EUROPEAN COMMISSION
EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

Meeting of the HERA Board

27-28 September 2023

Final Report

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

Participants: AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HR, HU, IE, LT, LV, LU, MT, NL, PL, PT, RO, SE, HERA, DG SANTE, DG GROW, DG ECHO, DG RTD, SG, ECDC, EMA, representatives of the Icelandic and Norwegian bodies relevant to public health emergencies. Industry representatives present in the first part of the agenda item 6 on 28 September: Antibiotice, Aurobindo, Biogaran, Eberth, Fidia, Fresenius, GSK, Hameln, Infectopharm, Kela Pharma, Kent-Athlone, Krka, Menarini, Navamedic, Pfizer, Reig Jofre, Roche, Sandoz, Stada, Teva, Viatris, Efpia, Medicines for Europe, AESGP.

Agreed follow up actions:
- HERA Advisory Forum will advise on the 2024 threat identification process.
- HERA Board will review the AMR-related proposal, and Member States are urged to expedite internal consultations given the limited time to use EU4Health resources.
- HERA will increase information sharing and to provide further information on the review of the wastewater directive.
- HERA will organise a workshop in early 2024 on the review of HERA.
- HERA will invite Ukraine to one of the upcoming meetings of the Board.
- HERA will prepare a discussion paper on RescEU stockpiling and to organise a dedicated meeting on this subject, to promote complementarity with national stocks.
- HERA will organize a session on HERA Invest at the next HERA Board meeting.
- HERA will carry out a study to better understand the best practices and particularities of health emergency preparedness and response structures at national level.
- EMA and HERA agreed to share related materials with the Board for feedback, aiming to consolidate and disseminate the feedback thereafter.

1. WELCOME AND ADOPTION OF THE AGENDA

The Chair extended a warm welcome to all participants. He thanked the Government of Ireland for hosting the meeting in Dublin, which marks the first in-person meeting of the HERA Board hosted by a Member State. The two-day meeting offers a unique opportunity for Board members to get to know one another and learn from each other's experience.

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The draft agenda was presented and adopted without modifications.

2. UPDATE ON THE ACTIVITIES OF HERA

Under the Item 2 of the agenda, HERA informed Board members of the state of play on a number of recent activities.

Regarding **adapted vaccines given the situation with new COVID variants**, HERA informed that even though the pandemic has ended, the mutating COVID-19 virus persists, requiring the EU's monitoring and readiness to deploy adapted vaccines. In coordination with the EMA, ECDC and vaccine manufacturers, HERA is actively monitoring the situation. Both ECDC and EMA issued guidelines on 6 September regarding the use of newly authorized adapted vaccines for upcoming seasonal campaigns. Emphasizing the critical role of vaccination in safeguarding vulnerable groups this autumn/winter, HERA ensures that Member States receive these adapted vaccines, which are more potent against prevalent virus strains. Deliveries of the adapted vaccines are underway, and Member States can access COVID-19 therapeutics under the Joint Procurement Agreement. HERA has also initiated a joint procurement for another COVID-19 mRNA vaccine, with a tender announcement expected soon. A combined COVID-19/Influenza vaccine is in early stages of development. Brief discussion on vaccines ensued, with question by one Member State on when the Moderna Joint Procurement could be concluded. Regarding the **threat prioritisation exercise**, HERA reminded the Board that in 2022 it completed its inaugural threat assessment, identifying three major threats: pathogens with pandemic potential, CBRN threats from accidental or intentional release, and health threats from antimicrobial resistance. These priorities are shaping HERA's actions. HERA is proposing to revise its strategic document to include environmental health threats, particularly those linked to climate change's impact on vector-borne diseases and AMR, as well as the dual-use/misuse of emerging technologies. This enhanced focus was endorsed by the HERA Advisory and Civil Society Forums. During the discussion, several Member States strongly supported the establishment of new priorities while warning that a large number of actors are active in that area and that clarity is required on who does what. A mapping of activities would be appreciated, especially as this threat will gain momentum over the years to come. One Member States called for enhanced collaboration with DG DEFIS when it comes to dual use technologies and CBRN, and that it is high time to develop a biosecurity strategy.

Agreed follow up action: The HERA Board agreed to direct the Advisory Forum to advise on the 2024 threat identification process.

HERA then informed about efforts to combat **antimicrobial resistance,** with the Commission and the Council having introduced comprehensive strategies encompassing legislative reforms and incentives for drug development and access. Two types of incentives were proposed: transferable data protection vouchers for the development of new antimicrobials to be granted and used under strict conditions., and procurement mechanisms for access to new and existing antimicrobials that would ensure revenues for antimicrobial marketing authorisation holders, regardless of sales volume. HERA has suggested a revenue guarantee for new antimicrobials through an EU multi-country scheme without affecting Member States' pricing powers, funded by the EU budget. HERA plans to engage in service contracts with antibiotic producers to ensure swift product availability in participating Member States.

Agreed follow up action: The HERA Board will be asked to review the proposal, and Member States are urged to expedite internal consultations given the constrained timeframe to use EU4Health resources.

In the ensuing discussion, some Member States regretted the lack of implementation of the results from the push & pull incentive studies which was highly appreciated but questioned the proposal on use of voucher system. Other members asked for clarification on ongoing programmes, and commented on pull-incentives, mentioning that they should also focus on current shortages of antibiotics. One Board member enquired whether selected antibiotics would have to go through national procurement or JPA, which has not yet been decided due to complexities. Belgian presidency will make AMR one of the major topics of their Presidency over the next six months.

HERA also informed about multiple initiatives to improve **wastewater surveillance** efforts in Europe and globally. In 2023, HERA partnered with the Joint Research Centre, dedicating EUR 2.5 million for European projects, and launched the EU-WISH Joint Action with a EUR 15 million budget, involving 61 partners across 26 countries. Additionally, HERA is establishing a global consortium to monitor strategic locations for health threats, with an international conference scheduled in November. Aiming for a global reach, HERA is collaborating with major international stakeholders, including the Bill and Melinda Gates Foundation, Africa CDC, WHO, and others, emphasizing the importance of widespread surveillance. In the ensuing discussion, Board members expressed strong support for wastewater surveillance, with calls to strengthen activity in that area.

Agreed follow up action: HERA to increase information sharing and to provide further information on the review of the wastewater directive.

HERA then provided an update on the outcomes of the June workshop on **clinical trials in emergency**, led by EMA, which highlighted the need for a coordination mechanism at the EU level. This mechanism would align funding, maintain a readily scalable clinical trial network, and prioritize pipeline products. The Commission aims to establish a centralized body to expedite coordination and funding for clinical trials during health emergencies, ensuring a swift and evidence-based response. EMA then provided a more detailed update on the meeting on clinical trials in emergency, which showed clear requests for more coordination, need for more action on regulatory side, trying to ensure research funding can be approved quickly. One Board member suggested that it may be worthwhile having specific action plan on this issue. Better evidence is needed, as well as a more structured initiative to prioritise funding and direct it towards several specific medical countermeasures. Another speaker commented on public health and social measures – realized during pandemic how weak evidence was in evidence-based interventions and decided to establish a national competence centre to systematically improve evidence. Great interest in incentivizing and optimizing clinical trials, identifying several possible actions (quick research funding, MCM, CBRN incidents). There were also calls for a more structured initiative to harmonise work between MS and avoid misplacing resources. RTD is preparing a Horizon partnership to cover the whole spectrum from research to clinical trials, envisaging PIs and clinical trial sites to be quickly activated.

HERA then reminded the Board that the Commission is set to review HERA's operations by 2025, evaluating its effectiveness in enhancing the EU's health emergency readiness and response. This **review of HERA** will also assess HERA's alignment with other EU

bodies. An external contractor has been selected to gather data and feedback from stakeholders, and the input of the HERA Board will be crucial in this exercise. Several Board members took the floor to request a dedicated discussion on the subject. The issue on the table is the mandate, the role of HERA as well as funding, which merits a strategic reflection. A member stressed the need to take this opportunity to look strategically not only at HERA, but more broadly at health systems, surge capacities, training for doctors, etc. Another member said that HERA's mandate should remain focused on crises and medical countermeasures. ECDC reminded that HERA have been invited to participate in assessments of Member States prevention, preparedness and response planning undertaken under Article 8 of SCBTH

Agreed follow up action: HERA will organise a workshop in early 2024 on the review. Going beyond the mandate of HERA, the workshop should define the MS vision for the role of the EU in pandemic preparedness.

Having been briefed on **HERA's cooperation with third countries**, the Board took note of the ongoing activities between HERA and third countries including US, Japan, Korea, but also India and neighbouring countries.

Agreed follow up action: HERA will invite Ukraine to one of the upcoming meetings of the Board.

The HERA Board also took note of the **capacity-building and training** activities which are planned until the end of 2024.

3. STOCKPILING

HERA is actively working to establish the rescEU medical stockpile and formulate a stockpiling strategy. Four Member States which have received the grant are procuring essential items, and the evaluation process for the second call is ongoing. In the meantime, HERA is also exchanging best practices and lessons learned with third countries with experience in stockpiling. Some challenges around stockpile sustainability have emerged, including replenishment, long-term continuity, and the complications of unapproved medicine donations. To address these issues, an upcoming Communication on the availability of critical medicines will be released in October. HERA has been engaging with Member States through workshops to determine strategies around stockpiling, including shelf life, allocation, and distribution. As part of this effort, a EUR 10 million Joint Action on Stockpiling under EU4Health will be launched next year, focusing on sustainable EU stockpiling strategies. To guide these efforts, HERA seeks feedback on key priorities and how to address medicine shortages, as well as the preferred format for the stockpiling strategy.

Member States who took the floor on this item raised the topics of expiration and transportation of stockpiles, privileging European production, focusing on high-risk medical countermeasures. Some members regretted that the announced communication will no longer be adopted. More cooperation between Member States and a strategic vision is necessary. Stockpiling should be an insurance, strategic, focusing on specific geographical areas, particular strategic stocks, thinking about ways of extending shelf life. But current approach does not sometimes allow this. Several Board members stressed the need to redefine existing allocation mechanism and to prepare for replenishment needs. **Agreed follow up action:** HERA was asked to prepare a

discussion paper on RescEU stockpiling and to organise a dedicated meeting on this subject, to promote complementarity with national stocks.

4. HERA WORK PLAN 2024 AND EU4HEALTH PROGRAMME

The third draft of 2024 HERA Work Plan was presented to the Board. The document has been shaped through feedback from various consultations, including comments from the Spring meeting of the HERA Board, and interactions with Member States and stakeholders. The structure mirrors previous Work Plans, and encompasses an overview of future priorities, detailing six core tasks – improved threat assessment, multinational efforts to develop health solutions, addressing market challenges, developing a strategic EU-level stockpiling approach, implementing a comprehensive training programme, and strengthening international collaborations.

Member States who took the floor were satisfied with the document. Several questions were raised on the change in the distribution of funding between tasks between the different drafts of the document, on the vaccine strategy development, and the European stockpiling management. Suggestions were made to widen the spectrum of antibodies, in order to target not only viruses, but also bacteria. Some Board members praised HERA Invest, while other requested more information about this initiative.

Agreed follow up action: Board Members were invited to provide their comments on the work programme by Friday 6 October and it was agreed that HERA will organize a session on HERA Invest at the next HERA Board meeting.

5. DISCUSSION ON HERA-LIKE STRUCTURES IN MEMBER STATES

HERA Board was then invited to share and discuss best practices in establishing national health emergency preparedness and response structures, aiming to streamline and enhance coordination with HERA. The Chair informed the Board members that this exchange is timely, given the global health landscape and the ongoing adjustments in response to health emergencies. Participants were reminded of the provided background materials and were encouraged to reflect on their national frameworks, comparing them with HERA's approach to pinpoint areas for enhancement.

A number of Board members took the floor to share their national strategies for crisis-coordination and preparedness. In most cases, competences are split between different ministries and entities, which complicates crisis response. One member informed about their plans to create a new national structure – emerging threats agency, which is now in the process of being set up. During the discussion it became clear that Member States do not have the equivalent of HERA’s dual function structure, and that there would be added value in carrying out a mapping of existing structures in the EU.

Agreed follow up action: It was decided that HERA will carry out a study to better understand the best practices and particularities of health emergency preparedness and response structures at national level.

6. REPORT OF THE JOINT EMA/HERA EXERCISE MONITORING SUPPLY AND DEMAND OF ANTIBIOTICS

As a follow-up to its 20 July meeting, the HERA Board reconvened with industry stakeholders to discuss the winter supply and demand dynamics for a subset of antibiotics used to treat respiratory infections. The Board was informed of the results of the Joint EMA/HEA exercise monitoring supply and demand of a subset of antibiotics. During the discussion taking place in the first part, the industry urged Member States to consider the recommendations of EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), minimise national stockpiling, and simplify regulatory processes at the national level. They lauded electronic product information (ePI) pilot and sought its broader adoption among Member States. EMA highlighted the efforts of the Medicine Shortages SPOC WP and the MSSG in relation to the use of regulatory flexibilities and referred to the ongoing pilots for the use of ePI. The conversation then steered toward existing drug shortages, with some Board members emphasizing the need for strategic deliberations on the limited supply of essential medications. One Board member emphasized the need for transparency in monitoring these shortages, proposing the creation of an interoperable IT tool for the same, garnering significant support from industry representatives. In the second part of meeting, the HERA Board continued the discussion on medicine shortages in a closed session with Board members and observers only. One Board member inquired about the development status of the Product Management System (PMS) platform and potential expansion of EMVS. EMA referred to the complexity of the national IT systems and the key role of PMS in ensuring data interoperability, for which the work is ongoing. With the industry business model skewing towards higher profitability, Board members voiced concerns over Member States' reliance on industry, urging discussions on the European production of specific antibiotics. Another Board member stressed the environmental costs tied to antibiotic manufacturing. Calls for better exchange of information and knowledge, stronger incentives, and broader support beyond innovation emerged from other Board members. HERA then presented prospective actions to address these shortages in the upcoming months.

Agreed follow up action: EMA and HERA agreed to share related materials with the Board for feedback, aiming to consolidate and disseminate the feedback thereafter.