



Brussels, 5 April 2024
HERA.1/SG

HERA Civil Society Forum meeting

19 March 2024

Minutes

1. Opening remarks by HERA and adoption of meeting agenda

The European Commission welcomed the participants to the first HERA Civil Society Forum (hereafter ‘CSF’) meeting of 2024. The agenda was adopted without changes.

2. Debrief from the HERA Board

The chair provided a debrief of the HERA Board (16-17 January), going through the key agenda items discussed during the two-day meeting. The topic of medicines shortages was discussed in the context of the Critical Medicines Alliance (CMA), an initiative bringing together Member States, the health industry, and stakeholders to target high-risk medicine shortages identified by supply chain vulnerability analysis. Member States expressed support for the CMA, although some communicated preference for HERA to focus on crisis preparedness considering the EU4Health budget cuts. Member States also vocalised support for HERA’s work on Anti-Microbial Resistance (AMR). On Stockpiling, HERA will organise a series of workshops in the first half of 2024, closely coordinating with Member States to develop a common strategic approach to stockpiling. A representative from the Centre for European Policy Studies (CEPS) presented its analysis commissioned by the Belgian Presidency on improving the health emergency response governance in the EU. This was followed by a presentation from one of the coordinators of Working Group 1 on their discussion paper on the review of HERA. Finally, there was a presentation on the clinical trial coordination mechanism that HERA is preparing with the European

Medicines Agency (EMA), DG RTD and DG SANTE, with the goal to establish an ever-warm network of clinical trials. The second day was dedicated to the Review of HERA, and the input gathered will feed into the ongoing review process. The next HERA Board meeting will take place online on 22 May 2024, followed by a physical meeting under the Hungarian presidency in September 2024.

Discussion

CSF members enquired about the timeline of the Pandemic Preparedness Plan. CSF members also enquired about the network of clinical trials. The Chair explained that the Commission is establishing a HERA Board sub-group to advise on the prioritisation of clinical trials and their funding for public health emergencies. On stockpiling, CSF members were informed that the HERA Board is working on a stockpiling strategy.

3. Critical Medicines Alliance

HERA gave a presentation on the CMA, to which many CSF members applied to be a part of. The European Commission established this mechanism after recognising the lack of initiatives on shortages of critical medicines with an industrial angle, inspired by the model of existing industrial alliances, such as the European Battery Alliance or the European Raw Materials Alliance. On 16 January, HERA published the Terms of Reference of the CMA and opened the call for expression of interest. On 16 February, the call for applications to participate in the inception of the Alliance was closed (but the Alliance is and will always remain open to new applicants). Members of the Steering Board and of the working groups will be selected among the applicants who applied before 16 February. More than 250 applications were received in this first month, 135 of which from industry representatives (companies or trade associations) and 43 from civil society organisations. Overall, 50 applications were received from non-EU organisations, and 24 Member States have applied to date. HERA explained the structure and purpose of the CMA, composed of the Critical Medicines Alliance Forum, the Steering Board, and Working Groups. A timeline on the work of the CMA was provided, specifying that the official launch of the Alliance will be on 25 April 2024. Essentially, the CMA will help identify what kind of tools we should develop at the EU-level to address the issue of medicines shortages.

Discussion

CSF members enquired about the establishment of working groups, including topics and timeline. HERA explained that the European Commission will look at the composition of the Working Groups to ensure a good inclusiveness and diversity of point of views, and topics will be public at the end of May. Topics of Working Groups include, for the moment, strengthening manufacturing capacities in the EU, and the diversification of supply, international partnerships and cooperation. Other potential topics would need to be approached with caution to not overlap with the Pharmaceutical review nor duplicate the work of the EMA and discussions happening in other fora. On the fact that not all Member States have applied, HERA explained that participation is voluntary, and that some

Member States may join the Alliance later on. On the nomination of the members of the Steering Board, HERA clarified that the choices are made by the Commission. Accountability of the work of the Alliance will be ensured via regular reporting on activities. Coordination of the work on the CMA with other relevant ongoing initiatives will be guaranteed via the presence of DG SANTE, DG GROW, COMP, INTPA, NEAR and DG TRADE, as well as the inclusion of the EMA in the Steering Board.

4. Update on the Review of HERA

HERA explained that there had been many developments in work on the Review of HERA since the last CSF meeting in November, where the discussion paper produced by Working Group 1 was adopted. The presenter recalled the context of the Review: the Commission committed to carry out an in-depth review of HERA's operations (Article 8 of Commission Decision C(2021) 6712). This assessment will include a performance analysis assessing HERA's structure and governance, the scope of its mandate, the tools and resources as well as its status. The views of the general public and stakeholders interacting with HERA are a key source of information HERA thanked the CSF members for their contribution in this process.

Discussion

As regards the timeline, HERA explained that the Public Consultation and the call for evidence ran from 27 November until 19 February 2024 and that around 90 contributions had been received. The final study report will be published . On the methods used to consult Member States, the presenter explained the use of targeted surveys and the HERA Board review workshop which took place in January. CSF members asked to be kept informed on the next steps.

5. Healthcare staff for the purpose of clinical research

In response to the discussion paper adopted by the CSF on health care training needs (prepared by Working Group 3), DG RTD gave a presentation on the importance to also consider adequately training healthcare staff for the purpose of clinical research (trials and cohorts). DG RTD presented on the role of research in pandemic preparedness and response, giving the examples of the Ebola and Zika virus epidemic, followed by the COVID-19 pandemic. EU research investment for pandemic preparedness and response is done through call topics in the annual work programmes under Horizon Europe, which also include an emergency provision. As part of the COVID-19 response, great emphasis was put on large-scale and multi-national clinical research for timely evidence generation to inform clinical patient management and public health policy. For future preparedness, "warm-based" or "always on" clinical trials networks are being established, to enable the continuous running of clinical trials that can quickly adapt in case of an emergency. A similar strategy is taken for observational (cohort) studies. Trained healthcare staff is

essential to enable the implementation of such clinical research studies. DG RTD concluded that discussions on training of healthcare professionals in the context of pandemic preparedness should therefore systematically cover training on clinical research, and emphasised the importance of well-trained clinical staff for clinical research.

Discussion

The presentation was followed by a lively debate amongst the CSF, in particular on the topic of the ‘tension’ between clinical care and clinical research, as clinicians can be torn between their role as a scientist versus their role as caretaker for their patients. For some CSF members, the existence of an ethical committee is the solution to that ‘tension’, whereas others expressed the need for enhancing the regulatory skills of practitioners. Some clarifications were provided on the concept of warm-based clinical trial network: “warm” refers to clinical trial sites continuously implementing a study protocol that can switch or adapt quickly in case of an emergency. The presenter gave the example of the REMAP-CAP trial in intensive care which focuses on patients with severe pneumonia on a continuous basis, but which could immediately include COVID-19 patients when the pandemic occurred. On funding, DG RTD explained there was an initial emphasis on clinical trials in the beginning of the COVID-19 pandemic, but that there was a specific call for cohort studies already by mid-2020 under Horizon 2020.

6. Working group 2 - health threats

HERA reminded the CSF on the context and purpose of the work of WG2: to deliver technical advice on needs for Medical Countermeasures against HERA priority threats. On AMR, the feedback provided by the CSF was delivered and taken into account in discussions with Member States for the prioritisation of candidate antibiotics. The first meeting of WG2 took place on 8 March 2024, during which it was agreed that WG2 coordinators will keep working with HERA to explore more structured ways to provide feedback, considering some challenges in terms of timing, diversity of members, and the scope of the pre-designed questions. The second part of the exercise on AMR is on pause at the moment, awaiting the updated WHO antibiotic pipeline analysis to be published soon. In the context of the work on vector-borne diseases, WG2 presented funding and gaps for neglected diseases, with a focus on the case of the Dengue, as well as Chikungunya, and Zika.

Discussion

Questions touched upon vaccination and personal protection against vector-borne diseases as some members pointed out that it was not possible to vaccinate the whole population against them. CSF members also enquired about the establishment of a collaborative platform to be used for communications among WG members: The CSF Teams channel was created a year ago, but HERA will investigate on the matter as it is currently not used

actively. The possibility of getting more coordination support from the HERA Secretariat in the activities of WG2 was also discussed.

7. HERA Civil Society Forum members on the next Commission

HERA invited CSF members to present their priorities for the next Commission. There were 8 presentations in total, from the European Federation of Allergy and Airways Diseases Patients' Association (EFA)/European Respiratory Society (ERS), The European Union of General Practitioners/Family Physicians (UEMO), The European Federation of Nurses Associations (EFN), The European Patients' Forum (EPF), The Biomedical Alliance in Europe (BioMed Alliance), The European Consumer Organisation (BEUC), The Standing Committee of European Doctors (CPME), and The Deutsche Stiftung Weltbevölkerung (DSW). EFA/ERS did a joint presentation on "Keep Breathing", a vision for EU action on lung health 2024-2029, for better prevention, respiratory care and research and patient participation in lung health. UEMO made a case for the importance of family medicine. EFN presented priorities for the nurses including investment in education, and better wages and conditions. EPF called for better involvement of patient organisations in healthcare systems and policies, and also presented the EU4Health Civil Society Alliance. BioMed Alliance emphasised the importance of operating funding for NGOs and investment in education, as well as addressing workforce shortages. BEUC called for the adoption of an ambitious health programme, including in its fight against drug shortages and the adoption of a mechanism for EU compulsory licensing. CPME presented a plea to tackle the health workforce crisis, ensure a safe digital transformation of healthcare, access to medicines, and to take action on health inequalities and the climate crisis. Finally, DSW advocated for EU policies with a global health issues perspective, including sexual and reproductive health rights in low- and middle-income countries and investments in R&D to address neglected diseases, based on a climate change and health perspective.

8. AOB

The next meeting of the CSF will be held on 8 October 2024.