

Inception Impact Assessment on European Health Emergency Preparedness and Response Authority (HERA) Initiative

Health Action International (HAI) appreciates the opportunity to offer our reaction to the proposed European Health Emergency Preparedness and Response Authority. We welcome the political support for public-funded research and development and fundamentally agree there is a need to move away from overuse of emergency instruments. The ad hoc actions the EU institutions have had to take to respond to the COVID-19 pandemic have undermined transparency and shaken the balance of competencies between the European Union (EU) institutions and Member States. It is evident that an alternative route must be sought. However, we have concerns about whether developing a so-called European BARDA is the best way to achieve these aims.

We query whether the creation of a new body is required when the European Centre for Disease Control (ECDC) and European Medicines Agency (EMA) have clear and, in the case of EMA, recently extended mandates. A new body with such an ambitious mission risks hindering the development of previous, similar initiatives, such as Horizon Europe.

We note positively mention of antimicrobial resistance and supply chain disruptions as cross-border health threats, and we expect decisive action on both counts. Regarding the proposed horizon scanning activities, we would like to see coordination with horizon scanning and mapping processes already in existence, be that via the EMA or through existing voluntary inter-country cooperation schemes.

The whole edifice seems to be based on public-private partnerships. It is concerning that there are no explicit safeguards for public interest nor mechanisms to ensure public return on public investments via accessibility clauses of end products. Of particular concern is the discussion regarding incentives for private industry to invest in unmet public health needs without the necessary transparency and accountability mechanisms.

Finally, we are surprised by the fact that key preliminary components of HERA seem to have already been designed as part of the HERA Incubator without consultation or involvement of civil society. While it is encouraging to see the European Commission supporting intellectual property pooling mechanisms, we must caution about the wisdom of suggesting a geographically limited version of an initiative already being tried at the global level. In this case in the form of the World Health Organization's COVID-19 Technology Access Pool (C-TAP), a mechanism that the Commission has so far failed to support. Regarding the announced Clinical Trials Network, we will seek more information on how it will complement the soon-to-be operational Eudamed and CTIS databases.

We remain open and willing to collaborate with HERA and other EU institutions to protect and promote public health and improve access to medicines and vaccines in Europe and beyond.

