



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2023
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European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party meeting

15 February 2023, from 10:00 to 13:00 (CET), WebEx

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

Item	Topics
1.	Welcome, declaration of interest, adoption of draft agenda EMA Chair welcomed participants to the meeting of the Medicine Shortages SPOC Working Party. 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. The SPOC WP Secretariat announced the competing interests identified and announced the applicable restrictions for topics on the agenda. The agenda was adopted with no additional topics under AOB.
2.	Adoption of draft minutes of the SPOC WP TC held on 18 January 2023 The Vice-chair informed that the minutes of the meeting held on 18 January 2023 had been distributed via email one week prior to the meeting. No comments were received before or during the meeting. Minutes were adopted.
3.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) update: meeting held on 26 January 2023 The Vice-chair gave a high-level update from the MSSG meeting held on 26 January 2023. The following points were highlighted: • Ongoing Public Health Emergencies (COVID-19 and Mpox): List of critical medicines – update on supply and demand. It was confirmed that there are no new signals or confirmed shortages notified by MAHs;



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	- Monitoring of events: no change in availability issues with thrombolytics or antibiotics and certain antipyretic/analgesic medicines as a consequence of energy issues, increased demand and other factors impacting the supply and; - Major event definition: criteria for the MSSG to grant a positive opinion on an actual or imminent major event were discussed and will be adopted at next meeting; - Amoxicillin shortage: The MSSG discussed whether the shortage meets the definition of a 'major event' as foreseen in Regulation (EU) 2022/123, and came to the conclusion that at present it is not considered to be a major event and that current mitigating measures are improving the supply situation in the short-term.
4.	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
	a) Antibiotic shortages: Update on coordinated actions EMA updated the group on the MSSG discussions on shortages of antibiotics including on the outcome of the meetings held with certain Marketing Authorisation Holders. <u>Comments raised</u> Many SPOC WP members noted that antibiotic supply situation has somewhat improved nationally since the last SPOC WP meeting held on 18 January 2023. Nonetheless, some SPOCs noted that the situation in their territories remains constrained for certain antibiotic formulations. Joint EMA/HERA proposal for monitoring supply and demand of a set of antibiotics in preparation for 2023/2024 winter's season EMA and DG HERA presented its plan to monitor the supply and demand for subset of antibiotics with an aim to prepare for the next autumn/winter season.
	b) Feedback from the "crisis monitoring and preparedness" focus Group EMA presented the feedback from the crisis monitoring and preparedness focus group meeting held on 7 February 2023, including an update on supply of antipyretics and antivirals. In relation to Ukraine and energy crisis or COVID-19 cases in China no new significant information has been identified. Some issues with packaging materials have been noted.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) No new emerging information was raised.
5.	<u>Update on ongoing shortages reported by the SPOC WP (non-PHE related):</u>
	a) Update on Menopur (NAP) shortages Closed pre-discussion with SPOC WP Members

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	EMA presented the latest information on the supply situation for Menopur based on the ongoing discussions with the MAH, as well as availability of alternative gonadotropins. • Presentation by Marketing Authorisation Holder: Ferring and discussion on supply and future planning The MAH presented an overview of the situation along with their plans for distributing limited supplies. <u>Comments raised</u> EMA and SPOCs asked the MAH for information about their timelines for increasing supply, and regulatory plans to achieve this. • Closed post-discussion with SPOC WP Members SPOC WP members thanked the EMA for coordinating the shortage considering the complexity and different approached across the MSs.
	b) Update on Norditropin Nordiflex (somatropin injection) shortages EMA presented the background information on a shortage of Norditropin Nordiflex and presented the outcome of the SPOC WP survey conducted in late January 2023.
	c) Ozempic (CAP): update on activities from subgroup EMA presented an update on the status of the DHPC and the outcome of the discussions with the MAH in early February 2023. <u>Comments raised</u> SPOC WP member questioned whether there is correlation between a number of shortages from the same MAH; EMA informed that based on the information made available no correlation has been identified. One SPOC noted an issue with another GLP-1 receptor agonist but most of the SPOC WP members have not observed any concern with supply issues.
	d) Update on Thrombolytics: Metalyse (CAP) and Actilyse (NAP) EMA provided an update on the shortage of thrombolytics and ongoing discussions on mitigating measures, including the support provided to Member States and the MAH to manage the limited supplies during the shortage period.
	e) Update on Human normal immunoglobulins (IGs) subgroup activities EMA presented an update on the preliminary analysis of the data on the survey of supply and availability of immunoglobulins from fall 2022. In addition, EMA provided an overview of the immunoglobulin breakout session of the HMA/EMA workshop planned for 1-2 March 2023.
6.	Major event. Criteria for the MSSG to grant a positive opinion on an actual or imminent major event EMA presented the revised draft of the criteria for the MSSG to grant a positive opinion on a major event.

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7.	Joint Action (JA) on shortages - Update Feedback was provided from the kick-off meeting that took place in Rome on 10 February 2023, where all working packages were presented, and the interplay between the EMA, EC and JA explained in detail.
8.	HMA/EMA Multi-stakeholder Workshop on shortages 1-2 March 2023 EMA presented the background information and the agenda for the Multi-stakeholder Workshop taking place on 1-2 March 2023, which was distributed to the SPOC WP members in advance of the meeting.
9.	Update on the EMA extended mandate implementation a) Status update on implementation activities for Medical Device Shortages EMA presented an update on the activities related to the establishment of the Executive Steering Group on Shortages of Medical Devices (MDSSG) and Medical Device Shortages SPOC Working Party (MDSPOC WP). EMA presented the preparatory activities such as development of the governance documents, and the activities of the ad-hoc drafting group.
10.	European Commission DG HERA - update DG HERA presented an update on the medical counter measures prioritisation exercise and the feedback from the workshop that took place on w/c 6 February 2023. DG HERA provided an update on the joint EMA-DG HERA-DG GROW joint industrial cooperation forum (JICF) subgroup for data collection, which is co-Chaired by EMA and DG HERA. <u>Comments raised</u> SPOC WP members highlighted the need to consider the consequences of stockpiling.
11.	<u>Improving transparency and communication to the public on shortages discussed in the SPOC WP</u> Proposal for publication of SPOC WP Meeting Summaries in EMA website EMA presented a proposal for review and publication of SPOC WP Meeting Summaries in EMA website. Agreed actions SPOC WP members endorsed EMA's proposal on the publication of meeting summaries in the EMA's website and the presented timelines (within 4 weeks after the SPOC WP meeting). Proposal to extend EMA shortage catalogue to also include shortages reflected in SPOC WP minutes EMA presented proposal to extend EMA shortage catalogue to include shortages reflected in SPOC WP minutes. <u>Comments raised</u>

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	SPOC WP members highlighted the possibility that information on shortages may raise public undue concern and the information should therefore also address this concern.
12.	Conclusions and next steps

Next meeting: 21 March 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).