

European Health Union

Input on the European Commission's inception impact assessment of the European Health Emergency Preparedness and Response Authority (HERA)

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MedTech Europe agrees with and welcomes the Commission's analysis of the vulnerabilities in European health preparedness and crisis response for cross-border health threats highlighted by the COVID-19 crisis, as well as the structural weaknesses which are the underlying contributing factors to these vulnerabilities. Taking into account the experience of the medical technology sector during the COVID-19 crisis we propose the following reflections on the inception impact assessment for the European Health Emergency Preparedness and Response Authority (HERA).

In order to effectively reach the objectives of the European Health Emergency Preparedness and Response Authority, it is essential that an independent structure in the form of an agency be setup in order to ensure dedicated resources are maintained over time, as there is a genuine risk that material support for preparedness in the face of public health emergencies will decline over time otherwise. Equally important is the need to maintain focus on the mission of emergency preparedness.

The Commission noted as one of the weaknesses of the EU response regulatory hurdles faced by new technologies. This should be actively addressed to overcome regulatory hurdles in accessing the European market for innovative technologies. Many of which will be developed to overcome future public health threats. This would include a role in ensuring that derogations or emergency authorizations can be coordinated at the EU level for medical technologies needed to deploy effective countermeasures.

Ensuring continuity of care for the population who needs medical attention not directly related to the public health crisis should be a core element in any preparedness strategy. Just as it is important to minimize the impact of the root cause of any public health emergency, it is also essential to minimise the excess mortality which relates directly to the state of crisis that healthcare systems may be operating under in times of a public health emergency.

We have also experienced severe disruptions to global logistics during the COVID-19 crisis. Thus, mechanisms for the mobilisation of logistic capacity to ensure the prompt delivery and distribution of medical countermeasures across the EU should also be part of the remit of HERA.

As such we believe that the best option going forward is that of a standalone executive agency as an operational authority similar to what is proposed in option 2.1 of the impact assessment which would include the mandates and the three additional responsibilities outlined above. For the medical technology industry in particular the following areas of activity and responsibility remain critical:

- Establishment of mechanisms to assess cross-border health threats and identifying and deploying suitable medical countermeasures.
- Supply and demand analysis coupled with market intelligence to enable the allocation of manufacturing capacity as needed during an emergency.
- A review of the current procurement practices both in preparation of and during a public health emergency in particular a review of the joint procurement practices to ensure a more effective process that closely matches the real demands for medical countermeasures is key.
- An integrated mechanism for stockpiling and distribution of medical countermeasures.
- Support in the development of new technologies needed to address new public health emergencies.
- Implementing effective mechanisms for the rapid regulatory approval of innovative technologies developed to overcome future public health emergencies.
- Ensure public health systems continue operating for all patients, thus minimizing excess mortality.
- Enable the mobilisation of logistics capacity in times of crisis to mitigate the disruption of the distribution of medical countermeasures.

We remain committed to supporting projects like this one for the mitigation of future public health threats.