



27 March 2023
EMA/64146/2023
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

18 January 2023, from 10:00 to 13:00 (CET), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Johan Andersson (SE)

Item	Topics
1.	<p>Welcome, declaration of interest, adoption of draft agenda</p> <p>EMA Chair welcomed participants to the meeting of the Medicine Shortages SPOC Working Party and wished the new Vice-Chair a successful term.</p> <p>SPOC WP Secretariat reviewed members and experts declared interests in accordance with the Agency's policy on handling of declarations of interests (DoI) of scientific Committees, applicable to members and experts of the SPOC WP.</p> <p>The SPOC WP Secretariat announced the competing interests identified and announced the applicable restrictions for topics on the agenda</p> <p>Changes to the SPOC WP membership were announced. The agenda was adopted with no additional points under AOB.</p>
2.	<p>Adoption of draft minutes of the SPOC WP meeting held on 13 December 2023</p> <p>The Vice-chair informed that the minutes of the meeting held on 13 December 2022 had been distributed via email one week prior the meeting.</p> <p>No comments were received before or during the meeting. Minutes were adopted.</p>
3.	<p>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) update: ad hoc meeting held on 11 January 2023</p> <p>The Vice-chair gave a high-level update from the MSSG meeting held on 11 January 2023. The following points were highlighted:</p> <ul style="list-style-type: none">• Monitoring of events: Availability issues as a consequence of energy issues, increased demand and other factors impacting the supply and demand of antibiotics and certain antipyretic/ analgesic medicines;• National measures & regulatory flexibility conducted by DE/BfArM;• COVID-19 increase of cases in China: update on the current situation and the need for close monitoring.



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4.	<p>Potential impact of the international situation (e.g. Russia-Ukraine War) and energy crisis on the supply of medicinal products for human and veterinary use to the European market</p>
	<p>a) Antibiotic shortages: update on coordinated actions</p> <p>EMA presented an update on actions undertaken by EMA and the Medicines Regulatory Network, including an update on the interactions with the MAHs and manufacturers, as well as the feedback from the MSSG.</p> <p>In preparation for the discussion at the next MSSG meeting on 26 January 2023, the SPOC members provided an update on the situation in their territories during a <i>tour de table</i>.</p> <p><u>Comments raised</u></p> <p>Some SPOC WP members noted the need to prepare for the next autumn/winter's season in advance.</p> <p>SPOC members compared the ongoing MPox Public Health Emergency (PHE) with the shortages of antibiotics in relation to the impact on patients/citizens. EMA explained the process for declaring a PHE is different from the declaration of a ME, and that for the former there is no involvement from EMA/National Competent Authorities (NCA), i.e. a PHE is declared by the WHO/European Commission.</p> <p>SPOC members asked about the available regulatory tools to import additional supplies to their territories. EMA confirmed that there are a few mechanisms to be considered at a national level, incl. framework defined under Art. 5.2 or Art. 126a of the Directive 2001/83/EC.</p> <p>Agreed actions</p> <ul style="list-style-type: none"> SPOC WP members interested in additional supplies of amoxicillin and amoxicillin/clavulanic acid from 1 manufacturer to inform EMA.
	<p>b) Antipyretic (oral paediatric formulations) shortages, including supply disruptions related to increased RSV infections</p> <p>EMA presented the findings from the survey on availability issues with certain antipyretic medicines (including ibuprofen and paracetamol) and provided an update on the monitoring of antivirals. EMA presented the feedback from the MSSG meeting on 26 January 2023 in relation to monitoring of these shortages.</p> <p>Agreed actions</p> <ul style="list-style-type: none"> SPOC WP members to inform EMA in case the supply situation for antipyretic medicines in paediatric formulations in their countries deteriorates. SPOC WP members to inform EMA in case of any supply disruptions related to RSV infections are observed.
	<p>c) Monitoring and preparedness activities related to China's COVID-19 cases surge</p> <p>Taking into consideration that information from MSs and industry associations was compiled and shared with the SPOC WP members in advance of the meeting, and the feedback from the MSSG was presented under agenda point above, the topic was not presented.</p>

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	<p>d) Feedback from the “crisis monitoring and preparedness” focus Group</p> <p>EMA presented the feedback from the focus group meeting held on 10 January 2023. No new significant information has been identified by the group, although some signals related to packaging materials have been noted.</p>
	<p>e) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)</p> <p><u>Comments raised</u></p> <p>One SPOC member noted an increase in demand for corticosteroids in certain areas.</p>
5.	<p>Update on ongoing shortages reported by the SPOC WP (non-PHE related):</p>
	<p>a) Ozempic (CAP): update on activities from subgroup</p> <p>EMA presented an update from the activities of the SPOC WP subgroup, as well as activities related to information gathering on off-label use and potential measures for controlled distribution. EMA provided an update on the mitigating measures undertaken by the MAH and the next steps.</p>
	<p>b) Update on Thrombolytics: Metalyse (CAP) and Actilyse (NAP)</p> <p>EMA presented an update from the discussions with the MAH and other companies. EMA highlighted the outcome of the discussion with the manufacturers of thrombolytic “bio-copies”.</p>
	<p>c) Update on Menopur (NAP) shortages</p> <p>EMA provided the feedback from the weekly meetings with the MAH and the SPOC WP subgroup, including the update on the quality defect, MAHs activities, the shortage situation, as well as the outcome of the meetings with other MAHs and manufacturers.</p> <p>Agreed actions</p> <ul style="list-style-type: none"> • EMA to invite the MAH to present an update on Menopur shortages at the next SPOC WP meeting.
6.	<p>Update on monitoring of the supply and demand for the ongoing PHEs (COVID-19 and Monkeypox) in EU/EEA</p> <p>Topic could not be taken and was postponed.</p>
7.	<p>Major event definition: Criteria for the MSSG to grant a positive opinion on an actual or imminent major event</p> <p>EMA presented the draft guidance document on the criteria for the MSSG to grant a positive opinion on a major event which underwent a SPOC WP consultation until 17 January 2023. EMA noted that the draft document will be circulated to the MSSG for review and subsequent discussion and potential adoption at the meeting on 26 January 2023.</p> <p><u>Comments raised</u></p>

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	<ul style="list-style-type: none"> SPOCs WP members noted that the examples section within the document may cause additional questions. EMA agreed that the list of examples is limited and highlighted the challenges in finding the examples. SPOCs noted that antimicrobial resistance (AMR) could be considered of pandemic potential; EMA clarified that those elements will be conveyed to the MSSG for discussion, including considerations on AMR. <p>Agreed actions</p> <ul style="list-style-type: none"> SPOC WP members to consolidate with their respective MSSG members any additional comments that may have arisen after the consultation deadline.
8.	<p>Joint Action on shortages - Update</p> <p>SPOC WP member provided an update on the Joint Action on shortages, including the signing of the grant agreement and the kick-off meeting scheduled for 10 February 2023 in Rome.</p>
9.	<p>Update on the EMA extended mandate implementation</p> <p>Frequently asked questions (FAQ) document on data exchange between NCAs and other National Health Institutions to meet reporting obligations defined under Regulation (EU) 2022/123 at Member State level</p> <p>Topic could not be taken and was postponed.</p>
10.	<p>European Commission DG SANTE: general update</p> <p>DG SANTE confirmed that no relevant updates were available.</p>
11.	<p>European Commission DG HERA: general update</p> <p>DG HERA informed about the publication of the report on the results of the "AMR feasibility study on stockpiling" and thanked the SPOC WP for contributions to the study.</p> <p>DG HERA provided an update on the activities related to diphtheria antitoxin (DAT).</p>
12.	<p>Improving transparency and communication to the public on shortages discussed in the SPOC WP</p> <p>Topic could not be taken and was postponed.</p>
13.	<p>Conclusions and next steps</p> <p>Actions agreed are highlighted above.</p>

Next meeting: 15 February 2023

Note on access to documents

Some documents mentioned in the meeting summary 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).