

# Abhandlungen

## The European Health Union Set Up, Challenges, and Global Outlook

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### Introduction

The concept of a European Health Union emerged in November 2020 as a political response to the structural deficiencies within the European Union's system of preparedness and crisis management revealed by the COVID-19 pandemic. The pandemic exposed the limited capacity of the existing coordination mechanisms to ensure a timely and coherent response to cross-border health threats and brought renewed attention to the fragmented allocation of competences in the field of health under EU law.

Even after an acute crisis like COVID-19, health policy remains, in its core, a domain reserved for the Member States. The organisation and delivery of medical care fall within their exclusive responsibility, while Union competences are confined to specific aspects of public health and health security.<sup>1</sup> The most far-reaching legal basis is found in Article 168(4) Treaty on the Functioning of the European Union (TFEU), which forms part of the shared competences pursuant to Article 4 TFEU and allows the Union to adopt measures addressing common safety concerns. This competence underpins, inter alia, the establishment and functioning of the European Medicines Agency (EMA), which is additionally supported by internal market harmonisation under Article 114 TFEU. By contrast, the European Centre for Disease Prevention and Control (ECDC) operates primarily on the basis of

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<sup>1</sup> Seminal works on this subject include: Tamara Hervey and Jean V. McHale, *European Union Health Law. Themes and Implications* (Cambridge University Press 2015); Anniëk de Ruijter, *EU Health Law & Policy* (Oxford University Press 2019).

Article 168(5) TFEU, which enables the Union to support, coordinate, and supplement Member State action through monitoring, early warning and risk assessment in relation to serious cross-border threats to health. These activities fall within the category of supporting competences as defined in Article 2(5) TFEU.

Against this constitutional background, the academic and policy debates on the European Health Union have been accompanied by calls for far-reaching institutional and legal reforms. Some commentators on European Union (EU) Law have advocated either an expansion of Union competences in the health sector through Treaty amendment, arguing that only a recalibration of primary law would enable the EU to respond effectively to future pandemics;<sup>2</sup> or, alternatively, not to ‘expand’ but rather to ‘settle’ the question of competences between the EU and Member States as the division in both shared and supporting competences in health makes it difficult to draw lines.<sup>3</sup> Even at the political level, the possibility of Treaty revision was not categorically excluded. Nonetheless, such proposals face considerable legal and political obstacles,<sup>4</sup> and are not currently being pursued. In the absence of primary law reform, the development of the European Health Union proceeds within the existing Treaty framework.

The European Commission has framed this process in programmatic terms, emphasising the objectives of strengthening the EU’s health security framework, reinforcing the crisis preparedness and response role of key Union agencies, and enhancing the Union’s capacity to address present and future health emergencies.<sup>5</sup> Yet, the notion of a ‘European Health Union’ itself remains legally indeterminate. It is a political concept and strategy designed to bring greater focus to the previously neglected area of health rather than a term of art, and its normative implications are far from clear. While Article 168(1) TFEU requires that a high level of human health protec-

<sup>2</sup> Claudia Seitz, ‘The European Health Union and the Protection of Public Health in the European Union: Is the European Union Prepared for Future Cross-Border Health Threats?’, *ERA Forum* 23 (2023), 543 (565).

<sup>3</sup> Vincent Delhomme and Carina van Os, ‘Building the European Health Union (2019–2024): Successes, Limits and Future Perspectives’, *European Journal of Risk Regulation* 16 (2025), 942–960 (958).

<sup>4</sup> On the hurdles for Treaty reforms and how they were politically discussed at the European Parliament: Karolina Borońska-Hryniewiecka and Jan Kotýnek Krotký, ‘Easier Said Than Done: the European Parliament’s Entrepreneurs in the Treaty Change Discourse’, *West European Politics* (September 2025), 1–27 (14), available at: <<https://www.tandfonline.com/doi/full/10.1080/01402382.2025.2557032#abstract>>.

<sup>5</sup> European Commission, *The European Health Union: Acting Together for People’s Health*, COM(2024) 206 final (22 May 2024), <[https://commission.europa.eu/document/download/98c6e4dc-0fc3-4ec6-8ec2-bfcdcb2f018a\\_en?filename=policy\\_com-2024-206\\_en.pdf](https://commission.europa.eu/document/download/98c6e4dc-0fc3-4ec6-8ec2-bfcdcb2f018a_en?filename=policy_com-2024-206_en.pdf)>, last access 22 December 2025.

tion be ensured in the definition and implementation of all Union policies and activities, health does not constitute an overarching objective to which all other Union aims are subordinated. The terminology of a 'Health Union' therefore raises fundamental questions concerning the constitutional status of health within the EU legal order and the permissible depth of integration in this field.

In practice, the European Health Union seeks to enhance coordination among the Member States in addressing cross-border health threats and to strengthen the mandates of existing Union agencies. The revised secondary law framework significantly expands the tasks of both the ECDC and the EMA through the adoption of new regulations and reform of existing ones. The ECDC is now empowered<sup>6</sup> to, among other things, deploy an EU Health Task Force – which will provide technical assistance to Member States but may not override decisions made by national public health authorities – and develop a network of reference laboratories, much like the World Health Organization, albeit focusing on facilities within EU Member States. Moreover, in light of a new Regulation to strengthen its role in public health emergencies, the EMA is now tasked<sup>7</sup> with monitoring and mitigating the shortages of critical medicines and medical devices, particularly through a Medicines Shortages and Safety Steering Group composed of representatives of both EMA and EU Member States.<sup>8</sup> This will allow for joint decision-making on how to address shortages of medical products, even beyond pandemics.

Beyond the reinforcement of these agencies, the Commission has established a new body, the Health Emergency Preparedness and Response Authority (HERA).<sup>9</sup> HERA was founded in September 2021 to improve coordination before and during health crises, to bring together Member States, industry and other stakeholders, and to support the development, procurement, stockpiling and equitable distribution of medical countermeasures, while also contributing to the global health emergency response architecture. Given the urgency of the situation due to the COVID-19 pandemic,

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<sup>6</sup> Regulation 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control, PE/82/2021/REV/1, L314/1.

<sup>7</sup> Regulation 123/2022/EU 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, L20/1.

<sup>8</sup> Emer Cooke, 'Preparing Europe for Future Health Threats and Crises – the European Medicines Agency; Ensuring Safe and Effective Medicines and Medical Devices', *Eurosurveillance* 27 (2022), doi: 10.2807/1560-7917, 2200798.

<sup>9</sup> Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02.

HERA was first created as a Directorate by a European Commission Decision,<sup>10</sup> a fact that raised major questions about its degree of autonomy, competences, and relationship with EU Member States.<sup>11</sup> Subsequently, HERA was given a concrete mandate for monitoring and reviewing the implementation of the European Regulation on Cross-Border Threats to Health,<sup>12</sup> one of the key legal instruments underpinning the European Health Union.

It is against this evolving legal and institutional landscape that the present special issue situates its inquiry into the European Health Union. We, the guest editors, conceived this theme in response to the legal questions raised in the wake of the COVID-19 pandemic about the role of the EU – and, in particular, its institutions – in coordinating health emergency responses across its Member States.<sup>13</sup> The seven contributions in this issue address these questions from both legal and multidisciplinary perspectives. We believe that they offer new insights into the remaining challenges to make the European Health Union a legally sound and effective initiative that protects individuals and communities both within and beyond the EU against future pandemics. Meanwhile, since the inception of this issue, new legal fields within the European Health Union that warrant further analysis have emerged. First, a package known as the European Pharmaceutical Legislation has been proposed. Second, the so-called European Health Data Space was created, through which access to health data by both public and private actors is regulated in detail to strike a balance between allowing the use of such data for innovation, on the one hand, and safeguarding the privacy rights of individuals whose data are collected, on the other hand. The latter development, in particular, is examined more closely in one of the timely pieces of this special issue.

<sup>10</sup> Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, 2021/C 393 I/02.

<sup>11</sup> Olivier Wouters, Rebecca Forman, Michael Anderson, Elias Mossialos, Martin McKee, ‘The Launch of the EU Health Emergency Response Authority (HERA): Improving Global Pandemic Preparedness?’, *Health Policy* 133 (2023), doi:10.1016/j.healthpol.2023.104844.

<sup>12</sup> Regulation 2371/2022/EU 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, L 314/27.

<sup>13</sup> For an in-depth legal examination of the EU’s actions during the COVID-19 pandemic, see Tamara Hervey, Sabrina Roettger-Wirtz and Alexandra Fyfe, ‘The European Union: Legal Response to Covid-19’ in: Jeff King, Octavio Ferraz, Pedro Villarreal, Andrew Jones, Alan Bogg, Nicola Countouris, Eva Pils, Nico Steytler, Elena de Nictolis, Bryan Thomas, Michael Veale, Silvia Suteu, Colleen Flood, Cathryn Costello and Natalie Byrom (eds.) *The Oxford Compendium of National Legal Responses to Covid-19* (Oxford University Press online, 2024), available at: <<https://oxcon.oupplaw.com/display/10.1093/law-occ19/law-occ19-e35>>.

The contributions assembled here examine the concept of a European Health Union from complementary perspectives, ranging from competence allocation and constitutional principles to emergency governance, global supply chains, and data governance. The resulting studies offer a critical assessment of whether and to what extent the European Health Union can deliver a coherent and sustainable framework for health governance within the limits of the existing Treaties. In his contribution, *Markus Frischhut* adopts a historical perspective by revisiting the plans for a European Health Community developed in the 1950s. He explores the lessons that can be drawn from these early integration projects for the present debate and examines whether human health should be elevated to the status of a Union value or even recognised as a fundamental right. This inquiry is situated against the background of the Court of Justice's judgment of December 2020, in which animal welfare was explicitly recognised as a value of the Union. *Christian Calliess*, in turn, addresses the scope and limits of the European Union's capacity to act in the field of pandemic prevention and response. Drawing on legal and economic evaluative criteria, he assesses the existing distribution of competences under the Treaties and exposes the structural deficiencies that constrain effective Union action. On this basis, he argues for a targeted amendment of Article 168(4) TFEU, designed to enhance the EU's regulatory capacity and to enable a more adequate and timely response to future cross-border health crises. *Giacomo Di Federico* investigates the most salient elements of the still ongoing reform of the EU's health emergency governance. His analysis assesses the efficiency and internal coherence of the emerging system of preparedness and crisis management in light of both the objectives of the European Health Union and the orientations set out in the new EU Global Health Strategy. The contribution offers a critical appraisal of whether the current reform trajectory is capable of delivering a genuinely integrated and effective emergency management framework. *Vincent Delhomme* turns to the regulation of non-communicable diseases and critically examines the reliance on Article 114 TFEU as a legal basis for Union measures concerning tobacco, food, and alcoholic beverages. He identifies a series of constitutional tensions, in particular with regard to the principles of conferral and subsidiarity, as well as the systematic use of minimum harmonisation. The contribution submits that these tensions reveal structural shortcomings in the current constitutional framework and proposes a Treaty amendment that could be integrated into the broader reforms required for the establishment of a coherent and balanced European Health Union. In their contribution, *Michael Bayerlein*, *Prachi Agarwal* and *Bettina Rudloff* analyse the legal and economic mechanisms for securing medical supply chains, focusing on the legal framework of the World Trade Organization

(WTO). Identifying critical import dependencies within EU Member States, they highlight the potential repercussions of export restrictions on medical goods, stressing the importance of securing supply chains. They conclude with an analysis of how the EU may pursue a legally sound and economically sustainable strategy to strengthen the resilience of medical supply chains. *Julian Sellner, Giovanni Francois Nantcha and Fruzsina Molnár-Gábor* address the creation of the European Health Data Space. They analyse its envisaged functioning and institutional structure, its relationship with the General Data Protection Regulation, and its legislative evolution. The contribution further assesses the initiative from the perspective of Union legislative competence in the fields of the internal market, data protection and public health, and critically examines its compatibility with the principle of proportionality. The special issue concludes with a practitioner's perspective by *Bartolomej Kurcz*, who draws on his experience as Deputy Head of Unit (Policy and Coordination), HERA, at the European Commission. His article examines the institutional, legal, and practical constraints on Union action in the field of health emergency preparedness and response. By analysing the limits of coordination, competence and implementation at EU level, the contribution provides an insider's account of the challenges faced in operationalising the European Health Union.

Taken together, the emergence of the European Health Union illustrates a broader transformation of Union governance under conditions of crisis. It exemplifies a mode of integration driven less by formal competence expansion rather than by institutional adaptation, reinterpretation of existing legal bases, and the strategic use of secondary legislation. Evidently, it is more of a political approach that works around the fact that the Member States are not yet willing to create a European Health Union with a broader legal basis in the Treaties. This development raises fundamental questions concerning the constitutional balance between the Union and its Member States, the limits of functional integration in the absence of Treaty change, and the role of agencies and executive coordination in areas traditionally characterised by national autonomy.

The European Health Union thus constitutes neither a fully-fledged policy field nor a clearly delineated legal regime. Rather, it represents a dynamic and contested process situated at the intersection of public health, internal market regulation, emergency governance, and fundamental constitutional principles. Whether this process will result in a stable and coherent framework for Union action, or remain a crisis-induced assemblage of sectoral measures, depends on its legal consolidation, democratic accountability, and judicial scrutiny.

The present special issue seeks to contribute to this debate by subjecting the European Health Union to a systematic legal analysis. By examining its conceptual foundations, institutional architecture, and normative implications, the contributions aim to clarify the legal nature and constitutional significance of this evolving project. In doing so, the issue does not proceed from the assumption that ‘more Europe’ in health is necessarily desirable or legally unproblematic. Instead, it explores the conditions under which Union action in the field of health may be both effective and constitutionally legitimate within the existing framework of European integration.

