18 April 2023
EMA/137098/2023
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

21 March 2023, from 10:30 to 13:30 (CET), virtual meeting WebEx

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

Item	Topics
1.	**Welcome, declaration of interest, adoption of draft agenda** The Vice-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. Changes to the SPOC WP membership were announced. Agenda was adopted with no additional points under AOB.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 15 February 2023** The Vice-chair informed that the minutes of the meeting held on 15 February 2023 had been distributed via email one week prior the meeting. No comments were received before or during the meeting. Minutes were adopted.
3.	**MSSG update: meetings held on 23 February and 15 March 2023** The Vice-chair gave a high-level update from the MSSG meetings held on 23 February 2023 and 15 March 2023. The following points were highlighted: • Proposal to consider the closure of European Medicines Regulatory Network (EMRN) COVID-19 Business Continuity Plan (BCP);

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	• COVID-19 vaccination plan for next winter's season and scientific updates on vaccines and therapeutics, including a survey on molnupiravir; • Adoption of the major event definition: criteria for the MSSG to grant a positive opinion on an actual or imminent major event; • Availability of antibiotics, including an update on the supply and availability situation and presentations from amoxicillin manufacturers; • Shortages of thrombolytics; • Shortages of Visudyne CAP.
4.	**Major event definition: criteria for the MSSG to grant a positive opinion on an actual or imminent major event** EMA gave an update on the internal MSSG guidance on assessment of possible major events. EMA informed that the document was adopted at the MSSG meeting on 23 February 2023.
5.	**Potential impact of the international situation (e.g. War in Ukraine) and energy crisis on the supply of medicinal products for human and veterinary use to the European market:**
	a) Antibiotic shortages: general update on coordinated actions EMA presented an update on the shortage situation in the EU and globally as well as on the MSSG discussion outcome on the proposal to monitor the supply and demand of a subset of antibiotics. EMA also presented the feedback from the meetings with a number of amoxicillin manufacturers. <u>Comments raised</u> Some SPOC WP members noted that situation with amoxicillin in paediatric formulations remained constrained, while other SPOC WP members did not consider the shortage situation to be critical due to availability of alternatives in other strengths or pack sizes. SPOC WP member noted the need for cooperation at the MAHs' local affiliate level to support the exercise in estimating the supply and demand for the next autumn/winter season. **Agreed actions:** • EMA to share the outcome report from the meetings with the MAHs (main suppliers of amoxicillin) with the SPOC WP members.
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) SPOC WP members noted issues with supply of certain antiepileptic medicines. **Agreed actions:** • EMA to include the topic on a situational update of availability of antiepileptics into the agenda of the SPOC WP meeting in April 2023.

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6.	**Update on ongoing shortages reported by the SPOC WP (non-PHE/ME related):**
	a) Visudyne CAP (MAH: Cheplapharm Arzneimittel GmbH) EMA presented an update on the shortage situation, including the absence of short- or mid-term mitigating measures from MAH and the feedback from the MSSG meeting on 15 March 2023. EMA presented the mitigating measures proposed by the drafting group for discussion. Comments raised SPOC WP members discussed the possibility to allocate products based on criticality however the difficulty to execute the allocation was noted. The drafting group would discuss this approach post-meeting. **Agreed actions** • EMA to update the DHCP and distribute for the review of the SPOC WP as per the current DHPC process. • The dedicated drafting group to formulate a draft approach to swich allocation from historical consumption to criticality and present the proposal for discussion at the next SPOC WP meeting.
	b) Thrombolytics: Metalyse CAP and Actilyse NAP (MAH: Boehringer Ingelheim) EMA presented an update on the situation with thrombolytics including the newest information on the availability of alteplase, tenecteplase and alternative treatments. Comments raised SPOC WP member asked for further information on the allocation of alteplase, and EMA highlighted the feedback received from the MAH. **Agreed actions** • EMA to further discuss with the MAH the allocation and the measures to reduce product wastage, and keep the SPOC WP informed.
	c) Menopur NAP (MAH: Ferring) EMA presented the current and long-term supply situation, as well as an update on the activities to mitigate the impact of shortages and an overview of discussions with manufacturers of alternative products.
	d) Ozempic CAP (MAH: Novo Nordisk) EMA presented the current supply situation of Ozempic, which remains critical in a number of EU/EEA markets. EMA and the dedicated SPOC WP Subgroup are in continuous dialogue with the MAH to ameliorate the impact of actual/incoming supply interruptions. SPOC WP agreed to continue monitoring the situation. The group agreed the MAH should provide monthly reports on the progress of their action plans.

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	Comments raised SPOC WP member raised question around Wegovy's market share in the US, to anticipate future EU marketing launch and draw parallels in the EU/EEA of possible impact to MAH's GLP1 supplies (for both Ozempic and Saxenda). **Agreed Actions** • EMA and the Subgroup to continue dialogue with the company on regular basis and provide feedback to the SPOC WP.
	e) Ixiaro CAP (MAH: Valneva Austria GmbH) EMA presented Ixiaro's marketing cessation in few Member States as well as the feedback collected from the SPOC WP and the MAH. EMA noted that interactions with the MAH will continue and possibilities to mitigate the impact to the affected countries will be explored. Comments raised SPOC WP member highlighted the measures at the NCA level and the need for cooperation from the MAH to mitigate the impact. SPOC WP member also emphasised the need of the medicinal product to be available in all EU/EEA markets.
7.	**Impact of nitrosamines on the availability of medicinal products:** • **Presentation of FIMEA's position paper on *"Nitrosamine Issues – Risks to Public Health and Proposed Actions for Consideration"*** FIMEA presented a position paper on nitrosamine issues which includes a review of foreseen risks concerning availability, considering the latest reports on complex API related nitrosamines (NDSRIs), and proposals for further actions to mitigate the effects of the nitrosamine issue on the availability of medicines. • **Update from EMA on coordinated actions on nitrosamines** EMA highlighted that the challenges raised by FIMEA are recognized in the network and there are ongoing discussions with the CMDh and CHMP, which also consider the proposal from FIMEA. EMA also noted that any decision on policy changes should take place at the Nitrosamine Implementation Oversight Group (NIOG), where CMDh and CHMP are represented. Discussions with international partners with the aim to align any policy changes will also be considered. Comments raised 2 SPOC WP members supported the problem statement raised by FIMEA and noted the risk of shortages due to precautionary measures taken by the MAHs once risk has been identified. **Agreed actions** • EMA to invite SPOC WP members to participate in the discussions of the Nitrosamine Implementation Oversight Group (NIOG).

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8.	**CAP shortage reporting process in the MSs and EMA** Topic could not be taken and was postponed.
9.	**Feedback from HMA/EMA Multi-stakeholder Workshop on shortages 1-2 March 2023** EMA shared key insights from HMA/EMA multi-stakeholder workshop on shortages which was well received by the high number of participants from the NCAs, industry associations, patients' organisations, HTA bodies and academia. Communication and transparency was highlighted as key issue during the workshop, and stakeholders called for proactive approach in preventing shortages. EMA confirmed that the report from the workshop is planned to be published in April 2023.
10.	**EC DG HERA – update** Topic could not be taken and was postponed.
11.	**Update on proposals to enhance shortage communication and transparency to the public** EMA presented a proposal to enhance shortage communication and transparency of the work on shortages at EU level, which includes the publication of minutes and agendas of MSSG and SPOC WP meetings. In addition, the proposal includes increased communication of individual shortages through the EMA shortages' catalogue. <u>Comments raised</u> SPOC WP members noted the need for guidance for answering questions from the media. **Agreed action** • EMA to include the topic on guidelines on communication on shortages into the agenda of the SPOC WP meeting in April 2023.
12.	**Conclusions and next steps** EMA thanked the SPOC WP members for their active participation and encouraged to raise any suggestions for topics for the SPOC WP face-to-face meeting in Amsterdam on 18 April 2023.

Next meeting: 18 April 2023, Amsterdam

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).