

Response to the European Health Emergency Preparedness and Response Authority Public Consultation

The Confederation of Danish Industry would like to thank the European Commission for the opportunity to comment on the initiative to establish a European Health Emergency Preparedness and Response Authority (HERA).

The COVID-19 crisis made it evident that Europe was not prepared for a public health crisis of international concern of this dimension. The severe consequences of the crisis underline that action needs to be taken at European level. The Confederation of Danish Industry believes that the establishment of HERA is a strong instrument towards better European health preparedness.

Preparedness and crisis response for serious cross-border threats to health are complex issues, and the solutions are likewise complex. It is our firm believe that these solutions should be based on European and global collaboration rooted on close public-private partnerships. In this regard, HERA could become a critical entity in the future European health preparedness.

Organisation

The current epidemic crisis has amplified that we need permanent and thought-through structures for health preparedness and response at European level. Permanent structures will facilitate a more agile and speedy process for decision-making, response, and action. For the permanent structures to be well-functioning, HERA must be an empowered EU-agency with a degree of decision-making autonomy. Agile decision-making is crucial in crisis response where timing is everything. Too much red tape and too many steps in the decision process can cause delayed response, which can have fatal consequences.

To succeed in addressing the complexity of epidemic response it is important that HERA does not become an isolated entity. HERA will not solve all aspects of the challenges we face and should focus on the general cross-border challenges. The agency must operate and integrate with all relevant stakeholders, this includes; 1) other EU-agencies, especially ECDC and EMA, 2) national authorities in Member States and third countries 3) private sector in public-private-partnerships, 4) Academia, 5) other international organisations e.g. WHO and 6) other emergency preparedness and response authorities e.g. BARDA.

It would be advantageous to establish clear lines for collaboration with these different stake holders. With reference to question 4 in the questionnaire, we would consider it due diligence to ensure increased coordination of efforts at EU-level. In this regard, the COVID-19 crisis has highlighted the benefits and importance of close public-private partnerships in the response to public health emergencies. Neither the public nor the private sector can solve this degree of crisis alone. Public-private partnerships must key in the organisation of HERA.

Furthermore, HERA must have sustainable funding at its disposal. We know from experience, e.g. with BARDA, that the operation of an emergency preparedness and

response authority is not without cost. If funding is uncertain it will put unfortunate restraints on the work of the organisation. A funding option could be pre-approved grants for immediate disposal, which are earmarked for the prompt development and production of medical countermeasures. The activation of such mechanism could be conditional to the WHO declaring a Public Health Emergency of International Concern (PHEIC).

Scope

A European HERA should supplement the existing EU-agencies ECDC and EMA. The added value of HERA is the focus on research and innovation targeted emergency preparedness. Referring to questions 4, 5 and 6 in the questionnaire specific focus-areas for HERA could be;

Research, innovation, and development of medical countermeasures should be at the core of the HERA mandate. The research should take into account all parts of the supply chain – from research and development to innovative procurement models. The work should be done in public-private partnerships with close involvement of academia.

Horizon scanning and surveillance of potential health emergencies. This work should be done in close collaboration with ECDC. ECDC should undertake the day-to-day epidemic surveillance, while HERA should focus on using the ECDC data for foresight and modelling research.

HERA should facilitate *supply management to ensure a security of supply* within the EU e.g. of personal protective equipment and medical countermeasures. HERA should facilitate a structured dialogue with the industry's stakeholders with the aim of identifying vulnerabilities in the global supply chain of critical medicines and raw materials. Furthermore, it is important to ensure a strong coordination within the EU regarding the security of supply of medical equipment and critical medicine to achieve an efficient distribution and avoid undermining of the Single Market.

To facilitate surveillance, research, supply management etc. it is important to ensure a *high-quality entry of data and information*. The data should be real-time, reliable, and comparable. The data supply should be coordinated with national authorities and all relevant stakeholders in industry and academia.

To conclude, it is the clear view of the Confederation of Danish Industry that HERA could become a critical entity in European health preparedness and response. However, to succeed HERA must operate in close interaction with all relevant stakeholders, based on close public-private partnerships, and supplied with sustainable funding sources.

The Confederation of Danish Industry is at the disposal of the Commission to elaborate on the comments made in this letter.

Kind regards,

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