



Brussels, 19 December 2023
HERA.1/KC

Meeting of the HERA Advisory Forum

4 December 2023 – 13:00-17:00

Meeting Minutes

1. Opening remarks by HERA

The European Commission welcomed the participants at the Advisory Forum meeting (hybrid format).

2. Adoption of the draft agenda

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

3. Update on recent HERA activities

- *HERA Board outcomes*

The Commission presented the outcomes of the HERA Board meetings held on 20 July in Brussels ([link to the report](#)), as well as on 27 and 28 September in Dublin ([link to the report](#)). The Advisory Forum will be requested to contribute to the follow-up actions on the health threat prioritisation exercise for the next year (see further below). The next HERA Board will take place on 16 and 17 January 2024.

- *Review of HERA*

The Commission presented an update on the review of HERA. A public consultation will run from 27 November until 19 February. Additionally, targeted consultations will take place with the surveys open for contributions until 20 December 2023. An external contractor will conduct a study to support the Commission in carrying out the review. The

Advisory Forum members are invited to contribute to both consultation activities. Next year, a workshop with the HERA Board will take place on 17 January 2024. The final study report is expected in early April. The final Communication on the findings of the assessment is foreseen for summer 2024.

- *Health Threat Prioritization – 2024 exercise*

On the health threat prioritisation exercise for 2024, the Commission provided a recap of the 2022 exercise and further development and refinement of priorities in 2023. HERA communicated that it will share with the Advisory Forum a preliminary report for comments and input in early 2024. This will feed into the 2024 Threat Prioritization Report, a draft version of which will be discussed in the next Advisory Forum meeting. Following this meeting, a wider outreach to relevant stakeholders will take place. The aim is to present the final report to the HERA Board for its adoption in June 2024. The conclusion of this exercise will then allow for the translation of results to different HERA workstreams e.g. selecting the priority medical countermeasures. HERA further highlighted that additional supporting actions, notably a call for tender to support intelligence gathering, are getting established, to support subsequent exercises, on aspects such as value for money, or cost-benefit assessments in general.

4. Communication on addressing the EU medicine shortages

The Commission presented the Communication on addressing shortages of medicines in the EU, adopted on 24 October 2023. The Communication puts forward a toolkit of short, medium and long-term measures, aimed at improving the management of critical shortages and enhancing the supply of critical medicines. Notably, the Commission announced the plan to launch the *Critical Medicines Alliance* by early 2024. The Alliance will allow national authorities, the Commission and EU agencies, as well as industry and relevant stakeholders, to discuss how to address the supply chains vulnerabilities, prevent shortages and ensure security of supply. It will focus on the targeted number of products, identified through a process of supply chain vulnerability assessment (see further below).

Discussion

During the discussion, the Advisory Forum members expressed their support for the Critical Medicines Alliance. They acknowledged the importance of strategic dialogue with industry, also on national level. Following the inquiries of the members, the Commission explained the mandate of the Alliance and its role in relation with the Joint Industrial Cooperation Forum. As for reaching the right level of involvement, it was suggested by the members to involve with stakeholders at the level of ministry of health or agency level, as well as maintain the ongoing dialogue between ministries of health, economy and science. As for the public-private partnerships, sectoral pools were mentioned as a good example. Lastly, a point was made on the issue of equitable access during the pandemic.

The Commission clarified that a lot of actions aim at open strategic autonomy, hence their EU perspective. Nevertheless, there is also a reflection on international aspects and supporting third countries. With Team Europe, over 1 billion is invested in creation of production sites in Africa.

- *Outcomes of the Joint Industrial Cooperation Forum (JICF)*

The Commission presented an update on the latest meeting of the Joint Industrial Cooperation Forum on 22 November in Brussels. The meeting was co-chaired by HERA and DG GROW. The participants had the opportunity to discuss incentives for the development of medical countermeasures, the Communication on addressing medicines shortages in the EU and JICF subgroup work on data collection.

5. Vulnerability analysis of supply chain bottlenecks

The Commission presented their plan to assess the vulnerability of supply chain bottlenecks of the critical medicines on the Union list (over-dependency on a limited number of external suppliers, limited diversification possibilities, limited production capacities, etc). Following the publication of the Staff Working Document on the “Structured dialogue on security of medicines supply” in October 2022, the first version of the Union list of critical medicines, developed by the European medicines regulatory network, will be published in mid-December 2023. As a next step, the Commission services will assess the supply chain vulnerability for a limited number of medicines included in this list. This analysis will then show where additional measures are needed to strengthen the supply chains for critical medicines.

Discussion

Following questions from the members, the Commission ensured that they will share the methodology early in advance. The Commission will also work closely with the Joint Industrial Cooperation Forum and organize a workshop with them.

6. Deliverables from the HERA Civil Society Forum (CSF)

The Commission updated the members on the latest meeting of the Civil Society Forum held on 13 November. A representative of the Civil Society Forum Working Group 1 presented the recommendation paper on the review of HERA. The paper was adopted (by written procedure) on 17 November and published on the HERA website. It will also be shared with an external contractor who is supporting HERA in the process of the HERA Review.

Discussion

The members thanked the HERA Civil Society Forum for their comprehensive paper. An opinion was shared that HERA should be independent with its legal mandate and budget. It was suggested that HERA should be a focused agency working on stockpiling and research funding. A point was also made to be careful about duplication of work with other existing structures. The HERA CSF Working Group 1 representative stressed that their paper has a reflective character.

7. Study on HERA-like structures

Following calls from previous Advisory Forum meetings, the Commission presented an update on study mapping of HERA-like structures, both in the EU and globally. The plan is to identify government bodies and organizations with similar mandate to HERA and to gather information on their mission, organization structure, embedding into the wider ecosystem, budget, and current projects of those bodies. Relevant information will be stored in a database. At this stage, the Commission selected a contractor and is in the process of signing the contract with them. The contractor might reach out to experts from the EU ministries for targeted interviews to collect information. The preliminary results of the study are expected for March 2024, and it is aimed to be finalized in May 2024.

8. AOB

No other business.

9. Conclusions – next meeting

The Commission committed to report on a regular basis to the Advisory Forum on implementation status of the actions laid out in the Communication on addressing the EU medicine shortages.

Importantly, the Critical Medicines Alliance will be launched in mid-January at the next HERA Board meeting. The Call for interest will be published at the same time and it is important for the work of the Alliance to have the support of the Member States.

The Commission will present in the next HERA Board meeting the planning of all HERA governance groups for 2024. Dates and indicative agenda items will be communicated to the Advisory Forum after that meeting.