

3 November 2021

Subject: Joint letter calling HERA to prioritise the public interest, remain accountable to citizens, and ensure equitable and affordable access to medical tools

Dear Health attaché,

Dear Commissioner Kyriakides,

We, the undersigned 19 organisations representing patients, consumers, health professionals, and civil society, urge the Council and the Commission to reconsider crucial aspects of the recently launched Health Emergency Preparedness and Response Authority (HERA) and its proposed Regulatory framework.

We welcome the creation of the EU HERA with substantial funding, an ambitious role to accelerate R&D, manufacturing, procurement and stockpiling of medical tools, and a collaborative ecosystem with other EU agencies, the European Commission, and the Member States. Nonetheless, we would like to express our concerns regarding the processes that are being used to set up HERA and propose some recommendations to ensure that HERA will work for the public interest, focus R&D on public health needs/priorities, remain accountable to EU citizens, and place the EU as a global leader leveraging equitable and affordable access to medical tools.

A democratic and participatory debate is needed

The proposal on HERA has moved forward without a meaningful discussion with the European Parliament and civil society. While the current emergency is putting pressure on everyone to act fast, the fundamental role that HERA will play and the substantial funding it has been allocated, call for a democratic debate. Good governance and transparency must be ensured even in situations of urgency, and both the Parliament and stakeholders have proved they can mobilise swiftly during the crisis. We urge the Council and the Commission to hold an open discussion with Parliament on the creation of HERA.

Good governance, transparency and accountability should be incorporated

HERA should have clear governance rules, including for transparency and accountability, which have been deemed fundamental by stakeholders¹. In its current form, there is insufficient clarity about the mechanisms that would be put in place to guarantee this. HERA should be a strong and independent public Authority with clear public health missions, free from vested interests, and remain accountable during and in between emergencies. We urge the Council to

¹ <https://medicinesalliance.eu/getting-hera-right/>; <https://epha.org/hera-should-serve-patients-and-promote-public-health-a-shared-vision-for-the-eus-new-authority/>; https://www.feam.eu/wp-content/uploads/2021_Wellcome-FEAM-HERA-report.pdf.

include good governance, transparency and accountability in the proposed Regulation of the Council and the Commission to do the same under the Decision creating HERA.

Stakeholders, including patients, civil society, healthcare professionals and researchers should be involved

The current proposal leaves the possibility open but creates no obligation to involve stakeholders. Additionally, their role is primarily focused on information exchange and not as implementing partners critical to prepare and respond against epidemics. In contrast, industry has been given a preeminent role in HERA, including through the “Joint Industrial Cooperation Forum”. We believe that the meaningful participation of stakeholders including civil society, patients, healthcare professionals and researchers should be facilitated and required at least at critical points of HERA’s operation. We urge the Council and the Commission to explicitly include stakeholders through a formal structure within the governance of HERA.

Ensure other public health priorities are protected

HERA has been given ample capacity to set priorities and mobilise a significant amount of public funding. Therefore, proper mechanisms are needed to ensure that priorities are not shifted away from the public interest and to ensure that areas suffering from market failure, such as poverty-related neglected diseases or airborne disease threats like tuberculosis, are supported. The ability of HERA to mobilise funding from different funding streams may disrupt other research fields. So far there is a lack of clarity about which funding programmes will be affected and to what extent. We call for a proper and transparent mechanism to ensure that HERA investments do not reduce other critical public health investments and to stimulate international partners and EU member states to bring up additional resources. Stakeholders, including civil society, patients, consumers, healthcare workers and researchers, free from commercial interests, should also be involved in periodic revisions of the priorities of HERA.

Ensuring accessibility and affordability of the outputs that HERA will support

The creation of HERA offers the EU an opportunity to learn from the COVID-19 experience and create strong mechanisms to ensure public return on investments². The US Biomedical Advanced Research and Development Authority (BARDA), which is considered a model for the creation of HERA, faced problems with the lack of inclusion of conditionalities and transparency requirements. This left companies at liberty to use substantial public funding without guaranteeing a public return, and free to raise prices despite unprecedented profits, in the middle of a global health emergency³. Conversely, the use of conditionalities on the contracts used by the Coalition for Epidemic Preparedness Innovations (CEPI), shows that

² <https://medicinesalliance.eu/getting-hera-right/>; <https://epha.org/hera-should-serve-patients-and-promote-public-health-a-shared-vision-for-the-eus-new-authority/>.

³ <https://www.theguardian.com/world/2021/aug/11/covid-19-vaccines-the-contracts-prices-and-profits>.

these are not a barrier for a quick response in crises⁴. It is important that HERA incorporates these learnings. Safeguards must be put in place to ensure it acts as a wise public investor, ensuring a public return on investment as well as the creation of synergies and complementarities. We urge the Council to ensure that HERA commits to act in the public interest and to subject its public funding to conditions of affordability, transparency, access to the results, open data requirements and intellectual property management under equitable conditions. This is crucial to ensure equitable and affordable access to future medical countermeasures⁵.

Outlining a clear global vision

Transparency on the functioning and the capacities of the global supply chain is a prerequisite to make well-informed decisions to overcome bottlenecks and guarantee a sustainable supply of needed health technologies. Effective mechanisms to ensure global access for vaccines and therapies developed with the help of public funding are and will be crucial to avoid global vaccine inequities and ineffective responses to future pandemics⁶. If the EU wants to lead global action in health emergencies through HERA, it will need to treat the medical tools resulting from public investments as global public goods. This will require that HERA use the above-described conditionalities with a view towards ensuring global access to medical countermeasures. It will also need to develop a global health strategy that identifies priorities, outlines a clear and measurable intervention plan, and helps to pool member states' efforts. We urge the Commission and Council to develop clear binding policies outlining the commitments of HERA towards global access to medical tools and transparency of global supply chains. The Commission should also refresh and revamp the EU's 2010 strategy on global health to make sure it is updated and consistent with the new landscape, including HERA.

Support not-for profit EU infrastructure

HERA should support long-term sustainable not-for-profit manufacturing infrastructure at EU level to facilitate the production of medicines as a non-profit public activity and as recommended by the European Parliament⁷. HERA's cooperation with other non-commercial research institutions would ensure much-needed coordination of clinical trials and transparency of clinical trials data and research and development costs.

We urge the Commission and Council to prioritise the development of sustainable not-for-profit infrastructure, including by facilitating broad cooperation with other non-commercial research entities.

⁴ Moon, S., Alonso Ruiz, A., & Vieira, M. (2021). Averting future vaccine injustice. *New England Journal of Medicine*, 385(3), 193-196..

⁵ Wouters, O. J., Shadlen, K. C., Salcher-Konrad, M., Pollard, A. J., Larson, H. J., Teerawattananon, Y., & Jit, M. (2021). Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. *The Lancet*.

⁶ Wagner, C. E., Saad-Roy, C. M., Morris, S. E., Baker, R. E., Mina, M. J., Farrar, J., ... & Grenfell, B. T. (2021). Vaccine nationalism and the dynamics and control of SARS-CoV-2. *Science*. Vol 373, Issue 6562.

⁷ https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.html.

We look forward to further exchanges to address HERA as well as a responsible R&D model within and outside public health emergencies. It is imperative that the voices of patients, consumers, health professionals, and civil society organisations are heard in further discussions and initiatives to address these and other issues affecting access to affordable medicines.

The undersigned organisations would welcome the opportunity to meet with you to discuss our concerns and recommendations.

List of signatories

1. Global Health Advocates
2. European Public Health Alliance
3. Treatment Action Group
4. Asociación por un Acceso Justo al Medicamento
5. Health Action International (HAI)
6. Access to Medicines Ireland
7. SOMO-Centre for Research on Multinational Corporations
8. Prescrire
9. Wemos Foundation
10. Consilium Scientific
11. Salud por Derecho
12. Consumer Association the Quality of Life-EKPIZO
13. Plataforma NoGracias
14. Universities Allied for Essential Medicines (UAEM Europe)
15. AIDES
16. Médecins du Monde International Network (Mdm International)
17. Pharmaceutical Accountability Foundation
18. France Assos Sante
19. Ligue contre le cancer

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