

Strengthen Democratic Oversight of HERA

Effective coordination of health risks in the EU requires regulated powers

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In light of experiences with the pandemic, the new health authority HERA (Health Emergency Preparedness and Response Authority) is to improve the EU's preparedness for and response to health crises. The powers, however, basically lie with the Member States. The EU can create its own bodies but cannot issue any strategies with binding effect on the Member States. In order for a meaningful coordination of the different health policies to succeed, institutional and legal prerequisites must be fulfilled relating in particular to the division of responsibilities and oversight. cep has the following recommendations in this regard:

- ▶ The Head of HERA should be jointly selected by the Commission, the Council and the EU Parliament to strengthen legitimacy, transparency and oversight.
- ▶ The EU Parliament should have a voting representative on the HERA Coordination Committee.
- ▶ Once an emergency is over, HERA and the Health Crisis Board should report to the EU Parliament on the measures taken, justify the decisions and outline the resources used.
- ▶ HERA's Coordination Committee should be expanded to include one voting representative of the Member States, preferably the Minister of Health of the Member State holding the rotating Presidency of the Council.
- ▶ Adequate involvement of the Member States is necessary particularly in "crisis mode", when direct executive decisions are made. This is currently provided for but the existing level must not be allowed to drop.

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1 Introduction

Especially at the beginning of the COVID 19 pandemic, worldwide demand for key medical products increased so sharply¹ that individual Member States had to issue export bans on respirators, protective clothing, gloves and other medical protective equipment.² Some saw this as a major challenge to the survival of the European Union³ - others have said that successful pandemic control may also strengthen European integration.⁴

Overall, the current pandemic has shown that there is a significant need for coordination regarding both the preparations for and response to EU-wide health crises. In certain cases, the effectiveness and efficiency of national health policies, regarding preparedness and crisis management, can be significantly increased through coordination. However, this coordination is being held back by a conflict of interests that should not be underestimated: on the one hand, the EU must be able to react more effectively to health crises in the future; on the other, health policy is fundamentally a matter for the Member States.⁵

The new European Health Emergency Preparedness and Response Authority (HERA) is to be responsible for the necessary coordination and, above all, to ensure Member States have rapid and equal access to key medical products in the event of an emergency. HERA will thus make a substantial contribution to the future security of supply.

However, these (financially) immense tasks will also require democratic oversight.⁶ This is especially true in view of the extensive financial resources directly and indirectly available to HERA and the fundamental responsibilities of the Member States in the area of health policy.

This cepInput analyses the underlying legislation with regard to the decision-making structures and participation of the EU Parliament and Member States and provides concrete recommendations for improved governance of EU crisis preparedness and response.

¹ See e.g. Welt (2020), [USA sollen von Berlin bestellte Schutzmasken abgefangen haben – Weißes Haus widerspricht](#). All sources last accessed on 7 July 2022.

² See e.g. Welt (2020), [Coronavirus: Das deutsche Exportverbot ist die Antwort auf Frankreichs Masken-Embargo](#).

³ See e.g. aerzteblatt.de (2020), [Coronapandemie: Bewährungsprobe für Europa](#).

⁴ See e.g. Häberle/Kotzur, Die COVID-19-Pandemie aus der kulturwissenschaftlichen Perspektive einer europäischen und universalen Verfassungslehre, in: NJW 2021, p. 135. Thus also Janda, Die europäische Gesundheitsunion – Vorschläge der EU-Kommission, in: Spiecker gen. Döhmman (Hrsg.), Ein Jahr Corona: Welche Lehren zieht das Mehrebenensystem? Zur Krisenresilienz und Alltagstauglichkeit des Gesundheitswesens, p. 39 - forthcoming, Peter Lang Verlag.

⁵ In practice, this conflict is apparent in various situations – we refer by way of example to the Council Recommendation of 25 January 2022 in which it was agreed that a person was deemed to be "recovered" six months after a confirmed infection – see No. 12 (c) of [Recommendation \(EU\) 2022/107](#) – shortly before this, the corresponding time interval had been lowered in Germany to three months; see RKI (2022), [Fachliche Vorgaben für Genesenennachweise, mit Wirkung vom 15.01.2022](#).

⁶ Thus also HERA's current Director; see Euractiv.com (2022), ["Democratic control" on Commission's HERA is needed, says director](#).

2 Crisis Preparedness and Response: Fundamentals, Decision-making Structures and Tasks

2.1 Fundamentals

General

Initially, it was assumed that HERA - in line with the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC)⁷ - would be established as an independent EU agency. Instead, the EU Commission has decided to establish it purely as a Commission service - see Art. 1 Establishing Decision⁸. This approach should benefit from the current political momentum towards a European health policy⁹ and above all enable HERA to start its work more quickly because the establishment of an independent EU agency would require agreements that are not easy to reach, for example regarding the location of the head office of the agency.¹⁰

This approach has in turn provoked criticism, as the path taken minimises the involvement of the EU Parliament¹¹ and above all limits it to budgetary scrutiny.¹² Ensuring adequate involvement of Member States in the governance of HERA is also demanded by the Member States themselves¹³ and - according to the current distribution of powers under the European Treaties¹⁴ - will be crucial for long-term success.¹⁵

The responsibilities and competences of HERA in the event of a crisis are currently still being negotiated in the Council.¹⁶ The functioning of HERA is also to be reviewed annually up until 2025 and adjusted if necessary. An in-depth review will then be carried out.¹⁷ In this respect, the "current" HERA, its status

⁷ Regarding the first Commission proposals for an EU Health Union, whereby the competences of the EMA and the ECDC, among others, are to be expanded, see [cepPolicyBrief 12/2021](#), [cepPolicyBrief 17/2021](#) and [cepPolicyBrief 19/2021](#).

⁸ [Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority \(HERA\)](#) – hereinafter "Establishing Decision".

⁹ See e.g. EPRS (2021), [European Health Emergency Preparedness and Response Authority \(HERA\)](#), p. 11: "However, it should be observed that, during this pandemic, Member States have increasingly shown more predisposition to work collectively [on health policy issues] than in the past".

¹⁰ See e.g. Handelsblatt (2017), [Künftige Standorte von EU-Behörden – Deutschland und Frankreich streiten über Brexit-Beute mit Blick auf die EMA](#).

¹¹ See e.g. Euractiv (2021), [Health NGOs: Commission to reconsider "crucial aspects" of HERA](#), there: "MEPs have long complained about being left out of the decision-making process". This refers to the fact that neither the establishment of HERA as a Commission service nor the "Emergency Framework Regulation", to be taken up later, requires legislative approval by the EU Parliament.

¹² Thus, in the negotiations on the Multiannual Financial Framework, the EU Parliament was able to secure, inter alia, the introduction of a "budgetary scrutiny procedure" for the setting up of crisis mechanisms based on Art. 122 TFEU - see EU Parliament (2021), [Multiannual Financial Framework](#), p. 6. As will be shown later, HERA's competences in "crisis mode" are based on such a mechanism (see Section 2.4).

¹³ See e.g. Conclusion No. 3 of the [European Council Meeting of 21 and 22 October 2021](#), and earlier [aerzteblatt.de \(2021\), Spahn pocht auf Mitsprache bei neuer EU-Behörde Hera](#).

¹⁴ See [cepInput Three steps towards a European Health Union](#).

¹⁵ This is also the conclusion of Janda, Die europäische Gesundheitsunion – Vorschläge der EU-Kommission, in: Spiecker gen. Döhmman (Hrsg.), Ein Jahr Corona: Welche Lehren zieht das Mehrebenensystem? Zur Krisenresilienz und Alltagstauglichkeit des Gesundheitswesens, p. 39 - forthcoming, Peter Lang Verlag.

¹⁶ The present comments are based on the [Political Agreement in the Council of 20 December 2021](#) on Commission proposal COM(2021) 577.

¹⁷ See overall Art. 8 (1) Establishing Decision as well as EU Commission (2021), [EU Health Emergency Preparedness and Response Authority \(HERA\): Countermeasures in the event of a public health emergency](#).

as well as its organisation and working methods, will undergo structural development over the next five years.

Preparedness mode and crisis mode

There are two aspects to HERA's work: preparedness and crisis management. Thus, it will undertake the strategic assessment of health threats, promote research and development, and procure and distribute essential medical supplies, e.g. vaccines, medicines and medical equipment^{18, 19}

The establishment of HERA, its structure and its specific tasks are currently based primarily on two legal foundations: the Establishing Decision of the EU Commission²⁰ and the Proposal for a Council Emergency Framework Regulation²¹. The Establishing Decision mainly regulates the structure (Section 2.2.1) of HERA and the "preparedness mode" (Section 2.3) - the Emergency Framework Regulation regulates the "crisis mode" (Section 2.4). The latter Regulation is still being negotiated in the Council.

2.2 Decision-making Structures

2.2.1 HERA - an EU Commission "Service"

Structure

As HERA has been established as a Commission service, it is not an independent authority but part of the EU Commission.²² Thus, it has the same structure as a Directorate General, with the current Director General, Pierre Delsaux,²³ and four departments ("Policy and Coordination", "Intelligence Gathering, Analysis and Innovation", "Medical Counter-Measures" and "Emergency Office")²⁴. HERA has a budget of € 6 billion (2021-2027) from the Multiannual Financial Framework and the NextGenerationEU programme, as well as indirect funding from other EU programmes.²⁵

In addition to the aforementioned Head of HERA, which is appointed by the Commission and required to coordinate closely with the Directorate-General for Health and Food Safety,²⁶ the new Authority is

¹⁸ See Recital 6 of the Establishing Decision - legally referred to as "medical countermeasures"; see on this Art. 3 No. 8 of the [Proposal for a Regulation on serious cross-border threats to health - COM\(2020\) 727](#).

¹⁹ Art. 2 (1) and (2) Establishing Decision.

²⁰ [Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority \(HERA\)](#) – hereinafter "Establishing Decision".

²¹ See [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, as amended by the Political Agreement of 20 December 2021](#); see also Footnote 16.

²² See overall Art. 1 Establishing Decision.

²³ IEU Monitoring (2021), [EU Commission appoints Pierre Delsaux as Director-General to DG HERA](#).

²⁴ EU Commission (2022), [DG HERA](#).

²⁵ See EU Commission (2021), [Communication on Introducing HERA](#), p. 12 et seq. Thus, the € 6 billion will come mainly from the "EU4Health", "rescEU", "Horizon Europe" and "NextGenEU" programmes. In addition, other EU programmes will also contribute, both directly and indirectly, such as the Recovery and Resilience Facility and REACT-EU within the EU, as well as the work of the Neighbourhood, Development and International Cooperation Instrument outside the EU. Together with the € 6 billion directly earmarked for HERA, this amounts to about € 30 billion. HERA will also mobilise private funding, including through the use of financial instruments (such as loans, equity, budgetary guarantees) in cooperation with the European Investment Bank and other financial actors. National budgets can be mobilised in the field of health following the launch of Important Projects of Common European Interest (IPCEIs) and through transnational projects; see overall EU Commission (2021), [Questions and Answers: EU Health Emergency Preparedness and Response Authority \(HERA\)](#), Point 9.

²⁶ Art. 4 Establishing Decision.

comprised of the following bodies: the Coordination Committee, the HERA Board and the HERA Advisory Forum.²⁷

The Coordination Committee, which is responsible for the political steering of HERA, consists of five members of the EU Commission: the Commission Vice-President in charge of Health and the Commissioners for Health, Internal Market, Innovation and Research and Crisis Management. It is co-chaired by the Commission Vice-President (Margaritis Schinas) and the Commissioner for Health (Stella Kyriakides).²⁸

The HERA Board assists and advises the EU Commission and aims to ensure close cooperation with the Member States.²⁹ It consists of one representative per Member State, nominated by them and appointed by the EU Commission.³⁰ It is chaired by the Head of HERA.³¹ The ECDC, the EMA and a representative of the EU Parliament may participate in the meetings as observers.³² The HERA Board mainly delivers opinions, for example on promoting the research and development of "medical countermeasures", e.g. vaccines, antibiotics, protective equipment,³³ and their procurement.³⁴

The HERA Advisory Forum serves as a mechanism for the exchange of information and to ensure cooperation between HERA and the competent bodies of the Member States. Scientific and technical advice to the HERA Board is provided by subgroups of the HERA Advisory Forum, e.g. the "Joint Industrial Cooperation Forum", which is composed of representatives of industry and Member States.³⁵

Financing

For 2022, HERA will receive a total contribution of almost € 1.3 billion from the EU budget, mainly for preparedness activities. Specifically, the contributions will come from the following programmes: EU4Health (€ 275 million), Horizon Europe (€ 395 million) and UCPM/rescEU (€ 630 million). The final allocations for individual items of expenditure depend on the projects that are selected.³⁶ The total amount is summarised in the following table according to the areas of responsibility.

²⁷ Art. 3 Establishing Decision.

²⁸ See overall Art. 5 (1) and (2) Establishing Decision.

²⁹ Art. 6 (4) Establishing Decision.

³⁰ See overall Art. 6 (1) Establishing Decision.

³¹ Art. 6 (2) Establishing Decision.

³² See overall Art. 6 (3) Establishing Decision.

³³ Such "medical countermeasures" are deployed to diagnose, prevent, protect against or treat illness during an emergency. Other examples are: Therapeutics, diagnostic tests or personal protective equipment such as gloves or masks; see overall EU Commission (2021), [Factsheet - HERA](#). See also on this Art. 3 No. 8 of the [Proposal for a Regulation on serious cross-border threats to health - COM\(2020\) 727](#).

³⁴ Art. 6 (5) Establishing Decision.

³⁵ Art. 7 (3) and (4) Establishing Decision.

³⁶ Health Emergency Preparedness and Response (HERA), [HERA Work Plan 2022](#), p. 2.

Table: EU HERA budget in 2022 for preparedness activities³⁷:

Tasks	Euro
1. Threat assessments and intelligence gathering	139.5 m
2. Promoting advanced research and development of medical countermeasures and related technologies	306.08 m
3. Addressing market challenges and failures and boosting the Union's open strategic autonomy	165.3 m
4. Ensuring the provision of medical countermeasures	666.5 m
5. Strengthening knowledge and skills	5 m
6. International dimension ³⁸	2 m (+101 m from Task 2) ³⁹
Total amount for 2022	1 284.38 m

Source: Health Emergency Preparedness and Response (HERA), [HERA Work Plan 2022](#).

2.2.2 The Health Crisis Board

In addition to HERA, a "Health Crisis Board" - consisting of the EU Commission and one representative per Member State - will become a central part of the decision-making structures in an emergency.⁴⁰ It will then coordinate the actions of the Council, the Commission and other EU bodies and of the Member States. This Crisis Board will be co-chaired by the Commission and the Member State holding the rotating Presidency of the Council.⁴¹ One representative each from the EU Parliament and the Health Security Committee⁴² will be invited as observers.⁴³

The Health Crisis Board assists and provides guidance to the Commission in the preparation and implementation of activated measures. At the same time, the EU Commission must always act in close coordination with the Health Crisis Board. In particular, the Commission will consult it in a timely manner, where possible before taking action, and take the utmost account of the result of deliberations in the Health Crisis Board. The EU Commission reports to the Health Crisis Board on the measures taken.⁴⁴

³⁷ Health Emergency Preparedness and Response (HERA), [HERA Work Plan 2022](#), p. 2.

³⁸ The aim is to improve coordination and cooperation inside and outside Europe in order to strengthen resilience and respond in a timely and appropriate manner to possible health crises in the future.

³⁹ This is funding for increased international cooperation and support for crisis-related medical countermeasures with global actors; they fall under Task 6 but will be charged to the allocations for Task 2.

⁴⁰ If and insofar as a health emergency has occurred and a "public health emergency at EU level" has been declared in accordance with the law; see [cepPolicyBrief 19/2021](#).

⁴¹ Art. 5 (1), (2) and (2a) Emergency Framework Regulation.

⁴² The Health Security Committee is an existing body that aims to coordinate the response of Member States to cross-border health threats at EU level. It is the representative body of the health authorities of the EU countries. See also EU Commission (2022), [Health Security Committee \(HSC\)](#).

⁴³ Art. 5 (2a) Emergency Framework Regulation.

⁴⁴ Art. 5 (1) and (6) Emergency Framework Regulation.

2.3 Tasks in "Preparedness Mode"

In "preparedness mode", HERA has the following tasks [Art. 2 (2) Establishing Decision]⁴⁵:

- Assessment of health threats and intelligence gathering - i.e. specifically: collecting information, developing predictive models and preparing risk analyses;
- Promotion of research and development - i.e. specifically: merging the existing clinical trial networks into an EU platform for multi-centre clinical trials;
- Strengthening the EU's "open strategic autonomy" in the production of medical goods, e.g. vaccines, medicines and medical devices⁴⁶ - i.e. specifically: developing a strategy for manufacturing capacities and investments in dialogue with industry.

2.4 Tasks in "Crisis Mode"

The Council may extend the remit of HERA and authorise it to implement certain measures. The mandatory requirement for this is that a health emergency has occurred and a "public health emergency at EU level" has been declared.⁴⁷ The Emergency Framework Regulation⁴⁸ defines the measures that the Council can "activate"⁴⁹. Upon the proposal of the Commission, the Council can effect activation by adopting a regulation^{50, 51}.

Activation lasts for up to six months.⁵² A prolongation of up to six months is possible, as is repeated prolongation of the activation. Without an active prolongation by the Council - or when the "public health emergency at EU level" has ended - the activation measures expire automatically.⁵³

In "crisis mode", HERA may be given the following tasks [Art. 6 - 12 Emergency Framework Regulation]⁵⁴:

- Monitoring crisis-relevant medical goods - i.e. specifically: preparing the relevant lists and reporting obligations of the Member States;
- Procurement of crisis-relevant medical goods - i.e. specifically: conclusion of contracts with economic operators on behalf of the respective participating Member States as a centralised purchasing body;
- Preparation of lists of crisis-relevant manufacturers and production facilities for medical goods - i.e. specifically: manufacturers of crisis-relevant medical goods may be required to provide information within five days regarding total production capacity, storage capacity and

⁴⁵ See in detail also EU Commission (2021), [Questions and Answers: EU Health Emergency Preparedness and Response Authority \(HERA\)](#) as well as the Austrian Federal Chancellery (2021), [HERA: New EU Health Emergency Preparedness and Response Authority](#).

⁴⁶ See Recital 6 of the Establishing Decision - legally referred to as "medical countermeasures"; see on this Art. 3 No. 8 of the [Proposal for a Regulation on serious cross-border threats to health - COM\(2020\) 727](#).

⁴⁷ See on this [cepPolicyBrief 19/2021](#).

⁴⁸ Art. 122 (1) TFEU has been chosen as the legal basis for this Regulation. One of the consequences of this is that only the Council decides on the legal act and Parliament has no involvement here as legislator

⁴⁹ See Art. 3 Emergency Framework Regulation.

⁵⁰ "Regulation activating the emergency framework".

⁵¹ See Art. 3 (1) and (2) Emergency Framework Regulation.

⁵² Art. 3 (3) Emergency Framework Regulation.

⁵³ Art. 4 (1) - (5) Emergency Framework Regulation.

⁵⁴ See in detail also EU Commission (2021), [Questions and Answers: EU Health Emergency Preparedness and Response Authority \(HERA\)](#) as well as the Austrian Federal Chancellery (2021), [HERA: New EU Health Emergency Preparedness and Response Authority](#).

production facilities, and to submit schedules of expected production for the next three months.

3 Involvement of the European Parliament and the Member States

The following section will look at the involvement of Parliament (Section 3.2) and of the Member States (Section 3.3) in the decision-making structures. The analysis distinguishes between preparedness mode and crisis mode as these have different levels of urgency and vary in the extent to which they encroach upon national competences. Firstly, we will consider the procedure for appointing the Head of HERA (Section 3.1) as the inclusion of the EU Parliament and Member States could strengthen HERA's political legitimation.

Overall, five recommendations will be made corresponding to the following five subject areas:

- "Appointment of the Head of HERA" (3.1),
- "Involvement of Parliament in Preparedness Mode" (3.2.1),
- "Involvement of Parliament in Crisis Mode" (3.2.2),
- "Involvement of Member States in Preparedness Mode" (3.3.1) and
- "Involvement of Member States in Crisis Mode" (3.3.2).

3.1 Involvement of Parliament and Member States in the Appointment of the Head of HERA

Neither Parliament nor the Member States have a say in the appointment of the Head of HERA. This is the sole responsibility of the Commission.⁵⁵ However, HERA's tasks are caught up in the conflict of interests between the Member States' fundamental responsibility for health policy and the need for EU-wide coordination of crisis response. The choice and appointment of the Head of HERA should be changed to the extent that Parliament, the Council and the Commission decide on it jointly. This could increase transparency, legitimacy and political accountability.

Recommendation 1 (Section 3.1): The Head of HERA should be jointly selected by the Commission, the Council and the EU Parliament.

3.2 Further Involvement of Parliament

3.2.1 Preparedness Mode

3.2.1.1 Description

The European Parliament is invited to designate an observer to the HERA Board⁵⁶ but the role of the HERA Board is only to assist and advise on the formulation of strategic decisions.⁵⁷ Thus, membership of this body does not give rise to any decision-making powers regarding specific measures.

⁵⁵ Art. 4 Establishing Decision.

⁵⁶ Art. 6 (3) Establishing Decision.

⁵⁷ Art. 6 (4) Establishing Decision.

Although the Commission has given a public assurance that Parliament will be regularly informed about the measures,⁵⁸ this does not give it the power to participate in decisions or scrutinise them in any concrete manner.

3.2.1.2 Criticism

Parliament's limited involvement in the creation of the new EU health authority and its specific decisions has provoked criticism from MEPs in various political groups, who say that Parliament's marginal role - as a mere observer - is not in the spirit of cooperation between the European institutions.⁵⁹ The current structure of HERA as a Commission service - rather than an independent agency -, they say, leaves little room for parliamentary scrutiny. They also see a need for greater transparency, e.g. regarding what contracts are concluded, together with the prices to be paid for medical goods, financing and the companies involved.⁶⁰ There has even been talk of "some democratic deficiencies" which the MEPs will currently accept but only for a limited time. Parliament has demanded to be given a decisive role in the decision-making structures in future⁶¹ and has thus also voted for more transparency, close cooperation and a thorough review of HERA's activities.⁶²

The Commission has countered the criticism of Parliament's lack of involvement by saying that it would have taken at least three years to set up HERA as an independent agency and that the Member States had just concluded intensive negotiations on the EU's multiannual budget at the time of the proposal. Setting HERA up as a service meant that the Commission was able to draw on existing budget lines and get an early start.⁶³ EU Health Commissioner Stella Kyriakides reminded MEPs that Parliament will be able to negotiate the final budget and will in any case have a representative on the HERA Board, ensuring an open, honest and systematic dialogue on all HERA's actions.⁶⁴

3.2.1.3 Assessment and Recommendation

The question of the extent of parliamentary involvement in HERA's decision-making processes is primarily a matter of legal policy: Thus, the current decision-making structures do not violate the EU Treaties. Nonetheless, the concerns expressed by several MEPs from various political groups indicate that the issue is of fundamental political importance.

⁵⁸ EU Commission (2021), [Questions and Answers: EU Health Emergency Preparedness and Response Authority \(HERA\)](#), Point 5.

⁵⁹ On the first point: "Today I am very disappointed. The European Commission has no reason to exclude the European Parliament, and I believe it is a worrying move. Article 122 of TFEU is an article to use for emergencies, not for setting up new structures in the EU. The European Parliament is the only directly elected institution, we represent the people, and we should have a say and scrutiny over how millions of euros are being spent, especially on something as crucial as health.", see Miguel Antony M Chevalier, [Renew Europe Insists that Parliament should have a Say on HERA](#), 19.6.2021. On the second point: "We are not transparent vis-à-vis these purchasing agreements, there is no transparency about the public financing, or the enterprises, or the vaccine prices.", see Florin Zubaşcu, [MEPs call for closer scrutiny of EU's €6B health emergency authority](#), Science Business, 7.10.2021.

⁶⁰ "We are not transparent vis-à-vis these purchasing agreements, there is no transparency about the public financing, or the enterprises, or the vaccine prices.", see Florin Zubaşcu, [MEPs call for closer scrutiny of EU's €6B health emergency authority](#), Science Business, 7.10.2021.

⁶¹ Florin Zubaşcu, [MEPs call for closer scrutiny of EU's €6B health emergency authority](#), Science Business, 7.10.2021

⁶² Generally on this, see the proposed amendments in [Report on the proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health repealing Decision No 1082/2013/EU](#). See also European Parliament amendments of 14 September 2021 and 11 November 2021 on the proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health repealing Decision No 1082/2013/EU, [P9_TA\(2021\)0377 of 14 September 2021](#) and [P9_TA\(2021\)0449 of 11 November 2021](#). See also Giedre Peseckyte, [MEPs demand active participation in HERA's governance](#), Euractiv.com, 11 November 2021.

⁶³ Giedre Peseckyte, [MEPs demand active participation in HERA's governance](#), Euractiv.com, 11 November 2021.

⁶⁴ Giedre Peseckyte, [MEPs demand active participation in HERA's governance](#), Euractiv.com, 11 November 2021.

In preparedness mode, HERA's main tasks are to organise, prepare and provide for future health emergencies. These are purely precautionary measures - there is no "imminent danger" in this respect. In order to ensure an appropriate level of transparency, Parliament should therefore be involved to a higher degree in the decisions. Thus, in terms of legal policy, it is unclear why Parliament should only play an observing role in "preparedness mode".

More comprehensive involvement of Parliament in "preparedness mode" would also allow for greater oversight of the financial resources provided - and thus a higher degree of transparency. Parliamentary scrutiny, which is also provided for under budgetary law,⁶⁵ is a duty that cannot currently be fully executed.⁶⁶

Recommendation 2 - Parliament/Preparedness Mode (Section 3.2.1): Parliament should at least have a voting representative on the HERA Coordination Committee.

3.2.2 Crisis Mode

3.2.2.1 Description

In crisis mode, the Health Crisis Board plays a central role alongside HERA. Here too, the European Parliament only acts as an observer.⁶⁷

3.2.2.2 Criticism

With regard to the criticisms made, we refer to the foregoing remarks.⁶⁸

3.2.2.3 Assessment and Recommendation

With regard to the question of parliamentary involvement in "crisis mode", a more nuanced view is required as the emergency situation gives rise to new considerations.

Even in "crisis mode", Parliament currently only acts as an observer in the decision-making structures: both with regard to HERA and with regard to the Health Crisis Board.

Prima facie, and from a purely legal point of view, this may be understandable because decision-making powers in "crisis mode" are characterised by the need for an immediate response to health emergencies. In such a context, more extensive decision-making processes would not be very compatible with the exceptional situation of an emergency.

However, once the emergency is over, in order to at least partially remedy the lack of parliamentary involvement, HERA and the Health Crisis Board should publicly report to Parliament on all actions taken during "crisis mode", justifying them and outlining how funds were used during "crisis mode".

Official reporting to Parliament would also ensure transparency and accountability with regard to the measures taken during "crisis mode". Thus, the Head of HERA would take political responsibility for

⁶⁵ Primarily Art. 314 TFEU: "The European Parliament and the Council, acting in accordance with a special legislative procedure, shall establish the Union's annual budget [...]".

⁶⁶ This very concern has also been clearly expressed as follows: According to Green MEP Michele Rivasi, "the current rules deprive MEPs of any possibility of transparency or oversight regarding the proper use of the €6 billion earmarked for HERA over five years", see Michèle Rivasi, [Crise sanitaire / HERA : la proposition actuelle méprise le travail parlementaire et constitue un déni démocratique](#), 14.9.2021.

⁶⁷ See Art. 5 (2a) Emergency Framework Regulation.

⁶⁸ See Section 3.2.1.2.

ensuring that the measures taken in this context were in line with the mandate and justified by the emergency for which they were introduced.⁶⁹

Recommendation 3 - Parliament/Crisis Mode (Section 3.2.2): After an emergency has ended, HERA and the Health Crisis Board should report to the EU Parliament on the measures taken, justify the decisions and outline the resources used.

3.3 Further Involvement of the Member States

3.3.1 Preparedness Mode

3.3.1.1 Description

The Member States are more involved than Parliament in the decision-making structures but they too are not members of the Coordination Committee, for example, which is HERA's political steering body.⁷⁰

The HERA Board, on the other hand, consists of representatives of the Member States but this body only provides assistance and advice.⁷¹ It is also chaired by the Head of HERA.⁷²

The HERA Advisory Forum aims to ensure cooperation with the competent national bodies.⁷³ Advisory Forum members are appointed by the Member States but these must be different from those who serve on the Board.⁷⁴ The Advisory Forum supports the Board by providing scientific and technical advice.⁷⁵ It meets at the invitation of the Head of HERA and is also chaired by the Commission.⁷⁶

3.3.1.2 Criticism

The fact that the Member States are only sketchily integrated into the decision-making structures has led to corresponding criticism.⁷⁷ This is not simply an issue of a "technical nature" regarding just a few Member States, but an important political concern for all Member States: Thus, the European Council - the body which brings together the Heads of State and Government and which, according to Art. 15 TEU, defines the general political directions and priorities⁷⁸ - has stated that it must be ensured that "Member States are adequately involved in the governance of (...) HERA (...)".⁷⁹

⁶⁹ The importance of ensuring that people's representatives are involved in decision-making processes during emergencies was demonstrated when it came to combating the Covid emergency. In Germany, for example, the lack of participation by the Bundestag in the national and regional government decisions led to strong protests from MPs and from political and legal experts. The idea that representatives of the people should be reduced to merely rubber-stamping the decisions of others, has provoked protest. Thus, this also threatened to impair acceptance of the emergency measures, the public's compliance with them and ultimately their effectiveness, see zdf.de (2021), [Corona ohne Parlament - "Eine schwere Missachtung des Bundestages"](#).

⁷⁰ Art. 5 Establishing Decision.

⁷¹ Art. 6 (1) and Art. 6 (4) and (5) Establishing Decision.

⁷² Art. 6 (2) Establishing Decision.

⁷³ Art. 7 (1) Establishing Decision.

⁷⁴ Art. 7 (2) Establishing Decision.

⁷⁵ Art. 7 (3) Establishing Decision.

⁷⁶ Art. 7 (5) Establishing Decision.

⁷⁷ See e.g. aerzteblatt.de (2021), [Spahn pocht auf Mitsprache bei neuer EU-Behörde Hera](#).

⁷⁸ „Der Europäische Rat kümmert sich in der Regel nicht ums Alltagsgeschäft der EU, sondern um die großen zukunftsbestimmenden Fragen.“ – see Bundesregierung (2022), [Der Europäische Rat – kurz erklärt](#), Was ist die Aufgabe des Europäischen Rats?

⁷⁹ See Conclusion No. 3 of the [European Council of 21 and 22 October 2021](#).

3.3.1.3 Assessment and Recommendation

The EU's powers regarding health policy are limited by the Member States' responsibility for health policy, which is guaranteed by primary law [Art. 168 (7) TFEU]. The EU has a coordinating role in combating cross-border diseases and health threats [Art. 168 (5) TFEU].⁸⁰ Thus, it can establish bodies in which the Member States exchange risk assessments with each other and with the EU Commission in the event of a crisis. However, the national risk and communication management itself cannot be delegated to the EU Commission.⁸¹ The EU is also allowed to set up its own EU institutions - such as the ECDC. However, formulating strategies that have binding effect on Member States is not covered by this legal basis.⁸²

The current involvement of the Member States in the decision-making structures of HERA in "preparedness mode" is in principle still in line with the EU Treaties. However, it seems highly questionable in terms of legal policy that the Member States are not represented on the Coordination Committee. For example, the health policy representative of the Member State holding the rotating Presidency of the Council could be involved in the work. There is no indication that this would unduly hamper the preparedness decisions to be taken in this regard by the Coordination Committee. In fact, it could bring coherence, which is urgently needed and often lacking, at least when it comes to the controversial area of two-dimensional health policy.⁸³

Recommendation 4 - Member States/Preparedness Mode (Section 3.3.1): HERA's Coordination Committee should be extended to include one voting representative of the Member States, preferably the Minister of Health of the Member State holding the rotating Presidency of the Council.

3.3.2 Crisis Mode

3.3.2.1 Description

In "crisis mode", the Member States are represented in the decision-making structures: Firstly, via the Council, which must specifically authorise HERA by adopting an activation regulation.⁸⁴ It is at the discretion of the Council whether and what measures⁸⁵ to activate⁸⁶ - in other words: the Council decides what HERA is actually allowed to do in "crisis mode".

Secondly, the Member States are involved via the Health Crisis Board, which is the central coordination and steering body in "crisis mode". This body consists of one representative of the Commission and

⁸⁰ See generally Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Eds.), *Das Recht der Europäischen Union*, August 2020, Art. 168 TFEU, para. 70

⁸¹ Art. 168 (5) TFEU. See Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Eds.), *Das Recht der Europäischen Union*, August 2020, Art. 168 TFEU, para. 70. See also the comments by Niggemeier, in: von der Groeben/Schwarze/Hatje (Eds.), *Europäisches Unionsrecht*, 7. Edn. 2015, Art. 168, para. 60.

⁸² Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Eds.), *Das Recht der Europäischen Union*, May 2020, Art. 168 TFEU, para. 70. The extension of the ECDC's competences [COM(2020) 726] took this into account - see [cepPolicyBrief No. 17/2021](#).

⁸³ This conflict is apparent in many situations – we refer by way of example to the Council Recommendation of 25 January 2022 in which it was agreed that someone is deemed to be "recovered" six months after a confirmed infection – see No. 12 (c) of [Recommendation \(EU\) 2022/107](#) – shortly before this, the corresponding time interval had been lowered in Germany to three months; see RKI (2022), [Fachliche Vorgaben für Genesenennachweise, mit Wirkung vom 15.01.2022](#).

⁸⁴ See above, Section 2.4.

⁸⁵ In accordance with the Emergency Framework Regulation.

⁸⁶ Art. 3 (1), (1a) and (2) Emergency Framework Regulation.

one of each of the Member States.⁸⁷ Direction is shared by the Commission and the rotating Presidency of the Council.⁸⁸

3.3.2.2 Criticism

There has also been some criticism of the Commission's original proposal for the Emergency Framework Regulation^{89, 90}. The adjustments provided for by the Council in its "Political Agreement" on the proposed Regulation⁹¹ make it clear that the Member States want more influence in the decision-making structures.⁹²

3.3.2.3 Assessment and Recommendation

The Member States are adequately represented in the decision-making structures in crisis mode via the Council and via their respective representatives on the Health Crisis Board.

Recommendation 5 - Member States/Crisis Mode (Section 3.3.2): Due to their national powers, the involvement of the Member States is significant, especially in "crisis mode" where executive decisions are made. Currently, the Member States are adequately involved.

4 Conclusion

The study has shown that there is a need for further adjustment to ensure successful and transparent European health emergency preparedness and response in the long term. Adequate involvement of the EU Parliament and the Member States will be crucial.

Further participation will also strengthen the oversight of activities. Such oversight is necessary - this is also the view of the current Head of HERA Pierre Delsaux, who says that HERA needs more democratic control.⁹³ Transparency and accountability must be increased. The reasons for implementing specific measures must be comprehensible both at the institutional level and for the public. This will bring about a higher level of acceptance, effectiveness and ultimately legitimacy.

The recommendations devised and set out above, on the involvement of Parliament and the Member States aim to offer possible solutions. The distinction between preparedness and crisis mode is crucial, as the context is very different in each case: Thus, the level of urgency when organising preparatory measures for future emergencies is different to that which exists when an acute health emergency actually occurs.

In this respect, the following recommendations are intended to contribute to the discussion on strengthening the democratic oversight of HERA:

⁸⁷ Art. 5 (2) Emergency Framework Regulation.

⁸⁸ Art. 5 (2a) Emergency Framework Regulation.

⁸⁹ See Commission Proposal [COM\(2021\) 577](#).

⁹⁰ See e.g. [aerzteblatt.de \(2021\), Spahn pocht auf Mitsprache bei neuer EU-Behörde Hera](#).

⁹¹ Which is the basis of the considerations in this Input, see footnote 16.

⁹² See also, e.g., [Europe.Table \(2021\), Hera: EU-Länder sichern sich Mitspracherecht](#).

⁹³ "We need the European Parliament to exercise democratic control, and MEPs must be involved in the agency's work"; see [Euractiv.com \(2022\) 'Democratic control' on Commission's HERA is needed, says director](#).

General Recommendation (No. 1): The Head of HERA should be jointly selected by the Commission, the Council and the EU Parliament.

Recommendation on the involvement of Parliament (No. 2): The EU Parliament should at least have a voting representative on the HERA Coordination Committee.

Recommendation on the involvement of Parliament (No. 3): Once an emergency is at an end, HERA and the Health Crisis Board should report to the EU Parliament on the measures taken, justify the decisions and outline the resources used.

Recommendation on the involvement of the Member States (No. 4): HERA's Coordination Committee should be expanded by one voting representative of the Member States, preferably the Minister of Health of the Member State holding the rotating Presidency of the Council.

Recommendation on the involvement of the Member States (No. 5): Due to their national powers, the involvement of Member States is significant, especially in "crisis mode" where executive decisions are made. Currently, the Member States are adequately involved.

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