



Brussels, 5 December 2022

## MEETING OF THE HERA ADVISORY FORUM

**5 DECEMBER 2022**

MEETING MINUTES

**14.00-17.00**

### **1. Introductions**

HERA welcomed participants at the third Advisory Forum (hybrid format). Technical meetings with this group will take place regularly in the future.

### **2. Adoption of the draft agenda**

The agenda was adopted. The points 5c (Template/questionnaire for data collection on crisis-relevant MCM – Producers) and 5d (Template/questionnaire for data collection on crisis-relevant MCM – Member States) will be discussed together. Addition of “Discussion on HERA network” as an AOB-point.

### **3. Adoption of the Rules of Procedure (RoP) of the Advisory Forum and its subgroups**

The RoP were shared with the members mid-November. Comments were raised about the 5 calendar days deadline to send the invitation and the draft agenda. HERA will try to send the documents as early as possible. The RoP, however, are clear (“at least” 5 days).

Further, the question of 1 member = 1 vote or 1 Member State = 1 vote and the issue of the open call (*Note: resolved by clarifying it refers only to the industry representatives and the call took place in April 2022*) were raised. Besides the change of the element about the open call to clarify that the open call is only for industry and not for Member States, no further changes are foreseen to the version that was sent.

### **4. Member States best practices exchange workshops in 2023**

The mandate of the Advisory Forum also includes to facilitate not only the interaction between Member States and EC but also between Member States. The GR Ministry of Health proposed to organise a virtual workshop under the auspices of HERA with participants from EU countries on EU HERA initiatives to address COVID-19, and tools and processes to optimise stock management and forecasting for COVID-19 critical medicines and best practice exchange, which will likely take place in January 2023.

HERA is happy to facilitate exchange. Member States are highly encouraged to come up with ideas like GR.

## **5. Intelligence gathering on medical countermeasures (MCMs)**

### **a) COVID-19 Therapeutics mapping platform project (update and results)**

As a preparatory action for HERA's IT platform, a feasibility study for a mapping platform on COVID-19 therapeutics has been conducted by HERA. The study is in the handover phase and HERA will present the results in December. The contractor identified major barriers to obtain data from industry, including hesitancy to share data due to commercial confidentiality and limited overview of their own supply network.

#### **Discussion**

- The ambition and scale of the IT platform project was discussed, as it was pointed out that it will be very challenging to track the full pharmaceutical space. HERA outlined that if not possible to monitor the end-to-end supply chain, then HERA will try to optimize based on the degrees of freedom and flexibility for analysis allowed by the availability of data.
- It was brought up that data collection in crisis mode will be too late. Currently, industry is mandated to share data only in crisis mode. It should be considered to mandate actors to share data also in preparedness phase.
- Some concern was voiced that too much data will be gathered to maintain a good overview. HERA responded that it is therefore necessary to only focus on a limited number of critical MCMs, identified in the MCM prioritisation exercise.
- A comment was raised about the approach and if it is better to proceed with a step-by-step approach, going from small to bigger with small advances and not trying to address too many questions at once. HERA confirmed that this is the approach followed for the HERA MCM platform.

### **b) EMA-HERA cooperation for data collection and access**

HERA closely cooperates with EMA to align on collection of supply and demand data from industry and Member States. To address concerns about duplication in data collection, EMA and HERA agreed to (i) collect data for authorised medicines and medical devices based on a common core-template (ii) to mutually rely on defined datasets; e.g. EMA database (sharepoint) on supply and demand data from producers and national competent authorities. Technical meetings on the development of the common core template and access to existing databases are ongoing.

#### **Discussion**

Member States asked for a continued clear delineation of EMA and HERA activities, further avoiding duplication going forward.

### **c) Template/questionnaire for data collection on crisis-relevant MCM – Producers**

### **d) Template/questionnaire for collection on supply and demand data – Member States**

*(points c and d were discussed together)*

HERA currently establishes a list of high-priority medical countermeasures to be closely monitored during preparedness. The monitoring of these critical products relies on supply and demand data from established databases as well as, from producers and Member States. To collect the information, HERA develops questionnaires which will be the basis for data collection of medicinal products as well as of medical devices, in-vitro diagnostics (IVDs), personal protective equipment (PPE) from industry and Member States during preparedness and crisis mode.

HERA gave an update on all the questionnaires and provided an overview of the objective for data collection, the legal context of data collection and the processes, followed by a discussion about the questionnaires to industry and Member States. HERA received feedback from several Member States and prepared an overview with further in-depth questions. On these questions, HERA received already some feedback. Member States are kindly invited to give feedback before 16 December 2022.

## **Discussion**

- A challenge of monitoring supply and demand is that the supply chain is dynamic and may rapidly change particularly during a public health emergency. To address this concern, HERA will request information from producers and Member States on a regular basis for a short list of MCMs with high-risk of supply chain disruptions during preparedness and for crisis-relevant MCMs during a health emergency.
- Data on demand forecast, production capacities as well as, information on Member States needs for joint actions will guide HERA's support measures in response to a shortage and/or during a declared health emergency.
- The assessment of the supply chain vulnerabilities substantially relies on the timely provision of supply and demand data by producers and Member States.
- Several options were discussed how to increase producers' willingness to share data on a voluntary basis during preparedness times. One option is to provide industry with analysis/reports based on the data collected; e.g. demand forecasts that may support production capacity planning.
- Data provision by Member States plays a substantial role in increasing supply chain transparency for critical MCMs, to strengthen preparedness.

HERA will continue technical discussions on strategies/policies to increase industry's willingness to share data on supply and demand with members of the Joint Industrial Cooperation Forum (JICF) and of the HERA Advisory Forum.

### **e) Update on the list of critical medical countermeasures**

HERA is in the process of establishing a list of critical MCMs to guide different policy actions at EU level. On 5 December 2022, HERA held a workshop with Member States, civil society and industry to establish for which purposes a list should be established (e.g., stockpiling, R&D support) and what criteria should be used to prioritise MCMs. HERA will define a prioritisation methodology with Member States MCM experts, aiming for the critical MCM list to be finalised by Q1 2023.

## **6. Antimicrobial resistance: incentives for innovation and access to antimicrobials and other AMR MCM**

HERA summarised the preliminary results of the study on “bringing AMR MCM on the market” (carried out by PwC). Final results are expected by the end of the year. Based on the final results, HERA will define potential follow-up actions.

HERA concentrated in the presentation on the study’s second part, i.e. the analysis of options for HERA to support development of and access to AMR MCM. Options considered focus on pull incentives in form of “market entry rewards”, “milestone payment” and “revenue guarantee”, as these are the ones that may be implemented by HERA, notably through procurement mechanisms.

To follow-up on the recommendations provided by the study, HERA included an action in the EU4Health WP 2023 to support innovation and access to antimicrobials.

### **Discussion**

- Questions were raised, about the short-term/long-term vision of HERA towards antimicrobial resistance, and whether implementing incentives for innovation and access to antimicrobials belongs to preparedness to health emergencies.
- HERA reminded that AMR is one of its top 3 priority threat categories, as agreed with the HERA Board. HERA clarified that its initiatives on AMR MCM, including pull incentives, aims at addressing the current ongoing AMR pandemic.

## **7. Current threats: Ebola and Monkeypox (MPX), including an update on the purchases and MPX trials**

### **MPX MCMs**

#### **Purchase for Donation**

HERA purchased over 330 000 vaccines (Jynneos) to donate to participating countries. The second batch is allocated using both population and epidemiological situation, with deliveries currently taking place and scheduled to be finished in January.

#### **Joint Procurement**

HERA is organising two joint procurement procedures, one for vaccines (Jynneos/Imvanex) and one for antivirals (TPOXX/tecovirimat). The framework contract for up to 2m vaccines for 14 participating countries was signed on 17 November 2022.

### **Ebola research**

Following the start of the Ebola outbreak in Uganda in September 2022, HERA (advised by EMA) discussed the lack of an authorised vaccine for the Sudan strain with Coalition for Epidemic Preparedness Innovations (CEPI) and BARDA. HERA secured EUR 5mn from the 2023 EU4Health Work Plan to support clinical trials for such a vaccine.

## **8. AOB - Update on recent and planned events**

- **Information on the Advisory Forum subgroups recent meetings**

The Joint Industrial Cooperation Forum (JICF): Inter alia, three topics of focus: EU capacity and scale-up capabilities, including MCMs and supply chain bottlenecks; funding gaps; procurement and purchasing (including stockpiling). A working group will

be established on the topic of MCMs, tasked, amongst others, with defining what data is needed and preventing the duplication of reporting requests. The next meeting will take place in spring 2023. Members of the Advisory Forum were encouraged to nominate a representative at the JICF if not done yet and to ensure attendance and participation at the meetings of the forum.

Civil Society Forum: Second meeting (hybrid) took place on 28 November 2022. The main discussion was around the possibilities of the Civil Society Forum members' role in supporting HERA's tasks especially in the fields of communication and skills and training. The next meeting will take place in early 2023.

- **Announcement of One year of HERA conference and Vaccines 2.0 workshop**

HERA reminded the "One Year of HERA" conference on 8 December 2022 and the Workshop on Next Generation vaccines on 9 December 2022.

- **Discussion on HERA network**

HERA presented the HERA network, which will support information exchange. Letter to HERA Board members was sent (together with the request to nominate Sherpas) asking for the proposal/nomination of the "HERA like agencies/entities" in their Member States. Members of the Advisory Forum are kindly invited to give their feedback if they have not done so yet.