

## European Health Emergency Preparedness and Response Authority

### A Statement by the Helmholtz Association of German Research Centres

The Helmholtz Association welcomes the initiative of the European Commission to establish an authority to address cross-border threats to the health of European citizens. Learning from the ongoing COVID-19 pandemic is crucial for the improvement of healthcare and research alike, and the new HERA can help bring together these sectors. This statement addresses the **research and innovation aspects** of the proposed legislation, which are evidently a prerequisite to overcoming any health challenge.

#### Identification of future cross-border health threats

“Strategic investment in innovation for identified threats,” as mentioned in the inception impact assessment, requires knowledge about said threats. **Horizon-scanning activities** can help with this important task: Based on empirical data from the past and present as well as simulations about future developments, data science-based approaches supported by high-performance computing can yield crucial insight as to which threats should be monitored particularly carefully before they become a threat to European citizens.

These tools, which combine knowledge from the biomedical sciences, data science, and information technologies, must be continuously improved and developed to remain weapons against health threats. Therefore, research into horizon-scanning methods and approaches must be a key mission of HERA as well: **to constantly improve and refine its own toolkit in order to lead to more effective prevention and mitigation strategies.**

#### Development of new countermeasures

For a given health threat, appropriate countermeasures must be chosen carefully to ensure an effective and efficient response. The prioritization of research activities, e.g. on vaccines and therapeutic agents, must be tailored to the respective health threat, and must be backed up by up-to-date knowledge about the disease and its causative agent.

HERA support of the development capacity should not just focus on “end-stage research and development,” but should include **early-stage research into potential future emerging diseases**. For example, especially for poorly known pathogens, intricate knowledge of their biology is necessary to develop and provide weapons against the health threats that they pose. Continual support for innovative fundamental and preclinical research will provide the basis and engine for the development and validation of these effective therapeutic concepts.

**Clinical trials** are one of the bottlenecks during the development of tools against emerging health threats. Additional funding of academia-initiated clinical trials is urgently needed to expedite patients’ access to novel medicines. Epidemiological studies on the prevalence and incidence of health threats will contribute to the development of prevention and treatment strategies. Moreover, there is a need for a consistent, unified regulatory landscape in Europe to make it feasible to carry out such trials and share data involving different countries. This is especially important when rarer diseases or those with highly diverse outcomes are concerned, making international multi-centric studies a necessity to achieve adequate patient cohorts.

For all of the above-mentioned approaches, **research infrastructures** are of the highest importance. Europe must base its fight against cross-border health threats on the most advanced, powerful instruments, including but not limited to high-performance computers, analytical facilities, data repositories, and comprehensive cohort studies. They must be adequately funded and continuously expanded, and this

funding must receive a boost in times between health crises, so these infrastructures stand ready to assist in the fight against the next threat.

Besides methods and infrastructures, training and knowledge transfer will be crucial to successfully overcome future cross-border health threats. In particular, the international exchange of experts and know-how must be supported to ensure that knowledge and best practices are disseminated across the EU. It will be vital to include not just experts from public authorities and pharmaceutical companies, but also research and foresight specialists from various scientific disciplines.

### Relationship with other organizations

HERA will define health risks and orchestrate “corresponding public-private policy interventions,” as outlined in the inception impact assessment. Given the complexity of the challenges at hand, it is crucial that HERA maintain structured, particularly well-organized, reliable relations with other entities, such as public authorities, industry associations, and academic partners. We recommend a **Scientific Advisory Committee** that continuously provides HERA with up-to-date knowledge from research (including infection biology and epidemiology), pharmaceutical sciences (including chemistry, manufacturing and logistics), and the simulation sciences. This Committee should also act ad-hoc in case of suddenly emerging crises. A concomitant goal of HERA should be not only to deal with emerging health threats, but through its actions, to help to mitigate the risks and negative consequences of such threats with regard to other health conditions. For example, preliminary studies show that the COVID-19 pandemic has led to delays in the diagnosis and treatment of cancer patients, which could lead to increased mortality.

Helmholtz welcomes the focus on long-term solutions for these complex threats to the health of European citizens. Science-based intelligence can enable us to overcome cross-border health threats, if it is utilized appropriately, as shown in the current pandemic. This will also be true in subsequent crises of a similar nature.

#### Brief portrait of the Helmholtz Association

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