

Brussels, 13 April 2023 HERA.1/SG

# Meeting of the HERA Advisory Forum

21 March 2023 - 10:00-13:00

# **Meeting Minutes**

# 1. Introductions

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

# 2. Adoption of the draft agenda

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

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

The Commission presented an update on the situation. At the HERA Board meeting on 30 January 2023, Member States (MS) requested HERA, together with other EC services and EMA, to identify the planned manufacturing capacity for the EU/EEA of key antibiotics used to treat respiratory infections for the winter 2023-2024 season. This is to identify appropriate EU level action to ensure sufficient supply (e.g. reservation contracts).

#### Discussion

• Member States asked for an update on the cooperation with EMA. The Commission stressed that EMA and HERA worked on the issue of monitoring of antibiotics together. Reference was made to the recent working arrangements signed between

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HERA, SANTE and EMA to strengthen cooperation and to coordinate their work for medical countermeasures (<sup>1</sup>).

• The Commission took note that sharing of demand/supplies information by Member States' may come with some reluctance. However, it encouraged MS to share demand data reassuring that those will only be used for internal purposes ty. The up-to-date data is needed to assess whether the industry forecasts were sufficient. An alternative to consider is to make use of historical consumption data as a proxy.

### 4. Preparation of a future Pandemic Preparedness Partnership (BE READY)

ANRS MIE (Maladies Infectieuses Emérgentes - Agency of INSERM, France) introduced the project called BE READY. It is a joint project and partners include Public Health Organisations, Ministries (of Science, Education, Health, Innovation or Environment), and Research Performing Organisations. BE READY is the acronym for a Coordination and Support Action aimed at building a Horizon Europe Partnership to improve the EU's preparedness to predict, prevent and respond to emerging infectious health threats. It has an ambition to create a strategic research and innovation agenda (SRIA) in this area.

BE READY reiterated its request to Member States and Associated countries representatives to share documents on National strategies and Research Priorities in pandemic preparedness with the CSA. To be submitted to: <u>Herve.Raoul@inserm.fr</u> and <u>Laurent.Jaboeuf@inserm.fr</u>

#### Discussion

It was underlined that the partnership could be a powerful tool if it managed to better coordinate research priorities and funding between Member States and EU level, which had been challenging during the Covid-19 pandemic.

#### 5. Avian flu – feedback from Member States (actions for preparedness)

The Commission presented a short update on medical countermeasures (MCM) preparedness against a potential influenza pandemics. MCM preparedness against pandemic influenza includes specific MCM such as vaccines, diagnostics, therapeutics, as well as horizontal MCM such as personal protective equipment and medical devices for severely ill patients. The Commission presented the existing arrangements regarding influenza vaccine manufacturing and procurement: HERA has two framework contracts in place for "pandemic preparedness vaccines". Furthermore, the Commission reminded that the ongoing stockpiling initiative under REscEU includes notably antivirals and personal protective equipment relevant for pandemic influenza.

The participants were asked to update on their national MCM preparedness, and the support they expect from HERA in this area, based on a set of questions prepared ahead of the meeting.

<sup>(&</sup>lt;sup>1</sup>) <u>HERA signs agreement with ECDC and with EMA to strengthen cooperation on health emergency</u> <u>preparedness and response (europa.eu)</u>

#### Discussion

- The Commission and MS highlighted the importance to establish close collaboration between human and veterinary labs, at EU level, but also at national level. The Commission indicated that the recently launched DURABLE consortium would support the rapid characterisation of virus identified in animals or humans, and thus the rapid adaption of pandemic influenza vaccines. Some MS asked whether they could join the existing Joint Procurement Agreement (JPA) for **pandemic preparedness vaccines.** The Commission explained that the current Joint Procurement for pandemic preparedness vaccines could not be reopened, but that it is currently surveying MS' interest in an additional Joint Procurement for this type of vaccines.
- Some MS showed interested in the organisation of a JPA for pre-pandemic "zoonotic influenza vaccines". The Commission will explore whether a JPA for this type of vaccines could be organised.
- The Commission explained that the EU FAB tender was currently under evaluation and covers mRNA, protein and vector-based vaccines, thus is not suitable for influenza vaccines, which are inactivated or live-attenuated vaccines.
- Some MS also suggested to prepare for the potential need to rapidly scale-up the production also for PPEs and tests, which would require pre-contracts with diagnostics manufacturing companies. The Commission will consider such elements in the preparation of future calls and will reflect on expanding the capacity reservation.
- The Member States were invited to send their written replies to the questionnaire before the next HERA Board meeting.

#### 6. Updating on recent HERA activities

- <u>HERA Labs DURABLE</u>: It was stressed that the link between the LAB-Net network and HERA Labs was crucial. On the development of diagnostic tests, it was suggested to explore pre-contracts with diagnostics manufacturers. The Commission is working with the consortia to figure out how to scale up such actions in case of emergency. It was highlighted that there was a need to build synergies and avoid overlaps with different networks.
- <u>Update on the list of critical MCMs</u>: The Commission presented the methodology used to establish a list of priority MCMs for the stockpiling call together with MS.
- <u>Antimicrobial resistance: incentives for innovation and access to</u> <u>antimicrobials and other AMR MCMs:</u> The Commission informed on the publication of the study on "bringing AMR MCM on the market". Furthermore, the Commission shared a summary of the input received so far by AMR experts from Member States
- <u>Update on HERA stockpiles under rescEU</u>: The Commission presented the establishment of HERA's MCMs stockpiles under rescEU, as well as the ideas behind upcoming EU strategy on the stockpiling of MCMs. Some Member States expressed interest to receive more information on this initiative.
- **<u>HERA Invest</u>**: HERA organised workshops with Member States and with industry explaining the main features of HERA Invest. HERA Invest will be part of INVEST

EU and ultimately the decision on financing projects via venture loans will be taken by EIB.

- <u>**Civil Society Forum working groups:**</u> Civil Society Forum will contribute to the development of topics relevant for HERA. It will work on three main topics: the future of HERA, health threats and training programmes and information.
- **<u>HERA Conference</u>**: The Commission is preparing the second HERA conference to be organised at the end of the year (likely in December).

# 7. AOB - Update on recent and planned events

The members of the HERA Advisory Forum were asked to nominate one contact point from each MS to facilitate meeting organisation. This should be done via email to <u>HERA-ADVISORY-FORUM-SECRETARIAT@ec.europa.eu</u>. The contact point will be in charge of dispatching all practical communication related to future meetings (logistical aspects, reimbursement etc.) to the Advisory Forum members of their respective MS.

The next meeting is planned to be hold on the  $20^{th}$  of June 2023 (hybrid). Member States are encouraged to attend in person to stimulate networking. Member States are invited to propose any item for the agenda.