20 June 2024
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

22 May 2024, virtual meeting – WebEx

Chair: Monica Dias (EMA), Vice-Chair: Sybille Schotte (FAMHP, Belgium)

Wednesday, 22 May 2024	
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 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. The Chair welcomed observers from eight pre-accession countries to the SPOC WP meeting. Observers will currently only follow certain parts of the SPOC WP meetings. 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 15-16 April 2024** The Vice-Chair informed that the minutes of the meeting held on 15-16 April 2024 had been distributed one week prior to the meeting. No comments were received before or during the meeting. Minutes were adopted.
3.	**Data Analysis and Real World Interrogation Network (DARWIN EU®): studies to support shortage monitoring and preparedness** EMA presented the DARWIN EU network and explained how real world evidence can support regulatory decision-making. EMA presented the ongoing studies to support the SPOC WP in shortage monitoring and preparedness, which include monitoring prescriptions of medicines for public health emergencies at risk of shortages, monitoring prescriptions of essential medicines

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	administered in ICU, trends in utilisation of ADHD medications, and the use of GLP-1 Receptor Agonists (RA). Comments raised The Chair welcomed the DARWIN EU initiative in the area of medicine shortages. The group asked for clarity on the timelines for conducting the studies, the ARIMA model used for forecasting antibiotic prescriptions, and whether other epidemiological data such as learnings from the situation in the Southern Hemisphere can be considered in this model. EMA explained that timelines for assessing and conducting the study depend on the complexity of the study design and can vary between 1-2 months for in-house studies, 3 months for standard DARWIN EU studies and 5-6 months or more for complex DARWIN EU studies. Additionally, EMA clarified that the (seasonal) ARIMA model takes into account the seasonality and the auto-correlated nature of the data; various other parameters such as the COVID-19 pandemic, data on reimbursement/restriction of use and potentially estimates obtained from the situation in the Southern Hemisphere can be considered (with pros and cons for such modelling and the need for individual evaluation). **Agreed actions:** • EMA to bring the topic back for discussion when the results on studies to support shortage management and preparedness are available.
4.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:** **a) Impact on the supply of medicines of the takeover of three Catalent sites by Novo Nordisk** EMA continue to assess the potential impact of the takeover of three Catalent manufacturing sites by Novo Nordisk. Currently the SPOC WP and EMA are monitoring the potential shortage of an antibiotic medicine manufactured at one of the impacted sites and are actively working with the MAH regarding the next steps to mitigate the potential impact for the patients in Europe.
	b) Suspension of API manufacturing site EuroAPI in Brindisi EMA provided an update on the preliminary results of the inspection of the manufacturing site EuroAPI in Brindisi which led to its suspension. The SPOC WP is currently monitoring the impact on the availability of the impacted medicines. **Agreed action:** • SPOC WP members to inform EMA in case a critical shortage for any of the APIs is identified.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member informed about the expected availability issues for an antibiotic medicine due to the planned withdrawal from the market in the coming years. A number of SPOC WP members informed that there are no shortages of this medicinal product in their countries.

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5.	**Critical shortages escalated to the SPOC Working Party:**
	a) Solidarity Mechanism: feedback from 2nd and 3rd cases EMA informed the SPOC WP about the positive outcome of the second (cisplatin) and third (methotrexate) solidarity mechanism procedures. As the next steps, MSSG Working Group on Solidarity Mechanism will be reinstated to assess the outcome and process for the first three pilot cases, undertake a lessons learned exercise and fine-tune operational aspects of the procedure.
	b) Methotrexate IV NAP (methotrexate) – MAH: Teva Sante EMA provided an update on the shortage situation and informed about the outcome of the meetings with alternative MAHs. SPOC WP members experiencing a critical shortage situation were encouraged to reach out to alternative MAHs. EMA will continue to hold bilateral meetings with additional suppliers to understand their ability to increase supply. Additionally, one SPOC WP member provided an update on the situation in their territory and informed the group of the continued use of the Solidarity Mechanism to alleviate the critical shortage.
	c) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide), Victoza CAP (liraglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide) – MAH: Eli Lilly Nederland B.V. EMA presented the supply situation of GLP-1 RAs with a focus on Ozempic, Victoza and Trulicity and introduced the new MAH shortage reporting approach. Furthermore, EMA provided a high level overview of the consultation with the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) on the MSSG recommendations and the next steps that will include SPOC WP and Working Group of Communication Professionals (WGCP) consultation. In addition, the outline of the MSSG multistakeholder workshop on GLP-1 RA shortages taking place on 1 July 2024 was presented.
	d) Supply and availability of IV/SC human normal immunoglobulins in the EU/EEA EMA provided an update on the availability situation of Rho(D) Immune Globulin (human)/anti-D immunoglobulins in the EU/EEA as well as feedback received from MAHs. <u>Comments raised</u> The Chair informed that a dedicated agenda point on anti-D immunoglobulins is planned for the SPOC WP meeting in June 2024.
	e) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim EMA informed that the situation is expected to continuously improve in 2024.
	f) Shortages of medicinal products from MAH: Cheplapharm EMA provided an update on the ongoing shortages of Visudyne, Zypadhera, Zyprexa and Cymevene. <u>Comments raised</u>

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	A SPOC WP member shared information on the expected Cymevene quantities for their market. **Agreed actions:** • SPOC WP to inform EMA if the supply situation deteriorates.
	g) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH EMA informed the SPOC WP about the latest meeting with MAH Valneva and provided the feedback on the company's supply plan. EMA informed that supply situation is expected to improve from July 2024 onwards, nonetheless, the situation will continue to be monitored in cooperation with the MAH.
	h) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris EMA presented the feedback from the last meeting with MAH Viatris and their short term shortage mitigation measures. EMA informed that a Dear Healthcare Professional Communication (DHPC) and a shortage catalogue entry have been published. <u>Comments raised</u> A SPOC WP member noted dependency on parallel imports and informed about the measures considered to be implemented at a national level.
	i) Ventolin NAP (salbutamol sulfate) – MAH: GlaxoSmithKline EMA provided an update on the shortage situation in EU/EEA as well as an overview of the feedback from GSK and alternative MAHs. EMA informed the SPOC WP about the possibility for an alternative manufacturer to increase production capacity to support MSs that may experience a critical situation. EMA highlighted the need to coordinate further actions ahead of the autumn/winter season and noted the possibility to reach out to all MAHs to understand their supply planning. <u>Comments</u> SPOC WP members shared the feedback on the current supply situation in their territories and agreed that current measures are sufficient to address the situation without the need to escalate to the MSSG. **Agreed actions:** • SPOC WP members interested in importing alternative product to contact the company.
	j) Menopur NAP (menotrophin) – MAH: Ferring EMA informed the SPOC WP that the ongoing shortage will continue further into 2025 and provided the feedback from the MAHs of alternative products. As the next steps, the situation will continue to be monitored in cooperation with Ferring and alternative MAHs.
6.	**EC DG HERA update** DG HERA presented the results of the outcome of the pilot phase consisting of 11 medicines selected from the Union list of critical medicines. DG HERA explained the data collection process and information collected from MAHs, indicators used to identify the vulnerability of the supply chain and the results of the risk matrix applied to classify those vulnerabilities.

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	DG HERA also presented the information collected from the MSs and acknowledged the significant engagement from MAHs and MSs in this exercise. In addition, DG HERA explained the caveats identified during this exercise and the start of the lessons learnt exercise to refine the methodology. Lastly, DG HERA presented the launch of the Critical Medicines Alliance (CMA) and the next steps.
7.	**Impact of new national law on supply of medicinal products and availability of medicines on European market** A SPOC WP member highlighted the potential consequences of national stockpiling strategies on the supply to smaller and low-priced markets and noted that similar concerns linked to the impact on medicine shortages have also been raised by industry. Comments raised Another SPOC WP member noted that there are currently no signals that such activities are causing critical impact, nonetheless, further interactions with stakeholders will take place to better understand the potential impact and contingency measures put in place to avoid it. **Agreed actions:** • SPOC WP to continue the discussion at the next meeting.
8.	**HMA/EMA Task Force on Availability of Authorised Medicines:**
	a) Union list of critical medicines The topic could not be taken.
9.	**Conclusions and next steps** The Chair encouraged the MSs to complete the categorisation of the first batch for the second phase of the Union list of critical medicines, and informed them that the second batch is available for review by mid July 2024. Additionally, the Chair informed that the SPOC WP Secretariat launched a call for volunteers to join a SPOC WP subgroup on the shortage definition and thanked the MS that already volunteered. The agreed actions are detailed above.

Next meeting: 20 June (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).