



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 November 2023
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

12 September 2023, from 10:00 to 13:15 (CEST), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Maria Criado (AEMPS, Spain)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda The Chair and Vice-Chair welcomed participants to the Medicine Shortages SPOC Working Party meeting. SPOC WP Secretariat reviewed members' and experts' declared interests in accordance with the Agency's policy on handling declarations of interests (DoI) of Scientific Committees applicable to members and experts of the SPOC WP and announced the relevant restrictions. The agenda was adopted with no additional points under AOB.
2.	Adoption of draft minutes of the SPOC WP meeting held on 6 July 2023 The Vice-chair informed that the meeting minutes held on 6 July 2023 had been distributed on 6 September 2023. No comments were received before or during the meeting. Minutes were adopted.
3.	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 joint EMA/HERA preparedness activities EMA presented the outcomes of matching the supply and demand for a subset of antibiotics, the recommendations of the MSSG, actions undertaken over the summer and the next steps of the preparedness exercise. <u>Comments raised</u> SPOC WP discussed the outcomes for certain antibiotics in the demand scenarios, NCAs' demand and the situation at a national level. EMA explained the differences between historical demand and NCA estimates. Furthermore, EMA explained that the analysis was subject to a number of assumptions and was undertaken at EU level and not at MS level.

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	NCA SPOC questioned whether the outcomes could be used in discussions with MAHs, and EMA responded that further details from the SPOC WP on the antibiotics in shortages are required to be able to take follow-up actions, including discussions with the industry. Agreed actions: SPOC WP to report all ongoing and potential shortages of the set of antibiotics to EMA.
	b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) NCA SPOC noted shortage issues for ADHD medicines methylphenidate and lisdexamfetamine and also for the growth hormone somatropin. Another NCA SPOC presented NAP shortages of antithrombotic agent dipyridamole and a cardiac glycoside, digoxin immune fab. Additionally, the NCA SPOC highlighted a permanent marketing cessation of certain fenoterol/ipratropium bromide-containing medicinal products. <u>Comments raised</u> EMA informed that a SPOC WP member reported a shortage of lisdexamfetamine in August 2023, and the root causes were presented. SPOC WP members shared their experience using certain regulatory flexibilities to mitigate the shortage. Agreed actions: - EMA to bring the shortages of ADHD medicines to the Global Regulatory WG on Drug Shortages meeting in September 2023. - SPOC WP will continue monitoring the availability of disrupted medicines presented under this item.
4.	Ongoing critical shortages reported by the SPOC WP:
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim; EMA provided an update on the ongoing shortages of thrombolytics. EMA also provided a status update on the MAH supply plans for 2024 and the ongoing regulatory activities to increase the availability in the long term.
	b) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH EMA presented the supply situation for Visudyne in the EU/EEA, including the measures to be implemented by the MAH to mitigate the impact. EMA also presented the status of shortages of other medicinal products marketed by Cheplapharm, such as Rivotril (clonazepam), Hydrea/Litalir (hydroxycarbamide), Fungizone (amphotericin B), Etalpa (alfacalcidol) and Valcyte (valganciclovir) and the shortage management plans for each of them. Agreed actions: SPOC WP members to inform EMA if the above shortages worsen as well as of any new critical shortages of Cheplapharm's authorised medicinal products. This will support the ongoing interaction with the company.

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	c) Glucagon-like Peptide-1 (GLP1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide); MAH: Eli Lilly Nederland B.V. EMA presented an update on the communication activities, such as publishing the shortage catalogue entries on Ozempic, Rybelsus, Trulicity and Saxenda. EMA also gave an outlook on the supply plans for GLP-1 receptor agonists for the 2nd half of 2023 and the next steps. <u>Comments raised</u> NCA SPOC shared that the communication to inform patients and HCPs about these shortages has also been published nationally.
	d) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited EMA provided an update on the discontinuation of Integrilin, including the expected stock-out dates per country. EMA presented the proposed mitigating actions, including interactions with alternative manufacturers. <u>Comments raised</u> NCA SPOC questioned how the shortage is mitigated at national level, and EMA explained that some feedback was received from the SPOC WP members at the beginning of the summer 2023.
	e) Hycamtin CAP (topotecan) – MAH: Sandoz Pharmaceuticals d.d. EMA provided an update on the critical shortages of topotecan oral formulations. EMA informed that some MSs use IV topotecan formulations as a mitigating measure. Lastly, EMA presented MAH's resupply plans and its mitigating actions.
	f) Methotrexate IV NAP – MAH: Medac GmbH EMA provided an overview of the supply situation of methotrexate injections in the EU/EEA and the feedback from various methotrexate manufacturers. EMA also provided feedback from the exchanges with international regulators and informed the SPOC WP that the situation will continue to be monitored.
5.	Update from EC DG HERA DG HERA provided an update on the activities related to RSV vaccines and therapeutics.
6.	Joint Action on Shortages (CHESSMEN): Update on the CHESSMEN questionnaire regarding the shortage definition NCA representative presented the outcomes of the survey in relation to the shortage definitions, categorisation, and MAH reporting requirements. NCA representative informed the SPOC WP that the questionnaire on the shortage definition, distributed to the Joint Action on Shortages (CHESSMEN) Work Package 5 members and the SPOC WP, aims to support the standardisation of key terminology related to medicines shortages. <u>Comments raised</u> The Chair highlighted that discussions on the shortage definition took place at the SPOC WP last year, and the information already collected should be considered. Additionally, the Chair informed that the root causes of shortages have been agreed upon by the SPOC WP and the work of the HMA/EMA TF AAM on definitions should be used as a starting point.

Item	Topic
	Agreed actions The topic to be brought back to the SPOC WP face-to-face meeting on 26 - 27 October 2023.
7.	HMA/EMA Task Force on Availability of authorised medicines: Union list of critical medicines – launch of Phase 1 EMA provided an update on the rollout of the 1st phase of the Union list of critical medicines. The SPOC WP was requested to review the 1st batch of medicines subject to criticality categorisation by September 2023, and many MSs have engaged in the process. The 2nd batch review is due in October 2023. EMA explained the steps to be undertaken in preparation for the rollout of the 1st phase of the Union list and thanked the SPOC WP for their valuable contributions.
8.	MSSG Recommendations on shortages of medicinal products toolkit EMA presented the draft MSSG toolkit on recommendations for tackling shortages of medicinal products. The toolkit is a living document built on experience gained during COVID-19 and recent critical shortages (e.g., antibiotics, thrombolytics). Recommendations will be tailored according to the criticality of the shortage and may include monitoring supply/demand, European cooperation, increased supply and fair distribution, regulatory flexibilities, communication and international collaboration. EMA informed that the written consultation (SPOC WP, CMDh, IWG and QRD WG) is ongoing until 15 September 2023, and the outcomes will be discussed at the MSSG on 22 September 2023.
9.	Presentation of results of the survey on safety stocks EMA presented the results of the survey on national safety stocks. The survey was conducted in light of the ongoing work on the MSSG solidarity mechanism. The study aimed to map the existing national systems and understand the views of the MSs.
10.	ESMP status update and interoperability EMA presented a progress update on the ESMP and the priorities – from the analysis, development, and testing perspective – for the upcoming Programme Increment (PI) Planning event at the end of September 2023. EMA also informed the SPOC WP of the forthcoming workshops on ESMP interoperability starting in October 2023.
11.	Presentation of results of the recent surveys on shortages: feedback from surveys on communication practices of medicine shortages EMA presented the feedback from a survey to NCAs on their experience communicating on the shortages of amoxicillin, Ozempic and Visudyne, including any challenges and potential future changes in NCA communication practices. In addition, EMA presented the feedback from surveys to patients and healthcare professionals to understand how they were informed about these recent medicine shortages and their feedback on the usefulness of the information provided and any missing information.
12.	Conclusions and next steps EMA Chair reiterated the need for contributions from all SPOC WP members in the review of the 1st and 2nd batches of the EU list of critical medicines.

Item	Topic
	EMA Chair reminded that the SPOC WP October 2023 meeting will be held at EMA premises in Amsterdam and invited members to participate in person. WebEx connection will also be available for participants to join remotely.
	The agreed actions are detailed above.

Next meeting: 26-27 October 2023 (F2F in Amsterdam + 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).