



Towards HERA: can it live up to European citizens' expectations?

The Biomed Alliance strongly supports the EU's drive to learn from COVID-19 and to improve its crisis preparedness and response. The proposal to establish a European Health Emergency Preparedness and Response Authority (HERA) is an important contribution towards that direction, if implemented with a strong scientific basis. To ensure HERA can live up to its full potential, the European Commission must secure continuous involvement of the scientific community throughout the implementation and operation and provide appropriate communication with all stakeholders and the public.

The recent Commission Communication announced that HERA will not be a standalone agency, but will rather be established within the Commission, with a 6-billion-euro budget from 2022 until 2027. This will allow the European Commission to quickly put in place a very complex structure but will prevent the involvement of the European Parliament and a longer institutional negotiation process. Also, the budget will be redirected from existing EU programmes from 2022-2027 such as EU4Health, Horizon Europe and NextGenEU. Moreover, the governance and structure of HERA is supposed to facilitate concrete engagement and involvement of Member States, industry and ad-hoc interactions with healthcare professionals when considered necessary.

A successful HERA must:

1. **Involve the scientific community from cross-disciplinary fields from the start and not merely on an ad-hoc basis**

We must build on research evidence which is already available. We cannot prepare for and respond to health threats without concrete planning of involvement of researchers and healthcare professionals with multidisciplinary expertise. During the COVID-19 crisis, BioMed Alliance members diagnosed and treated patients, they conducted research to understand the impact of COVID-19 and its relationship with other diseases and they shared invaluable information. Our members representing healthcare professionals and researchers from cross-disciplinary fields are at the frontline of any health threat response and can share invaluable information both on upcoming health threats but also related to the monitoring and response to current health challenges. They are also the ones developing and using medical countermeasures, and it will be a missed opportunity with grave consequences for patients to not use our members' expertise to help build an effective structure. They should therefore be involved from the early stages of the development of HERA to the implementation and operation stages.

2. **Provide clear information about its structure**

Appropriate and clear communication on the specificities around the creation and operation of HERA is necessary to obtain strong political support from Member States, the public and stakeholders. The European Commission opted for a swift establishment of HERA by creating an in-house structure, skipping a lengthier legislative process with a stronger role for the



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European Parliament and additional consultation of stakeholders. While it is understandable that the European Commission opted for this procedure due to time considerations, it is even more important that the European Commission ensures proper and detailed information on key elements of the future operation of HERA. The Communication is a good first step, but more detailed information on practicalities, including a break-down of the funding, the exact relation with industry, interaction with other agencies, and the concrete framework of cooperation with all stakeholders, must be provided so that all actors can meaningfully contribute to the new HERA.

3. Be founded on a good budgetary balance between HERA development and other health priorities

HERA needs to be very well-resourced financially to carry out its mandate and achieve the ambitious goals. However, diverting important budget from the EU4health programme and Horizon Europe will put the funding to address other important EU health priorities at risk. The COVID-19 pandemic has demonstrated the fragility of healthcare systems, the need to invest and support health research, the urgency to work towards European clinical trials infrastructures and to have a system in place that facilitates health data sharing. These priorities cannot be put on hold due to diverted investment.

4. Live up to European citizens' expectations

The BioMed Alliance welcomes the European Commission's progress regarding HERA, however we think that additional elements need to be considered to avoid having just an instrument with limited impact. European citizens need a robust structure able to tackle pressing health issues, address unmet medical needs and enhance European coordination in health research. To ensure that HERA lives up to citizens' expectations, we must involve healthcare professionals and researchers to build on the science and knowledge that is already out there. Together with our members we are ready to provide additional input and feedback to ensure the creation of a functional policy and health instrument.

It is necessary to build on research evidence which is already available and on the invaluable lessons learned over the past 18 months to ensure we are equipped to deal with similar health crises in the years to come.

About the BioMed Alliance:

The Biomedical Alliance in Europe (BioMed Alliance) is an initiative of 36 leading European medical societies that together include more than 400,000 researchers and health professionals. Together we have advocated for robust mechanisms to better coordinate and support health research, for an increased EU budget for biomedical research and strengthen Europe's capacity to translate basic health research into new ways of delivering healthcare and new treatments for patients.