



## WORLD **PRIVACY** FORUM

### **Comments of the World Privacy Forum to the European Commission regarding creation of European Health Emergency Preparedness and Response Authority (HERA)**

24 February, 2021

Dear Commissioners:

Thank you for the opportunity to comment on the proposed creation of a European Health Emergency Preparedness and Response Authority, HERA.<sup>1</sup> We acknowledge the need for such an institution. We urge the Commission to ensure from the outset that HERA will fulfill its mission with a focus on data interoperability and will include specific data governance and protection measures that will analyze and address informational risks, including those relating to privacy, among other informational risks.

We also urge the Commission to ensure that HERA will, as a prominent feature, include governance structures and policies that facilitate increased coordination and harmonization with external organizations both in Europe and the rest of the world. For example, the World Health Organization (WHO), the European Centre for Disease Prevention and Control, and the Biomedical Advanced Research and Development Authority (BARDA,) among other such institutions.

The Inception Impact Assessment<sup>2</sup> states that: “It [HERA] will respect the competencies of Member States and relevant national authorities in this field, and seek to ensure coordination of preparedness and response capacities of medical countermeasures for serious cross-border threats to health, undertaking tasks which take account of the reality that no one country can effectively prevent or tackle a cross- border public health crisis on its own.”

We agree that no one country on its own can effectively prevent a cross-border, multi-jurisdictional health crisis. HERA, even though rooted in Europe, will still need to be multi-jurisdictional in approach and will need to have built-in procedures for working with existing coordinating bodies such as the WHO, and procedures for working collaboratively with other regional, national, and subnational stakeholders.

Additionally, it is essential that the institutional design of HERA ensure collaboration with and consideration of all jurisdictions, including the low and middle income countries (LMIC) in meaningful ways through the design, purpose, and functioning of HERA.

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<sup>1</sup> European Commission, Consultation regarding the creation of European Health Emergency Preparedness and Response Authority (HERA).

<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Response-Authority>

<sup>2</sup> European Commission, Inception Impact Assessment, HERA. Ref. Ares (2021) 674649-27/01/21. <https://ec.europa.eu/e836e584-5dab-4dff-9a4c-c84d09f8f925>

Building the ecosystem that will support HERA will be challenging due to the size, complexity, and unwieldy qualities of health, health data, and biomedical research and delivery ecosystems. These are key considerations in choosing a policy pathway. No matter which path the Commission decides upon for its proposed policy options, to accomplish its goals, HERA will need proper guardrails in the form of legal construction and basis, and appropriate governance structures, including crisis governance structures.

In closing, we understand the impetus for the creation of HERA. We urge appropriate data governance be applied, and we urge a harmonized, interoperable, and multi-jurisdictional approach that is inclusive in regards to low and middle income countries and existing global infrastructures. It is essential that HERA earn the public's trust through transparent, inclusive governance.

Thank you for your work.

Respectfully submitted,

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