



Brussels, 21 May 2024  
HERA.1/KC

## Meeting of the HERA Advisory Forum

16 May 2024 – 14:00-16:30

### Meeting Minutes

#### 1. Opening remarks by HERA

The European Commission welcomed the participants of the Advisory Forum meeting (online format). The agenda was adopted. No additional points were added under AOB.

#### 2. Critical Medicines Alliance

- **Critical Medicines Alliance – key developments**

The Commission presented the state of play of the Critical Medicines Alliance. It reminded the background of the Alliance's creation and explained its structure, including the two working groups (1) WG 1 on strengthening manufacturing capacities, and (2) WG 2 on diversifying supply chains, international partnerships and cooperation. The participants received an overview of their main objectives as well as the challenges ahead. Finally, they were informed about the next steps, including the meeting of the Steering Board and the first meetings of WG 1 and WG 2.

- **Vulnerability assessment of supply chains**

The Commission presented the scope and objectives of the pilot exercise of the supply chain vulnerability assessment for critical medicines which identified six indicators. The methodology for data collection and analysis was presented, followed by the conclusions and the lessons learnt. The Commission thanked the stakeholders for their contributions.

- **Possible Critical Medicines Act – preparatory study**

The Commission presented the starting point of the study, covering the political and analytical context. This includes the Belgian non-paper on improving the security of

medicines supply in Europe, the Communication on addressing medicine shortages in the EU, the EU pharmaceutical reform and the European Commission's 2021 study on medicine shortages, which identified some reasons for these shortages.

In the current study, the aim is to assess whether our understanding of the root and systemic causes of shortages improved since the 2021 study. It will also look the necessity of new legislation in the light of existing initiatives. Then, it will explore potential policy options to reduce shortages, as well their potential impacts.

Lastly, the Commission presented the timeline and next steps. Ultimately, next year the study's output and recommendations from the Critical Medicines Alliance will be ready for consideration by the next Commission.

### **3. Common strategic approach to stockpiling**

The Commission presented the process followed for the common strategic approach on stockpiling and shared an advanced look on the approach. The three main priorities:

- a coordinated mechanism for the identification and quantification of the stockpile items based on threat assessment;
- a coordinated layered stockpiling system to meet the needs of the Member States;
- principles and best practices for cost-efficient and sustainable stockpile management and deployment.

Some key corresponding actions were also presented.

### **4. Capacity building / crisis preparedness**

The Commission presented the Technical Support Instrument (TSI) and explained how it operates. The TSI operates in a yearly cycle and supports various reforms, in the area of health – from digital to hospital sectors. It was explained that it is demand-driven and tailor-made. It can support any reform phase, from design to implementation. It is an important pillar of the EU recovery plan.

The Commission presented the yearly cycle, from application until decision. The counterparts of DG REFORM are usually Ministries of Finance. It was explained that TSI projects are usually short and intense, 18 months on average. They cover different life cycles of the reforms, with the expectation that MS will build enough capacity to continue independently. The Commission also presented the added value of multi-country (and multi-region) projects.

The Commission also explained the flagship technical support projects and presented the timeline for TSI 2025.

The Greek member of the Forum presented the support to functional modernization of public health systems in Greece. The goal was to support the functional modernization of the public health system and enhance the capability of the Ministry of Health and other

healthcare stakeholders to implement related reforms. The outcomes included improved epidemiological surveillance, and preparedness and response systems, enhanced health monitoring system and options for the reorganization of the public health system.

Lastly, the Commission presented PACE (Public Administration Cooperation Exchange), an exchange program for civil servants that lasts from 1 week to 3 months.

### ***Q&A***

The Commission responded to questions from the members of Advisory Forum about the recruitment of experts assessing the requests, explained that the scope of the exercise is prioritized at the national level and that the TSI provides technical support and experts, without transferring any budget to Member States.

## **5. Threat Prioritization Report for 2024**

The Commission explained that in 2022, HERA identified three serious cross-border health threats to guide its actions on monitoring, research and development, production, procurement and stockpiling of medical countermeasures (MCMs): agents with pandemic potential, CBRN and antimicrobial resistance (AMR). In 2023, HERA identified two additional ‘threat subtopics’ to support the existing categories: environmental health threats and emerging technologies.

The objective of 2024 Report is to update the prioritization report where necessary, considering recent epidemiological, scientific, and political developments. Therefore, the Commission is revising the three chapters of the report to assess if any fundamental changes need to be addressed:

1. the first chapter: viral families of concern / pathogens with pandemic potential + environmental health threats;
2. the second chapter: deliberate and accidental release of CBRN threats;
3. the third chapter: antimicrobial resistance.

The Commission encouraged members of the Forum to submit their comments.

### ***Discussion***

Members inquired about how the Commission intends to use this exercise. The Commission explained that it aims to support HERA’s activities, including the full cycle from enhancing MCM development to stockpiling. The follow-up on research, production and procurement will be conducted through funding programmes such as EU4Health and creating the MCM list. On the pathogens list, ECDC noted that the first chapter of the draft includes a long list of pathogens, many of them not yet present in Europe. Moreover, clarification is needed on the prioritisation related to MCM. HERA thanked for the comments, explained the methodology which led to the conclusion of the priorities in 2022, with particular focus on their serious cross-border health threat potential, as well as the link to existing MCMs, thus providing insights to HERA concerning subsequent actions. Further, it reminded that at this stage the draft report should not be publicly accessible or

referenced in other work. The Advisory Forum is planned to be re-consulted on the report ahead of the HERA Board meeting in September.

## **6. Study on Market Research and Mapping of Innovative Diagnostics and Testing Solutions**

The Commission presented the scope and results of the study, which examines the whole life cycle of diagnostics – from academic research to uptake in public health systems. The Commission gave an (1) overview of currently used gold-standard diagnostic technologies, most promising pipeline technologies, and suggested innovation policy actions; (2) overview of accessibility and availability issues, including regulatory and supply chain bottlenecks; (3) overview of key report recommendations.

Members were invited to share their feedback, which will be integrated by the contractor before publication.

## **7. Recent HERA activities**

- **Review of HERA**

The Commission presented the state of play and potential timeline of the study.

- **Overview of ongoing joint procurements**

The Commission presented an overview of ongoing joint procurements, including open and upcoming calls for tender.

- **Developing the 2025 preparedness report**

The Commission invited the Advisory Forum members to take stock on previous editions of the State of Health Preparedness Report. In view of next editions, the Members are invited to share areas of possible improvements (for example on data sharing, feedback on methodology, sharing their insights and best practices), in order to bring more value for them.

- **Updates on the HERA groups (HERA Board, JICF, CSF)**

The Commission updated the Members on the recent activity of the HERA Board, Joint Industrial Cooperation Forum and Civil Society Forum.

## **8. AOB & conclusions**

The Commission reminded the Forum on ongoing consultation activities (on the EU4Health; on the study on gap analysis on knowledge and skills on medical countermeasures) and encouraged the members to take part in targeted interviews and focus groups.

Finally, the Forum members were invited to give feedback on the operation of the Advisory Forum and ensuring efficiency of meetings in the future.