21 January 2025
European Medicines Agency

Meeting Summary — Medicine Shortages (SPOC) Working Party

5 December 2024, Webex

Chair: Monica Dias (EMA), Vice-Chair: Veronika Horváth (NNGYK, Hungary)

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. The Chair thanked the Vice-Chair for the successful term and announced that the PL SPOC WP member will take over in January 2025 as the new rotating Vice-Chairperson under the Polish Presidency of the Council of the 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, applicable to members and experts of the SPOC WP, and 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 6 November 2024** The Vice-Chair informed that the minutes of the meeting held on 6 November 2024 had been distributed one week prior to the meeting. No comments were received prior to or during the meeting and the minutes were adopted.
3.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG meeting on 19 November 2024 SPOC WP Vice-Chair provided the feedback on the topics discussed during the November meeting of the MSSG, highlighting updates on preparedness activities for autumn/winter 2024-2025 in relation to antibiotics availability and the impact of Hurricane Helene on the availability of medicinal products.

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	Additionally, the MSSG discussed the supply and availability of insulin-containing medicinal products, methodology to identify the vulnerabilities in the supply chain, the launch of the SPMP pilot and recommendations to stakeholders for radiopharmaceuticals. Additionally, the Vice-Chair informed that updates from the MSSG WG on Voluntary Solidarity Mechanism (VSM) and the Critical Medicines Alliance (CMA) were provided.
	b) MSSG recommendations to address the vulnerabilities in the supply chain EMA presented the proposed approach to develop the Critical Medicines Vulnerability Analysis Methodology. A working group of the MSSG will be established to develop the methodology, which will then be applied to identify vulnerabilities in the supply chains of critical medicines on the Union list and inform MSSG recommendations, in accordance with the proposed pharmaceutical legislation. In the meantime, critical shortages will continue to be raised through the SPOC WP with the possibility for the MSSG to issue recommendations, including to address identified vulnerabilities in the supply chain. In addition, EMA provided information on the 6-month pilot on Shortage Prevention and Mitigation Plans (SPMP), which will be launched in December 2024 and is voluntary for MAHs and NCAs. Lastly, EMA detailed that the MSSG will continue to progress with the proposal for recommendations to address identified vulnerabilities in the supply chain of radioisotopes (including ensuring the security and continuity of supply, addressing transport challenges, expanding monitoring to additional radioisotopes and horizon scanning activities).
4.	**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 informed the SPOC WP that the MAHs have not reported any signals of concern, nor were signals of concern raised by international regulators. <u>Comments raised</u> Most MSs reported that the antibiotic supply situation remains stable, but two MSs reported some local issues and EMA agreed to liaise with these MSs individually to provide support if needed.
	b) Impact of the hurricane over US territory on availability of medicinal products in Europe EMA provided recent feedback from the SPOC WP and affected MAHs regarding products affected by Hurricane Helene, and shared contact information for alternative suppliers. A SPOC member presented mitigation measures implemented to facilitate importation of IV fluids (one of the affected products) from abroad. <u>Comments raised</u> Most SPOC WP members confirmed that the shortages of IV solutions have either been resolved or are no longer critical.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)

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	A SPOC WP member provided an update on a recent national ruling indicating that general permission to obtain medicines from abroad in the event of a shortage is in violation of the national Medicines Act. The SPOC WP member noted that the ruling is in response to a complaint brought forward by an individual compounding pharmacy and that a viable pathway to have medicines available for patients during shortages is being explored. A SPOC WP member informed of a critical shortage of immunotherapy for treatment of bee/wasp allergy and asked if other countries have a similar experience. Based on the immediate feedback from the SPOC WP, the product is not marketed in most other MSs and the issue is being followed up at national level.
5.	**Critical shortages escalated to the SPOC Working Party:**
5.1	**Ongoing shortages**
	a) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists EMA provided an overview on the GLP-1 RA shortage and informed the WP that a Medicine Shortage Communication (MSC) for Ozempic and Victoza will be published and the shortage catalogue entries for Trulicity, Ozempic and Victoza will be updated.
	b) Insulin-containing medicinal products EMA presented results of the criticality analysis on the discontinuation of selected Novo Nordisk insulin products, details of the discontinuation strategy, and information on historic sales and market shares of the impacted products. <u>Comments raised</u> EMA informed that SPOC WP members may nominate members to the clinical expert group on insulin products and GLP-1 RAs to further discuss the impact of the discontinuations. **Agreed actions:** • SPOC WP members to nominate members to the clinical expert group and to provide further feedback to EMA on the impact of the discontinuation.
	c) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH EMA provided an update on the Pegasys supply situation following the meeting held with the MAH and the SPOC WP members from the most affected countries, noting that the situation is unchanged and EMA is cooperating with the MAH on fair stock allocation, following SPOC WP guidance. <u>Comments raised</u> Several SPOC WP members emphasised the need to ensure fair allocation of products.
	d) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris This topic could not be taken.
	e) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk This topic could not be taken.

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	f) Medicinal products from Cheplapharm EMA provided an update on the ongoing critical shortage of Visudyne and noted that the MAH is invited to the MSSG meeting on 11 December to provide a detailed update on the supply situation and mitigating activities.
5.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments to the written updates)
	a) Medicinal products containing salbutamol (inhalation use) b) Oncology medicinal products from Accord Healthcare B.V. c) Nakom NAP (levidopa/carbidopa) – MAH: Sandoz d) Chenpen NAP (epinephrine) – MAH: Bioproject Pharma; Jext NAP (epinephrine) – MAH: Alk-Abello e) Synulox NAP (amoxicillin/clavulanic acid) – MAH: Zoetis
6.	**European Shortages Monitoring Platform (ESMP) update** EMA informed the SPOC WP that ESMP went live on 28 November with the functionality of routine reporting of CAP shortages by MAHs; other functionalities will go-live by February 2025. EMA clarified that the functionalities currently anticipated are those of the minimum viable product (MVP) laid out in Regulation (EU) 2022/123. Development of further functionalities after March 2025 can only be initiated when budget permits. EMA also provided updates on the routine shortage reporting training webinar for MAHs, the Monitoring Country Tool user acceptance testing (UAT) with NCAs in November, and the crisis simulation UAT with MAHs and NCAs taking place in December. Comments raised In response to questions, EMA clarified that the ESMP does not currently have a public interface planned as the EMA shortage catalogue already fulfils the Regulation's requirements for release of information to the public; the ESMP training sessions are anticipated in February 2025 and the recordings will also be available afterwards.
7.	**HMA/EMA Task Force on Availability of Authorised Medicines (TF-AAM)**
	a) Union list of critical medicines EMA provided an update on version 2 of the Union list of critical medicines (ULCM), which was developed using feedback from MSs and various stakeholder groups. EMA presented the version 2 of the ULCM, provided insights on the feedback received during the stakeholder consultation, informed on the planned activities for the adoption and publication (planned in mid-December), and acknowledged the EU-level coordinated effort of the HMA/EMA TF-AAM "Union List" Working Group, SPOC WP, and NCAs in the development of the list.
	b) The closure of the HMA/EMA TF-AAM EMA informed the SPOC WP about the closure of the HMA/EMA TF-AAM (Task Force on Availability of Authorised Medicines for Human and Veterinary Use). Specifically, EMA

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	explained that the structures and work of the TF-AAM will be transitioned to the MSSG, SPOC WP and Working Group of Communication Professionals (WGCP), going forward. EMA noted that the TF-AAM will formally close at the joint TF-AAM/MSSG face-to-face meeting on 11 December 2024.
8.	**Communication on shortages: feedback from EMA media seminar** On 22 November, EMA hosted journalists from countries all over the EU/EEA in a media seminar that aimed to increase awareness of the work the Agency and the EU regulatory network are doing to fight medicines shortages. The seminar included presentations by healthcare professionals' and patients', DG SANTE and DG HERA, EMA on EU level coordination, ESMP and case studies on antibiotic and GLP-1 RA shortages. Lastly, EMA informed that the overall feedback from the journalists was positive and the event has generated positive media coverage. <u>Comments raised</u> A SPOC WP member asked whether EMA has launched any social media campaigns and additionally asked about involvement of healthcare professionals (HCPs) and patients in communication activities. EMA responded positively noting the social media campaign on antibiotics and campaigns informing about good practice guides to HCPs and patients organisations developed under TF-AAM.
9.	**EC DG SANTE update**
	EC DG SANTE provided an update from the 19 November 2024 *ad hoc* Pharmaceutical Committee meeting on national contingency stocks, which included a presentation of the results of the survey on contingency stocks as well as a discussion on possible common principles of proportionality, solidarity and transparency. As the next steps, a document on common principles will be drafted and discussed at a future Pharmaceutical Committee meeting. <u>Comments raised</u> A SPOC WP member asked whether the outcomes of the discussion are publicly available to which EC responded that the information will be published on a dedicated page of the EC website.
10.	**EC DG HERA update**
	EC DG HERA provided an update on the activities of the Critical Medicines Alliance (CMA), highlighting the set of recommendations and their adoption process. DG HERA explained that the recommendations will subsequently be transposed into a Strategic Action Report, planned to be finalised by early 2025.
11.	**AOB** No additional topics were raised.
12.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 21 January (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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