



Meeting of the HERA Board

3 May 2023

Final Summary Report

Chair: Pierre Delsaux, Head of the Health Emergency Preparedness and Response Authority (HERA)

Participants: AT, BE, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HR, HU, LT, LU, NL, PL, PT, SE, SI, SK, HERA, DG SANTE, DG GROW, DG RTD, DG ECHO, ECDC, EMA, SG, representatives of the Icelandic and Norwegian bodies relevant to public health emergencies

1. WELCOME AND ADOPTION OF THE AGENDA

Head of HERA welcomed Board representatives, including new representative of France and observer from Iceland. He also welcomed EMA, ECDC, other Commission services and observers, and introduced Laurent Muschel, Deputy Head of HERA.

Head of HERA informed the Board that next meeting will be in person, scheduled to take place in September in Ireland. Exact date will be confirmed, as the proposed date of 21-22 September is close to the High-level meeting on pandemic preparedness which will take place on 20 September in New York.

The second HERA Conference will take place in Brussels on 5 December 2023.

The draft agenda was presented and adopted without modifications.

2. UPDATE ON THE ACTIVITIES OF HERA

HERA provided an update on stockpiling, particularly on the 25-26 April Stockpile Strategy Workshop, where 23 Member States participated to identify priorities for inclusion in the stockpile strategy. A second stockpile strategy workshop with Member States, also including the Joint Industrial Cooperation Forum and the Civil Society Forum will be conducted in June at which point a first draft of the strategy will be discussed. HERA also informed the Board members about the second round of calls for proposals to establish the HERA Medical and CBRN Countermeasures stockpile under rescEU will close on the 11 May.

Some Member States expressed appreciation with the speed with which HERA is building stockpiles and developing a stockpiling strategy, but some stressed the short timeline for handing in proposals. There was generally excellent feedback about the stockpiling workshop. One Member State enquired how selection of items was made, and questioned

whether the list of items were always well suited, and in line with MS priorities. Member States asked if the 11 May deadline for call applications could be extended.

HERA stressed that a quick approach was necessary. The selection of items was done in 2022 by HERA and DG ECHO, while in 2023, the selection was done with experts from the Member States.

Conclusion: HERA will organise the second stockpile strategy workshop with a view to developing a stockpiling strategy. It will be difficult to postpone the deadline for the second round of calls for proposals, given the need to sign the grants rapidly. There is agreement on the need to further reinforce coordination and combine resources between the EU and national levels when it comes to stockpiling.

3. AVIAN FLU

HERA provided an overview of the threat of a zoonotic-origin influenza virus pandemic, which continues to be concerning, as infections of humans with avian influenza virus continue to be reported, most recently in Chile. Various Commission services and agencies are coordinating their action to better prepare the EU against this threat. MCM preparedness to avian influenza was discussed with MS at the last meeting of the HERA Advisory Forum. HERA presentation provided additional information concerning avian influenza MCM preparedness: HERA LAB (DURABLE) assessments on the efficacy of vaccines and antivirals towards circulating strains, a summary of MS answers regarding their MCM preparedness, and an update on JPA for influenza vaccines.

EMA outlined their work on updating the strain, informing the Board that there are still some administrative issues which will be resolved. **ECDC** monitors trends, and said that, while risks are currently low, we should not be complacent.

Conclusions: While there is no case of human-to-human transmission, it is necessary to remain vigilant and monitor the threats to health. HERA is taking precautionary measures on pre-pandemic vaccines that may be purchased through Joint Procurement Agreements.

4. STRENGTHENING SUPPLY CONTINUITY OF ANTIBIOTICS

HERA informed the Board that supply of antibiotics is an ongoing concern for most, if not all, EU Member States. HERA under its actions on medical countermeasures and on antimicrobial resistance is currently working on various measures to improve supply continuity for antibiotics in the short-term, so for next autumn/winter, but also in the mid to long-term. In relation to the mid- to long-term, HERA is working on antibiotic supply chain mapping and vulnerabilities analysis, antibiotics provisions in HERA's stockpiling strategies and pull incentives.

Some Member States stressed the importance of access to antibiotics, and the challenge of medicine shortages in general, agreeing that the related difficulties will continue over the next years. They praised the related work of HERA – pointing to a study on pull incentives financed by the EU. It was also mentioned that a pull incentive financed by EU funds would be most appropriate. It was highlighted that it was important to think through how Member States can access stockpiles if necessary. Since demand forecasting is difficult, it was suggested that it would be good if Commission could provide a methodology for this to help MS. One Member State shared that it has a new roadmap for medicine shortages.

Need to have a coherent approach with national and EU level. Quota measure and wholesale measures could be examined. Low price of antibiotics may have impact on production and supply. Another Member state outlined its plans for ramping up production with financial support from the government. There are plans for more centralised purchase, but have not materialised yet.

HERA assured Member States that any related mitigation measures will be taken in conjunction with MS, and with a view to improve the situation. Method for collecting demand is a pilot exercise, to see how the supply and demand matching works, and will use the lessons learned to see how to take this forward.

Conclusion: The problem of shortages will continue, and the solution is to work together. We need coordination, to understand what our needs are, what is a possible joint approach, and what are the lessons learned and good practices that can be shared among MS. For the next meeting, it is suggested to come up with concrete ideas on the way forward – looking at bottlenecks, looking at EU production, looking at incentives, and ensuring more transparency in the market. Finally, HERA will continue working on relevant pull incentives.

5. HERA WORK PLAN 2024

HERA provided an overview of the 2024 HERA Work Plan document, outlining some priority areas of work which are proposed under the six tasks: ATHINA IT system, the global wastewater surveillance, EU libraries and accelerators for vaccines and antibodies, HERA Invest, EU FAB, flexible manufacturing, strategic approach to stockpiling, training and exercises, and the international dimension of HERA. HERA explained that the document shared with Board members is a first draft which will be subject to wider consultations.

Following the presentation of the Work Plan, HERA then provided an overview of the actions proposed under the EU4Health programme for 2024.

The Head of HERA stressed that these are preliminary proposals, and that HERA is looking forward to hearing from Member States, both at this meeting and in writing. He mentioned in particular the importance of developing a vaccines hub, and the actions related to wastewater surveillance. Saying that all these priorities also have to be discussed and agreed in EU4Health and Horizon Europe programmes, he encouraged a coherent approach of MS.

A few Member States commented on EU FAB, asking whether its scope could be extended to cover therapeutics and PPE. It was stressed that more information on HERA's role in strengthening the global health architecture are welcome, as HERA has a strong role to play, not only in Europe but globally. Work on EU-financed pull incentives for antibiotics should be further stressed in the work programme, that HERA's operational and coordinative roles should be better distinguished as well as general actions from those directed to one type of threat. Aside from that, measures should be coordinated with member states to avoid double-funding and to keep the subsidiarity principle. Roles of responsibilities of HERA vis-à-vis DG SANTE and other Commission services should be better delineated. Many Member States indicated that they would provide detailed written comments.

In response to comments on EU FAB, HERA explained EU FAB is focused on vaccines, but not only for Covid-19. Therapeutics or PPEs are not included in the framework contracts. For 2024, HERA is planning to top up using the same framework contracts.

Head of HERA agreed that HERA has a strong role in its international dimension, and outlined the cooperation agreements signed with bilateral partners, and the work on the global level. He thanked MS for comments, and asked them to provide comments in written by 12 May for the EU4Health programme, and by end of May on the 2024 Work Plan.

Conclusion: Board members will provide further feedback on the EU4Health programme priorities by 12 May, and on the 2024 HERA Work Plan by 31 May 2023. The next draft, including these comments, will be shared with Board members in June.

6. OVERVIEW OF HERA GOVERNING STRUCTURES

HERA provided an overview of HERA governing structures, which have been set up in line with the HERA Decision and the accompanying Communication. HERA's governance structure ensures a continuous, close relationship with national authorities, with industry and with civil society representatives. **HERA** explained the origins, membership, and modus operandi of the main bodies - HERA Board, Advisory Forum and its sub-groups Joint Industrial Cooperation Forum and Civil Society Forum, and the Coordination Committee. In addition, **HERA** explained the work of other Ad-hoc groups and the HERA Crisis Board which is not in existence, but will be set up in case of a declared public health emergency.

The presentation was well received as it provides clarity, interactions between the committees and stakeholders that participate in more than one committee could be further optimised. In this sense, it would be good to have a list of future areas of focus for each committee, and also a list of participants in various groups – for those who have indicated that they are willing to share this information. Efforts should be redoubled to avoid duplications between EU-level structures, as well as with the national level.

Conclusions: Presentation will be uploaded on CIRCABC, and interaction and exchange of information between various organs will be improved, including with inventory of actions to be carried out and shared. Efforts will be made in avoiding duplications and to work together.

7. AOB – POINT ON UKRAINE

HERA provided an update on the response to the current measles outbreak in Ukraine. It was mentioned that HERA has regular calls with WHO Euro and UNICEF on the supply of medical countermeasures to Ukraine. In the most recent call, UNICEF explained that it had expected to supply Ukraine with 273,000 doses of MMR vaccines. These vaccines would be used to fight the current measles outbreak in Ukraine; there are also mumps cases. Other doses are provided separately to do a catch-up vaccination campaign.

However, for the 273,000 doses to fight the current outbreak, UNICEF learned recently that GSK and Merck do not have the production capacity to provide the doses, probably also not in 2024. This is quite concerning as it might exacerbate the measles outbreak in Ukraine. On 24 April, Ukraine has therefore requested these 273,000 doses of MMR

vaccines through the Union Civil Protection Mechanism. HERA asked Member States to consider whether they could donate some doses.

Conclusions: Member States will consider whether they could donate some doses to help to address the measles outbreak currently ongoing in Ukraine