



**European Committee
of the Regions**

NAT-VII/023

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OPINION

Health Emergency preparedness and Response Authority

THE EUROPEAN COMMITTEE OF THE REGIONS

- considers that the objectives of securing EU health and protecting the population "cannot be sufficiently achieved by the Member States, either at central level or at regional and local level," and that greater EU intervention in this area is therefore in line with the principle of subsidiarity (para 3);
- is concerned about HERA's ability to succeed (7) and points out that cities and regions have to play an active role alongside the EU and Member States in developing new approaches to protecting communities. This role must be recognised at national and European level in accordance with the principle of active subsidiarity (24);
- finds that drawing up HERA's multiannual strategic plan is a top priority and must also involve the European Parliament, cities and regions (14);
- considers it essential for HERA to develop, in partnership with the other relevant EU bodies, a health security vulnerability scoreboard and to build, together with the Member States and regions, response programmes for the various kinds of emergencies and stress test programmes for health systems (17);
- stresses the need for an industrial and innovation policy ahead of crises, and the imperative need to create a new regulatory and support framework to give the EU sovereignty in the field of health and capacity to manufacture the products of R&I industrially (32); is convinced that what is happening in the field of semiconductors should be conceivable in the field of health (35).

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Opinion of the European Committee of the Regions – Health Emergency Preparedness and Response Authority

I. POLICY RECOMMENDATIONS

General comments

1. The European Committee of the Regions points out that in March 2020, its presidency called on the European Commission and the Member States to establish a European health mechanism¹, and that it developed this idea in its subsequent opinion, also of 2020, on an EU Health Emergency Mechanism²; it draws attention to the fact that Commission communication COM(2021) 576 took inspiration from the points made therein;

The debate on establishing HERA is taking place against the backdrop of the ongoing COVID-19 epidemic, which is more reason than ever to make health a priority for the European Union. However, HERA is being established with a broader aim relating to all types of risk to human health, large-scale and/or cross-border, the phases of both crisis preparedness and management and the challenges of prevention and resilience of societies and areas and all this in the broader context of the war in Ukraine, which is having a huge impact on health services, infrastructure, and cross-border cooperation that were already severely strained and depleted during the worst of the COVID pandemic.

2. The European Committee of the Regions supports the creation of HERA as the authority responsible for preparing for and managing health crises, taking into account, on the one hand, Member States' primary responsibility for prevention, public health and healthcare, crisis preparedness and crisis management, and, on the other, the key role played by the regions, as in Europe two thirds of the Member States have decentralised health systems that follow different procedures. It stresses the need for an overall approach to protecting people, while the Commission's action is still split between multiple decision-making centres, and the support the EU must provide for states and regions.
3. Health crises, whatever their origin, are a danger to communities, which they affect in a very unequal way, but they are also threatening to European integration itself if it is unable to respond to them in a rapid, effective, coherent and inclusive manner. The COVID-19 crisis has put the solidarity between Europeans, the integrity of the internal market and cooperation on the Schengen area to the test. The European Committee of the Regions considers that the crisis has also shown that the objectives of securing EU health and protecting the population "cannot be sufficiently achieved by the Member States, either at central level or at regional and local level," and that greater EU intervention in this area is therefore in line with the principle of subsidiarity³.

¹ <https://cor.europa.eu/en/news/Pages/COVID-19-CoR-President-calls-for-a-EU-Health-Emergency-Mechanism-to-support-regions-and-cities.aspx>.

² [OJ C 440, 18.12.2020, p. 15.](#)

³ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008M005:EN:HTML>.

4. While management of health and care systems is under national remits, the European Commission has an important role to play in protecting the health of the population and upholding the single market in line with the Treaties, which include protecting the health of the population as an essential requirement and entrust it with the role of protecting the Community acquis. This must be carried out working closely with the Member States, and there is good reason to involve the European Parliament. The European Committee of the Regions intends to make its voice heard in this debate, firstly because in this crisis local action is essential to protect communities, secondly because many regions have significant powers in the field of health and, lastly, because regions' support for innovation and industry is key in making countermeasures available to deal with crises.

HERA's scope for action, governance and scale-up path

5. The European Committee of the Regions advocates giving HERA very broad scope for action, as proposed by the Commission, while respecting the remits of other existing bodies⁴. The aim is to tackle threats to human health caused naturally, accidentally or deliberately, including as a result of terrorist acts, whether from pandemics or of biological, environmental, nuclear or unknown origin.
6. It stresses that, over and above its scope for action, the extent of HERA's activities is also very broad, including identifying and analysing the risks ahead of crises, encouraging proactive measures, increasing societies' and regions' capacity to deal with crises, defining management scenarios including appropriate responses, strengthening the industrial and research and innovation (R&I) ecosystem to develop and produce appropriate countermeasures, and finally to ensure that these countermeasures are available in all EU cities and regions and to all communities.
7. Given these huge challenges, the European Committee of the Regions is concerned about HERA's ability to succeed in its tasks.
8. While establishing HERA as an internal Commission department has to be seen as a pragmatic choice allowing rapid progress and coordination between the different activities of the Commission, this should only be a temporary solution, to be reviewed in due course. Giving it the status of internal Commission department must not hold up recruitment of the specialised and high-level staff needed to prepare for and manage health crises. It is important to guarantee decision-making autonomy in line with principles of subsidiarity and proportionality, which is essential to analyse risks independently and to take the necessary measures to protect human lives without delay.
9. The 2022 action plan published on 10 February provides for an annual budget of EUR 1.3 billion, which sends out a positive signal, but is not consistent with the budget forecast of EUR 6 billion over six years. A close look at this annual budget shows the importance being attached to countermeasure purchases and to setting up and managing European stocks (EUR 675.5 million), but there is no mention of the impact on the financing of other European

⁴ In particular, the Emergency Response Coordination Centre (ERCC – Civil Protection), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).

civil protection measures, of the support for new production capacities (EUR 160 million) or of the Horizon Europe research programmes (EUR 350 million), most of which are not new. That leaves only EUR 100 million for measures to anticipate risks and adapt health systems;

10. HERA's governance is a third weak point. It is strictly limited to the Commission and the Member States, confining the European Parliament to an observer role and excluding all stakeholders, cities and regions as well as civil society players from HERA's permanent bodies. This governance is neither adequate nor effective, as crisis preparedness and management require a wide variety of players and expertise. Cities and regions, health professionals of all types, patients' associations, other key science and research players and health and solidarity NGOs are vital players in successfully tackling crises, and need to be fully taken into account. At the very least, the various stakeholders should be permanent members of the advisory forum, which should be able to provide recommendations to HERA's governing bodies and be involved in the various aspects of its work.
11. The European Committee of the Regions recognises the primacy of national powers and the crucial importance of the joint work of the Commission and the Member States, but calls on the Commission and the Council to return to an open and inclusive method of coordination with stakeholders and to give local and regional government representatives and the European Parliament their full say independently of legal considerations.
12. HERA's operational action seems to focus on the provision of medical countermeasures. However, there are many other significant aspects of crisis management, particularly in the areas of prevention and civil protection. The European Committee of the Regions considers that the term countermeasures should cover all medicines and drugs (including their active ingredients), and all antibiotics, vaccines, tests and diagnostics, medical devices and supplies, personal protective equipment and hospital and local equipment, but also information systems, and systems monitoring infectious diseases and emerging contaminants. All these resources are necessary to deal with crises and protect people and their health.
13. It calls for equal attention to be paid to developing resilient societies and a common culture of crisis and disaster management. Within this framework, greater support should be given to the European Civil Protection Mechanism, whose budget should not be undermined by the establishment of HERA. Including the word "emergency" in HERA's title should not create confusion or lead HERA to duplicate the crisis management arrangements already developed within the EU's Civil Protection Mechanism, the cornerstone of which is the Commission's Emergency Response Coordination Centre (ERCC). There is a need for very close coordination and a clear division of roles between these two Commission tools, which could be aligned in the future. It is also necessary to draw a distinction from the measures under the revised legislative act on cross-border health threats currently being negotiated between the Council and Parliament, and from the tasks of the European Medicines Agency (EMA) and, in particular, the European Centre for Disease Prevention and Control (ECDC).
14. Drawing up HERA's multiannual strategic plan is a top priority and must also involve the European Parliament, cities and regions, as well as stakeholders. This plan should set out the level of resources needed for HERA to carry out its numerous tasks effectively, describe the stages of its scale-up and establish monitoring indicators. The strategic plan should also specify

the mechanisms for cooperation between HERA and other EU intervention instruments, including the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the Civil Protection Mechanism, and state how they can also be strengthened to fully play their role in coordination with HERA.

Preparing Europe for crises and disasters, protecting all people in all EU cities and regions effectively

15. The COVID-19 experience shows that there is no effective action without a common response at European level, which should be tailored to different national, regional and local needs and circumstances. HERA must also promote high, increasingly aligned European ambitions when it comes to protecting people from crises. However, COVID-19 currently highlights the inequalities between regions and social inequalities in access to care and inoculation, which undermine the response to health crises and endanger Europe as a whole.
16. The European Committee of the Regions would like HERA to have the role of analysing regions' and communities' vulnerabilities to health crises. This role of analysing vulnerabilities must factor in the availability of stocks across Europe and the operational capacity to reach all communities, prioritising those whose health is most fragile and those living in a situation of exclusion and instability. It must also cover the ability of health systems, hospitals and other healthcare facilities to increase their capacity in the event of a crisis in order to keep planned care going as much as possible while accommodating additional patients arising from the crisis.
17. It therefore considers it essential for HERA to develop, in partnership with the other relevant EU bodies, a health security vulnerability scoreboard and to build, together with the Member States and regions, response programmes for the various kinds of emergencies and stress test programmes for health systems. On the basis of the results of these tests, the Commission and the Council should draw up recommendations for Member States and regions, which should be followed up, to strengthen their health systems and consolidate, where necessary, the health response capacities of regions and equality in the protection of the various communities.
18. Similarly, HERA should help to develop research programmes under Horizon Europe to address the most vulnerable communities (people experiencing poverty or exclusion, minorities, refugees, female victims of violence, older people and people with disabilities, people with comorbidity factors, etc.), who the COVID-19 experience has shown are often the first victims. These research programmes should also specifically address inequalities in access to healthcare for older people, children and young people's mental health, complementarity between hospital and community-based healthcare, and innovations, including digital innovations, in the way health systems are organised. They must incorporate a permanent gender-sensitive approach, ensuring appropriate representation of women's needs.
19. Preparing people for future disasters and epidemics is a key challenge which HERA must help to meet. At European level we also need to reinforce and coordinate public health prevention programmes and programmes for promoting public health and for combating the digital divide and disinformation. These health prevention measures must span all public policies. HERA's activities must be part of a more ambitious European prevention policy set out in the framework of EU4Health, which should be strengthened and take better account of the challenges of mental health, disability and fighting chronic diseases as well.

20. It is also necessary to draw specific lessons from both the COVID-19 crisis and the war in Ukraine through research. Actions should thus be initiated focused on the rapid response of health systems and the accelerated deployment on the ground of countermeasures (modular hospitals, mobile and simplified medical devices, mobile medical units, small vaccination centres, enlisting sufficient qualified medical staff, etc.).
21. Particular consideration should be given to the specific challenges of remote rural areas, mountain areas and outermost regions. It should be noted that this set of measures is largely absent from the HERA work programme for 2022, which the European Committee of the Regions regrets, and it calls for this matter to be reviewed as of 2023;
22. The European Committee of the Regions believes that this set of measures is not a threat to the powers of the Member States but, on the contrary, is an opportunity for each Member State, in coordination with the regions, to be more effective in protecting its population.
23. An in-depth analysis by the European Commission of the health spending from Cohesion Funds and the Recovery and Resilience Facility during the pandemic could be useful for managing future crises. It could identify good national, regional and local practices to help design future health crisis prevention and management measures.
24. The European Committee of the Regions calls for a specific approach to expenditure for strengthening health systems and crisis preparedness, which can only increase, to be established in the context of the European Semester and for this expenditure to be permanently eligible for cohesion policy funds following the Coronavirus Response Investment Initiative. It is concerned that health expenditure has so far been only a very minor part of the recovery plan and calls for greater support for cities and regions as regards resilience and equipment in the area of health and civil protection.
25. It points out that cities and regions have to play an active role alongside the EU and Member States in developing these new approaches to protecting communities. This is even more true where they have specific powers in the area of health and where they manage the hospital and health system. This role must be recognised at national and European level in accordance with the principle of active subsidiarity.

Lessons to be learned from the war in Ukraine

26. The European Committee of the Regions welcomes HERA's involvement in the vaccination campaign for Ukrainian refugees in the EU and its support for the EU Civil Protection Mechanism, which provides vaccines for children and other essential medical supplies thanks to support from the pharmaceutical industry and health ministries;
27. The European Committee of the Regions considers that the war in Ukraine is a powerful reminder that Europe must be prepared for all kinds of crises: just as COVID-19 struck our regions without warning, armed conflict in the Union's direct neighbourhood was not expected either. Its impact on health systems, especially in Central and Eastern Europe, is constantly growing and needs to be closely monitored in order to prevent a tipping point being reached.

HERA's analytical and predictive capacities need to be developed rapidly to ensure that the next impending disaster does not take the European Union by surprise;

28. therefore reaffirms that priority must be given to boosting the capacity of health systems in all EU Member States and regions to adapt rapidly to unforeseen events. For this to happen, the "health security vulnerability scoreboard" and stress test programmes for health systems therefore, now more than ever, appear to be priority measures;
29. The European Committee of the Regions draws attention both to the risk of radiation exposure due to possible damage to civil nuclear infrastructure and to the risks inherent in delays in the treatment of chronic diseases, including cancer and HIV (Ukraine has one of the highest rates of HIV prevalence in Europe); these risks are also likely to have an impact on the health systems of host countries;
30. The war in Ukraine, which has resulted in the influx of millions of unvaccinated people into the EU, is prompting us to develop closer international cooperation on access to countermeasures, particularly vaccines, with priority given to our neighbouring countries. The European Committee of the Regions is therefore concerned at the inadequacy of these measures in the 2022 HERA work programme;

An industrial and public procurement policy for health

31. The European Committee of the Regions welcomes the initiatives taken since the beginning of the crisis to make countermeasures available faster and the draft Council Regulation on crisis management measures. However, it feels that the current proposals as yet fail to provide a sufficient mechanism for preparing effectively for health crises.
32. It stresses the need for an industrial and innovation policy ahead of crises, and the imperative need to create a new regulatory and support framework to give the EU sovereignty in the field of health and capacity to manufacture the products of R&I industrially.
33. It believes that the European Union must give itself the means to produce the "essential" countermeasures largely common to the management of various types of crisis on its own soil. These medicines (including their active ingredients), medical devices, tests, diagnostics and basic equipment cannot be produced in Europe without a proactive public purchasing policy that absorbs potentially higher supply costs. There is currently no indication of how the European rules and principles for action are going to enable this essential objective to be achieved.
34. It is deeply concerned about the difficulties faced by many companies that invested at the request of public authorities at the beginning of the crisis to address shortages and are now being abandoned in favour of purchases from outside the EU. It feels that the lessons of the crisis have not been learned and that this issue should be dealt with as a matter of urgency. In particular, it calls for national and European strategic stocks to be built up and renewed wherever possible with goods produced in Europe.
35. The European Committee of the Regions therefore calls on the European Commission to research and propose an appropriate legislative framework allowing exemption from State aid

and public procurement rules, particularly when it comes to "essential" countermeasures. What is currently happening in the field of semiconductors (European Chips Act) should be conceivable in the field of health.

36. This new legal framework should relax the rules on public procurement, particularly in the area of innovation, step up screening of foreign investment and make it possible to provide sufficient direct aid to contribute effectively to accelerating the development of medical innovations such as vaccines and placing them on the market. As things stand, the European Union cannot legally make the same kind of intervention as the United Kingdom or the United States, and this is endangering its access to vaccines.
37. The European Committee of the Regions is concerned at the amount of time lost, regrets that the publication of the 2022 HERA work programme was not accompanied by the launch of an associated initiative, and calls on the Commission to submit a proposal to the Parliament and the Council without delay;
38. The European Committee of the Regions takes note of the recent progress made in structuring R&I in the area of preparedness for health crises. Indeed, the French presidency is strongly in favour of an important project of common European interest (IPCEI) "in order to strengthen the EU's industrial policy and strategic positioning in the health sector by fostering innovation in the various segments of the healthcare industry." Furthermore, in April 2021 the Commission began consultations with a view to launching a public-public European partnership on pandemic preparedness in the framework of Horizon Europe's 2023-2024 work programme in order to coordinate research carried out by the Member States. However, there is currently no framework for ensuring the consistency of all Horizon Europe actions that can contribute to the tasks of HERA and the planned budget of EUR 1.7 billion, whereas EUR 4 billion was mobilised under the previous two framework programmes for pandemic and vaccine research. The European Committee of the Regions therefore calls for:
 - the creation of a scientific council for HERA which is pluralist and involves stakeholders, to establish scientific priorities and an R&I roadmap which Horizon Europe should address;
 - an increased budgetary mobilisation under Horizon Europe to meet HERA's R&I needs;
 - the launch of a reflection on the creation of a future "mission" dedicated to health crisis management and preparedness that would allow for a cross-cutting approach within Horizon Europe, scientific and operational coordination, and the involvement of all stakeholders, with particular emphasis on promoting public-private collaboration.
39. Research on antimicrobial resistance would seem to be a top priority for HERA. The overuse of antimicrobials, in livestock farming and in human healthcare, is a ticking time bomb. Unless a solution is found rapidly, the "no cure, no treatment" scenario is likely to happen soon. Almost all of the new antibiotics that have been marketed in recent decades are variations of antibiotic families that were discovered in the 1980s. So far, no conclusive results have been obtained by the Commission in this area, as demonstrated by the Court of Auditors' 2019 report⁵. It is therefore necessary to reinforce preventive health services so that they can coordinate all those

⁵ <https://www.eca.europa.eu/en/Pages/DocItem.aspx?did={8892C8C4-6776-4B27-BE36-C181456EED71}>.

involved in controls on the use of antimicrobials locally, in hospitals and in the community and to invest in research into new antibiotics and alternative preventive methods.

40. A new legislative framework would enable a strategic partnership to be developed between the EU and the pharmaceutical industry, in order to take better account of public health objectives of general interest. The direct support of the EU must be met by industrialisation in Europe, privileged access to products, and a right of scrutiny with regard to the price of countermeasures and licensing policies.
41. Consideration should also be given to the R&I measures envisaged and the role of HERA there. The implementation of this strand within Horizon Europe needs to be improved fast so that HERA can quickly be given an R&I roadmap to clarify the procedure for deploying the EUR 1.8 billion in its budget that come from the programme.
42. The European Committee of the Regions stresses the need to strengthen without delay the fabric of innovative SMEs in the field of medical countermeasures and all types of devices and equipment to protect people and cope with crises. The first priority is to support business creation and innovation, which is the remit of cities and regions, and then to help them grow and build up the capacity to conduct clinical trials and manufacture products in Europe.
43. This will involve considerable investment and increasing the capital of the businesses concerned. The European Innovation Council (EIC) needs to be brought into play, in order to better structure a European innovation ecosystem around developing countermeasures and managing health crises and to strengthen risk and development capital intervention tools to enable innovative companies to grow while keeping their roots in Europe. These measures should also make it possible to share the industrial risk of developing and producing countermeasures.
44. The effectiveness of the medical countermeasures goes hand in hand with a more flexible management of clinical trials, while ensuring compliance with rules on ethics and the protection of personal data. HERA must propose a stronger framework for cooperation with the EMA for the coordination of medium and large-scale clinical trials, which was sorely lacking at the height of the COVID-19 crisis. The "Vaccelerate" and "HERA incubator" initiatives are a promising start in making up for these shortcomings, but clearer operational links must be established with national authorities in order to remove any regulatory or protocol barriers faster. The review of the new European Pharmaceutical Strategy should facilitate significant developments, in particular the centralisation of clinical trial authorisations for medicines requiring EU marketing authorisations.
45. Research infrastructure is also crucial. When it comes to combating major cross-border health scourges, proper analytical facilities, high-performance computers, repositories of data from epidemiological studies and comprehensive cohort studies are essential so that emerging threats and model response scenarios can be analysed.

International action based on prevention and solidarity

46. The European Committee of the Regions considers that it is in Europe's interest to act where new health risks are emerging to limit the EU's exposure to risks. HERA must therefore have the means to network with many partners (including, at international level, the United Nations and the Council of Europe) and to participate in action outside the EU, in collaboration with the countries concerned, as soon as risks are identified, with significant resources to draw on. This cooperation must also cover the preparatory phase and, in particular, prevention measures, reducing vulnerabilities, and preparing societies for crises. To this end, HERA should forge partnerships with civil society players, local and international NGOs and multilateral organisations involved in risk prevention programmes.
47. Releasing intellectual property for vaccines and other medical products will not be a sufficient solution if less-developed countries do not have the capacity to develop production on their own. The European Committee of the Regions calls for the price of certain medicines to be regulated where needed and for the pharmaceutical industry to be required to grant manufacturing licences as suggested by the WTO. It calls for EU policies to contribute to the development of products adapted to the specific context of less-developed countries. It calls on the EU to commit to an active policy of technology transfer and support for local production, and to provide appropriate direct aid to help ensure health coverage for communities wherever it is needed.
48. The European Committee of the Regions notes and shares European citizens' very high expectations as regards giving the EU a greater role in the area of health. It notes that the current, very restrictive wording of Article 168 of the Treaties is, at present, an obstacle to this, and considers that the issue of strengthening European competences in the field of health should be on the agenda following the Conference on the Future of Europe. The EU's competences in the field of the internal market should already make it possible to go further in Community action in the field of health; it should be possible to strengthen the EU4Health programme; and EU health ministers should meet very regularly in a dedicated Council formation, rather than only twice a year as an afterthought at the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO).

Brussels, 27 April 2022

The President
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Apostolos Tzitzikostas

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Petr Blížkovský

II. PROCEDURE

Title	Health Emergency preparedness and Response Authority
Reference(s)	COM(2021) 576 final
Legal basis	Article 307(4) TFEU
Procedural basis	Rule 41(b)(i) of the Rules of Procedure
Date of Council/EP referral/Date of Commission letter	
Date of Bureau/President's decision	
Commission responsible	Commission for Natural Resources (NAT)
Rapporteur	Christophe CLERGEAU (PES/FR)
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Previous Committee opinions	
Date of subsidiarity monitoring consultation	
