra* n 126).

[128] Art 5 TEU.

[129] SL Greer, "Health, Federalism and the European Union: Lessons from Comparative Federalism about the European Union" (2021) 16 Health Economics, Policy and Law 90.

[130] Ibid., p 98.

[131] Greer (*supra* n 9).

inequalities, which still run deep within and between Member States,[132] and is essential to foster a feeling of we-ness and loyalty to the EU.[133] From this perspective, the NGEU recovery package constitutes a significant step forward.

Hence, from a competence point of view – i.e., the legal capacity to act – little change is needed for the EU to strengthen or improve its health policies. Fighting health inequalities, within and outside the EU, helping to strengthen national health systems, tackling major cross-border health scourges: all this can be done under the current framework, as interpreted by the EU institutions and the Court of Justice. We submit, however, that a Treaty change is needed to clarify the current division of competences in the field of health, which would in turn improve the quality and legitimacy of EU action in the field.

As is apparent from the developments in Section II, there is a clear discrepancy between the classification of health as a supporting competence and the reality of the EU's involvement. Health is better conceptualised as a shared competence,[134] also because a number of legal bases used to regulated health maters – Article 114 TFEU, mostly, but also Article 193 TFEU – belong to areas of shared competence. This discrepancy is problematic from the point of view of conferral, not least because Article 114 TFEU is often stretched to its limits to square health into the circle of free movement objectives.[135] The 'tobacco' saga is a prime example of this.[136] The current situation is also problematic for citizens, who do not have a clear idea of what the EU does in relation to health, if they know of its involvement at all. A clarification exercise is therefore needed, which should in turn improve the legitimacy of EU action.

The recourse to indirect legal bases to regulate the field of health also affects the quality of legislation, in the sense that it prevents health interests to be fully taken into account and reflected into the law. This is clearly visible in the field of lifestyle risks and non-communicable diseases. With regards to tobacco, the EU is for instance currently prevented from adopting laws regulating local advertising[137] – e.g. billboards, cinemas, as opposed to cross-border advertising.[138] The use of Article 114 TFEU also affects the capacity for the EU to adopt measures of minimum harmonisation,[139] or the respect for the principle of subsidiarity.[140] More fundamentally, there is something disingenuous in using a market-making competence to conduct a vigorous tobacco control policy, which has very

[132] N Scholz, "Addressing Health Inequalities in the European Union: Concepts, Action, State of Play" (2020) EPRS.

[133] H Vollaard, H van de Bovenkamp and DS Martinsen, "The Making of a European Healthcare Union: A Federalist Perspective" (2016) 23 Journal of European Public Policy 157.

[134] S Garben, "Supporting Policies" in PJ Kuijper and F Amtenbrink (eds), *The Law of the European Union* (5th edn, Alphen aan den Rijn, Kluwer Law International 2018) p 1208.

[135] See V Delhomme, "Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health" (2020) 11 European Journal of Risk Regulation 747; V Delhomme, "Minimum Harmonization, Experimentation and the Internal Market" in T Van Den Brink and V Passalacqua (eds), *Balancing Unity and Diversity in EU Legislation* (Cheltenham, Edward Elgar Publishing 2024) pp. 194–210.

[136] See Case C-376/98 *Tobacco Advertising*, EU:C:2000:544; Case C-380/03 *Germany v European Parliament and Council (Tobacco Advertising II)*, EU:C:2006:772; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco*, EU:C:2002:741; Case C-547/14 *Philip Morris Brands e.a.*, EU:C:2016:32 ; Case C-151/17 *Swedish Match AB v Secretary of State for Health*, EU:C:2018:938.

[137] Case C-376/98 *Tobacco Advertising*.

[138] Vincent Delhomme, "The Ban on Tobacco for Oral Use Upheld by the Court of Justice: On Subsidiarity and Proportionality in EU Lifestyle Risks Policy" (2019) 10 European Journal of Risk Regulation 227; Delhomme, "Emancipating Health from the Internal Market" (supra n 135); Delhomme, "Minimum Harmonization, Experimentation and the Internal Market" (*supra* n 135).

[139] Delhomme, "Minimum Harmonization, Experimentation and the Internal Market" (*supra* n 135).

[140] Case C-151/17 *Swedish Match*., See Delhomme, "The Ban on Tobacco for Oral Use Upheld by the Court of Justice" (*supra* n 138).

little to do with the improvement of cross-border trade flows but seeks on the opposite to eradicate an entire activity from the market.[141]

> Further, the use of indirect legal bases also has practical institutional consequences, affecting the voices that might be heard in policymaking. Because those legal basis used are not strictly speaking related to "health," the relevant measures are discussed by other Council formation and European Parliament committees, related to the internal market for instance, and will be initiated by another Directorate General (DG) in the European Commission rather than DG SANTE. This affects the interests and expertise represented in the discussion, to the detriment of national health ministries, health experts and civil society.[142] Bringing the rights stakeholders to the table does not necessarily involve a Treaty change. A new self-standing European Parliament Committee on Public Health (SANTE) was for instance created in 2025, in lieu of the former Committee on the Environment, Public Health and Food Safety (ENVI). National health ministers in the Council could meet more often and in a more concentrated health formation.[143]

A Treaty amendment could be designed as follows. The protection of human health would become an area of shared competence, with direct harmonisation powers granted to the EU. A Treaty minimum harmonisation clause, of the kind used in Article 193 TFEU for the environment, should be added, to ensure that Member States can always go beyond the level of protection prescribed by EU law. In concrete terms, the area of "protection and improvement of human health" would be moved from Article 6 to Article 4 TFEU. Article 4(2)(k) TFEU would hence no longer be needed and the prohibition of harmonisation contained in Article 2(5) TFEU would cease to apply to health. Article 168 TFEU would be amended to reflect these changes and to provide the Union with general harmonisation powers in the field, excluding healthcare.[144] Indirect legal bases would remain relevant where the primary objective of a measure is not health. Article 114 TFEU, for instance, would be used for measures *genuinely* concerned with the removal of barriers to trade, with only an incidental and indirect effect on health. It would however cease being used for measures having health as their primary purpose. There are good reasons not to bring changes to Article 168(7) TFEU, which states that "Union action shall respect 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," for it gives enough flexibility for the EU to have an influence on healthcare, with the field remaining primarily in the orbit of the Member States.[145]

V. Conclusion

Those are exciting times for EU health law and policy, a field that has gained in depth and coherence since the early days of European integration, with the EU taking on an ever-greater role. Initially developed as an auxiliary to the internal market and economic integration – supporting the free movement of workers, patients and professionals in

[141] As already mentioned, the objective of the Commission, as part of the Beating Cancer Plan, is to achieve a tobacco-free generation – i.e., ensuring that less than 5 per cent of the population uses tobacco by 2040.

[142] McKee and de Ruijter (supra n 125).

[143] Ibid.

[144] For an example of how Art 168 TFEU could be redrafted, see Delhomme, "Emancipating Health from the Internal Market" (supra n 135).

[145] M Guy, "Towards a European Health Union: What Role for Member States?" (2020) 11 European Journal of Risk Regulation 757.

particular – public health came to constitute an EU competence in its own name. Thanks to its broad legislative powers, the EU is now able to devise and conduct a comprehensive health policy, which supports and steers that of the Member States. As outlined in the present contribution, the EU plays a pivotal role in public health today, i.e. the prevention and treatment of both communicable and non-communicable diseases, while exercising a more limited influence on the organisation of healthcare, including in times of crisis. This division of tasks, we argue, is satisfactory, given the specificities of health and its importance for national Welfare States.

It is, however, not the time to be complacent. The COVID-19 pandemic, while triggering an ambitious and legally creative response on the EU's part, also revealed weaknesses in the EU's health architecture, as well as the fragility existing in national healthcare systems, in the hospital sector in particular. The reforms brought to the EU framework for cross-border health threats will help alleviate some of these shortcomings, ensuring greater preparedness and coordination among European and national actors. Yet, to address the many challenges ahead – improving the performance and resilience of national health systems, tackling health inequalities, strengthening the voice of the EU as a global health actor – one must seriously consider the plea for a European Health Union. Such a new "Union" should translate into greater investment in health at the EU level, supporting care, research and innovation. Most importantly, it should be based on a new competence settlement, strengthening the EU mandate in the field of health and thus acknowledging the extent of what is already done. To the current model of harmonisation, "by stealth," should be substituted clear and direct legislative powers for the EU. This, according to us, is the best way forward to improve the clarity, quality and legitimacy of EU health law and policy.

Cite this article: V Delhomme and C van Os, "Building the European Health Union (2019–2024): Successes, Limits and Future Perspectives". *European Journal of Risk Regulation*. https://doi.org/10.1017/err.2025.10021