



## Meeting of the HERA Board

30 January 2023

### Draft Summary 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, IT, LT, LV, NL, PL, PT, RO, SE, SI, SK, HERA, DG SANTE, DG GROW, DG RTD, DG ECHO, ECDC, EMA, JRC, SG, representative of a Norwegian body relevant to public health emergencies

#### 1. WELCOME AND ADOPTION OF THE AGENDA

Head of HERA welcomed Board representatives, EMA, ECDC, and Commission services to the first meeting of the year. An overview of the planning for the next HERA Board meetings for 2023 will be shared with Board members in the coming weeks. The draft agenda was presented and adopted without modifications.

#### 2. SHORTAGE OF MEDICINES

The **European Medicines Agency (EMA)** provided an overview of relevant activities in response to the number of medicine shortages in Europe in line with the EMA's extended mandate. Initiatives include: a task force with the Heads of Medicines Agencies (HMA) for availability of authorised medicinal products, focused on development of guidance; a Medicine Shortages Single Point of Contact (SPOC) working party; and an Executive steering group on shortages and safety of medicinal products (MSSG); and the Joint Action on Shortages, a three-year plan to enhance national systems in tackling medicines shortages in a harmonised way.

As part of the EMA extended mandate, the MSSG establishes a list of critical medicines to be monitored, provides recommendations and coordinates measures to prevent or mitigate shortages.

The SPOC Working Party, responsible for monitoring and reporting events that could affect the supply of medicines in the EU, has engaged with Member States and pharmaceutical companies. In its last update, it reported that shortages of antibiotics confirmed in 28 countries (EU+NO) are due to increase due to an increased demand and production-related problems. No regulatory support was required, and in terms of short-term actions, all companies expected an increase in supply and availability of medicines by Q1 / Q2 of this year.

Looking forward, EMA indicated that they will continue engagement with industry associations, and – in coordination with HERA and DG GROW – investigate long-term measures required to ensure supply of medicines during next autumn/winter season.

**DG GROW** presented to the Board the activities to better understand the root causes of current shortages and to identify possible actions, looking mainly on the supply side and production of medicines. Discussions with and survey of related industry associations revealed that many shortages have structural causes.

Board members then presented specific measures taken locally and proposed both immediate and long-term strategies. Measures being considered include early supplies from producers, seeking supplies from unaffected countries, and extending discussions beyond antibiotics to other medications like thrombolytics. The industry's profit model differs, leading to varied challenges. One member emphasized the importance of EU-level cooperation, while another highlighted their use of basic penicillin, experiencing shortages of penicillin and amoxicillin. Proposals were made to strengthen national stockpiling, potentially supported by EU funds, enforce minimum purchase requirements, and ensure continuous monitoring and forecasting of demand. Some members provided examples of national strategies, such as dedicated shortage websites and task forces, suggesting an initial focus on national stockpiling before expanding to an EU-wide approach.

In relation to the thrombolytics shortage, the European Medicines Agency (EMA) noted that only one provider exists in Europe, but they're in dialogue with additional manufacturers abroad. The EMA agreed on the necessity of forecasting demand and underscored the importance of establishing a list of critical medicines at the EU level, a practice already adopted in several Member States.

**HERA** informed that it is working on a list of critical MCMs, under the framework of strategic stockpiling under RescEU, and stressed the need for efficient internal EC coordination. This is also where better forecasting will play a role.

**Conclusion:** HERA will work with national experts to draw a list of concrete short-term and long-term actions, focusing on critical outcomes, that need to be implemented for next winter. While it is important to address shortages of antibiotics in the short term, there is a need to have a broader outlook on all medicines. This action plan will also address the coordination with EMA, ECDC, and other EC directorates.

### **3. ANTIMICROBIAL RESISTANCE**

Under this item of the agenda, HERA provided an update on the two AMR studies, shared with the Board members prior to the meeting.

The first study entitled “stockpiling options for antimicrobials” focuses on supply chain vulnerabilities. The preliminary results were presented in the last HERA Board meeting. The report has now been published, and the Board members were informed on the follow-up actions.

The second study entitled “Bringing AMR MCM on the market” focuses on incentives for innovation and access. The study has been recently finalised, and the main results were presented to Board members. The study addressed pull and push incentives, as well as non-financial coordination of support measures. The Board was in particular informed

of the four pull incentive schemes studied. Two of these incentives were found to be efficient, one with low risk and low foreseen effect, and the other with higher risk, but also higher expected effect.

One Member State shared that pre-commercial procurement based on incentives could be useful. It was underlined that it is surprising to see that there is no study on the “value” of a new antibiotic that we are considering rewarding with incentives: it would be useful to know how big is the problem the new medicine is expected to solve. It was highlighted that this is a priority for the Swedish Presidency, and it will be discussed at the high-level AMR meeting in Stockholm on 6 and 7 March. A combination of incentives should be investigated. One member asked whether the TEEV (transferable exclusivity extension vouchers) granted to antimicrobial developers could be bought by other entities than Market Authorisation Holders, for example by HERA.

**Conclusion:** Board members will provide further feedback by 13 February 2023 on preferred and less preferred options, ideas on how to ensure proper governance and funding, and the potential articulation of this type of pull incentives with TEEVs. HERA will circulate details on the forthcoming Presidency meeting in Stockholm.

#### **4. UPDATE ON STOCKPILING**

**HERA** presented an update on stockpiling. HERA was allocated a large budget for stockpiling of MCMs: EUR 1.2 billion for 2022 and 2023. It set up a working group of experts working in CBRN area, and in 2022 spent EUR 575 million on CBRN countermeasures. Four countries will receive funds – Finland, France, Poland and a fourth country which will sign soon. In 2023, the budget available is EUR 641.5 million. The call for proposals will be launched on 15 February 2023. It will focus on the three main health threats that HERA has identified.

The MCM prioritisation exercise is used to shortlist priority items to stockpile. It involves Member States in the process of scoring the priority MCMs. Two HERA working groups are involved: the MCM group and the stockpiling group. Last week the HERA Board received the minutes of working group meetings on MCM prioritisation and the 2023 stockpiling call. Sharing the timeline of events leading to the 2023 call, the Board will also be consulted in the coming weeks.

**France** indicated its commitment to implement the signed grant agreement under the 2022 exercise. For 2023, the 15 February call and the mid-May deadline were considered short, and some flexibility would be appreciated.

#### **5. UPDATE ON WASTEWATER SURVEILLANCE**

A letter with specific information on the actions undertaken following the Health Security Committee and Integrated Political Crisis Response (IPCR) recommendations in the context of the COVID-19 outbreak in China was shared with the Board members. These recommendations include the stepping up wastewater monitoring, in particular those waters stemming from airports with international flights and/or aircrafts. Support of wastewater surveillance started with the HERA incubator, and action increased over the past year. HERA and JRC have worked together to develop a specific guidance. A Joint action on wastewaters is being launched to support Member States in these activities, to ensure that information coming from wastewater monitoring is combined with other

relevant information. **HERA** presented the timeline and nomination process for the joint action. It aims to facilitate sampling management, enhance surveillance capacities, further develop the DEEP database, and enable better overview at EU level.

**JRC** is currently talking to partners around the world to initiate discussions on global cooperation on wastewater and dirty water surveillance for public good.

**Conclusion:** Wastewater surveillance is an important issue and a powerful tool which HERA and Member States need to develop jointly.