EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 February 2025
EMA/55604/2025
European Medicines Agency

Meeting Summary — Medicine Shortages (SPOC) Working Party

21 January 2025, from 09:30 to 13:30 (CET), Webex

Chair: Monica Dias (EMA), Vice-Chair: Magdalena Rychter (GIF, Poland)

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1.	**Welcome, declaration of interest, adoption of draft agenda** The Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party (WP). EMA Chair welcomed the PL SPOC WP member as the new rotating Vice-Chairperson under the Polish Presidency of the Council of EU. The 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 meeting topics, the SPOC WP secretariat announced the applicable restrictions. Changes to the SPOC WP membership were announced. The agenda was adopted with no additional points under AOB.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 5 December 2024** The Vice-Chair informed that the minutes of the meeting held on 5 December 2024 had been distributed one week prior to the meeting. No comments were received before or during the meeting. The minutes were adopted. SPOC WP Secretariat informed the SPOC WP that, for transparency purposes and to ensure alignment with other EMA Committees and groups, from December 2024 the meeting minutes and summaries will include a list of participants and their competing interests.
3.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG meeting on 11 December 2024 EMA gave an update on the topics discussed during the face-to-face MSSG Meeting on 11 December 2024, highlighting updates on the European Shortages Monitoring Platform (ESMP)

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	and presentations from marketing authorisation holders (MAHs) Cheplapharm and Novo Nordisk, which were invited to the MSSG to discuss the supply and availability situation of specific products. Finally, EMA also informed about the last meeting of the Task Force on Availability of Authorised Medicines (TF-AAM), which was also held on 11 December 2024 as a joint TF-AAM/MSSG meeting and described the proposal to transfer TF-AAM structures to MSSG, SPOC WP and Working Group of Communication Professionals (WGCP).
	b) Voluntary Solidarity Mechanism (VSM): Presentation of the latest VSM procedure EMA presented the results of the latest VSM procedure launched in December 2024 for vincristine and the positive replies from 2 Member States (MSs). EMA added that, ultimately, the MAH was able to redistribute supply thus the issuing country did not need to make use of the support offered by the MSs. However, another MS experiencing a critical shortage was able to make use of this support.
	c) MSSG Working Group on the Vulnerability Assessment Methodology EMA informed the SPOC WP about an ongoing call for volunteers from the SPOC WP to establish two MSSG Working Groups (WGs). The MSSG WG on the Vulnerability Assessment Methodology will, in preparation for the proposed pharmaceutical legislation, progress the work on the development of a methodology to identify and evaluate vulnerabilities in the supply chains of critical medicines. The MSSG WG on VSM and policy will work on various topics that were previously under the TF-AAM Steering Committee (SC) remit and continue the activities of the current MSSG WG on VSM. Comments raised: One SPOC WP member asked about the current composition of the MSSG WG on VSM and the activities the group will undertake once expanded to include former TF-AAM activities. EMA explained that the group consists of members from the MSSG, SPOC WP, EC s and one Ministry of Health. EMA further noted that the group will continue to work on activities taken over from the TF-AAM which discontinued its activities in December 2024. Activities include the periodic review and update of the Union list of critical medicines and the pilot on Shortage Prevention and Mitigation Plans (SPMPs) pilot. In addition, the group will give guidance on activities outlined in the current European Medicines Agencies Network Strategy (EMANS) 2028 draft and will work in close collaboration with the to-be established SPOC WP subgroup on EMANS 2028 in this regard. Another SPOC WP member asked whether the groups will also focus on veterinary medicines. EMA Chair noted that, as per Regulation 2022/123, the mandate of the MSSG is only for human medicines; however, the MSSG WG on VSM and policy will also work on EMANS 2028, which also encompasses veterinary medicines. The Chair encouraged SPOC WP members from NCAs for veterinary medicines to volunteer for the Working Group.
4.	**Joint Action on shortages (CHESSMEN)** IT SPOC WP member presented an update on the outcomes of webinars, study visits and the multistakeholder workshop held in November 2024, with the latter having been summarised in a report. IT SPOC WP member stressed the importance of the strong collaboration and the possibility of additional exchanges and ad-hoc CHESSMEN meetings, which could also include participation from SPOC WP members that are not part of this Joint Action.

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	Comments raised: EMA Chair noted that CHESSMEN updates will be discussed regularly in the SPOC WP meetings to ensure input and agreement on CHESSMEN outputs from all MSs. EMA also asked whether the webinars and study visits have been recorded or whether reports are available. IT SPOC WP member noted that recordings and study visit reports will be made available. EMA Chair asked how CHESSMEN is ensuring that activities reach national stakeholders and are supporting the MSs. IT SPOC WP explained that support at national level is available through facilitation of contacts or by providing tools for implementation.
5.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	a) Availability of antibiotics — preparedness for autumn/winter 2024–2025 EMA provided an update noting that no new signals of supply disruptions were reported by key antibiotic MAHs and that supportive activities for two MSs have either concluded positively or are ongoing. EMA asked the SPOC WP whether the situation remains stable. Comments raised: Most SPOC WP members confirmed that the situation remains stable in their territories. Three SPOC WP members informed about supply constraints of antibiotics and respective mitigation measures in their territories. EMA agreed to liaise with these MSs to understand the need for any further support. **Agreed actions** • SPOC WP members to proactively inform EMA if critical shortages of antibiotics are identified.
	b) Availability of perfusion solutions following hurricane Helene EMA provided the latest updates received from an affected MAH, noting that while the production has resumed, shortages of irrigation and IV solutions could still be expected. A SPOC WP member presented local supply issues with irrigation and IV solutions due to increased demand and informed that efforts are ongoing with support of EMA to mitigate the situation.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) One SPOC WP member informed about an ongoing critical shortage of quetiapine containing medicinal products, noting manufacturing constraints as the root cause for the shortage. The SPOC WP member will follow up by submitting a critical shortage notification. In addition, supply issues for aprepitant and linezolid were noted. Some SPOC WP members indicated that they are experiencing shortages of quetiapine containing medicinal products, though they are not critical.
6.	**Critical shortages escalated to the SPOC Working Party:**
6.1	**Ongoing shortages**

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	a) NovoSeven (eptacog alfa) CAP – MAH: Novo Nordisk EMA provided an update on suggested mitigation measures by the MAH, feedback received from SPOC WP members in this regard and the current supply situation of NovoSeven. Comments raised: One SPOC WP member highlighted the need for increased transparency from the local affiliates on the supply information at national level.
	b) Availability issues of Teva medicines
	• **Overview of the overall shortage situation ("Closed session" for SPOC WP members)** EMA presented ongoing production issues which have either resulted in shortages or increase the risk of future shortages of a high number of Teva's oncology medicines. In addition, it was noted that VSM procedures have been launched for some of these medicines.
	• **Presentation delivered by MAH: Teva, followed by a Q&A session** Teva representative presented the root causes and activities conducted to mitigate the shortages. Teva representative explained that, as part of the shortage mitigating measures, bi-weekly updates and reporting on the supply situation will be provided to EMA. Comments raised: SPOC WP and the Chair highlighted the delays in communication and stressed the importance of fair and need-based stock distribution and timely and accurate information at affiliate level. EMA Chair further noted that EMA remains available to collaborate and the importance of timely communication regarding any future shortages. Teva representative noted that they were not aware of delays or discrepancies in communication and agreed to follow-up on these points post-meeting. Finally, Teva representative suggested a follow-up presentation to the SPOC WP in the future to update on the action plan and situation.
	• **Debrief on next steps/actions ("Closed session" for SPOC WP members)** SPOC WP agreed that follow up activities could include close monitoring of the supply situation and regular meetings with the MAH, inclusion of the products in the SPMP implementation pilot, and the development of an EU-wide communication on these shortages. Finally, the group discussed potential regulatory flexibilities that could be applied.
	c) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists EMA provided an update on the supply and availability situation of GLP-1 Receptor Agonists (RAs), with a focus on the supply situation for Trulicity which has improved and will be reflected in an upcoming update of a shortage catalogue entry. In addition, EMA informed the SPOC WP about the marketing authorisation of a generic liraglutide product. Furthermore, EMA informed the SPOC WP about an upcoming meeting with EMA and MAH Eli Lilly, the planned MSC for Victoza and Ozempic, and the published DARWIN EU Drug utilisation study on GLP-1 RAs.

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	Comments raised: Several SPOC WP members provided updates on the GLP-1 RA supply situation in their countries.
	d) Insulin-containing medicinal products EMA presented an overview of the criticality assessment on the discontinuation of selected insulin-containing medicinal products by Novo Nordisk, proposed alternative medicinal products and mitigating actions. As the next steps, EMA highlighted the ongoing activities of the clinical expert group on insulins and GLP-1 RAs as well as EMA and SPOC WP activities on risk assessment related to the discontinuations. The outcome of the expert group will be used to draft an MSC to inform healthcare professionals on the discontinuations.
6.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments to the written updates)
	a) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH b) Medicinal products from MAH: Cheplapharm c) Medicinal products containing salbutamol (inhalation use) d) Oncology medicinal products from Accord Healthcare B.V. e) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer Comments raised: SPOC WP members discussed the Pegasys supply situation in their territories.
7.	**European Shortages Monitoring Platform (ESMP) update** EMA provided a progress update on the development of the first version of the ESMP and shared the feedback on the shortage routine reporting by MAHs of centrally authorised medicines, launched on 28 November 2024. EMA informed the SPOC WP about the preparatory activities for the go-live of the full version of the ESMP on 29 January 2025, including the release of features for NCAs and MAHs to be used in crises and MSSG-led preparedness activities. EMA also provided feedback from the crisis simulation user acceptance testing (UAT) that took place mid-December 2024 with volunteers from several NCAs and MAHs — overall, the testing identified no issues that would prevent the ESMP from its planned launch. Finally, EMA informed about the ESMP training for NCA functionalities on 30 January 2025. Comments raised: Several SPOC WP members congratulated the ESMP team on the achievement. One SPOC WP member asked how the information for routine shortage reporting for CAPs collected through ESMP will be accessible to relevant NCAs. EMA explained that the shortage reporting of CAPs through the ESMP only replaces the current process at EMA and is not meant to replace national reporting processes. Nonetheless, the data will be continuously analysed and escalated as needed to the SPOC WP, as it is being done at the moment. Another SPOC WP member asked for further elaboration on the interoperability of the ESMP with national systems. EMA explained that interoperability to allow the exchange of data between

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	different systems is being worked on but there is a need for further development on NCA side to link submissions from national systems to the ESMP.
8.	**EC DG HERA update** DG HERA provided an update on the Critical Medicines Alliance (CMA), noting that recommendations from the Working Groups have been finalised and will be submitted to the CMA forum for open consultation and presented in a CMA forum plenary meeting, planned for mid-February 2025. DG HERA also noted that the CMA's future workstreams are also currently being planned. DG HERA further noted that DG SANTE is leading and progressing work on the Critical Medicines Act.
9.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 18 February (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).

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* Competing interest declared resulting in no participation in discussions and decisions with respect to agenda point 3 b), 5 a), 6.1 b) and 6.3 c)	
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