



Brussels, 19 December 2023
HERA.1/SG

HERA Civil Society Forum meeting

13 November 2023

Minutes

1. Opening remarks by HERA and adoption of the meeting agenda

The European Commission welcomed the participants at the Civil Society Forum (hereafter 'CSF') meeting. The agenda was adopted without changes

2. Debrief from the HERA Board

The chair went over the two HERA Board meetings that took place since the last meeting of the Civil Society Forum on 15 March 2023. On 20 July, the Board met specifically to discuss the shortages of antibiotics. On 27 and 28 September, the HERA Board held its first in-person meeting in a member state, in Ireland (Dublin). During the two-day meeting, the HERA Board discussed a number of topics, including the vaccines adapted to new COVID variants, the update to the threat prioritisation, initiatives to improve wastewater surveillance, stockpiling, and the review of HERA exercise. In addition, the HERA Board provided their views on the HERA annual work plan and the EU4Health programme. The next meeting of the HERA Board is planned for the 16 and 17 January in Brussels.

3. Final recommendations from Working Groups

Working group 1 (WG1) – Review of HERA

WG1 presented their final draft recommendations structured around three guiding questions. The first question focusing on HERA's mandate, WG1 acknowledged HERA's

added value based on the development of priority lists, mapping of Medical Countermeasures (MCMs), stockpiling, HERA Invest, and the initiation of a strategic alliance with global actors. Recommendations were made to refine HERA's mandate further. Suggestions included distinguishing between preparedness and response phases, better coordination and cooperation with institutions involved in emergency response, such as EMA and ECDC. The importance of investing in preparedness was also mentioned, as well as strengthening capabilities in monitoring and mitigating risks. WG1 members stressed the need for a strong and separate budget for HERA to effectively carry out its mission. The second question focusing on the tools at HERA's disposal to carry out its mission, WG1 argued for the need of a more holistic view of health which would go beyond medical countermeasures. The group also highlighted the need for a health threat priority list, harmonised communication, and a European strategy for health threats.

Working Group 3 (WG3) – Training

WG3 presented their final draft recommendations regarding preparedness for future pandemics with a focus on workforce training. The paper expressed worries about the readiness for the next pandemic, citing the swift and impactful nature of COVID-19. The presenter emphasised the need for a more holistic approach to workforce training, extending beyond traditional roles like nurses and general practitioners (GPs). The recurring challenges faced by the nursing profession was emphasised, noting the closure of emergency rooms due to a shortage of nurses. The importance of connecting training initiatives between nurses and GPs was stressed, as well as the inclusion of various healthcare professions in training and education initiatives.

Discussion

Members of the CSF congratulated WG1 on the document and agreed to adopt it in time for the HERA Advisory Forum on 4 December 2023.

On the WG3 paper, following comments by some participants on the limitation of the WG3 paper to nurses and GPs and a call to include a broader scope of healthcare workers, it was agreed that the commenting period for this specific paper will be prolonged, for adoption before the end of the year. Participants also discussed the need for a separate paper dealing specifically with communication with the public during emergency response.

For both papers, there will be a disclaimer stating that the views reflected are the ones of the assenting members of the CSF only. One CSF member suggested to prepare a reflection paper on priorities for the new College, which would need to be ready by April/May.

4. HERA's international relations

Upon request by the Civil Society Forum, HERA presented its ongoing collaborations with international stakeholders, including the US, Canada, Japan and South Korea. Cooperation is also ongoing with Norway, Iceland, Ukraine, Moldova and Western Balkan countries.

HERA is also working closely with organisations in the global South, particularly with Africa CDC and WHO AFRO.

Discussion

The discussion touched upon potential CSF collaboration with external entities that are interested to know more about the group (in particular Canada, WHO and CEPI). HERA funding, fund allocation, and the upcoming work plan were also topics of discussion.

5. HERA's emergency framework regulation

Upon request by the Civil Society Forum, HERA presented its emergency framework regulation. The main measures under the emergency framework regulation (EFR) were introduced: 1) Monitoring of crisis-relevant countermeasures; 2) Procurement, purchase and manufacturing of crisis-relevant MCMs; 3) Activation of EU FAB facilities; 4) Activation of emergency research and innovation plans; 5) Establishment of an inventory of crisis-relevant MCM production facilities; and 6) Activation of emergency funding.

Discussion

Clarification was provided about the funding of the EFR, as well as the activation of the Emergency Support Instrument and the support of Member States. Explanation was given on the roles and decision-making process of different institutions and organisations during a health crisis (international organisations, EU institutions, agencies etc.). The open call for experts for the Advisory Committee by DG SANTE was mentioned. On the potential inclusion of the CSF in health crisis boards, the Chair explained that the CSF can be invited to meetings of the board if questions require opinions from experts.

6. Communication on the availability of critical medicines: A toolbox towards Member States and Marketing Authorisation Holders

HERA presented the Communication on addressing shortages of medicines in the EU that the Commission adopted on 24 October. The Communication builds on ongoing work in the areas of shortages of critical medicines and puts forward a broad set of short and longer-term actions to mitigate critical shortages, including the launch of the Solidarity Mechanism for medicines, the set up of the communication tools for better supply and demand forecasting (EU Mechanism for Demand Signalling), adoption of the Reform of the Pharmaceutical Legislation and the joint Procurement for antibiotics and treatments for RSV ahead of the winter 2024-25 seasons. Structural measures include the set up of a Critical Medicine Alliance, to develop coordinated action at EU-level against shortages of medicines, and the conclusion of strategic partnerships with third countries for production/supply chains.

Discussion

Members of the CSF enquired about the Critical Medicine Alliance and information was shared about a call of interests to which they will be able to apply. More information was shared about the objective of the Alliance, which is to bring stakeholders together, identify bottlenecks and needs for regulations, etc. Clarification was also provided on the list of critical medicines to be adopted mid-December. Participants called for HERA to work on raising awareness on capacity of production, availability, and stockpiling.

7. Working group 2 - health threats

It was suggested that WG2 works on three concrete example of HERA priority threats for which a better understanding of MCM gaps and needs is required: Vector-borne diseases, Antimicrobial resistance (AMR) and Avian influenza. Vector-borne diseases being a climate-sensitive threat, are of increasing concern, making the work even more relevant. On Avian influenza, HERA is working on an overview of different MCMs and would like feedback from CSF on expectations. On AMR, the perspective of the CSF for questions on the AMR list would also be useful.

Discussion

One organisation volunteered to coordinate the work of WG2, but informed HERA that they would need to check capacity before officially accepting, also considering the short timeline to ask input from the CSF on the AMR list (early December). CSF members also enquired about the Advisory Forum health threat exercise.

8. Outlook for 2024

CSF members were invited to provide HERA with a list of topics on which they would like to produce a paper on. They were reminded of the HERA Conference taking place in Brussels on 5 December. The Chair said that the next meeting of the CSF is planned in February 2024, and that the work programme will be adopted before the end of the year and shared with the CSF members.

9. AOB

No other business.