7 October 2024
EMA/453004/2024
European Medicines Agency

Meeting Summary- Medicine Shortages (SPOC) Working Party

11 September 2024, 09:30 – 13:40 (CEST), Webex

Chair: Monica Dias (EMA), Vice-Chair: Veronika Horvath (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 (SPOC WP). The SPOC WP secretariat reviewed members' and experts' declared interests in accordance with the Agency's policy on the handling of declarations of interests (DoI) of scientific committees. Based on the meeting agenda topics, the SPOC WP secretariat announced the applicable restrictions. Changes to the SPOC WP membership were announced. The agenda was adopted with an additional point under AOB to inform about the next steps for Medicine Shortage Communication (MSC) template and process.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 17 July 2024** The Vice-Chair informed that the minutes of the meeting held on 17 July 2024 had been distributed one week prior to the meeting. No comments were received before or during the meeting. The minutes were adopted.
3.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Solidarity Mechanism: feedback from the etoposide case EMA presented the results of the fourth Voluntary Solidarity Mechanism (VSM) procedure and the positive feedback received from Member States (MSs) and marketing authorisation holders (MAHs). EMA noted that the VSM was launched due to the urgency of the situation, despite the fact that some of the VSM conditions not having been met (i.e. prior escalation of the shortage to the SPOC WP).

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Item	Topic
	Comments raised: The SPOC WP member of the country that launched the VSM expressed their thanks for the support received from MSs, and noted the need for improved oversight by companies on the stocks available in different MSs. The SPOC WP member explained that the transfer of stock was simplified due to a special import license and will further investigate how this tool can be improved in the future. A few SPOC WP members informed the SPOC WP that, in some cases, knowledge of the VSM launch in a MS led to stockpiling activities in hospitals of other MSs.
4.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	a) Impact of tightened espionage laws in China The SPOC WP was informed that, in contrast to what was reported in the media, inspections in China continue to take place and supply constraints for medicinal products are not expected at this point in time.
	b) Suspension of API manufacturing site EuroAPI in Brindisi EMA informed the SPOC WP that the manufacturing site was inspected with a positive outcome. As a consequence, the GMP certificate was issued with no restrictions on product manufacturing.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) Comments raised Some ongoing shortages of antibiotics were noted by a few MSs, although alternatives are available. EMA added that interactions are ongoing with MAHs of key antibiotics to understand expected supply constraints for the autumn/winter season and further feedback will be shared in the MSSG meeting on 18 September 2024 and the SPOC WP F2F meeting on 7–8 October 2024. EMA informed the SPOC WP of a shortage of the veterinary medicinal product containing telmisartan, noting the MAH's mitigating plans to accelerate the supply. **Agreed actions:** • SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP if the abovementioned shortage situations in their territories deteriorate.
5.	**Activities under Joint Action on Shortages (CHESSMEN) work package 8 (WP 8): Export bans and parallel trade and other planned mitigation and prevention measures** SPOC WP member provided an update on WP 8 activities, timelines and next steps. As part of the WP 8 activities, SPOC WP members will be surveyed on export restrictions and other prevention and mitigation measures that can be taken at national level to address shortages. The survey results will be used to provide an overview of national measures and to inform best practices. They will be presented in a future SPOC WP meeting and during the CHESSMEN multi-stakeholder meeting taking place in November 2024.

Item	Topic
6.	**Impact of serialisation on multilingual packaging** CMDh representative informed the SPOC WP about the CMDh survey to the pharmaceutical industry on aspects linked to the safety features introduced by the Falsified Medicines Directive and its Delegated Regulation. Considering the difficulties in achieving further harmonisation of serialisation codes, CMDh has asked the SPOC WP and the Expert Group 'Delegated act on safety features for medicinal products for human use' to provide additional feedback as a follow-up to the survey.
7.	**Critical shortages escalated to the SPOC Working Party:**
7.1	**Ongoing shortages**
	a) Oncology medicinal products from Accord Healthcare B.V. EMA presented an update on critical shortages of cisplatin and fluorouracil, including the feedback from discussions with Accord and alternative MAHs, and ongoing regulatory support. EMA also provided feedback from a few alternative MAHs on their ability to support MSs experiencing critical shortages, by increasing their supply of cisplatin and fluorouracil. Lastly, EMA has invited Accord to attend the face-to-face SPOC WP meeting in October 2024.
	b) Chenpen/Anapen NAP (epinephrine) – MAH: Bioprojet Pharma; Jext NAP (epinephrine) – MAH: ALK-Abello EMA provided background information on a shortage of epinephrine by Bioprojet Pharma, presented the results of the SPOC WP survey and informed the WP that discussions on the current situation with Bioprojet Pharma and other MAHs will take place. EMA also noted that a medicinal product Eurneffy (epinephrine) has been authorised in the EU/EEA recently (August 2024) which could potentially improve the supply situation of epinephrine, once available. <u>Comments raised</u> SPOC WP members informed about the situation in their territories, highlighting the aspects linked to availability of alternatives on the market and ongoing discussions with MAHs to minimise the impact of the ongoing shortage.
	c) Synulox NAP (amoxicillin/clavulanic acid) – MAH: Zoetis EMA presented a CMDv query to the SPOC WP on the supply situation of Synulox products for injection and intramammary use in specific animals. EMA presented the SPOC WP survey results and the criticality assessment which will inform further discussions. <u>Comments raised</u> A SPOC WP member noted that in their country, in the event of a shortage of an antibiotic of first choice such as amoxicillin/clavulanic acid, it is likely that second- or third-line antibiotics will start to be used, which will have a negative impact on antimicrobial resistance (AMR).

Item	Topic
	d) Mimpara CAP (cinacalcet) – MAH: Amgen Europe B.V. EMA shared the latest update received from the MAH, including the implemented mitigation measures, and next steps. EMA informed that MAH Amgen will determine the feasibility of further mitigation measures and will stay in continued discussions with EMA. One SPOC WP member presented the situation and the national measures undertaken, linked to recommendations for alternative treatments and product import.
	e) Medicinal products containing atomoxetine A SPOC WP member presented an overview of shortages of atomoxetine-containing medicinal products, informed about short and long-term measures that have been or will be implemented to alleviate the shortage and noted ongoing discussions with the MAH. Comments raised EMA informed that the SPOC WP has conducted a criticality assessment that identified the availability of alternatives for atomoxetine medicinal products in most countries. EMA informed that the situation for other ADHD medicines remains stable with some local shortages; ADHD medicines are being closely monitored in the Global Regulatory Working Group.
	f) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists EMA provided an update on the current supply situation of GLP-1 RAs and informed the WP that the latest Direct Healthcare Professional Communication (DHPC) for Ozempic and Victoza was circulated in August and subsequently published. EMA's shortage catalogue entries have also been updated and are being finalised. EMA provided feedback from meetings with the marketing authorisation holders of relevant GLP-1 RAs in shortage.
	g) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk EMA provided an update on the shortage of NovoSeven due to a manufacturing issue and the potential impact of this on the supply of other medicinal products. EMA provided the feedback from the latest discussions with the MAH regarding potential mitigation actions and informed that the DHPC was published in August 2024. Comments raised: One SPOC WP member highlighted the difficulties in receiving commitment on product replenishment by the MAH and noted the discrepancies in the information shared with EMA and NCAs. Several SPOC WP members exchanged information about the ongoing shortages of NovoSeven in their territories.
	h) Medicinal products from Cheplapharm EMA provided an update on the ongoing shortages of Visudyne (verteporfin) and Zypadhera (olanzapine). EMA informed about the mitigation measures planned by the MAH including a detailed report listing all shortage mitigation proposals.
7.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments to the written updates)
	a) Medicinal products containing salbutamol (inhalation use)

Item	Topic
	b) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris No comments were raised on the abovementioned shortages.
8.	**HMA/EMA Task Force on Availability of Authorised Medicines:**
	a) Union list of critical medicines EMA updated on the progress of the second version of the Union list, noting that the deadline to complete the MSs categorisation activities for Phase 2 Batch 3 is 13 September 2024. EMA informed that replies from MSs will be processed as next steps. EMA also informed on the planned engagement activities with targeted stakeholder groups and across the Regulatory Network before the list is finalised. Version 2 of the Union list is planned to be published in the first half of December 2024.
	b) Shortage prevention and mitigation plans (SPPs/SMPs) EMA provided an update on the pilot for the SPPs/SMPs implementation after its adoption by the TFAAM-Steering Committee on 10 September 2024. For the pilot, SPPs/SMPs for a reduced number of molecules are suggested. EMA explained that the launch of the pilot is planned for December 2024.
9.	**Survey on national approaches to shelf life extension of medicines stockpiled in preparedness to health threats** EMA introduced a survey to collect information from the SPOC WP on national approaches to extending the shelf life of medicines that have been stockpiled in the context of preparedness activities for future public health threats (mainly chemical, biological, radiological or nuclear (CBRN)). EMA noted that the survey results will be shared with the SPOC WP and MSSG and the results may inform discussions on additional need for support and coordination at EU level.
10.	**EC DG HERA update** EC DG HERA provided an update on the progress of the Critical Medicines Alliance (CMA), and its Working Groups (WGs) noting that the WGs results will be developed into recommendations as part of a strategic report. <u>Comments raised</u> EC DG HERA explained that the CMA WG1 is elaborating a concept note, outlining the potential of the methodology and framework to conduct the vulnerability assessment of critical medicines. The outcome of the concept note will be summarised in the strategic recommendations and could provide useful reflections for the future vulnerability assessment. The CMA WG recognised that the concept note discussion on VA methodology requires involvement of technical expertise that resides within MSSG. Upon SPOC WP member question, DG HERA confirmed that draft CMA recommendations will undergo CMA consultation from end of November. Final CMA strategic recommendations are expected in early 2025.
11.	**AOB** EMA shared an update on the Medicine Shortages Communication (MSC), which is a new process for communicating medicine shortage information to HCPs when there are no safety, efficacy or quality issues. In such situations, the usual Direct Healthcare Professional Communication (DHPC) is not considered appropriate. After written consultation with the SPOC

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	WP, the MSC process and template will now be presented at the MSSG September 2024 meeting for endorsement. The new process will be implemented through a pilot starting in October 2024. The pilot would support identifying potential issues with implementation and dissemination, and on the need to adjust the process or template based on experience.
12.	**Conclusions and next steps** EMA highlighted two events related to the European Shortages Monitoring Platform (ESMP), i.e. a System Demo on 18 September 2024 and a Webinar on Product Management Service (PMS) data mapping support for NCAs on 19 September 2024.

Next meeting: 7–8 October (hybrid – F2F+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).