Legal Preparedness and the European Health Union

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Abstract

The pandemic has made clear the absolute need to coordinate Member States' action on health matters and to create a supranational health governance capable of anticipating and responding to health crises. The attention towards legal preparedness in the context of public health emergencies is well reflected in the post-pandemic acts adopted by the European Union (EU) legislator. This contribution aims at singling out the most prominent aspects of the (still ongoing) reform process with a view to assess the efficiency and coherence of the overall system of emergency management in light of the objectives of the European Health Union and the new EU Global Health Strategy.

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Keywords

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I. Preliminary Remarks

The pandemic has made clear the absolute need to coordinate Member States' action on health matters, to create a supranational health governance capable of anticipating and responding to health crises, and to share skills, knowledge and expertise across the European Union and beyond. These objectives are at the heart of the European Health Union[1] but also pivotal elements of the new EU Global Health Strategy.[2] Indeed, notwithstanding the limited competences of the Union in the field of public health, the shortcomings in terms of preparedness and response capacity emerged during the sanitary crisis have been promptly addressed by the EU legislator in the immediate aftermath of the pandemic. As a consequence of man-made or natural disasters, the proliferation of health emergencies in the last decades has brought to the forefront – at least in democratic societies – the need to be legally prepared to prevent, respond and overcome the ensuing crises.

The attention towards legal preparedness as a 'crucial sub-category of public health emergency preparedness'[3] was already well-reflected in the EU legal order, but COVID-19 undoubtedly highlighted regulatory shortcomings that needed to be addressed. This paper aims to assess the scope and possible added value of the new post-pandemic framework. For present purposes, the following acts are particularly noteworthy (European Health Union Package): the Decision establishing the Health Emergency Preparedness and Response Authority (HERA),[4] Regulation 2022/123 on a reinforced role for the European Medicines Agency (EMA) in crisis prepared-

1 The need for a true European Health Union in which Member States work together to detect, prepare, and respond collectively was advocated by President of the Commission Ursula von der Leyen in her State of the Union Speech of 2020.

2 Communication from the Commission, 'EU Global Health Strategy – Better Health for All in a Changing World', COM/2022/675 final 2022.

3 Stefania Negri, Sandro Bonfigli, Emanuele Cesta and Giacomo Di Federico, Strengthening Legal Preparedness and Response Within the Global Health Emergency Framework: the Role of the GHSA Legal Preparedness Action Package, Journal of Global Health Law 1 (2024), 88-105 (90).

4 Commission Decision of 16 December 2021 establishing the Health Emergency Preparedness and Response Authority, OJ 2021, C 393I/3.

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ness,[5] Regulation 2022/2370 extending the mandate of the European Centre for Disease Prevention and Control (ECDC),[6] Regulation 2022/2371 revamping the legal framework on serious cross-border threats to health,[7] Regulation 2022/2372 on measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level,[8] and the amended Decision 1313/2013 on the Union Civil Protection Mechanism (EUCPM).[9]

After briefly recalling the role of law in combating cross-border threats in the European Union (Section II.), this contribution will focus on health governance and response capacity resulting from the European Health Union package (Section III.). Subsequently, the main features of the post-pandemic EU legislation will be singled out and assessed against the need for greater preparedness when the next pandemic strikes (Section IV.). Some final remarks on the effectiveness, *rebus sic stantibus*, of the post-pandemic EU legal framework and future perspectives will conclude (Section V.).

Before proceeding, however, a caveat is needed. This contribution will not tackle the need to regulate in compliance with the rule of law,[10] ensuring the protection of fundamental rights and the subsistence of adequate political

5 Regulation 2022/123/EU of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ 2022 L 20/1.

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

7 Regulation 2022/2371/EU of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU, OJ 2022 L 314/26.

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

9 Regulation 2021/836/EU of 20 May 2021 amending Decision No. 2013/1313/EU on a Union Civil Protection Mechanism, OJ 2021 L 185/1.

10 See, inter alia, International Development Law Organization, *Preventing Pandemics through the Rule of Law: Strengthening Countries' Legal Preparedness for Public Health* Emergencies (IDLO 2023); Global Health Law Consortium, *The Principles and Guidelines on Human Rights and Public Health Emergencies* (2023) and European Parliament, 'The Impact of Covid-19 Measures on Democracy, the Rule of Law and Fundamental Rights in the EU', PE 651.343, 23 April 2020, all accessible online. In legal literature, see also Filipe Brito Bastos and Anniek De Ruijter, 'Break or Bend in Case of Emergency?: Rule of Law and State of Emergency in European Public Health Administration', European Journal of Risk Regulation 10 (2020), 610-634 and Joelle Grogan, 'COVID-19, The Rule of Law and Democracy. Analysis of Legal Responses to a Global Health Crisis', Hague Journal on the Rule of Law 14 (2022), 349-369. On the admissibility under EU law of national restrictive measures issued during the sanitary crisis, see also ECJ, *Nordic Info BV v. Belgium*, judgment of 5 December 2023, case no. C-128/22, ECLI:EU:C:2023:951.

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debate during health emergencies[11]. These aspects are indispensable for the legitimacy of Union law,[12] and are addressed elsewhere in this special issue.[13]

II. The Role of Legal Preparedness in Public Health Emergencies

Legal preparedness facilitates prevention, detection, and rapid response to public health emergencies in accordance with international standards.[14] According to the Global Health Security Agenda (GHSA), 'In the context of public health emergencies, legal preparedness is the capability to map, develop, refine, and implement the use of legal instruments across sectors to help to prevent, detect, react, and respond to and recover from infectious disease threats'.[15] The GHSA effectively brings together many of the actors that operate on the international scene advocating multisectoral awareness, the development of technical tools, capacity building through training, as well as the adoption of legal benchmarks to support the process of preparedness and response to public health emergencies.[16]

Although health is eminently a state responsibility, there is a growing attention towards legal preparedness at the global[17] and regional level, includ-

11 See inter alia Annalisa Volpato, Mariolina Eliantonio and Kathryn Wright, 'Transparency and Participation in the Face of Scientific Uncertainty: Concluding Remarks', European Journal of Risk Regulation 14 (2023), 371-381. It is also worthwhile noting that the General Court has recently annulled the European Commission's decision to withhold text messages exchanged between Commission President Ursula von der Leyen and Pfizer CEO Albert Bourla (General Court, *Stevi and The New York Times v. Commission*, judgment of 14 May 2025, case no. T-36/23, ECLI:EU:T:2025:483). See further Pielpa Ollikainen, 'Inconsistent and Imprecise Explanations: NYT v. Commission, Transparency, and the Search for Lost Documents', European Papers 10 (2025), 451-462.

12 Vincent Delhomme and Tamara Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order', YBEL 41 (2022), 48-82 (48).

13 See in this special issue Christian Calliess, 'Filling the Gap in the Health Policy of the European Union (EU) – Lessons Learned from the Corona Crisis (Covid-19 Pandemic) –, HJIL 85 (2025), 1045-1074.

14 On the origin, development and reach of the concept of legal preparedness, see further Georges C. Benjamin and Anthony D. Moulton, 'Public Health Legal Preparedness: A Framework for Action', Journal of Law, Medicine and Ethics 36(S1) (2008), 13-17.

15 Legal Preparedness Action Package, *Defining Legal Preparedness in the Context of Public Health Emergencies*, Official Website of the Global Health Security Agenda. On the importance of global health lawyers supporting the development of this young field of law, see also Roojin Habibi, '"Someone Call a Global Health Lawyer!": Global Health Law as an Emerging Community of Practice', Journal of Global Health Law 1 (2024), 71-87.

16 GHSA is an international group that brings together more than seventy countries and several international organisations. A full list of the members is available on the Official website of GHSA <https://globalhealthsecurityagenda.org/>, last access 12 November 2025.

17 In this regard, the reader is referred to Gian Luca Bussi, 'The COVID-19 Pandemic and the Development of Global Health Law: Managing Crises or Achieving Structural Changes?', Journal of Global Health Law 1 (2024), 8-25.

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ing the European Union and the African Union.[18] The health package presented by the Commission in November 2020 begins by stating that there should be 'a strengthened framework for cross-border cooperation against all health threats in order to better protect human lives and the internal market and to maintain the highest standards in terms of protection of human rights and civil liberties'.[19]

The lack of a sound legal framework is broadly acknowledged in the reform package,[20] and ultimately justifies the adoption of more stringent rules on surveillance, preparedness, early warning, and response during public health emergencies, as well as stronger powers for the main actors, namely EMA and the ECDC. COVID-19 brought to the forefront some central questions that needed to be tackled at the national level, but also at the EU level: is there an *ad hoc* regime for public health emergencies? Which subjects of the system are legitimised to proclaim a state of emergency? When can the applicable regime be activated? What kind of coordination is ensured between public agencies? Are surveillance and early warning mechanisms for shortages of medicinal products and medical devices in place? How is access to the protective equipment and medical supplies actually guaranteed?

As will be seen shortly hereafter, the post-pandemic legal framework under consideration addresses these concerns in the attempt to establish greater legal preparedness through a solid framework to prevent, detect, and respond to cross-border health threats.[21] Although the overall efficiency of the system could certainly be improved, it can hardly be doubted that the legal instruments developed in the immediate aftermath of the crisis offer the relevant institutional actors new and more effective ways of shaping the

18 In December 2020, a new platform was created to enable stakeholders from both continents to exchange ideas, best practices and make recommendations on major challenges affecting both Africa and Europe.

19 European Commission, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM/2020/724 final.

20 See Recital 3 Regulation 2022/123/EU, Recital 3 Regulation 851/2004/EU (as amended by Regulation 2022/2370/EU), and Recital 2 Regulation 2022/2371/EU.

21 An analysis of all the post-pandemic acts relevant during a sanitary crisis falls beyond the remit of this contribution. The plethora of measures is quite impressive for magnitude, including the Regulation 2022/2065/EU of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act), OJ 2022 L 277/1; the revised Schengen Borders Code (COM/2021/891 final); Regulation 2024/2747/EU of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Regulation 2679/98/EC, OJ 2024, 2747; Regulation 2024/1689/EU of 13 June 2024 laying down harmonised rules on artificial intelligence, OJ 2024 L 1689; Regulation 2025/327 of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation 2024/2847/EU, OJ 2025 L 327; and the new pharmaceutical framework to make the EU more resilient, fair and competitive and to ensure timely and equitable access to safe and effective medicines (COM/2023/193 final and COM/2023/192 final).

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Union's public health policy in case of emergencies. The strengthening of the overall capacity to respond to cross-border health threats is particularly important now, with "Russia's illegal war of aggression against Ukraine, rising geopolitical tensions, state-sponsored hybrid and cyberattacks, sabotage targeting critical assets, foreign information manipulation and interference, and electronic warfare".[22]

III. The Health Package Presented by the Commission

In the European Union, the need to respond to serious cross-border health threats (Bovine Spongiform Encephalopathy [BSE], Severe Acute Respiratory Syndrome [SARS], Ebola, Zika, COVID-19) has gradually led to the enhancement of the legal capacity to respond.[23] In that respect, the European Health Union currently rests on three pillars: 1) the new Regulation on the response to serious cross-border health threats, complemented by the decision to create an internal service within the Commission called HERA (Authority for Preparedness and Response) and by a strengthened and extended mandate for EMA and the ECDC; 2) the new Regulation reforming the decision on the Union Civil Protection Mechanism; 3) the Regulation on a framework of measures to be activated in the event of public health emergencies.

As anticipated, we shall now try to single out the distinctive features of the reform process concentrating on health governance and response capacity. Although the purely financial *volet* of preparedness falls outside the remit of this contribution, it is nevertheless worth underlining that in order to implement the health package, the Union and the Member States must find adequate resources: on the one hand, vital support was offered by the Next GenerationEU recovery plan to sustain recovery and favour resilience;[24] on

[22] Joint Communication to the European Parliament, the European Council, the Council, the European economic and social Committee and the Committee of the Regions on the European Preparedness Union Strategy, JOIN(2025) 130 final, p. 1.

[23] On the constitutional developments in the field of health at the EU level, see Anniek De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2017), 76-79; Markus Frischhut and Scott Greer, 'EU Public Health Law and Policy – Communicable Diseases' in: Tamara Hervey, Calum Young and Louise Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar 2017), 315-346 (318-325) and Tamara Hervey and Jean McHale, *European Union Health Law. Themes and Implications* (Oxford University Press 2015), 30-53.

[24] Delhomme and Hervey (n. 12), 55. The Next Generation is based on Art. 122 TFUE, which allows the Council the power to grant financial assistance to a Member State struck by 'severe difficulties caused by natural disasters'. However, the authors correctly note that 'NGEU is not only an emergency instrument, it is here to support "recovery" and "resilience" and the funds allocated will be used for long term objectives that ostensibly have little to do with Covid-19, such as the green and digital transitions sought for the Union's economy'.

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the other hand, one cannot overstate the importance of the EU4Health Programme – 'a vision for a healthier European Union'. With a €5.3 billion budget during the 2021-2027 period, it provides an unprecedented support in health signalling that investment in this area represents a priority for the Union.[25]

1. Health Governance

As far as governance is concerned, the health package strengthens the role and powers of existing bodies, rationalises their internal organisation, creates a new Directorate-General within the Commission and sets up advisory bodies and networks. Proceeding in orderly fashion, the new Regulation on cross-border threats generalises the guidance power of the Health Security Committee (HSC) through the 'adoption of opinions and guidelines, including on specific response measures for Member States for the prevention and control of serious cross-border health threats'.[26] Indeed, the HSC, comprising a representative from each Member State (but with the meetings chaired by a representative of the Commission), is entrusted with a stronger control and supervision function on preparedness and response planning and implementation at the national level, monitoring, early warning and assessment capacity in relation to serious cross-border threats to health. In this respect, suffice it here to mention, on the one side, that the HSC has turned into a forum for regular coordination, as opposed to a 'simple' (occasional) consultation room,[27] and, on the other side, that Member States are now obliged to report to it 'any substantial revision of their national prevention, preparedness and response plan'.[28] Moreover, it should be noted that to secure

25 Regulation 2021/522/EU of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, OJ 2021, 107/1 (EU4Health). See also Decision No. 1786/2002/EC of 23 September 2002 adopting a Programme of Community action in the field of public health (2003-2008) – Commission Statements (budget: EUR 312 million), OJ 2002 L 271/1; Decision No. 1350/2007/EC of 23 October 2007 establishing a second Programme of Community action in the field of health (2008-2013) (budget: EUR 321.5 million), OJ 2007 L 301/3; Regulation 282/2014/EU of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) (budget: EUR 449.3 million), OJ 2014 L 86/1.

26 Regulation 2022/2371/EU (n. 7), Art. 4 para. 3 lit. d).

27 See Decision No. 1082/2013/EU of 22 October 2013 on serious cross-border threats to health and repealing Decision No. 2119/98/EC, OJ 2013 L 293/1, Art. 4 para. 1 and Regulation 2022/2371/EU (n. 7). In this sense, see also Dimitri Eerens, Rok Hrzic and Timo Clemens, 'The Architecture of the European Union's Pandemic Preparedness and Response Policy Framework', European Journal of Public Health 33 (2022), 42-48 (46).

28 Regulation 2022/2371/EU (n. 7), Art. 6 para. 3.

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legitimation, consistency, and coherence, as well as to increase transparency and accountability, the HSC works as a two-tier structure of senior and technical level, with the involvement of the pertinent Union agencies and bodies, as well as of the European Parliament, as observers.[29]

On the other hand, with a view to ensure a real capacity to monitor shortages of medicines and medical devices, the EMA revised mandate envisages two executive steering groups, the Medicine Shortages Steering Group (MSSG) and the Medical Device Shortages Steering Group (MDSSG), responsible for managing problems relating to the supply of medicines and medical devices, respectively.[30] Moreover, under the new mandate, a Single Point of Contact (SPOC) Working Party has been created to support timely and effective monitoring via information sharing between Member States, EMA and the European Commission during major events or public health emergencies.[31]

Similarly, to support the ECDC's epidemiological surveillance, preparedness and response tasks, Member States are called upon to designate a coordinating competent body, a national coordinator, national focal points and operational contact points for public health functions with reporting duties and advisory functions. But it is also worth mentioning the EU Health Task Force (HTF) set up under the reinforced mandate of the ECDC, comprising 'the Centre's staff and experts from Member States, fellowship programmes and international and non-profit organisations'[32] and offering science-based recommendations for prevention, preparedness and response planning.[33]

In addition, as is well known, HERA has been created as a Directorate General of the Commission with the objective to 'strengthen Europe's capa-

29 Regulation 2022/2371/EU (n. 7), Art. 4 para. 1. The HCB HSC is co-chaired by the Commission and the rotating presidency of the Council. The representatives of the Member States each have one vote and the Board deliberates by consensus or, in the lack thereof by a majority of two thirds (Regulation 2022/2371/EU (n. 7), Art. 4 para. 4).

30 To ensure the widest participation, these steering groups involve one observer member of the Patients' and Consumers' Working Party (PCWP) and one observer member from the Healthcare Professionals' Working Party (HCPWP). See Regulation 2022/123/EU (n. 5), Art. 3 para. 2 and Art. 25 para. 1.

31 The working party is based on the pilot SPOC network that the HMA / EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use set up in April 2019.

32 Regulation (EU) 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, Art. 11a.

33 Regulation 851/2004/EC of 21 April 2004 establishing a European Centre for disease prevention and control, OJ 2004 L 142/1 (as amended by Regulation 2022/2370/EU (n. 6)), Art. 5.

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city to prevent and detect health emergencies of a cross-border nature and to respond rapidly to them, ensuring the development, production, acquisition and equitable distribution of key medical countermeasures'. The HERA Board brings together high-level representative from each Member State, as well as representatives from the ECDC and EMA as permanent observers, with a view, *inter alia*, to draw up opinions on threat assessment and monitoring the supply and demand of medical countermeasures.[34] The HERA Board is assisted by the HERA Forum, a group of experts providing scientific and technical expertise.[35] Leaving the more operational aspects to the next section, it is here useful to anticipate that HERA can operate in two different modes: a preparedness mode to steer investment and enhance prevention, and an emergency mode to react to public health emergencies.[36]

As indicated, advisory bodies have also been set up to offer assistance and guarantee evidence-based decisions. This is the case with the Advisory Committee on Public Health Emergencies (ACPHEs) created under Regulation 2022/2371, which includes independent experts in public health and representatives of the ECDC and EMA as permanent observers to offer multidisciplinary support to the HSC on topics ranging from the existence of an emergency at Union level to the formulation of response measures.[37] This is the case, moreover, with the Emergency Task Force (ETF) established in accordance with Regulation 2022/123, and composed of experts from the EMA committees and working parties and from the national clinical-trial authorities, which is entrusted with the task of providing scientific advice and supporting clinical trials.[38]

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34 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, C(2021) 6712 final. It is interesting to note that the high-level representative from each Member State (with a two-year term, renewable once) is appointed by the Commission on the basis of nominations by the relevant national authorities (Art. 6 para. 1).

35 Two sub-groups assist the HERA Forum: on the one side, the Joint Industrial Cooperation Forum and, on the other side, the Civil Society Forum, Decision C(2021) 6712 final (n. 34), Art. 7.

36 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, COM/2021/576 final, 1-15 (2).

37 Regulation 2022/2371/EU (n. 7), Art. 24 paras 1 and 2.

38 To ensure proper coordination with Regulation 536/2014/EU of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ 2014 L 158/1, the Clinical Trials Coordination and Advisory Group (CTAG) is also represented (Regulation 2022/123/EU (n. 5), Art. 15 para. 3 lit. e).

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Regulation 2022/2372 on medical countermeasures, on its part, provides for the creation of a Health Crisis Board (HCB) to ensure coordination in the supply of, and access to, crisis-relevant material during an emergency. It comprises a representative of the Commission and one representative from each Member State, with the participation of EMA, ECDC, and the HSC.[39] Its function is to advise and assist the Commission when the situation so requires, most notably on the drafting of a list of crisis-relevant medical countermeasures and raw materials,[40] as well as on the appropriate mechanism to purchase crisis-relevant gear.[41] Moreover, the Regulation on cross-border health threats creates a network of EU reference laboratories for public health and a network for substances of human origin, both operated and coordinated by the ECDC[42] to connect expertise throughout the Union on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.[43]

Likewise, the decision on the EUCPM has been amended to allow for the creation of an EU civil protection knowledge network, a supranational hub connecting first responders, disaster risk managers, centres of excellence, universities and researchers and decision-makers, and matching their needs for expertise and good practices with methodologies, tools, solutions, and resources.[44]

2. Response Capacity

Turning the attention towards response capacity, the updated legal framework enhances instruments and mechanisms designed to prevent, contain, manage, and overcome sanitary crisis. In particular, legal preparedness de-

39 Regulation 2022/2372/EU (n. 8), Art. 5 para. 4.

40 Regulation 2022/2372/EU (n. 8), Art. 7 para. 1. See also Communication from the Commission to the European Parliament, the Council, the European economic and social Committee and the Committee of the Regions - Preparing the EU for the next health crisis: a Medical Countermeasures Strategy, COM/2025/529 final.

41 Regulation 2022/2372/EU (n. 8), Art. 8 para. 1.

42 In the former case, reference laboratories with certain characteristics spelled out in the text of the regulation are designated by the Commission by means of implementing acts; in the latter case each Member State designates the competent authorities responsible for the use of substances of human origin, including transfusion and transplantation (Regulation 2022/2371/EU (n. 7), see Art. 15 para. 1 and Art. 16 para. 3). See also Commission implementing regulation 2024/892/EU of 22 March 2024 designating European Union reference laboratories for certain specific areas of public health, OJ 2024 L 892/1 and Commission Implementing Regulation 2024/2959/EU of 29 November 2024 designating European Union reference laboratories for public health on food- and water-borne bacteria; on food-, water- and vector-borne helminths and protozoa; and on food- and water-borne viruses, OJ 2024.

43 Regulation 2022/2371/EU (n. 7), Art. 15 para. 1.

44 Decision 2013/1313/EU (n. 32) (as amended by Regulation 2021/836/EU (n. 9)), Art. 13.

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mands that specific obligations, viable tools and appropriate procedures are in place, and fully operational.

Based on the pandemic experience, the new measures pursue a double objective.

First, they are intended to increase the ability to gather, share, and process health related data for monitoring, risk assessment, and training purposes. Concretely, this means dedicated services and IT tools. The European Health Union package builds upon the existing services for risk management, surveillance, and preparedness control, such as the Emergency Response Coordination Centre (ERCC), rapid alert mechanisms, like the Early Warning and Response System (EWRS) and the Common Emergency Communication and Information System (CECIS), and technical and communication web-based platforms, such as the European Surveillance System (TESSy) and the Epidemic Intelligence Information System (EPIS). At the same time, it fosters the creation of additional IT tools such as European shortages monitoring platform (ESMP), activated within EMA (with a dedicated Working group),[45] the new Vaccine Monitoring Platform (VMP),[46] governed by a steering group and supported by a joint EMA-ECDC secretariat, the Data analysis and real-world interrogation network (DARWIN EU) to allow and facilitate the collection by EMA and national authorities of reliable and timely real-world evidence from routinely collected electronic health data,[47] and the Advanced Technology for Health Intelligence and Action It System (ATHINA), developed by HERA in collaboration with the recently created European Health and Digital Executive Agency.[48] All these IT tools support monitoring and surveillance through a web of competences and authorities.

The capacity to acquire, exchange, and elaborate data also entails more control by EU institutions and agencies and more notification and reporting duties, not only for the Member States, but also for the industry. To exemplify, if in the preparedness mode HERA is committed, *inter alia*, to collect intelligence in order to assess threats, under EMA's new mandate marketing authorisation holders are bound to offer the Agency all relevant information on

45 Regulation 2022/123/EU (n. 5), Art. 13. The basic version of the European Shortages Monitoring Platform was launched on 28 November 2024. The platform is fully operative (with all functionalities) since 29 January 2025.

46 Regulation 2022/123/EU (n. 5), Art. 20.

47 Regulation 2022/123/EU (n. 5), Art. 20 lit. a).

48 Implementing Decision 2021/173/EU of 12 February 2021 establishing the European Climate, Infrastructure and Environment Executive Agency, the European Health and Digital Executive Agency, the European Research Executive Agency, the European Innovation Council and SMEs Executive Agency, the European Research Council Executive Agency, and the European Education and Culture Executive Agency and repealing Implementing Decisions 2013/801/EU, 2013/771/EU, 2013/778/EU, 2013/779/EU and 2013/779/EU, OJ 2021 L 50/9.

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critical medicinal products,[49] and pursuant to Regulation 2022/2372 economic operators must disclose in a timely manner (within 5 days) to the Commission information concerning their facilities, the actual total production capacity, the expected production output for the following three months and the possible existing stocks of the crisis-relevant medical countermeasures.[50]

Improving monitoring and risk assessment, however, also means standardising the kind and quality of the pertinent data provided to the competent supranational bodies. By means of implementing acts, the Commission is entrusted with the task of developing templates for monitoring supply and demand of crisis-relevant material, 'including production capacity, stockpiles, possible critical aspects or the risk of disruption in the supply chains and purchasing agreements'.[51] In line with the evidence-based approach, the ECDC is to report on communicable disease trends over time pursuant to agreed indicators, harmonised data collection specifications and epidemiological modelling with the use of Artificial Intelligence (AI).[52] More generally, it is among its (new and reinforced) goals to develop, together with the Member States and the Commission, 'preparedness, monitoring and evaluation frameworks', and to elaborate 'indicators for preparedness based on the IHR, in cooperation with the WHO'.[53] The introduction of a Union preparedness plan, elaborated by the Commission in accordance with the International Health Regulations (IHR), has also been accompanied by the desire to detail its structure and content.[54] Additionally, the Member States' reports on prevention, preparedness, and

49 Regulation 2022/123/EU (n. 5), Arts 9 and 10.

50 Regulation 2022/2372/EU (n. 8), Art. 10 para. 2.

51 Regulation 2022/2372/EU (n. 8), Art. 7 para. 1.

52 Regulation 851/2004/EC (n. 33) (as amended by Regulation 2022/2370/EU (n. 6)), Art. 3 para. 2 lit. b). In this respect, privileged access to health data for research and epidemiological aspects (secondary use) in the context of the European Health data space will augment exponentially its assessing ability.

53 Regulation 2022/2370/EU (n. 6), 5 b para. 2, lit. b). The provision also adds that these frameworks and indicators will be discussed within the HSC.

54 Regulation 2022/2371/EU (n. 7), Art. 5. See also the European Preparedness Union Strategy and the Communication from the Commission to the European Parliament, the Council, the European economic and social Committee and the Committee of the Regions – Introducing the Union prevention, preparedness and response plan for health crises, COM/2025/745 final. As is well known, the IHRs have been amended in 2024. For an overview of the relevant changes, see Roojin Habibi, Mark Eccleston-Turner and Gian Luca Burci, 'The 2024 Amendments to the International Health Regulations: A New Era for Global Health Law in Pandemic Preparedness and Response?', Journal of Law, Medicine and Ethics 53(S1) (2025), 47-50 and Ashley Bloomfield and Abdullah Assiri, 'The Updated International Health Regulations: Good News for Global Health Equity', The Lancet 403 (2024), 2761-2762. Concomitantly, a pandemic treaty is being discussed within the WHO and should be adopted in the near future. See further, Alexander Finch et al., 'The Promise and Compromise of the WHO Pandemic Agreement for Spillover Prevention and One Health', The Lancet 405 (2025), 1800-1802. A (still) provisional text of the Pandemic Agreement (12th April) can be found on the WHO website.

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response planning and implementation shall be based on agreed common indicators and include a set of data included in a dedicated template (possibly consistent with the IHR State Parties reporting framework).[55] Similarly, in the pillar dedicated to the EUCPM, the Commission has been empowered to set, in cooperation with the Member States, non-binding Union objectives for disaster resilience in the field of civil protection through recommendations.[56]

Second, the new measures are aimed at enhancing the capacity to acquire and allocate essential goods, raw materials, and human resources that are crucial during an emergency. The formal recognition of emergency situations is perhaps among the most prominent features of the reform. Pursuant to Regulation 2022/2371, the pertinent assessment is the responsibility of the Commission via implementing acts after consulting the ECDC (and other competent agencies) and the ACPHEs.[57] The decision is autonomous (but the Commission must liaise with the World Health Organization [WHO]) and implies the application of a specific legal regime that goes well beyond the variation of the terms of the marketing authorisation for medicinal products and influenza vaccines for human use previously provided for by Decision 1082/2013.[58] To begin with, the measures on medicinal products and medical devices covered by Regulation 2022/123 on the enhanced role of EMA may be activated. *In concreto*, this determines the involvement of the ETF and may lead the Agency to establish a list with the main therapeutic groups of medicinal products required to face the sanitary crisis.[59] Within EMA, the MSSG and the MDSSG are competent to adopt the relevant critical medicines and medical devices lists,[60] and the ETF will perform a systematic scientific assessment of evidence on medicines and issue recommendations on medicines that are not yet authorised.[61]

55 See Regulation 2022/2371/EU (n. 7), Art. 7 and Commission implementing Regulation 2023/1808/EU setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health, OJ 2024 L 234/105. According to the Union prevention, preparedness and response plan for health crises, 'To date, all 30 EU/EEA countries have national prevention, preparedness and response plans in place and reported on their capacities in the first self-reporting exercise in 2023' (p. 10).

56 This is intended to improve the ability of the Union and the Member States 'to withstand the effects of a disaster which causes or is capable of causing multi-country transboundary effects' (Decision 2013/1313/EU (n. 32) as amended by Regulation 2021/836/EU (n. 9), Art. 4).

57 Regulation 2022/2371/EU (n. 7), Arts 23 and 24.

58 Decision 1082/2013/EU (n. 27).

59 Regulation 2022/123/EU (n. 5), Art. 6.

60 Regulation 2022/123/EU (n. 5), Arts 7 and 22.

61 More precisely, the members of the ETF comprise representatives of the scientific committees, working parties and staff of the Agency, as well as representatives of the Clinical Trials Coordination and Advisory Group established in accordance with Regulation 536/2014/EU (n. 38) and clinical trial experts on behalf of the national authorities competent for medicinal products (Regulation 2022/123/EU (n. 5), Art. 15 para. 3).

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In addition, it is possible to have recourse to the mechanisms set out in the Medical Counter Measures Regulation, with the involvement of the HERA in crisis response mode.[62] Most notably, the Commission, after having sought the advice of the Health Crisis Board, can draw up (by means of implementing acts), a list of crisis-relevant medical countermeasures and raw materials,[63] and purchase crisis-relevant medical countermeasures and raw materials under one of the available instruments, namely the financial support foreseen in Regulation 2016/369, the joint procurement procedure established in Regulation 2022/2371 – with possible restrictions to parallel negotiation activities by the participating countries for the countermeasure in question – or a European Innovation Partnerships contemplated in Regulation 2021/695, but also following an autonomous procurement mode.[64] Moreover, the Commission can draw up and regularly update an inventory of crisis-relevant medical countermeasure production and production facilities; an inventory that can be extended to crisis-relevant consumables, medical devices, equipment and infrastructure.[65] When there is a risk of a shortage of such material, the Commission is entitled to adopt 'specific measures to ensure the efficient reorganisation of supply chains and production lines and utilise existing stocks to increase the availability and supply of crisis-relevant medical countermeasures'.[66] Furthermore, it should not be forgotten that in order to reserve manufacturing capacities and obtain a priority right for manufacturing of vaccines in case of a future public health emergency, the Commission and the European Health and Digital Executive Agency, using HERA's budget in accordance with the 2022 working programme, have established the EU FAB Programme, 'a network of manufacturing facilities reserving capabilities for the production of vaccines'.[67]

As mentioned, human resources are another crucial element of the overall system of prevention, preparedness, and response, and an essential component of the Union plan and the national plans. Hence, investing in capacity building through recruitment and training is of the essence. HERA, EMA,

62 See to this effect Regulation 2022/2372/EU (n. 8), Recital 4.

63 Regulation 2022/2372/EU (n. 8), Art. 7 para. 1.

64 Regulation 2022/2372/EU (n. 8), Art. 8. Very significant is the power granted to the Commission to conclude purchase contracts after having carried out on-site visits to the economic operators concerned (i. e. potential suppliers).

65 Regulation 2022/2372/EU (n. 8), Arts 10 and 11.

66 Regulation 2022/2372/EU (n. 8), Art. 12. The Commission will have to seek the agreement of the Member States and consult with the economic operators concerned.

67 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions State of Health Preparedness Report, COM/2022/669 final, 1-21 (17).

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ECDC, and HERA (and more generally the Commission[68]) are all involved in training activities, with a particular attention towards international standards (WHO), the One Health approach, digital literacy, multi-disciplinarity and inter-specialty (e. g. for cancer healthcare professionals), vulnerable groups and non-discrimination, but also towards making healthcare professions more appealing. These activities are funded with EU money and should promote a leadership, patient-centred, whole-of-government/whole-of-society approach.[69] In addition to traditional training activities, the exchange of health professionals and public health personnel and even the temporary secondment of personnel between Member States, candidate countries or Union agencies and bodies is envisaged, possibly in the framework of Union-supported programmes with the contribution of health professional organisations.[70]

Under the EUCPM, instead, the HTF will complement and integrate the capacities of the European Medical Corps and will also be able to contribute to the relevant mechanisms of the WHO. Furthermore, quite tellingly, in April 2023 the Commission allocated EUR 106.2 million to eight countries

68 According to Art. 11 para. 1 of Regulation 2022/2371/EU (n. 7): 'The Commission may organise training activities, in close cooperation with the relevant Union agencies and bodies and professional health organisations and patient organisations, for healthcare staff, social service staff and public health staff in the Member States, in particular interdisciplinary One Health training, including on preparedness capacities under the IHR.' In addition, the reformed Decision 2013/1313/EU (n. 32) entrusts the Commission with the task of developing and managing a training and exercise programme on disaster prevention, preparedness and response aimed at civil protection personnel as well as emergency management personnel, including health professionals. This programme, aimed at improving complementarity between the resources made available by the Member States upon request (Art. 9), the resources of the European Civil Protection Pool (Art. 11) and the resources deployed under rescEU (Art. 12), 'includes joint courses and a system for the exchange of expertise in the field of emergency management' (Art. 13 para. 1 lit. a)).

69 For reasons of cost-efficiency and sustainability, as well as to increase participation, training can also take place at a distance and the pertinent administrations are invited to promote the dissemination of the knowledge acquired by the participants in the national context (Regulation 2022/2371/EU (n. 7), Art. 11 paras 1, 2 and 4). More detailed rules concerning the organisation of training activities are left to an implementing decision of the Commission (Art. 11 para. 6). The training activities are organised in cooperation with the relevant Member States and the ECDC (Art. 11 para. 3).

70 See Regulation 2022/2371/EU (n. 7), Art. 11 para. 5 and Decision 2013/1313/EU (n. 32) (as amended by Regulation 2021/836/EU (n. 9)), Art. 13 para. 1, lit. a). The need for adequate training programmes has also been stressed in legal literature. See, for instance, Mariana Peyroteo et al., 'European Health Information Training Programme: a Sustainable Strategy for Strengthening Capacity in Health Information', European Journal of Public Health 34 (2024), 35-42 and Anu-Marja Kaihlanen et al., 'Continuing Education in Digital Skills for Healthcare Professionals – Mapping of the Current Situation in EU Member States', International Journal of Health Policy and Management 13 (2024), 1-7.

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to develop the new rescEU EMT (Emergency Medical Team) capacity,[71] and thereby enhance emergency medical support to populations affected by natural or man-made disasters.[72]

IV. Emergency Management, Response Capacity and Resources: the Main Features of the Post-Pandemic Reform Process

Especially following the entry into force of the Lisbon Treaty, it is possible to observe the emergence of an elaborate and complex network of bodies, mechanisms, and procedures aimed at facilitating risk identification, sharing of epidemiological data, threat assessment, coordination of response and cooperation in the implementation phase. However, it should be borne in mind that pursuant to Article 168(7) Treaty on the Functioning of the European Union (TFEU), the Union is bound to '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', which deeply affects the reach and scope of the European Health Union.[73]

That being said, the distinctive features of the European Health Union package all revolve around the three main elements of the Union prevention,

71 More specifically, these are: Belgium, France, Germany, Italy, Luxembourg, Portugal, Romania, and Turkey. According to the consolidated version of Decision 2013/1313/EU (n. 32), it is up to the Commission to define, by means of implementing acts, the rescEU resources taking due account of the shortcomings at Union level in the area of emergency health response (Decision 2013/1313/EU (n. 32), Art. 12 para. 2, as amended by Regulation 2021/836/EU (n. 9)).

72 The new rescEU EMT will comprise three Emergency Medical Teams with seventeen specialised care teams: from intensive care to advanced diagnostics, from maternal and child support to mental health support, from orthopaedic care to oxygen supply. rescEU EMT is expected to become (gradually) operational in 2024, complementing the fifteen Emergency Medical Teams that make up the European Medical Corps of the European Civil Protection Pool.

73 Mary Guy, 'Towards a European Health Union: What Role for Member States?', European Journal of Risk Regulation 11 (2020), 757-765 (759). In this regard, one should bear in mind that there is no separate Council of Ministers health formation, which means that EU action in this field does not necessarily imply the involvement of the relevant ministerial departments (Anniek de Ruijter and Eleanor Brooks, 'The European Health Union: Strengthening the EU's Health Powers?', Eurohealth 28 (2022), 47-49 (49)). In turn, the European Parliament has (albeit only recently) created a Committee on Public Health <https://www.europarl.europa.eu/committees/en/sant/home/highlights>, last access 24 November 2025. Vincent Delhomme, 'Where Market and Health Collide: The Limits of Policy Experimentation in EU Prevention of Non-Communicable Diseases and Tobacco Control', HJIL 85 (2025), 1095-1117; Markus Frischhut, 'The Missing Keystone of the "European Health Union". Historic Development, *status quo* and Ideas *de lege ferenda*', HJIL 85 (2025), 1011-1043.

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preparedness, and response plan, i. e. governance, capacities, and resources. The enhancement of the Union's ability to react to a cross-border health threat strongly depends on standardisation, expertise, digitalisation, and international cooperation. These are the main priorities resulting from a more attentive reading of the measures under consideration. Credible risk assessment postulates the existence of comparable data, common indicators, and agreed benchmarks. An evidence-based approach to decision making, especially in emergency situations, demands the involvement of strategic economic operators, experts, patient and healthcare professions associations in the decision-making process. The secure, rapid, and reliable processing of large amounts of data requires the use of IT tools and AI. Finally, since the focus is on cross-border health threats, special attention needs to be paid to the international context and to the coordination with the WHO.

The analysis of the European Health Union package suggests that, in line with the concept of legal preparedness outlined above, the emerging institutional architecture designed to handle future pandemics is based on synergic multi-sectoral cooperation between political and technical bodies for intelligence gathering, on digital platforms, big data, and machine learning for performance evaluation and on decentralised networks for the collection of specific information. All this through a system of governance that, far from entailing a transfer of sovereignty to the centre, rests on the joint exercise of competences at the centre. This process of institutional centralisation has wittily been labelled 'expansive unification' and effectively allows the Member States to retain their responsibility in the field of public health.[74] Besides form being represented in the various agencies and bodies, they have a strict control over the application of the relevant measures. As a matter of law, sensitive matters such as the state of implementation of the national preparedness plans and their coherence with the Union plan or the list of 'the categories of personal data that may be exchanged for the purpose of the coordination of contact-tracing measures'[75] have been left to delegated acts, while implementing acts are adopted pursuant to the examination procedure.[76]

Given the plethora of EU acts dealing with prevention, preparedness, and response to public health emergencies, there is a risk of normative stratification

74 Maurizio Ferrera, Anna Kyriazi and Joan Miró, 'Integration Through Expansive Unification: The Birth of the European Health Union', Publius 54 (2024), 1-26 (2).

75 Regulation 2022/2371/EU (n. 7), Art. 28 para. 6, lit. b).

76 Regulation 2011/182/EU of 16 February 2011 on laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ 2011 L 55/13, Art. 5. Interestingly enough, the European Health Union package contemplates two ad hoc committees: the Committee on serious cross-border threats to health established (Regulation 2022/2371/EU (n. 7), Art. 29) and the Health Crisis Committee (Regulation 2022/2372/EU (n. 8), Art. 14).

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and inconsistency. These are perhaps the most evident *vulnera* of the current legal framework. Of course, this state of affairs is closely related to the principle of conferral, which forces the EU legislator to follow a silos-like regulatory approach where the scope and form of action, and the involvement of the Parliament, effectively depend on the applicable legal bases. To be sure, the cross-border health threats Regulation and the revised mandate of the ECDC are grounded on Article 168(5), the amended Decision on the EUCPM is founded on Article 196 TFEU, the reinforced mandate of EMA relies on Arts 114 and 168(4), lett. c, TFEU and the counter-measures Regulation on Article 122 TFEU. Whilst the latter entitles the Council to act single handedly, the other legal basis contemplate the ordinary legislative procedure. However, the fact remains that outside the exceptions concerning the safety of medicinal products and medical devices, the Union is prevented from harmonising national laws and regulations in the field of public health protection.[77]

In truth, 'the discrepancy between the European task and competence' gives rise to *ultra vires* concerns when it comes to prevention, preparedness, and response during pandemics.[78] Indeed, some provisions, like those on the elaboration of templates and evaluation methods could be questioned under (a strict reading of) the principle of conferral. In this sense, it should not go unnoticed that in its recent resolution on proposed amendments to the current treaties, the European Parliament advocates the conversion of public health into a shared competence and a modification of Article 168(4), lett. c).[79] This would (formally) allow the Union to set common indicators for healthcare systems and adopt (minimum) harmonised rules for 'early notification, monitoring and management of serious cross-border threats to health, in particular in the event of pandemics'.[80]

V. Final Remarks

Over the last two decades, the Union has equipped itself with an increasingly comprehensive framework of rules applicable in the event of health

77 See Art. 4 para. 2 lit. k), Art. 6 lit. a), Art. 168 para. 5 and Art. 196 para. 2 TFEU.

78 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), 543-566 (561-562). The author advocates the inclusion of a fourth 'exception' in the list of Art. 168 para. 4 lit. c), namely: 'measures to prevent, control and combat communicable diseases with pandemic potential'.

79 Proposals of the European Parliament for the amendment of Treaties, European Parliament Resolution of 22 November 2023 on proposals of the European Parliament for the amendment of the Treaties (2022/2051(INL)), C/2024/4216, pt. 14.

80 Proposals of the European Parliament (n. 79), Amendment No. 150.

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emergencies. After several health crises of a cross-border nature, three revisions of the treaties (Treaty of Amsterdam, Treaty of Nice, and Treaty of Lisbon) and the transfer of more competences to the Union in the field of public health in emergency contexts of a cross-border nature, it is now possible – more than 70 years after the failure of the European Health Community[81] – to finally imagine a 'strong' European Health Union.[82]

This contribution has tried to single out the most prominent aspects of the (still ongoing) reform process, taking into consideration the legal challenges posed by public health emergencies at the global level. In this respect, supranational action can be said to have succeeded in tackling all the main issues raised by the conceptual framework on legal preparedness. Limited competences notwithstanding, the EU institutions have consolidated health governance, advanced IT tools, designed procedures and mechanisms to detect and address shortages of crisis-relevant goods and resources.[83]

Although institutional coordination and the efficiency of working methods can certainly be improved, one has to bear in mind that health emergencies are complex phenomena that intercept various areas of EU competences, be it shared or supporting competences. Regardless of governance unification and independently of the extensive and pervasive 'normalisation' of numerous issues linked to the gathering, sharing, and processing of data, or more operational aspects such as procurement and stockpiling of crisis-relevant material, the European Health Union package can broadly be said to have remained within the limits of the principle of conferral. Member States retain important decision-making, normative, and implementing, powers –, and HERA could possibly turn into a fully-fledged EU agency.[84]

Independently of future (improbable) treaty amendments granting the EU more shared competences in areas pertaining to cross border health threats,

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81 Maryse Cassan, *L'Europe communautaire de la santé* (Économica 1989).

82 It is worth recalling that above and beyond stronger crisis preparedness, the European Health Union also comprises a comprehensive action against cancer, antimicrobial resistance, and mental health, a far-reaching pharmaceutical strategy to ensure access to more affordable medicines, and a number of initiatives to promote and facilitate the digital transition in health. European Commission, *A Strong European Health Union for All – Stepping-Stones for Better Healthcare and More Resilient Health Systems*, 2024, accessible online at <https://ec.europa.eu/commission/presscorner/api/files/attachment/878547/Factsheet%20Strong%20Health%20Union_EN.pdf>, last access 26 November 2025.

83 Kai P. Purnhagen et al., 'More Competences Than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak', European Journal of Risk Regulation 11 (2020), 297-306.

84 The choice to opt for the creation of an internal service has indeed been criticised by some authors. See Olivier J. Wouters et al., 'The Launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving Global Pandemic Preparedness?', Health Policy 133 (2023), 1-6.

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the current legal framework is believed to have great potential and should be fully exploited.[85] Nonetheless, to push the pursuit of convergence beyond the current level of normative intervention would most probably imply an ultra vires action. *Rebus sic stantibus*, effectiveness seems to largely depend on the supervisory role of the HSC and the Commission. Unlike what happened during the pandemic, under Decision 1082/2013, the latter should exercise its prerogatives in accordance with Article 258 TFEU, most notably in relation to the elaboration, development and updating of national preparedness plans. The new legal framework must be taken seriously, regardless of whether the obligations imposed on Member States stem from acts adopted within the realm of supporting competences.

85 See further, Ilona Kickbusch and Anniek de Ruijter, 'How a European Health Union Can Strengthen Global Health', The Lancet Regional Health – Europe 1 (2021), 1-2.

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