European Alliance for
Responsible R&D and Affordable Medicines

Feedback to the inception impact assessment of the European Health Emergency Preparedness and Response Authority - HERA

COVID-19 has shown (and still showing) the importance of cooperation to respond to cross-border health threats. The mobilisation of public (and philanthropic) funds for research and development of vaccines and treatments has been unprecedented and it highlighted the extremely important and needed role that the public can play in biomedical research.
After the first scattered efforts, the European Commission and Member States have opted for a joint response with the EU vaccine strategy and joint advance purchase agreements: this should be considered a success story, yet with some flaws. Those flaws are mainly related to the overreliance on the current pharmaceutical business model and companies. Europe has been criticised for its vaccine regionalism, yet, found itself with limited amounts of doses despite the considerable investments - as blank checks - given to the industry to scale-up production. The publication of some of the contracts show that the European Commission and Member States had too much trust in companies and didn't include any concrete safeguards to protect the public interest.

HERA is the opportunity to get it right. The COVID-19 pandemic, like previous coronavirus outbreaks, the Zika epidemic, Ebola outbreaks and the ongoing antibiotic resistance pandemic, clearly demonstrate a need for an independent and transparent public agency (option 3). HERA should have a strong and broad end-to-end mandate with a public health driven approach to foresight, preparedness and research which will enable the rapide scale-up of production and distribution of key medical tools when the need arises. The agency should be established in the spirit of treating health as a human right, not just as a threat to safety.

Strong principles should drive its set-up and be the basis of every action:

- **Inclusive public interest driven governance**
  HERA's governance structures should ensure public control complemented with a balanced representation of relevant stakeholders including public health civil society organisations, patients, consumers and payers. Whilst the industries will be important partners, they should not be part of any governance structure of the new agency.
  Declarations of conflict of interest of all members in its governance structures should be publicly available.
  Transparent, timely and inclusive public consultation processes should be the norm.

- **Evidence-based and global health driven priorities**
  Priorities should be decided based on scientific evidence and be driven by global public health needs. Close collaboration with the WHO on priority-setting will be crucial to avoid wasteful duplication of research efforts. Lists such as the WHO R&D Blueprint, which identifies diseases and pathogens to be prioritized for R&D in public health emergency contexts, should drive the priority-setting of the new agency.

- **End-to-end approach**
  A broad enough mandate to address bottlenecks from the discovery phase all the way to production and distribution is crucial to ensure the public oversight and control necessary to ensure equitable distribution and affordable access to end products.
  The public agency should be financially sustainable to ensure long-term planning.

- **Full transparency and accountability at all levels**

HERA should adopt transparency practices at all levels. It should publish all documentation in a timely manner, including annual work plans and activity reports, budgets, R&D agendas, research and product pipeline, minutes of meetings, lists of experts and conflict of interest declarations.
Timely publication of joint procurement and direct contracts, both with public and private organisations, should be HERA's standard practice.

- **Public goods**
  HERA's results should be considered global public goods and the guiding principle of its actions must be to ensure a positive societal impact and public return on public investments.
  Concrete clauses must be included in all contracts to protect the public interest. Legal provisions must ensure the affordability, accessibility, availability and efficiency across HERA's work areas.
  Public ownership, control and management of resulting IP should be prioritised. In exceptional cases, where this will not be possible, various forms of IP management and licensing, including equitable licensing, must be required.
  Open access and open data requirements should be standard practice to ensure that knowledge gained with the support of public funding is accessible and reusable. This should include all data and results including data where research outcomes failed to avoid wasteful duplication of research efforts.
  Learning from the COVID19 vaccines supply failure, HERA should be set up to be able to ensure that health technologies will be available in a timely manner and are delivered in appropriate quantities and at an affordable price for those who need them.

- **Efficiency and collaboration**
  Coordination and collaboration with WHO, other agencies and global health actors should be maximised to increase efficiency and avoid duplication or waste of resources.