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Head of Unit  
SG.E4 Health, Education, and Culture  
Secretariat General  
European Commission  
Rue de la Loi 200  
1049 Brussels  
Belgium

February 19, 2024

Dear Ms. Gligor,

On behalf of the U.S. Chamber of Commerce, I am writing to express our views on the review of the EU Health Emergency Preparedness and Response Authority (HERA).

The Chamber is the world's largest business advocacy organization, promoting free enterprise and representing businesses of all sizes and sectors of the economy. In Europe, we work closely with our partner organizations at AmCham EU, American Chambers of Commerce in all 27 member states, and with our counterparts at BusinessEurope and other member state business organizations.

We commend the European Commission for establishing HERA as a key instrument to strengthen the EU's health emergency preparedness and response. We believe that HERA can play a vital role in addressing current and future health threats by ensuring the availability and accessibility of medical countermeasures, such as vaccines, therapeutics, diagnostics, and personal protective equipment.

We welcome the opportunity to comment on the effectiveness, efficiency, and coherence of HERA's mandate and tools, as well as its scope and objectives.

- We support further coordination and collaboration among Member States to ensure that EU citizens have consistent and equitable access to medical countermeasures, regardless of their location or income level. We urge HERA to foster a harmonized approach to the distribution, allocation, and deployment of medical countermeasures across the Single Market, in line with the principles of solidarity and subsidiarity, while maintaining open supply chains for quick and flexible production ramp-up.
- We encourage HERA to have a reliable and predictable IP framework that protects privately funded IP and enables industry to develop and commercialize medical countermeasures.



- We encourage improvement of the regulatory environment to better enable the procurement of medicines, especially for emergency situations, be it under the current or an alternative regulatory pathway. Medicines developed during emergency situations and not yet authorized may face specific challenges, including reimbursement, liability, and indemnification arrangements. The establishment of a no-fault compensation system established at the Member State level will provide the right level of protection and compensation in case of injuries. We call for more clarity and predictability for industry partners on the criteria, procedures, and timelines governing this process. We also suggest the establishment of a single point of contact within HERA to facilitate the communication and coordination with industry partners on these matters.
- HERA must also be adequately resourced to fulfill its mission. We propose that HERA leverage its budget and expertise to create a common EU strategic reserve of medical countermeasures, as well as to support the research and innovation of novel and emerging medical countermeasures. We support consolidation of demand estimations and financial resources across the EU for targeted stockpiling and development of medical countermeasures. This should be done in a way that does not impact market dynamics for existing medicines. We recommend that stockpiles be limited to emergency situations. Stockpiling should be assessed jointly by authorities and manufacturers, and the process should ensure sufficient time for companies to build and plan the stocks.
- We recommend that HERA coordinate with other EU bodies, such as the European Medicines Agency and the European Centre for Disease Prevention and Control, to identify and prioritize the most urgent and relevant medical countermeasures for the EU.
- We endorse the expansion of HERA's coordinating and facilitating roles between Member States, as well as with third countries and international organizations. We propose that HERA act as a platform for exchange of best practices, lessons learned, and data sharing among Member States and industry partners, as well as for the promotion of joint initiatives, partnerships, and agreements with third countries and international organizations, such as the World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI), to enhance global health security and resilience. We also encourage HERA to play a leading role in promoting an effective and coherent international approach to ensure immediate and unhindered sharing of pathogens and associated information.
- We recommend that any administrative requirements placed on the industry to secure medicines supply are balanced in terms of complexity and costs and aligned with market incentives to support medicines availability.



- We support measures to ensure the availability of essential medicines for EU citizens and appreciate the efforts of the European Commission and HERA to prepare for future health crises and high-priority threats such as pandemics, bioterrorism, or chemical, biological, radiological, and nuclear incidents. We agree that it is important to move now to build the necessary capacities and capabilities, and to address regulatory bottlenecks, rather than relying on presumed future industry flexibility or regulatory waivers. Any measure potentially affecting industry operations should be subject to pre-consultation and continued dialogue for lessons learned and adjustments.

Thank you for your kind consideration of our views. For additional discussion or clarification on these inputs, please contact Zach Helzer, Senior Director for Europe, at [zhelzer@uschamber.com](mailto:zhelzer@uschamber.com).

Sincerely,

Marjorie Chorlins  
SVP, Europe  
U.S. Chamber of Commerce