Health policy 133 (2023) 104844

Contents lists available at ScienceDirect

Health policy

journal homepage: www.elsevier.com/locate/healthpol

The launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving global pandemic preparedness?

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ARTICLE INFO

Keywords:
European Union
Global health security
Horizon scanning
Research and development
Medical countermeasures

ABSTRACT

The crowded global health landscape has been joined by the European Union Health Emergency Preparedness and Response Authority (HERA). HERA will assume four broad areas of responsibility: horizon scanning for major health threats; research and development; support for capacity to manufacture drugs, vaccines, and equipment; and procuring and stockpiling key medical countermeasures. In this Health Reform Monitor article, we outline the reform process and describe HERA's structure and responsibilities, explore issues that arise from the creation of this new organisation, and suggest options for collaboration with existing bodies in Europe and beyond. The COVID-19 pandemic and other infectious disease outbreaks have shown the need to treat health as a cross-border issue, and there is now a broad consensus that greater direction and coordination at the European level is needed. This ambition has been matched with a considerable increase in EU funding to tackle cross-border health threats, and HERA can be used to deploy this funding in an effective manner. Yet this is contingent upon clearly defining its role and responsibilities vis-à-vis existing agencies to reduce redundancies.

1. Introduction

The European Union (EU) Health Emergency Preparedness and Response Authority (HERA) is a new Directorate-General within the European Commission [1]. With a budget of at least €1 billion per annum [2], about the same as the World Health Organization (WHO) holds in its core budget [3], HERA is set to become a major global health player [4]. In this Health Reform Monitor we examine the rationale behind the launch of this new Directorate-General, the wider context, the issues that shaped HERA's design, and the organisation's planned roles. We conclude with some questions that remain unresolved.

2. Why was HERA created?

The idea for HERA arose from a recognition that the EU and its member states had been inadequately prepared for the COVID-19 pandemic [5]. National authorities were faced with a novel, poorly understood, but obviously lethal virus that was spreading extremely rapidly. Initially, only a few member states seemed to be affected, but those that were, with northern Italy in the vanguard, were clearly struggling. Yet rather than implementing a carefully coordinated response, with mutual support, each member state went its own way. Borders, long open under the Schengen Agreement, were sealed and public authorities struggled to secure scarce resources, such as personal protective equipment, from wherever they could get them [5].

It was against this background that HERA was launched in September 2021. Its stated aim was "to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures" [6]. It draws inspiration from the US Government's Biomedical Advanced Research and Development Authority (BARDA), established in 2006 [7]. BARDA has several functions including procurement and stockpiling of essential supplies, research and development of medical countermeasures, and establishing manufacturing capacity for use in an emergency.

3. The wider context: political and economic background

HERA joins an already crowded global health landscape, which is populated by both long-established organisations (e.g., WHO and World Bank) and more recent additions (e.g., G20, Global Fund, Gavi, and several regional political groupings) [8]. There is also a layer of

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https://doi.org/10.1016/j.healthpol.2023.104844
Received 24 August 2022; Received in revised form 22 May 2023; Accepted 26 May 2023
Available online 27 May 2023

complexity and crowding introduced by the institutional makeup of the EU. In 1992, the EU gained an explicit responsibility for public health. [9] However, this responsibility is shared amongst several agencies, including the European Centre for Disease Prevention and Control, European Environment Agency, European Food Safety Authority, and European Medicines Agency. And while health-related matters fall mainly under the remit of the European Commission's Directorate-General for Health and Food Safety (DG SANTE), they also feature, often less directly, in the work of other directorates. The challenges that will arise as HERA navigates this complex web and explores ways to work together with all these organisations are obvious, with an imperative to avoiding the duplications and gaps that often characterise international systems.

4. Making it happen: health policy processes in the EU

While there was little disagreement that Europe needed to improve its preparedness for future threats, the question arose as to what form any new initiative should take. This had echoes of the discussions that would, eventually, lead to the establishment of the European Centre for Disease Prevention and Control in the early 2000s [10]. Specifically, there was considerable debate within the EU about whether HERA should be a new agency, with its own budget, or a Directorate-General of the European Commission [11]. The former model was blocked by several EU member states in favour of creating HERA as a Directorate-General, which has led to tensions between HERA and DG SANTE over budget allocation. Both HERA and DG SANTE are governed by the same commissioner, with DG SANTE retaining several directorates whose roles align closely with HERA, e.g., One Health (Directorate A), public health, cancer, and health security (Directorate B), digital, EU4Health and health systems modernisation (Directorate C), and medical products and division (Directorate D). The precise rationale for launching HERA as a separate Directorate-General remains unclear, but it likely reflected both political pressures and a reluctance to launch yet another agency with the attendant costs involved and concerns about the EU's perceived over-reliance on agencies [12].

5. What is HERA and what is its role?

The HERA board adopted its first work plan in February 2022 [13]. It then, in summer 2022, identified the top three health threats requiring EU coordination: pathogens with high pandemic potential; chemical, biological, radiological, and nuclear threats; and antimicrobial resistance [14]. It is expected that HERA will take on some of the roles undertaken by BARDA, namely horizon scanning, research and development, manufacturing capacity for drugs, vaccines, and equipment, and procuring and stockpiling key medical countermeasures (Fig. 1).

Building on the work conducted in 2022, HERA adopted its 2023 work plan which focused on five flagship initiatives: (1) establishing an information-technology system to enable its effective operations, (2) continuing development of medical countermeasures for epidemic and pandemic preparedness, including next-generation COVID-19 vaccines, (3) reserving manufacturing capabilities for vaccines, (4) establishing a financial mechanism to support the development and production of medical countermeasures, and (5) developing a strategy on medical countermeasure stockpiling at the EU level [15]. Under its 2023 workplan, HERA has nearly €475 million to support the advancement of research and development for medical countermeasures and related technologies, and over €650 million to support the provision of medical countermeasures.

Previous analyses of the potential role and responsibilities of HERA predate publication of HERA's work plans [1,16]. Building on these analyses, we examine the four main functions that HERA is expected to undertake and the barriers and enablers to achieving HERA's work plans. Although HERA is still under development, with its specific roles and responsibilities subject to change, this analysis provides a useful lens through which to analyse the rollout of HERA and can help inform ongoing policy discussions.

5.1. Horizon scanning

Horizon scanning seeks to identify threats ranging from pandemics and antimicrobial resistance to climate change. While the entry of HERA into this space introduces potential risks of duplication, it also represents an opportunity to bolster existing efforts if HERA adequately recognises the roles of other bodies in this arena.

A key challenge will be to determine its scope and remit in tackling threats which cut across disciplines, given the many factors that increase the risk of infectious disease outbreaks. These threats often arise at the complex interface between human, animal, and environmental health,

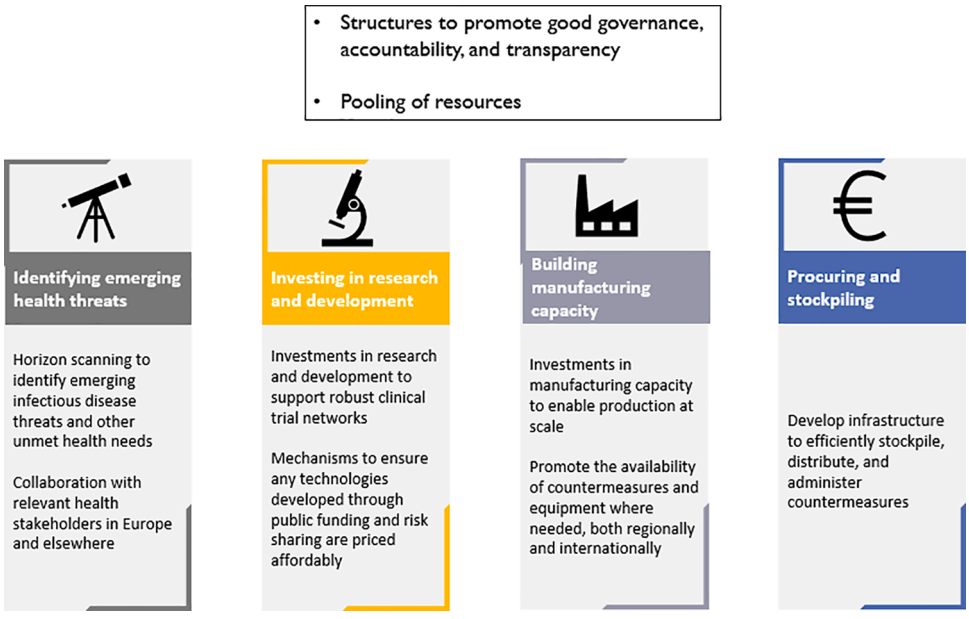

Fig. 1. Four pillars of an effective strategy for the European Union Health Emergency Preparedness and Response Authority.
Source: The authors.

where successful responses can be hampered by organisational boundaries [17]. For example, climate change will continue to pose threats from extreme weather events, food insecurity, and changes in infectious diseases [18]. And recent events in Ukraine have served as a reminder that conflict on European soil has not been confined to history [19]. The methods used to detect such varied threats differ, and those responsible are located in settings as diverse as food inspectorates, meteorology, and military intelligence.

Several EU institutions already undertake horizon scanning, most notably DG SANTE and European Centre for Disease Prevention and Control. There is also the Early Warning and Response System, an EU-wide rapid alert system that works with national authorities on serious cross-border threats to health. Anderson et al. noted the importance of close collaboration between the European Centre for Disease Prevention and Control and HERA, in light of their complementary roles [1].

As COVID-19 and mpox (formerly known as monkeypox) have made clear, successful horizon scanning requires cooperation far beyond the EU, including the WHO headquarters (and its Health Emergencies Programme and national focal points for International Health Regulation, which are located in countries around the world), the US Centers for Disease Control and Prevention, and the newly formed Global Virome Project. Other international initiatives include the WHO's Global Outbreak Alert and Response Network, the Program for Monitoring Emerging Diseases [20,21], the World Economic Forum's annual report on global risks, and the World Bank's fund for pandemic prevention, preparedness, and response [22].

HERA's 2022 work plan envisaged that it would sign memoranda of understanding with the WHO Hub for Pandemic and Epidemic Intelligence (led by WHO), European Centre for Disease Prevention and Control, and European Medicines Agency to establish structured collaboration [13]. HERA and WHO have since announced a partnership to strengthen pandemic preparedness and response. As part of this collaboration, HERA has committed €15 million in funding for various global initiatives aimed at, amongst other things, developing medical countermeasures to tackle antimicrobial resistance and promoting the sharing of epidemic and pandemic intelligence data through the WHO Hub for Pandemic and Epidemic Preparedness [23]. Separate deliverables relate to agreeing memoranda with other international and domestic agencies, including the Africa Centres for Disease Control and Prevention, BARDA, Coalition for Epidemic Preparedness Innovations, and UK's Advanced Research and Invention Agency. While this is a step in the right direction, further efforts are needed to avoid fragmentation and duplication. For example, a global forum which operates on a voluntary basis could be established to coordinate and strengthen horizon scanning efforts.

In September 2021, the Pan-European Commission on Health and Sustainable Development proposed the establishment of a pan-European system for disease control [24]. This would provide "an interoperable health data network based on common standards developed by WHO, recognizing that governments will move at different speeds" [25]. However, the geopolitical situation has changed since the report was published and current thinking sees this taking the form of a voluntary network, with different countries and organisations participating in ways appropriate to their capacity, needs, and ambition. It will be important to ensure the closest possible links between HERA and the WHO Hub for Pandemic and Epidemic Intelligence, building upon the strengths of existing national and international actors working in this space. This will, however, require imaginative solutions to organisational relationships and technical and governance aspects of sharing large quantities of data internationally.

5.2. Research and development

The existing research and development ecosystem is highly fragmented [26], and HERA must avoid duplicating efforts by other bodies. The most obvious first step is to ensure close coordination with bodies currently engaged in research and development related to emergency preparedness within the EU [26]. However, the necessary coordination will be challenging, in particular with the European Commission's Directorate-General for Research and Innovation and related European initiatives, such as the Innovative Medicines Initiative [27]. HERA will also have to coordinate with agencies beyond the EU, such as the larger and more generously funded BARDA and, in due course, the UK's Advanced Research and Invention Agency. This suggests a need for some sort of joint committee to define priorities and avoid duplication.

The European strategy for COVID-19 vaccines highlighted weaknesses in the EU's approach to developing and procuring emergency countermeasures. This began as a joint effort by four countries (France, Germany, Italy, and the Netherlands) acting as the so-called Inclusive Vaccines Alliance, but responsibility later transferred to the European Commission on behalf of its 27 member states. It allocated more than $3.2 billion (€2.7 billion) for research and development and pre-orders for several hundred million doses of COVID-vaccines [28]. Yet there was no pressure on vaccine manufacturers to engage with WHO and others to share the intellectual property and technical knowledge that could have enabled expansion of production [29].

Both in times of health emergency and times of stability, HERA can help promote the development of lifesaving countermeasures, and importantly, attach conditions to its funding relating to access and affordability of technologies developed using public money. It is important that HERA avoid merely subsidising the activities of pharmaceutical firms, and instead that it draws up plans to link its funding to clear public health objectives, influencing the pricing and distribution strategies of the companies it supports (with a view to promoting global access). This would help HERA avoid repeating mistakes made during the COVID-19 pandemic, where vast amounts of money were given to companies with little oversight. Governments and non-profit organisations contributed over US$10 billion to the development of new COVID-19 vaccines [29], yet most of this funding was not conditioned on data sharing, fair pricing, or equitable distribution [30]. The few organisations that did provide funding with access conditions did not seem to enforce these conditions [31].

5.3. Manufacturing capacity and production

HERA aims to adopt a lifecycle approach that supports companies from the discovery and development stages through to the production, distribution, and use of emergency countermeasures. The manufacturing of countermeasures was overlooked by many funders in the early stages of the COVID-19 pandemic [32,33]. Countries experienced shortages of key emergency countermeasures, including personal protective equipment[34] and vaccines [29].

The pandemic exposed the limited capacity in Europe to manufacture countermeasures, with the European Commission forced to procure most countermeasures from abroad. To ensure the EU is more self-sufficient in the next crisis, HERA will need to map existing manufacturing capacity across European countries for different countermeasures and identify where potential vulnerabilities and unmet need exist. Once identified, HERA will need to engage in public-private partnerships to increase investment in manufacturing capacity in a manner that can be rapidly scaled up to respond to major threats to health such as future pandemics.

HERA, by virtue of its purchasing power, can play an important role in promoting deep technology transfer as a way to expand production capacity. While intellectual property rights, data, and cell lines can be easily transferred with little involvement from the originator firm, it is time consuming, if not impossible, to transfer technical knowledge for manufacturing without the help of the originator. However, challenges would remain: because technical knowledge about how to produce vaccines and other complex biological products is often tacit, residing within the heads of individuals within companies, it may be difficult to

monitor companies' commitment to this aspect of technology transfer [35].

It should be noted that some progress was made during the COVID-19 pandemic. For instance, governments worked with some companies, like AstraZeneca, to set up regional and global production networks for COVID-19 vaccines [29]. Yet there are still many challenges, and much more can be done to help companies ramp up production of vaccines, therapeutics, and medical devices to mount a rapid and comprehensive response to future pandemics, and to achieve health objectives more broadly [36,37]. Some commentators have argued that voluntary measures, including financial incentives for companies to boost production are preferable to coercive measures, such as breaking patents [38].

5.4. Procuring and stockpiling

The EU learnt lessons from the shortages of medical supplies during the COVID-19 pandemic, which HERA can build on [39]. However, there are already several EU initiatives and players working in the procurement space, and it remains unclear how HERA will coordinate with them and what role it will play within this area.

While the Emergency Response Coordination Centre and rescEU were established pre-COVID-19 to coordinate disaster assistance efforts and manage stockpiles of medical equipment, they had never dealt with a sudden shock in which all EU countries required the same supplies simultaneously [40]. At the start of the pandemic, rescEU held a list of materials that each EU member state would be willing to provide during emergencies, but it did not maintain its own stockpiles. Thus, rescEU was unable to respond adequately when COVID-19 hit. It was only after an additional injection of funds that rescEU was able to establish a medical reserve and stockpile, hosted by nine member states [41].

HERA's 2022 work plan said it would strike "procurement and reservation contracts for medical countermeasures" and support "member states with their stockpiling and deployment to facilitate access for all European citizens when a health crisis occurs" [13]. However, HERA may need to consider how to expand an independent stockpile owned and maintained by rescEU that is ready for rapid deployment rather than continuing to rely upon agreements to deploy member states' stockpiles to countries. HERA will also need to negotiate a framework that clearly distinguishes the stockpiling roles of HERA from those of the Emergency Response Coordination Centre and rescEU. Such a framework should aid in coordination amongst these groups to reduce duplication and ensure resources are used efficiently [1].

Beyond mapping EU member states' and EU agencies' current stockpile capacities, HERA will need oversight of procurement and stockpiling systems hosted at the broader European and global levels through agencies like the WHO, to align efforts, share best practice and data, and ensure there are appropriate stockpiles to respond to international health emergencies [42]. This will involve working with Specific Procurement Procedure Steering Committees for pandemic influenza vaccines, COVID-19 booster vaccines, ventilators, personal protective equipment, therapeutics, and more. HERA will also need to support existing measures, such as advance purchase agreements for vaccines under the Emergency Support Instrument and Joint Procurement Agreements for medical countermeasures addressing cross-border health threats.

Thus far, HERA has led procurement efforts to secure vaccinations in response to the mpox outbreak, but medium- and long-term plans for this have not yet been announced [43]. Stockpiles will also need to be adapted to different threats to health that may emerge in coming decades. For example, the necessary countermeasures required to respond to pandemics created by a respiratory virus will be very different to those needed to respond to threats from antimicrobial resistance, the health consequences of climate change, or biological weapons. For this reason, the structure and composition of stockpiles will need to be informed by the horizon scanning activities of HERA and other organisations. There appears to be acknowledgement of this within HERA, as one of HERA's deliverables in its 2022 work plan was a feasibility study to explore solutions for stockpiling medical countermeasures to combat antimicrobial resistance, and its 2023 work plan built upon this with the development of a priority list of resistant pathogens and a pipeline analysis of medical countermeasures for antimicrobial resistance [13,15].

6. Remaining issues

There are several questions that go beyond those related to the specific roles that HERA is expected to perform.

6.1. Relationship with other stakeholders

The first set of questions relate to its relationships with other parts of the increasingly complex global health architecture.

We can identify four areas where HERA must consider how it interacts with existing entities. The first is within the 27 EU member states (and, on some issues, the 30 European Economic Area members), both individually and collectively. This will be especially important when it comes to implementing any international treaty on pandemic prevention, preparedness, and response (also referred to as the WHO pandemic instrument), which is expected to be adopted in 2024 and would apply to individual EU member states. While HERA could not oversee the implementation of the instrument, barring any changes to EU legislation, it could monitor implementation at the EU level. However, this risks a clash with work being done by DG SANTE in the area of health system resilience [44]. For this process to run smoothly, it will be important to clarify roles, responsibilities, and resource allocation to minimise tensions.

The second is work with neighbouring countries. The European Economic Area only covers part of Europe (30 countries), while the WHO's European Region spans 53 countries. There are well-established mechanisms for EU agencies to work with countries in Eurasia, both through cooperation agreements and through the WHO's Regional Office for Europe, which HERA can learn from. The Regional Office and European Centre for Disease Prevention and Control, for instance, already collaborate on a tuberculosis reporting programme covering the entire WHO European Region [45].

Third, at a global level, HERA must collaborate with international agencies involved in health, such as the WHO [46], and utilise multilateral platforms, such as the G20 and G7 group of countries, to promote collective agreements on sustainability and resilience. In line with objectives outlined within the EU Global Health Strategy [47], HERA will also need to collaborate with institutions such as the Africa Centres for Disease Control and Prevention and support actions related to sustainability and resilience in low- and middle-income countries, such as enhanced surveillance, expansion of manufacturing capacity, and rapid deployment of countermeasures [48,49].

Fourth, HERA must develop bilateral collaborations, both on an intergovernmental basis and with private companies, especially in countries with strong research infrastructure, such as Australia, Canada, Japan, the UK, and the USA. This will include developing partnerships and shared objectives with key organisations that have similar remits in other countries, such as BARDA and the UK Health Security Agency. It will also be necessary to navigate the more complex relationship with the North Atlantic Treaty Organization (NATO), given shared interests in health security.

6.2. Ambition and scope of HERA

The second set of questions relate to the ambition and scope of HERA [11]. As mentioned earlier, HERA was originally envisaged as an independent agency, but, after push back from several EU member states, HERA was established as a Directorate-General of the European Commission. This means that HERA does not have dedicated funding and

instead relies on resources from existing programmes. This could limit the ability of HERA to undertake rapid decision-making during crises. Several stakeholders have noted that this arrangement limits the autonomy and powers of HERA [48], and the organisation must work within the constraints imposed by the EU treaties that reserve competence for most aspects of health care to the member states [50].

This ambiguity continues to create tensions between member states and EU policymakers. For example, several member states pushed back against proposals contained within the European Health Union for the European Commission to have powers to audit member states' pandemic preparedness plans [51]. Re-negotiating this boundary of EU-level decision-making may not be politically and legally feasible in the short-to-medium term, and this could pose a significant obstacle for HERA when developing and implementing policies consistently across the EU.

6.3. Governance of HERA

The third set relate to governance. There are concerns around how HERA will be governed and how to ensure transparency and accountability in its operations [48]. Because HERA was established as a Directorate-General within the European Commission and not a stand-alone agency, it is not subject to the same level of scrutiny (including impact assessments, annual reports, audits, and ex-post evaluations) as EU agencies, as per the Common Approach adopted by the European Parliament, Commission, and Council. As noted in a recent report, "the absence of these measures during the establishment and operation of HERA raises concerns about the transparency of its governance and its pursuit of public interest" [48].

HERA is taking steps to address such concerns. It has established a board which brings together representatives from the European Commission and member states to collaborate on strategic planning and ensure alignment between EU and national health preparedness and response actions. HERA has invited other EU institutions, agencies, and bodies to be observers in its board. Recently, HERA signed an agreement with the European Centre for Disease Prevention and Control and the European Medicines Agency which outlined working arrangements to enable and strengthen coordination and collaboration and efficiency of their work [52]. HERA envisages creating a HERA Advisory Forum to promote cooperation with other EU bodies [53].

Conclusion

HERA offers an opportunity to strengthen the ability of health systems in Europe and beyond to respond to health emergencies. Yet HERA now faces challenges in developing a sustainable structure and achieving its work plan effectively and efficiently.

The COVID-19 pandemic and other infectious disease outbreaks have shown the need to treat health as a cross-border issue, and there is now a broad consensus that greater direction and coordination at the European level is needed. This ambition has been matched with a considerable increase in EU funding to tackle cross-border health threats, and HERA can be used to deploy this funding in an effective manner. Yet its success will depend on clearly defining its role and responsibilities vis-à-vis existing agencies to reduce redundancies. The ball is now in HERA's court.

Role of the funder/sponsor

The funder had no role in the preparation of the manuscript or the decision to submit the manuscript for publication; representatives from the World Health Organization Regional Office for Europe provided feedback on an earlier draft of the manuscript.

Declaration of Competing Interest

A grant from the World Health Organization Regional Office for Europe supported Dr Wouters. Dr McKee reports being Research Director of the European Observatory on Health Systems and Policies. No other disclosures were reported.

Acknowledgments

We are grateful to Peter Piot and Christian Wimmer for comments on an earlier draft, although the views expressed here are solely those of the authors.

References

[1] Anderson M, Forman R, Mossialos E. Navigating the role of the EU Health Emergency Preparedness and Response Authority (HERA) in Europe and beyond. Lancet Reg Health Eur 2021;9:100203.
[2] European Commission. European Health Emergency preparedness and Response Authority (HERA): getting ready for future health emergencies. 2021. https://ec.europa.eu/commission/presscorner/detail/en/ip_21_4672 (accessed 7th July 2022).
[3] Nature. The WHO deserves more money for its core mission - and more respect. Nature 2022;602:7–8.
[4] Reiss M. High hopes for Europe's new Health Emergency and Response Authority. BMJ 2022;376:o127.
[5] Anderson M, McKee M, Mossialos E. Covid-19 exposes weaknesses in European response to outbreaks. BMJ 2020;368:m1075.
[6] European Commission. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee Of The Regions. Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union. 2021. https://ec.europa.eu/health/system/files/2021-09/hera_2021_comm_en_0.pdf (accessed 15th March 2022).
[7] Department of Health and Human Services. Biomedical advanced research and development authority. 2023. https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/default.aspx (accessed 17th May 2023).
[8] Greer SL, Amaya AB, Jarman H, Legido-Quigley H, McKee M. Regional international organizations and health: a framework for analysis. J Health Polit Policy Law 2022;47:63–92.
[9] McKee M, Mossialos E, Belcher P. The influence of European law on national health policy. J Eur Soc Policy 1996;6:263–86.
[10] MacLehose L, McKee M, Weinberg J. Responding to the challenge of communicable disease in Europe. Science 2002;295:2047–50.
[11] Deutsch J. HERA isn't the hero Parliament wants — Or the game-changer Council fears. Politico 2021. https://www.politico.eu/article/hera-eu-commission-health-emergency-preparedness-response-authority/(accessed. 30th April 2023.
[12] Schout A. EU agencies after 25 years: a missed opportunity to enhance EU governance. Den Haag: Clingendael Institute (Netherlands Institute of International Relatons); 2018. https://www.clingendael.org/publication/eu-agencies-after-25-years. accessed 30th April 2023.
[13] European Commission. HERA work plan 2022 - responding to the current pandemic, preparing for future health emergencies. 2022. https://ec.europa.eu/commission/presscorner/detail/en/fs_22_944 (accessed 21st June 2022).
[14] European Commission. Health Union: HERA delivers list of top-3 health threats to prepare against. 2022. https://ec.europa.eu/commission/presscorner/detail/en/ip_22_4474 (accessed 23rd August 2022).
[15] European Commission. 2023 annual work plan of the Health Emergency, Preparedness and Response Authority (HERA) 2023. https://health.ec.europa.eu/system/files/2022-11/hera_2003_wp_en.pdf (accessed 17th May 2023).
[16] Villa S, van Leeuwen R, Gray CC, van der Sande M, Konradsen F, Fröschl G, Nord DG, da Costa CP, Ramirez-Rubio O, Abubakar I, Bärnighausen T, Casamitjana N, Berner-Rodoreda A, Cobelens F, Plasència A, Raviglione M. HERA: a new era for health emergency preparedness in Europe? Lancet 2021;397:2145–7.
[17] Bloomer E, McKee M. Policy options for reducing antibiotics and antibiotic-resistant genes in the environment. J Public Health Policy 2018;39:389–406.
[18] Oliver I. Understanding the health effects of climate change. 2021. https://ukhsa.blog.gov.uk/2021/11/09/understanding-the-health-effects-of-climate-change/(accessed 7th July 2022).
[19] McKee M, Murphy A. Russia invades Ukraine again: how can the health community respond? Bmj 2022;376:o548.
[20] World Health Organisation. Global outbreak alert and response network 2021. https://extranet.who.int/goarn/#banner (accessed 26th May 2021).
[21] ProMED. ProMED. 2021. https://promedmail.org/(accessed 26th May 2021).
[22] World Economic Forum. The global risks report 2021. 16th Edition. Geneva: WEF; 2021.
[23] World Health Organisation. The European Union and WHO further enhance their partnership for stronger pandemic preparedness and response. 2022. https://www.who.int/news/item/08-12-2022-the-european-union-and-who-further-enhance-their-partnership-for-stronger-pandemic-preparedness-and-response (accessed 30th April 2023).

[24] Forman R, Azzopardi-Muscat N, Kirkby V, Lessof S, Nathan NL, Pastorino G, Permanand G, van Schalkwyk MC, Torbica A, Busse R, Figueras J, McKee M, Mossialos E. Drawing light from the pandemic: rethinking strategies for health policy and beyond. Health Policy (New York) 2022;126:1–6.
[25] Monti M. Report of the Pan-European commission on health and sustainable development Copenhagen: WHO, 2021.
[26] Lurie N, Keusch GT, Dzau VJ. Urgent lessons from COVID 19: why the world needs a standing, coordinated system and sustainable financing for global research and development. Lancet 2021;397:1229–36.
[27] Innovative Medicines Initiative. Europe's partnership for health. 2022. https://www.imi.europa.eu/(accessed 22nd June 2022).
[28] European Commission. Communication from the commission to the European Parliament, the European Council, the Council, and the European Investment Bank. EU Strat COVID-19 Vaccines 2021. https://ec.europa.eu/info/sites/default/files/communication-eu-strategy-vaccines-covid19_en.pdf. accessed 21st June 2022.
[29] Wouters OJ, Shadlen KC, Salcher-Konrad M, Pollard AJ, Larson HJ, Teerawattananon Y, Jit M. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. Lancet 2021;397:1023–34.
[30] Moon S, Agarwal S, Becker A, Alonso Ruiz A. Embedding global access in development of future pandemic vaccines. BMJ 2021;374:n2256.
[31] Usher AD. CEPI criticised for lack of transparency. Lancet 2021;397:265–6.
[32] Emanuel EJ, Persad G, Upshur R, Thome B, Parker M, Glickman A, Zhang C, Boyle C, Smith M, Phillips JP. Fair allocation of scarce medical resources in the time of Covid-19. N Engl J Med 2020;382:2049–55.
[33] Wu HL, Huang J, Zhang CJP, He Z, Ming WK. Facemask shortage and the novel coronavirus disease (COVID-19) outbreak: reflections on public health measures. EClinicalMedicine 2020;21:100329.
[34] Ranney ML, Griffeth V, Jha AK. Critical supply shortages - the need for ventilators and personal protective equipment during the Covid-19 pandemic. N Engl J Med 2020;382:e41.
[35] Sampat BN, Shadlen KC. The COVID-19 innovation system. Health Aff (Millwood) 2021;40:400–9.
[36] Adepoju P. Africa CDC warns COVID-19 vaccine production could cease. Lancet 2022;399:1683.
[37] Nweneka CV, Disu T. The future of vaccine manufacturing in Africa. Brookings; 2022. https://www.brookings.edu/blog/africa-in-focus/2022/02/14/the-future-of-vaccine-manufacturing-in-africa/. accessed 23rd August 2022.
[38] Frieden T., Buissonnière M. The U.S. has the power to tamp down coronavirus variants — if we're willing to use it. 2022. https://www.politico.com/news/agenda/2021/03/02/us-coronavirus-variants-471981 (accessed 18th March 2022).
[39] Jit M, Ananthakrishnan A, McKee M, Wouters OJ, Beutels P, Teerawattananon Y. Multi-country collaboration in responding to global infectious disease threats: lessons for Europe from the COVID-19 pandemic. Lancet Reg Health – Europe 2021;9:100221.
[40] Forman R, Mossialos E. The EU response to COVID-19: from reactive policies to strategic decision-making. JCMS: J Common Market Stud 2021;59:56–68.
[41] MedTechEurope. Stockpiling as an instrument to strengthen public health emergency preparedness and healthcare systems' resilience. 2020. https://www.medtecheurope.org/wp-content/uploads/2020/09/2020_mte_reflection-paper-stockpiling_092020.pdf (accessed 21st June 2022).
[42] European Industrial Pharmacists Group. First steps of the HERA authority and comments from industrial and medical associations. 2022. https://eipg.eu/tag/stockpiling-of-medical-countermeasures/(accessed 21st June 2022).
[43] European Commission. HERA secures vaccines for EU Member states in response to the monkeypox outbreaks. 2022. https://ec.europa.eu/commission/presscorner/detail/en/IP_22_3674 (accessed 23rd August 2022).
[44] EU Expert Group on Health Systems Performance Assessment. Assessing the resilience of health systems in Europe: an overview of the theory, current practice and strategies for improvement. European Commission; 2020. https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/2020_resilience_en.pdf. accessed 30th April 2023.
[45] European Centre for Disease Prevention and Control. Annual TB surveillance reports. (undated). https://www.ecdc.europa.eu/en/tuberculosis/surveillance-and-disease-data/annual-tb-surveillance (accessed 6th December 2021).
[46] European Commission. Statement by commissioners Stella Kyriakides and Jutta Urpilainen – towards a new EU Global Health Strategy. 2022. https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_22_3128 (accessed 23rd August 2022).
[47] European Commission. EU global health strategy: better health for all in a changing world. 2022. https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en (accessed 17th May 2023).
[48] Renda A., Del Giovane C., Vu H., Iacob N. Improving the mission, governance and operations of the EU HERA. 2023. https://www.ceps.eu/download/publication/?id=38637&pdf=CEPS-In-depth-analysis-2023-01_Mission-governance-and-operations-of-the-EU-HERA.pdf (accessed 17th May 2023).
[49] McKee M., Field S., Vella S., Legido-Quigley H., Kazatchkine M. The EU has a global health strategy: the challenge will be in the implementation. Lancet:DOI: 10.1016/S0140-6736(23)00328-8.
[50] Mossialos E, Permanand G, Baeten R, Hervey TK, editors. Health systems governance in europe: the role of European Union law and policy. New York, N.Y: Cambridge University Press; 2010.
[51] Deutsch J. Europe's 'Health Union' prepares for its first feeble steps. Politico 2021. https://www.politico.eu/article/european-health-union-coronavirus-ema-hera-barda/. accessed 30th April 2023.
[52] European Commission. HERA signs agreement with ECDC and with EMA to strengthen cooperation on health emergency preparedness and response. 2023. https://health.ec.europa.eu/latest-updates/hera-signs-agreement-ecdc-and-ema-strengthen-cooperation-health-emergency-preparedness-and-response-2023-03-14_en (accessed 17th May 2023).
[53] European Commission. Governance. 2022. https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/governance_en (accessed 17th May 2023).