



LERU and EGHRIN Response Public Consultation on Impact Assessment for HERA

The COVID-19 pandemic unveiled significant weaknesses in the harmonization of policies and practices among the Member States of the European Union (EU) and demonstrated the need for coordinated EU-level action to respond to health emergencies, resulting from global and cross-border threats. It revealed gaps in surveillance and forecasting, foresight, including demand/supply dimensions, preparedness and response tools (including risk assessment, risk management and risk communication) and coordination of interventions. In January 2021, the European Commission (EC) published the Inception Impact Assessment on a new central element to address this challenge: a European Health Emergency Preparedness and Response Authority (HERA). The EC proposed HERA to strengthen the European Health Union with better EU preparedness and response to serious cross-border health threats (including communicable diseases, AMR, biotoxins, chemical, nuclear or environmental and climate threats), by enabling rapid availability, access and distribution of needed countermeasures. The Inception Impact Assessment on HERA aims to inform citizens and stakeholders about the Commission's plans to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities.

In response to this Impact Assessment, two pivotal advocacy, educational, and research promoting networks from European Universities - the League of European Research Universities (LERU) and the European Global Health Research Institutes Network (EGHRIN)– jointly would like to provide their views on the Commission's perceptions and understanding of the problem and possible solutions making available any relevant information they have, including on possible impacts of different options, with a special focus on the role of research, innovation and education in the support of HERA's key functions.

LERU and EGHRIN believe that to meet its objectives, as outlined in the Inception Impact Assessment, HERA should conceptually evolve from an entity focused mainly on stockpiling towards a **five-part bundled model** within which its primary stockpiling function can effectively be delivered, while strengthening other key elements of a comprehensive and timely response to health emergencies occurring in EU, or elsewhere.

Therefore, for LERU and EGHRIN it is key that the new HERA includes the following key functions:

- (1) **Stockpiling** should be the first function of HERA. To ensure its success, several strategic approaches are necessary. Promotion of **development capacity** – identifying and addressing market and regulatory challenges, or weakness (promoting public inversion boosting but also incentivizing private investments) and promotion of advanced research, innovation and development of corresponding technologies and countermeasures for cross-border threats to health are fundamental to success. This needs to be linked to **production capacity** through EU flexible and scalable manufacturing capabilities which need to be strengthened or established via training to improve skills in Member States in **biopharmaceutical sciences and**

biomanufacturing. We note that the monitoring of member country medical emergency stock piles and preparedness plans touch the realm of civil defense, which could make some of this data sensitive from the point of national security. This aspect should be considered carefully in developing the HERA.

- (2) **Policy harmonization**, with regards to the required preparedness to prevent and manage epidemics, pandemics and other health emergencies, is the second function to be pursued through stockpiling; and delivery of key tools as catalytic components of a supportive package to Member States. This is best done in close collaboration with other EU agencies as the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), besides the World Health Organization and other global agencies. A key element of a harmonized policy is the strengthening of disease surveillance that needs a unified, integrated and cross-border reach to ensure a prompt communication between Member States of any threat or hazard, thus facilitating a joint and harmonized response across the EU. This also implies building of accessible information systems available to all Member States through which information can be shared across borders. Finally, there is an opportunity to address harmonization of policy across decentralized or federal systems where difficulties exist in ensuring a coherent response. Establishing an accountability framework with clear description of responsibilities will help identify focal points, for example, for distributions of commodities and furthering targeted education and training of personnel. Therefore, accountability is a top aim of policy harmonization. Again, such information systems touch on the realm of defense and national security and appropriate measures should be taken with regard to information security.
- (3) **Monitoring of the status of preparedness** as recommended within the 2005 International Health Regulations (IHR) of which EU Members States are co-signatories is a third crucial function that is clearly needed as revealed by the COVID-19 pandemic. Each Member State is required to adhere to international standards of preparedness such as those described by the IHR. Therefore, a condition to benefit from stockpiling should include compliance with the established recommendations for annual self-assessment and for regular external evaluations that agencies such as HERA and ECDC could jointly conduct. Close links with public health institute networks are also highly recommended in this context.
- (4) **Horizon scanning** to detect cross-border threats and hazards much earlier than what is possible today is a fourth essential function of the bundled approach. In an ideal situation, a well-structured system of early warning and forecast capacity will dramatically limit human suffering, social disruption and economic damage. While well-established, existing surveillance systems as implemented today must be further strengthened, research and innovations are fundamental areas for rapid support and expansion towards better forecasting. New technologies for health and medical countermeasures, such as artificial intelligence (AI) and high-performance computing, digital tools, big data, market intelligence, and foresight are crucial components of precision global health interventions capable of limiting the impact of health emergencies worldwide. Likewise, projects aiming at increasing our understanding of diversity and ecology of



viral threats (including vector borne diseases) and the drivers of their emergence, will help mitigate disease emergence and damage and project the EU on the forefront of detecting emerging threats. HERA can facilitate research in all these fronts as well as coordinate and manage relations and knowledge sharing among relevant EU agencies, national governmental authorities, and the key non-state sector stakeholders such as industry and academia. Universities are well placed to deliver state of the art knowledge regarding threats both of human and non-human origin.

- (5) Finally, the bundled approach is completed through its final element that spans across the other functions: **education and training**. Capacity building needs to be expanded through competent EU academic institutions that can start educational programs in all aspects of preparedness for international threats. Prestigious EU academic institutions and other research institutes competent in a variety of different disciplines, as required by a complex interdisciplinary public health problem such as that of health emergencies, can support HERA objectives by strengthening their capacity and build new skills that are important to ensure students, professionals and any relevant individual can receive the education necessary for sound preparedness and response planning and implementation. Through the Erasmus+ Program knowledge, skills, and experiences can be exchanged and thus harmonizing and enriching the way preparedness strategies can be developed and applied. A clear accountability system, which is an aim of policy harmonization, where responsibilities are described in detail will help identify key personnel to be trained and needs for training. Education can focus, among the various fields, on augmenting surveillance and preparedness monitoring skills, on pursuing better policies that are both effective and cost-effective, on improving biopharmaceutical development and production, on developing and utilizing advanced tools for horizon scanning, and on studying emerging health threats.

A crucial point will be to pursue **international partnerships with non-EU countries** and entities which may be critical for timely communication and containment of threats before they reach the EU borders. This may require a well-structured global cooperation.

Through this 5-prong, bundled approach, HERA will become a lighthouse in the EU and worldwide driving the response to emerging threats, supporting key research, ensuring surveillance and preparedness monitoring, facilitating establishment of new cadres of multi-disciplinary experts, and providing proper, high-quality tools to its Member States. This should be accompanied by a global health approach, including health security, to create a more just and equal world so that in the future, the world will have the tools and architecture in place to respond to pandemics.

Additional considerations with regard to the 5-part bundled model.

If the focus on HERA is to encompass both natural cross border threats as well as man-made issues such as chemical, biological, radiological and nuclear (CBRN) threats, great care must be taken to coordinate not only with regular research universities but also with research institutes with a specific orientation



towards defense. In Sweden, for example, much of the CBRN research is in fact conducted by the Swedish Defense Research Agency (<https://www.foi.se/en/foi/research/cbrn-issues.html>). For the EU members that are also NATO countries, there is the *Combined Joint Chemical, Biological, Radiological and Nuclear Defence Task Force* (https://www.nato.int/cps/en/natohq/topics_49156.htm) with tasks clearly overlapping with those envisioned for the HERA. The issues around coordination of CBRN threats with the defense agencies of member countries may turn out to be very sensitive and legally complicated. Again, clear divisions of responsibility must be made for the right expertise from academia to be utilized by the right organization. Because the HERA will likely work with handling highly sensitive information, there needs to be:

- a proper vetting/security clearance of experts from academia. This must be set up correctly from the start, so it will not hamper the acquisition of top expertise in times of urgency by adding too many bureaucratic hurdles.
- An excellent awareness of those entities involved in such technological foresight on dual use export control issues.

Governance options

The EC has presented five different policy scenarios for the HERA governance model (pages 6 and 7) which range from no action to a fully end-to-end authority and streamlining EU level initiatives on medical countermeasures for serious cross-border threats to health. The European Commission considers establishing HERA as an agency that is comparable to the U.S. Biomedical Advanced Research and Development Authority (BARDA). In the 2020 State of the Union address, President von der Leyen called on Europe to draw lessons from the current crisis and build a European Health Union, including a 'European BARDA – an agency for biomedical advanced research and development' to support capacity and readiness to respond to cross-border threats and emergencies – whether of natural or deliberate origin.

LERU and EGHRIN welcome the suggestion to model HERA to the example of the US BARDA, which has demonstrated that investments in health preparedness are key in enabling and accelerating the development of new countermeasures and surge manufacturing capacities when needed. BARDA has served as a key player helping to create a robust and dynamic pipeline of medical countermeasures through advanced research and development. This latter objective has gradually become an essential contributor to BARDA's successes¹. In fact, over the years BARDA has developed a fully integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for several health emergencies, including bioterrorist attacks, pandemic influenza, and other emerging infectious diseases, such as COVID-19.

LERU and EGHRIN therefore suggest that HERA should be established as a full end-to-end Authority & streamlining of EU level initiatives on medical countermeasures for serious cross-border threats to health (option 3). In this way, HERA can be most effective in delivering a bundled response and creating



synergies and complementarity with existing EU bodies, programs and instruments such Horizon Europe, European Partnership for EU-Africa Global Health (previously EDCTP), the European Partnership for Innovative Health (previously IMI), European Innovation Centre, the European Defense Fund etc.

Such model should also foster Member States’ existing preparedness capabilities and governing bodies, ensuring adequate coordination and homogeneous tools and interventions among them. Moreover, HERA should avoid duplication, and hence not become a research, innovation and education entity by itself, but use the top players and networks in Europe. Models on how to best implement robust and effective interactions and cooperation efforts with research, innovation and training and education players need to be discussed, including commissioning and funding schemes. Finally, HERA will need to be closely coordinated at the global level, promoting multilateral partnerships and collaborations with key stakeholders, including low and middle income countries (LMICs).

It is clear that research universities can significantly contribute to several of HERA’s goals. We anticipate that most of the EU’s major research universities will want to play an active role in setting up such an organization and by contributing in depth, innovation and academic leadership, but to draw the right expertise from academia into the correct organization, it is critical that the task distribution among the agencies is made clearer in the future. The Table below provides an non-exhaustive overview of possible contributions from research-intensive universities other research and public health institutes to HERA:

MAIN Items	Research & Innovation	Training & Education	Other
Governance	<ul style="list-style-type: none"> Participation of research-intensive universities and other research institutes in the Governing Board, as well as the private sector 		
Technical Functions: 1- Stockpiling 2 - Policy harmonization 3. Preparedness monitoring 4 -Horizon scanning 5- Education and training - -	<ul style="list-style-type: none"> Biopharmacological research Innovations in surveillance and research on advanced forecasting tools Risk/Benefit assessment methods of outbreak surveillance and monitoring of interventions 	<ul style="list-style-type: none"> Master & postgraduate courses on global health (including field epidemiology, pharmaco- and clinical epidemiology) Courses on preparedness for health emergencies 	<ul style="list-style-type: none"> Strengthening and coordinated outbreak surveillance systems and benefit/risk monitoring systems for (pharmaceutical/vaccine related) interventions



	<ul style="list-style-type: none"> • AI, Big Data, Digital technology advances, Distributed Healthcare database networks and frameworks • Virome project • Operational research to pilot interventions • Research into countermeasures 	<ul style="list-style-type: none"> • Summer and short courses • PhD programs • Erasmus+ Program <p>Public health training programs for agencies.</p>	
Links with other agencies/private sector	LERU and EGHRIN as networks of prestigious academic institutions and other research institutes can facilitate links with stakeholders for both research and training		
International Cooperation	EGHRIN, thanks to its global health perspective, can facilitate links with non-EU countries, including LMICs, for multiple purposes		

About LERU and EGHRIN

The League of European Research Universities (LERU) is a prominent advocate for the promotion of basic research at European research universities. Their 23 members bring together representatives to work on LERU policy development and engage in mutual learning in many areas. LERU maintains a dialogue and cooperates with the EU institutions and EU-related organisations active in the higher education and research arena on topics such as the European Research Area, Open Science, Horizon 2020, FP9 and Erasmus+. They do this through direct communication and discussions within the policy community, sound proposals for improvement and progress, and carefully considered publications on fundamental issues affecting Europe’s research universities.

The European Global Health Research Institutes Network (EGHRIN) has been established as a new network of leading research institutions in Europe precisely to promote and advocate for the EU and its research institutes to step up and become the world leader Global Health research and innovation. To date, EGHRIN currently unites/encompasses 21 European Global Health Institutes that wish to align



their efforts. While each institute will keep its own research agenda, through EGHRIN we will foster collaboration with the aim to achieve more impact in the field of global health.

LERU and EGHRIN collaborate in the area of health with the intent to jointly facilitate and strengthen equitable collaboration among the network's institutes and their global partners on high quality research to achieve improvements in health systems. LERU and EGHRIN are especially committed to helping shape the achievement of the UN Sustainable Development Goals (SDGs), specifically SDG 3 to ensure healthy lives and promote well-being.

Contact and information

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ⁱ Eichberg MJ. Public funding of clinical-stage antibiotic development in the United States and European Union. *Health Secur.* 2015;13(3):156-165. doi:10.1089/hs.2014.0081/<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486734/> Eichberg et al. provide a comparison between BARDA and IMI programs with regards to the development of novel antimicrobials. They observe that in contrast to BARDA, the IMI instrument imposes severe restrictions on any EU funding spent outside of Europe, as well as requiring EFPIA membership to participate. This limits access to development projects, as well as to antibiotic projects that may have all or substantially all development components conducted on other continents.