



12 April 2024  
EMA/118868/2024

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

19 March 2024, from 10:00 to 11:45 (CET), WebEx

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

Item	Topics
1.	<p><b>Welcome, declaration of interest and adoption of the agenda</b></p> <p>Co-Chairs welcomed the 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><b>European Shortages Monitoring Platform (ESMP) - update from the MSSG Working Group</b></p> <p>EMA presented the status update and the objectives for Q2 2024. The high-level timeline for the planned activities up to the launch of the platform in Q1 2025 was presented, together with the dependencies between ESMP and the Product Management System (PMS). In addition, the web interface of ESMP was also presented.</p> <p>The Co-Chair of the ESMP Working Group presented the implementation roadmap for interoperability with national and industry systems.</p> <p>The MSSG endorsed the interoperability approach and roadmap.</p>
3.	<p><b>Union list next steps - Supply chain vulnerability assessment: Update</b></p> <p>HERA presented an update on the progress of the supply chain vulnerability assessment, including preliminary feedback received from MAHs and Member States.</p> <p>As next steps, HERA will finalise the data collection and hold bilateral meetings with key suppliers and Member States.</p>



Item	Topics
	<p>The results of the supply chain vulnerability assessment will be presented to the MSSG and to the Critical Medicines Alliance (CMA) in April. After that, the HERA Board and Joint Industrial Cooperation Forum (JICF) will be informed on the results of the exercise.</p> <p>BfArM Co-Chair requested HERA to clarify the composition of the CMA and to implement the proposal discussed at the last MSSG meeting to include a member from the EMA and a member from HMA representing NCAs in the Steering Board of the CMA, in addition to the Co-Chairs of the MSSG.</p>
4.	<p><b>MSSG recommendations to strengthen supply chains of critical medicinal products</b></p> <p>EMA provided an overview of the MSSG recommendations to strengthen the supply chains of critical medicinal products, together with the adoption process which will include a consultation with the Medicine Shortages SPOC WP and the CMDh.</p> <p>The importance of avoiding duplication of work between the MSSG and the CMA was discussed. It was clarified that the MSSG will develop regulatory recommendations focused on short- to medium-term actions while the CMA will develop recommendations on industrial policy focused on long-term activities.</p> <p>It was clarified that the MSSG may issue recommendations to other entities, including the CMA.</p> <p>This work is anticipating the implementation of the revised pharmaceutical legislation.</p>
5.	<p><b>Union list of critical medicines – second phase deployment</b></p> <p>EMA provided an overview of the development of version 2 of the Union list, including a targeted stakeholder consultation planned between March and May 2024 involving Learned Societies, Patients &amp; Healthcare Professionals Organizations and Industry Associations. Version 2 of the Union list is anticipated to be published in December 2024. The Union list will subsequently be reviewed and updated as needed on a yearly basis.</p>
6.	<p><b>Preparedness activities:</b></p>
	<ul style="list-style-type: none"> <li data-bbox="293 1435 983 1464">• <b>Antibiotics – Update on preparedness activities</b></li> </ul> <p>EMA provided feedback from 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 key manufacturers of amoxicillin, amoxicillin/clavulanic acid, azithromycin and clarithromycin. EMA noted that industry associations have been requested to undertake an antibiotic matching of supply and demand exercise using EMVS data as a pilot exercise.</p>
	<ul style="list-style-type: none"> <li data-bbox="293 1758 588 1787">• <b>Ozempic – Update</b></li> </ul> <p>EMA provided a status update on the shortages of GLP-1 RA. In addition, EMA shared information from the joint EMA/FDA meeting held with Novo Nordisk on 8 March 2024 and from the Drug Shortages Global Regulatory Working Group.</p> <p>EMA informed the MSSG on the status of the report on Member States’ best practices on mitigation measures and the survey on national communication campaigns on shortages of</p>

Item	Topics
	Ozempic. The learnings from the survey will help shape future communication campaigns on Ozempic.
7.	<p><b>Administrative announcement – moving towards SharePoint</b></p> <p>The MSSG Secretariat informed the MSSG that pre/post-mailings would be distributed only via SharePoint as of the March’s meeting.</p>
8.	<b>AOB</b>

---

**Next meeting:** 12 April 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).