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Published Online  
May 24, 2021  
[https://doi.org/10.1016/S0140-6736\(21\)01019-9](https://doi.org/10.1016/S0140-6736(21)01019-9)

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## HERA: a new era for health emergency preparedness in Europe?



Published Online  
May 17, 2021  
[https://doi.org/10.1016/S0140-6736\(21\)01107-7](https://doi.org/10.1016/S0140-6736(21)01107-7)

After the first wave of COVID-19 in Europe, the European Commission (EC) committed to take bold actions in preventing and managing similar threats in the future.<sup>1</sup> The EC recognised that there was a lack of capability in the EU regarding the demand-to-supply dimension of devices, commodities, and products essential for preparedness and response. Consequently, the EC proposed to create a new agency devoted to well organised stockpiling of preparedness and response tools as countermeasures: the European Health Emergency Preparedness and Response Authority (HERA). Public consultation was open until May 12, 2021, and the exact remit of HERA will be set out in a legislative proposal later in 2021.

We believe HERA should embrace the global dimension of health threats and the three main components of preparedness (ie, risk assessment, risk management, and risk communication), in close collaboration with other existing

For more on HERA see [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-_en)

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**Panel: A five-prong bundled model for health emergency preparedness**

- Technological innovation and rapid response to market and regulatory challenges
- Harmonisation of policy development and adaptable policy implementation at national and sub-national levels
- Monitoring, preparedness and response mechanisms
- Horizon scanning to adequately detect cross-border threats and hazards in Europe or elsewhere and to monitor and evaluate new countermeasure products, devices, and technologies
- Education and training with the contribution of academic and public health institutions offering cross-disciplinary didactic plans

EU agencies (eg, the European Centre for Disease Prevention and Control [ECDC] and the European Medicines Agency [EMA]) and relevant non-EU agencies (eg, WHO), in a five-prong bundled model (panel). HERA, through effective stockpiling, could incentivise a more coherent response to emergencies and simultaneously strengthen all key elements of a comprehensive and timely response to health emergencies in the EU and elsewhere.

First, HERA must support technological innovations and rapid response to market and regulatory challenges, starting with stockpiling and distribution mechanisms of key response countermeasures (eg, protective equipment, medical devices, reagents, medicines, vaccines) and protocols. This response will require a stimulation of technologies and identification of solutions to overcome market and regulatory challenges for existing or new products. Essential to this response is facilitating equitable global access by removing or addressing existing barriers and promoting transparency in the procurement and costs of these products. A strong market intelligence focus is needed to monitor available stocks of countermeasures and to ensure that market blockages for needed supplies are detected and addressed where necessary. As stockpiling and emergency preparedness data are sensitive, interlinkages with civil defence bodies will be necessary.

Second, HERA could bring member states together to pursue common and homogeneous ways for flexible policy formulation and adaptable implementation at national and sub-national level in close collaboration with other EU (eg, ECDC and EMA) and non-EU entities (WHO, Africa Centres for Disease Control and Prevention [CDC] and US CDC) that are crucial in the international pandemic response. This harmonisation of policy development should include coordinated stockpiling rules, development of joint operational procedures, and essential item lists for an effective EU and global response. Harmonisation of policies across decentralised or federal systems where difficulties exist in ensuring a coherent response can thus be addressed. Emphasis is also needed in developing and implementing consistent tools for timely adaptive risk communication to the general public on risks and mitigation strategies to prevent undermining of shared policy frameworks. Establishing an accountability framework with a clear description of responsibilities will help identify focal points—eg, for distributions of commodities and furthering targeted education and training of personnel.

Third, monitoring, preparedness, and response mechanisms should be regularly tested to allow an early and bold response. Weaknesses should be identified with preparedness assessment tools. Adherence to established WHO recommendations for 2005 International Health Regulations self-assessment and regular external evaluation and the United Nations Office for Disaster Risk Reduction's Sendai Framework for Disaster Risk Reduction 2015–2030, coordinated jointly by agencies such as HERA and ECDC, should become a condition to benefit from stockpiling.

Fourth, horizon scanning activities will require strengthening and establishment of a robust and accessible joint EU and WHO surveillance system, managed by ECDC, with the capacity

to identify cross-border threats early, and a monitoring framework in collaboration with EMA to gain knowledge and assess countermeasure products, devices, and technologies under development worldwide in a timely fashion. Both surveillance and monitoring require backing by strong political commitment and engagement with other EU agencies like ECDC and EMA, as well as global initiatives for pandemic preparedness and WHO.<sup>2,3</sup> Use of data science and digital technology (eg, artificial intelligence) is important to predict future scenarios for risk mitigation. Technologically advanced horizon scanning tools would promote a more precise global health response.<sup>4</sup>

Fifth, building fresh and specific competence for health and non-health personnel across the EU through education and training is fundamental. Training activities should focus on augmented surveillance and preparedness monitoring, pursuing cost-effective policies, improving biopharmaceutical development and production, developing and using advanced tools for horizon scanning, and studying emerging health threats. Through the Erasmus+ programme, for example, knowledge, skills, and experiences can be exchanged, thereby harmonising and enriching the way preparedness strategies are developed and applied. European universities and research institutions have much to offer through programmes of strategically important research, platforms for specialised technical knowledge, and additional know-how on risk and mitigation strategies, as well as education and training opportunities for future experts (eg, in biomanufacturing capacities). Multidisciplinarity, interdisciplinarity, and transdisciplinarity will be vital to solve complex public health emergencies of the future.

Finally, the bundled approach cannot be accomplished without two additional cross-cutting elements: promoting research and innovation for a preparedness agenda; and fostering

For more on the **International Health Regulations** see [https://www.who.int/health-topics/international-health-regulations#tab=tab\\_1](https://www.who.int/health-topics/international-health-regulations#tab=tab_1)

For the **Sendai Framework** see <https://www.undrr.org/implementing-sendai-framework/what-sendai-framework>

international partnerships with non-EU countries, including low-income and middle-income countries, and stakeholders who are critical for timely communication and containment of global threats. These partnerships require a new vision for a well structured bilateral and multilateral cooperation with all regions worldwide, starting with a closer engagement with WHO as a global supranational moderator. This approach will be equally attractive to partners outside the EU, as health threats might originate inside the EU and spread beyond its borders.

By bundling together these five components and the two cross-cutting elements, HERA can become a lighthouse in the EU and worldwide, equipping each member state for timely and effective response to emerging threats. This goal, however, cannot be achieved without a modern and sustainable global health approach that promotes a more just and equitable preparedness system. If, through HERA, the EU successfully implements an exemplary preparedness framework, the global community would enjoy efficient tools and a balanced architecture to boldly respond to future pandemics and emergencies.

The authors received no specific funding for this Correspondence. RvL is a member of the Biotech companies in Europe combating AntiMicrobial Resistance Alliance. TB reports grants from Horizon 2020, EIT Health, German Research Foundation, US National Institutes of Health, German Ministry of Education and Research, Alexander von Humboldt Foundation, Else-Kröner-Fresenius-Foundation, Wellcome Trust, Bill & Melinda Gates Foundation, KfW, UNAIDS, and WHO. All other authors declare no competing interests. FC, AP, and MR contributed equally.

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For more on US Food and Drugs Administration patient engagement see <https://www.fda.gov/patients/learn-about-fda-patient-engagement>

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