HERA-lding more integration in health? Examining the discursive legitimation of the European Commission's new Health Emergency preparedness and Response Authority

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Abstract

Context: Since COVID-19, the European Commission (EC) has sought to expand its activities in health through the development of a 'European Health Union' and within it, the Health Emergencies Preparedness and Response Authority (HERA).
Methods: We applied a discourse analysis on documents establishing HERA to investigate how the creation of this institution was legitimated by the EC. We focused on how it framed health emergencies; how it framed the added value of HERA; and how it linked HERA to existing EU activities and priorities.
Findings: Our analysis demonstrates that security-based logics have been central to the EC's legitimation of HERA – in alignment with a 'securitization of health' occurring worldwide in recent decades. This legitimation can be understood as part of the EC's effort to promote future integration in health in the absence of new competencies.
Conclusions: Securitization has helped the EC raise its profile in health politically, without additional competencies, thereby laying the groundwork for potential future integration. Looking at the discursive legitimation of HERA sheds light not only on *whether* the EC is expanding its health powers, but also *how* it strategizes to do so. HERA, while constrained, allows the EC to further deepen security-driven integration in health.

Introduction

The COVID-19 pandemic provided an impetus for the European Commission (EC) to raise its profile in public health. Although at the very beginning of the pandemic member states (MS) were driven by nationalistic instincts, shut borders and were reluctant to share resources, by late March 2020 the EC took on a more substantive leadership role – even if it was a somewhat ad hoc one[i]. The EU's renewed emphasis on health during and since COVID went against the pre-pandemic direction of travel, in which the budget allocated for public health in the then upcoming multiannual financial framework (MFF) for 2021-2027 was set to be eliminated as a stand-alone program and incorporated in the EU Social Fund. That budget now stands at around €5 billion over the 7-year period, a considerable increase compared to the €400 million in the previous (2014-2020) MFF. Along with the increased financial commitment to public health, in September 2020 the Commission President launched the idea of a 'European Health Union' (EHU), signaling a desire to develop a strategic vision for the future of EU engagement in health (European Commission 2020a).

The stated purpose of the EHU is to address weaknesses identified during the COVID pandemic: the lack of an EU-wide coordinated response; inadequate availability of 'medical countermeasures' (MCMs) such as vaccines, pharmaceuticals, and PPE; and vulnerable national health systems. The key initiatives of the EHU include establishing a European Health Emergency Preparedness and Response Authority (HERA, our focus in this article), creating a Health Data Space, developing a Pharmaceutical Strategy, and extending the mandates of the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and the European 'Beating Cancer Plan'. The EHU also provides the context within which the 2013 Decision on cross-border health threats was repealed and replaced with the stronger and more comprehensive 2022/2371 Regulation on serious cross-border threats to health (European Union 2022a). While some researchers have hailed the EHU as a highly significant step towards 'post-Westphalian governance' (Fraundorfer and Winn 2021), the EU studies literature is divided on the extent to which the EHU really represents a significant shift towards supranationalism (Quaglia and Verdun 2023).

Our starting point in this article, given the EU's limited mandate in health, is that the very creation of HERA is itself a notable development – and one that required legitimation by the EC (whose initiative it was). As we will discuss in detail below, HERA's mandate is to strengthen health security coordination within the EU, to improve the resilience of supply chains of MCMs (development, production, procurement, stockpiling, and distribution), and to contribute to strengthening the global health security architecture (European Commission 2021a). In this article, we are interested in understanding how the EC discursively legitimated the creation of HERA – and what that legitimation strategy can tell us about the prospects for further EU integration in health. To do so, we apply a discourse analysis approach to the key EC documents and statements that made the case for establishing HERA, paying attention to how the EC framed health emergencies; how it framed the added value of HERA; and how it argued that the establishment of HERA was consistent with existing EU activities and priorities. The article then draws on concepts from neofunctionalism to reflect on the implications of this legitimation approach for further integration.

We show that security-based logics have been central to the EU's legitimation of HERA – in alignment with a more general 'securitization of health' that has taken place worldwide in recent decades in which infectious diseases have increasingly come to be seen not 'merely' as health problems, but as security problems. Through this discursive strategy, the EC's sought to build

a case that the creation of HERA was an effective way to secure the Union against future health threats, emphasizing the added value of HERA as a body able to address a need that cannot be satisfied at national level, whilst also arguing that it was consistent with the EU's activities and priorities in other areas, thereby making the case that it was not acting beyond its competencies. We agree with De Ruijter and Brooks's (2022) assessment that HERA's scope currently remains limited (and is certainly considerably narrower than the EC's initial ambition to emulate the US' BARDA[ii]), but argue that its creation nevertheless has political significance. Building on their argument, our analysis adds the importance of considering the role of discursive framing and legitimation in shaping the possibilities and limits of supranational health governance, shedding light on *how* the EC pushes for potential future integration, and how it shapes the terms of engagement with health issues towards securitized responses.

Our argument in this article, in line with the Special Issue of which it is a part, hinges on an approach that stresses the close relationship between health and politics (Bambra et al 2005), which scholars have captured in the concept of 'political determinants of health' (Ottersen et al 2014). In this case, COVID-19 raised the importance of health on political agendas world-wide, including at EU level. At the same time, political considerations, and power dynamics shaped responses (as they do to all health problems), in turn influencing the possibilities for new developments in the (EU-level) governance of health. Our focus in this paper is on discursive legitimation as a political determinant of health governance, and consequently of health.

The article is divided into four sections: The first introduces the EU's growing role in public health, along with neofunctionalist concepts that have proven useful to explain this evolution. Section two presents our analysis of the legitimation of HERA. After introducing HERA and outlining our methodological approach, we show how the EC discursively legitimated HERA through i) presenting health emergencies as a collective security threat to MS (building a case for the need for EU-level action); ii) arguing that HERA would make a positive contribution to the health security of the EU, MS and, ultimately, European citizens; and iii) building a case that HERA was consistent with, and would positively contribute to, existing areas of EU engagement in health. In the third section, we interpret the results by exploring the synergies between health securitization and EU integration dynamics. In the fourth section, we conclude and reflect on what the discursive legitimation of HERA can add to the study of the political determinants of health.

The EU's involvement in public health

The historical development of the EU's involvement in public health has been a contentious, politically sensitive, and 'messy' process (Brooks et al 2023). Its competencies in public health were formally institutionalized under the Maastricht Treaty in 1992. Article 152 TEC (Article 168 TFEU) was the first formal legal basis for a shared competence in public health and mandated the EU to complement member state action in the 'fight against the major health scourges'. Its realms of action focused on three main areas: cross-border health threats, so-called 'common safety concerns'[iii], and, to a lesser degree, health promotion in matters such as drug, alcohol, and tobacco control (Lamping and Steffen 2009).

It is, however, well-understood that the EU's involvement and impact on public health extends beyond these shared competencies (Greer et al. 2022). Greer (2014) theorized this as 'three faces' of EU involvement in health: (1) via public health competencies – which, arguably, so far has been the least influential one, (2) via Single Market integration beyond the common safety concerns, and (3) via economic governance and fiscal coordination processes. The EU's

far-reaching public health impact despite its limited competencies is illustrative of how complex and multifaceted the drivers and determinants of health are, and that policies in non-health areas often affect health indirectly (Godziewski 2022).

The far-reaching, and growing, impact of the EU on public health via activities that are not initially about health, is also a good illustration of neofunctionalist spillover. Several EU health scholars have drawn on (aspects of) neofunctionalism to explain gradual integration 'creep' in health (Greer 2006), also highlighting the precipitating effects of crises (Brooks et al. 2023). Neofunctionalism places emphasis on the role of supranational institutions and non-state actors in driving the integration process (Bulmer et al. 2020). Health is a good case of this dynamic, with integration happening in an incremental, technocratic, ad-hoc manner, despite the reluctance of member states to confer on the EU powers in health. 'Spillover' refers to path-dependencies: the notion that integration in one area will have implications that require more integration beyond the initially defined area – effectively, that integration begets more integration (Bulmer et al. 2020). Early neofunctionalist work differentiated between functional and political spillover: the former being where the goal of integration in one area cannot be technically achieved without integration in another; the latter being cases where national elites intentionally push to 'upload' an issue to EU level to bypass deadlocks at the national level (Niemann 1998). Further types of neofunctionalist integrative pressures that have been examined in the literature include, among others, 'cultivated spillover', and 'build up' (Schmitter 1970). Cultivated spillover describes how supranational institutions (especially the EC) actively push for spillovers – both functional and political – to further EU integration and increase its own supranational power (Niemann 1998). A 'build-up' of power, on the other hand, refers to 'the concession by Member States of greater authority to the supranational organization without expanding the scope of its mandate' (Niemann 2021: 121).
Further integration, whether via spillover or otherwise, must be justifiable in relation to the key principles that govern EU competencies: conferral, subsidiarity, and proportionality. This means that demonstrating the added-value of EU-level action, as well as alignment with existing activities (if no new competence is to be conferred), are important legitimacy criteria for the EC, which need to be understood in conjunction with the framing of the health issue itself.

Our analysis of the discursive legitimation of HERA contributes to better understanding *how* the EC seeks to further – via build up and laying the groundwork for future cultivated spillover – its involvement in public health, specifically cross-border health threats. This is an area in which the EC has increased its powers over time and often in response to crises: a dynamic which relates to the 'securitization' of health which, in its classic formulation (Buzan, Waever, and de Wilde 1998) involves constituting political issues as matters of 'security', in doing so enabling types of response (in this case, the expansion of EU activities) that may not be possible in 'normal' times (see our analysis p.7 'Framing health emergencies' and the discussion on p.11).

Monitoring, early warning and combatting cross-border health threats is a priority in Article 168 of the TFEU. It involves a mix of institutions responsible for epidemiological surveillance (the ECDC; Bengtsson, Borg, and Rhinard 2019), emergency response (the Health Security Committee (HSC; De Ruijter 2018) and the Civil Protection Mechanism (European Council 2023; Brooks, De Ruijter, and Greer 2021). Both the HSC and the ECDC were created in response to emergencies: the former following the terrorist attacks of 2001, which led to a new prioritization of 'manmade' as well as naturally-occurring disease outbreaks; and the latter after the 2003 SARS outbreak, which significantly accelerated the securitization of health at the global level (Davies, Kamradt-Scott and Rushton 2015) and in the EU (Bengtsson and Rhinard

2019; De Ruijter 2018; Kittelsen 2013). The mandates of both the HSC and ECDC have been strengthened over time – often in response to further health-related crises which have opened political space for expanding their roles (Deruelle and Engeli 2021). Until 2022, the legal basis for this expanding role was found in the 2013 Decision on Cross-Border Health Threats (European Union, 2013) which, in addition to funding research and coordinating evidence, gave the EC the power to determine whether there is a public health emergency and set up channels for adopting extraordinary measures in such emergencies. In 2022, a new Regulation on Cross-Border Health Threats, repealing the 2013 Decision, was adopted. This further strengthened the EU's role in addressing cross-border health threats.

The purpose of this section was to draw attention to some of the main characteristics of the EU's developing role in public health, and to show how this has historically been linked with emergencies that have been perceived as threats to health security. Although its official competencies remain limited, the EU's activities are a significant political determinant of health, both directly and indirectly. In relation to cross-border health threats, we have seen in recent years a gradual expansion of its remit – often in response to crises which have provided windows of opportunity for deepening the supranational governance of public health. Neofunctionalism, and its central concept of spillover(s), has proven a useful theory to explain integration in health (Becker and Gehring 2022; Brooks et al. 2023). The EC gradually (though not necessarily linearly) expanding its role in a policy area jealously guarded by MS raises a need to investigate how it discursively legitimates these moves, and how legitimation supports the type(s) of expansion at play. HERA represents an interesting recent empirical case for this investigation.

Through the analysis that follows, we highlight the importance of considering discursive dynamics when looking at the EC's efforts to push for further integration in health. We concur with the neofunctionalist assessment of HERA as representing a build-up of power which has the potential to lead to future cultivated spillover. But to this assessment, our contribution adds an emphasis on discourse: we argue that the security-based discursive legitimation of HERA, through its 'two phase' logic (preparedness and crisis), is particularly effective as a means of laying the groundwork for future cultivated spillover in the event of future health crises, while necessitating limited change (merely 'build-up') during the preparedness phase. An implication of our argument is that focusing on discursive strategy is useful to better understand neofunctional pressures in EU health integration.

The discursive legitimation of HERA

Launched at the height of COVID-19 in 2021, HERA started as an 'incubator' project geared towards anticipating and responding to new COVID-19 variants (European Commission 2021b). It subsequently became institutionalized as a Commission Service and its scope of action broadened. As a Commission Service (European Union 2022b), HERA falls under the Commissioner for Health and Food Safety. The authority is structured around four units: policy and coordination; intelligence gathering, analysis, and innovation; medical countermeasures; and an emergency office (European Commission 2022). Strategic planning is undertaken by the HERA Board, which is composed of EC and MS representatives. It currently operates with a budget of €6 billion over 6 years, which comes from a variety of sources including the EU4Health Programme and the Next Generation EU economic recovery package.

HERA is set up to operate in two phases: 'preparedness' and 'crisis'. HERA was created via a simple Commission Decision, as its activities under the preparedness phase did not involve any new mandate. On the day that it published that Decision, the Commission also proposed a 'Council Regulation 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' (European Commission 2021c) to cover the activities foreseen in case HERA's 'crisis phase' was activated, enabling the EC 'to have special arrangements in place to better react in times of health crisis' (European Union 2022b: 1). The proposal resulted in a Council Regulation (EU) 2022/2372 of the same name being adopted in October 2022. In the EC's September 2021 Communication introducing HERA, this was portrayed as 'the next step towards completing the European Health Union'.

In the remainder of this section, we examine how the creation of HERA was discursively legitimated. The section first explains the methods used to explore this question, and then goes on to identify the key features of the EC's legitimation strategy, on which we build in the remainder of the article.

Methods

This section presents the findings of a discourse analysis of four key documents representing the EC's statements on the creation of HERA. The documents were aimed at a variety of audiences, providing a good insight into the ways in which the EC sought to legitimate HERA. Each of these documents was published on the same date: 16 September 2021. We chose to focus on these four documents because they are the outputs marking the EC's big announcement of the HERA launch. Institutions are not static, and their legitimation can thus evolve over time. In this article, we focus on the discursive legitimation at the time of the launch of HERA. As detailed below, the selected documents cover different aspects of this launch and are targeted at different audiences, which gives us good insight into the discursive strategies adopted by the EC at that moment in time. We utilized the official English language version of the documents, as available from the EC website (European Commission n.d.). The four documents are:

- *Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. 'Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union'. COM(2021) 576 final.* This 14-page document (plus 5-page Annex) sets out the EC's rationale for the establishment of HERA; how it will operate; what tasks it will perform during both the 'Preparedness Phase' and the 'Crisis Phase'; how it will relate to other EU agencies; its global role beyond the EU; and how it will be governed, structured, and funded. The Annex provides a breakdown in tabular form of the respective competences of HERA, the ECDC and the EMA across a range of activities in both the 'Preparedness Phase' and the 'Crisis Phase'. [Hereafter "Communication"].
- *Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority. C(2021) 6712 final.* This 7-page Decision document provides the legal basis for the establishment of HERA by the EC. It provides the background to the creation of the new body, and over 9 Articles sets out its status as a Commission Service (Article 1); its mission and tasks (Article 2); its organizational structure and governance arrangements (Articles 3-7); the arrangements for review (Article 8); and the details of the Decision's (immediate) entry into force (Article 9). [Hereafter "Decision"]

- *Proposal for a Council Regulation 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. COM(2021) 577 final.* This 19-page document sets out the EC's proposal for a Council Regulation pertaining to HERA's activities during the crisis phase. The proposed text of the Regulation (pp.8-19) is preceded by an 'Explanatory memorandum' (pp.2-7) which sets out the rationale and objectives of the proposal; its consistency with other EU activities; its legal basis; the consultations that have taken place in advance of the proposal; and the budgetary implications. The same document also contains a 22-page 'Legislative Financial Statement'. [Hereafter "Proposal"]
- *Press release: European Health Emergency preparedness and Response Authority (HERA): Getting ready for future health emergencies.* Aimed at a wider public/media audience, this 3-page document announces the creation of HERA, explains the rationale for its existence, and outlines the roles it will play in both the preparedness and crisis phases of future health emergencies. It also explains the source of HERA's budget, the arrangements for its creation and review, and includes five quotes from Commissioners. [Hereafter "Press Release"].

These documents were coded in NVivo 14 through an iterative, structured approach. This was structured by applying three questions to the documents: i) how does the document 'frame' health emergencies? ii) what claims are made in the document for the benefits of establishing an EU-level body? iii) what claims does the document make that the establishment of HERA is consistent with existing EU activities and priorities? Each document was coded in three 'passes', with each 'pass' focusing on one of the three questions.

In each pass, we identified and categorized relevant parts of the text (ranging from individual words to entire sections), creating new codes and/or adding text to existing codes. At the conclusion of each pass, the resulting codes, sub-codes, and sub-sub codes were analyzed and organized, allowing for an analysis in relation to each question. The final coding files are provided as supplementary materials. Although the coding strategy did result in quantitative data on the frequency of individual codes (both within and between documents), given the nature of the documents and our research questions, our analysis instead relied on a qualitative approach.

In the remainder of this section, we present and provide illustrative examples to support our key findings in relation to each question, contextualizing this with reference to the existing literature.

Framing health emergencies

Health issues can be 'framed' in various ways, with frames being understood here as "linguistic, cognitive and symbolic devices used to identify, label, describe and interpret problems and to suggest particular ways of responding to them" (Rushton and Williams 2012: 154). As such, they are key to the legitimation of policy initiatives – especially where a case is being made for new initiatives. The global health literature has identified a wide range of ways in which health emergencies have been 'framed': as a risk to public health (perhaps the most obvious), as an economic problem, as a security threat, or as a humanitarian crisis (Labonté and Gagnon 2010; McInnes et al. 2014; Shiffman 2009; Shiffman and Shawar 2022). Our analysis identified the presence of three frames, although with an overwhelming dominance of a security framing.

The framing of health emergencies as a threat to *public health* was present in some documents, for example in the quote from Ursula von der Leyen in the Press Release that "With HERA, we will make sure we have the medical equipment we need to protect our citizens from future health threats" and in the Proposal document which, echoing Art. 168, noted that "The proposal contributes to achieving a high level of human health protection". Interestingly, public health was most often discussed in combination with the *economic consequences* of cross-border disease crises, as illustrated by this example from the Communication:

> HERA operations require a significant and sustainable budget. Investing in prevention and preparedness now will result in a significantly lower human and economic cost later and will have a large return on investment – not only for the economy, but also for society and the health of European citizens.

It was likewise relatively rare for the economic consequences to be discussed alone, although the Proposal did note that "The social and economic activity in the EU should be secured in all times".

Security framings of health emergencies were by far the most common throughout the four documents and were evident in two main ways: a) in the drawing of explicit connections to other, established security threats; and b) through language and conceptual apparatus that had, over preceding decades, become part of the *lingua franca* of '(global) health security'.

In relation to the former, there were frequent references to the links between health emergencies and well-established security issues. For example:

> Globalisation, climate change, natural and man-made disasters, biodiversity loss, habitat encroachment as well as armed conflicts and terrorism drive the emergence and escalation of health emergencies, which can emerge anywhere on the globe and rapidly spread across continents. (Communication)

There were also regular reminders that health emergencies can be either 'natural' or deliberate (e.g. as a result of bioterrorism):

> "The HERA would seek to improve public health by strengthening the EU's preparedness and response for serious cross-border threats to health, both of natural and intentional origin" (Proposal)

In relation to the established language and concepts of (global) health security, we find in the documents direct references to the term "health security" itself; copious examples of 'security-related language' (for example "emergency", "crisis response", "preparedness"); an emphasis on the inevitability of future health crises; but also, a foregrounding of three themes that have become emblematic of 'securitized' approaches to health.

First, there have been efforts directed towards 'horizon scanning' for identifying future/emerging health security threats through the strengthening of national and international disease surveillance systems (UKHSA 2023: 14).[iv] Although this is, for the most part, a task carried out by the ECDC, HERA is described as having significant horizon-scanning functions including that "HERA should mean that the EU and Member States work together to analyze and define threats" (Communication) as well as contributing to "strengthening the global health security architecture for preparedness, prevention, detection of, and response and recovery to health emergencies" (Communication).

Second, the (global) health security discourse has put significant emphasis on local, national, and international efforts to enhance preparedness for future disease emergencies. These have taken various forms, including assessing current preparedness levels (Global Health Security Index 2019); developing stockpiles of medicines and other medical equipment (Elbe, Roemer-Mahler, and Long 2014); providing training for policymakers and/or health workers, for example through outbreak simulation exercises (Copper et al. 2020); developing inter-operability protocols to ensure that different emergency services or aid providers can effectively coordinate during a health crisis (Kim, Ku, and Oh 2022); and working with the private sector to put in place business continuity plans (WHO 2018). Such activities, and the language of preparedness, are strongly present in the documents: indeed, as already discussed, HERA's planned activities are explicitly presented in terms of two 'Phases': 'Preparedness' and 'Crisis Response'. The documents note, for example, that "The best way to master future health crises is to anticipate and prepare before they materialize" (Communication) and that "intelligence gathering and analysis …is crucial for underpinning preparedness and response plans".

Third, pharmaceutical-based responses to health threats – MCMs – have been particularly prominent. Elbe, Roemer-Mahler and Long (2015) have referred to this as the 'pharmaceuticalization of security', showing not only how pharmaceuticals have become important parts of the national security strategies of many (especially Western) countries, but also the extent to which this has led to the need for the state to partner with, and provide support to, private pharmaceutical companies to stimulate Research and Development into pandemic-related medical technologies (e.g. Long 2022 on the United States' BARDA). MCMs are the 'core business' of HERA: the Communication describes one of HERA's key tasks (Task 3) as being to

> Identify and ensure the availability of critical technologies and production sites for medical countermeasures in the EU capable of increasing their production in times of need, including through support of breakthrough innovation. (Communication)

Similarly, Commission Vice-President for Promoting the European Way of Life, Margaritis Schinas, is quoted in the Press Release as saying that

> HERA will have the clout and budget to work with industry, medical experts, researchers, and our global partners to make sure critical equipment, medicines and vaccines are swiftly available when and as necessary.

Taken together, the documents overwhelmingly frame health emergencies in terms of security, evident in both the language used and the objectives of HERA. Indeed, this is not a case in which a public health institution is 'merely' being framed in terms of security: HERA itself, we would argue, can best be understood as fundamentally a (health) security institution. Key to the success of the framing, however, is the notion that MS can, through accepting an expansion of the EC's role in relation to public health, gain security benefits that would not be possible though acting in isolation. Acting in isolation, the EC argues, can undermine those benefits. It is to these claims of the 'added value' of HERA that we now turn.

The added value of HERA

When acting on an area of shared competence, the principle of subsidiarity means that the EU must make the case that EU-level action is necessary and adds value; that MS alone cannot

achieve the desired goal. The added value of HERA is explained in a number of ways in the documents analyzed including: improving cooperation and coordination between MS; improving collective crisis response; enhancing data and information sharing between MS; providing economies of scale; opening up avenues for emergency funding; allowing coordination and cooperation with industry; supporting MS to improve preparedness; effective monitoring of supply and demand for MCMs on an EU-wide basis; and – perhaps most importantly – enabling action at all stages of the MCM supply chain (Research & Innovation; Production; Procurement; Stockpiling; and Distribution) that would not be feasible for individual MS acting alone. Although each of these is an important aspect of HERA's activities (and each is supported by detailed references in the supplementary coding file), here we focus only on the last one: the added value of HERA in terms of monitoring and management of the supply chain of MCMs.

First, the documents are explicit that inadequate supply-chain management for MCMs, and competition between MS for scarce resources, was a major cause of problems during the COVID-19 pandemic, for which EU-level action offers a potential solution.

> Public health emergencies of the magnitude of the COVID-19 pandemic have an impact on all Member States. Actions by individual Member States could neither address the challenges resulting from such an emergency nor are they able to provide a sufficient response on their own. Unilateral action through Member State initiatives aiming to ensure the sufficient and timely availability and supply of crisis-relevant medical countermeasures runs the risk of increasing internal competition and suboptimal Union level response. Such unilateral action can ultimately result in significant economic consequences and affect the health of Union citizens. (Proposal)

Second, the documents seek to build a case for the specifics of HERA's potential future contribution at each stage of the supply chain for MCMs, from Research and Innovation:

> Promoting research on key and emerging pathogens as well as incentivising advanced research, innovation and development of relevant technologies and countermeasures – including diagnostics, therapeutics, and vaccines – will be an important aspect of work during the preparedness phase. (Communication)

to ensuring there is sufficient production capacity to meet demand:

> HERA will address market challenges and boost industrial capacity. Building on the work done by the Task Force for Industrial Scale up of COVID-19 vaccines, HERA will establish a close dialogue with industry, a long-term strategy for manufacturing capacity and targeted investment, and address supply chain bottlenecks for medical countermeasures.
>
> The EU FAB facilities, a network of ever warm production capacities for vaccines and medicines manufacturing, will be set in motion to make available reserved surge manufacturing capacities, as well as emergency research and innovation plans in dialogue with Member States. (Press release)

to procurement:

> Efficient procurement procedures for crisis-relevant medical countermeasures and raw materials should be ensured, and the Commission should be entrusted with a negotiating mandate to act as a central procurement body for Member States, using rules and procedures under Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council26 as well as Council Regulation (EU) 2016/36927. (Proposal)

And finally, to stockpiling and, during a future crisis response phase, distribution (although the Proposal notes that "The deployment and use of the crisis-relevant medical countermeasures shall remain the responsibility of the participating Member States"):

> HERA will reinforce stockpiling capacity in the EU and work with EU agencies, national authorities, and external stakeholders to coordinate coverage and deployment across the EU. (Communication)

Through its presentation of these tasks, and the lessons of COVID, the EC sought to build a case for the added value of HERA as an EU-level mechanism. In doing so, it relies upon making claims for the benefits of (EU-level) collective action by supporting MS to overcome the competition and coordination problems that had hampered the COVID response.

Consistency with existing EU activities

The third element of the EC's attempts to legitimate HERA that emerges from the documents is that it is consistent with, and indeed contributes to, existing EU-level activities. Here, we coded for cross-references to other EU bodies, plans, policies, and programs, generating a list of 21 explicit links drawn[v]. Some of these connections are proximate (for example, with ECDC and EMA, where the Annex to the Communication sets out a clear division of labor across the Preparedness and Response phases), others are more distal, including arguments that HERA will contribute to the coherence of the internal market, the research and innovation agenda, and the protection of workers.

In addition, the EC made explicit efforts in three of the four documents (the exception, understandably, being the Press Release) to outline the Treaty basis for HERA's operation in the Crisis Phase being Art122 TFEU. This article is increasingly drawn upon to pursue (economic) policy through crisis measures (Chamon 2023). It relates to exceptional measures to be adopted in response to a crisis with adverse economic consequences, justified based on the principle of solidarity between Member States – in this case, to guarantee the availability and accessibility of crisis-relevant MCMs.

Overall, then, our analysis of the four documents reveals a three-pronged strategy for the legitimation of HERA: i) framing health emergencies as a threat to security (of the EU as a whole, or individual MS, and ultimately of citizens), justifying a need for action; ii) building on the failures of COVID, arguing that HERA would have significant added value, enabling collective security through actions that would not be possible or effective if taken by individual MS; and iii) that HERA was consistent both with other EU activities and programs, and also had a firm legal basis.

HERA, legitimation, and (future) integration in health

In the previous section, our analysis outlined the EC's efforts to legitimate the creation of HERA. Two of the three aspects identified are classic (expected and required, even) EC

supranational legitimation moves: demonstrating EU added value and justifying the Treaty basis and consistency with other activities. The third aspect of the EC's legitimation of HERA relates to the discursive framing of health emergencies themselves. Both health emergencies and the EU added value of HERA are framed using security-based logics and Article122 TFEU's 'emergency/crisis' focus is the hook used as the legal basis for HERA's establishment. Although there is no counterfactual case to show whether the EC's proposals would have been accepted without such a security framing, what these findings demonstrate is that the EC itself saw this as a viable discursive strategy, and that security framings were prominent in the EC's written justification to a variety of institutional and public audiences.

Securitization of health at EU level is not a new phenomenon (Bengtsson and Rhinard 2019), and indeed the relationship between EU integration and health securitization has previously been explored by Sonja Kittelsen (2013) who argued that securitization supranationally presents unique features that differ from the traditional securitization theory developed by the 'Copenhagen School' (Buzan, Waever, and de Wilde 1998). In the technocratic EU environment, Kittelsen argued, securitization is better understood as a *process* that unfolds over time, rather than an act. The process leads to changes that are not necessarily sudden and exceptional (as suggested in the Copenhagen School) but can instead be gradually incorporated into 'normal politics' (Floyd 2016). For Kittelsen (2013: 274):

> […] a successful securitization in this *[EU]* context is not likely to be expressed by the breaking free of otherwise binding rules. Rather, the relative success of the process of securitization can be measured on the basis of the push for further EU-level competences and activities in governing the threat of an influenza pandemic.

Echoing her argument, our analysis demonstrates that security framings were crucial in legitimating the creation of HERA, and that the creation of HERA can be seen as part of the EC's effort to push for more EU integration in public health.

That said, to what extent does HERA represent a successful case of integration in health? Here, we concur with Brooks et al's (2023) assessment that, for now at least, HERA represents a 'build-up' of power, given that no new competencies have been conferred. Nevertheless, its creation is significant, reflecting a push for stronger coordination of pre-existing EU-level activities, and has the potential to develop into further cultivated spillover over time (Brooks et al. 2023: 727), especially during the institution's 'crisis phase of operation. These developments are consistent with the EC's past reactions to health crises (Brooks and Geyer 2020). While HERA in its preparedness phase represents a relatively limited expansion of the EU's role in public health (mainly involving stronger coordination of pre-existing activities and discursive profile raising), we would suggest that it is only when the next health emergency occurs and the crisis phase is activated that HERA's scope will become more visible, and that cultivated spillover might occur. The security-based legitimation, including the future-oriented nature of security discourses, helps prepare for future spillover – when the (inevitable) next crisis occurs.

The EC's security framing of HERA should also be contextualized within the EC's move to take on a 'crisis leadership' role during the COVID-19 pandemic. The creation of HERA further strengthens the EC's discursive power and its perceived legitimacy both to articulate and pursue a leadership role in future health emergencies. The institutional characteristics of HERA – an intra-Commission service as opposed to an executive agency as might have originally been the plan (European Commission 2020a) – can thus be seen as sign of EC leadership, a way for the EC to build itself up, assert its role in health (security), and promote future integration in this

area. Kassim (2023) argues that the EC's leadership during crises is often underestimated. During this pandemic, it was clearly leading, while the Council followed, and the European Parliament complained about being sidelined from the process of HERA's establishment (European Parliament 2021; European Parliamentary Research Service 2022). HERA's institutional set up in that sense also reflects the aligned interests of the Council – because it does not require politically sensitive maneuvers like the transfer of competencies – and of the EC, because it raises its profile in health governance, laying the ground for potential future cultivated spillover.

Conclusion

Security framings were seen by the EC as key to strengthening its activities in a field where the EU's competencies are weak. The fact that health crises can lead to more EU involvement in health is a common and well-documented phenomenon and supports the interpretation of our findings.

HERA as it stands does not represent significant further integration. Rather, it represents the consolidation, strengthening, and coordination of pre-existing EC activities in the preparedness phase. This is more akin to what the neofunctionalist literature calls a 'build up' of power. However, HERA is still in the making, and we have yet to see the activation of the crisis phase, which may well have the potential to lead to cultivated spillover in health. The future-oriented nature of the security logic, along with the EC's display of leadership in the EU's response to COVID, and the radical budgetary changes dedicated to health in the MFF, all suggest that HERA may well become an avenue for future cultivated spillover. At this stage, it remains to be seen whether, when, and how this will materialize. But our article draws attention to how security-based logics have been key to legitimate the creation of HERA, and how this strengthens the hand of the EC in public health.

To return to the theme of this special issue – the political determinants of health – we have emphasized the importance of discursive power and discursive strategies to highlight *how* the EC is pushing for further integration, which ultimately will have an impact (even if that impact is not yet known) on the handling of future health crises affecting Europe. Security as a frame proved useful for the EC's efforts to legitimate the swift (albeit still work-in-progress) creation of HERA, which now has a large budget, indicating a shift compared to the pre-COVID status quo. But, like any approach to governance, the discourses within which it is embedded are likely to shape the terms on which health issues become thought about and acted upon – in this case: aligned with the (global) health security trend worldwide.

We do not seek to determine whether this is fundamentally 'good or bad' but highlight that any discursive framing of policy issues is not neutral, that it contains reflections of power dynamics, strengths, and trade-offs, as well as potential unintended consequences (Bacchi 2012). And while securitization has come to be widely accepted and may well be a suited response to the failures the EC identified and spelled out, it is not immune to criticism (Rushton 2019). First, health security is premised on a response-mode approach to health problems that seeks to identify and mitigate problems when they occur, rather than examining and acting on the root causes of health crises (which include the social, economic and environmental processes that increase the likelihood of pandemics occurring) (Bengtsson 2022) and the reasons behind the inadequacy of existing response capacities (which include the legacies of austerity and eroded social welfare structures). Second, these approaches avoid disrupting the operation of existing

markets by working with – and subsidizing – pharmaceutical corporations to produce MCMs for the EU, while neglecting *global* health justice implications (Usher 2021). In that sense, the discursive legitimation of HERA can be understood as: 1) a political determinant of health in itself, affecting the response to health crises; 2) as having wider implications for multilevel governance dynamics in public health in the EU, including opening up opportunities for future cultivated spillover in health which will, in turn, impact on health; and 3) as reflective of global ideological trends which themselves can be understood as political determinants of health (Rushton and Williams 2012).

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[i] For an account of the EU's response to COVID, see: Brooks, De Ruijter and Greer (2021); European Commission (2023)

[ii] BARDA, the US Biomedical Advanced Research and Development Authority, "provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks; pandemic influenza (PI), and emerging infectious diseases (EID).". (US Department of Health and Human Services 2023).

[iii] The 'common safety concerns' mentioned in Article 168 TFEU refer to the safety of three categories of goods: organs and substances of human origin, blood and blood derivatives; goods requiring sanitary and phytosanitary standards (for example foodstuffs and feeds); and medicinal products and devices for medical use. Here, the Treaty empowers the EU to implement measures setting baseline quality standards.

[iv] One of the key international policy instruments for this has been the 'International Health Regulations' (IHR), last updated in 2005. The IHR, an international framework agreed under the auspices of the WHO, put a number of obligations on WHO member states including the development of capacities to detect the emergence of disease outbreaks of potential international concern; a duty to rapidly notify the WHO of the emergence of such a threat (serving as an international early warning system); and the development of capabilities to be able to contain the outbreak to prevent local epidemics becoming global pandemics.

[v] Biodefence Preparedness Plan; CBRN Action Plan; Cohesion Policy; Digital Europe Programme; Digital Single Market; Emergency Support Instrument; EU FAB; EU Industrial Strategy; European Green Deal; European Regional Development Fund; EY4Health; ECDC; EHU; EMA; Horizon Europe; InvestEU fund; One Health Action Plan; Pharmaceutical Strategy for Europe; Recovery and Resilience Facility; Single Market Programme; Union Civil Protection Mechanism.