

18 March 2025
EMA/97390/2025
European Medicines Agency

Meeting Summary — Medicine Shortages SPOC Working Party

18 February 2025, from 09:30 to 13:30 (CET), Webex

Chair: Monica Dias (EMA), Vice-Chair: Magdalena Rychter (GIF, Poland)

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 (WP).</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.</p>
2.	<p>Adoption of draft minutes of the SPOC WP meeting held on 21 January 2025</p> <p>The Vice-Chair informed that the minutes of the meeting held on 21 January 2025 had been distributed one week prior to the meeting.</p> <p>No comments were received before or during the meeting. The minutes were adopted.</p>
3.	<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) Availability of antibiotics - preparedness for autumn/winter 2024–2025</p> <p>EMA informed the WP about the results of a SPOC WP criticality assessment for clarithromycin. Based on the information received, only one country required support in addressing critical shortages and EMA is interacting with the relevant marketing authorisation holders (MAHs) to find suitable solutions.</p> <p>One SPOC WP member presented the situation in their country, highlighting an increased demand for clarithromycin due to whooping cough and atypical respiratory infections. The</p>

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	<p>SPOC WP member provided an update on ongoing monitoring efforts regarding the supply level, expedited supplies and exploration of alternative treatments.</p> <p><u>Comments raised</u></p> <p>All other SPOC WP members confirmed that the situation with the supply of antibiotics is stable in their countries. Some SPOC WP members noted that an increase in whooping cough cases played a part in increased demand for antibiotics in their territories.</p>
	<p>b) Availability of perfusion solutions following Hurricane Helene</p> <p>EMA provided updates from the key MAHs on shortages of intravenous and irrigating solutions and informed that a SPOC WP survey identified sodium chloride as the most impacted product.</p> <p>EMA noted that discussions with the MAHs, global monitoring and identification of alternative MAHs are ongoing. EMA Chair also noted that this will be brought to the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) on 26 February 2025.</p> <p>Agreed Action:</p> <ul style="list-style-type: none"> SPOC WP members to notify EMA of critical shortages of IV and irrigating solutions.
	<p>c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)</p> <p>One SPOC WP member raised an issue with long term shortages of a glucocorticoid medicine fluticasone, understood to be caused by an increased demand and ongoing shortages in other MSs. SPOC WP members noted either no shortages or non-critical limited availability of this medicinal product.</p> <p>Another SPOC WP member informed about issues with another glucocorticoid medicine, methylprednisolone, highlighting limited availability throughout EU/EEA. Some SPOC WP members noted local shortages, though alternatives are available or mitigating measures are being considered.</p>
4.	Critical shortages escalated to the SPOC Working Party:
4.1	Ongoing shortages
	a) Medicinal products containing quetiapine
	<ul style="list-style-type: none"> Voluntary Solidarity Mechanism (VSM): presentation of the ongoing VSM procedure <p>EMA presented the results of the latest VSM procedure launched for quetiapine and the positive replies from four Member States (MSs) and alternative MAHs.</p> <p>EMA noted that the VSM was launched due to the urgency of the situation (the shortage has not been previously escalated to the SPOC WP).</p>
	<ul style="list-style-type: none"> Status update on supply and availability of quetiapine <p>The SPOC WP member from an impacted country informed the WP that the root cause of the quetiapine shortage is linked to manufacturing issues and presented the measures implemented at national level. The SPOC WP member informed that the</p>

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	<p>feedback from the SPOC WP did not identify EU-wide critical shortages of quetiapine. Finally, the SPOC WP member concluded that, despite the support received through the VSM and upcoming deliveries from MAHs, the total supply remains insufficient to meet demand.</p> <p><u>Comments raised</u></p> <p>SPOC WP members noted that while some shortages exist, these are not deemed critical as alternatives are available.</p> <p>Agreed action:</p> <ul style="list-style-type: none"> SPOC WP to provide information on the shortage of quetiapine-containing products published on national websites and recommendations provided to healthcare professionals on patient prioritisation and alternative treatments.
	<p>b) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH</p> <p>The ongoing shortage of Pegasys was presented by EMA, including information from the company on supply and safety stocks expected in 2025.</p> <p><u>Comments raised</u></p> <p>SPOC WP exchanged their views, noting the need for data on replenishment from the company and supply dependency on ongoing regulatory procedures.</p>
	<p>c) Menopur NAP (menotropin) – MAH: Ferring</p> <p>EMA provided an update on the current supply situation after the meetings with MAH Ferring and alternative manufacturer.</p> <p><u>Comments raised</u></p> <p>SPOC WP members provided an update on the situation in their markets, noting that the situation is unchanged and shortages are still ongoing, although they are not critical.</p>
	<p>d) Medicinal products from MAH: Cheplapharm</p> <p>EMA provided an update on the critical shortage for Zypadhera CAP including weekly stock reporting from the company, additional identified stocks and their availability. This also included feedback from the SPOC WP subgroup meeting on 13 February 2025.</p> <p>EMA also informed the SPOC WP on the recent actions taken for Visudyne CAP such as its inclusion into the Shortage Prevention Plan (SMP) and Shortage Mitigation Plan (SMP) pilot, planned Medicine Shortage Communication (MSC) and shortage catalogue update, regulatory support, product allocation updates and next steps.</p> <p><u>Comments raised</u></p> <p>SPOC WP members highlighted that additional identified stocks could support national needs for Zypadhera CAP.</p>
	<p>e) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists (RAs)</p> <p>EMA presented an analysis of the number of shortages reported to NCAs between May 2024 and January 2025, noting that the information received from the MAH indicates improvement of the Ozempic shortage situation overall. In addition, EMA provided the</p>

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	<p>feedback from the SPOC WP subgroup meeting on GLP-1 RAs and insulins that was held on 13 February 2025.</p> <p>As the next steps, EMA highlighted the need to update the joint shortage DHPCs and shortage catalogue entries for Ozempic CAP and Victoza CAP as well as the shortage catalogue entry for Trulicity CAP; the topic will also be discussed at the MSSG meeting on 26 February 2025.</p> <p><u>Comments raised</u></p> <p>SPOC WP members provided updates on the situation at national level, noting improvements in some territories but also increasing or extended shortages in others. In countries with shortages, mitigation measures such as controlled distribution are being used.</p>
	<p>f) Insulin-containing medicinal products</p> <p>EMA provided an update on the criticality assessment performed by the SPOC WP and presented a proposed approach for the risk assessment of the discontinuation of selected insulins. In addition, feedback from the SPOC WP subgroup meeting on GLP-1 RA and insulins on 13 February 2025 was provided.</p> <p><u>Comments raised</u></p> <p>One SPOC WP member informed the WP about their interactions with local affiliates of MAHs, highlighting the need to have information on marketing cessation timelines as early as possible.</p> <p>Another SPOC WP highlighted the need to identify the remaining patient population, which is needed to determine the demand for alternative medicines at an early stage. This is important as a possible adjustment of production volumes of alternative medicines is based on this.</p>
	<p>g) Zinplava CAP (bezlotoxumab) – MAH: Merck Sharp & Dohme B.V.</p> <p>A SPOC WP member informed about a critical shortage of Zinplava CAP and presented the outcomes of the SPOC WP criticality assessment, which identified that no other countries are experiencing critical shortages and that there are therapeutic alternatives available in other countries where this product is marketed.</p>
4.2	<p>Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)</p>
	<p>a) Oncology medicinal products from Accord Healthcare B.V. and Teva</p> <p>b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk</p> <p>c) Medicinal products containing salbutamol (inhalation use)</p> <p>d) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer</p> <p>One SPOC WP member noted that the shortage of 5-fluorouracil is critical, stressed the need for clarity on delivery dates and highlighted that patient needs must take priority. EMA responded that the situation was already raised to the MAH and EMA will follow-up with the SPOC WP member to further understand the local situation.</p>

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5.	<p>EC DG HERA update</p> <p>DG HERA provided an update on the Critical Medicines Alliance (CMA) noting that a consultation for the draft Strategic Report has been launched at the level of the CMA forum, inviting feedback from SPOC WP members through their national counterparts who are members in the CMA. DG HERA informed the SPOC WP that the final Strategic Report will be finalised by the end of February 2025. <i>Post-meeting note:</i> Strategic Report of the CMA was published on 28 February 2025.</p> <p><u>Comments raised</u></p> <p>One SPOC WP member inquired about the status of the Critical Medicines Act, to which DG HERA noted that the CMA Strategic Report recommendations are taken into consideration for the Critical Medicines Act. DG HERA further noted that DG SANTE is spearheading the Critical Medicines Act proposal.</p>
6.	<p>Joint Action on shortages (CHESSMEN): Work Package 8 – SPOC WP survey and implementation plan of the most effective preventive and mitigating measures</p> <p>CHESSMEN WP8 lead presented key outcomes of the survey on preventive and mitigation measures used or planned, highlighting different measures considered and next steps. Amongst preventive measures, stakeholder dialogue, list of critical medicines, shortage prevention plans and regulatory elements were mentioned, whereas for the shortage mitigation, elements linked to impact assessment and stakeholder collaboration were noted. The SPOC WP member asked SPOC WP for comments on the implementation plan of the most effective preventive and mitigating measures, which is being drawn up based on NCA proposals.</p> <p><u>Comments raised</u></p> <p>EMA Chair noted that the presented activities of the implementation plan resonate and inquired whether specific examples will be included in the report to further substantiate actions to be implemented at national level, such as multistakeholder interactions. WP 8 lead noted that specific examples could be included into the deliverable.</p>
7.	<p>Global Regulatory Working Group on Drug Shortages: focus areas for EMA Chairmanship in 2025</p> <p>EMA provided an update on the Drug Shortages Global Regulatory Working Group, including EMA's role as Chair in 2025 with the Ministry of Health, Labour and Welfare (MHLW) of Japan as Vice-Chair. EMA presented the draft workplan for discussion with the Working Group, proposing priorities to tackle global medicines supply challenges and noted that the next meeting will take place on 19 March 2025.</p> <p><u>Comments raised</u></p> <p>One SPOC WP member inquired about the scope of the group and the possibility to share the group's agendas with the SPOC WP in the future. Support for the activities was expressed.</p> <p>EMA explained that the group exchanges information on relevant medicines supply issues and cooperates on shortage mitigation and prevention strategies and policies. EMA further confirmed the possibility for enhanced communication with the SPOC WP on this matter.</p>

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8.	AOB EMA informed on the launch of a survey to NCAs on the European Shortages Monitoring Platform (ESMP) to understand from NCAs the need for Q&A clinics, trainings or any other activities to ensure they are fully comfortable with using the ESMP in crises and MSSG-led preparedness situations.
9.	Conclusions and next steps The agreed actions are detailed above.

Next meeting: 18 March (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).

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 18 February SPOC WP meeting, which was held virtually.

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	
Sybille Schotte	Belgium	Member	No interest declared	
Sanne Vandelanotte	Belgium	Alternate	No interest declared	
Emilia Stoyanova	Bulgaria	Member	No interest declared	
Mateja Mervić	Croatia	Member	No interest declared	
Vasileios Loutas	Cyprus	Alternate	No interest declared	
Jakub Velík	Czechia	Member	No interest declared	
Michaela Kosová	Czechia	Alternate	No interest declared	
Mathilde Moe Møldrup	Denmark	Member	No interest declared	
Anita Tuula	Estonia	Alternate	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Laurent Fabry	France	Alternate	No interest declared	
Thomas Brouwers	Germany	Member	No interest declared	
Gabriele Eibenstein	Germany	Member	No interest declared	
Inke Reimer	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	
Mary Kinane	Ireland	Alternate	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Oscar Cruciani	Italy	Alternate	No interest declared	
Kristīne Edolfa-Kalniņa	Latvia	Member	No interest declared	
Linas Mažeika	Lithuania	Member	No interest declared	
Maura Olechnovic	Lithuania	Alternate	No interest declared	
Maxime Salade	Luxembourg	Member	No restrictions applicable to this meeting	
Jessica Zarb	Malta	Alternate	No interest declared	
Eric Hergarden	Netherlands	Alternate	No interest declared	
Helena Ponte	Portugal	Member	No interest declared	
Susana Penedo Alves	Portugal	Member	No interest declared	
Viviana Anghel	Romania	Alternate	No interest declared	
Alina Iordache	Romania	Member	No interest declared	
Jaroslav Kollárik	Slovakia	Member	No restrictions applicable to this meeting	
Simona Palovcikova	Slovakia	Alternate	No restrictions applicable to this meeting	
Saša Martinc	Slovenia	Member	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
María Esplugues Argente	Spain	Member	No restrictions applicable to this meeting	
Patricia Rodríguez	Spain	Alternate	No restrictions applicable to this meeting	
Samuel Silkestrand	Sweden	Member	No interest declared	
Hafþís Birna Baldursdóttir	Iceland	Alternate	No interest declared	
Andreas Sundgren	Norway	Alternate	No interest declared	
Olga Röggelsperger	Austria	Expert	No restrictions applicable to this meeting	
Rita Rom	Austria	Expert	No interest declared	
Johanna Linnolahti	Finland	Expert	No interest declared	
Hajar Youssoufi	France	Expert	No restrictions applicable to this meeting	
João Simões	Portugal	Expert	No interest declared	
Nuno Simões	Portugal	Expert	No interest declared	
Marta Casalengua Domínguez	Spain	Expert	Direct interests declared	Competing interest declared resulting in no participation in discussions and decisions with respect to agenda point 4.2.c
Maria Criado	Spain	Expert	No interest declared	
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.				