22 January 2024
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

14 December 2023, 10:00-13:00 (CET), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Patricia Tabernero (AEMPS, Spain)

Item	Topic
1.	**Welcome, declaration of interest, adoption of draft agenda** The Chair and Vice-Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party. EMA Chair thanked the Vice-Chair for the successful term and announced that the BE SPOC WP member will take over in January 2024 as the new rotating Vice-Chairperson under the Belgian Presidency of the Council of the EU. 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. Based on the topics in the agenda of the meeting, the SPOC WP Secretariat announced the applicable restrictions. 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 20 November 2023** The Vice-Chair informed that the minutes of the meeting held on 20 November 2023 had been distributed one week prior the meeting. One comment was received, and the minutes were updated to reflect this. Minutes were adopted with the above mentioned amendments.
3.	**MSSG Update: meetings held on 23 November and 13 December 2023** The Vice-Chair provided a high-level update on the points discussed at the 23 November and 13 December 2023 meetings of the MSSG, such as the EC communication on shortages and the Union list of critical medicines. The Vice-Chair informed that the discussion on preparedness activities for antibiotics, GLP-1 receptor agonists and Visudyne shortages also included oral explanations from the respective MAHs.

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4.	**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: Update on preparedness activities EMA provided an update on the shortages reported by the SPOC WP, and the feedback that in several MSs the situation is considered to be better than last year. Moreover, EMA presented the feedback from Sandoz oral explanation during the MSSG meeting in November 2023 and the feedback from alternative antibiotic suppliers. <u>Comments raised</u> A number of SPOC WP members informed that the situation is manageable, and no additional support is required at this stage. Nevertheless, SPOC WP members noted that the situation may change quickly depending on the epidemiological situation and ability to increase supplies if necessary, therefore potential future need for additional actions cannot be excluded. **Agreed action:** • SPOC WP members to continue reporting critical and non-critical shortages to EMA for the set of antibiotics.
	b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) Several SPOC WP members reported a potential shortage of an immunosuppressant medicine due to quality issues and another SPOC WP member highlighted issues with antibiotic suspensions due to a surge of mycoplasma pneumoniae cases for paediatric patients. Additionally, a SPOC WP member noted a shortage of a medicinal product used to treat tuberculosis due to company's commercial decisions. The SPOC WP member noted that there are no alternatives in their Member State with the same active substance. To mitigate the impact, the SPOC WP member is exploring the possibility of import from abroad. **Agreed action:** • SPOC WP members with critical shortage issues to report the information to the SPOC WP Secretariat for further action. **Impact of ongoing referral of Synapse Labs Pvt. Ltd. on availability of medicinal products in the EU/EEA** EMA informed the SPOC WP on the referral for Synapse Labs due to concerns raised during good clinical practice (GCP) inspection. EMA explained that CHMP recommended to suspend the marketing authorisations of a number of generic medicines tested by Synapse Labs, and the EC decision will be issued in due course. Nonetheless, the MAHs will be able to request a lifting of the suspension by providing new data demonstrating bioequivalence.

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	Comments raised SPOC WP member asked for clarity on the process and timelines in case MAHs appeal the EC decision. Other SPOC WP member informed that for medicines with the highest impact the evaluation is ongoing. **Agreed action:** • EMA to provide feedback to SPOC WP on the process and timelines in case of EC decision appeal.
	c) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets No immediate impact of the war is foreseen on the supply chain of medicines with manufacturing steps in Israel. **Agreed actions:** • SPOC WP members to report to EMA any impact of the Israel-Hamas war at the national level. • EMA to continue monitoring the situation by liaising with MAHs and Industry Associations.
	d) Update on impact of BREXIT on medicines availability SPOC WP member gave an update on the impact of BREXIT on medicines availability in their country. While the impact of BREXIT was of concern initially, the situation is now considered to be stable. Following the implementation of Directive (EU) 2022/642, a low number of derogation requests were submitted by MAHs and granted by Drug Council, hence the impact of the adopted legislative derogations was considered to be limited at a national level. Lastly, the SPOC WP member noted that the main root causes for shortages at a national level are currently linked to their Member State being a small market for pharmaceutical companies.
5.	**Ongoing critical shortages reported by the SPOC WP:** **a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim** EMA provided a brief update on the current status of the thrombolytics shortages in the EU/EEA, including the status of planned shortage mitigation activities in relation to distribution of additional Actilyse vials, new manufacturing site and new Metalyse strength and indication. Comments raised A planned communication by the company to stakeholders regarding future thrombolytics supply plans was discussed. EMA confirmed that the company will approach each Member State for agreement on the content prior to dissemination.

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	b) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited EMA provided an update on the expected relaunches of eptifibatide in the EU/EEA territories including pending actions and anticipated timelines. EMA also presented the latest feedback from alternative tirofiban suppliers as well as two newly identified eptifibatide manufacturers. **Agreed actions:** • EMA to liaise with the new identified eptifibatide manufacturers. • EMA to publish the shortage catalogue entry. *Post meeting note: Shortage catalogue entry was published on EMA website on 16 January 2024.*
	c) Abraxane CAP (paclitaxel) – MAH: Bristol-Myers Squibb Pharma; Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH EMA informed that Pazenir supplies are anticipated to be available until the end of 2023 and September 2024 for certain affected Member States; widespread shortages of nab-paclitaxel in 2024 are not anticipated due to the mitigating measures taken by Bristol-Myers Squibb Pharma for Abraxane.
	d) Attention deficit hyperactivity disorder (ADHD) medicine shortages EMA provided an update on the latest supply situation for lisdexamfetamine and methylphenidate from the key MAHs. However, shortages are anticipated to continue into 2024. **Agreed action:** • EMA together with the SPOC WP to continue monitoring ADHD medicines supply situation throughout 2024.
	e) Visudyne CAP (verteporfin) – MAH: Cheplapharm EMA provided an update on the supply situation of Visudyne including a new delay in the distribution of a specific batch, lack of measures to expedite the supply of batches to MSs in general as well as lack of timely and accurate communication from the MAH to the SPOC WP on allocation and delivery dates. Furthermore, EMA provided the feedback from Cheplapharm oral explanation during the MSSG meeting on 13 December 2023 and commitments made by the MAH in relation to the regular list of countries receiving units during the allocation process. Comments raised: SPOC WP members discussed the possibility of being more involved in Cheplapharm's allocation process. EMA also noted that MSSG agreed on the need for the SPOC WP to be closely involved in the allocation. **Agreed actions:** • EMA to contact Cheplapharm to request an equitable distribution of vials between all Member States.

Item	Topic
6.	**Definition of medicine shortage: follow up discussions from the F2F meeting in October 2023** As a follow-up to the discussion at the SPOC WP meeting in October 2023, the SPOC WP discussed the definition of a shortage and whether the definition should be applied to all medicines and which part of the supply chain determines when there is a shortage. Comments raised: A majority of the SPOC WP members agreed that all medicines should be included in the scope for the definition of a shortage. There were different views among SPOC WP members as to which part of the supply chain determines whether there is a shortage or not. The SPOC WP concluded that continued discussion is needed to better understand the level of the supply chain where the definition applies. **Agreed action:** • SPOC WP Secretariat to set up an ad hoc meeting to continue the discussion.
7.	**EC DG HERA update** DG HERA provided an update on the joint work with DG GROW on the supply chain vulnerability analysis for the first tranche of medicines included in the Union list of critical medicines. DG HERA presented the procedure, methodology and next steps for 2024.
8.	**Update on the Joint Action on Shortages (CHESSMEN) coordination activities** SPOC WP member provided an update on the JA CHESSMEN activities. It was highlighted that the current focus is on creating a stronger network through intersectoral cooperation and delving into other potential Joint Actions. Additionally, the SPOC WP member mentioned that a survey was launched to gather feedback and better understand whether there is an interest in undertaking any new activities.
9.	**HMA/EMA Task Force on Availability of authorised medicines**
	a) Union list of critical medicines EMA provided an update on the adoption and publication of the first version of the Union list of critical medicines on 12 December 2023. EMA presented the roadmap and next steps in relation to "Phase 2" and the aim to release the next version of the list by Q4 2024. EMA informed that "Phase 2" will include a larger number of medicines to be reviewed and will incorporate consultation with industry, patients and consumers and healthcare professionals.
	b) Shortage prevention and mitigation plans (SPMPs) EMA informed that the written consultation on SPMPs was launched on 1 December 2023 and reminded the SPOC WP members to provide their comments by 15 December 2023. EMA also informed the SPOC WP about the next steps, including the planned written consultation with industry.

Item	Topic
10.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 22 January 2024 (WebEx)

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).