European Health Emergency Preparedness and Response Authority (HERA) Consultation

Feedback from EuropaBio

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1. Introduction:

Hera has a critical role to play in public health and better crisis preparedness to address cross-border health threats and improving crisis management capacity. It should learn lessons from ongoing initiatives world-wide, including BARDA and collaborate where suitable with wider international partners. It should be autonomous in decision-making, risk-taking, be allowed to fail given the nature of its investments and well-funded to address the long-term challenges. Its scope of responsibilities should start with pandemics and AMR to allow it to grow robustly and effectively. An appropriate governance structure should allow for transparency of decisions, flexibility of operation, speed of implementation and sustainability of operation.

2. Enabling an agile ecosystem:

Policy, framework and society: Health challenges will be tackled by working together across borders with increased coordination at EU level. Within Covid the strength of European science was evident, with the biotechnology industry joining forces to deliver vaccines in unprecedented speed. Implementation will depend on clear division of competences between the EU and the Member States, good governance, and clarification of the future role of the Health Security Committee and the European agencies.

A policy environment that understands the high attrition rate of biotechnology R&D is critical, with policy makers and funding providers within an enabling framework. This extends to IP rights, where short term restrictions may impact long term investment and prevent technology maturation.

3. Mapping resources and risks:

Harmonised mapping of European landscape is needed, as many assets are already identified but often fragmented. Europe has the tools to respond in the short term e.g. production of hand gel to long term production and completion of vaccines. Public and private capabilities should be mapped that could respond to coordinated European actions.
HERA should take on a catalysing and coordinating role monitoring health threats and addressing them by connecting the dots of the current ecosystem and stimulating set-up of additional needs in R&D and production in collaboration with public and private partners. Hera should remediate structural gaps in the EU’s health preparedness and response capacities.

4. **Stimulating research, discovery and development:**

Hera initiatives should include further stimulation of bioscientific research, rapid patient access and uptake of innovative treatments in Europe in the future. Creating the right incentives and rewarding innovation is critical to recovering European leadership position in life sciences. There is a need to invest in technology platforms that aim at providing broad responses to emerging pathogens. The example from Moderna and BioNTech shows that only a long-term effort can pay off. EuropaBio encourages a holistic approach in its preparatory work for HERA by engaging with all stakeholders from science, academia, clinical research networks, industry and citizens.

5. **Funding:**

The ability to respond quickly and at scale requires sufficient funding appropriated in advance, in both public and private spaces. HERA needs to be structured to maintain long-term effort and investment decisions, regardless of threat level from health risks. If Europe is to have local innovative companies with R&D and manufacturing capabilities that provide the ability to respond to health emergencies, we need to have the ability to fund them in Europe.

6. **Supporting scale up and production:**

Public financing has been critical in supporting companies to run in parallel R&D and ramping up production capabilities allowing them to be ready to distribute vaccines much faster than what would normally be expected. EuropaBio is looking forward to actively participating in the discussions around the role and extended mandates of the HERA proposal in 2021.

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**About EuropaBio**

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 1800 biotech SMEs. Read more about our work at [www.europabio.org](http://www.europabio.org).