8 August 2023
EMA/323383/2023

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

14 July 2023, from 13:00 to 14:00 (CEST), WebEx

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

Item	Topics
1.	**Welcome, declaration of interest and adoption of the agenda** Co-chairs welcomed the participants to the meeting of the MSSG. 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 EMA 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. The agenda was adopted with no additional topics.
2.	**Adoption of the minutes of the meeting of the MSSG held on 19 June 2023** BfArM Co-Chair informed that the draft minutes of the meetings of the MSSG held on 19 June 2023 were distributed via email prior the meeting. No comments were received before or during the meeting. Minutes were adopted and will be published on the EMA website.
3.	**MSSG Solidarity Mechanism Working Group** The Co-Chair of the MSSG Working Group on the Solidarity Mechanism presented the group composition, topics discussed during the kick-off meeting held on 4 July 2023 and timelines for establishing the solidarity mechanism, including a pilot phase for its implementation. The solidarity mechanism is intended to be a voluntary mechanism where NCAs from Member States can request help from other Member States in obtaining medicines affected by a critical shortage in their national territory. HERA confirmed strong commitment to support the setting up of a solidarity mechanism among Member States under the MSSG.

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Item	Topics
4.	**Preparedness activities:** • **Antibiotics – outcome of the Joint EMA exercise with DG HERA** • **MSSG recommendation** EMA presented the outcome of the joint EMA-HERA exercise based on matching supply and demand data according to an "Intermediate" demand scenario to match with the supply data. The results of the joint EU-level exercise on matching supply and demand (based on historical data) were presented, and several recommendations for measures that could be undertaken for actions to avoid shortages of key antibiotics used to treat respiratory infections for European patients in the next winter season were adopted by the MSSG. EMA informed the MSSG that the recommendations would be published after the meeting, together with a joint news announcement also highlighting the importance of the prudent use of antibiotics and the need to avoid stockpiling. *Post-meeting note: The joint news announcement and recommendations on the availability of a subset of antibiotics were published on 17 July on the EMA, HMA and EC websites.* HERA informed the MSSG that, during the HERA Board scheduled on 20 July, the findings of the exercise and potential additional mitigating measures, based on the recommendations provided by the MSSG, will be discussed with Member States, marketing authorisation holders for the antibiotics in scope of the exercise and Industry Trade Associations. Multiple bilateral meetings with relevant key antibiotic marketing authorisation holders and informal, preparatory calls with relevant Industry Trade Associations will occur before 20 July. A report on the joint EMA/HERA exercise on monitoring supply and demand of antibiotics will be provided to the MSSG, and the HERA Board members. The work conducted by the regulatory network was acknowledged and appreciated.
5.	**EU list of critical medicines** EMA presented the high-level methodology, the roadmap and the agreed process to set up an EU list of critical medicines, which had been adopted by the Steering Committee of the Joint HMA/EMA Task Force on the Availability of Authorised Medicines for human and veterinary use (TFAAM) on 29 June 2023. The release of the EU list of critical medicines will follow a staggered approach in two phases. The release of the first version is expected in Q4 2023 based on published national lists of critical medicines or lists currently under development, followed by a second phase with subsequent versions prioritising review by therapeutic groups of major interest.

Next meeting: 14 September 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).