HEALTH EMERGENCY RESPONSE GOVERNANCE IN THE EU AFTER THE COVID-19 PANDEMIC

Andrea Renda, Timothy Yu-Cheong Yeung, Hien Vu
Jane Arroyo, Amy Kokalari, Panka Rékasy

CEPS IN-DEPTH ANALYSIS February, 2024 - 04

EXECUTIVE SUMMARY

More than three years on since the start of the COVID-19 pandemic, this paper provides an assessment of reforms implemented at EU level to enhance the Union's preparedness and response to future health threats. The EU has made significant strides towards greater integration and cohesion, with plans to amend EU Treaties to bolster EU-level competences in health matters. However, there are still uncertainties around crucial issues such as determining the coordinating institution or body during a health emergency, data collection for existing and required countermeasures, funding sources for procurement and medical countermeasure development, fund management, and effective communication strategies during a health emergency. These aspects must be addressed if lives are to be saved in the future. It may require more than mere legislative adjustments, for example, rigorous stress-testing of existing rules through simulations and preparedness exercises.

In Section 2, we present an overview of the EU crisis management approach post the COVID-19 pandemic. The pandemic shifted the Union's crisis management strategy from reactive to proactive, emphasising prevention and preparedness. Recognising the need for an integrated response framework covering social, economic, public health, and other dimensions, the EU has embraced a more holistic approach.

Section 3 delves into the institutional and legislative changes reflecting the evolving EU approach to public health emergencies. These changes primarily focus on areas where joint action among Member States can provide significant benefits. Key developments include the establishment of the Health Emergency Preparedness and Response Authority (HERA) as a Commission service, strengthening the mandates of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and the adoption of pivotal regulations – Regulation (EU) 2022/2371 on serious cross-border threats to health, and Council Regulation (EU) 2022/2372 on the supply of crisis-relevant medical countermeasures.

In Section 4, we identify 21 issues comprising ambiguities and deficiencies that merit extensive discussion and clarification within the Union. By leveraging EU legal texts, this section envisions how the EU might respond to a public health emergency chronologically – ranging from advisory mechanisms before acknowledging a public health emergency to activating an emergency framework concerning medical countermeasures, and ultimately terminating the public health emergency or the emergency framework.

Section 5 offers a set of recommendations, suggesting actions the Union could adopt to enhance its response framework. Recommendations include clarifying relationships between different institutional bodies during a public health emergency, improving the allocation of roles among various advisory bodies, ensuring adequate resources for EU agencies and crisis-relevant medical countermeasures, enhancing data utilisation for policymaking, promoting transparency and accountability in EU emergency decision-making, and formulating a robust strategy to combat disinformation. Furthermore, the research team advocates for a comprehensive simulation exercise involving independent external observers, encompassing every step from recognising a public health emergency to deactivating the emergency framework. This exercise will not only reveal areas for resource optimisation but also identify potential problems and obstacles within the response framework, gauging the effectiveness and efficiency of recently introduced yet untested institutional changes.

Table 1 summarises the main issues identified by the research team and the related recommendations.

Keywords: Health Emergencies, EU Treaties, Coordination, Countermeasures

Andrea Renda is the Director of Research at CEPS, Timothy Yu-Cheong Yeung is a Research Fellow, Hien Vu is an Associate Researcher, Jane Arroyo is a Research Assistant, Amy Kokalari and Panka Rékasy are Interns at the Global Governance, Regulation, Innovation, Digital Economy (GRID) unit at CEPS. The authors would like to express their gratitude to Belgium's SPF Santé Publique for their invaluable support throughout the study. Special thanks are also extended to all the reviewers whose feedback has significantly enhanced the quality of the paper. This research received funding from Belgium's SPF Santé Publique, under the framework of the Belgian Presidency of the Council of the European Union.

LIST OF ISSUES AND RECOMMENDATIONS

Table 1. Summary of issues and recommendations

Area	Issue	Recommendation
Governance framework	Ambiguous relation between Health Crisis Board and HERA	Clarify if HERA would set up a HERA's Crisis Board and its relationship with the Health Crisis Board (HCB) in the upcoming review of HERA's operation, and ensure HERA has the necessary competence and autonomy to act effectively during a crisis
		Explain whether HERA, in crisis mode, would set up a 'HERA crisis board'
	Potential overlaps of Health Crisis Board and Health Security Committee	Working on the implementations of Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372 to clarify the relationship and allocation of responsibilities between the HCB and the Health Security Committee with regard to MCMs
		Provide a single point of contact for Member States wishing to raise an issue during emergency
	Overlapping competences and mandates on threat monitoring and assessment	Evaluate the efficiency of the overlaps in HERA and ECDC's monitoring activities and consider re-assigning this mandate among the two bodies in the upcoming review of HERA's operation
	The new governance framework is not tested against a health emergency	EU institutions, agencies, bodies and relevant entities to jointly conduct a simulation exercise from the recognition of a public health emergency to its termination
	Lack of competence of the EU over national public health	Continue to discuss a Treaty change; establish and maintain a strong and independent Union advisory body that reaches areas beyond MCMs; better utilise the Integrated Political Crisis Response mechanism for cross-sectoral emergency response
	Lack of a coordinated approach to national border closure	
Scientific advisory mechanisms	Potential lack of resources to sustain EMA's activities in a health emergency	Beyond what provided for by Regulation (EU) 2022/123, ensure adequate resources to EMA so that it can sustain the proper functioning of the Emergency Task Force during emergencies, and conduct adequate Health Technology Assessments (HTA) for crisis-relevant health technologies

	Difficulties in ensuring the emergency capacity of the EU Health Task Force	Enhance ECDC's ability to mobilise sufficient staff and funding to allow the EU Health Task Force to cope with large-scale public health emergencies
	The Advisory Committee has not yet been formally established	Clearly specify the role, the sets of expertise and the selection criteria in the Commission's call for experts for the Advisory Committee for public health emergencies
	Ambiguities in the factors warranting scientific advice on the recognition and termination of a public health emergency	Clarify how the different advisory bodies and their recommendations will relate to one another and their legal effects; examine the efficiency gains or losses of having multiple advisory bodies for recognising a public health emergency, be they ad hoc bodies for a specific consultation or existing agencies for thematic questions
	Multiple and potentially overlapping advisory mechanisms	Clarify the functions of different advisory bodies and ad hoc groups already during non-emergency times, in order to avoid conflicting messages and recommendations during an emergency
Data and information	Potential duplications and inefficiencies in the collection of medical countermeasures data by EMA and HERA	Establish regular communication between HERA and EMA, avoid potential duplications in their data collection and ensure interoperability between their IT platforms
	Potential difficulties in accessing data from Member States and companies	Ensure that Member States and pharmaceutical companies provide data on MCMs both during preparedness and emergency times, by leveraging Regulation 2022/123 123 (Articles 3 to 14 and 21 to 30 thereof), the forthcoming pharmaceutical legislation (Articles 116 to 126, Chapter X) and the Data Act (Chapter V)
	Availability of data relevant for policymaking in an emergency is not guaranteed	Include a clause similar to the one in Chapter V of the Data Act in a sense that it injects flexibility into the legislation during an emergency to ensure the European Health Data Space is emergency ready
Funding and procurement of medical countermeasures	Lack of transparency in the prioritisation of health threats	Back the prioritisation exercise with scientific independence and inclusive stakeholder consultation, and make available relevant documents related to the methodology and findings of the prioritisation process
	Potential limitation of EU FAB	Work on an improved structure of the current EU FAB going beyond its current term of eight years and on extending the categories of medical countermeasures of EU FAB beyond vaccines, e.g., including antivirals, antibiotics, personal protection equipment and other relevant medical devices

	Suboptimal EU funding to support at-risk investment	Adopt an 'at-risk' investment approach, providing funds to support the development and production of MCMs even before they have been granted marketing authorisation (as in the US's Operation Warp Speed model)
		Draw inspiration from the US use of priority-rated contracts, i.e., measures aimed at re-shoring the production of critical inputs (e.g. active pharmaceutical ingredients, bioreactor bags, filters and tubes) through supporting innovative manufacturing technologies, as well as subsidies along critical supply chains and investment to scale up manufacturing capacity
		Consider introducing an emergency clause in its budgetary rules, mandating that different funding streams contribute to one single budget line (i.e., the Emergency Support Instrument) in time of emergency
		Consider reinforcing HERA's budget autonomy, e.g., through giving HERA a specific budget line in the EU annual budget or establishing a funding programme for HERA under the next multiannual financial framework (2027-2033)
	Lack of a long-term EU vision on R&D funding	Promote a long-term, foresighted vision of R&D support, facilitating the blending and sequencing of different funding programmes, particularly between those supporting preparedness and those for emergency R&D activities
	Transparency issues related to the procurement of crisis-relevant medical countermeasures	Establish more specific rules and guidelines to ensure transparent decision-making process in the joint procurement of crisis relevant MCMs
Communication	Lack of effective instruments in combating mis- and disinformation	Establish a crisis public communication strategy to avoid conflicting recommendations being published by different entities
		Tackle the issue of scientific advice, foresight and communication through the implementation of Regulation (EU) 2022/2371. One first step could be developing an all-round strategy against disinformation that includes a global dimension (e.g., through developing joint anti-disinformation plans or facilitating innovative technologies to identify misinformation) and a bottom-up channel (e.g. through boosting literacy and awareness in areas such as new media technologies and health, or supporting bottom-up dialogues).

GLOSSARY

CBRN	Chemical, biological, radiological and nuclear
DG ECHO	Directorate-General for European Civil Protection and Humanitarian Aid Operations
DG RTD	Directorate-General for Research and Innovation
DG SANTE	Directorate-General for Health and Food Safety
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EEA	European Environmental Agency
EHDS	European Health Data Space
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
ERCC	Emergency Response Coordination Centre
ETF	Emergency Task Force
EU	European Union
EU FAB	Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing
EUHTF	EU Health Task Force
EWRS	European Warning and Response System
GOARN	Global Outbreak Alert and Response Network
HCB	Health Crisis Board
HERA	Health Emergency Preparedness and Response Authority
HSC	Health Security Committee
IPCR	Integrated Political Crisis Response
PPE	Personal protective equipment
PPR	Pandemic preparedness and response
MCMs	Medical countermeasures
MDSSG	Medical Device Shortages Steering Group
MSSG	Medicine Shortages Steering Group
UCPM	Union Civil Protection Mechanism
WHO	World Health Organization

CONTENTS

List of Boxes, Figures and Tables

1. INTRODUCTION AND STRUCTURE OF THE WORK

The emergence of COVID-19 presented an unprecedented challenge for the European Union, having a profound impact on its Member States. While having some successes, it also revealed deficiencies in the EU's crisis management capacity. The pandemic exposed the strengths and vulnerabilities of the EU's healthcare systems and highlighted the lack of a coordinated and efficient response in several areas. Disparities in testing capabilities, medical supplies, and vaccination strategies across Member States laid bare the shortcomings of a fragmented approach to crisis management. The crisis also strained EU institutions and exposed divisions among Member States, particularly regarding the distribution of financial resources and the coordination of border controls. The EU's suboptimal response to COVID-19 reflects its limited competence in public health and a lack of solidarity among Member States – particularly at the onset of the pandemic. In turn, these weaknesses manifested in various areas of the EU's response capacity.

The pandemic revealed a lack of well-tested preparedness and response plans, both at the national and at the pan-European level. Pre-Covid reporting tools like the State Party Self-Assessment Annual Reporting (SPAR) and the Joint External Evaluation (JEE) mechanism – required under the International Health Regulations (2005) and binding on the 196 member states – are today considered poor predictors of the COVID-19 mortality rate of a country, showing flaws in the construction and measurement of the indicators (Fukuda-Parr, 2022). In the EU, Member States' implementation of the SPAR and JEE is weak and sporadic (Razavi et al., 2021). This justifies the need for stronger prevention, preparedness and response planning capabilities at both Union and national level, which is now introduced under Regulation (EU) 2022/2371, and expected to allow for effective monitoring, early warning of and combating of serious cross-border threats to health. It also calls for further embedding of foresight and horizon scanning into the EU's policy cycle to anticipate future risks in view of what is now called an age of 'poly-crisis', or – in the words of the Council of the EU (2023) – a time of 'parallel long-lasting, cross-sectoral, and cross-border crises'.[1]

More than three years have elapsed since the emergence of the COVID-19 pandemic. The pandemic had devastating impacts on society and the economy globally. In Europe, the pandemic caused more than 275 million infections and over 2 million reported deaths as

[1] Council of the European Union, Council Conclusions on Strengthening Whole-of-society Resilience in the Context of Civil Protection, including CBRN Preparedness, 8 June 2023.

of August 2023,[2] and 36 million cases of Long COVID during 2020-2022.[3] These deaths could have been partly avoided, had the European Union (EU) and its Member States been better prepared, and thus able to respond more effectively. Numerous problems emerged, among which, the weakness of health systems at national and local level (despite the obligations stemming from the 2005 International Health Regulations);[4] the lack of evidence-informed policymaking and effective communication to citizens while fighting misinformation; delays and transparency issues in the procurement of medical countermeasures (MCMs), and uncoordinated national border closure measures.

Importantly, in the EU, problems also emerged because of the lack of a common, adequately coordinated approach to crisis management. The pandemic unveiled a lack of cohesion and coordination among Member States, as evidenced by early attempts to limit the circulation of MCMs within the Single Market. Legal constraints also stood in the way of EU institutions' ability to manage the crisis. This is due to the wording of Article 168 TFEU, which allows the EU to promote coordination, yet prohibits 'any harmonisation of the laws and regulations of the Member States' and stipulates that the EU must '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'. Some of these limits have been overcome, since 2016, by a rather extensive use of Article 122 TFEU, which provides more powers to the Council in the event of exceptional occurrences (including health emergencies). However, such measures lead to processes which are significantly driven by Member States, which leave little space for EU-level coordination (for example, by the European Commission), and do not involve the European Parliament in the decision-making process.[5]

The limited competences held by the EU on health translated into an incomplete institutional framework for pandemic preparedness and response. Existing agencies, such as the European Centre for Disease Prevention and Control (ECDC), were overwhelmed by the scale of the threat.[6] Member States called for urgent guidance yet had to take immediate action in the early days of the pandemic, and this in turn led to the adoption

[2] World Health Organization. WHO Coronavirus (Covid-19) Dashboard [Internet]. 2023. Available from: https://covid19.who.int/data

[3] Institute for Health Metrics and Evaluation. Long Covid is a serious health concern in Europe [Internet]. Seattle ; 2023. Available from: https://www.healthdata.org/news-events/insights-blog/acting-data/long-covid-serious-health-concern-europe

[4] More details about the international Health Regulations are available at https://www.who.int/health-topics/international-health-regulations#tab=tab_1

[5] Consolidated version of the Treaty on the Function of the European Union, available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:en:PDF

[6] European Centre for Disease Prevention and Control. Strategic and performance analysis of ECDC response to the Covid-19 pandemic [Internet]. Solna; 2020 Nov. Available from: https://www.ecdc.europa.eu/sites/default/files/documents/ECDC_report_on_response_Covid-19.pdf

of uncoordinated measures across and within EU countries. The European Commission struggled to defend the integrity of the Single Market and orchestrate actions by Member States. This was also seen in the lack of influence of existing institutional bodies where Member States coordinate their actions, such as the Health Security Committee.[7]

Eventually, the European Commission managed to address many of the coordination issues, and successfully paved the way for a coordinated approach in key aspects of crisis response, such as the negotiation of vaccine procurement and the development of a common Covid certificate, which was also widely adopted beyond EU borders. However, the lack of both a well-defined pan-European crisis response plan and a suitable legal basis for adequate EU-level crisis management left significant scars. Public health measures at Union level arrived late (compared to economic support measures, where the experience of the financial crisis provided a clearer division of responsibilities),[8] and had to be adopted speedily, often sacrificing transparency and due process (as in the case of vaccine procurement) (Beke et al., 2023).[9]

The past three years have seen progress in the direction of greater EU integration and cohesion; yet the drive towards institutional reform eventually lost momentum and ambition due to tensions between EU institutions, as well as with Member States. Steps towards greater integration include, inter alia, the launch of the European Health Union, and in particular the adoption of Regulation (EU) 2022/2371 on serious cross-border health threats and Council Regulation (EU) 2022/2372 on an emergency framework of MCMs, the strengthening of the mandate of existing institutions (ECDC and EMA); and the announcement of a new institutional body in charge of health emergency preparedness and response (HERA); and most recently the Commission's Communication on actions to address critical shortages of medicines and strengthen security of supply in the EU. Other major reforms include prevention, preparedness and response planning at national and Union level, the establishment of an EU reference laboratory network, and

[7] The EU Health Security Committee was set up in 2001 at the request of EU Health Ministers as an informal advisory group on health security at European level, and was formalised under Decision 1082/2013/EU. The Committee is mandated to reinforce the coordination and sharing of best practice and information on national preparedness activities. Yet, due to diverse expectations of the function of the Committee, Member States assign officials of different seniority levels to the Committee, making decision-making difficult.

[8] In the area of fiscal policy, the 'institutional memory' of the 2008-2009 financial and economic crisis had already led to a strengthening of EU-level coordination. As a result, the EU managed to raise sufficient resources to give life to a massive stimulus plan (Next Generation EU). By comparison, reactions in the health domain were patchier and slower. While the month of March 2020 saw several emergency measures adopted in the domain of economic and fiscal policy, in the area of health key decisions such as the appointment of an independent panel of epidemiologists and virologists in support of national government decisions (together with ECDC) and the creation of a 'clearing house' for medical equipment only started in April.

[9] Also see European Court of Auditors. Special report 19/2022: EU Covid-19 vaccine procurement – Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed. Luxembourg; Sept. 2022.

enhances epidemiological surveillance and risk assessment. The EU has also strengthened its use of the One Health approach to preventing, preparing for and responding to health emergencies. Its public health measures also aim to address broader categories of cross-border threats to health, covering threats of biological, chemical, radiological and nuclear origin.

Given the magnitude of the threat posed by COVID-19, momentum for a possible Treaty change to enable stronger EU competences in public health even started to emerge).[10]

However, this momentum partly waned, ushering in a season of important, yet less ambitious policy initiatives. For example, HERA had initially been announced as homologous to the US BARDA (Biomedical Advanced Research and Development Authority), and many expected it to be established as an independent agency.[11] Yet, eventually the policy process that could have led to this outcome was set aside, and HERA was launched as an internal service of the Commission, in part due to the need of speedy actions with competences and resources that (as will be explained below) may warrant a new intervention in the future.[12]

Key provisions in this season of reforms include two consecutive, yet very different regulations: Regulation 2022/2371 on serious cross-border health threats,[13] and Regulation 2022/2372 introducing a framework to ensure the supply of crisis-relevant medical countermeasures in the event of a public health emergency at EU level,[14] both entered into force on 26 December 2022. These regulations establish a governance framework for future responses to health crises, with a key role entrusted to a newly created 'Health Crisis Board' (HCB); and to a strengthened Health Security Committee (HSC).

[10] Among its four proposals in the health area, the CoFoE's recommendation to i) ensure equal and universal access to healthcare for all EU citizens (through a supranational healthcare system) and ii) enable health and healthcare to be a shared competence between the EU and Member States would require Treaty changes (by amending Article 4 TFEU) (6). CoFoE's proposals led to a vote in the European Parliament to call for establishing a constitutional convention to reopen the EU treaties (4). Indeed, these forward steps are hopeful indications that the EU will be more prepared for another major health emergency.

[11] Se comment by the European Public Health Alliance https://epha.org/hera-for-public-health-or-industrial-policy-in-disguise/

[12] See (19) for an in-depth analysis of HERA's governance and recommendations on possible future reforms.

[13] 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 (Text with EEA relevance). Available at: http://data.europa.eu/eli/reg/2022/2371/oj

[14] 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. Available at: http://data.europa.eu/eli/reg/2022/2372/oj

In this report, we take stock of existing reforms and assess their potential to contribute to a more effective framework for crisis governance, management and response in the Union. Importantly, this report not only asks the question whether the EU would be better equipped to face a pandemic like COVID-19 in the future. This would only amount to 'solving for the last pandemic' but would not help assess whether the EU would be ready to adequately manage future health crises of different natures, as they are likely to emerge. Instead, we take a broader view to possible future health threats (an all-hazard approach), as well as a forward-looking approach to the tools and procedures that could be leveraged to effectively mitigate their adverse effects once they materialise. We find that despite the many reforms introduced, the EU public health emergency response framework is too complex in some areas (and may prove ineffective and cumbersome should a health crisis hit in the future), while in other areas loopholes or ambiguity are observed. We, therefore, find several areas in which reform would be needed in the future.

The remainder of the report is structured as follows. Section 2 summarises the overall framework for crisis management in the EU, and Section 3 particularly focuses on the main reforms introduced in the health sector in the aftermath of COVID-19. Section 4 contains a step-by-step analysis of the EU health crisis governance and management and identifies areas where clarification or further reform would be needed. Finally, Section 5 translates these findings into policy recommendations.

2. CRISIS MANAGEMENT IN THE EU: TOWARDS AN ALL-HAZARD, WHOLE-OF-SOCIETY APPROACH

Good crisis management requires good situational awareness (e.g., through the Early Warning and Response System as is the case for the EU); the ability to anticipate a wide variety of potential threats; clearly defined responsibilities; streamlined decision-making processes; and the ability to couple transparent and legitimate decision-making with agility and speed. A general view among researchers and experts is that the EU has gradually moved from being a reactive institution, with limited capability to anticipate risks, towards a more proactive approach aimed at prevention and early detection of emerging risks. The Treaty of Lisbon specifies that the European Union shall 'encourage cooperation between Member States in order to improve the effectiveness of systems for preventing and protecting against natural or man-made disasters' (Article 196). In the early 2000s, dramatic events such as 9/11, the 2005 Madrid terrorist attacks and the 2004 Fukushima Daiichi nuclear disaster led to the creation of an integrated system for crisis response at the EU level. In 2006, the Council adopted the emergency and crisis coordination arrangements, and seven years later adopted the Integrated Political Crisis response (IPCR) arrangements with a view to achieving greater flexibility, scalability and

efficiency.[15] Since 2013, a Union Civil Protection Mechanism (UCPM, established by Decision no. 1313/2013) has become the overarching coordination mechanism for crisis management. In terms of detection instruments, besides the IPCR, integrated tools such as ARGUS, the EU Situation Room and the European Response Coordination Centre 2.0 (ERCC 2.0) have been set up to improve coordination, combining multi-level governance and the need for swift action. As shown in Figure 1, this integrated governance has been gradually supported by horizontal and sectoral legislation and instruments, which incorporate many complementary dimensions of emerging crises, from food shortages to cybersecurity and health threats.[16]

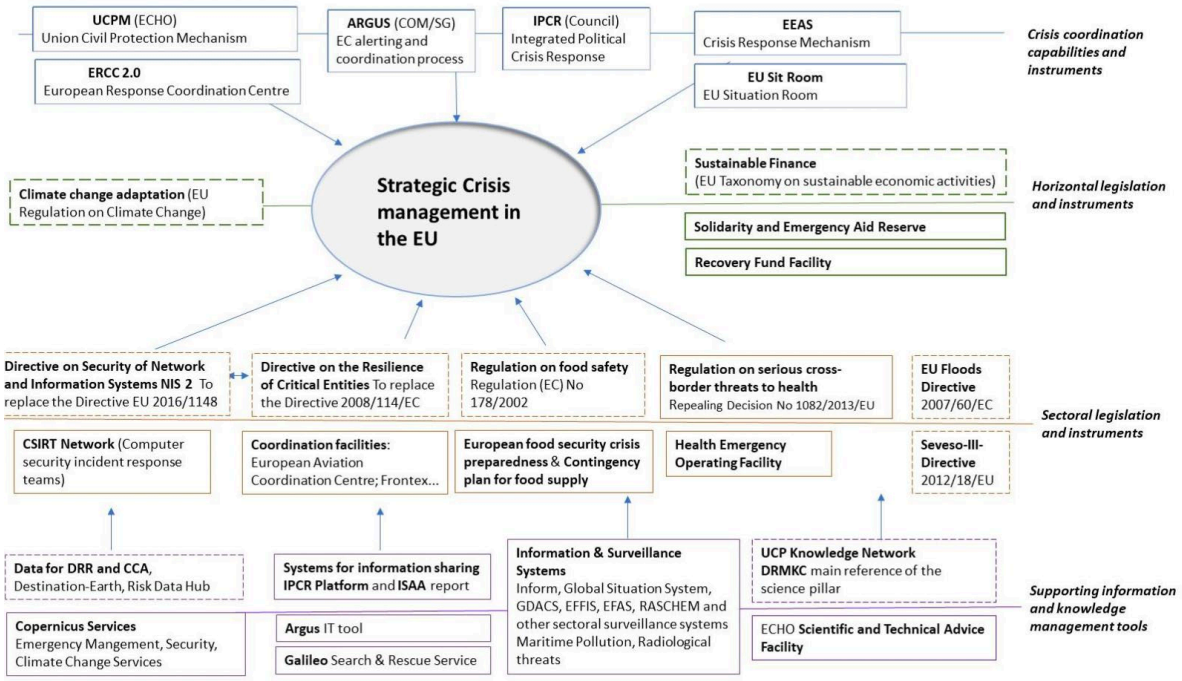
This sophisticated and admittedly complex governance system was severely put to the test during the COVID-19 pandemic.[17] Throughout the pandemic, it also became clear that (i) large-scale crises cannot be analysed in isolation, but in fact they trigger a series of cascading events, which warrant a broad scope of response, and a variety of coordinated instruments to enable suitable mitigation; (ii) crises can be of different nature, with broadly heterogeneous phenomenology, ranging from sudden onset to creeping, 'slow-burning' or protracted crises, and the EU needs to be agile enough to be able to recognise and manage all of these types; (iii) the use of data and technology for crisis preparedness and response requires adequate preconditions and policies, which were absent when COVID-19 hit. Importantly, adequate crisis response could be designed across different levels of government, without requiring a centralisation of competences in the hands of the EU (as originally envisaged by the European Commission at the onset of COVID-19). However, the more decentralised competences are, the greater the need for effective coordination across all phases of crisis management. Otherwise, transaction costs and conflicting interests can severely undermine the effectiveness of crisis management, in the EU as well as in all multi-level governance systems (including within some Member States).

[15] The new arrangements were codified in a legal act in 2018. See https://eur-lex.europa.eu/eli/dec_impl/2018/1993/oj

[16] For a description of each instrument and legislation, see European Commission, Directorate-General for Research and Innovation, *Strategic crisis management in the EU : improving EU crisis prevention, preparedness, response and resilience*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2777/517560.

[17] On the complexity of the system, the SAPEA Evidence Review Report recalls that 'The Inventory of Crisis Management Capabilities developed internally by the EC listed about 100 instruments, tools and mechanisms within the European Institutions and bodies.' See page 29, footnote 23.

Figure 1. A selection of main instruments, mechanisms and legislation in the field of crisis management at the EU level



Source: Group of Chief Scientific Advisers, 2022.

Against this background, during the COVID-19 pandemic, the EU crisis management system showed at once a remarkable responsiveness, and a number of areas for improvement. Following a well-known distinction into the phase of detection of an emerging threat, that of mobilisation of relevant capacities, and the publicness and legitimacy of the crisis response (Boin and Rhinard, 2023), several interesting elements emerge.

First, as regards the early detection of the pandemic, it is worth remembering that ECDC issued a first Threat Assessment Report on 9 January 2020, acknowledging the virus, but downplaying the threat of a pandemic. Nevertheless, the EU's Early Warning and Response System (EWRS) was activated on the same day, and the European Commission convened a meeting of the Health Security Committee on 17 January. On 28 January, the Croatian Presidency of the Council activated the IPCR information sharing mode[18] and the EU's civil protection mechanism was also activated for the repatriation of EU citizens

[18] See https://eu2020.hr/Home/OneNews?id=160

abroad.[19] The IPCR then moved to full activation mode on 2 March 2020.[20] While these actions were adopted quite swiftly, they took quite some time to translate into concrete political action.[21] Finally, in March 2020 a Coronavirus Emergency Response Team was created in the European Commission, with the participation of five Commissioners.

Second, when it came to mobilising resources to tackle the pandemic, EU institutions realised that there were significant shortages of personal protective equipment (PPE) throughout Europe. This points to a lack of information on existing stocks of PPE, which slowed down the response despite a very rapid deployment of joint procurement (requesting countries obtained the first EU-procured materials on 21 April 2020). Yet, the EU appeared faster at putting economic measures rather than health measures in place. While the month of March saw several emergency measures adopted in the domain of economic and fiscal policy, in the area of health key decisions such as the appointment of an independent panel of epidemiologists and virologists in support of national governments' decisions (together with ECDC) and the creation of a 'clearing house' for medical equipment only started in April.

Third, the legitimacy and publicness of the response was heavily affected by the lack of preparedness, especially in the health domain. The lack of transparency in the negotiation of vaccine contracts could be justified by the need for swift action but would not be justified a second time in a future crisis (Arroyo, 2023). As observed by Boin and Rhinard (2023), 'no major efforts were made to publicly set out what was at stake, or who might win or lose under certain decision outcomes', which leads the authors to conclude that there was very little public discussion of crisis decisions at the EU level, and the transparency of key decisions was 'weak at best'.

Since the onset of the pandemic, and also due to new and unforeseen events such as the war in Ukraine, a deep reflection was launched on the need for a more integrated crisis management system in the Union. Such reflection was facilitated by the contribution of the European Commission's Scientific Advice Mechanism, which issued an in-depth evidence review report and a high-level report with important recommendations. Among them, the need to deal with the increasingly systemic nature of large-scale crises, by

[19] See https://ec.europa.eu/commission/presscorner/detail/it/IP_20_142

[20] The IPRC has three operational modes, depending on the situation: a monitoring mode to easily share existing crisis reports; an information-sharing mode, triggering the creation of analytical reports and the use of the web platform to better understand the situation and prepare for a possible escalation; and a full activation mode, involving the preparation of proposals for EU action to be decided upon by the Council of the EU or the European Council. See https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/.

[21] Herszenhorn, D. M., & Wheaton, S. (2020, April 7). How Europe failed the coronavirus test. Politico. https://www.politico.eu/article/coronavirus-europe-failed-the-test/

better integrating existing and future legislation and instruments; foster inter-agency cooperation and coordination through more agile and adaptive crisis management structures coordinated by focal hubs (e.g. ERCC 2.0); adopt a more structured approach to the coordination between Member States and the Commission during acute crises; develop forecasting and anticipatory capabilities to be shared between the IPCR, also through platforms for the collection of more and better data; strengthen the joint stockpiling of resources and talent; run training and emergency exercises with decision-makers from different levels of government; improve the provision of integrated, holistic, and transdisciplinary scientific advice during crisis phases; create pre-determined procedures to reallocate research funding in case of crisis and, more generally, make existing EU financial instruments and resources more scalable, rapidly deployable, and efficient. All in all, the direction indicated is an all-hazards, multi-level, whole-of-society approach to the detection and management of crises in the future.

In view of the poly-crisis age, the European Commission responded, inter alia, by adopting a Communication and a Recommendation setting new Disaster Resilience Goals, based on five pillars (*anticipate*, *prepare*, *alert*, *respond*, and *secure*), mostly revolving around the role of the Union Civil Protection Mechanism; and announcing that the ERCC 'will further strengthen its role as a central hub in a network linking all crisis management actors, respecting existing competencies'. In particular, for the purposes of this report, the 'respond' pillar entails a strengthening of the rescEU strategic reserve, and regularly reviewing the overall capacity of the Union to face extreme risk scenarios. In the health domain, the Commission Recommendation contains specific indicators and targets related to the treatment capacity of the UCPM, and its emergency medical teams; and also on medical evacuation and mobile laboratory analysis.[22]

Finally, on 8 June 2023 the Council of the EU, under the Swedish Presidency, issued important conclusions on 'strengthening whole-of-society resilience in the context of civil protection, including chemical, biological, radiological and nuclear (CBRN) preparedness', which echo the contribution of the Group of Scientific Advisers. Among other recommendations, the Council observes that during an activation of the IPCR in relation to possible CBRN incidents, the informal Crisis Communicator's Network should be tasked to enhance communication to the public, ensuring coherent 'messaging on different aspects of the ongoing crisis'; and explore 'possibilities for joint communication, information actions and efforts in relation to possible CBRN incidents'.

[22] European Commission, Commission Recommendation of 8 February 2023 on Union disaster resilience goals (2023/C 56/01), *Official Journal of the European Union*, 15 February 2023.

3. CRISIS MANAGEMENT IN THE HEALTH DOMAIN: A BIRD'S EYE VIEW OF THE REFORMS INTRODUCED AFTER COVID-19

The COVID-19 pandemic has led EU institutions to take action and introduce sectoral, institutional and regulatory reforms to better equip the Union in case of severe and/or multiple crises, which have significantly changed the landscape of crisis management and response in this domain. The governance of public health crisis management and response was revamped with the adoption of two important regulations: Regulation (EU) 2022/2371 on serious cross-border threats to health and Council Regulation (EU) 2022/2372 on a framework of measures for ensuring supplies of medical countermeasures. In addition, the strengthening of the mandates of EMA and ECDC, the establishment of HERA, and the creation of the Health Crisis Board during an emergency have transformed the EU top-level governance framework. These institutional and regulatory reforms under the European Health Union rely on the current Treaty provisions, notably the Treaty on the Functioning of the European Union.[23] Below, we briefly outline these reforms with a view to enable a critical assessment of their fitness-for-purpose, consistency and effectiveness, which will be provided in Section 4.

3.1 THE NEW REGULATORY FRAMEWORK ON CROSS-BORDER HEALTH THREATS

Regulation (EU) 2022/2371 on serious cross-border threats to health, adopted on 23 November 2022, lays down the legal framework for EU actions to prevent and respond to future threats such as pandemics.[24] It repeals Decision No 1082/2013/EU. Some of the most important elements of the Regulation include:

i) a strengthened Health Security Committee (HSC);
ii) prevention, preparedness and response planning at national and EU level;
iii) joint procurement of medical countermeasures;
iv) a strengthened, integrated surveillance network at EU level;
v) a new risk assessment framework;
vi) recognition of a public health emergency at Union level; and
vii) the introduction of an Advisory Committee on public health emergencies.

[23] See the Commission's Communication of 11 November 2020 on building a European Health Union: reinforcing the EU's resilience for cross-border health threats, and the Commission Decision of 16 September 2021 establishing HERA.

[24] In EU legislation, a 'serious cross-border threat to health' means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin, which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection.

Below, we outline the key provisions of the Regulation, with a specific focus on the 'response' phase of health crisis management, in line with the scope of this report.

Under the Belgian Presidency in 2001, the Health Security Committee (HSC) was set up as an informal coordination and cooperation group on health security at European level.[25] Under the Belgian Presidency in 2010, the Council conclusions reiterated the instrumental role of the HSC in coordinating Member States' responses to the H1N1 pandemic, and emphasised the need to solidify the Committee with sounder legal footing.[26] Subsequently, the HSC was formalised under Decision 1082/2013/EU.[27]

Regulation (EU) 2022/2371 further reinforces the role of the HSC.[28] Notably, it provides the basis for the HSC to provide opinions and recommendations to better support EU Member States, and coordinates the European Commission and the Member States' actions in case of a cross-border health threat, including all phases of prevention, preparedness and response, as well as risk-crisis communication. The Regulation also introduces a representative from the European Parliament to participate in the HSC as an observer, and further mandates that the HSC and the Commission consult with public health experts, stakeholders and international organisations (notably WHO) on a regular basis.

Regulation (EU) 2022/2371 also contains important provisions on future prevention, preparedness and response (PPR) planning in the EU. It mandates that the European Commission, in cooperation with the Member States, develop an EU PPR plan, which reflects the need for multi-level, inter-institutional cooperation. The plan is expected to undergo stress tests, exercises and reviews. In parallel, Member States must act and report on their PPR plans by 27 December 2023, and every three years thereafter. Based

[25] Council of the European Union, 2586th Council Meeting: Employment, Social Policy, Health and Consumer Affairs, ec.europa.eu/commission/presscorner/detail/en/PRES_04_163

[26] Council of the European Union, Council conclusions on Lessons to be learned from the A/H1N1 pandemic – Health security in the EU, 13 September 2010, available at https://data.consilium.europa.eu/doc/document/ST-12665-2010-INIT/en/pdf. The Council conclusions were followed by the Commission Staff Working Document of 18 November 2010, available at https://health.ec.europa.eu/system/files/2016-11/commission_staff_lessonsh1n1_en_0.pdf

[27] It meets regularly, based on circumstantial requirements, Commission and/or Member State request. The HSC adopts its rules of procedure by a two-third majority, which include procedures of meetings, the participation of experts, and the arrangements for the HSC to examine the relevance to its mandate. The Committee was the main coordination forum in the early phase of the Covid-19 pandemic, where representatives from the Member States, the Commission, ECDC and occasionally EMA came together weekly to exchange latest information.

[28] Its tasks more concretely are to i) support information and experience sharing; ii) facilitate a coordinated response and preparedness plan with the Member States and the European Commission; and iii) coordinate the risk and crisis communication of Member States. The HSC is chaired by a Commission representative and consists of representatives from the health ministries of Member States together with five observing nations

on these national reports, the Commission shall open a discussion in the HSC on the progress and gaps in the plans. The strengthened ECDC will then assess every three years the state of implementation of the national plans and their fitness with the Union PPR plan, issuing recommendations where needed. The HSC will continue to play a key role in ensuring multi-level coordination, through activities such as sharing of best practices and experience; the active promotion of interoperability between national and the multi-sectoral Union-level PPR planning; monitoring the gaps identified in the plans; and facilitating the exchange of information on medical countermeasures (outside of the joint procurement procedure), including pricing and delivery dates.

The Regulation also provides the preconditions for permanent multi-level and inter-institutional coordination of the Union's response to cross-border health threats. This occurs through the Early Warning and Response System (EWRS), in which EU institutions and Member States notify alerts related to cross-border health threats. When an alert is issued, the Commission shall make available at its own initiative, or at the request of a Member State or the HSC, a public health risk assessment on the severity of the public health threat, including possible measures. Such risk assessment can be carried out by one or more of the relevant EU technical bodies, including ECDC, EMA, the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

Article 24 of the Regulation establishes an Advisory Committee on public health emergencies, which if requested by the HSC or the European Commission advises on whether a threat constitutes a public health emergency at Union level, as well as on potential response measures, and on whether the emergency has ended.[29] The formal competence to recognise a public health emergency rests with the European Commission, which before making the decision must take into account the opinion of ECDC or other relevant EU agencies, and the Advisory Committee. A formal recognition of a public health emergency at Union level has the legal effects of enabling the following measures:

[29] The Advisory Committee is composed of independent experts selected by the Commission, and may include health and social care workers, and civil society representatives. ECDC and EMA representatives will be permanent observers. Membership in the Advisory Committee shall foster multi-disciplinarity to address the health threat at stake from a public health, economic, biomedical, social and other lenses. Meetings of the Committee can be called on an ad hoc basis, at the request of the Commission, the HSC or a Member State.

1. measures related to medicinal products and medical devices (under EMA's responsibility);
2. mechanisms to monitor, develop, procure, manage and deploy medical countermeasures;
3. activation of support from ECDC to mobilise and deploy the EU Health Task Force; and
4. activation of the Integrated Political Crisis Response (IPCR) Arrangements.

After an emergency has been recognised, most of the mitigating measures will be designed and implemented by the Member States, while at Union level the Commission will manage joint procurement of relevant medical countermeasures subject to a prior agreement, as well as an *ex ante* assessment by the European Commission.[30] However, Article 22 of the regulation allows for the possibility for the Commission to adopt recommendations on common temporary measures and to notify Member States through the EWRS and to the HSC.

Regulation (EU) 2022/2371 in principle strengthens the surveillance, coordination and response throughout the Union. At the same time, it introduces several new bodies and procedures, which, without a clear division of labour, add to the complexity of the system without offering sufficient certainty as to what would happen in case of a public health emergency. This applies also to the preparedness and surveillance phases of crisis management, which fall outside the scope of our analysis in this report. More importantly, Regulation (EU) 2022/2371 hardly refers to the role of other bodies, which feature prominently in Council Regulation (EU) 2022/2372. These include in particular HERA (mentioned only three times in the text) and the Health Crisis Board (HCB – mentioned only twice in the text).

Council Regulation (EU) 2022/2372 introduces measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency. Here, upon the recognition of a public health emergency, the European Commission can propose to the Council to decide whether to adopt a regulation to activate an emergency framework, which entails, inter alia, the activation of the HCB and the adoption of emergency measures on the monitoring, development, production, procurement and purchase of

[30] Before the launch of a new procedure, the Commission shall prepare an assessment of the conditions of the joint procurement, the potential limitations on parallel procurement and negotiation processes by the participating states. Based on this assessment and information on predicted pricing, delivery times, and deadline for indicating participation, the parties to the Joint Procurement Agreement shall demonstrate their interest in participating.

crisis-relevant medical countermeasures.[31] The HCB consists of one representative from each Member State and is co-chaired by the European Commission and the Member State holding the presidency of the Council of the European Union. It is tasked with ensuring the coordination of crisis-relevant medical countermeasures at Union level and shall be the central decision-making body within the EU governance framework over MCMs. It is supported by the Commission through ad hoc working groups and the preparedness and response planning carried out by HERA. The HCB acts by a two-thirds majority if a consensus cannot be reached, with one vote given to each Member State.

The HCB shall guarantee the involvement of all relevant EU agencies, EMA, ECDC, the Advisory Committee. Representatives from the European Parliament, a Member State representative of HSC, and when deemed appropriate a representative of WHO, shall also be invited as observers. The HCB also coordinates with the IPCR. Importantly, the HCB has the final say on the mechanism to be used for the procurement of relevant medical countermeasures, and in particular whether existing or new contracts should be relied upon, and whether a joint procurement procedure (as detailed in Article 12 of Regulation (EU) 2022/2371) should be used. In this respect, the HCB shall advise the Commission to act as a central purchasing body of crisis-relevant MCMs. Member States have, in this context, significant powers and discretion through the HCB. Moreover, Member States can opt out of the joint procedure within five days of the Commission concluding the contract, and the Commission can also add contracting authorities (including Member States) that are not identified in the procurement procedures after the signing of the contact (Article 8).

Council Regulation (EU) 2022/2372 also assigns to the Commission the responsibility to monitor crisis-relevant medical countermeasures and to take measures to ensure the supply chain thereof. The Regulation also provides the legal mandate for the Commission to activate the Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing (EU FAB) facilities, funded under the HERA annual work plan in cooperation with the European Health and Digital Executive (HaDEA); and the emergency research and innovation aspects of the Union PPR plan as referred to in Regulation (EU) 2022/2371 (in coordination with EMA Emergency Task force, the European Clinical Research Infrastructure Network, and ECDC).

[31] Article 3 (5) of the Regulation states that the regulation activating the emergency framework shall be without prejudice to the overall coordination role of the Emergency Response Coordination Centre (ERCC) under the Union Civil Protection Mechanism (UCPM), and the political coordination role of the Integrated Political Crisis Response (IPCR).

All in all, Regulations 2317 and 2372 show a complex and ambiguous governance of public health emergency response at the EU level in which the roles of some institutional bodies may significantly overlap with those of other bodies (e.g. the EWRS and the HSC). Although the two regulations are confined to some specific areas of public health emergency response, it is far from obvious that the strengthened or newly created institutional bodies would not encounter frictions with other existing cross-sectoral mechanisms, such as the IPCR or the UCPM (in particular ERCC 2.0).

3.2 INSTITUTIONAL REFORMS: STRONGER INSTITUTIONS AND NEW BODIES

The governance arrangements outlined above are accompanied by the reinforced mandate of existing institutions such as ECDC and EMA, as well as the creation of a new service inside the European Commission (HERA). Without pretending to be exhaustive, below we briefly take stock of the role each of them is expected to play in times of public health emergency.

3.2.1 European Centre for Disease Prevention and Control (ECDC)

Regulation (EU) 2022/2370 extends the mandate of ECDC, which enables it to develop real-time epidemiological surveillance capacity and to provide non-binding recommendations and options for risk management to EU Member States, which are often proactively requested by Member States. Following the increased role of ECDC in the HSC during the COVID-19 pandemic (Deruelle & Engeli, 2021), a major change of Regulation (EU) 2022/2370 is that it explicitly states that ECDC shall support the work of the HSC.[32] More specifically, in the area of response coordination, Article 8b states that ECDC shall support the HSC in the case of a serious cross-border threat to health by providing science-based recommendations and options for: (i) national or cross-border interregional responses to the serious cross-border threat to health; and (ii) the adoption of guidelines for EU Member States for the prevention and control of the serious cross-border threat to health. Regulation (EU) 2022/2370 states the obligations of Member States, which shall notify ECDC of any serious cross-border threats to health, as soon as

[32] Article 3 specifies that ECDC must undertake the following non-exhaustive list of tasks: Search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information; Develop in collaboration with Member States relevant common indicators for risk assessments; Provide analyses, advice , opinions, guidelines, recommendations and support for actions by the Union and Member States; Promote and coordinate the networking of bodies, organisations and experts; Facilitate exchanges of information, expertise and best practices; Monitor in cooperation with Member States their health system capacity; Support national monitoring of response; Provide, at the request of the Commission or the HSC, or on its own initiative, guidelines, recommendations and proposals for coordinated action for case diagnosis and case management of communicable diseases, in cooperation with national and international organisations while avoiding any duplication of existing guidelines; Provide, at the request of the Commission or the HSC, or on its own initiative, timely and easily accessible and evidence-based communication messages to the public on communicable diseases.

detected, through the EWRS provided for under Article 18 of Regulation (EU) 2022/2371. Finally, the new mandate introduces the ability of ECDC to mobilise an EU Health Task Force to assist Member States in their preparedness and response to public health emergencies.

3.2.2 European Medicines Agency (EMA)

Regulation (EU) 2022/123 extends the mandate of EMA.[33] The Emergency Task Force (ETF), which was instrumental during the COVID-19 pandemic in providing support to pharmaceutical companies for marketing authorisations of vaccines, is institutionalised under this regulation. The ETF, in liaison with existing committees, working parties and advisory groups of EMA, provides scientific advice and reviews the data on medicinal products that have the potential to address a public health emergency. It also supports clinical trials and provides scientific recommendations on the use of any potentially useful medicinal products. Another important new task allocated to EMA is the monitoring and reporting of medicine shortages. In particular, the Medicine Shortages Steering Group (MSSG) for medicinal products and the Medical Device Shortages Steering Group (MDSSG) for medical devices are established within EMA. The MSSG and the MDSSG consist of a representative of EMA, a representative from the Commission and one representative appointed by each Member State. Both the MSSG and the MDSSG are co-chaired by EMA and the Head of the Medicines Agencies.

3.2.3 Health Emergency Preparedness and Response Authority (HERA)

The Health Emergency Preparedness and Response Authority (HERA) was established as a Commission service (instead of an independent authority) by Commission Decision of 16/9/2021, adopted by the Council on 24 October 2021.[34] Article 2 of the Decision states three overarching objectives for HERA: i) strengthening health security coordination within the Union during preparedness and crisis response phases, and bringing together EU Member States, the industry and the relevant stakeholders in a common effort; ii) addressing vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures; and iii) contributing to reinforcing the global health emergency preparedness and response architecture. The tasks assigned to HERA are all related to MCMs, and include intelligence gathering, promoting advanced R&D, boosting the Union's open strategic autonomy; swift procurement and distribution; increasing

[33] The European Commission, 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, 25 January 2022.

[34] European Commission, Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority, 16 September 2021.

stockpiling capacity and strengthening knowledge and skills in preparedness and response.[35] HERA is led by the HERA Board, which consists of representatives from the Commission and Member States. The HERA Board helps prepare HERA's strategic planning and set objectives. The Board is not only a bridge between the Commission and Member States concerning MCMs, but also a key communication channel where the industry and the research community can share their opinions.

HERA works in two operating modes, a preparedness and a crisis mode. When in crisis mode, HERA is expected to work under the direction of the Health Crisis Board.

DG SANTE

DG SANTE oversees the implementation of the Regulation (EU) 2022/2371, ensuring and supporting Member States' prevention, preparedness and responses to the emergency.

Table 2. Summary of the EU public health emergency response framework

EU Public Health Emergency Response Framework			
	Legislation	Main functions	Governance
Health Crisis Board	• Council Regulation (EU) 2022/2372	• Set up only after the activation of a public health emergency framework of measures on medical countermeasures • Coordinate approaches between the Commission, the Council and agencies • Provide opinions to the Commission	• Co-chaired by the Commission and the Council Presidency • One representative from each Member State • Observers include representatives from Health Security Committee, the Parliament, ECDC, EMA and WHO, determined by the rules of procedure
Health Security Committee	• Decision 1082/2013/EU • Regulation (EU) 2022/2371	• Discusses regularly issues on serious cross-border threats • Adopt opinions and guidance for a better EU response to health emergencies	• Chaired by a representative of the Commission without the right to vote • One representative from each MS • Observers include one representative from the Parliament, and also representatives from EEA non-EU members, Serbia and Turkey
HERA	• Commission Decision (2021/C 393 I/02)	• Assess health threats and gather intelligence relevant to medical countermeasures (MCMs)	• Officials of the Commission

[35] For a more detailed analysis, see Renda et al. (2023), https://www.ceps.eu/ceps-publications/improving-the-mission-governance-and-operations-of-the-eu-hera/.

		• Promote research and development of MCMs and related technologies • Address market challenges and boost the Union's open strategic autonomy • Procure, stockpile and distribute MCMs • Strengthen knowledge and skills related to MCMs	• Overseen by HERA Board and advised by the HERA Advisory Forum • HERA Board consists of representatives from MS
ECDC	• Regulation (EC) 851/2004 • Regulation (EU) 2022/2370	• Perform epidemiological surveillance • Provide non-binding recommendations on risk management • Build a network of reference laboratories	• Management Board consists of representatives from Member States, the Parliament and the Commission • Advisory Forum is composed of senior officials from national public health institutes and agencies, and a representative from the Commission • Director office supported by five units • Audit Committee
EMA	• Regulation (EU) 2022/123	• Evaluate marketing authorisation applications of medicinal products • Monitor medicine shortages	• A management board consists of 36 members who do not represent any government, organisation or sector • The Executive Steering Group of Shortages and Safety of Medicinal Products (MSSG) • The Medical Device Shortages Steering Group for medical devices (MDSSG) • An executive director supported by the agency's staff • Seven scientific committees • Working groups composed of experts from national competent authorities of Member States

Advisory Committee on public health emergencies	• Regulation (EU) 2022/2371	• Provides advice to the Commission or the HSC at their request on:
		  ○ The recognition of a public health emergency at Union level;
		  ○ The termination of a public health emergency at Union level;
		• Response measures.
			• Composed of independent experts, which may include representatives of healthcare and social care workers and civil society representatives, selected by the Commission according to their fields of expertise and experience
			• Representatives of ECDC and EMA as permanent observers
			• Option to have representatives of WHO as observers
			• Representatives of other Union agencies or bodies relevant to a specific threat as non-permanent observers

Integrated political crisis response (IPCR) arrangements in the Council	• Council Decision 2014/415/EU • Council Implementing Decision (EU) 2018/1993	• Activated by the Council in the event of a terrorist attack or a natural or man-made disaster • Support arrangements for solidarity clause • Provide an informal roundtable • IPCR information sharing mode obliges the Commission and the European External Action Service (EEAS) to draft an Integrated Situational Awareness and Analysis (ISSA) report • IPCR full activation entails the preparation of proposals for action prepared at the presidency-led roundtables	• Informal roundtables convened by the Presidency with the support and advice of the General Secretariat of the Council
Emergency Response Coordination Centre (ERCC)	• Decision No 1313/2013/EU	• Ensures 24/7 operational capacity for Union Civil Protection Mechanism (the Union Mechanism) • Assist with a response to immediate adverse consequences of a disaster following a request for assistance through the Union Mechanism	• A permanent body • A voluntary pool of pre-committed capacities from Member States, trained experts • A Common Emergency Communication and Information System (CECIS) managed by the Commission

4. LANDSCAPE OF THE EU'S RESPONSE TO FUTURE HEALTH CRISES

The institutional and regulatory reforms introduced since the COVID-19 pandemic are considerably extensive, however most of them have not been tested against an actual public health emergency. Against this backdrop, this section attempts to take stock of the reforms and to build an overview on how the EU public health emergency response framework would unfold in the event of a health crisis.

Figure 2 presents a visual illustration of the EU governance of public health emergency. The left-hand side of the diagram shows the institutional bodies involved in actions before a public health emergency is declared at EU level (the Preparedness phase). Then follows a major step which is the Commission's recognition of a public health emergency at Union level. The Advisory Committee on public health emergencies, ECDC and other relevant agencies and bodies can provide opinion to the Commission on recognising such a public health emergency. The Commission's recognition of a public health emergency at Union level has the legal effects of enabling the introduction of the following measures:

1. measures on the monitoring of medicinal products and medical devices, and EMA Emergency Task Force provided under Regulation (EU) 2022/123;
2. mechanisms to monitor, develop, procure, manage and deploy medical countermeasures in accordance with Article 12 of Regulation (EU) 2022/2371, Regulation (EU) 2022/123, and Council Regulation (EU) 2022/2372;
3. activation of support from ECDC to mobilise and deploy the EU Health Task Force; and
4. activation of the Integrated Political Crisis Response (IPCR).

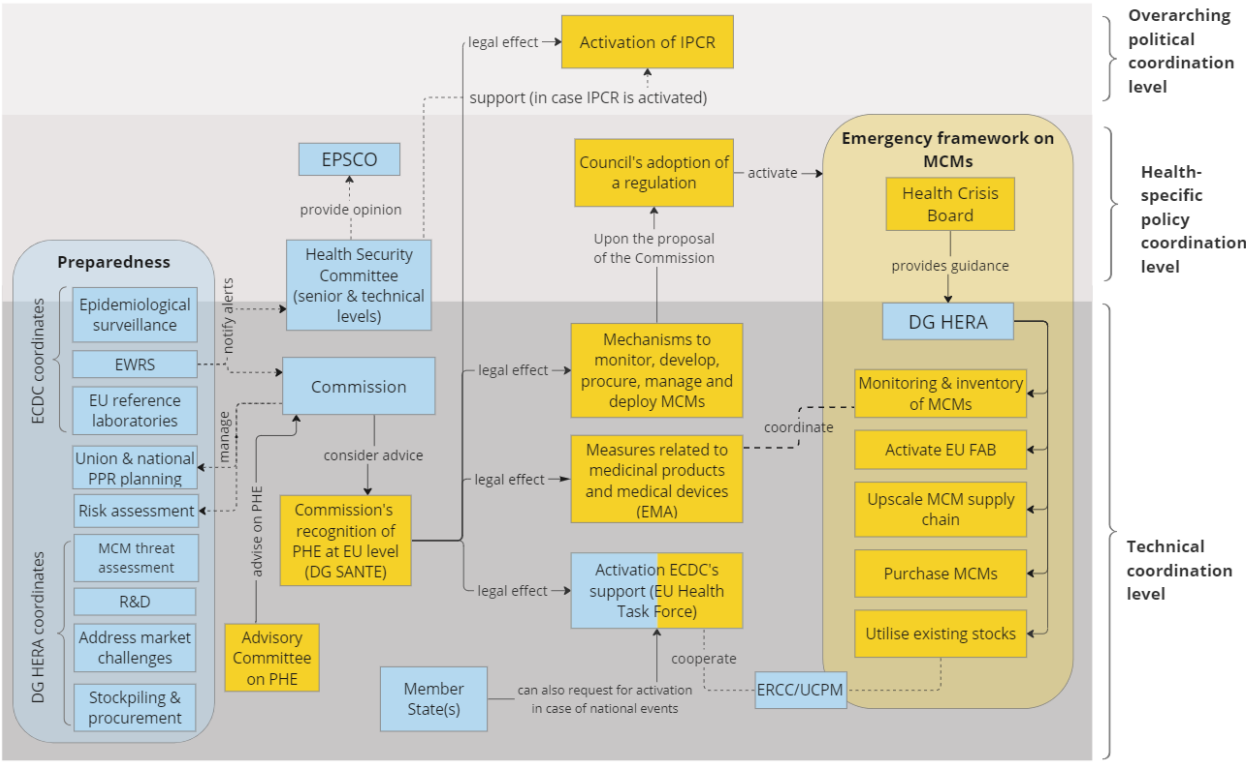
The right-hand side of the diagram illustrates the chain of events following the Commission's recognition of a public health emergency at Union level. Upon the Commission proposal, the Council activates an emergency framework for ensuring the supply of crisis-relevant medical countermeasures (Council Regulation (EU) 2022/2372).[36] The activation of the emergency framework establishes the Health Crisis Board (HCB), which then acts as the coordinator between the Council, the Commission, EU bodies and agencies, and EU Member States to ensure the supply of relevant countermeasures. The HCB will provide guidance to the Commission (particularly HERA) to implement actions related to the monitoring, procurement, funding, development, production and, to a certain extent, distribution of relevant MCMs. Meanwhile, the HSC acts as the highest body in the EU for health security. It can issue opinions and guidance

[36] Six months after the activation of the emergency framework, the emergency framework will be terminated unless the Council decides to extend it. If the Commission decides to terminate the recognition of the public health emergency at any point, the emergency framework will also be terminated.

for Member States, ensuring the sharing of information and cooperation among Member States.

Six months after its activation, the emergency framework will be terminated unless the Council decides to extend it. If the Commission decides to terminate the recognition of the public health emergency at any point, the emergency framework will also be terminated.

Figure 2. Institutional landscape of the EU's health emergency response



Source: Authors' compilation.

Note: Blue boxes depict permanent EU institutions, bodies, measures cross-border threats to health; and yellow ones depict those deployed during a public health emergency at Union level

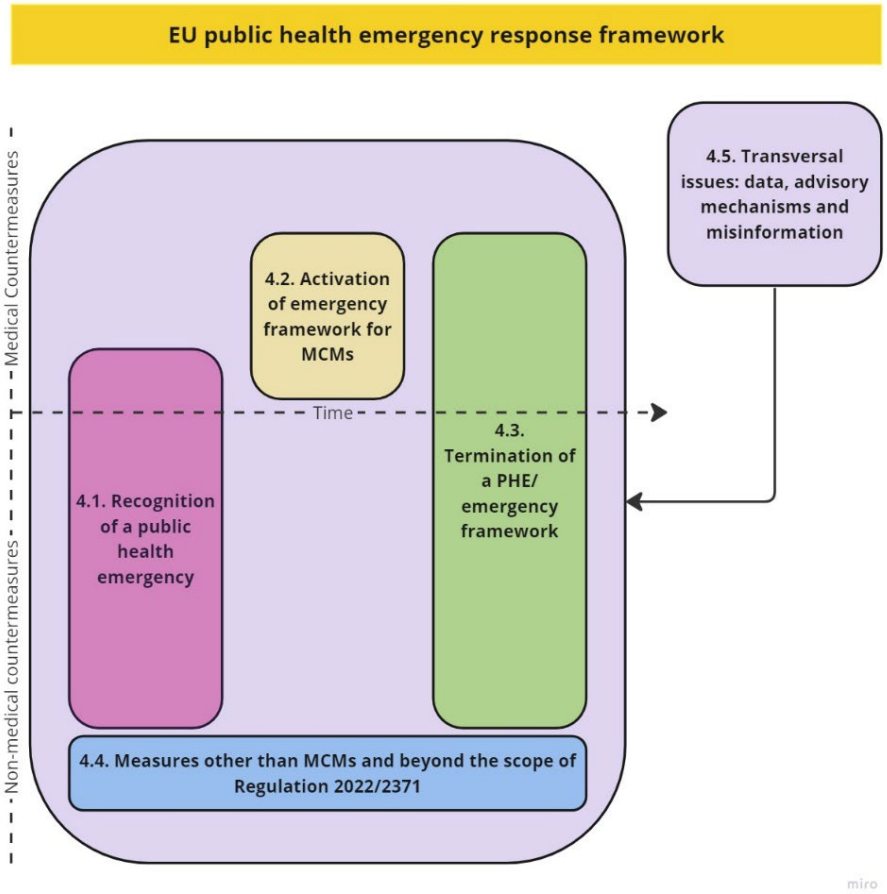
The EU Health Task Force has both blue (preparedness) and yellow (emergency) colour because it can be activated both by requests from Member States for local events and by the Commission's recognition of public health emergency (PHE) at Union level

Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372 are designed to target specific objectives within a confined scope. Regulation (EU) 2022/2371 provides the Commission the legal basis to 'recognise' a public health emergency that leads to some legal effects, including new tasks for ECDC and EMA. It also requests the Council to activate an emergency framework of measures concerning crisis-relevant MCMs laid down by Council Regulation (EU) 2022/2372. Nevertheless, there are other areas of emergency response which these the two regulations do not directly address, such as border closure. For public health and social measures (PHSMs), new institutional and

regulatory changes are far fewer compared to the area of MCMs.[37] The HSC may serve as the main communication channel and coordination venue for PHSMs among Member States. However, given the limited share of competence of the Union over national health policy, any centralised EU action over PHSMs could only come from a consensus inside the Council, very likely through the IPCR or the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO).[38]

Despite this seemingly straightforward workflow, the research team identifies some ambiguities and problems in the public health emergency response framework. To better structure the logic of our discussion, the rest of this section follows Figure 3, which provides a visual illustration of the ideas.

Figure 3. Visual illustration of the ideas in Section 4



[37] In this work, we define PHSMs in a way that they cover the measures other than MCMs.

[38] EPSCO is responsible for three main streams of policies, namely, consumer policy, health protection policy, and social and employment policy. During the pandemic, ministers from the Member States discussed any relevant pandemic policies in sessions of all streams. For example, the meetings of employment and social affairs ministers discussed and exchanged views about remote working and also the rise in domestic violence during lockdowns.

The x-axis refers to the flow of time. In particular, the analysis identifies three stages of a public health emergency, namely, recognition of a public health emergency by the Commission (Section 4.1), activation of emergency framework on MCMs by the Council (Section 4.2), and termination of a public health emergency or an emergency framework (Section 4.3). However, the EU's actions in these three stages do not necessarily cover the same scopes. More specially, the recognition of a public health emergency, based on Regulation (EU) 2022/2371, leads to effects beyond MCMs while the activation of an emergency framework concerns crisis-relevant MCMs only. The above also explains the rationale of the y-axis. This axis refers to the nature of an emergency response, which falls either within the scope of MCMs or PHSMs. In the category of PHSMs, there are measures not covered directly by either Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372 (Section 4.4), for example, border closure. Finally, there are important areas transcending scope and time, such as data availability, advisory mechanism and management of mis- and disinformation (Section 4.5).

4.1 RECOGNITION OF A PUBLIC HEALTH EMERGENCY

4.1.1 Issues related to the monitoring and risk assessment of health threats

Issue 1: Overlapping competences and mandates between the different European bodies on threat monitoring and assessment

Several EU agencies and bodies are involved in threat monitoring and risk assessment at EU level.

Regarding threat monitoring, ECDC, HERA and EMA continuously and jointly conduct this task in collaboration with Member States, other EU agencies and international partners. The mission of ECDC is to 'identify and assess current and emerging threats to human health from communicable diseases and related special health issues' (Article 3(1) of Regulation (EU) 2022/2370), and EMA is tasked under its reinforced mandate to continuously monitor any event that is likely to lead to a public health emergency (Article 4(1) of Regulation (EU) 2022/123). Similarly, HERA is responsible for the assessment of health threats and intelligence gathering relevant to MCMs.[39] In that sense, ECDC, EMA and HERA are tasked with similar responsibilities, such as epidemiological surveillance, modelling and forecasting, and threat prioritisation.

[39] Article 2(2a) of Commission Decision CI 393/3.

Acknowledging these potential overlaps, in March 2023, HERA signed working arrangements with both ECDC and EMA, listing their identified areas for collaboration, notably the assessment of serious cross-border health threats.[40] Accordingly, HERA and ECDC will work together through collaboration, coordination and information exchange on threat prioritisation relevant to medical countermeasures; epidemic intelligence relevant to medical countermeasures; epidemiological surveillance relevant to medical countermeasures; and laboratory activities.[41] Similarly, HERA and EMA intend to share information and data on their intelligence gathering, horizon scanning and threat assessment activities in the area of medical countermeasures, including on priority health threats.[42] Yet, how the collaboration will take place in practice and how coordination will save duplicate efforts are uncertain, especially considering that other European bodies and mechanisms also monitor public health threats (such the ERCC, EEA, ECHA, EFSA, etc.).

Regarding threat assessment, Regulation (EU) 2022/2371 stipulates the Early Warning and Response System (EWRS) – a coordinated EU alert notification and risk assessment system through which national competent authorities and the Commission issue an alert about the development of serious cross-border health threats (Article 19). Article 20 states that a public health risk assessment is to be undertaken by each agency or body (ECDC, EMA, EFSA, ECHA, EEA, EMCDDA) if the threat falls under their mandate. If it totally or partially falls outside these mandates, it is the Commission that conducts an ad hoc assessment. Article 20(1) also states that the assessment needs to be made in cooperation with Europol when the threat emanates from terrorist or criminal activity and with EMA when it is linked to medicinal products. While this appears to be a clear distinction of roles depending on the case at play, in practice this cooperation could become much more complex in the case of a hybrid or multifaceted crisis.

Issue 2: Lack of transparency in the prioritisation of health threats

A scientific-based, transparent and inclusive prioritisation of health threats is crucial for the EU to allocate appropriate effort and resources to preparedness activities. The composition of stockpiles needs to adapt to the ever-changing landscape of public health threats – e.g., the medical countermeasures required to control respiratory viruses are very different from those for climate change-induced health consequences (Wouters et al., 2023). At the EU level, at least two bodies, HERA and ECDC, are tasked with identifying top-priority health threats at EU level. While ECDC has adopted a transparent tool for

[40] See https://health.ec.europa.eu/latest-updates/hera-signs-agreement-ecdc-and-ema-strengthen-cooperation-health-emergency-preparedness-and-response-2023-03-14_en

[41] See https://health.ec.europa.eu/system/files/2023-03/hera_ecdc_working-arrangements_en.pdf

[43] See ECDC tool for the prioritisation of infectious disease threats (europa.eu)

prioritisation based on its multi-criteria analysis,[43] HERA works on prioritising threats in relation to MCMs. For example, on 12 July 2022, HERA announced a list of the three most pressing health threats.[44] This list informs the EU's strategic agenda for the development, production capacity and scaling-up of manufacturing, procurement and potential stockpiling of crisis-relevant medical countermeasures. Reportedly, HERA identifies the priority health threats in consultation with Member States, Union and national agencies, international stakeholders and experts.[45] Besides a brief factsheet, no further publications with detailed explanation of the methodology of the prioritisation exercise carried out by HERA seems to be made available to the public.[46] Despite the existence of the HERA Advisory Forum, HERA does not have an independent scientific advisory committee in its governance framework and its interactions with the scientific community remain ad hoc exercises (Renda et al., 2023).

Such a setup raises concerns about the integrity and scientific quality of the prioritisation procedure. This, in turn, would lead to allocating preparedness resources to unnecessary health threat areas while ignoring the more urgent ones. The EU's budget for the rescEU stockpiles of CBRN relevant countermeasures is EUR 580 million in 2023, and over EUR 1.2 billion for the period of 2022-2026.[47] Given its significant financial implication, an independent, inclusive and scientific prioritisation of health threats is therefore critical to strengthening the EU supply chain of crisis-relevant MCMs.

4.1.2 The formal recognition of a public health emergency at Union level

Issue 3: Ambiguities in the factors warranting the recognition of a public health emergency at Union level

Regulation 2022/2371 empowers the Commission to formally recognise a public health emergency based on 'expert opinion'. The Regulation mandates that different EU bodies, such as the European Environment Agency (EEA), ECDC, the Advisory Committee or other relevant Union agencies can give advice to the Commission on an equal footing. There is a lack of a single advisory body who is ultimately responsible for examining available evidence, gathering 'expert opinion' and advising the Commission. The existence of such

[43] See ECDC tool for the prioritisation of infectious disease threats (europa.eu)

[44] The list includes pathogens with high pandemic potential; chemical, biological, radiological, and nuclear threats; and anti-microbial resistance. More information available at the Commission's press release on 12 July 2022.

[45] European Commission's State of Health Preparedness Report 2022, pp. 21-22

[46] European Commission, HERA factsheet – Health Union: Identifying top 3 priority health threats, 8 July 2022.

[47] According to European Commission's State of Health Preparedness Report 2022, p.23

a single advisory organ is particularly crucial should different EU bodies provide different or even contradicting opinions to the Commission. For instance, ECDC might advise the Commission to recognise a PHE at Union level while the Advisory Committee does not. Such a possibility is, however, fairly likely as the Advisory Committee, given its multidisciplinary nature, may take a different approach to risk assessment from ECDC. As it stands now, it is up to the Commission to weigh up different views and make a final decision.

It is also unclear whether the 'expert opinion' necessary for the Commission's decision would be linked to the alert notifications of the EWRS (Article 19). Moreover, Regulation 2022/2371 provides no rule specifying the chain of events preceding the recognition of a public health emergency. To give a benchmark, Regulation (EU) 2022/123 specifies the chain of events for the Commission to recognise a major event following the opinion of EMA's Medicine Shortages Steering Group (Article 4(3)).

Finally, the Commission must liaise with WHO before recognising a PHE at Union level, in order to share its analysis of the situation and inform the international organisation of its intention (Article 23(3) of Regulation (EU) 2022/2371). It is possible that the Commission is advised to declare a PHE at Union level while it does not constitute a PHEIC in the WHO definition. Question marks would thus appear around how the EU should address the health threat. Shall the EU go ahead without the WHO sharing the same opinion? Will the recognition induce negative externalities to non-EU countries?

These questions boil down to a crucial consideration that the Regulation does not address. What will be the downside of recognising a PHE? The Commission could be cautious and recognise a PHE given a minimal amount of evidence. The Commission could be demanding and only recognise a public health emergency given an overwhelmingly amount of data. The choice will be contingent on the health impacts or financial costs to the EU and beyond of recognising a PHE. Would it cause chaos and unnecessary fear? Would it lead to overly protective but economically wasteful behaviours and measure? These questions are related to how far ahead the EU should plan for shortages of crisis-relevant MCMs. For instance, when COVID-19 hit China severely in early 2020, Europe endured shortages of clinical masks and other personal protective equipment because China and East Asia bought up the inventories in Europe. Should the EU have recognised a PHE at the time the virus hit China so that the Union and Member States could have prepared their MCMs, or at the time it hit Europe when shortages of MCMs had already begun?

Issue 4: Potential duplications and inefficiencies in the collection of crisis-relevant medical countermeasure data by EMA and HERA

Regulation (EU) 2022/123 stipulates that the two executive steering groups established within EMA (the Medicine Shortages Steering Group – MSSG (for medicinal products) and the Medical Device Shortages Steering Group - MDSSG (for medical devices)[48] should develop a list of medicinal products and devices critical for a public health emergency. In addition, MSSG and MDSSG should monitor the supply and demand of the products in the list, and report the monitoring results to the Commission and Member States regularly. EMA will set up its own IT platform – the European Shortages Monitoring Platform (ESMP)[49] – to carry out this task in 2025. The ESMP, once fully functional, should be the sole platform where marketing authorisation holders provide required information (such as manufacturing sites, available stocks, potential supply chain vulnerabilities, demand forecast) during public health emergencies or major events.

Meanwhile, Council Regulation (EU) 2022/2372 mandates that in a time of crisis, the Commission (presumably HERA) gathers the monitoring data from EMA, collects additional information that has not been collected by other Union agencies and reports the monitoring results to the HCB, the European Parliament and the Council (Article 7). HERA's Medical Countermeasures Intelligence Platform – to be set up in 2023 – is expected to handle this task.[50]

The joint operation of two Institutions is, of course, not per se a problem. However, it is unclear to what extent their two platforms will collect information separately from Member States and the industry or they will share information to avoid duplication of efforts. Therefore, the two platforms should be carefully designed, and EMA and HERA should communicate and collaborate to avoid imposing additional burden on stakeholders to report data and information during a PHE.

[48] The MSSG members consist of a representative of EMA, a representative of the Commission and one representative appointed by each Member State; the MSSG is co-chaired by EMA representative and one of the MS representatives, according to Articles 3 and 21 of Regulation (EU) 2022/123.

[49] According to the timeline estimated by EMA

[50] The call for tender for HERA's ATHINA system (Advanced Technology for Health INtelligence and Action IT system) was launched on 25 April 2023

Issue 5: Potential challenges in accessing data from Member States and pharmaceutical companies

By right, the recognition of a public health emergency at Union level allows the Commission (notably HERA) to access the data possessed by Member States and economic operators (e.g., pharmaceutical companies). The requested data can be on the manufacturing sites of crisis-relevant MCMs, their estimated shortages, possible causes of the shortages, the supply and demand, potential supply chain bottlenecks, and available alternative products. Articles 9-11 of Regulation (EU) 2022/123 provide EMA with the legal basis to request relevant information on medicinal products from marketing authorisation holders. However, such legal provision does not apply outside emergencies. Meanwhile, continuous monitoring of certain crisis-relevant materials is crucial to quick and effective monitoring during crisis time, e.g., for the case of active pharmaceutical ingredients (McKinsey, 2022).

To complement the above shortcoming, the proposed Pharmaceutical Legislation will provide EMA with the legal basis for continuous monitoring of shortages of critical medicinal products, notably through requesting information from marketing authorisation holders, Member States and other relevant actors (e.g. wholesale distributors, importers of medicinal products) (Articles 116-126, Chapter X).[51] The category of information is, however, limited to that on marketing authorisation holders' decision to cease or suspend the marketing of a medicinal product, their request to withdraw the marketing authorisation of their products, or a temporary or expected disruption in supply of a medicinal product. Compared to the set of information required for an emergency phase (under Regulation (EU) 2022/123, as discussed above), the information requested under the Pharmaceutical Legislation is much less comprehensive and might not help reveal critical supply chain vulnerabilities.

More importantly, the actual implementation of the above legal provisions might depend on Member States' ability and willingness and pharmaceutical companies' willingness to share data:

- As for Member States, the meetings of HERA's Advisory Forum reported national authorities' difficulties to share information on supply and demand of MCM.[52] This might derive from the lack of legal basis to share data during the preparedness time, the confidentiality of data collected from the producers, and the Commission's

[51] European Commission, Reform of the EU pharmaceutical legislation, 26 April 2023. available at: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

[52] On 9 September 2022, 5 December 2022 and 21 March 2023

unclear purposes of such data collection, especially the risk of sharing the demand data further with third parties.[53] Member States' inability to share up-to-date data might hinder the precise forecast of market demand and supply and the EU's effective management of critical countermeasures.

- As for producers of MCMs, much company data (e.g., those on the quantity and origins of raw materials) are considered commercially confidential because of the industry secret elements. In addition, several industrial players also report having a limited overview of their supply chain, as concluded by the feasibility of HERA's COVID-19 Therapeutics mapping platform – a prototype for HERA's future Medical Countermeasures Intelligence Platform.[54] The industry's limited sharing of supply chain data reflects the lack of legal basis for HERA to investigate commercial supply chains during both preparedness and emergency phases. The provision on government access to privately held data in the proposed Data Act, which is currently in the process of trialogue, has the potential to enhance quicker and broader flows of data from business to public authorities. Chapter V of the proposed Data Act enables public authorities to access companies' data during an emergency or for emergency prevention.[55] However, what constitutes an 'emergency' is not well-defined in the Data Act and it is unsure whether it will occur.
- In our interview, Pierre Delsaux, Director-General of HERA, noticed an increasing willingness to share stockpiling data from Member States. The industry also acknowledges the interest in sharing supply chain information, e.g., through HERA's Advisory Forum, and companies have shown some openness and willingness to share information.

4.1.3 EMA Emergency Task Force

Issue 6: The operation of EMA's ETF during a public health emergency may be too resource-intensive

Regulation (EU) 2022/123 iterates that the operation of EMA Emergency Task Force (ETF) will build largely on the good practices witnessed during the COVID-19 pandemic. Indeed, the ETF's accelerated scientific advice process has effectively contributed to EMA's flexible regulatory process during the pandemic, notably the rolling review and the conditional marketing authorisation of medicinal products including COVID-19 vaccines

[53] Minutes of the HERA Advisory Forum on 21 March 2023

[54] Minutes of the HERA Advisory Forum on 5 December 2022

[55] European Commission, Proposal for the Data Act

(Cavaleri et al., 2021). However, the experience of the ETF during the pandemic shows that its operation in the longer term will likely encounter challenges.

More specially, the operation of the ETF involves continuous and intensive communication between the ETF and vaccine developers, frequent publications of guidelines, press briefings, and stakeholder meetings. It would be challenging to sustain the proper functioning of the ETF without additional personnel and financial resources (Beke et al., 2023). Regulation (EU) 2022/123 mentions this area briefly, mentioning that resources for remuneration, travel and accommodation of the ETF rapporteurs should be ensured (Recital 54). It does not however clearly indicate the plan to mobilise sufficient staff to support the work of the ETF when an emergency hits the EU.

4.1.4 Activation of the EU Health Task Force under ECDC's reinforced mandate

Article 25 of Regulation (EU) 2022/2371 states that the recognition of a PHE at Union level would legally enable ECDC to mobilise and deploy the EU Health Task Force (EUHTF). The EUHTF is an EU deployable workforce that would assist Member States and third countries in an operational response to outbreaks of communicable diseases or diseases of unknown origin, either remotely or on the ground. This would notably be done through:

- remote support and rapid in-country field deployment;
- support for outbreak investigations and response;
- provision of science-based recommendations;
- support for operational research;
- provision of guidance, protocols, resources and tools.

Additionally, the EUHTF can support in strengthening countries' emergency preparedness through:

- development, testing and updating of preparedness protocols and plans;
- assessment of preparedness gaps through self-assessments and external evaluation of country preparedness and response planning;
- simulation exercises;
- in-and-after action reviews;
- tailored capacity-building activities and trainings.[56]

The establishment of the EUHTF involves ECDC in the coordination of risk management at Union level and reinforces its role in providing direct support and operational capacity for local response. Articles 11a(1) and 11a(2) of Regulation (EU) 2022/2370 specify that

[56] See ECDC, European Union Health Task Force

ECDC must build a permanent capacity and an enhanced emergency capacity, and also develop a framework to define its organisational structure.[57] According to a podcast published by ECDC on 30 May, this work is currently being undertaken by ECDC.[58] The EUHTF is already operational since the revision of ECDC's mandate was accepted, and can receive requests for support from countries through its permanent capacity.

At the moment, the public health expertise to be mobilised in the EUHTF includes experts in epidemiology, microbiology, infection prevention and control, emergency preparedness and response, and risk communication. The spectrum of expertise may be widened in the future as the EUHTF takes shape and learns from the specific requests it receives. ECDC is currently building mechanisms to rapidly reach and include experts across the EU for the enhanced emergency capacity team, and is working on establishing such an expert pool based on advice from Member States, the Commission, and WHO.[59]

Issue 7: Difficulty in ensuring the readiness of the enhanced emergency capacity team under the EUHTF

Some issues arise regarding the resources needed to set up and deploy these enhanced emergency capacity teams.

First, the availability and interest of experts to participate in the EUHTF is of concern: while their salaries should be ensured by their host institutions during their involvement in the EUHTF and their expenses covered by ECDC, the recruitment of a pool of competent and relevant experts in times of crisis will be challenging. This is especially true if there were a large number of requests for assistance during a large-scale crisis. The challenge of mobilising experts during crises has emerged in other sectors, not only health. For instance, in the area of border control, the European Border and Coast Guard (EBCG) provides an example of capacity deficit during a crisis. The EBCG encountered challenges of mobilising adequate national guards to carry out EU missions in a short time frame. One of the key reasons is that the EBCG relies on deploying national personnel instead of building its in-house European border guards – Member States have to reserve a 'pool' of guards ready for EBCG's missions. The EUHTF can take some lessons from the example of the EBCG (Carrera and den Hertog, 2016) . While the EUHTF is expected to

[57] European Commission, Consolidated text: 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

[58] See the podcast here: https://podcasters.spotify.com/pod/show/ecdc/episodes/Episode-38---Orla-Condell---A-Health-Emergency-Task-Force-e24tood

[59] See https://podcasters.spotify.com/pod/show/ecdc/episodes/Episode-38---Orla-Condell---A-Health-Emergency-Task-Force-e24tood

deploy multiple teams in parallel, it has to be clarified or tested on how it would manage to mobilise sufficient workforce and resources to address a serious cross-border crisis.

Second, while Article 11a(2) of Regulation (EU) 2022/2370 states that the enhanced emergency capacity of the EUHTF shall be mobilised at the joint request of the Commission and Member States, it needs to be clarified whether requests for support can be made by countries on their own. The Regulation does not specify the rule dealing with multiple requests at the same time. The criteria according to which requests are reviewed and accepted by ECDC could be further clarified. One known criterion of prioritisation at the moment is the origin of the request, with an order ranging from EU countries to EU candidate countries, potential EU candidate countries, countries from the EU neighbourhood policy, and third countries.[60]

The expert pool and procedures for the enhanced emergency capacity of the EUHTF should be operational from next year and will be communicated clearly to Member States and stakeholders once it is ready – which will be the first step in clarifying how the task force will actually work in practice.

4.2 ACTIVATION OF THE EMERGENCY FRAMEWORK FOR MEDICAL COUNTERMEASURES

Following the Commission's recognition of a public health emergency at Union level, the Council – upon the Commission's proposal – may activate an emergency framework for crisis-relevant medical countermeasures. It is important to note that Council Regulation (EU) 2022/2372, which provides the ground for this emergency framework, explicitly mentions that the activation of this framework is dependent on whether it is deemed to be 'appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health'. This section discusses the main measures and mechanisms introduced by the activation of this emergency framework and highlights specific issues that could cause uncertainty or inefficiency in the EU response to future public health crises.

Issue 8: Ambiguous relations between Health Crisis Board, HERA and HERA Board

The Health Crisis Board's mandate covers only measures related to the supply of crisis-relevant MCMs. According to Article 3(10) of Regulation (EU) 2022/2371, medical countermeasures are defined as:

> 'medicinal products for human use as defined in Directive 2001/83/EC of the European Parliament and of the Council, medical devices as defined in point 12

[60] As stated by Orla Condell in the ECDC podcast on the EUHTF.

> of this Article and other goods or services that are necessary for the purpose of preparedness for and response to serious cross-border threats to health'.

Prior to the adoption of Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372, HERA, established as a Commission service, is endowed with the mandate to 'improve preparedness and response to serious cross-border threats in the area of medical countermeasures'.[61] HERA should also coordinate and cooperate with Member States, which are represented in the HERA Board.

Recital 4 of Council Regulation (EU) 2022/2372 specifically states the relationship between the HCB and HERA. First, HERA shall support the HCB with preparedness and response planning, which include establishing the rules of procedure of the HCB and drafting negotiating mandates and procedural rules for joint procurement. Besides, the HCB 'should be able to also coordinate, where appropriate, with the HERA Board (referred to in the Commission Decision of 16 September 2021).' Member States are also represented in the HERA Board.

The legal texts however do not specify the chain of command between the HCB and HERA or the HERA Board. To add to the ambiguity, HERA is sometimes mentioned in the legal texts as a separate entity from the Commission while legally HERA is a Commission service.[62] Unless HERA is explicitly mentioned in the legal text for a specific task, it is unclear how the HCB will work with HERA on other tasks.

Judged by the possibility of participation of high-level government figures in the HCB, the HCB will very likely be the leading institutional body making decisions and instructing the Commission/HERA. Nevertheless, the composition of the Board will be critical. It requires a common expectation of the function and power of the HCB among all Member States. The HCB should be populated by high-level government officials who can make decisions on behalf of their corresponding state.

Note that the Commission Decision does not grant HERA the autonomy to conduct joint procurement for Member States and Member States do maintain their strong voice. For example, the EU's joint procurement of monkeypox vaccines signed in November 2022 was in fact laid down by the EU's Joint Procurement Agreement.[63] The Agreement states that at least 4 of the 36 participating countries should be interested in jointly procuring a medical countermeasure, the Commission, or HERA after it was established, shall start a joint procurement process. In the case of the monkeypox vaccine, 14 Member States are

[61] Article 2 of Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority, the European Commission, 16 September 2021.

[62] In Regulation (EU) 2022/2372, 'HERA' is mentioned 9 times, while 'the Commission' is mentioned 98 times.

[63] European Commission, Joint Procurement Agreement to procure medical countermeasures, available at https://health.ec.europa.eu/system/files/2016-11/jpa_agreement_medicalcountermeasures_en_0.pdf

participating, and the vaccine doses are funded through the EU4Health programme.[64] Yet, if an emergency framework is activated and the HCB is set up, the positions of the HCB and the HERA Board in the chain of command are unclear as their relationship is not sufficiently explained in the legislation, considering that Member States will have their representatives in both institutional bodies.

Article 8 of Council Regulation (EU) 2022/2372 states that the HCB 'shall advise the Commission on the appropriate mechanism to purchase crisis-relevant medical countermeasures and raw materials, either through the activation of existing contracts or the negotiation of new contracts, using available instruments…' Yet, a full-fledged description of the chain of command over crisis-relevant MCMs at top-level governance, which would significantly enhance clarity and accountability, and facilitate easier discussion and evaluation of the existing emergency response framework, is missing. This should happen alongside the review of HERA, to be conducted by 2025, which will very likely discuss the possibility of transforming HERA into an independent agency, or of absorbing it into DG SANTE.

Another puzzle concerns the existence of a HERA Crisis Board (not to be confused with the Health Crisis Board). The Commission Decision that established HERA does not mention a 'HERA's Crisis Board', but only a 'HERA Board'. Yet, on the webpage explaining HERA,[65] it is written that: 'Member States are closely involved in the governance of HERA. During the preparedness phase, one representative per Member State sits on the HERA Board. The Board assists and advises the HERA in the formulation of strategic decisions. During the emergency phase, Member States sit on HERA's Crisis Board together with the President of the European Commission, the Commissioner for Health and Food Safety and other members of the Commission as appropriate. It is the Member States through the Council that activates HERA's emergency powers, upon a proposal by the European Commission.'

It is the only appearance of 'HERA Crisis Board' in EU official documents and websites. One might question whether HERA's Crisis Board is only a nominal transformation of the HERA Board during a crisis phase, or is it a distinct entity that co-exists and co-leads HERA with the HERA Board, or is it only a mistake on the HERA webpage. If a HERA Crisis Board were ever to exist in a crisis, what would be the relationship with the Health Crisis Board?

---

[64] European Commission, EU4Health-Performance , available at https://commission.europa.eu/strategy-and-policy/eu-budget/performance-and-reporting/programme-performance-statements/eu4health-performance_en

[65] European Commission, Questions and Answers: European Health Emergency preparedness and Response Authority (HERA), https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_4733 .

Council Regulation (EU) 2022/2372 explicitly states that the Health Crisis Board will be coordinating with the HERA Board, implying that the Health Crisis Board is definitely not a transformation of the HERA Board and designed as an external monitor of HERA. In other words, the HERA Crisis Board, if it were to ever exist, would co-exist with the Health Crisis Board.

Even if the HERA Crisis Board is only a nominal transformation of the HERA Board during a public health emergency, its functions have not been described in any legal texts. No details are given concerning the position of the HERA Board during an emergency. For examples, how frequently the HERA Board will meet, and the level and scope of guidance or intervention are not elaborated.

Issue 9: Potential overlap of mandates of Health Crisis Board, Health Security Committee and EPSCO

The Health Security Committee (HSC) is a permanent body that coordinates the EU's rapid response to serious cross-border threats to health during an emergency.[66] The HSC can adopt opinions and guidance for the Member States on the prevention and control of serious cross-border threats to health.[67] The task of the HSC is not limited to areas related to MCMs.

The HSC is a venue for exchanges of information on public health among EU institutions and agencies, Member States, and external counterparts like WHO. The scope of the HSC is however not explicitly confined to a certain area. The HSC can certainly discuss and exchange information about MCMs, implying certain overlaps between the HSC and the HCB (and the HERA Board, and EPSCO (Health Policy), and perhaps the IPCR). This potential overlaps in the competences of the HSC and HCB and might raise several issues. First, it may not be efficient to separate discussions on MCMs from other public health measures. For instance, measures on border closures can have substantial impacts on the supply chain of MCMs. Second, it may be impossible to do so. For example, in the meeting of the HSC on 24 May 2023,[68] ECDC joined and presented an update on its guidance concerning mpox (monkeypox), which suggested no mass vaccination. In the same meeting, the Commission reported an update of the Transatlantic Taskforce on Antimicrobial Resistance, which has agreed a work plan for mpox covering MCMs. So far, the HSC is a venue for exchanges of health policy-related information. However, with the creation of a new body like the HCB, it is unclear whether during an emergency, crucial information and decisions about MCMs (for example, their stocks, development,

[66] European Commission, Crisis Management, Public Health Webpage.

[67] Article 4, point (3d) of Regulation (EU) 2022/2371.

[68] Health Security Committee, Summary Report, 24 May 2023.

procurement and distribution) will be shared smoothly across the HSC, the HCB and the HERA Board. While it may be necessary to report the same information to different audiences, national governments may prefer a central hub of information. In any case, some pre-emergency planning of the configuration of information exchanges would be helpful. Reportedly, the Commission is working on specifying the coordination between the HSC and the HCB. It is expected that such an exercise takes the above concerns into account.

Another EU body which would add complexity to the EU's health emergency governance is EPSCO. In practice, the dynamics in the HSC is very different from those in EPSCO in that the former has been regarded as a venue of communications rather than decision-making. On the one hand, Member States might assign officials of different seniority levels to the HSC and because of these different seniority levels it can be difficult to reach concrete conclusions. There may be very different expectations among Member States of what the HSC should do and achieve. On the other hand, EPSCO is a Council configuration that gathers relatively higher-level officials from EU Member States which can adopt Council conclusions. Moreover, discussions at ministerial level gives political backing to decisions and allows moving forward on issues stuck at technical level. Therefore, without further empowerment of the HSC, it is unlikely that the HSC will be a key institutional body during an emergency.

Issue 10: Limitation of EU FAB's surge manufacturing capacity to cover future health threats

Expanding the European Union's surge manufacturing capacity is a critical step to guarantee the timely provision of essential medical countermeasures and raw materials, as stated in Article 8(8) of Council Regulation (EU) 2022/2372. The EU Network of Ever-warm Production Capacities for Vaccines and Therapeutics Manufacturing (EU FAB) was established with the goal of ensuring sufficient and flexible manufacturing capacity. Although EU FAB is anticipated to secure ample manufacturing capabilities during public health crises, its efficacy in future public health emergencies is uncertain.

Initially introduced in the Commission's Communication on September 16, 2021, presenting the Health Emergency Response Authority (HERA), EU FAB was designated to reserve production capacity for both vaccines and therapeutics.[69] However, in practice, the scope of this provision seems confined to vaccines only, as outlined in the Commission's factsheet on EU FAB.[70] The first round of EU FAB contracts was tendered

[69] European Commission, Communication on the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union, 16 September 2021.

[70] European Commission, Factsheet – EU FAB, 27 April 2022

in 2022 and is set to be implemented in 2023, specifically focusing on three types of vaccines[71]. To the best of our knowledge, no additional EU FAB call has been published for various other types of critical medical countermeasures.[72]

Future health crises are likely to encompass a broader range of threats beyond vaccine-preventable diseases, including antimicrobial resistance, biotoxins, chemical threats, radiological and nuclear agents, among others. Consequently, there is a pressing need for surge capacity in Medical Countermeasures (MCMs) extending beyond vaccines. However, EU FAB has not yet addressed many other vital categories of crisis-relevant medical countermeasures such as antivirals, antibiotics, diagnostics, personal protective equipment, and more.

In addition to its relatively limited scope, EU FAB requires a substantial budget (EUR 160 million per year) within a confined time frame (maximum of 8 years starting from 2022), as per HaDEA's EU FAB tender specification.[73] One might question the political commitment to sustain and justify the EU FAB budget beyond 2030, particularly when it is considered that this funding does not seem to culminate in actual deliveries of medicines. Political attention is likely to shift towards other priorities apart from public health, mirroring the current situation exacerbated by Russia's invasion in Ukraine and challenges pertaining to inflation, energy security, and supply chains.

Issue 11: Inadequate tools to ensure the availability of manufacturing inputs for the production of medical countermeasures

Ensuring that medical countermeasures are available in sufficient quantity within a certain timeframe is key to efficient responses to public health threats. The COVID-19 crisis, however, revealed vulnerabilities in the supply chain of medicinal products, leading to intense competition among countries for these limited resources at the onset of the pandemic. Back in the 1990s, the EU together with the US and Japan produced 90% of the world's active pharmaceutical ingredients (APIs) – important chemical substances to produce medicines. As the production of APIs is characterised by low fixed cost and high labour cost, most of the production has moved to China and India. When COVID-19 hit, the shutdown of factories in China lead to a reduction in its API export to India, who in turn introduced export restrictions of medicines like paracetamol and antibiotics to the rest of the world (Bayerlein, 2023; Hamilton, 2022). Similarly, in the case of mRNA vaccines or antimicrobials (of which material and active ingredient costs are strong

[71] See the tender information here: https://etendering.ted.europa.eu/cft/cft-display.html?cftId=10547

[72] European Commission, Factsheet – EU FAB, 27 April 2022

[73] HaDEA's technical specification of tenders for the reservation of capacities and a priority right for manufacturing of vaccines, https://etendering.ted.europa.eu/cft/cft-documents.html?cftId=10547

drivers of the total production cost), the cost of producing medicinal products is higher in the EU than in many third countries like China or India (Bayerlein, 2023).

During public health crises, shortages of inputs essential for crisis-relevant MCMs will very likely worsen. As observed during the COVID-19 pandemic, the demand for scarce inputs (such as lipids, bioreactors, glass tubing, vials) increased enormously while multiple manufacturers competed for these resources from a limited number of suppliers. The EU should learn the lesson from the use of priority-rated contracts by the US (under Operation Warp Speed and relying on the Defence Production Act – DPA) to allocate scarce inputs among vaccine manufacturers. Entering a DPA contract with the US government has two major implications: they have priority in accessing vaccine production inputs over a producer without a priority-rating, and they must deliver their contracted quantity of vaccines to the US government before producing for other buyers (Bown and Bollyky, 2021). The DPA proved to be a critical tool to ensure the speed, scale and diversification of vaccine manufacturing in the US in early 2021. In February 2021, the US was the first country outside China to produce 100 million doses of COVID-19 vaccines. At the same time, the use of DPA for vaccine contracts encountered criticism about its transparency. DPA was also seen as an export restriction tool by third countries. Faced with uncertainties of whether they can use the US manufacturing capacity to export vaccines to other countries, towards the summer of 2021, many major vaccine providers (notably Pfizer-BioNTech, Moderna) chose instead to expand their production capacity in the EU and India to meet global demand (Bown, 2022) . The EU should learn from the successes and also limitations of the DPA to build its input allocation policy to ensure sufficient capacities of MCM production in future health crisis (e.g., under the new Single Market Emergency Instrument[74]).

Other strategies to ensure input capacity such as re-shoring the manufacturing of inputs to the EU should ensure the determination to develop advanced manufacturing technologies to offset the cost disadvantage of production in the EU. Such policies should also detach from the practice that cost difference shall be subsidised by public money. One example of advanced technologies is a continuous production system, which is an organised production system that allows inputs and outputs to flow continuously, thus optimising the uses of materials and energy (Hamilton, 2022). Deep technology transfer can also expand the production capacity in the EU (Wouters et al., 2023). To ramp up production capacity, EU bodies managing funding programmes on the R&D of MCMs like HERA or DG RTD must play a strong role in promoting transfers of crisis-critical technologies.

[74] European Commission, Crisis-proofing the Single Market: equipping Europe with a robust toolbox to preserve free movement and availability of relevant goods and services, 19 September 2022, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_22_5443

Issue 12: Lack of EU funding tools to support at-risk investment to upscale manufacturing capacity

A health emergency must be accompanied, besides policy measures, also by an immediate effort to boost research and development of new MCMs, as well as actions to secure the availability of existing ones. The EU supported research and innovation projects and initiatives to tackle the spread of coronavirus and preparedness for other outbreaks, including two emergency calls on Coronavirus research, the HERA incubator call for urgent research into coronavirus variants, and the setting up of two European trial networks to ensure the development of medical countermeasures to fight the COVID-19 pandemic (include footnote to webpage Coronavirus research and innovation (europa.eu)). The COVID-19 pandemic was a revealing moment in this respect, with the European Commission also being involved in providing funding to innovative technologies, such as mRNA, and managing to strengthen its ability to jointly procure vaccines, although partly at the expense of transparency and due process.[75]

The experiences of developing and producing COVID-19 vaccines show how governments can invest in the supply chains of medical countermeasures during an emergency. They also reveal several aspects where the manufacturing of COVID-19 vaccines in the EU lagged behind countries like the US in early 2021.

Article 8 and 12 of Council Regulation (EU) 2022/2372 provide the legal basis for the EU's support to upscale the manufacturing of crisis-relevant medical countermeasures during public health emergencies, notably the procurement or support for production. However, these tools may not be sufficiently effective in redirecting the EU's supply chain of MCMs for the public in future health crises.

Vaccine development and production is a complex process, going from pre-clinical research and development, clinical trials, production, packaging, labelling, to distribution. The process also involves multinational pharmaceutical companies, contract manufacturing organisations (providing manufacturing services to pharmaceutical companies) and regulators (Bown and Bollyky, 2021). Scaling up the production supply chain of crisis-relevant vaccines, particularly those relying on novel technologies such as mRNA vaccines, encountered significant challenges. Many of the potential COVID-19 vaccine candidates did not have their own clinical trials or production capacity before the pandemic. The tremendous global demand for doses further amplified the challenges

[75] Information relating to the preliminary negotiation process of the biggest COVID-19 vaccine contract signed by the Commission as of 2023 (with Pfizer/BioNTech) has not been made available to the European Court of Auditors as requested. Critical information of public interest such as unit prices, liability, and the amount of public funding support during the development phase has not been made available to the public either, raising concerns from, among others, the European Ombudsman.

(Wouters et al., 2021). In this context, public at-risk investment, i.e., investment in advance of regulatory approval of vaccine candidates, played a pivotal role in incentivising companies to develop and manufacture vaccines at scale during the COVID-19 pandemic.

Several factors might explain the relatively quick upscaling of the manufacturing of COVID-19 in the US. The US made considerable at-risk investment through 'Operation Warp Speed'. This initiative coordinated clinical trials and expedited the upscaling of manufacturing supply chain. Operation Warp Speed funding supported the very upstream stage of vaccine manufacturing (from Phase 1 clinical trials) to downstream steps including companies' expansion of manufacturing capacity, production of drug substance, contract for packaging and advance purchase of vaccine doses. In total, the US government had spent more than USD 3 billion on vaccine candidates that did not obtain FDA approval as of July 2021 (Table 3).

Table 3. Public financing support for COVID-19 vaccine supply chains

	The EU*	The US*
Support for non-clinical studies and clinical trials	N/A	USD 6 057 million
• First date	N/A	11 February 2020
• Number of beneficiaries	N/A	6
Support for manufacturing capacity	EUR 175 million	USD 5 835 million
• First date	June 2020	24 May 2020
• Number of beneficiaries	2	9
Contract for 'fill and finish', packaging	N/A	USD 1 359 million
• First date	N/A	5 June 2020
• Number of beneficiaries	N/A	8
Purchase of doses	EUR 2.55 billion**	USD 12 690 million
• First date	August 2020	21 July 2020
• Number of beneficiaries	8	2

Source: Author's compilation of information presented in Bown & Bollyky (2021) and the EU Vaccines Strategy page.
Note: (*) The cut-off dates for the US are 11 February 2020–30 June 2021; the EU: June 2020–November 2021; (**) A proxy for the sum of the EU's APAs is the down payments which the EU made to vaccine manufacturers by the end of 2021, estimated to be EUR 2.55 billion according to a report of the European Court of Auditors on COVID-19 vaccine procurement.

Compared to the US, the EU's investment came at a later stage of the vaccine development cycle and was smaller in amount. The EU particularly lacked adequate financing support in the following steps:

- Transparency is low about the scale of EU funding support for the pre-clinical and clinical trials of crisis-relevant medicinal products during the COVID-19 pandemic. While one can assume that the Commission provided certain upfront de-risking investment to support the development of CureVac,[76] GSK and Nonavax[77] vaccines, the amount of upfront payment given to each company remains unknown as the Commission does not publish this information in their heavily redacted vaccine Advance Purchase Agreements.[78]

- With regards to other stages of the development and production of crisis-relevant medical countermeasures, the EU also seemed also to provide much less financing support than the US. The EU provided only EUR 175 million in 2020 to support the manufacturing capacity of COVID-19 vaccines for two companies (BioNTech[79] and CureVac[80]) through loans. This amount is relatively small compared to that of the US (USD 5 835 million). Our research shows, there is no EU financing support to the production of inputs or packaging of vaccines (e.g. lipids, vials, single use filter bags, fill and finish capacity). Looking forward, HERA's budget would not cover funding for these stages, as indicated in the Communication of 16 September 2021 introducing HERA.

- Another challenge is the readiness of the Emergency Support Instrument (ESI) to support such activities. According to Council Regulation (EU) 2022/2372 and HERA's Work Plan 2022, the EU health emergency activities will mainly rely on the ESI (established under Regulation (EU) 2016/369). It can therefore be assumed that this funding programme will cover the R&D aspect. Nevertheless, as observed during the pandemic, the Emergency Support Instrument provided funding only for non-research activities (notably procurement of vaccines and therapeutics, management of the Vaccine Steering Board, detection and categorisation of COVID-19 variants, data collection).[81] Meanwhile, funding of the development of vaccines mostly ran through the 2020 InnovFin Infectious Disease Finance Facility.[82] Moreover, a large part of funding on preparedness R&D activities are being managed under Horizon

[76] According to the Commission's answer to a parliamentary question.

[77] According to a public hearing with the COVI committee on 10 October 2022.

[78] The Commission publishes its Advance Purchase Agreements through its Vaccines Strategy page.

[79] European Commission's press release of 11 June 2020.

[80] European Commission's press release of 6 July 2020.

[81] HERA Work Plan 2022, pp. 2, 20, 21.

[82] European Commission, Investment Plan for Europe: European Investment Bank to provide BioNTech with up to EUR 100 million in debt financing for Covid-19 vaccine development and manufacturing, press release, 11 June 2020;

European Commission, Commission and EIB provide CureVac with a € 75 million financing for vaccine development and expansion of manufacturing, press release, 6 July 202.

Europe (EUR 389 million for HERA's 2023 R&D budget) and EU4Health (EUR 86 million for the same year).[83] The above entails concerns about how to transfer the knowledge and research outputs from Horizon Europe and EU4Health to projects under Emergency Support Instrument to support R&D of crisis-relevant MCMs.

Generally speaking, the EU's at-risk investment came at later stage of the vaccine development cycle and was of a lower amount than the US. The EU's upfront investment was concentrated on end products through its advanced purchase agreements. As for the US, combined with measures like the Defense Production Act which subsidised manufacturing inputs (e.g., lipids, vials, bioreactor bags) across vaccine producers, the restriction of export of vaccine doses to third countries, and its quicker authorisation of vaccines, vaccine production in early 2021 ramped up rapidly in the US. By the end of February 2021, US manufacturing plants had delivered 103 million doses of Pfizer-BioNTech and Moderna vaccines, compared to 27 million doses by EU plants. Towards mid-2021, the EU was able to expand and even surpassed the US's production of these vaccines. One of the main reasons was that companies like Pfizer and Moderna chose to increase their supply chains outside the US as a way to deal with the uncertainty related to their ability to export globally under the DPA's framework. However, there is still criticism of the EU's delay to upscale vaccine manufacturing and thus its lack of access to early doses in early 2021, which likely cost lives and economic loss (Bown, 2022).

President von der Leyen, in her speech at the European Parliament Plenary on the COVID-19 Vaccination Strategy on 10 February 2021, admitted that 'Today we are not where we want to be in combating the virus. […] We were too optimistic about mass production. And maybe we also took for granted that the doses ordered would actually arrive on time.'

Looking forward, HERA, expected to upscale crisis-relevant medical countermeasure manufacturing, does not, however, have the necessary resources and tools. Resource-wise, HERA does not have a strong budget autonomy to take prompt and adequate investment decisions when a crisis hits. Overall, HERA's funding come from fragmented funding programmes managed by different EU bodies, e.g., Horizon Europe and EU4Health.[84] HERA-funded projects are thereby constrained by the conditions of the funding programmes.[85] It also has to extensively coordinate with the bodies managing the funding programmes. For example, under Horizon Europe and EU4Health, HERA must

[83] HERA Work Plan 2023 , pp. 13, 16

[84] HERA 2023 Work Plan, pp. 13, 16.

[85] For instance, Horizon Europe stipulates that consortia must comprise of at least three partners operating in limited geographic areas, and the research priorities is only decided on a biannual basis through a comitology procedure. These conditions might not be optimal for both preparedness and response, where multiple developers (including those located outside EU) need to be mobilised in a short time frame.

launch its project calls and coordinate closely with DG SANTE and DG RTD – the overall managing body of this funding programme. The recent launch of the funding stream for HERA – HERA INVEST[86] – does not substantially improve the situation. More specifically, while the creation of this funding scheme marks a positive step in HERA's increased budgetary autonomy, it is HaDEA and the European Investment Bank (not HERA) who co-manage the programme and take the ultimate financing decisions for projects under this scheme,[87] entailing questions about HERA's authority over the use of this funding.

Finally, readers are reminded that investment is only the first step, and a larger amount of investment may not guarantee more benefits to the EU. The Union should ensure that EU citizens will benefit from the money spent and maintain reasonable cost-benefit ratios of the investments.

Issue 13: Lack of an EU long-term vision on R&D funding

Other challenges associated with the EU's funding support mechanism for crisis-relevant MCMs is its lack of a long-term vision, while the research, development and marketing of MCMs is a long process. Horizon Europe projects, for instance, mainly last for 3-5 years, focusing on short-term impacts, with suboptimal blending or sequencing with other funding programmes in the later phase of technology development (Florio et al., 2021).

Issue 14: Transparency issues and a lack of pre-determined procedures and rules in the EU's joint procurement of crisis-relevant medical countermeasures

As observed during the COVID-19 pandemic, the EU entered negotiations with pharmaceutical companies with insufficient bargaining power. The EU's relatively low at-risk investment in vaccine development and production, discussed above, led vaccine sponsors to prioritise their supply to the US in early 2021 compared to the EU (Table 3) (Jagusiewicz et al., 2023). Further measures introduced by the US, e.g. the Defense Production Act, restricted exports of vaccines to outside the US (Bown and Bollyky, 2021) and caused the EU to face an even more difficult negotiation situation. In addition, the fact that the intellectual property rights (IPR) to effective vaccines were concentrated in a handful of pharmaceutical companies gave them tremendous power when negotiating with governments, especially with regards to critical contract terms such as price, delivery, and control of supply chains (Florio, 2022; Schanze, 2021). For instance,

[86] European Commission, press release of 12 July 2023 on HERA Invest, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_377.

[87] Minutes of the HERA Advisory Forum on 21 March 2023, pp. 3-4

companies like AstraZeneca used the 'best efforts clause' in their contract with the EU to justify the delay in their delivery of vaccines (Hyde, 2021).

The negotiations were mainly conducted behind closed doors with limited transparency. One key reason was that the EU had not specified any pre-determined procedures and rules at Union level on negotiations with large pharmaceutical companies. In this respect, Regulation (EU) 2022/2371 partly addresses this need for procedures and tools regarding joint procurement of MCMs. Article 12(3)(c) states that the Commission should prepare a 'joint procurement assessment' document before launching a joint procurement procedure, which should indicate the general conditions envisaged for the procedure. However, such an assessment without additional provisions or safeguards regarding how it should be established and what it should contain is unlikely to provide the appropriate tools and procedures for the EU to enhance transparency and to gain trust. Moreover, Article 12(4) and 12(5) reinstate the role of the Commission as ensuring coordination and exchange of information between the different parties, but provide no specific safeguard to ensure that this is done transparently and that the Commission can be held accountable.

A related issue is that during the COVID-19 pandemic, EMA largely limited itself to its traditional regulatory role of providing the Commission scientific advice on granting marketing authorisation of COVID-19 vaccines, which was conducted through an institutionalised fast-track marketing authorisation process. However, EMA had not conducted adequately Health Technology Assessments (HTAs) with regard to the efficacy of the COVID-19 vaccines and therapeutics. A HTA assesses whether a new health technology, which could be a medicinal product, a medical equipment or a treatment method, works better or worse than existing alternatives and also assesses its potential side-effects. The main purpose of a HTA is to provide national authorities with evidence for decisions on which technology should be reimbursed at national level. Council Regulation (EU) 2021/2282 has established a Coordination Group on HTA; yet such a group has no specific mandate in a public health emergency.

The lack of HTAs for COVID-19 vaccines at Union level led to noticeable differences in the use of the vaccines. Indeed, given some reports of potential harms of the AstraZeneca vaccine for some age groups, the administration of the vaccine across the Member States has been uneven with some discontinuing the use for some age groups and some other stopping the use altogether.[88] The differences in the guidelines of the use of COVID-19

[88] It was only under pressure from the Belgium government that EMA conducted a benefit-risk assessment of different age cohorts for the AstraZeneca vaccine that has helped aligning Member States' guidelines on the use of the vaccine.

vaccines among countries fuelled conspiracies and damaged the credibility of the vaccines as well as the joint procurement process.

Failing to provide HTAs for vaccines might not have caused severe problems during the COVID-19 pandemic as COVID-19 vaccines have in general proved effective. Yet, the lack of HTAs in future public health emergencies could be a major issue. A joint procurement agreement of a medicinal product may imply a joint 'reimbursement' decision of all participating Member States. Usually, it is the national government who decides on reimbursement decisions given the HTA of a therapeutic. Hence, a joint 'reimbursement' decision should be accompanied by a HTA conducted by EMA and linked to ensure that the joint procurement, as well as reimbursement, is cost-effective compared to purchasing other existing alternatives.

4.3 TERMINATION OF A PUBLIC HEALTH EMERGENCY OR AN EMERGENCY FRAMEWORK

Issue 15: Lack of clarity regarding the decision to declare the end of a PHE at Union level and discontinue related emergency measures

Article 23(2) of Regulation (EU) 2022/2371 states that 'The Commission shall terminate the recognition […] as soon as the condition pursuant to paragraph 1 is no longer met', and Article 24 states that the Advisory Committee shall advise the Commission on the termination of a public health emergency, upon the request by the Commission or the HSC. Without a sunset clause, the question of when to mobilise scientific advice is also left to the discretion of civil servants within the Commission. Moreover, the consequences of the termination of the recognition of a public health emergency at Union level are unclear. It does not specify the immediate termination of the legal effects of the recognition.

To provide a comparison, such an ambiguity however does not present in the emergency framework on MCMs laid down by Council Regulation (EU) 2022/2372. The framework will automatically be deactivated 6 months after activation, unless prolonged by a Council decision or following the termination of the associated public health emergency in accordance with Article 23(2) of Regulation (EU) 2022/2371. All measures activated will also be deactivated due to the termination. To prolong the emergency framework, an assessment shall be done by the Commission in consultation with the HCB. Upon the Commission's proposal, the Council can decide to prolong the period for which the emergency framework is activated for up to another six-month period.

However, very likely the measures may lead to consequences or follow-ups beyond the six-month period. Council Regulation (EU) 2022/2372 does not clearly state that, if the framework is deactivated, which institutional body shall follow up those consequences,

though the Commission may bear most of the responsibilities. For example, the joint procurement contracts of COVID-19 vaccines concluded in 2020 led to unwanted deliveries in 2023 and Member States urged the Commission to renegotiate the contracts with suppliers.[89]

4.4 MEASURES OTHER THAN MEDICAL COUNTERMEASURES

When a policy area falls beyond the scopes of Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372, it remains largely a Member State competence. Article 168 of the Treaty of the Functioning of the European Union (TFEU) clearly states that the Union shall complement national public health policies. As Council Regulation (EU) 2022/2372 clearly delineates, these remaining policies will be mainly public health and social measures, which include but not exclusively stay-at-home order, quarantine policy, and border closure. On these policies and measures the new emergency response framework does not add much to the current architecture (Blauberger et al., 2023).

Issue 16: Lack of competence of the EU over national health policy

Article 168 of the Treaty of the Functioning of the EU (TFEU) states that the competence on health remains primarily with the Member States while the EU can provide coordination, analysis and advice. This article however prohibits 'any harmonisation of the laws and regulations of the Member States', and stipulates that the EU must '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'. A rather expansive use of Article 122 TFEU since 2016, which provides more powers to the Council in the event of exceptional occurrences (including health emergencies), has helped overcome some of the above limits. However, such measures lead to significantly Member States'-driven processes, which leave little space for EU-level coordination (for example, by the European Commission), and side-step the European Parliament in the decision-making process.[90] COVID-19 had showed that infectious diseases see no borders and the EU's competence in the area of health might be insufficient in protecting EU citizens. It is observed that reforms were built upon pre-existing structures that enhance governance rather than competences (Brooks et al., 2023).

The resistance to transfer further power from Member States to the Union has been persistent (Beke et al., 2023, p.140).[91] The barrier to a Treaty change that transfers more

[89] Commission renegotiates vaccine deals to quell overstocking, Euractiv, 27 March 2023.

[90] Consolidated version of the Treaty on the Function of the European Union, available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:en:PDF

[91] Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Sweden showed scepticism towards a treaty change on public health competence (Beke et al, 2023, p.140).

power to the EU over the public health domain is high – unanimity and a series of national referenda and ratifications – formal expansion of EU competence over public health is unlikely (Brooks et al., 2021).[92] Yet, with the potential revision of the EU Treaties coming very soon due to the vote of the European Parliament on 9 June 2022, discussion over public health competence may return to the negotiation table.

Nevertheless, the Union's competences to respond to the COVID-19 pandemic have been gradually expanding even without a Treaty change. The legal limitations on Union actions are not the main issue, the issue is rather that there is a political or policy desire to carry out those actions (Purnhagen et al., 2020). The use of Joint Procurement Agreements to procure COVID-19 vaccines was an example that the Member States are willing to hand over competences to the Union if they see the benefits. The same argument applies to the establishment of HERA, despite opinions about its independence and transparency. The Union can gain competences as long as it can demonstrate to the Member States that the transfer of authority will be beneficial. Over the area of PHSMs, the question is whether the Union can do better than an individual Member State or can coordinate in a way that it will benefit all the Member States *ex ante*.

There are numerous measures under the umbrella of PHSMs. Some PHSMs, such as school closure, gathering restrictions, and remote working policy, public transport closure, tend to mainly affect nations internally and thus interventions from the Union or coordination at Union level may be less desirable. Yet, within the Single Market, internal matters could easily impact other EU Member States. During the pandemic, stay-at-home order and border closure were two controversial PHSMs that disturbed the normal functioning of neighbouring economics. It was particularly concerning in the EU because the Single Market has been built upon the freedom of movement. Coordination in the future and exchanges of information at Union level will be necessary to minimise any disturbances generated by these measures in future public health emergencies.

Meanwhile, lacking common public health emergency policies and measures may breed the spread of misinformation, which should be combated by a strong and single voice in the Union. The EU currently lacks a strong scientific authority that provides independent advice to EU Member States on these measures. During the COVID-19 pandemic, ECDC played an important role in providing guidance to Member States. As early as March 2020, ECDC published the 'Considerations relating to social-distancing measures in response to COVID-19' that identified the level of authorities responsible for the measures and also the related considerations and potential barriers. Yet, as the mandate of ECDC states, guidance is supposed to be non-binding and does not contain detailed instructions. In the guidance published by ECDC, there was little or no mention about

[92] Covid-19 and European Union health policy: from crisis to collective action.

coordination. Also, those guidance documents did not specify the prerequisites of implementing a measure, leaving the decision to individual Member State. During the COVID-19 pandemic, regarding national social-distancing policies, their timing, extent and enforcement level, Member States mainly relied on the advice of national expertise. Consequently, the EU response to the emergency, especially in the early phase, was highly fragmented (Gontariuk et al., 2021). Besides, there were voices from some Member States that ECDC should take a less influential and passive role so that their national advisory groups and authorities could take a more solid control of the advice given to their citizens. Such tension prevented ECDC from delivering a strong and robust response to the crisis. There were also criticisms that ECDC was not quick enough in answering the doubts by Member States, which then attempted to figure them out themselves with their national experts. Indeed, the scale of and the uncertainty associated with the pandemic was overwhelming. ECDC has two main sources of revenues, namely, the European Union contribution and the subsidy from the European Economic Area, which amounted to EUR 59 million in 2019. Meanwhile, the Robert Koch Institute, the German national scientific authority responsible for disease control and prevention, was endowed with roughly EUR 100 million.[93] Comparing the two, it is not difficult to understand why while smaller Member States relied heavily on the advice and guidance given by ECDC, many others preferred to seek the support of their national experts and authorities.

Even if the Union lacks the competence to handle national health policy, the EU can still provide a venue for exchanges of information and coordination. Currently the EU lacks a central point of contact concerning information of public health threats. To communicate or share intelligence, national governments may go through the HSC, the health policy meetings of EPSCO, ECDC, the ERCC, the IPCR if activated, and other informal channels. To what extent the information will be picked up is, however, uncertain. As a result, Member States may try all channels until they get satisfactory feedback, but frustration could make them stop trying.

The new developments divide public health emergency policies into the area of MCMs and the rest (while border closure stands out from the rest as it concerns the freedom of movement of EU citizens). Such a division has been driven by the belief that the biggest benefit brought by the Union to its Member States during the COVID-19 pandemic was the joint procurements of vaccines and other medical suppliers. The establishment of HERA, the consolidation of the joint procurement arrangement and the reinforced support to developments of MCMs at Union level can be considered as a transfer of competence from the Member States to the Union without a change to the Treaties. On

[93] See https://www.dw.com/en/coronavirus-what-is-germanys-robert-koch-institute/a-53416437.

national pandemic control measures the Member States tended to prefer to maintain their national competence for various reasons. Yet, the EU and the Member States should examine the practical difficulties of this division of competences. Very often public health emergency measures are all interrelated and complement one another at Union and also national level.

In fact, the EU is endowed with a potentially very powerful crisis response mechanism, the Integrated Political Crisis Response (IPCR), which is within the framework of the Council. The IPCR was activated due to COVID-19 by the Croatian Presidency of the Council. The IPCR is indeed an important platform for information exchange and collection with a 24/7 contact point to ensure constant liaison. The mechanism allows the Presidency to call crisis meetings with various actors, including the Commission, EU agencies, representatives from Member States, experts, etc. It will be an important venue for high-level discussion and will maintain the unity of the EU in any major internal and foreign affairs. To a large extent, the effectiveness of the IPCR depends on how the Presidency of the Council exercises its power of coordination. For instance, when nationalistic measures by a Member State harms the overall welfare of other Member States, the IPCR in principle can be the venue where the presiding Member State alerts other Member States and also exerts pressure on the deviating Member State.

For instance, the IPCR roundtable meeting on 4 January 2023, chaired by the Swedish Presidency, discussed measures to deal with the easing of travel restriction by China and international travellers coming from or destined for China.[94] The Health Security Committee, one day later, issued its opinion for a common EU approach on the same topic, mentioning that their opinion 'supports the technical implementation of IPCR operational conclusions' of the roundtable conclusion of the IPCR arrangement.[95] At the time of writing, there seems to be no clear allocation of competence between the IPCR and HSC (and other EU bodies like EPSCO) on public health and social measures when a health emergency occurs in the EU. In future pan-EU health crises, the functioning of these bodies in parallel on the same issues might create confusion and duplication of efforts. Some consider that the IPCR would be in a better position to take the driving seat, since the health emergency could cross-cut many other policy areas (border control, economic security, etc.), as observed during the COVID-19 pandemic (Blauberger et al., 2023).

[94] Presidency Statement on the Coordination of Covid-19 Travel Measures, available at https://swedish-presidency.consilium.europa.eu/en/news/presidency-statement-on-the-coordination-of-covid-19-travel-measures/

[95] Opinion of the Health Security Committee for a common EU approach in response to the Covid-19 situation in China, available at https://health.ec.europa.eu/system/files/2023-01/security_hsc_covid_20230105_opinion.pdf

The IPCR seems to be the mechanism that could centralise some power to the Union level temporarily. Yet, it is largely an 'informal' roundtable. The power of the IPCR is thus up to the presiding Member State of the Council to define. The Member State can call upon the Commission, governments, EU agencies and bodies, as well as experts to discuss approaches and measures. However, as the position of the IPCR in the chain of command of the EU crisis response is never clearly stated, it could create a competition of leadership between the Commission and the presiding Member State through the IPCR. As the presidency lasts for only six months, even if a strong leader of the Member State steps up to take the torch of leadership, the comparatively short length of the term of a presidency means they have to pass the torch quite quickly considering that a pandemic could last for multiple years. Such an institutional setting naturally favours the Commission taking the driving seat, as it did during the COVID19 pandemic (Kassim, 2023). Therefore, the actual impacts of the IPCR in any future crises could vary depending on the wills and actions of the leaders of the EU.

Issue 17: Lack of a coordinated approach to national border closures

With the establishment of HERA and the activation of the HCB during a public health emergency, the EU expects a more coordinated approach to addressing shortages of PPE and medicines in Member States. Yet, it is less clear that other measures, such as border closure within the EU (or more precisely the Schengen zone), will be more coordinated or more in line with the Commission's interpretation of the proportionality principle.

It is believed that closing borders can stop infected people from moving into a country, establishing a 'firewall' between countries. Yet its effectiveness is questionable (Timur and Xie, 2021). Its implication could be far-reaching. First, essential goods may be blocked from being exported to or imported from other countries. Second, many cross-border workers are unable to work as usual. Some exceptions may apply, but the restrictions may still cause delays of movement of goods and people. More importantly, the COVID-19 experience shattered the dream of a 'borderless Europe' (Opiłowska, 2020) that border region residents would have to reorganise their transnational lives to avoid future disturbances. To add to the complexity, border closure and some other social-distancing measures do not conventionally fall within the domain of health policy but managed by various ministries, such as internal affairs, social and economic policies and even foreign affairs. The complex national decision-making process makes transferring the authority over borders, even only during emergencies, to the EU almost impossible.

The direct consequence of this was the uncoordinated closures of Member States' borders. For example, in March 2020 Belgium banned all non-essential movement of people, while in the Netherlands people were allowed to move freely as long as they kept

1.5 metres apart.[96] The complex border between two nations[97] and the difference in lockdown measures led to some arrangements by shops that split their shops in half.[98] Some Belgian citizens went to the Netherlands for shopping and meals and later came back home, this stirred up discontent that the less stringent measure would fail to stop the virus from spreading and thus jeopardise the Belgian lockdown measure.

National border closure, to a large extent, was driven by protecting the nation against the virus coming from other nations (Chetail, 2020) rather than stopping infected people from leaving the nation to protect other nations. It implies that when governments decided whether to impose border closures, they had studied the epidemiological circumstances and also the enforcement of measures in other nations. Therefore, one would expect a more coordinated approach on borders if EU Member States had had better managed the pandemic at national level and showed their commitment to enforcement of their own national pandemic measures to neighbouring countries.

Regarding border closure, the Commission funded independent research that offers some recommendations (Peyrony et al., 2020). The research pointed out that local cross-communities shall be the focus of a border closure policy and their needs and opinions should be heard. Besides, it is important to maintain mutual trust between neighbouring countries.

Currently most of the EU Member States are protected by the Schengen Borders Code that allows temporary reintroduction of border controls or closure in exceptional circumstances.[99] Yet, a Member State must notify the European Commission and provide a justification that the measure is proportionate to the threat. In June 2022, the Council of the EU adopted a reform of the Schengen Borders Code that specifies the conditions for the reintroduction of internal border controls.[100] In particular, it makes consultations with directly affected Member States mandatory. The EU in the meanwhile should work to harmonise border crisis management and also deepen the partnership among the Union, Member States and regions. Still, uncoordinated border closures by Member States would not be avoided in similar public health emergencies provided no stronger intervention from the Union.

Indeed, in February 2021, the Commission put six Member States on notice that they should lift their border restrictions so as to not hinder the Union's free movement of

[96] Belgian towns turn coronavirus anger on the Dutch, Politico, 24 March 2020.

[97] See the map here: The border between Belgium and the Netherlands at Baarle-Hertog/Baarle-Nassau, Brilliant Maps, 3 March 2023.

[98] Shop shuts Belgian half over Covid-19 but keeps Dutch half open, The Guardian, 25 March 2020.

[99] Twenty-three EU Member States participate in the Schengen Area and three of them are obligated to join in the future, while Ireland maintains an opt-out.

[100] The Council of the European Union, Reform of the Schengen borders code, 9 June 2022.

people and goods.[101] Yet, national governments defended their decisions by claiming that the measure was necessary to protect the health of their citizens.

As pointed out by the European Court of Auditors, the only instrument the Commission could use to discipline Member States for their excessive travel restrictions is the infringement procedure.[102] However, it will take years for the Court of Justice of the European Union to finish the legal proceeding. If the alleged infringement no longer exists, the case will become inadmissible. In the context of a pandemic that travel restrictions may only be temporarily imposed, Member States will hardly be sanctioned for their excessive restrictions.

About public health and social measure issues, the EPSCO of the Council and the HSC is probably the venue where ministers discuss and exchange views. Since the Council follows the principle of consensus, the Council may not be able to deliver concrete conclusions and adopt a unified approach. This is an area where commercial interests may play a big role. The differences in the economic conditions of Member States will make reaching a consensus or adopting a unified approach difficult.

4.5 TRANSVERSAL ISSUES: DATA, ADVISORY MECHANISM AND MISINFORMATION

4.5.1 Data availability

The COVID-19 pandemic revealed challenges for public authorities to fully adopt digital technologies and innovations, as well as to effectively access data and intelligence to translate them into evidence-based policymaking. The very first problem was the poor availability of high-quality data (Naudé, 2020). The subsequent poor outputs or performance of those new digital technologies damaged the trust in technologies, institutions, and public health systems, while their applications were complicated by the spread of misinformation.

Issue 18: No guarantee for data availability

Regarding data availability for crucial policymaking, the Data Act provides a potentially useful legal basis for public use of private data. In the latest amendments adopted by the European Parliament on 14 March 2023 on the proposal for the Data Act,[103] it is proposed in Chapter V that: *'Upon a specified duly justified request limited in time and scope, a data holder that is a legal person shall make non-personal data which are*

[101] EU tells six countries to lift Covid border restrictions, The Guardian, 23 February 2021.

[102] European Court of Auditors, Free movement in the EU during the Covid-19 pandemic: Limited scrutiny of internal border controls, and uncoordinated actions by Member States together with the replies of the Commission and the European Centre for Disease Prevention and Control (ECDC), Special Report 13/2022.

[103] At the time of writing (July 2023), the Council had finished a third trilogue with the European Parliament.

available at the time of the request, including metadata available to a public sector body or to a Union institution, agency or body demonstrating an exceptional need to use the data requested.'

In case of emergency, the Union would be able to request privately held data from companies for decision-making – though it remains unclear to what extent this will materialise.

Article 17(2d) of the Data Act, as in the European Parliament amendments, stated that a request for data under the Data Act by the public sector shall 'concern only non-personal data'. Health data are personal data; geolocation of a person is also personal data.[104] In other words, the public sector can only request non-personal data or anonymised personal data (so they fall outside the scope of personal data). The data holders should perform the anonymisation given a reasonable compensation. Yet, anonymisation is costly and data holders very often cannot ensure if information, or a combination of pieces of information, is not re-identifiable unless they remove some relevant and useful features from the data. Such a strict requirement would first increase the burden on the private sector and also hinder potential beneficial uses of data.

After all, the possibility to request privately held data would not really enhance public authorities' ability to design a policy if the authorities do not possess the expertise to process the data. Outsourcing data analysis to academics, experts or private companies in the field will thus be the key to better utilising the available data. Given the possibility of outsourcing to third parties, the following paragraph of the European Parliament amendments of Article 19 of the Data Act aims to protect data holders: *'Where a public sector body or a Union institution, agency or body transmits or makes data available to third parties to perform the tasks that have been outsourced to it as a result of the outsourcing of technical inspections or other functions pursuant to Article 17(4), trade secrets as identified by the data holder, shall only be disclosed to the extent that they are strictly necessary for the third party to perform the tasks that have been outsourced and provided that all specific necessary measures agreed between the data holder and the third party are taken in advance, including technical and organisational measures to preserve the confidentiality of those trade secrets, including as appropriate through the*

[104] The European Commission defines personal data as: 'any information that relates to an identified or identifiable living individual. Different pieces of information, which collected together can lead to the identification of a particular person, also constitute personal data. Personal data that has been de-identified, encrypted or pseudonymised but can be used to re-identify a person remains personal data and falls within the scope of the GDPR. Personal data that has been rendered anonymous in such a way that the individual is not or no longer identifiable is no longer considered personal data. For data to be truly anonymised, the anonymisation must be irreversible.'

use of model contractual terms, technical standards and the application of codes of conduct.'

Accordingly, data holders play an important role in such a scenario. It requires cooperative behaviours from data holders to maximise the potential of the data for policy making.

The use of real-world evidence such as electronic health data to monitor the efficacy, safety and quality of medicinal products is also crucial in an emergency response. Real-world data or observational data can reveal many layers of the impacts of the medicinal products that clinical trials cannot show, especially if the randomised controlled trials are conducted with a limited group of population within a short timeframe due to the urgency of the crisis. In this regard, the use of electronic health record data from the proposed European Health Data Space (EHDS) can play an important role. While the EHDS could provide an enabling regulatory framework for the use of health data for public health, some barriers might hinder its effective implementation, particularly privacy and security risks, uneven development and lack of interoperability of eHealth systems across Member States, lack of willingness to share data, as well as inequality in health and digital literacy (Pagliari, 2021; Thiel et al., 2021; Varnai et al., 2019).

The Parliament, in its Resolution of 21 October 2021,[105] called for the publication of patient-level clinical trial data from COVID-19 vaccine developers. However, in practice, most of the vaccine companies did not commit to publishing such data or plan to do so in a vague or extended timeframe.[106] The new Clinical Trials Regulation that been in effect since January 2023 solves the problem, which enhances transparency on clinical trial data to a large extent.[107] Currently marketing authorisation applicants should submit to the EU the clinical study report, which contain some patient-level data, within 30 days of the granting of the authorisation. The change should allow developers, academics and any interested third parties access to the clinical trials data to first verify the original analysis and learn from past failures and successes (Zemła-Pacud and Lenarczyk, 2023). The publication of clinical trials data will also help avoid duplication of research efforts. In principle, anonymised individual patient data that includes individual response to

[105] European Parliament, 'EU transparency in the development, purchase, and distribution of Covid-19 vaccines', 21 October 2021.

[106] For example, Pfizer is estimated to make patient-level data available only in 2026 (Beke et al, 2023), while Moderna communicated a vague message about its plan to publish this data (Tanveer et al, 2021). Most of the pharmaceutical companies attending the Covid public hearing on 10 October 2022 were unable to give precise answer to the question about whether the available data showed that Covid-19 vaccines had stalled transmission rates of the virus and the length of such effects. See recordings of the COVI hearing of 10 October 2022.

[107] European Commission, Consolidated text: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)Text with EEA relevance.

treatment shall be made available. The newly revised regulation is a major step but whether it will facilitate better verification of research results is doubtful because of its unstructured format. The new requirement does not demand clinical trial data to be published in any specified data format but in a 'report' format. It renders replications of results difficult, considering recoding data for thousands of subjects. In the future, the Commission should consider adopting a similar data sharing policy as those of some scientific journals that require the publication of data used in the analysis in a certain format to facilitate easier verifications of results.

4.5.2 Advisory bodies and related procedures

At Union level, multiple bodies are working on providing scientific advice and recommendations to back governments' decisions. ECDC notably works as a coordinator of scientific assessment between the EU and national risk assessors, and also publishes scientific evidence and recommendations for the Commission and Member States in the form of reports, as well as data, infographics and videos. Other EU bodies have provided scientific advice to build government responses, such as EMA and ad hoc advisory panels in the HSC. Each Member State then has its own way of incorporating this scientific advice, coupled with its own national one. While EU-level recommendations have proven to be valuable, especially for smaller Member States, the consultation and communication process has not been optimal.

In November 2020, an independent expert report of the Group of Chief Scientific Advisers to the European Commission, the European Group on Ethics in Science and New Technologies, and the Special adviser to President Ursula von der Leyen on the response to the coronavirus and COVID-19 proposed to establish a standing EU advisory body for health threats and crises response. The report identified the need for this body to liaise with national, European and global advisory bodies, and to have a multidisciplinary and inclusive membership to advise not only on clinical aspects of the response, but also behavioural, economic, cultural, ethical, legal, technological and international ones. This body should liaise with national advisory bodies in Member States to enhance consistency and information exchanges, and ensure recommendations provided to the Commission and to Member States is consistent, and any differences are clarified and communicated.[108]

The suggestion was followed up by Regulation (EU) 2022/2371, which establishes the Advisory Committee on public health emergencies ('Advisory Committee', see Article 24) that will advise the Commission or the HSC at their request, notably on the formal recognition of a public health emergency at Union level, and on the formulation of

[108] European Commission, Improving pandemic preparedness and management, Independent Expert Report, November 2020.

response measures. These measures may include risk and crisis communication, identification and mitigation of significant gaps, inconsistencies or inadequacies in medical and public health and social measures, prioritisation of healthcare, civil protection and other resources, as well as any subsequent recommendation of policy measures to address the long-term consequences of a specific threat.

Issue 19: The Advisory Committee has not been formally established, and its role is still uncertain

As of July 2023, the Advisory Committee has not been formally established. Article 24(2) of Regulation (EU) 2022/2371 states that the Advisory Committee shall be composed of independent experts, with a multidisciplinary membership, which will be selected by the Commission according to their field of expertise and experience (and Member States can also suggest appointments of relevant experts). However, the Regulation does not state clearly how many members the group should contain, who will select the members, according to which criteria, and who should be the chair. Moreover, it is not clear in the Regulation to what extent the Advisory Committee can independently produce advisory reports without a request from the Commission. At the time of preparing this work, DG SANTE was working on its configuration.

Issue 20: Multiple and potentially overlapping advisory mechanisms

Article 5(7) of Council Regulation (EU) 2022/2372 stipulates that the co-chairs of the HCB can invite experts, and Article 5(1) states that the Commission may set up working groups on an ad hoc basis to support the work of the HCB. Moreover, Article 24(4) states that the Advisory Committee shall act in coordination with the HCB where applicable. These two advisory bodies would enter into tensions when advising on a given issue (e.g. the use of resources and measures to respond to a public health emergency).[109] This raises the question of coordination between the Advisory Committee, the HCB, and other working groups, as well as the overall efficiency of having numerous structures for expert advice. Article 24(1) of Regulation (EU) 2022/2371 specifies that the advice produced by the Advisory Committee shall build upon the advice of ECDC, EMA, WHO and other relevant Union agencies and bodies; and Article 24(2) that representatives of ECDC and EMA will be permanent observers of the Advisory Committee. Yet, especially as the members of the Advisory Committee will be multidisciplinary, its conclusions may differ significantly from those of ECDC and EMA which provide advice based on epidemiology and clinical evidence but not on economic or social factors. The same observation applies regarding the relation with the recommendations of the ad hoc advisory groups potentially created by the Commission. The same observation applies regarding the

[109] Article 24 (1) (c) of Regulation (EU) 2022/2371 and Article 5 (7) of Regulation (EU) 2022/2371.

relation with the recommendations of the ad-hoc advisory groups potentially created by the Commission.

4.5.3 Mis- and disinformation

The COVID-19 pandemic has not only produced a global health crisis but has also given rise to a significant phenomenon known as the 'infodemic', in which misleading information transmits quickly and poses a comparable level of danger to the virus itself (WHO, 2020). The infodemic conspiracy consists of theories and pseudo-scientific cures for the disease (Heiss et al., 2021; Rutter et al., 2020). Disinformation poses multifaceted risks as it redirects public opinion and could be used as a subversive technique by both state and non-state actors to disrupt political and social systems (European Commission, 2018). During the 'corona diplomacy', the European Union found itself in a complex situation, caught between counternarratives from the United States and China, the actions of the World Health Organization (WHO), and the challenges posed by the paralysed UN Security Council, G7, and G20 (Véliter et al., 2020). The widespread dissemination of misinformation about both the virus and vaccines underscores deficiencies in the European Union's strategic communication approach.

The world had already experienced the adverse impacts of misinformation years before the pandemic, especially during the 2016 Brexit referendum. The EU has responded by taking several steps to address the problem (Harrison, 2021).[110] The European Union published the EU Code of Practice on Disinformation in 2018, which is a voluntary framework to control and keep track of the online dissemination of false information. This framework involves collaboration with major platform providers, including Twitter, Google, and Facebook (European Commission, 2019).

Clear efforts were made to communicate to the public during the COVID-19 pandemic. Among other initiatives, the Commission established an ad hoc advisory panel in April 2020 and appointed a special advisor to the President of the European Commission as of May 2020. ECDC also published remarkable amount of data, information, reports, infographics and videos about the virus and relevant MCMs and PHSMs.

[110] Disinformation refers to the deliberate dissemination of false information with the intention to harm others, whereas misinformation refers to the sharing of false or misleading information without the intent to deceive (European Commission, 2020). In EU official documents, 'disinformation' is much more frequently used, for example as in 'Covid-19 disinformation monitoring programme' and 'The 2022 Strengthened Code of Practice on Disinformation'.

Issue 21: Lack of effective instruments to combat mis- and disinformation

The voluntary nature of the EU Code of Practice on Disinformation is a significant drawback. Popular instant messaging applications like WhatsApp and Facebook Messenger, which were among the main sources of false information during the pandemic (ERGA, 2020), had not committed to comply under this framework. Even if social media platforms provided reports explaining their policies and activities to combat COVID-19 disinformation in accordance with the 2018 Code guidelines, the effectiveness of these reports was limited because they frequently lacked precise information on each Member State and contained unrelated data regarding COVID-19 (IPOL, 2023).

As a result, the modified version of the Code, which was enacted in 2022, includes a co-regulatory backstop tied to the Digital Service Act (DSA) that seeks to enhance digital platforms' involvement while maintaining its voluntary nature.

Furthermore, the EU-funded and independent project European Digital Media Observatory (EDMO) seeks to create a cooperative, international community capable of identifying and assessing potential disinformation threats. EDMO will also support the European Regulators Group for Audiovisual Media Services (ERGA) in keeping track of the terms and conditions of online platforms and develop a safe environment that would permit academic researchers to access platform data while guaranteeing privacy compliance (European Commission, 2022, pp. 26-27).

Despite the reform since 2022, the EU still lacks effective instruments to combat disinformation. First of all, disinformation is not an EU-specific problem. Disinformation can easily spread across international borders through the internet. In the meantime, within a Member State, political parties are far from united in the fight against disinformation. Disinformation on social media is found to be driven by political parties which aim to shape public attitudes (Bradshaw and Howard, 2019).

The surge of the use of generative AI since 2023 has fuelled the spread of disinformation as pictures and even videos can be easily doctored to support false information, confusing the public and even professionals. Facing challenges posed by the new technology, the Union lacks an effective tool to counter false narratives.

5. RECOMMENDATIONS

5.1 CLARIFY AND IMPROVE THE CURRENT GOVERNANCE FRAMEWORK

All the new institutional and regulatory reforms in the domain of public health since the COVID-19 pandemic are undoubtedly major steps towards a more harmonious, solid and healthy Union. Commentators should evaluate their impacts, successes and failures considering the almost absence of public health competence at EU level before the pandemic. These steps will bring benefits but there are also potential improvements. One major recommendation this paper proposes is to better clarify the existing governance framework.

The governance framework is complex and can be examined in both vertical and horizontal dimensions.

Vertically, the EU should better leverage existing mechanisms for cross-sectoral emergency response, notably the Integrated Political Crisis Response mechanism. The advantage of the IPCR is its potential involvement of high-rank representatives from Member States to discuss a common approach and reach agreement. Upon a consensus among Member States, the Union can temporarily align policies and measures in areas which are normally managed by Member States, leading to breakthroughs without a Treaty change and also avoiding unnecessary dichotomy between MCMs and PHSMs. The IPCR could also be more proactive and visible in order to gain the authority of leading the Union through a crisis. On paper, the IPCR mechanism is flexible and can be powerful, however its effectiveness in practice also depends on the leader at the time of a crisis.

The IPCR seemed not to have proven its full potential to coordinate responses during the COVID-19 pandemic. The Council, the European Council included, took a rather secondary position in the leadership. Meanwhile, the Commission led by President von der Leyen was much more high-profile and proactive (Kassim, 2023). Such a pluri-institutional approach allows a different leading institution to emerge depending on the area of a crisis as resources to different EU institutions very between policy domains (ibid.). The Council could have done more to align border closures within the Union and to avoid export bans by individual Member States. However, the power of the Council depends on the willingness of Member States to put the Union's solidarity above national interests. When Germany banned the export of protective medical equipment, other Member States were fairly powerless in changing the situation. Similarly on border closure, the Commission put six Member States on notice concerning their exit and entry bans, but the current infringement procedure failed to discipline Member States since it will take years to finish the whole procedure. Thus, similar problems in the future should

be solved politically at a higher level. In this respect, vertical centralisation of emergency power could be beneficial because if the emergency measures fall outside the category of governance of crisis-relevant MCMs the leadership is less clear as Member States hold the authority over their national health policy. A strong central body, such as the Council through the IPCR, can impose a certain level of consistency and conformity among Member States.

Horizontally, the new reforms have created, or will lead to the creation of, new institutional bodies that to a certain extent work in a parallel fashion. **The implementations of Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372 should clarify the relationship and allocation of responsibilities between the HCB and the HSC**. It is understood that the HCB will only manage issues around MCMs during a public health emergency at Union level. Meanwhile, no legal texts exclude the Health Security Committee from discussing policies or exchanging information on MCMs. The potential overlaps in the mandates of these two bodies would lead to waste of scarce time and resources if they both present the same information and discuss the same issue, especially during a public health emergency when officials are extremely pressed and occupied. In that respect, further reviews of the two regulations should spell out the exact relation between the HCB and the HSC. Currently, the HSC consists of officials of various ranks from Member States, reflecting the differences in expectation of the functions and power of the HSC, despite the emphasis to strengthen the HSC in Regulation (EU) 2022/2371. Meanwhile, Council Regulation (EU) 2022/2732 does not specify the expected level of representatives from Member States of the HCB. Ideally, the HCB will consist of high-level representatives from Member States who can make decisions swiftly. The participation of higher ranked officials will also clarify the chain of commands between the HCB and the HSC.

The EU should examine the interplay between HERA and the Health Crisis Board in the upcoming review of HERA's operation, and ensure HERA has the necessary competence and autonomy to act effectively during a crisis. Once the Council activates an emergency framework, the HCB will be established to guide the development, procurement and distribution of medical countermeasures. The Board is expected to create a venue where the Commission can table proposals and solutions, Member States can make swift decisions, and HERA is guided to act according to the collective will of the Member States. Such a framework is reasonable as it considers HERA as a Commission service. With the upcoming potential review of the mandate of HERA and enhanced independence, the relationship between HERA and the HCB should also be reconsidered. The upcoming review of HERA should take this into account if the consensus is to grant HERA more authority and independence.

It is necessary to explain whether HERA, in crisis mode, would set up a 'HERA Crisis board'. The Commission Decision that established HERA does not mention a 'HERA Crisis Board'. Yet, on the European Commission's webpage explaining HERA, it is written that 'during the emergency phase, Member States sit on *HERA's Crisis Board* together with the President of the European Commission, the Commissioner for Health and Food Safety and other members of the Commission as appropriate. It is the Member States through the Council that activates HERA's emergency powers, upon a proposal by the European Commission'. It remains unclear whether a HERA Crisis Board would be set up, in addition to the HCB and the HERA Board. Note that a HERA Board has already existed with representatives of Member States sitting on it. Will there be two boards in parallel? Or will the HERA Board be transformed into a HERA Crisis Board? Note that it is written that the Health Crisis Board is supposed to coordinate with the HERA Board, implying that the HERA Board will maintain its existence during an emergency. So, what is the position of the HERA Crisis Board?

The EU should examine horizontally any overlaps of duties between the Commission and EU agencies. For instance, the EU should evaluate the efficiency of the overlaps in the monitoring activities of HERA and ECDC and consider re-assigning this task between the two bodies in the upcoming review of HERA's operations. Both ECDC and HERA carry out threats' monitoring with similar sub-tasks. Their working agreement, also signed on 14 March 2023, identifies this overlap and states that HERA and ECDC will work together notably through collaboration, coordination and information exchange on threat prioritisation relevant to medical countermeasures; epidemic intelligence relevant to MCMs; epidemiological surveillance relevant to MCMs; and laboratory activities. The upcoming review of HERA's operations (by 2025, according to Commission Decision C(2021) 6712) should evaluate the efficiency of the shared tasks among HERA-EMA-ECDC and consider re-defining tasks among the three bodies through revising their respective mandates.

A related issue is the multiplicity of information sharing and communication channels. Most of the discussed institutional bodies perform as venues of exchanges. While they serve their purposes, it is desirable to identify a single hub to gather information from Member States and the private sector and also for the public to seek useful guidance. The EU needs a centralised but open communication platform that allows authorities at different levels to exchange information, share best practices and report developments of events. The platform should also maintain a notification and alert system that informs the authorities about potential and actual public health threats. More importantly, the EU should provide a single point of contact for Member States to alert the Commission and other governments.

Given the EU's pluri-institutional approach which involve multiple actors, **the EU institutions, agencies, bodies and relevant entities should jointly conduct simulation exercises from the recognition of a public health emergency to its termination**, as foreseen in Article 5 of Regulation (EU) 2022/2371. As the European Commission works on its preparedness and response plan as required by Regulation 2022/2371, it is important that the plan is put to the test in ad hoc exercises to ensure it can effectively be implemented when an emergency occurs. These exercises can be supported by the EU Health Programme, and are particularly needed to also check the actual level of coherence between national preparedness and response plans (Regulation 2022/2371 requires that Member States seek coherence with the pan-European plan 'to the largest extent possible'). These simulation exercises should be comprehensive, allow the robustness of the EU's emergency framework to be tested against a set of scenarios and disruptive events, and be conducted with independent observers who will keep track of the workflow of the governance framework, identify ambiguities and loopholes in the responses, and evaluate the performance.

The EU should continue to discuss a possible Treaty change over the competence of public health. Article 168 of TFEU was not built on a vision that a public health threat might easily go beyond national borders, and the direct consequences of the shared competence on cross-border health threats are either voids in the governance framework or competition of leadership between the Union and Member States. The COVID-19 pandemic however revealed that the Union and national governments had not prepared for a major cross-border health emergency, and led to a short period of competence scramble. The European Commission emerged as the leading figure at Union level (Kassim, 2023), especially on the procurement of vaccines, despite some claims that the European Union appeared almost non-existent in the early phase of the pandemic. The early chaotic period showed that the old institutional framework may not be sufficient in protecting the EU health security. While the subsequent developments have transferred more competence from Member States to the Union without a Treaty change, it will still be constructive to continue the collection of ideas and discussion of the allocation of competence in the area of public health.

Box 1. Recommendations to clarify and improve the current governance framework

- Better utilise the Integrated Political Crisis Response mechanism for cross-sectoral emergency response (Issue 16, 17)
- Clarify the relationship and allocation of responsibilities between the HCB and the HSC with regard to MCMs (Issue 9)
- Examine the interplay between HERA and the Health Crisis Board in the upcoming review of HERA's operation, and ensure HERA has the necessary competence and autonomy to act effectively during a crisis (Issue 8)
- Explain whether HERA, in crisis mode, would set up a 'HERA Crisis Board' and, if yes, what is the configuration and relationship with the HCB and the HERA Board (Issue 8)
- Evaluate the efficiency of the overlaps in HERA and ECDC monitoring activities and consider re-assigning this mandate among the two bodies in the upcoming review of HERA's operations (Issue 1)
- Identify a single hub to gather information from Member States and the private sector and also for the public to seek useful guidance (Issue 8, 9)
- EU institutions, agencies, bodies and relevant entities to jointly conduct a simulation exercise from the recognition of a public health emergency to its termination (Issue 8, 9, 16, 17)
- Continue to discuss a Treaty change (Issue 16 and 17)

5.2 STREAMLINE SCIENTIFIC ADVISORY MECHANISMS

The Commission should clearly specify the role, the sets of expertise and the selection criteria in its call for experts for the Advisory Committee for public health emergencies. The Advisory Committee on public health emergencies, a permanent body established by Regulation (EU) 2022/2371, will soon be set up to provide advice on a wider range of threats to health and provide advice on the recognition of a public health emergency but also different response measures. Its composition will be crucial since the expertise of its independent members will to a large extent determine the areas of threats the Committee will be able to cover and successfully address.

The EU should also further examine the efficiency gains or losses of having multiple advisory bodies working on similar areas, and clarify how the different advisory bodies and their recommendations will relate to one another. Although it remains a rare scenario, opinions from different advisory bodies can be conflicting. In practice, it is likely that different bodies coordinate and exchange views on their tasks. Article 24 of Regulation (EU) 2022/2371 specifies that the advice provided by the Advisory Committee shall build upon recommendations of ECDC, EMA, WHO and other relevant Union agencies and bodies. This seems to suggest that the Advisory Committee will be the

central hub that will first collect and study recommendations by others and then provide clear and unified guidance to the Commission. Yet, depending on the threat at stake and the composition of the different groups, conflicting advice remains a possibility: for instance, ECDC may suggest stringent recommendations based on existing medical scientific research while the Advisory Committee, consisting of experts from social sciences and economy, may be less supportive of stringent measures that impact economic and social activity. The COVID-19 pandemic showed us that a lockdown or stay-at-home order could be highly controversial and lead to widespread socio-economic consequences (Collignon et al. 2021; Vasilopoulos et al., 2022; Liekefett et al., 2023).

It is essential to establish and maintain a strong and independent Union advisory mechanism that reaches areas beyond MCMs. For example, if a Union advisory body can quickly present pros and cons, and also whether there is a need, of border closure during a pandemic at national level, Member States can better manage their national policies. Some nationalistic measures, such as export bans, may seem beneficial to the nation but detrimental to the Union's solidarity. A strong advisory body can voice concerns and deliver impartial opinions on these matters that help national governments defend some unpopular policies.

Further review of EMA mandate should include a plan to mobilise sufficient staff and alternative funding sources to support the intense work of the ETF during an emergency. The capacity of EMA was heavily stretched during the pandemic due to the heavy work of reviewing COVID-19 vaccines. Regulation (EU) 2022/123 does not introduce additional resources for EMA to be able to sustain the proper functioning of the ETF during emergencies, except for covering the expenses of ETF rapporteurs. Drawing lessons from the experience of the COVID-19 pandemic, it should be already identified now how the ETF would be granted the ability to mobilise additional human and financial resources should a crisis increase its operating needs.

The lack of resources led EMA to fall back to its traditional regulatory role and unable to conduct adequate Health Technology Assessments (HTA) for COVID-19 vaccines and therapeutics as expected by the EU Member States. As discussed above, a joint procurement agreement of a product is also a joint reimbursement decision of all participating Member States. Therefore, a joint procurement agreement should also be accompanied by a HTA at Union level to ensure that the joint procurement of a product is cost-effective compared to purchasing other alternatives. EMA should be given sufficient resources or emergency human resources to conduct HTAs for vaccines and therapeutics.

Similarly, further review of the EUHTF operations under ECDC's coordination should include additional incentives to create a pan-European pool of experts that could be mobilised during public health emergencies. The ability of ECDC to mobilise sufficient staff and funding for the EUHTF to be able to cope with a large-scale public health emergency on European soil should be ensured. To constitute its enhanced emergency capacity, ECDC can draw experts from other institutions (e.g., national public health institutes), and these institutions would ensure the continuity of the experts' salaries while ECDC would cover their expenses linked to the EUHTF. Yet, these incentives are potentially not sufficient to ensure that key European experts would be willing to relocate temporarily nor that enough resources would be available in case of a surge in support request.

Box 2. Recommendations to streamline scientific advisory mechanism

- Clearly specify the role, the sets of expertise and the selection criteria in the Commission's call for experts for the Advisory Committee for public health emergencies (Issue 19)
- Examine the efficiency gains or losses of having multiple advisory bodies regarding the recognition of a public health emergency, be they ad hoc bodies for a specific consultation or existing agencies for thematic questions (Issue 3)
- Clarify the functions of different advisory bodies and ad hoc groups already during non-emergency times, in order to avoid conflicting messages and recommendations during emergency (Issue 15; Issue 20)
- Establish and maintain a strong and independent Union advisory body that reaches areas beyond MCMs (Issue 17)
- Beyond what is provided for by Regulation (EU) 2022/123, ensure adequate resources to EMA for it to be able to sustain the proper functioning of the Emergency Task Force during emergencies, as well as to conduct adequate Health Technology Assessments (HTA) for crisis-relevant health technologies such as medicinal products, medical equipment or treatment methods (Issue 6 and Issue 14)
- Enhance ECDC's ability to mobilise sufficient staff and funding, to allow the EU Health Task Force to cope with large-scale public health emergencies (Issue 7)

5.3 ENSURE A SMOOTH FLOW OF DATA AND INFORMATION RELEVANT FOR EMERGENCY RESPONSES

Between HERA and EMA, there should be regular communication to avoid potential duplications in their data collection and ensure the interoperability between their IT platforms. HERA and EMA's working agreement signed on 14 March 2023 can be a starting point for the collaboration between the two bodies in monitoring crisis-relevant MCMs. Joint activities including defining mutual datasets to avoid duplication in data collection and ensuring the interoperability between HERA's and EMA's IT platforms on MCMs must be followed by concrete action plans and allocation of resources. While the working agreement between HERA and EMA indicates that the two bodies should assign contact persons to ensure coordination in this area, in practice, it is critical that these contact points establish regular communication and information exchange.

The EU could ensure that Member States and pharmaceutical companies provide data on MCMs, by leveraging Regulation 2022/123, the forthcoming Pharmaceutical Legislation and the Data Act. To obtain supply chain data during the preparedness period, the EU should provide support, incentive or protection for Member States and companies to provide data to the Union. For instance, the Commission could set up an intelligence sharing space where participating governments and companies could benefit from the intelligence generated by data aggregation. By way of example, the EU could commit to deliver regular reports on the supply and demand forecasts of medical countermeasures at EU level, which could provide useful insights for companies. Through the exclusivity of this voluntary scheme, the benefit will attract governments and companies to participate. More importantly, the Commission should ensure that the data provided by governments and companies will not be used for purposes against their interests. The Commission should thus demonstrate the benefits of data aggregation at Union level. The Commission can employ its staff and experts to mine relevant data in a way that allows for useful supply and demand information and identifying risks. In addition, the EU can also promote the use of technologies such as blockchain to improve the traceability and transparency in the pharmaceutical supply chains (Musamih et al., 2021).

Regarding the use of health data during a time of crisis, it is necessary to ensure that the EHDS is emergency-ready. Data are the key to designing correct measures and also to developing effective medicinal products to fight a public health threat. The European Health Data Space will be the platform for sharing data for research and innovations; the European Parliament is working on its amendments at the time of writing. Supposedly, the EHDS will accelerate and broaden research and development in medicinal products, particularly in a public health emergency. However, the EHDS requires data holders to process the health data, e.g., standardisation, formatting and anonymisation, before sharing on the data space. This administrative hurdle could consume a considerable

amount of time and human resources, especially in a public health emergency. To avoid the EHDS becoming an obstacle in slowing down sharing of useful health data, the EU could consider including a clause similar to the Chapter V of the Data Act in a sense that it injects flexibility into the legislation during an emergency.

Box 3. Recommendations to ensure a smooth flow of data and information relevant for emergency responses

- Establish regular communication between HERA and EMA, avoid potential duplications in their data collection and ensure t interoperability between their IT platforms (Issue 4)
- Ensure that Member States and pharmaceutical companies provide data on MCMs both during preparedness and emergency times, by leveraging Regulation 2022/123 (Articles 3 to 14 and 21 to 30 thereof), the forthcoming pharmaceutical legislation (Articles 116 to 126, Chapter X) and the Data Act (Chapter V) (Issue 5)
- Include a clause similar to the Chapter V of the Data Act in a sense that it injects flexibility into the legislation during an emergency will be helpful in ensuring the EHDS is emergency-ready (Issue 18)

5.4 ENSURE ADEQUATE RESOURCES AND TOOLS FOR THE SUPPLY OF CRISIS-RELEVANT MEDICAL COUNTERMEASURES

The EU should strengthen its exercise of prioritising health threats relevant for the development, production capacity and scaling-up of manufacturing, procurement and potential stockpiling of crisis-relevant medical countermeasures. It can improve the transparency of this exercise through making available relevant documents related to the methodology and findings of the process. Such an exercise also needs to be backed by scientific independence and inclusive stakeholder consultation, ultimately ensuring the EU's pursuit of public health interest.

For the EU FAB tool to show benefits, the EU should extend the categories of medical countermeasures for the reservation of surge manufacturing capacity. Beyond vaccines, EU FAB should cover therapeutics (e.g., antivirals, antibiotics), personal protection equipment and other relevant medical devices. EU FAB's types of medical countermeasures should correspond to the list of priority health threats identified by the Commission in a transparent and inclusive way, as discussed above. In addition, the EU needs to clearly assign the role of activating and managing the EU FAB Network, ideally to HERA rather than another Commission service. This would allow constant management of this network through both the preparedness and crisis phase, mitigating coordination costs.

The EU can ensure timely and adequate funding to upscale the supply chains of medical countermeasures.

- First, the EU should **mobilise sufficient funding using the 'at-risk' investment approach**, i.e., provide funding to support the development and production of medical countermeasures even before they obtain regulatory marketing authorisation. This can be inspired by the US's Operation Warp Speed at-risk investment model in terms of the coverage of the funding support. More specifically, the EU's at-risk investment should provide financial support for a big enough portfolio of developers and manufacturers, from the very early stage (clinical trials) and throughout the production, packaging and distribution of the medical products. For the clinical trial phase in particular, funding should target not only trials carried by single pharmaceutical companies, but also clinical trial platforms which gather multiple smaller developers. Eligible trials can cover not only those for new medical countermeasures but also for existing ones, as well as test the effectiveness of public health and social measures.
- Second, to ensure adequate inputs for the manufacturing of crisis-relevant medical countermeasures, the EU can **be inspired by the use of priority-rated contracts agreed to under the US's Operation Warp Speed**. Meanwhile, taking the lessons learnt, the EU should avoid limitations of the Defense Production Act, such as the lack of transparency to identify which inputs are critical or its unintended consequence of pushing producers to move/expand their supply chain to third countries. The EU should also consider other input-ensuring policies, such as measures to re-shore the production of critical inputs (e.g., active pharmaceutical ingredients) through supporting innovative manufacturing technologies.
- Third, as suggested by Kathleen Van Brempt MEP, Chair of the COVI Committee of the European Parliament, the EU should **consider introducing an emergency clause in its budgetary rules**, mandating that different funding streams contribute to one single budget line (i.e., the Emergency Support Instrument) in time of emergency[111].
- Fourth, the EU should **strengthen the budgetary autonomy of HERA,** e.g., through allocating a dedicated budget to this authority. Such a budget allocation can be built on the upcoming review of HERA's operation, the EU can assess the option of providing HERA with dedicated own resources for its activities. One possibility could be to give HERA a specific budget line in the EU annual budget – similar to the EU's budget allocation to its agencies. The next multiannual financial framework (2027-

[111] Van Brempt K., 2022, COVI Committee: 5 important lessons learned from the pandemic, available at https://www.kathleenvanbrempt.be/europa/covidcommissie-5-lessen-geleerd-uit-de-aanpak-van-de-pandemie

2033) is another window for the EU to establish a HERA-dedicated funding programme.

- Last but not least, the EU should **promote a foresighted support to R&D**, facilitating the blending and sequencing of different funding programmes, particularly between those supporting preparedness and those on emergency R&D activities. The support should be comprehensive and planned ahead of a crisis. It should cover not only innovations that are ready for clinical purposes but also basic research and emergent solutions. Along with financial support to an emergent solution, the EU should seek to acquire a share of the intellectual property rights (IPR) or insert in the agreement a clause of IPR sharing if the innovation is identified by the Commission or EMA as one of the critical crisis-relevant MCM.

A highly controversial issue over the EU joint procurement of COVID-19 vaccines was the transparency of the process. The EU should thus learn the lesson and **establish a more transparent decision-making process covering the joint procurement of vaccines and other MCMs.** While Regulation (EU) 2022/2371 mentions that 'joint procurement procedures should abide by high standards of transparency in relation to Union institutions [...] and Union citizens', it remains settled in a voluntary implementation. Other references to transparency are made in the Regulation (e.g., Recital 40 and Article 13(5)), but always with the mention of the protection of commercially sensitive information and security interests, without introducing sufficient safeguards to protect the public rights to access public documents. If the legislation is to be kept reasonably flexible, such safeguards could take the shape of more specific guidelines on how to conduct certain processes and disclose certain types of information, and in strong accountability mechanisms that would ensure that EU officials are given sufficient and correct incentives to always work for the public interest.

Box 4. Recommendations to ensure adequate resources and tools for the supply of crisis-relevant medical countermeasures

- Back the prioritisation exercise with scientific independence and inclusive stakeholder consultation, and make available relevant documents related to the methodology and findings of the prioritisation process (Issue 2)
- Work on an improved structure of the current EU FAB going beyond its current term of eight years, and on extending the categories of medical countermeasures of EU FAB beyond vaccines, e.g., including antivirals, antibiotics, personal protection equipment and other relevant medical devices (Issue 10)
- Draw inspiration from the US use of priority-rated contracts, i.e., measures aimed at re-shoring the production of critical inputs (e.g. active pharmaceutical ingredients, bioreactor bags, filters and tubes) through supporting innovative manufacturing technologies, as well as subsidies along critical supply chains and investment to scale up manufacturing capacity (Issue 11)

- Mobilise sufficient funding using the 'at-risk' investment approach, i.e., providing financial support for a big enough portfolio of developers and manufacturers, from the very early stage (clinical trials) and throughout the production, packaging and distribution of the medical products (Issue 12)
- Consider introducing an emergency clause in its budgetary rules, mandating that different funding streams contribute to one single budget line (i.e., the Emergency Support Instrument) in time of emergency (Issue 12)
- Consider reinforcing HERA's budgetary autonomy, e.g., through giving HERA a specific budget line in the EU annual budget or establishing a funding programme for HERA under the next multiannual financial framework (2027-2033) (Issue 12)
- Promote a longer vision of R&D support, facilitating the blending and sequencing of different funding programmes, particularly between those supporting preparedness and those for emergency R&D activities (Issue 13)
- Establish a more transparent decision-making process covering the joint procurement of vaccines and other MCMs; provide more specific guidelines on how to conduct certain processes and disclose certain types of information – notably those of public interest (Issue 14)

5.5 IMPROVE COMMUNICATION AND TACKLE MIS- AND DISINFORMATION

The next European Commission and governments, through the implementation of Regulation (EU) 2022/2371, will have to seriously tackle the issue of scientific advice, foresight and communication, a key role that governments need to nurture in the age of poly-crisis. Otherwise, the public's temptation to adhere to conspiracy theories and populist discourse will further distance the Union from its citizens, inter alia, weakening the effectiveness of crisis response.

A crisis public communication strategy should be established, encompassing a clarification of how scientific advice was considered in the decision-making process, and why – perhaps – conflicting recommendations are published by different entities. With their reinforced mandates, ECDC and EMA have more power to communicate to Member States and the public directly, without the involvement of Member States, the Commission, or the Advisory Committee on public health emergencies. ECDC can for instance issue, on its own initiative, guidelines, recommendations and proposals for coordinated action for surveillance, monitoring, diagnosis and case management of communicable diseases. Moreover, the Commission itself can now issue recommendations on common temporary public health measures (Article 22 of Council Regulation (EU) 2022/2371) based on recommendations from ECDC, WHO, the Advisory Committee, and other relevant bodies. The Commission can publish these recommendations by notifying national competent authorities just 24 hours in advance of publication, and even without notice in case of urgent need. Given the variety of public

authorities who can communicate with the public-on-public health emergency, a crisis public communication strategy is critical to ensure consistent and coherent communication of scientific advice.

The EU should develop an all-round strategy against disinformation that includes a global dimension and also a bottom-up channel. At the global front, an international network of stakeholders is needed to develop joint anti-disinformation plans. Cooperation with nations and widely recognised international organisations like NATO, OECD, and UNESCO is essential (IPOL, 2023). Strengthening the utilisation of the Rapid System Alert, which is currently employed by the European Commission and the European External Action Service (EEAS) to monitor deceptive operations by foreign actors, is also crucial (European Commission, 2022).

Meanwhile, combating disinformation top-down may not be very effective without a bottom-up strategy that empowers citizens. It could be done through boosting literacy in areas such as health, politics, and new media technologies through innovative and also conventional education. Researchers should be encouraged or incentivised to engage the general public and share their scientific findings through EU funding opportunities and recognition with the objective to make science more accessible. Furthermore, public campaigns should raise awareness of social media disinformation, encouraging young people in particular to take part in fact-checking and correcting fake information online. EDMO can play a critical role in this effort by stepping up its efforts, providing citizens with media literacy tools, and encouraging bottom-up dialogue (Heiss, 2020).

In addition, the Union should encourage the development of new technology to identify false information. Fact-checking should be able to benefit from AI technology (Madani et al., 2021; Ozbay & Alatas, 2020; Paschen, 2019).

Box 5. Recommendations to improve communication and tackle mis- and disinformation

- Establish a crisis public communication strategy to avoid conflicting recommendations being published by different entities through the implementation of Regulation (EU) 2022/2371 (Issue 21)
- Develop an all-round strategy against disinformation that includes a global dimension and a bottom-up approach (Issue 21)
- Encourage the development of new technology to identify false information (Issue 21)

Table 4. Recommendations and corresponding issues

Area	Issue	Recommendation	Planning horizon	Feasibility
Governance Framework	Potential overlaps of Health Crisis Board and Health Security Committee	Clarify the relationship and allocation of responsibilities between the HCB and the HSC with regard to MCMs	The discussion should begin soon and feed into the implementations of the two regulations	Political resistance will likely be low from the Member States
	Ambiguous relationship between Health Crisis Board, HERA and HERA Board	Examine the interplay between HERA (also HERA Board) and the Health Crisis Board (HCB) in the upcoming review of HERA's operation, and ensure HERA has the necessary competence and autonomy to act effectively during a crisis	The discussion should begin soon and feed into the review of HERA in 2025	Political resistance will likely be low from the Member States
		Explain whether HERA, in crisis mode, would set up a 'HERA Crisis Board' and, if yes, what is the configuration and relationship with the HCB and the HERA Board	The Commission can decide internally and present the details in the next HERA Work Plan	High feasibility
	Overlapping competences and mandates on threat monitoring and assessment	Evaluate the efficiency of the overlaps in the HERA and ECDC's monitoring activities and consider re-assigning this mandate among the two bodies in the upcoming review of HERA's operations	The discussion should begin soon and feed into the review of HERA in 2025	Closer collaboration and removal of duplications of tasks may encounter internal resistance
	The new governance framework is not tested against a health emergency	EU institutions, agencies, bodies and relevant entities to jointly conduct a simulation exercise from the recognition of a public health emergency to its termination	The stress tests, simulation exercises and reviews of the Union prevention, preparedness and response plan should start as soon as the plan is available (i.e., December 2023, according to Regulation (EU) 2022/2371	The effectiveness of this exercise depends on the active participation of relevant entities
	Lack of competence of the EU over national public health / Lack of a coordinated	Better utilise the Integrated Political Crisis Response mechanism for cross-sectoral emergency response	Not applicable	The mechanism has already been institutionalised but will need the presiding

	approach to national border closure			Member States to take up the leadership
		Continue to discuss a Treaty change; establish and maintain a strong and independent Union advisory body that reaches areas beyond MCMs	The discussion should begin soon but it will take time to deliberate the idea	Some Member States have shown resistance to a Treaty change
Scientific advisory mechanisms	Potential lack of resources to sustain EMA's activities in a health emergency	Beyond what is provided for by Regulation (EU) 2022/123, ensure adequate resources to EMA for it to be able to sustain the proper functioning of the Emergency Task Force during emergencies, as well as to conduct adequate Health Technology Assessments (HTA) for crisis-relevant health technologies	The Commission should begin collecting ideas and prepare for the review of EMA mandate to be submitted by the end of 2026	The European Parliament will likely demand more transparency and accountability along with more funding
	Difficulties in ensuring the emergency capacity of the EU Health Task Force	Enhance ECDC's ability to mobilise sufficient staff and funding to allow the EU Health Task Force to cope with large-scale public health emergencies	The Commission should begin collecting ideas and prepare for the review of ECDC mandate to be submitted by the end of 2025	The European Parliament will likely demand more transparency and accountability along with more funding
	The Advisory Committee has not yet been formally established	Clearly specify the role, the sets of expertise and the selection criteria in the Commission's call for experts for the Advisory Committee for public health emergencies	The Commission is currently designing the configuration of the Advisory Committee	It shall be welcomed by stakeholders but consultations with other parallel advisory bodies will be appreciated
	Ambiguities in the factors warranting scientific advice on the recognition and termination of a public health emergency	Clarify how the different advisory bodies and their recommendations will relate to one another and their legal effects; examine the efficiency gains or losses of having multiple advisory bodies regarding the recognition of a public health emergency, be they ad hoc bodies for a specific consultation or existing agencies for thematic questions	The discussion should begin soon but could take time to streamline the EU advisory mechanisms	Resistance from Member States and parallel advisory bodies is likely

	Multiple and potentially overlapping advisory mechanisms	Clarify the functions of different advisory bodies and ad hoc groups already during non-emergency times, in order to avoid conflicting messages and recommendations during emergency	The discussion should begin soon but could take time to streamline the EU advisory mechanisms	Resistance from Member States and parallel advisory bodies is likely
Data and information	Potential duplications and inefficiencies in the collection of medical countermeasures data by EMA and HERA	Establish regular communication between HERA and EMA, avoid potential duplications in their data collection and ensure interoperability between their IT platforms	The discussion should begin soon and feed into the review of HERA in 2025	Closer collaboration and removal of duplications of tasks may encounter internal resistance
	Potential difficulties in accessing data from Member States and companies	Ensure that Member States and pharmaceutical companies provide data on MCMs by leveraging Regulation 2022/123 (Articles 3 to 14 and 21 to 30), the forthcoming Pharmaceutical Legislation (Articles 116 to 126, Chapter X) and the Data Act (Chapter V)	HERA should include this in the coming year's work plan	On data sharing, consultations with Member States and the industry will be useful
	Availability of data relevant for policymaking in emergency is not guaranteed	Include a clause similar to the Chapter V of the Data Act in a sense that it injects flexibility into the legislation during an emergency to ensure the European Health Data Space is emergency-ready	Currently the proposal of the EHDS legislation is being discussed in the European Parliament	The industry and Member States may not want extra obligations during emergencies
Funding and procurement of medical countermeasures	Lack of transparency in the prioritisation of health threats	Back the prioritisation exercise with scientific independence and inclusive stakeholder consultation, and make available relevant documents related to the methodology and findings of the prioritisation process	HERA should ensure this in the coming year's work plan	Resistance from stakeholders is unlikely
	Potential limitation of EU FAB	Work on a an improved structure of the current EU FAB going beyond its current term of eight years, and on extending the categories of medical countermeasures of EU FAB beyond vaccines, e.g., including antivirals, antibiotics, personal protection equipment and other relevant medical devices	HERA should ensure this in the coming year's work plan	Resistance from stakeholders is unlikely
	The activation of EU FAB is unclear	Clarify the competence for activating and managing EU FAB to allow constant management of this network through both preparedness and crisis phases	HERA should ensure this in the coming year's work plan	Resistance from stakeholders is unlikely but consultations with other relevant bodies are necessary

	Lack of EU funding to support at-risk investment	Adopt an 'at-risk' investment approach, providing funds to support the development and production of MCMs even before they have been granted marketing authorisation (as in the US's Operation Warp Speed model)	HERA should ensure this. However, this should be designed as a long-term plan	Resistance from stakeholders is unlikely.
		Draw inspiration from the US use of priority-rated contracts, i.e., measures aimed at re-shoring the production of critical inputs (e.g. active pharmaceutical ingredients, bioreactor bags, filters and tubes) through supporting innovative manufacturing technologies, as well as subsidies along critical supply chains and investment to scale up manufacturing capacity	Discussion should begin soon	This tool has substantial implication for the EU's budget and would face opposition from different EU entities and Member States
		Consider introducing an emergency clause in its budgetary rules, mandating that different funding streams contribute to one single budget line (i.e., the Emergency Support Instrument) in time of emergency	Discussion should begin soon	The implementation of this tool might face coordination deficits
		Consider reinforcing HERA's budgetary autonomy, e.g., through giving HERA a specific budget line in the EU annual budget or establishing a funding programme for HERA under the next multiannual financial framework (2027-2033)	The Commission should consider this in the coming review of HERA in 2025	Assigning new and independent budget line will induce questions about transparency and accountability of HERA's action. The European Parliament is very likely to demand more information on this
	Lack of a long-term EU vision on R&D funding	Promote a long-term, foresighted vision of R&D support, facilitating the blending and sequencing of different funding programmes, particularly between those supporting preparedness and those for emergency R&D activities	This should be designed as a long-term plan. But the Commission should begin collecting ideas now	On R&D, consultations with the industry and public research institutions are useful

	Transparency issues related to the procurement of crisis-relevant medical countermeasures	Establish more specific rules and guidelines to ensure a transparent decision-making process in the joint procurement of crisis-relevant MCMs	The Commission should begin the process soon	The Commission itself may be hesitant of implementing this
Communication	Lack of effective instruments in combating mis- and disinformation	Establish a crisis public communication strategy to avoid conflicting recommendations being published by different entities	The Commission should begin the process soon	The implementation of this tool might face coordination deficits
		Tackle the issue of scientific advice, foresight and communication through the implementation of Regulation (EU) 2022/2371. One very first step could be developing an all-round strategy against disinformation that includes a global dimension (e.g., through developing joint anti-disinformation plans or facilitating innovative technologies to identify misinformation) and a bottom-up channel (e.g. through boosting literacy and awareness in areas such as new media technologies and health, or supporting bottom-up dialogues)	The Commission should work on this and set up a long-term plan	Resistance to this is unlikely

6. CONCLUSION

The European Union (EU) implemented substantial institutional reforms in response to the COVID-19 crisis. These reforms are aimed at managing the pandemic and strengthening the EU's ability to respond effectively to future public health crises. This report endeavours to present and evaluate the EU's framework for responding to public health emergencies. It covers the process from recognising a public health emergency at the Union level and activating emergency measures to terminating the emergency at the Union level. In particular, the discussion revolves around significant institutional changes brought about by the new regulatory framework on public health security, notably Regulation (EU) 2022/2371 and Council Regulation (EU) 2022/2372. The establishment of the Health Emergency Preparedness and Response Authority (HERA), along with strengthened mandates for the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), are central aspects of these reforms. These changes undeniably bolster the EU's capacity and competence to respond to any future public health emergency.

However, these reforms alone may not suffice to deliver an effective response to future threats. The authors have identified several issues that could arise or be exacerbated within the EU response framework during a public health threat. The assessment uncovered complexity, ambiguities, potential overlaps, and gaps within the new framework. Lack of coordination among EU bodies and agencies could lead to duplicated efforts. Ambiguities in the emergency action chain, such as recognising or terminating a public health emergency at the Union level and supporting the procurement of medical countermeasures, could diminish the EU's response efficiency and speed. Financial constraints may impede the EU's ability to scale up its supply chains and ensure early access to crisis-relevant medical countermeasures. Additionally, potential lack of transparency in EU decision-making, the influence of the private sector, and suboptimal utilisation of data, information, and scientific advice could further weaken the effectiveness and efficiency of the EU's response capabilities.

Moreover, many measures within the framework currently exist only on paper and have not been tested against a real public health emergency. New issues might emerge, altering the dynamics of interactions among actors in the existing framework. For instance, if the upcoming review of HERA transforms this Commission service into a new institutional se-up (e.g., an independent agency), it could introduce new ambiguities into the already complex emergency response framework.

To ensure the framework's effectiveness during future health crises, the research team recommends that the EU conduct a comprehensive simulation exercise with independent

external observers, simulating all steps from recognising a public health emergency to deactivating it. The issues identified in this paper could serve as starting points for such an exercise. This simulation would aid in identifying problems and obstacles in the response framework and estimate the effectiveness and efficiency of the newly introduced, untested institutional changes.

The substantial reforms reflect the EU's determination to build a European Health Union with enhanced capacity and competence, instilling confidence in the public regarding the EU's preparedness for future crises. The report concludes by highlighting a critical factor not yet discussed—the human factor. Even the most comprehensive and effective institutional framework, on paper, will not achieve its intended effects in the absence of competent leaders and a trusted relationship between representatives of different institutions at various levels of government. The European Health Union stands as a remarkable concept that encapsulates invaluable lessons gleaned from the crucible of the COVID-19 pandemic. However, a well-crafted institutional framework on paper necessitates capable leaders and diligent individuals to translate vision into action. The presence of a strong leader, adept at clarifying hierarchies and establishing a clear chain of command, can leverage institutional complexity to advantage. It enables the ability to address various facets of health crises, which can often evolve into systemic crises, as witnessed during the COVID-19 pandemic. This approach facilitates the establishment of effective checks and balances. The Integrated Political Crisis Response (IPCR) indeed has the potential to be a game-changer. When effectively utilised by the presiding Member State of the Council during a crisis, IPCR can mobilise national governments, agencies, and experts, coordinating Member States' responses through astute negotiations at the Union level. A well-defined governance structure managed by effective governance bodies significantly contributes to the successful management of public health emergencies. In essence, it is the fusion of a sound institutional design with competent leadership and effective execution that will enable the European Health Union to live up to its potential and effectively respond to future health crises.

Nevertheless, Regulation (EU) 2022/2371 was officially adopted by the EU for only a year. The Commission and other institutional bodies are still working on the implementing regulations – e.g., the first one being Regulation (EU) 2023/1808 on prevention, preparedness and response planning, which was adopted on 21 September 2023. That said, this paper aims to provide an interim evaluation and offer recommendations that the Union may consider in future evaluations and reviews of relevant regulations.

REFERENCES

Arroyo, J. (2023), 'Being prepared is all that's needed to address the European Commission's transparency woes'. *CEPS Expert Commentaries*, CEPS, Brussels.

Bayerlein, M. (2023), *The EU's Open Strategic Autonomy in the Field of Pharmaceuticals*. SWP (Stiftung Wissenschaft und Politik).

Beke, M., Berenschot, L., Dutta, S., Horlings, C., Pees, R., Arroyo, J., Del Giovane, C., Mizsei, B., Renda, A., Vu, H. and Yeung, T. (2023), *The European public health response to the Covid-19 pandemic: Lessons for future cross-border health threats.* European Parliamentary Research Service, Brussels..

Blauberger, M., Grabbe, C., Ripoll Servent, A. (2023), 'EU free movement of people: fully recovered or suffering from long COVID?'. *Journal of European Public Policy,* Vol. 30, No. 4, pp. 696-720.

Bown, C.P. (2022), *The US was quick to produce Covid-19 vaccines. Then it fell behind.* Peterson Institute for International Economics.

Bown, C.P. and Bollyky, T.J. (2021), '*How Covid-19 vaccine supply chains emerged in the midst of a pandemic*', SSRN Electronic Journal, available at https://doi.org/10.2139/ssrn.3902082.

Bradshaw, S. and Howard, P.N. (2019), 'Social media and democracy in crisis', *Society and the internet,* Vol. 24, pp.212-227.

Brooks, E., de Ruijter, A. and Greer, S.L. (2021), 'Covid-19 and European Union health policy: From crisis to collective action', In Vanhercke, B., Spasova, S. and Fronteddu, B. (eds.) *Social policy in the European Union: state of play*, ETUI, pp.33-52.

Brooks, E., de Ruijter, A., Greer, S.L. and Rozenblum, S. (2023), 'EU health policy in the aftermath of COVID-19: neofunctionalism and crisis-driven integration', *Journal of European Public Policy,* Vol. 30, No. 4, pp.721-739.

Boin, A. and Rhinard, M. (2023), 'Crisis management performance and the European Union: the case of Covid-19', *Journal of European Public Policy,* Vol. 30, No. 4, pp. 655–675.

Carrera, S. and den Hertog, L. A. (2016), 'European Border and Coast Guard: Fit for purpose', *CEPS Expert Commentary,* CEPS, Brussels.

Cavaleri. M., Sweeney, F., Gonzalez-Quevedo, R. and Carr, M. (2021), 'Shaping EU medicines regulation in the post Covid-19 era', *The Lancet Regional Health – Europe,* Vol. 9, No. 100192.

Chetail, V. (2020), 'Crisis Without Borders: What Does International Law Say About Border Closure in the Context of Covid-19?' *Frontiers in Political Science* Vol. 2.

Collignon, S., Makropoulo, I. and Rüdig, W. (2021), 'Consensus secured? Elite and public attitudes to 'lockdown' measures to combat Covid-19 in England', *Journal of Elections, Public Opinion and Parties,* Vol. 31(sup1), pp.109–121.

Deruelle, T. and Engeli, I. (2021), 'The Covid-19 crisis and the rise of the European Centre for Disease Prevention and Control (ECDC)', *West European Politics*; Vol. 44, No. 5–6, pp.1376–1400.

ERGA. (2020), *Report on disinformation: Assessment of the implementation of the code of practice*. Available at https://erga- online.eu/wpcontent/uploads/2020/05/ERGA-2019-report-published-2020-LQ.pdf

European Commission. (2018), *A multi-dimensional approach to disinformation. Report of the independent High level Group on fake news and online disinformation,* Publications Office of the European Union, Luxembourg.

European Commission. (2019), *Report on the implementation of the Action Plan Against Disinformation,* Publications Office of the European Union, Luxembourg.

European Commission. (2020), *Tackling Covid-19 disinformation – Getting the facts right. Joint Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions,* JOIN/2020/8 final.European Commission. (2022), *The Strengthened Code of Practice on Disinformation.*

Florio, M. (2022), 'To what extent patents for Covid-19 mRNA vaccines are based on public research and taxpayers' funding? A case study on the privatization of knowledge', *Industrial and Corporate Change,* Vol. 31, No. 5, pp.1137–1151.

Florio, M., Pancotti, C. and Prochazka, D.A. (2021), *European pharmaceutical research and development: Could public infrastructure overcome market failures?* European Parliamentary Research Service, Brussels.

Fukuda-Parr, S. (2022), 'When indicators fail: SPAR, the invisible measure of pandemic preparedness', *Policy and Society,* Vol. 41, No. 4, pp. 528–540. tps://doi.org/ 10.1093/polsoc/puac024.

Gontariuk, M., Krafft, T., Rehbock, C., Townend, D., Van der Auwermeulen, L. and Pilot, E. (2021), 'The European Union and Public Health Emergencies: expert opinions on the management of the first wave of the COVID-19 pandemic and suggestions for future emergencies', *Frontiers in Public Health* Vol.9, no. 698995.

Group of Chief Scientific Advisors. (2022), *Strategic Crisis Management in the EU*.

Harrison, R. (2021), 'Tackling disinformation in times of crisis: The European Commission's response to the Covid-19 infodemic and the feasibility of a consumer-centric solution', *Utrecht Law Review,* Vol.17, No. 3, pp. 18–33.

Heiss, R. (2020), 'Fighting health infodemics: the role of citizen empowerment', *Eurohealth,* Vol. 26, No. 3, pp. 23–25.

Heiss, R., Waser, M., Falkenbach, M. and Eberl, J.M. (2021), 'How have governments and public health agencies responded to misinformation during the COVID-19 pandemic in Europe*?' European Observatory on Health Systems and Policies*.

Hyde, R. (2021), 'Von der Leyen admits to COVID-19 vaccine failures', *The Lancet,* Vol.397, No. 10275, pp. 655–656.

IPOL. (2023), *The effect of communication and disinformation during the Covid-19 pandemic*.

Jagusiewicz, A., Uteh, C.O. and Götz, J.P. (2023), 'Centralized vaccine procurement in the post-COVID-19 European Union', *South East European Journal of Public Health*.

Kassim, H. (2023), 'The European Commission and the COVID-19 pandemic: a pluri-institutional approach', *Journal of European Public Policy,* Vol. 30, No. 4, pp. 612-34.

Liekefett, L., Bürner, A.K. and Becker, J.C. (2023), 'Hippies next to right-wing extremists?' *Social Psychology,* Vol. 54, No. 3, pp. 123–135. Madani, Y., Erritali, M. and Bouikhalene, B. (2021), 'Using artificial intelligence techniques for detecting Covid-19 epidemic fake news in Moroccan tweets', *Results in Physics,* Vol. 25, No. 104266.

McKinsey. (2022), *HERA AMR feasibility study on stockpiling – D1-D5 Final report*.

Musamih, A., Salah, K., Jayaraman R, et al. (2021), 'A Blockchain-based approach for drug traceability in healthcare supply chain', *IEEE Access,* Vol. 9, pp. 9728–9743.

Naudé, W. (2020), 'Artificial intelligence vs Covid-19: limitations, constraints and pitfalls', *AI and Society,* Vol. 35, No. 3, pp. 761–765.

Opiłowska, E. (2021), 'The Covid-19 crisis: the end of a borderless Europe?' *European Societies,* Vol.23(sup1), pp. S589–S600. Ozbay, F.A. and Alatas, B. (2020), 'Fake news detection within online social media using supervised artificial intelligence algorithms', *Physica A: statistical mechanics and its applications,* Vol. 540, No. 123174.

Pagliari, C. (2021), 'Digital health and primary care: Past, pandemic and prospects', *Journal of Global Health,* Vol. 11, No. 01005.

Paschen, J. (2019), 'Investigating the emotional appeal of fake news using artificial intelligence and human contributions', *Journal of Product and Brand Management,* Vol. 29, No. 2, pp. 223-233.

Peyrony, J., Rubio, J. and Viaggi, R. (2021), *The effects of COVID-19 induced border closures on cross-border regions*, Pulblications Office of the European Union, Luxembourg.

Purnhagen, K.P., de Ruijter, A., Flear, M.L., Hervey, T.K. and Herwig, A. (2020), '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,* Vol. 11, No. 2, pp. 297-306.

Razavi, A., Collins, S., Wilson, A. and Okereke, E. (2021), 'Evaluating implementation of International Health Regulations core capacities: using the Electronic States Parties Self-Assessment Annual Reporting Tool (e-SPAR) to monitor progress with Joint External Evaluation indicators', *Globalization and Health,* Vol. 17, No. 69. Renda, A., Vu, H., Del Giovane, C. and Iacob, N. (2023), Improving the mission, governance and operations of the EU HERA. *CEPS In-depth Analysis,* CEPS, Brussels.

Rutter, H., Wolpert, M. and Greenhalgh, T. (2020), 'Managing uncertainty in the Covid-19 era', *BMJ, N*o. 3349.

Schanze, E. (2021), 'Best Efforts in the Taxonomy of Obligation – The Case of the EU Vaccine Contracts', *German Law Journal,* Vol. 22, No. 6, pp. 1133–45.

Timur, L. and Xie, Y. (2021), 'Is border closure effective in containing COVID-19?' *Travel Medicine and Infectious Disease,* Vol. 44, No. 102137.

Thiel, R., Lupiáñez-Villanueva, F., Deimel, L., Gunderson, L. and Sokolyanskaya, A. (2021), *Study on eHealth, interoperability of health data and artificial intelligence for health and care in the EU: Lot 1 – Interoperability of electronic health records in the EU,* Publications Office of the European Union, Luxembourg.

Transparency International. (2021), *For what benefit? Transparency in the development and procurement of Covid-19 vaccines*.

Varnai, P., Nausedaite, R., Beckers, D., et. al. (2019), *eHealth - Future digital health in the EU.* Final Report, EPSON.

Vasilopoulos, P., McCavay, H., Brouard, S. and Foucault, M. (2023), 'Emotions, governmental trust and support for the restriction of civil liberties during the Covid-19 pandemic', *European Journal of Political Research,* Vol. 62, No. 2, pp. 422–442.

Vériter, S.L., Bjola, C. and Koops, J.A. (2020), 'Tackling Covid-19 disinformation: Internal and external challenges for the European Union', *The Hague Journal of Diplomacy,* Vol. 15, No. 4, pp. 569–582.

World Health Organization. (2020), *Speech by the director-general at the Munich security conference*. 2020. Available at https://www.who.int/director-general/speeches/detail/munich-security-conference.

Wouters, O.J., Forman, R., Anderson, M., Mossialos, E. and McKee, M. (2023), 'The launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving global pandemic preparedness?' *Health Policy,* Vol. 133, 104844.

Wouters, O.J., Shadlen, K.C., Salcher-Konrad, M. et al. (2021), 'Challenges in ensuring global access to Covid-19 vaccines: production, affordability, allocation, and deployment', *The Lancet,* Vol. 397, No. 10278, pp. 1023–1034.

Zemła-Pacud. Ż. and Lenarczyk, G. (2023), 'Clinical trial data transparency in the EU: Is the New Clinical Trials Regulation a game-changer?' *IIC – International Review of Intellectual Property and Competition Law,* Vol. 54, No. 5, pp. 732–763.

CEPS
PLACE DU CONGRES 1
B-1000 BRUSSELS