



22 May 2023
EMA/177968/2023

Minutes – Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

20 April 2023, from 10:00 to 12:00 (CEST), WebEx

Co-Chairs: Emer Cooke (EMA) and Karl Broich (HMA)

Item	Topics
1.	<p>Welcome, declaration of interest and adoption of the agenda</p> <p>Co-chairs welcomed the participants to the meeting of the MSSG.</p> <p>The MSSG secretariat reviewed members and experts declared interests in accordance with the Agency’s policy on handling of declarations of interests (DoI) of scientific Committees’ members and experts, applicable to members and experts of the MSSG, and when not available in accordance with the Management Board’s policy on the handling of competing interests. The MSSG Secretariat announced the competing interests identified and applicable restrictions for topics on the agenda.</p> <p>The agenda was adopted with no additional topics.</p>
2.	<p>Adoption of the minutes of the meeting of the MSSG held on 15 March 2023</p> <p>BfArM Co-Chair informed the MSSG that the draft minutes of the meetings of the MSSG held on 15 March 2023 had been distributed via email prior the meeting. No comments were received but an omission was noted.</p>
3.	<p>COVID19: Relevant scientific updates on vaccines and therapeutics</p> <p>EMA gave an update on the latest scientific discussions on vaccines and therapeutics, including considerations on how to support healthcare professionals when prescribing Paxlovid in the EU/EEA and the ongoing work to prepare for COVID-19 vaccine composition update for next cold season (including plans to hold a ICMRA workshop on this topic).</p>
4.	<p>European Shortages Monitoring Platform (ESMP) - update from the MSSG Working Group</p> <ul style="list-style-type: none">• ESMP Roadmap <p>The MSSG representative at the ESMP-MSSG working group presented the ESMP vision and roadmap which had been adopted by the working group on 10 March, including the main milestones to allow the functioning of the ESMP in February 2025.</p>



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	<p>The roadmap was also presented at the Industry Standing Group (ISG) on 21 March and to other groups involved in the development of the ESMP.</p> <p>The MSSG adopted the ESMP roadmap.</p> <ul style="list-style-type: none"> Update on the ESMP progress <p>EMA presented an update on the progress made by the three teams (strategic, interim solution and analytic teams) in Q1 2023 on the ESMP, as well as the scope committed to Q2 2023, in view of the planned milestones outlined in the roadmap. Some delays in deliverables accumulated in Q1 2023 due to additional technical complexity were highlighted.</p> <p>It was highlighted that the quality of the data of nationally authorised products, once integrated in PMS, will require special attention, as quality issues may lead to misinterpretations, especially in data analysis.</p> <p>EMA confirmed that after the adoption of the roadmap by the MSSG, communication activities will be deployed, including to healthcare professionals.</p> <p>EMA also informed of the ongoing activities to increase the MAH i-SPOC registration figures.</p>
5.	<p>Monitoring of events:</p> <ul style="list-style-type: none"> Antibiotics – Update and Joint EMA exercise with DG HERA <p>EMA presented a brief update regarding the overall situation with availability of antibiotics. While the situation is improving and is no longer considered to be critical in a number of MSs, some MSs are still experiencing tensions with supply of amoxicillin and amoxicillin/clavulanic acid in paediatric formulations as well as penicillin. EMA and the MSs continue to closely monitor the situation.</p> <p>A state of play of the joint EMA/HERA exercise was provided, including the actions undertaken for collecting data on supply from antibiotic MAHs. In addition, actions related to demand forecasting and matching of supply with demand that are necessary to undertake the exercise were also presented.</p> <p>DG HERA informed that they are working complementarily to ensure supply continuity of antibiotics for the next winter's season but also in the long-term.</p> <ul style="list-style-type: none"> Thrombolytics <p>EMA provided an update on the ongoing mitigating activities in relation to thrombolytics shortages.</p> <p>The MSSG supported the activities conducted so far and to continue monitoring this shortage.</p> <ul style="list-style-type: none"> Visudyne <p>EMA provided an update on the ongoing mitigating activities in relation to the Visudyne shortage, including importation from the US.</p> <p>The MSSG supported the activities conducted so far and to continue monitoring this shortage.</p> <ul style="list-style-type: none"> Ozempic <p>EMA provided an update on the ongoing mitigating activities in relation to the Ozempic shortage, including regular exchanges of information with the MAH.</p>

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	<p>Novo Nordisk antiobesity medicine (Wegovy) is authorised in Europe but has only been launched in Denmark and Norway. EMA confirmed Novo Nordisk’s launch rollout plan for Wegovy in other EU countries is being assessed in light of the Ozempic supply situation, and will be decided on an ongoing basis to mitigate the risk of potential stock outs after launch.</p> <p>Following the latest media reports, EMA confirmed it is closely monitoring Novo’ Nordisk conduct in light of breaches in the UK for Saxenda and queried NCA in DK and NO on further interventions from a regulatory standpoint. In NO, Wegovy is not reimbursed, and the media pressure with different stakeholders arguing for reimbursement is ongoing. Both DK and NO are monitoring the promotional activities of Wegovy, but have not seen similar promotional activities as in the UK.</p> <p>MSSG agreed that it would be important to hold a follow-up discussion at HMA on the (financial) implications of the rollout/reimbursement of antiobesity medicines (e.g. Wegovy) to national healthcare systems.</p> <p>EMA also informed the MSSG that the MAH sent a letter to the Co-Chairs of the MSSG, TFAAM and Chairs of EMA Management Board and HMA Management Group. A reply to the letter has been agreed and it will be shared with the MSSG and the Medicine Shortages SPOC WP members for awareness.</p> <p><i>Post-meeting note: the reply was circulated to the MSSG (on 24 April 2023) for awareness.</i></p> <p>The MSSG supported the activities conducted so far and to continue monitoring this shortage.</p>
6.	<p>HERA AMR feasibility study on stockpiling</p> <p>This topic was postponed to the next meeting of the MSSG.</p>
7.	<p>AOB</p> <p>EMA Co-Chair informed that the updated list of critical medicines for COVID-19 public health emergency (PHE) under Regulation (EU) 2022/12 was published on the EMA website after the email circulated to the MSSG on 15 April 2023.</p> <p>EMA Co-Chair informed that next meeting of the MSSG would be conducted in June.</p>

Next meeting: 19 June 2023

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).