



OPINION

European Economic and Social Committee

HERA

**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
[COM(2021) 576 final]**

SOC/702

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1. Conclusions and recommendations

- 1.1 The COVID-19 pandemic has demonstrated the need for better coordination of the European Union (EU) and its Member States in order to tackle public health crises, before, during and after they happen. Gaps in preparedness and response to the pandemic have been observed by people living in Europe at EU, national, regional, and local levels. When the pandemic spread across Europe, the EU institutions and bodies were not equipped to adequately coordinate actions with Member States and quickly and efficiently deploy measures to protect the lives of the population.
- 1.2 Through the creation of the European Health Emergency Preparedness and Response Authority (HERA) and by putting public health and equity at the centre of its decisions, the EU and its Member States will be able to achieve better preparedness and responses to existing and future cross-border health threat emergencies.
- 1.3 The European Economic and Social Committee (EESC) commends the European Commission's swift creation of HERA, building up on the work launched by the biodefence preparedness plan set up in February 2021 as the HERA Incubator¹. Quick action was necessary to respond to the spread and impact of the COVID-19 pandemic, including the many waves of infections and hospitalisation faced by all Member States, which remain a reality today.
- 1.4 However, swift measures should not be to the detriment of democracy and health equity. The creation of a new, permanent EU structure of such importance, operating with a substantial public budget, should not be based on exceptional clauses reserved for acute crises. The EESC is particularly concerned by the very limited role given by HERA to the European Parliament, regional authorities, health insurance bodies and civil society organisations, including social partners, such as trade unions representing workers in the health sectors, as well as public health, patient and equality organisations, service providers and not-for-profit infrastructure and non-commercial research institutions. The EESC believes that these stakeholders must be given an active role in the work of HERA. In particular, the EESC points to the crucial role played by frontline workers, especially those working in the healthcare sectors and volunteers, in the response to the COVID-19 pandemic.
- 1.5 While the EESC recognises the importance of the industry in tackling health emergencies, a fair balance must be guaranteed to ensure that public health and the interests of vulnerable groups are at the core of the EU's preparedness and response. The EESC asks the Commission to ensure that the European Parliament, social partners and civil society organisations are involved in HERA's Board and Advisory Forum in a meaningful way. The EESC calls for the creation of a subgroup of the Advisory Forum on an equal footing with the joint industrial cooperation forum. The EESC and the Committee of the Regions should have a seat in this subgroup.
- 1.6 The EESC is particularly concerned by the lack of transparency and openness in the current set-up of HERA. While the Commission formalises *ad hoc* measures introduced during the pandemic, it falls short of bringing greater transparency to its decision-making process.

¹ COM(2021) 78 final, 12 February 2021.

Transparent governance of public funding and of cooperation with private partners is essential to build trust and confidence in managing health emergencies. The EESC recommends that more attention be paid to ensuring full transparency with regard to the funds allocated and spent by and through HERA, open contracting and the possibility for civil society to be involved in the oversight of the financial aspects of the authority.

- 1.7 Other measures are also significant in ensuring that preparedness and response measures, including the deployment of medical countermeasures, are successful in Member States. The EESC feels that HERA should ensure better coordination of communication campaigns related to prevention and response to public health emergencies, including by targeting people who are the most at risk, and by working with local authorities, including in relation to education and training on science and vaccination.
- 1.8 The international dimension of cross-border health threats must also be addressed. The EESC considers that HERA must play an important role in global action against cross-border health threats and pandemics, in particular through COVAX as well as new candidate drugs and therapies, and by strengthening and supporting the global health security architecture. HERA should commit to working with global actors, including with the World Health Organisation, to share intelligence and to support global access to vaccines and other medical countermeasures. The EESC asks the Commission to lead an open debate at European level on a temporary TRIPS voluntary waiver, which would apply to COVID-19 vaccines, treatments and tests, in order to enable global vaccine production to be ramped up and costs reduced to ensure access for people across the world.
- 1.9 HERA has been presented as a flexible structure that will be adapted as required, with an in-depth review scheduled for 2025. It is crucial that the concerns raised about the structure, functioning and scrutiny of HERA be addressed as soon as possible, and that the impact of the measures taken by the authority is regularly monitored in light of the current pandemic. The EESC recommends that, during the 2025 review, the Commission consider transforming HERA into an independent public authority outside the Commission, through a legislative procedure involving the European Parliament as co-legislator, and after consultations with civil society organisations, including social partners.
- 1.10 Finally, the EESC asks the Commission to ensure that the financial efforts made to finance HERA do not lead to lower investment in other objectives of the EU4Health programme, in particular the Cancer Plan. After years of austerity, health policies and health systems continue to require major investment.

2. General comments

- 2.1 The EESC supports the commitment and initiatives of the European institutions, including those of the Commission, aimed at building a European Union of health and ensuring the sustainable well-being of its citizens. A population-based, cross-sectoral, holistic approach to health is a key dimension for the implementation of the European Pillar of Social Rights and its Action Plan, the Action Plan for the Social Economy and the Conference on the Future of Europe.

- 2.2 The EESC welcomes the swift creation and operationalisation of HERA by the Commission. The new HERA is set up with the objective of strengthening Europe's ability to prevent, detect and rapidly respond to cross-border health emergencies, emphasising the development, manufacturing, procurement and analogical distribution of key medical and medicinal countermeasures.
- 2.3 The COVID-19 pandemic and its successive waves have highlighted the need to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, emphasising the development, manufacturing, procurement, and equitable and analogical distribution of key medical and medicinal countermeasures. The EESC notes that besides the immediately visible effects of the pandemic, there are additional silent pandemics, notably the postponement of care for non-communicable diseases (among others, cancer), the exacerbation of social inequalities in health, the deterioration of mental health and the connection of health and the environment in an ecosystemic vision ("one health" approach).
- 2.4 The EESC observes that millions of lives have been lost since the beginning of the COVID-19 pandemic and that other millions are still affected. It recognises the important role played by frontline workers, in particular healthcare workers and volunteers, regional and local authorities, health insurance bodies and civil society organisations, including social partners, service providers and equality organisations, in ensuring swift responses and health equality.
- 2.5 HERA is one of the mechanisms for consolidated and increased European and international cooperation, coordination and solidarity. It must be integrated into a multi-stakeholder and multi-level governance framework. Sustainable and resilient cooperation on HERA can only be achieved by cooperation of Member States at Union-level aimed at preventing future pandemics with swift decision-making and the activation of emergency measures. At the same time, a variety of actors need to be involved, including the European Parliament, regional authorities, health insurance bodies and organised civil society, including social partners such as trade unions representing workers in the health sectors, public health, patients and equality organisations, service providers and non-for-profit infrastructure and non-commercial research institutions.
- 2.6 The EESC has previously expressed its opinion and recommendations on the creation of a future health emergency response authority in an opinion on *Building a European Health Union* adopted in April 2021². The EESC calls for follow-up to the Conclusions adopted by the European Council at its meeting on Thursday 16 December 2021 on the work to strengthen collective preparedness, response and resilience to future crises, which is a major cross-cutting political priority for the Union. The Council advocated "strengthening the EU's crisis response and preparedness in an all-hazards approach" and "building and monitoring resilience and addressing areas where we are exposed"³.

² [OJ C 286, 16.7.2021, p. 109](#)

³ <https://www.consilium.europa.eu/media/53575/20211216-euco-conclusions-en.pdf>

3. **Review of the institutional and operational frameworks of HERA**

- 3.1 In September 2021, the Commission announced the creation and immediate start of operation of HERA. The new authority has been established as a structure within the Commission with three core missions: (a) to strengthen health security coordination within the EU during preparedness and crisis response times, and bringing together the Member States, industry and the relevant stakeholders in a common effort; (b) to address vulnerabilities and strategic dependencies within the EU related to the development, production, procurement, stockpiling and distribution of medical countermeasures; and (c) to contribute to reinforcing the global health emergency preparedness and response architecture.
- 3.2 The EESC stresses that the Commission's decision, motivated by urgency, to opt for an "Authority", as an internal structure within the Commission, rather than an "Agency" should not exclude a possible review and evolution towards an independent authority or even a European agency. The annual evaluations and the in-depth evaluation in 2025 should be focused on this.
- 3.3 One of the dimensions of HERA is the different roles it will play during preparedness and crisis phases. In the "preparedness phase", it will steer investments and actions in strengthening prevention, preparedness and readiness for new public health emergencies. In the "crisis phase", it will draw on stronger powers for swift decision-making and implementation of emergency measures. Its actions in both phases will be aimed at ensuring swift access to safe and effective medical countermeasures at the scale needed. Preparedness and pandemic programmes should be initiated with the Member States since this is a collective endeavour and will be essential for HERA to fully fulfil its mission.
- 3.4 While it was urgent for the EU to create and operationalise a health emergency preparedness and response authority to immediately support the response to COVID-19, which is still spreading across Europe and the world, there is a need to guarantee that HERA has been equipped to efficiently strengthen coordination of preparedness and response efforts and adequately protect the health and lives of people living in the EU in case of public health emergencies. To that end, it must be ensured that the structure and functioning of HERA are transparent and can be scrutinised, including to monitor the impact on public health. Transparent governance and decision-making processes are essential to allow for public scrutiny, to build trust and confidence in the R&D system and ensure accountability.
- 3.5 The EESC notes that one of the guidelines that we must promote in the exchanges between the European and national committees and the Conference on the Future of Europe is health democracy. In view of the complex issues raised by health emergencies and by the resilience of health systems, the EESC recommends that a compulsory consultation mechanism be introduced as a prerequisite for decision-making. The aim is to involve all stakeholders as closely as possible in the decision-making process in the health sector.
- 3.6 The EESC stresses the importance that the work undertaken by HERA strengthen and complete the actions carried out by other EU bodies such as the European Medical Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency (EEA).

4. **The mandate of HERA and arrangements for its implementation**

- 4.1 The EESC particularly welcomes the coordination role HERA will play in order to ensure the development, production, procurement, stockpiling and equitable distribution of medical countermeasures. In that sense, HERA will fill an important gap in the EU framework on health. Development and production of medical countermeasures will require substantial investments. Stockpiling will require adequate planning and a high level of expertise to ensure the future protection of EU citizens and economic sustainability. There is always a risk of wastage, which would have a clear negative economic outcome. It is also important to define a list of active substances necessary for the manufacture of medicines which should be manufactured in the EU to ensure drug safety and independence.
- 4.2 The EESC points to the Commission Communication on "Drawing the early lessons from the COVID-19 pandemic"⁴, with a view to stepping up action at EU and national level, as a publication that should be expanded and systematised twice a year under the umbrella of HERA. In terms of enlargement, upstream multi-stakeholder consultations need to be carried out with a view to a complete overview.
- 4.3 The EESC considers that the current mandate of HERA lacks ambition. Under the current framework, HERA misses the opportunity to truly defend the public interest and ensure equity during preparedness and crisis response times. While the Commission announced that HERA will have capacities for data collection, analysis and sharing mechanisms, no commitment was made to ensure collection of better disaggregated data on vulnerable groups. Such data is a prerequisite for fighting health inequalities and is currently not gathered by the ECDC. HERA also does not commit to ensuring non-discrimination and equality in the distribution of medical countermeasures. In its opinion on *Building a European Health Union*, the EESC already highlighted the importance of focusing on non-discrimination in the EU's response to future pandemics and the role HERA could play in that regard⁵.
- 4.4 The EESC believes that HERA must take additional measures to ensure that its work contribute to equality during health emergencies, including cross-border health emergencies. Considering the lack of coordinated and accessible communication campaigns during the COVID-19 pandemic, HERA could also play a role in ensuring better coordination of communication campaigns related to prevention and response to cross-border health crises, specifically targeting people the most at risk and vulnerable groups. HERA should also address access to cross-border healthcare during pandemics and other cross-border health emergencies. Freedom of movement is a fundamental principle of the Union and should be guaranteed for patients, including in order to ensure greater health equity.
- 4.5 Further action should also be considered in relation to the international dimension of HERA to contribute to reinforcing the global health emergency preparedness and response architecture. The communication on HERA fails to include a requirement to share know how, data and

⁴ <https://ec.europa.eu/info/sites/default/files/communication150621.pdf>

⁵ [OJ C 286, 16.7.2021, p. 109.](#)

technologies created with the help of public research funding, as well as a reasonable pricing clause. The international dimension of HERA is particularly important, from preparedness to response to cross-border health threats. The current COVID crisis proves that cross-border health crises cannot be solved without ensuring rapid and efficient international response, including access to personal protective equipment and vaccination. HERA should also commit to working with global actors, share intelligence and support global access to vaccines and other medical countermeasures.

- 4.6 Provided HERA focuses on improving health security and is subject to checks and balances, Member States can significantly increase the resilience of their health systems and their capacity to respond to health crises. National governments and the Commission should therefore seek to strengthen HERA's structure and expand its scope in the future.
- 4.7 The EESC remains concerned about potential overlaps with the work of other bodies including the EMA and ECDC. In some areas such as crisis preparedness, research, data and coordinated distribution of medicines and medical devices the added value remains unclear in light of the proposals to extend the mandate of the ECDC and EMA, and the Regulation on serious cross-border threats to health. As an example, in its opinion on *Building a European Health Union*⁶, the EESC questioned whether the recommendations coming from the HERA would have precedence over those coming from the EMA in the case of the declaration of an epidemic affecting the EU. Therefore, the significance of coordination is evident to avoid overlapping and at the same time to reflect European values by embedding collaboration guided by the principles of transparency, accountability and integrity.
- 4.8 The HERA Board will have the mandate to "make sure to avoid overlaps with other key structures, such as the Health Security Committee, the Vaccine Steering Board and relevant committees involved in the management of EU programmes, with close contacts needed"⁷. The EESC doubts that this commitment will be enough to avoid overlap in the work of the different EU structures.
- 4.9 The EESC also calls for clarification of HERA's remit in relation to antimicrobial resistance (AMR) as a threat to global health, which continues to worsen, despite the emerging awareness of the seriousness and scale of the problem. Although AMR is a complex and cross-sectoral issue, unclear mandates threaten to blur responsibilities and policy initiatives. AMR is a key issue for a "One Health" approach.

5. The functioning and scrutiny of HERA

- 5.1 The EESC is concerned by the structure and the lack of independence of HERA. The Authority was initially inspired by the example of the US BARDA (Biomedical Advanced Research and Development Authority)⁸ and designed as an independent and autonomous agency. Instead,

⁶ [OJ C 286, 16.7.2021, p. 109](#)

⁷ https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/hera_2021_comm_en.pdf

⁸ https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_1655

HERA has been established as a structure under the remit of the Commission. HERA appears to be primarily a technical authority and still lacks a strategic, forward-looking (foresight) component for addressing the determinants of cross-border threats.

- 5.2 The EESC questions the lack of consultation and involvement of the European Parliament before and during the establishment of HERA. It is also concerned that in its current structure, the role of the European Parliament is reduced to a simple vote on the budget and an observer role on HERA's Board. While the Commission commits to regular exchanges with the European Parliament about HERA's work, this is not a requirement and no further specifications were given in the Commission communication. The EESC recalls that democratic scrutiny is essential in the development of public health policies, and it cannot happen without the European Parliament playing an active role in the work of HERA.
- 5.3 Civil society organisations, social partners and especially trade unions representing the workforce in the sectors concerned, as well as public health, patients and equality organisations and service providers, play an important role in ensuring that the public interest is at the core of public health policies and measures taken by the EU and its Member States in relation to crisis prevention and response. In particular, civil society can provide feedback on the acceptability of public health measures and information on the needs of vulnerable groups. The EESC is particularly concerned by the lack of inclusion of organised civil society, including social partners, in the structure and functioning of HERA. Under the present structure, organised civil society may only contribute to the work of the HERA Advisory Forum with other external stakeholders, including industry and academia. For example, civil society has not been allocated any role in the HERA Board and the Health Crisis Board that will coordinate urgent actions during a crisis phase.
- 5.4 In comparison, HERA gives a more predominant role to the industry. The Commission communication on HERA provides for enhanced collaboration with industry in relation to threat detection and reinforcing industrial resilience within and outside the EU. It also announced the creation of a Joint Industrial Cooperation Forum as a subgroup of the Advisory Forum, which will include industry representatives. While the EESC recognises the importance of industry in tackling health emergencies, it is concerned that the current structure of HERA could fail to ensure that public health and the interests of vulnerable groups are at the core of the EU's preparedness and response, instead favouring industrial policy. In any case a sustainable industrial policy must be in line with the objectives of HERA and must proactively involve all relevant stakeholders. The Joint Industrial Cooperation Forum needs therefore, to involve not only industry representatives but also trade unions to enhance worker participation⁹.
- 5.5 The EESC recommends creating of a subgroup of the Advisory Forum on an equal footing with the joint industrial cooperation forum. The subgroup should include civil society organisations such as patient and public health organisations, health insurance bodies, social partners - including trade unions from the health sector - and not-for-profit infrastructure and non-commercial research institutions. The EESC and the Committee of the Regions should also have a seat in this subgroup.

⁹ See, for example, the EPSR Action Plan where the Commission promotes greater worker participation.

- 5.6 Transparency is another concern under the current set-up of HERA. For example, there is not enough openness regarding the allocation of public financing or about purchasing agreements, the details of contracts or the beneficiary enterprises, including, for example, vaccine prices. Transparent governance of public funding and of cooperation with private partners is essential to build trust and confidence in managing health emergencies. The EESC recommends that more attention be paid to ensuring full transparency of the funds allocated and spent by and through HERA, open contracting and the possibility for civil society to be involved in the oversight of the financial aspects of the authority¹⁰.
- 5.7 While the EESC welcomes the allocation of a budget of EUR 6 billion up to 2027 from the Multiannual Financial Framework and NextGenerationEU and EUR 24 billion invested by other EU programmes such as the Recovery and Resilience Facility, REACT-EU and cooperation instruments, the EESC is of the opinion that greater scrutiny and democracy are necessary to make this investment worthwhile.
- 5.8 The EESC calls for this financial effort for HERA not to be made to the detriment of the other objectives of the EU4Health programme, in particular the cancer plan. The recommendations made by the EESC in its opinion on the EU4Health Programme remain relevant. After years of austerity, health policies and health systems require major investment.

6. The future of HERA

- 6.1 HERA has been designed to be a flexible structure that will be adapted as required. A review of its implementation and operation, including structure and governance, is foreseen in 2025.
- 6.2 The EESC is of the opinion that the governance of HERA should be reviewed as soon as possible to ensure better scrutiny and representation. In particular, it should:
- Ensure a stronger role of the European Parliament;
 - Increase the role of, and cooperation with, civil society organisations, including social partners;
 - Ensure the role of industry is well-balanced and scrutinised.
- 6.3 The EESC recommends that the Commission consider transforming HERA into an independent public authority outside of the Commission¹¹, through a legislative procedure involving the European Parliament as co-legislator. It is also essential that organised civil society is involved in any future discussion on the structure and mandate of HERA and during its in-depth review in 2025.
- 6.4 The revised HERA must put a stronger focus on public health and preparedness and crisis response at the service of EU citizens. The EESC considers that HERA must play a role to

¹⁰ The EESC had stressed in its opinion on Reshaping the EU fiscal framework for a sustainable recovery and a just transition that "transparency of revenue and spending, open contracting and the constant involvement of civil society in the oversight of public financial management are also necessary to ensure sustainable public finances.", [OJ C 105, 04.03.2022, p. 11](#)

¹¹ [OJ C 286, 16.7.2021, p. 109](#)

address health inequalities in cross-border health emergencies and the future impact that health emergencies have on high-risk social groups, as well as on health and care workers. This could be achieved by:

- 6.4.1 Guaranteeing better inclusion of civil society: the structure of HERA must be revised to include civil society organisations representing public health organisations, patients, equality organisations, and employees and their trade unions, in relevant decision-making bodies and processes. For example, in addition to the proposal for a subgroup of the Advisory Forum, HERA could set up a specific Task Force focusing specifically on populations at risk and vulnerable groups.
- 6.4.2 Collecting disaggregated data: as ensuring the collection of better disaggregated data in vulnerable groups and the number of healthcare workers is a prerequisite for fighting health inequalities and achieving adequate needs-based staffing levels, the EESC is of the opinion that HERA should invest in data collection and disaggregation.
- 6.4.3 Coordinating communication campaigns during cross-border health emergencies: the EESC reiterates its proposal that HERA coordinate communication campaigns during health emergencies to ensure people have a better level of understanding of how to protect themselves, what adaptations they need to make sure their daily activities remain safe and, if and when treatments are available, how to have access to them. In the preparedness phase, HERA could also ensure communication about prevention of a pandemic and prepare EU citizens for future health threats.
- 6.4.4 Developing reliable, verified, semi-specialised information for awareness-raising and education of the population through the Member States' health authorities and health actors (civil society, social economy, including mutual societies), in trusting science and being more adaptive to accepting vaccination not only in a pandemic crisis but also in endemics. HERA should also consider a specific EU training programme to be offered to public health officers and health professionals in order to promote and support the overall EU culture in building science and facing current and future health threats.
- 6.4.5 Organising upstream multi-stakeholder consultations with a view to drafting twice-yearly European reports and annual national reports.
- 6.5 Small and medium-sized enterprises (SMEs) specialising in medical and medicinal products have to play an essential role in future pandemics and certain incentives and protocols should be established under HERA to give them the tools and funding necessary to cover all aspects of fighting future pandemics and endemics that could become pandemics.
- 6.6 A real economic incentive for SMEs would be to encourage their participation in the Strategic Plan 2020-2024 and specially the InvestEU programme (2021-2027) which aims to give an additional boost to sustainable investment, innovation, digital transformation and job creation in Europe.

- 6.7 The production of over 1.3 billion vaccines was enough to vaccinate more than 75% of the adult population¹² and export half of the production to fight the global pandemic¹³. However, ensuring access to vaccination to the 25% of the population currently unvaccinated remains vital for saving lives. HERA should continue to lead global action against cross-border health threats and pandemics, including ensuring global vaccine equity. The EESC believes that the EU should continue to respond to the crisis in a consistent and global manner, in particular through COVAX as well as new candidate drugs and therapies, and to strengthen and support the global health security architecture. This must also strengthen the EU's role in the World Health Organization. In this context, in order to respond to the urgent needs of developing countries in particular, the EESC continues to ask the Commission to lead an open debate at European level on a temporary TRIPS voluntary waiver that would apply to COVID-19 vaccines, treatments and tests, in order to enable global vaccine production to be ramped up and the costs lowered to ensure access for people across the world¹⁴.
- 6.8 Effective mechanisms to ensure global access to vaccines and therapies developed with public funds are and will be crucial to avoid the current inequalities in vaccines around the world - where around 60% of people living in high income countries have received at least one dose, compared to only 24% in middle income countries and less than 2% in low income countries. The EU must take into account the – scientifically evidenced – mantra that "No one is safe until everyone is safe".

Brussels, 23 February 2022

Christa Schweng

The president of the European Economic and Social Committee

¹² https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans_en

¹³ https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/global-response-coronavirus_en#covax

¹⁴ EESC opinion on Emerging stronger from the pandemic, adopted at the 8/12/2021 EESC plenary session, (not yet published in the OJ).