



Meeting of the HERA Board

20 July 2023

Final 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, LT, LV, NL, PL, PT, SI, SK, HERA, DG SANTE, DG GROW, DG ECHO, DG TRADE, DG COMP, SG, SJ, ECDC, EMA, representatives of the Icelandic and Norwegian bodies relevant to public health emergencies. Industry representatives present in the first part of the meeting (for agenda items 1 and 2): Antibiotice, Aurobindo, Eberth, Fidia, Fresenius, GSK, HEC Pharm, Infectopharm, Kela Pharma, Krka, Medochemie, Menarini, Navamedic, Pfizer, Polpharma, Roche, Sandoz, Stada, Teva, Viatris, Efpia, Medicines for Europe, AESGP, Kent-Athlone.

1. WELCOME AND ADOPTION OF THE AGENDA

The Chair extended a welcome to all participants. He thanked EMA and colleagues who worked on the joint EMA/HERA exercise. He explained the primary purpose of the meeting was to present the outcomes of the joint EMA/HERA monitoring exercise, specifically focused on the supply and demand of a subset of antibiotics used to treat respiratory infections and discuss the recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) on the availability of the antibiotics in scope of the exercise.

He stressed that shortages, in even one Member State, were not acceptable, which is why it is important to have a transparent dialogue with industry to explore viable strategies to prevent antibiotic shortages, especially during the autumn and winter.

The need for a collective, unified approach to devise an effective solution was emphasised. In compliance with EU competition legislation, industry attendees were also requested to respond after the meeting in writing to specific questions on their production capacity and potential bottlenecks.

EMA highlighted the substantial progress made by the MSSG in adopting concrete recommendations in response to the results of the monitoring exercise. She reiterated that this is a joint effort and that the active cooperation of all stakeholders is needed for future success.

2. REPORT ON THE JOINT EMA/HERA EXERCISE MONITORING SUPPLY AND DEMAND OF ANTIBIOTICS (MS AND INDUSTRY)

HERA presented the results of the joint exercise on monitoring supply and demand of a subset of antibiotics. The exercise was launched to avoid a similar situation to last autumn/winter, when many Member States faced shortages of crucial antibiotics, specifically amoxicillin and amoxicillin/clavulanic acid.

The exercise matched supply forecasts provided by industry with possible demand scenarios based on historical sales data to identify potential shortfalls. On the supply side, HERA and EMA identified the top five companies with the highest market share and received supply forecasts from 21 out of the 27 marketing authorisation holders contacted in time to be included in the analysis. On the demand side, the evaluation was based on historical sales data over the past six years.

Based on the analysis of the historical ‘intermediate scenario’ (i.e. neither the highest nor lowest sales in the past six years), the exercise identified antibiotics, which are expected to meet the demand for all pharmaceutical forms and strengths, as well as those formulas where the projected supply is below the sales observed under the ‘intermediate scenario’.

In response, the MSSG has recommended that industry increase the production capacity for the identified formulations and strengths. Furthermore, HERA and EMA have been tasked with continuing to monitor the situation and all relevant stakeholders reminded not to stockpile antibiotics to avoid exacerbating shortages. The MSSG has also recommended that antibiotics are used prudently to maintain their efficacy and avoid antimicrobial resistance.

In the ensuing discussion, a number of industry representatives took the floor to offer their view of the situation and how shortages could be avoided. Industry raised a number of concerns, including the need for regulatory flexibility to increase production, the low prices of many antibiotics and the difficulty in reallocating stocks in light of national stockpiling requirements. They also noted issues such as price fluctuations, offshore production leading to longer lead times, low prices driving suppliers into potential losses, and the need for local manufacturers’ protection.

EMA acknowledged the multifaceted nature of shortages, explaining that regulatory flexibility, such as labelling exemptions, were possible to mitigate shortages, as well as the need for proactive planning.

ECDC explained that, based on the current influenza season in the Southern Hemisphere and SARS-CoV-2 trends, there were no signs, at this stage, of a severe winter, in terms of respiratory diseases. ECDC stressed the need for ongoing monitoring.

The Chair concluded the meeting by inviting industry to propose concrete strategies and actions for EU implementation and suggested continuing bilateral discussions during the summer. He also suggested a follow-up meeting in September and a possible match-making event in case there is a need to identify new suppliers for industry. The Chair considered stockpiling at EU level as one potential measure.

3. DISCUSSION WITH MEMBER STATES AND OBSERVERS

The second part of the meeting was open only to HERA Board members and observers. The Chair opened the meeting emphasising the need for solidarity between Member States.

EMA noted that accurate demand prediction remains a challenge for manufacturers in a competitive market with different Member States strategies. EMA recommended a balanced approach, avoiding fear-inducing narratives that could negatively affect the market.

Many Member State representatives highlighted the importance of pricing issues, recognising that current prices for certain antibiotics could be contributing to shortages. They suggested ensuring a viable market to encourage more companies to produce these antibiotics. Some Member States recommended more coordination within the EU and information sharing. However, concerns were raised about the idea of joint procurement at the same price for all MS.

Stockpiling at EU level was supported by several participants, which could help mitigate both demand and supply shocks. One Member State explained that their requirement for wholesalers to hold stocks of some medicines has helped to ensure supply of key antibiotics. Another Board member pointed out the need to face the reality of ongoing stockpiling, underlining the importance of MS solidarity.

Some participants suggested that data they gathered at national level provided a less optimistic picture of the situation. They suggested increasing production in the EU and building EU-level stockpiles and adding other products on the list.

In conclusion, the Chair underlined the importance of solidarity among Member States and the need for a comprehensive approach to avoiding shortages of antibiotics this autumn/winter. While acknowledging the challenges, he assured that specific suggestions to support each Member State could be provided. The Chair informed participants that a press statement would be issued after the meeting.