



Bruxelles  
HERA.1/SS/LH

## MEETING OF THE HERA CIVIL SOCIETY FORUM

30 JUNE 2023 10:30-13:30H

### Meeting Minutes

#### 1) Opening remarks by HERA

The European Commission welcomed the participants at the Civil Society Forum (hereafter 'CSF') meeting.

#### 2) Adoption of the draft agenda

The agenda was adopted. No additional points were added under AOB.

#### 3) Updates from the working groups

##### Working group 1 – Review of HERA

Working group 1 (Review of HERA) presented an update of their preliminary answers to the three guiding questions posed by the Commission.

According to working group 1, HERA was already able to provide added value by the example of the priority list of health threats, the mapping of medical countermeasures and stockpiling activities. The working group emphasised the need to further refine and define HERA's mandate and tasks, especially regarding enhanced collaboration among EU-level institutions active in emergency response. It was further requested to provide a clearer understanding of preparedness, along with HERA's role and responsibilities in ensuring preparedness. It was highlighted that preparedness entails more than medication and protective equipment availability.

Preliminary recommendations included the demand for HERA to have a stronger autonomy as well as a strong and separate budget. It was further requested to have a holistic approach to health by addressing health in multiple dimensions. This should include a broader focus on chronic non-communicable diseases and recommendations on training and workforce distribution. Additionally, communication about HERA's activities is considered crucial but should be harmonised and address knowledge and operational gaps. The working group calls for HERA to play a more significant role as an R&D coordinator.

The working group preliminary concluded that HERA could become a comprehensive crisis hub for health and could benefit from more autonomy, transparency, funding, fast decision-making and strong cooperation mechanisms with stakeholders.

The Commission thanked working group 1 for their input and is looking forward to receiving the first draft once finalised.

### ***Discussion***

Following the presentation by the working group, the Chair emphasised the significance of defining both preparedness and the concept of a health emergency, raising the question of whether situations like medicine shortages should be considered emergencies. The Chair expressed interest in hearing the perspective of the CSF on this matter.

The Chair emphasised the roles of SANTE and HERA, clarifying that SANTE serves as the regulatory body while HERA acts as the operational tool for health emergencies. In response to a Member's request for more practical solutions (such as PPE), the Chair argued HERA's complementary role in identifying suitable MCMs while ensuring continuous supply. Members also suggested that HERA provides comprehensive technical guidance for Member States and affected workforce such as first responders. The Chair reiterated that HERA's main focus is MCMs, but it remains open to incorporating input from first responders if they identify MCM needs.

On the question of HERA's form of entity, the Chair underlined that being a separate entity creates more autonomy but may lead to unique challenges, such as diminished political influence. The Chair stressed that in crisis mode, HERA requires rapid crisis response and proximity to decision-makers.

In response to several questions on how the emergency response is initiated, the Chair highlighted that this topic will be included on the agenda of the next CSF meeting.

Members also underlined the necessity for an EU strategy on preparedness, highlighting that the responsibility for preparedness should not solely fall on HERA. They stressed the importance of a comprehensive EU strategy and how the Commission can foster collaboration among Member States. It was also stressed the need to differentiate between the EU strategy and other entities involved in this field.

Members suggested enhancing preparedness efforts for vulnerable groups in future situations. Members emphasised the need to view health emergencies within a broader context, as they are interconnected and cited the example of how underlying health issues were linked during the COVID-19 pandemic.

Members emphasised that the current pandemic focus of HERA is too limited and requested that HERA should address the MCM gap for various diseases, including mosquito born diseases that are increasingly affecting Europe. Members highlighted the importance of considering tuberculosis due to its significant contribution to AMR. The Chair clarified that HERA's scope is not solely restricted to pandemic preparedness, as it is also addressing 10 pathogens including Dengue and Zika. While tuberculosis is not viewed as a high pandemic risk in Europe, efforts are still directed towards it, such as medicines for children. The Chair underscored HERA's ongoing collaboration with Gavi, Cepi, WHO and BMFG to address other diseases.

### **Working group 3 – Training and information**

Working group 3 (training and information) is comprised of 11 organisations and aims at providing recommendations to the development of HERA's training programme and communication actions.

Working group 3 gave an update about their first two meetings. The first one to discuss the scope and working methods of the group. The second meeting took place in the morning of 30 June 2023 before the main meeting of the CSF, and activities on training and information from ECDC and EMA were presented. HERA also presented an overview of the work of the European Commission on misinformation and disinformation. The meeting aimed at providing a better understanding of the mandates of the different services, the available training offer, as well as their work on information to better define the mandate of HERA and identify the areas where HERA can bring an added value and synergies can be created. The group will continue its work throughout the summer to ensure that recommendations are ready by the end of the year, in time to be presented at the last meeting of the year.

#### **4) General update on HERA's health threats approach**

The Commission gave an update on HERA's health threats approach. The Commission conducted and concluded its first threat assessment and prioritisation exercise in 2022, resulting in the selection of three high-impact threats, notably pathogens with high pandemic potential, chemical, biological, radiological and nuclear (CBRN) threats originating from accidental or deliberate release, and health threats associated to antimicrobial resistance.

HERA plans to regularly review and update the list of priority threats to prepare against, according to epidemiological or other contextual evolution. HERA recently shared with the HERA Board a proposal to address more prominently two additional topics, namely environmental health threats and biosecurity and potential dual use/misuse of emerging technologies.

As regards environmental health threats, HERA reminded that its mandate is not to prevent the occurrence of health threats of environmental origin by addressing their root causes, e.g. climate change, but rather to mitigate their consequences on human health through appropriate MCM preparedness and response. Therefore, an assessment will be carried out to identify the types of health conditions caused or promoted by environmental factors that are relevant for HERA, i.e. which require EU coordination for MCM preparedness and response. This assessment may lead to different types of action:

- improving MCM preparedness against the direct or indirect impacts on health of acute environmental hazards (e.g. floods or heat waves)
- better take into account longer term environmental factors to inform MCM preparedness against other HERA threat priorities (e.g. vector-borne diseases)

#### ***Discussion***

The CSF Members expressed their support for the inclusion of additional threats, particularly environmental health threats and enquired how the Commission's work will materialise. There is an increasing awareness of environmental health threats within the Commission. HERA is contributing to EU initiatives on climate and health through its specific mandate on MCM, i.e. measures to mitigate the consequence of threats from environmental origin on health.

CSF Members reminded the importance to work on access to medicines. HERA works closely with EMA on the shortages of medicines with a focus on antibiotics for next winter.

CSF members asked whether HERA interacts with the EU Climate and Health Observatory, who is looking at health impacts of climate change, and highlighted the high health burden of certain climate-related non-communicable diseases, like asthma and pollen allergies. here was

a general agreement that, during the first years, HERA's work to improve development and availability of MCM should be focused on a limited set of threats, but at the same time its horizon scanning and foresight activities must remain broad as to early identify future relevant threats to health that may require a MCM response.

The Commission welcomed the information shared by Members on threats to health from environmental origin and encouraged Members to share contact details of experts in the field to be included in future discussions.

## **5) HERA's initiatives on AMR**

The Commission gave an update on HERA initiatives on AMR, which are carried under the 2017 EU action plan against AMR. HERA actions concentrate on MCMs that can contribute to not only better treatments for patients infected with multi-resistant pathogens, but also to optimise and reduce the antimicrobial consumption, and thus to prevent the emergence and spread of AMR. By promoting innovation and access to MCMs against AMR, the Commission supports the EU action plan against AMR, including EU policies on surveillance, awareness, stewardship, infection prevention and control. Furthermore, the Commission commissioned two studies to prepare its action on AMR, both publicly available. A strong priority for the Commission is the implementation of direct financial pull incentives, in form of annual revenue guarantee, market entry reward or milestone payments, in articulation with the Commission proposal to include indirect pull incentives in form of "transferable data protection vouchers" in the EU pharma legislation.

### ***Discussion***

The Members recognised the importance of the topic and expressed their support and wish for HERA becoming the pipeline coordinator for AMR. Furthermore, they enquired on the discussion with Member States, the funding, and the integration of the project with EU legislation. The Commission explained that a working group was set-up with Member States and that the requirements for the revenue guarantee are discussed. HERA highlighted that its initiative on pull incentives focuses first on improving access to recently approved antimicrobials, and is carried out in articulation with the EU legal framework, which provides additional incentives for innovation. HERA highlighted that the pharmaceutical package will take a long time before being adopted, while actions need to be taken already now.

## **6) HERA's MCM prioritisation exercise**

The Commission gave an update on the MCM prioritisation exercise. In collaboration with Member States, the Commission has developed an MCM prioritisation methodology including prioritisation criteria. It was used to draw up a list of priority critical medical countermeasures for the 2023 call for stockpiling under rescEU. Later this year, the Commission will focus on establishing a list of a limited number of priority MCMs to guide its supply chain monitoring activities, covering different MCM categories. This work will be enhanced once HERA's ATHINA tool for intelligence gathering and monitoring is in place. A prioritisation of products under development to guide HERA's R&D activities will follow. HERA will map promising technologies as well as products in development tackling preliminary identified gaps. In a final step, experts from Member States will be requested to evaluate products on the pipeline list based on prioritisation criteria. This analysis is scheduled for the end of the year.

### ***Discussion***

The Members recommended to give healthcare providers the opportunity to provide input to ATHINA. Furthermore, concerns were raised about the waste within the life-cycle of MCMs. The Commission confirmed the importance of discussing waste and referred to the workshop on stockpiling, in which the end of shelf life was discussed. Members suggested to explore implementing pull incentives for pandemic preparedness. The Commission is currently focusing on pull incentives for AMR, but HERA is in an early stage at assessing the potential value and implementation opportunities for other health threats.

Following several remarks on HERA's international relations, the topic will be presented as a separate agenda point during the next CSF meeting.

## **7) Joint Industrial Cooperation Forum (JICF)**

The Commission presented the JICF and gave an update regarding the most recent developments. The JICF has been set up by HERA together with DG GROW to support the work on preparedness and response to cross-border health threats. Its objective is to identify and, where possible, reduce congestions within and outside the EU, including market failures and supply chain dependencies that could limit the production capabilities of relevant medical countermeasures and access to their raw materials. To ensure wide representation of relevant industry and supply chain stakeholder, 19 organisations have been selected to take part in the Forum following a call for applications published on 28 March 2022. It brings together the Commission, national representatives as well as industrial organisations representing relevant supply chains including pharmaceutical, medical device, biocidal products, Personal Protective Equipment industries and animal health organisations, as well as health procurement and distribution organisations. The JICF is meeting twice a year. HERA informed the CSF members of the main outcomes of the last meeting, which took place on the 26 April 2023.

### ***Discussion***

CSF members made several comments regarding the composition of the JICF, namely the presence of non-Member State members which do not represent industry and the lack of understanding that this forum could also feature non-industry representatives. Members also mentioned that the name does not fully reflect the composition of the forum. Following CSF Members' comments, the Commission will explore possibilities for additional memberships to address current and future unforeseen gaps or new challenges.

## **8) HERA Invest**

The Commission gave an update on HERA Invest. No European private or public/private investment fund currently specialises in financially supporting the development of medical countermeasures tackling HERA priority health threats. To address this gap HERA Invest will be a EUR 100 million top-up to InvestEU from EU4Health budget. It aims at de-risking and thereby attracting additional private and public investment into innovative European companies active in pandemic preparedness and response, focussing on the three priority health threats identified by HERA. For the execution of HERA Invest, HERA partners with the European Investment Bank (EIB). On behalf of HERA, EIB can invest up to 50% of project costs by means of venture loans.

### ***Discussion***

Following one question regarding potential misuse of funding, the Commission clarified that HERA Invest aims to de-risk and thereby attract additional private and/or public funding to mitigate market failures. Potential risks of misuse are further reduced significantly as the

venture loans will need to be repaid. Further, one Member asked about a safety net for the uptake of MCMs that are not necessarily attractive to the market. In that context, the Commission explores the extent to which additional measures (pull incentives) would be necessary and effective to guarantee the uptake of MCMs considering the severity of the underlying market failure and exploring how to ensure availability and affordability of final products.

One Member enquired whether capital under HERA Invest is proportionally distributed according to HERA priority health threats. The Commission explained that strict funding allocations for each health threat are not envisaged to allow for the necessary flexibility in selecting the projects. However, this option will be explored for a potential future revision of the tool.

Members will be informed about the launch of HERA Invest in a separate email, and are invited to share information within their networks and support HERA in identifying innovative projects suitable for HERA Invest.

## **9) AOB**

No other business.

## **10) Conclusion**

The Chair concluded the meeting by thanking the Members of the Civil Society Forum for their active participation. Suggestions for topics for the next meeting can be sent to HERA via email to [HERA-CIVIL-SOCIETY-FORUM-SECRETARIAT@ec.europa.eu](mailto:HERA-CIVIL-SOCIETY-FORUM-SECRETARIAT@ec.europa.eu).

The next meeting will take place in October 2023. The final date will be communicated as soon as possible.