



23 February 2024
EMA/43606/2024

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

29 January 2024, from 15:00 to 17:00 (CET), 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 new members 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 EMA Management Board’s policy on the handling of competing interests. The MSSG Secretariat announced that no competing interests had been identified for topics on the agenda.</p> <p>The agenda was adopted with no additional topics.</p>
2.	<p>Adoption of minutes of the MSSG meeting held on 13 December 2023</p> <p>BfArM Co-Chair informed that the draft minutes of the meetings of the MSSG held on 13 December 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.</p>
3.	<p>Union list next steps - Supply chain vulnerability assessment: Update on the HERA/GROW workshop on the vulnerability analysis for the first tranche of the EU list of critical medicines and HERA Board meeting</p> <p>HERA provided feedback from the workshop on the vulnerability analysis for the first tranche of medicines from the Union list of critical medicines held on 10 January as well as the HERA Board meeting held on 16 & 17 January 2024.</p> <p>In addition, HERA presented the criteria to select the first tranche of medicines, the proposed methodology to conduct the supply chain vulnerability assessment, the roadmap and the list itself which consists of 11 active substances. The decision on the first tranche of critical medicines is the responsibility of the Commission and as such no adoption is foreseen by either the MSSG or the HERA Board. As a next step, HERA Board members</p>



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	<p>and relevant stakeholders will be informed on the selection process and the medicines included in the pilot exercise . Both MSSG and HERA Board members are invited to provide feedback to the list of selected medicines in writing by 6 February.</p> <p>The first tranche of critical medicines will be used as a pilot to test the methodology to assess the vulnerabilities in the supply chain. The results of this pilot exercise will inform the refinement of the methodology and follow-up actions by the Critical Medicines Alliance.</p> <p>Regarding timelines for the pilot exercise, data collection from industry/MS will take place in February-March followed by data analysis in April. HERA confirmed that the vulnerabilities of the supply chain will be evaluated at formulation level.</p> <p>MSSG members raised potential challenges relating to the high workload and tight timelines proposed for the completion of the exercise.</p> <p>A working group composed of NCAs will be set up to review the questionnaires/surveys and to discuss data requests in order to streamline the process and to avoid duplication.</p> <p>The MSSG highlighted the importance to keep the SPOC WP involved to avoid duplication of requests.</p> <p>HERA confirmed it will provide regular updates to the SPOC WP as well as, to MSSG members on the pilot exercise.</p> <p>The EMA co-chair noted that EMA had provided suggestions for the list, based on experience, which had been taken into account by HERA. For future such exercises involvement of MSSG and SPOC WP would be very important.</p>
4.	<p>Update on the Critical Medicine Alliance and interaction with the MSSG</p> <p>HERA provided an overview of the Critical Medicines Alliance (CMA) objectives, composition, and timelines.</p> <p>The scope of the CMA will be limited to a number of critical medicines (first tranche of critical medicines) and will be focused on the following measures:</p> <ul style="list-style-type: none"> • Boost innovation and manufacturing capacity using available EU and national funding for strategic projects (including state aid where relevant). • Diversification of global supply chains via strategic partnerships with third countries • Public Procurement (contractual incentives, capacity reservation contracts, joint-procurements, etc.). • Stockpile medicines at the EU level building upon the development of a common strategic approach to medicines stockpiling in the first half of 2024 and the Joint Action on stockpiling. • Skills for the pharmaceutical industry support the launch of a partnership for skills in the pharmaceutical sector. <p>The CMA structure is divided in 3 levels:</p> <ul style="list-style-type: none"> • CMA forum: open to all members. The forum will discuss high level policy issues. They will meet a least once per year.

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	<ul style="list-style-type: none"> • CMA Steering board (SB): executive body which provides the strategy direction of the CMA, supervises and monitors the work of the working groups and may adopt opinions, recommendations or reports of the CMA. <p>For the MSSG representation in the SB it was agreed that both Co-Chairs of the MSSG would be members. The SB will also have a member from the EMA and a member from HMA representing NCAs.</p> <p>It was also clarified that there will be 2 representatives from civil society: one from patients/consumers and one from healthcare professionals.</p> <ul style="list-style-type: none"> • Working Groups: the SB may propose the setting up of working groups on specific topics to conduct the technical work. <p>The importance of avoiding duplication of work was stressed during the meeting. The CMA will complement the work of the MSSG and will take into account MSSG recommendations. The CMA will be focused on long term activities and the SPOC WP/MSSG recommendations are focused on short/medium-term activities to address shortages.</p> <p>The MSSG and the SPOC WP will be involved in the work of the CMA through representation in the CMA Steering Board and the Working Groups. The MS will decide their representation in the CMA. The importance of having a balanced representation from different stakeholder in the working groups, including patients and healthcare professionals, was highlighted.</p> <p>The first meeting of the CMA will be scheduled to April 2024 and the strategic action plan adoption is expected in Q4-2024. The MSSG will receive regular updates on the work conducted by the CMA.</p> <p>HERA also informed the MSSG that the Commission will launch a dedicated, preparatory study, paving the way for an impact assessment for a possible Critical Medicines Act, as described in the EC Communication on shortages.</p> <p>The Terms of Reference are published on the CMA webpage.</p>
5.	<p>Preparedness activities:</p>
	<ul style="list-style-type: none"> • Antibiotics –Joint EMA exercise with HERA <p>EMA provided feedback from international regulators, industry associations and the SPOC WP on the current supply situation for a subset of antibiotics, which appears to remain stable.</p> <p>Furthermore, EMA provided the latest feedback from the larger manufacturers of amoxicillin, amoxiclav and azithromycin.</p> <p>HERA presented the survey launched to MS in relation to a joint procurement of antibiotics for the next autumn/winter season.</p>
	<ul style="list-style-type: none"> • Thrombolytics lessons learnt exercise <p>EMA provided an update on the status of the ongoing shortage management activities, with particular focus on the proposed launch of a new strength and indication of Metalyse which is expected imminently.</p>

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	EMA also gave an update on the lessons learned exercise for the ad hoc gap analysis and clarified next steps to be taken: a process document will be shared with the MSSG for endorsement and a high-level user guide will be drafted to support the work of lead NCAs, EMA teams, and other stakeholders involved.
	<ul style="list-style-type: none"> • Update on the Cheplapharm ongoing shortages <p>EMA gave an update on the supply situation of Visudyne, including a further delay on the delivery to EU countries and the ongoing regulatory support that is being provided to the MAH.</p>
6.	<p>Solidarity mechanism procedures</p> <p>EMA provided an overview of the potential candidates for the solidarity mechanism which had been discussed at the MSSG at the end of 2023 and the explained the reason why the procedures were not launched by the impacted MS.</p> <p>EMA confirmed that the procedure for the Solidarity Mechanism was set up in October 2023 and it is ready to be used as soon as a MS requires support for the mitigation of a critical shortage.</p> <p>The lack of candidates for the pilot exercise demonstrates that the existing structures are adequate, and the coordinated actions put in place have had a positive impact in mitigating the shortages.</p>
7.	AOB

Next meeting: 19 March 2024

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).