



Brussels, 17 July 2023
HERA.1/SG

Meeting of the HERA Advisory Forum

20 June 2023 – 14:00-17:30

Meeting Minutes

1. Introductions

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. HERA's threat prioritisation exercise

The Commission provided an update on the situation and presented HERA's consideration of additional threats that may need to be prioritised, notably environmental health threats and biosecurity and potential dual use/misuse of emerging technologies. Currently, a regular assessment of the threat landscape within HERA refines the current threat categories and ensures they are up-to-date by adding new relevant elements in line with the current all-hazards approach. The proposed additional threat topics shall contribute to the existing threat categories. The Advisory Forum members were asked whether they supported the inclusion of the additional overarching topics. Moreover, ahead of the 2024 Threat Assessment exercise, the members were invited to indicate whether HERA should take into consideration potential additional topics.

Discussion

Advisory Forum members expressed their support for HERA's approach in relation to health threats. It was suggested to add different dimensions to the threat assessment including timelines, actions needed to meet the threat, and the urgency of the threat, with view on the MCMs. HERA and the Member States were invited to exchange practices and

share current frameworks (like the KCE in Belgium) and to work on this jointly. Another suggestion was to build a network of Member States working on wastewater surveillance to avoid the duplication of efforts. Following questions, the Chair reminded that the focus is not on the threat per se but on the identification of the relevant MCMs to match the threat. On this basis, HERA can prioritise its funding, ensuring the availability (funding research, innovation, production, stockpiling). The Chair further noted that HERA is already working with and funding Member States to support wastewater surveillance. Last year, 30 million euros was invested to develop their capabilities. HERA will now expand that on international level in airport hubs and is working with WHO and dedicated expert working groups on this aspect.

The Chair proposed to organise a dedicated workshop on the HERA health threat prioritisation to discuss this in detail.

4. Joint HERA Support to TB paediatric medicines

The Commission presented a potential action to improve EU access to paediatric medicines for drug-susceptible tuberculosis (TB). Child-friendly medicines for the treatment of TB are not adequately available in the EU. In many situations, physicians are forced to adapt and/or combine formulations intended for adults to treat children with TB, which may increase the risk of drug resistant TB. This is a potential threat that falls under the HERA priorities. An adequate TB treatment promotes the emergence of antimicrobial resistance. HERA therefore works in close with European Medicines Agency (EMA) on this matter. EMA carried out a survey in 2022 showing that 22 out of 28 Member States (79%) considered that there is an unmet medical need due to the lack of first-line child-friendly anti-TB medicines. Future HERA support would happen by mobilising EU4Health budget, in line with HERA's mandate to improve medical countermeasures response against antimicrobial resistance.

Discussion

During the discussion, the Advisory Forum members expressed their support for the actions taken by HERA on this topic and agreed on TB being a priority threat. Regarding additional measures to guarantee access, some members suggested that joint procurement could also be considered as a possible action. This should be further discussed at later stage. The Commission took note of the support and will continue work in this direction.

5. Joint EMA/HERA monitoring of supply and demand for a set of antibiotics in preparation for the next autumn/winter season

The purpose of this agenda point was to inform the HERA Advisory Forum of the progress of the joint EMA/HERA monitoring of supply and demand of key antibiotics. From a total of 27 marketing authorisation holders (MAHs) contacted, 16 have replied. In parallel, 20 national competent authorities have provided demand estimates. Work is ongoing to match supply forecasts with demand scenarios. In principle, most of MAHs do not foresee shortages for the next autumn/winter. Their supply forecasts are mostly based on consumption from 2022/23. Some MAHs with internal manufacturing capacity could increase their production in case of unexpected demand. However, those that purchase from contract manufacturers have little possibility to increase supply. The monitoring of supply and demand for key antibiotics will be based on voluntarily shared data from

Member States and the industry. Historical consumption data will also be used as a proxy. EMA and HERA currently prepare a report outlining the analysis and aggregated results of the analysis which will be shared with the Advisory Forum and other relevant fora.

Discussion

The Advisory Forum members were asked whether they had been in touch with their national antibiotic MAHs (or were taking additional actions to prepare for next winter). Also, whether they had national stockpiles of antibiotics. The discussion suggested that the situation varies between Member States and more work is needed. The Chair underlined the importance of the topic and invited all members to continue contributing to this exercise.

6. Strengthening knowledge and skills: best practices exchange workshops and simulation exercise

The Commission presented the actions taken on knowledge and skills, done in close cooperation with Member States and the Training Task Force under Preparedness. As mentioned in the work plan for 2023, HERA is currently developing a training and exercise strategy and program that should be fully operational in 2024. HERA is working on the identification of training needs, already existing offer and potential gaps. It is especially looking for areas and topics relating to medical countermeasures where HERA and the EU could provide an added value. HERA's governance bodies will be extensively consulted to ensure a complete and multi-sectorial view on training needs.

HERA is also encouraging the organisation of dedicated capacity building workshops that facilitate knowledge sharing and exchange on best practices between Member States on technical topics relevant to this group. A first workshop was organised together with NL on 31 May 2023. The NL representative explained the set-up of this first workshop and referred to the key messages on incentivizing EU production for critical pharmaceuticals. Following this first experience of co-organising a workshop (HERA and Member State), possible topics for future workshops could include 1. Joint procurement including on how it can be used as a tool to incentivize EU production; and 2. Data of vulnerability of supply chains.

Discussion

The Advisory Forum members were asked to indicate their interest on a follow up on past workshops and on co-organising future workshops with HERA. Overall, it was mentioned that the organisation of such workshops with Member States and HERA could bring value for Member States and promote exchange of best practices and knowledge. This is a core objective of the HERA Advisory Forum. The members were invited to suggest possible topics for future workshop to be organised later this year and to identify other services (e.g., civil protection, defense) that would benefit from training in the area of MCMs.

7. Updates on recent HERA activities

The Commission presented updates on recent HERA activities and projects in the areas of collection of supply and demand data; MCM prioritisation; on DURABLE; on wastewater; on EU FAB; the vaccines contracts state of play and the joint procurement.

Furthermore, the Commission presented updates on the steps towards adoption of the HERA work plan of 2024, the planning for HERA Invest and the organisation of the HERA 2023 Conference.

8. Updates from Advisory Forum sub-groups

On the Joint Industrial Cooperation Forum (JICF), the members were informed on the main outcomes of the meeting of 26 April 2023.

On Civil Society Forum, the Advisory Forum members were informed on the state of play of the three working groups. The first working group intends to discuss the future of HERA, particularly the in-depth review which is due for 2024. The working group 2 covers the three identified health threats: pathogens with high pandemic potential, antimicrobial resistance and CBRN threats. Lastly, and to respond to the interest in training and skills, expressed in previous meetings, the third working group is on training programme and information. The next CSF meeting will take place on 30 June 2023.

9. AOB

No other business.

10. Conclusions – next meeting

The Chair concluded the meeting with the proposal to organise the next meeting fully in person. The Advisory Forum Secretariat will send a follow up email with a request for the members to indicate their preferences and to send possible topics for this meeting.

For any further comment and question regarding the topics discussed during the meeting, the members are invited to contact HERA via email to HERA-ADVISORY-FORUM-SECRETARIAT@ec.europa.eu.

The next meeting will take place in Brussels in October 2023, depending on the majority preferences. The Advisory Forum members are also invited to block their calendars for the 2023 HERA Conference which will take place on 5 December 2023.