

14 July 2025
European Medicines Agency

Meeting Summary — Medicine Shortages SPOC Working Party

17 June 2025, from 09:30 to 13:30 (CEST), TEAMS

Disclaimer

Some of the information discussed during Medicine Shortages SPOC Working Party (SPOC WP) meetings are considered commercially confidential or sensitive and are therefore not disclosed.

Of note, the meeting summary is a working document primarily designed for SPOC WP members and the work the SPOC WP undertakes.

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).

Exploratory notes

Only shortages or availability issues that require EU level coordination are being brought to the SPOC WP meetings.

Shortages or availability issues that are being monitored and do require input from SPOC WP are brought for discussion under agenda point 'Critical shortages escalated to the SPOC Working Party'.

Updates on shortages or availability issues that have been previously discussed at the SPOC WP meetings and are being monitored, but do not require any specific input, are provided in writing and disseminated to SPOC WP members prior to the meeting. If required, SPOC WP members may provide comments under agenda point 'Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)'.

Item	Topic
1.	<p>Welcome, declaration of interest, adoption of draft agenda</p> <p>The Chair and Vice-Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party (SPOC WP). The Chair thanked the Vice-Chair for the successful term and announced that the DK SPOC WP member will take over in July 2025 as the new rotating Vice-Chairperson under the Danish Presidency of the Council of the EU.</p> <p>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 and changes to the SPOC WP membership were announced.</p> <p>The agenda was adopted with no additional points under AOB.</p>
2.	<p>Adoption of draft minutes of the SPOC WP meeting held on 13 May 2025</p> <p>The Vice-Chair informed that the minutes of the meeting held on 13 May 2025 had been distributed one week prior to the meeting.</p> <p>No comments were received before and during the meeting and the minutes were adopted.</p>
3.	<p>Administrative topic: meeting transition to MS Teams</p> <p>EMA informed SPOC WP that all future SPOC WP meetings will be held via MS Teams. In support of this transition, EMA provided best practices to ensure a stable connection and a number of solutions to help prevent technical issues during the meetings.</p>
4.	<p>Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:</p> <p>a) Feedback from the SPOC WP subgroup on crisis monitoring and preparedness</p> <p>EMA provided feedback from recent meetings of the SPOC WP subgroup indicating that no coordinated action at EU level is currently required, as no signals have been identified. Based on the findings from two industry surveys related to the ongoing geopolitical situations, EMA informed that no immediate concerns were raised and monitoring is ongoing.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> • SPOC WP subgroup to continue close monitoring of the impact of the geopolitical situation on the availability of medicinal products in the EU/EEA countries. <p>b) Availability of antibiotics: update on preparedness activities</p> <p>EMA informed SPOC WP about a regulatory support request from one MAH to increase antibiotic supply in the long term. EMA confirmed that possibilities to provide regulatory support are being explored together with the relevant EMA teams and the Regulatory Network.</p> <p><u>Discussion</u></p>

Item	Topic
	<p>SPOC WP members exchanged information on the availability of antibiotics in their countries, noting no availability issues in their territories.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> EMA to close the shortage catalogue entry for amoxicillin and amoxicillin/clavulanic acid as agreed by SPOC WP. SPOC WP members to continue monitoring the supply situation for antibiotics in their territories.
	<p>c) Oral status update on availability of human and veterinary medicines in MSS (only for new emerging information)</p> <p>SPOC WP members reported shortages of an immunosuppressive medicinal product due to manufacturing issues. In response, EMA noted that the issue will be raised in an upcoming meeting with the MAH and that a criticality assessment will be shared after the SPOC WP meeting.</p> <p>A SPOC WP member also noted a potential shortage of an antibacterial medicinal product due to manufacturing issues. EMA will keep SPOC WP members informed once more information becomes available.</p> <p>Additionally, a SPOC WP member notified about an upcoming discontinuation of Rifadin (rifampicin), although alternatives are available through imports. SPOC WP members exchanged information on the availability of rifampicin in their territories, noting shortages but also measures to mitigate the issue at national level.</p> <p>A SPOC WP member informed about a discontinuation of medicinal product Vitamine A Dulcis (synthetic vitamin A concentrate), and highlighted mitigation measures such as distribution restrictions or importations.</p> <p>Some SPOC WP members noted a discontinuation of Beriglobin (human normal immunoglobulin) in their countries, noting that importation of product from other countries is being considered. EMA will follow up in writing regarding next steps.</p> <p>A SPOC WP member notified about a shortage of an intestinal anti-inflammatory medicine linked to manufacturing issues. Other SPOC WP members confirmed similar shortages in their countries but did not consider this shortage critical due to the availability of alternatives.</p> <p>A SPOC WP member inquired about the availability of sodium chloride IV solutions. EMA will keep SPOC WP members informed in case more details become available.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> SPOC WP members to submit critical shortage notifications to EMA (if not previously done) for circulation to the SPOC WP if abovementioned shortage situations in their territories deteriorate.
5.	Critical shortages escalated to the SPOC Working Party:
5.1	Ongoing shortages
	a) Shortage and discontinuation of insulin containing medicinal products

Item	Topic
	<p>EMA provided an update on the ongoing process for identifying alternatives and assessing the impact of selected insulin preparations to be discontinued by Novo Nordisk. Additionally, EMA provided feedback from latest interactions with involved MAHs.</p> <p><u>Discussion</u></p> <p>SPOC WP members exchanged information on the situation in their countries, noting continuous monitoring, information on discontinuation notifications and their impact and the ongoing contact with MAHs at national level.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> • EMA to continue monitoring the situation and updating risk scores, as necessary, for each discontinued product across EU/EEA countries. • EMA to engage with MAHs to explore mitigation measures for high-risk products and MSs where shortages are critical.
	<p>b) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists</p> <p>EMA presented an overview of the supply situation of Ozempic and Victoza, noting improvements across EU/EEA countries. In addition, EMA provided feedback from the meeting of SPOC WP subgroup on GLP-1 RAs with Novo Nordisk.</p>
	<p>c) Moventig CAP (naloxegol) – MAH: Grünenthal</p> <p>EMA informed the SPOC WP about an ongoing shortage of Moventig (naloxegol) from MAH Grünenthal which is indicated for the treatment of opioid-induced constipation in adults. The root cause is linked to a manufacturing issue. Additionally, the outcome of the criticality assessment was presented highlighting that therapeutic alternatives are available in the EU and only a few MSs consider the shortage critical.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> • EMA to continue interactions with MAH to resolve manufacturing issue and keep SPOC WP members informed about further developments. • SPOC WP members to closely monitor the situation and notify EMA if the situation changes in their territories.
	<p>d) Biltricide NAP (praziquantel) – MAH: Bayer</p> <p>EMA presented feedback from recent interactions with MAH Bayer and proposals from alternative MAHs to mitigate the shortage. Furthermore, EMA shared contact details for alternative MAHs.</p> <p><u>Discussion</u></p> <p>SPOC WP members exchanged information on the situation in their countries and discussed the proposals by alternative MAHs. In addition, the SPOC WP members agreed with the development of a shortage catalogue entry.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> • EMA to continue interactions with MAH Bayer as well as alternative MAHs and keep SPOC WP members informed about further developments. • EMA to prepare a shortage catalogue entry for Biltricide as agreed by SPOC WP.

Item	Topic
	<p>e) Venlafaxine containing medicinal products</p> <p>Outcome of the voluntary solidarity mechanism (VSM) procedure</p> <p>EMA presented the results of the latest VSM procedure launched by FR SPOC WP member for venlafaxine containing medicinal products and outlined 3 positive replies received from Member States and alternative MAHs. EMA noted that the shortage was not previously escalated to SPOC WP and a criticality assessment was therefore launched in parallel.</p> <p>Presentation on national shortage mitigating measures</p> <p>FR SPOC WP member presented the shortage situation and implemented mitigation measures such as distribution restrictions, requests to MAHs to increase supply, and activation of the VSM. FR SPOC WP member also shared the national perspective on the VSM process and the outcomes since the launch of the mechanism. Additionally, EMA clarified the role of donating MSs and the responsibilities of EMA, issuing and donating MSs and MAHs.</p> <p><u>Discussion</u></p> <p>SPOC WP members discussed national specificities and barriers to transferring stocks between countries within the VSM context. EMA Chair highlighted the recent MSSG survey and future work to identify and overcome these barriers which will be done in the MSSG WG on VSM and Policy. Lastly, EMA noted that considerations highlighted by SPOC WP members will be further discussed in the MSSG WG.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> • EMA to update guidance to National Competent Authorities regarding the VSM procedure based on clarifications given.
5.2	<p>Status update on other critical shortages escalated to the SPOC WP (comments relating to previously circulated written updates)</p>
	<p>a) Ecalta CAP (anidulafungin) and Dynastat CAP (parecoxib) – MAH: Pfizer</p> <p>b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk</p> <p>c) Medicinal products from MAH: Cheplapharm</p> <p>d) Medicinal products containing salbutamol (inhalation use)</p>
6.	<p>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:</p>
	<p>a) Feedback from the MSSG meeting on 21 May 2025</p> <p>Vice-Chair provided feedback on the topics discussed during the MSSG meeting in May highlighting recent developments from the MSSG Working Groups (WGs), progress on the procedure to update the Union List of Critical Medicines and update on MSSG 2024 activity report.</p> <p>Vice-Chair also informed that MSSG discussed the recommendations to address anti-D immunoglobulin supply vulnerabilities and the outcomes of VSM procedures launched for critical shortages of 5-fluorouracil and Cyanokit.</p>

Item	Topic
	<p>b) Draft Recommendations of the MSSG to address anti-D immunoglobulin supply vulnerabilities</p> <p>EMA presented an update on the recommendations and next steps including adoption of the recommendations by the MSSG and subsequent publication of the document on the EMA website.</p>
	<p>c) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology</p> <p>EMA presented updates from recent technical meetings of the WG. The group is tasked with developing a methodology to carry out assessments of supply chain vulnerabilities.</p> <p>EMA also informed SPOC WP about the next steps including demonstration to get feedback on the proposed approach, and presentations from WG members on their national approach to vulnerability assessment methodologies.</p>
	<p>d) Feedback from the MSSG WG on Voluntary Solidarity Mechanism and Policy</p> <p>EMA presented an overview of topics discussed at recent meetings of the WG including the revised mandate of the WG, transparency in VSM procedures as well as findings from the MSSG survey to identify barriers to the transfer of stocks between countries within the VSM context.</p> <p>EMA also presented proposals to streamline the VSM procedure which included a simplified process to collect information and the integration of Union Civil Protection Mechanism, rescEU (a strategic reserve of disaster response capabilities and stockpiles established by the EC which also includes essential stockpiles of critical medical supplies), if no other support can be found through MSs or MAHs.</p> <p>Lastly, EMA informed SPOC WP about the end of the VSM pilot. EMA will analyse the process and outcome of the pilot to identify potential improvements.</p> <p><u>Discussion</u></p> <p>EMA Chair emphasized that rescEU would only be activated as a last resort when no support from MSs or MAHs has been identified.</p>
7.	<p>Global Regulatory Working Group on Drug Shortages: Q2 meeting</p> <p>This topic could not be taken due to time constraints and was postponed to SPOC WP meeting in July.</p>
8.	<p>AOB</p> <p>No topics raised under AOB.</p>
9.	<p>Conclusions and next steps</p> <p>The agreed actions are detailed above.</p>

Next meeting: 14 July 2025 (TEAMS)

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 17 June meeting, which was held virtually. Experts' declared interests were evaluated against the agenda topics or activities they participated in.

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Monica Dias	EMA	Chair	No interest declared	
Magdalena Rychter	Poland	Vice-Chair	No restrictions applicable to this meeting	
Sanne Vandelanotte	Belgium	Alternate	No interest declared	
Emilia Stoyanova	Bulgaria	Member	No interest declared	
Mateja Mervić	Croatia	Member	No restrictions applicable to this meeting	
Stela Lilek	Croatia	Alternate	No interest declared	
Vasileios Loutas	Cyprus	Member	No interest declared	
Mathilde Moe Møldrup	Denmark	Member	No interest declared	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Flore Demay	France	Member	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Marie-Laure Veyries	France	Alternate	No interest declared	
Thomas Brouwers	Germany	Member	No restrictions applicable to this meeting	
Gabriele Eibenstein	Germany	Member	No interest declared	
Andrea Stippler	Germany	Alternate	No interest declared	
Theoni Kousteni	Greece	Member	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petró	Hungary	Alternate	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Vincenza Giuseppina Azzarà	Italy	Member	No interest declared	
Domenico Di Giorgio	Italy	Member	No interest declared	
Cruciani Oscar	Italy	Alternate	No interest declared	
Linaz Mažeika	Lithuania	Member	No interest declared	
Maura Olechnovič	Lithuania	Alternate	No interest declared	
Maxime Salade	Luxembourg	Member	No restrictions applicable to this meeting	
Jessica Zarb	Malta	Alternate	No interest declared	
Hanneke Mulder	Netherlands	Member	No interest declared	
Eric Hergarden	Netherlands	Alternate	No interest declared	
Guri Wilhelmsen	Norway	Member	No interest declared	
Martyna Jakubowska	Poland	Alternate	No interest declared	
Helena Ponte	Portugal	Member	No restrictions applicable to this meeting	
Alina Iordache	Romania	Member	No interest declared	
Viviana Anghel	Romania	Alternate	No interest declared	
Jaroslav Kollárik	Slovakia	Member	No participation in discussions, final deliberations and voting on:	5.1 d) Biltricide NAP (praziquantel) – MAH: Bayer
Simona Paľovčíková	Slovakia	Alternate	No restrictions applicable to this meeting	
Saša Martinc	Slovenia	Member	No interest declared	
Maria Esplugues Argente	Spain	Member	No restrictions applicable to this meeting	
Maria Criado	Spain	Alternate	No interest declared	
Samuel Silkestrand	Sweden	Member	No interest declared	
Rita Rom	Austria	Expert	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Olga Rögelsperger	Austria	Expert	No restrictions applicable to this meeting	
Myllyntausta Minna	Finland	Expert	No interest declared	
Benjamin Vosse	Netherlands	Expert	No interest declared	
João Simões	Portugal	Expert	No interest declared	
Melita Tovornik	Slovenia	Expert	No interest declared	
Patricia Rodríguez Molla	Spain	Expert	No restrictions applicable to this meeting	
Laura Marrero Ortiz	Spain	Expert	No interest declared	
Representatives from the European Commission and EDQM attended the meeting.				
Meeting run with the help of EMA staff.				