EUROPEAN COMMISSION
HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

Meeting of the HERA Board

16-17 January 2024

Draft Report

Chair: Laurent Muschel, Acting 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, IT, LT, LV, LU, MT, NL, PL, PT, RO, SE, SI, SK, HERA, DG SANTE, DG GROW, DG ECHO, DG RTD, SG, DG DEFIS, ECDC, EMA, representatives of IS, NO and UA bodies relevant to public health emergencies, representative of working group 1 of HERA Civil Society Forum, representative of CEPS.

Agreed follow-up actions:

- HERA will keep the Board updated on the progress of the Alliance.
- The list of selected critical medicines for the vulnerability analysis pilot study will be shared with the HERA Board and relevant stakeholders (done on 31 January).
- Regular briefings on the progress of the vulnerability analysis pilot will be delivered at meetings of the HERA Board, MSSG, and JICF.
- HERA will organize a series of workshops in the first half of 2024, closely coordinating with Member States to develop a common strategic approach to stockpiling (the first one took place on 30 January).
- HERA will proceed with the preparation of the tender documents required for the implementation of revenue guarantee for a first antibiotic, in collaboration with the group of experts appointed by interested Member States.
- HERA will distribute the Terms of Reference for the Coordination Mechanism for clinical trials and the prioritisation group to the HERA Board and other relevant stakeholders.
- MS will be invited to appoint representatives to the working group on prioritisation of medicinal products for clinical trials.

1. WELCOME AND ADOPTION OF THE AGENDA

The Chair welcomed all participants to the meeting and expressed gratitude to the Government of Belgium for hosting the two-day event.

In its welcoming address, Belgium informed about the upcoming events in the health sector organised by the Belgian Presidency at the Council.

The draft agenda was presented and adopted without modifications.

2. ADDRESSING MEDICINE SHORTAGES IN THE EU

The Commission (HERA) introduced the Critical Medicine Alliance to address EU medicine shortages, bringing together Member States, the health industry, and stakeholders to target high-risk medicine shortages identified by supply chain vulnerability analysis. The initiative, announced on 16 January, will be launched in April, and the first strategic report will be issued in autumn. HERA presented the methodology and criteria for the critical medicines priotisation, subject of a pilot vulnerability analysis in collaboration with DG GROW.

Member States welcomed the swift and effective setup of the Alliance, emphasizing the need for EU pharmaceutical sovereignty to boost innovation and coordination across the sector.

Several Member States warned against added reporting burdens and duplication in the vulnerability analysis. Technical suggestions were offered, and the need for a forward-looking, systematic, and dynamic approach to vulnerability analysis was emphasised.

Some Member States stressed that the work on critical medicines should not jeopardise HERA's work on crisis preparedness, especially in light of suggested budget cuts to EU4Health. Concerns were raised about the security capacity for developing new vaccines for pandemic threats or CBRN antidotes.

The importance of sharing best practices among Member States was highlighted, as well as the presence of all sectors. One Member State called for the need to develop strategic partnerships and joint procurements with third countries.

On the composition of the Alliance, two Member States called for a balanced representation of members between industry and stakeholders, emphasising the need for the Alliance to be a forum for finding solutions, working towards an effective toolbox against shortages. Other Member States emphasized the importance of clearly defining the Alliance's role in relation to existing entities and delineating its interaction with the HERA Board.

HERA outlined the international aspect of the Communication and provided an update on ongoing and planned joint procurements under the scope of the Joint Procurement Agreement.

Agreed follow up action: HERA will keep the Board informed about the progress of the Alliance. HERA will also compile the initial selection of critical medicines for the vulnerability analysis pilot (to be distributed to key stakeholders in February 2024), and provide regular briefings on the pilot's progress at HERA Board, MSSG, and JICF meetings.

3. EU STOCKPILING INITIATIVE

The Commission (HERA) detailed the next steps for the Commission's proposed strategy on medicines stockpiling, as outlined in the Communication on addressing medicine shortages in the EU, including monthly meetings and ongoing consultations with Member States until June 2024. This effort is part of the HERA 2023 Annual Workplan flagship for stockpiling of medical countermeasures.

HERA is also working on the 2024 EU4Health Work Programme's Joint Action on Stockpiling, with delivery expected in 2025, to support the strategic approach.

Member States stressed the need to focus EU stockpiling efforts on medical countermeasures with clear EU-added value to stockpile, differentiating between routinely used items and niche products, and ensuring clarity and continuity in strategy, considering also national measures already in place and avoiding competition. The need for routine medicines stockpiling was also emphasised, considering the industry's reaction time. Two Member States suggested that EU stockpiling activities concentrate on niche products and should not be used as a tool to address shortages.

At national level there might be legal obligations for wholesalers to keep contingency stocks, EU stockpiles should not aggravate possible market pressure. One Member State warned against artificial demand provoked by stockpiles suggesting focusing on production initiatives such as EU FAB or pull-incentives. Other Member States recognised stockpiling's potential for industry support, urging for specific regulations.

Questions about the relationship between HERA and rescEU's roles were raised, prompting the need for clarification on their distinct functions and the use of rescEU stockpiles within or outside EU27/EEA.

Several Member States enquired about envisaged distribution keys for EU stockpiles, underlining their sensitivity and need for further discussions.

Accountability for unused stockpiles, which can lead to public criticism upon expiration, was raised by one Member State, while others echoed concerns about managing such stocks. Two Member States urged for quantitative elements and EU guidance for national stockpiling initiatives. Another Member State emphasised investigating the potential costs of forgoing stockpiling. Overall, there was a collective call for collaboration, clarity, and transparency in EU-level stockpile administration, placing a particular emphasis on transparent access. Rotation was underscored by one Member State, mentioning a need to adapt regulations and confer a specific status to insurance stockpiles, while another emphasised prioritising prevention over stockpiling.

Agreed follow up action: HERA will organize a series of workshops in the first half of 2024, closely coordinating with Member States to develop a common strategic approach to stockpiling.

4. AMR PULL INCENTIVES

The Commission (HERA) presented the pull incentive mechanism, developed with Member States through written consultation and in the working group on 11 January. HERA's proposal involves implementing an EU revenue guarantee via a service contract with the antibiotic producers through EU4Health budget.

Some Member States congratulated HERA on the initiative, stressing the possible future need to complement it with milestone payments. Some Member States mentioned this mechanism could apply both for old molecules not attractive for the industry and to trigger innovation.

Belgium will organise a conference on AMR from 6 to 8 May under its presidency, co-organised with ECDC, which included a high-level ministerial meeting on pull and push incentives.

Agreed follow up action: HERA will proceed with the preparation of the tender documents required for the implementation of revenue guarantee for a first antibiotic, in collaboration with the group of experts appointed by interested Member States.

5. GOVERNANCE

CEPS presented its study commissioned by the BE Presidency on improving the health emergency response governance in the EU.

One participant enquired about the finding on streamlining scientific advice. CEPS explained the potential for inconsistencies due to multiple actors (HSC, committees, agencies) providing advice to decision makers.

A representative of the Civil Society Forum Working Group 1 presented the recommendation paper ([1]) on the review of HERA.

The Commission (HERA) presented the clinical trial coordination mechanism for public health emergencies, focusing on the scope and governance structure. Its main objectives are the prioritisation of medical products, funding streamline, and establishing clinical trial networks.

Member States welcomed the initiative but stressed the need to avoid duplication. Some suggested to carry out a benchmarking exercise with other important stakeholders such as the UK and US to ensure acceleration of processes within the EU to reach the market; planned work on non-pharmaceutical interventions in the event of emergency was also enquired about.

Agreed follow up action: Once finalised, HERA will share with the HERA Board and other relevant stakeholders the Terms of Reference for the Coordination Mechanism and the working group on prioritisation of medicinal products for clinical trials, and invite Member States to appoint representatives to the prioritisation group.

6. WORKSHOP ON THE REVIEW OF HERA

On the second day, HERA Board members and observers discussed in a closed meeting the future scope of work of HERA, following the presentation from the Commission (SG) on the ongoing process for the Review of HERA.

In conclusion, SG thanked the Member States for their valuable input which will feed into the ongoing review process.

([1]) HERA Civil Society Forum working group 1 discussion paper, "The future of the Health Emergency Preparedness and Response Authority (HERA)"