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Consultation response on Inception Impact Assessment on European Health Emergency Preparedness and Response Authority

The Danish Government would like to thank the European Commission (EC) for the opportunity to comment on the HERA inception impact assessment.

We acknowledge that the outbreak of the COVID-19 pandemic has revealed vulnerabilities in European health preparedness and crisis response for serious cross-border threats to health and that action needs to be taken at EU level. In this regard, we are pleased that the Commission with the pharmaceutical strategy and the EU Health Union proposals has started the process towards possible solutions.

The current COVID-19 crisis has amplified the need for permanent structures in order to prevent and respond to threats in an agile, comprehensive and timely manner. Common strategic investments can potentially ensure better value for money and shared responsibility in today's reality with a global life science sector characterized by increasing complexity and a high innovation rate.

Therefore, HERA could become a critical entity in terms of safeguarding public health. However, a number of issues need further clarification. These include HERA's proposed tasks as well as any interfaces with existing agencies and bodies. If established, HERA will have many interfaces with existing agencies such as the EMA and the ECDC, but these interfaces are not fully mapped in the inception impact assessment. Member States have not received a detailed description of the Agency and thus there are still uncertainties with regards to overlapping tasks. First, the proposed regulations on the strengthening of the mandates of the EMA and the ECDC as well as the proposal on serious cross-border threats to health are still under discussion in the Council and the European Parliament. Secondly, the interface between other initiatives such as rescEU and the Civil Protection Mechanism are currently also lacking in transparency.

Due to these uncertainties, The Danish Government currently refrains from pointing to a particular preferred choice among the various policy options described in the inception document. However, having taken note of the proposed timeline, we would like to use this opportunity to further stress the need for a swift and timely response to address the current challenges of vaccine delivery.

We would like to highlight some observations that we deem vital for the further planning of HERA.

Interfaces
More information regarding HERA's interfaces, interactions and possible knock-on effects with other agencies need to be examined and clarified. Furthermore, interfaces with i.e. national competences, other sectors and global outreach need to be explored. However, The Danish Government notes that the new body will respect the competencies of Member States and relevant national authorities.

In this regard, it is worth mentioning the positive experiences gained through regulatory measures such as regulatory flexibilities/rolling reviews related to the authorization of pharmaceuticals, which may be translated into the pharmaceutical strategy with potential footprints in a HERA setting and collaboration with the EMA. With a reference to the acquired regulatory experiences with pharmaceuticals (conditional approval), the need for evidence generation and use thereof is accentuated. Pandemic coordination would on the other hand be well suited for such an agency, leaving e.g. EMA to concentrate on the regulatory tasks. Furthermore, HERA should also have strong ties with i.e. EDA, as well as international actors such as WHO and US BARDA.

The need for highly skilled employees, interfaces with other sectors, and global outreach
Regulatory agencies have multifaceted and highly complex mandates. Obviously, this requires recruitment and retention of highly skilled staff, in particular staff that possess STEM qualifications. In addition, an agency like HERA may also need to be part of an academic eco-system/interact with academia.

The Commission briefly mentions the interface with SME-measures. As the Commission rightly points out, we have seen small companies using break-through technologies for the benefit of public health, and we support a strengthened and increasingly sound business environment for SMEs and start-ups in order for these businesses and their indispensable knowledge to remain within the Union. This should first and foremost be done by ensuring a well-functioning Single Market with good framework conditions for all businesses. Attention to these aspects should therefore be given in strategies in areas such as industrial environment, competition, research/innovation, environment/Green Deal and education, in order to pave the way towards these valuable common goals that all support the work of the existing health agencies as well as the future one.

Public-private partnerships and mobilization of research funds
The Danish Government welcomes the fact that the Commission also points to the need for public-private partnerships and mobilization of funds in the inception impact assessment. Despite scarce knowledge on how this may translate into practice, we consider it vital that these measures are highlighted, as they will inevitably be among key drivers in the future system.

A close and thorough public-private partnership regarding vaccines would be fruitful. The partnership should include all steps from R&D, to effective clinical and regulatory mechanisms, production, fill and finish. With this in mind, it is important not to focus on a single or few technologies, but a wide range of technologies, as future threats can take many forms.

It is positive that HERA is expected to increase the incentive for the industry to invest in unmet public health needs, such as research and development of scarce medical countermeasures. However, it is important that such measures do not come at the

expense of general incentives for innovation in other parts of the industry. Any measures must be in addition to already existing incentives for manufacturers to produce innovative products and solutions so that the general market works efficiently.

On another note, we also welcome the statement from the Commission that attention will also be given to the challenges of AMR and technologically advanced products. There is no doubt that a future crisis could involve resistant bacterial infections.

Scope

Regardless of the policy options, a common EU overview of the supply of medical countermeasures overall, including in particular manufacturing and development capacities and demand and supply monitoring of raw materials, is vital to strengthen the EU's preparedness and response.

The Danish Government understands that one of the policy options may include a Union level stockpiling and thus also a distribution mechanism. Even though the scope of such potential initiatives is not yet defined, some challenges in this respect should be highlighted. On a general level, it should be noted that to alleviate some of the need for stockpiling, a mapping of the industry's ability of adapting production could also be taken into consideration, thereby decreasing the need for stockpiling products.

It is vital that an eventual stockpiling benefits all Member States and takes into account different needs. Thus the issue of which products to stockpile and the decision-making process around this need to be clarified. The interface with the rescEU stockpiling effort and the proposed regulation on the strengthening of the EMA mandate on preparedness also needs clarification. Differences in terms of treatment regimens across Member States may also add to the complexity and needs consideration.

Another key issue will be to ensure that individual Member States may receive a sufficient and timely quantity of products. In this regard, differences in distribution times between the Member States should also be considered. Finally, it is important that an eventual stockpiling at Union level will serve as a supplement to the national emergency supply in the Member States.

To conclude, it is the view of the Danish Government that HERA could become a critical entity in terms of safeguarding public health in crises where solid and timely reactions are vital for the benefit of patients and society. A number of issues need further clarification and Denmark would urge the Commission to put forward a more detailed outline of HERA's proposed tasks and interfaces with other agencies as soon as possible.

Yours sincerely,

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