



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 February 2026  
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European Medicines Agency

## Meeting Summary - Medicine Shortages SPOC Working Party

Tuesday, 9 December 2025, 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 brought to the SPOC WP meetings, either by EMA or SPOC WP members. These are listed 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)'.

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**Chair: Monica Dias (EMA), Vice-Chair: Mathilde Moe Møldrup (DKMA, Denmark)**

Item	Topic
1.	<p><b>Welcome, declaration of interest, adoption of draft agenda</b></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, no applicable restrictions were identified.</p> <p>The agenda was adopted with no additional points under AOB.</p>
2.	<p><b>Adoption of draft minutes of the SPOC WP meeting held on 11 November 2025</b></p> <p>The Vice-Chair informed that the minutes of the meeting held on 11 November 2025 had been distributed one week prior to the meeting.</p> <p>No comments were received before or during the meeting and the minutes were adopted with no changes.</p>
3.	<p><b>Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:</b></p> <p><b>a) Feedback from the SPOC WP subgroup on crisis monitoring and preparedness</b></p> <p>EMA provided feedback from the SPOC WP subgroup and noted that there have been no new signals of concerns indicating potential supply disruptions from industry associations, and no analysis ongoing at national level. Additionally, there have been no requests for EU level coordinated analysis at this time.</p> <p>Finally, EMA provided an update on the recently issued WHO global guideline on the use of GLP-1 receptor agonists (RAs) medicines in treating obesity. SPOC WP was further informed that GLP-1 RAs therapies were added to the WHO essential medicines list for managing type 2 diabetes in high-risk groups. It was noted that EMA continues to closely monitor the supply situation for all GLP-1 RAs medicines across EU/EEA countries by engaging with national competent authorities and communicating with MAHs.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"><li>• SPOC WP subgroup to continue meeting on a biweekly basis and monitor the impact of geopolitical situations on the supply and availability of medicinal products in EU/EEA countries.</li></ul> <p><b>b) Availability of antibiotics: update on preparedness activities</b></p> <p>EMA provided an update on the ongoing regulatory support requests submitted by marketing authorisation holders (MAHs) to increase the manufacturing capacity for antibiotics in the long term.</p> <p>In parallel, EMA continues monitoring the availability of antibiotics via information received from MAHs, other complementary data sources such as IQVIA, and European Centre for Disease Prevention and Control (ECDC) epidemiology reports to identify early warning signals and take action, if needed. For this, EMA is also piloting an Early Demand Signal</p>

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	<p>Template to enable key MAHs to voluntarily share early indications of increased demand (increased orders or backorders).</p> <p><u>Discussion</u></p> <p>SPOC WP members exchanged updates on the antibiotic supply situation. While several localised shortages persist, the majority of members confirmed that overall antibiotic availability remains stable.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• SPOC WP members to inform EMA in case critical shortages of antibiotics occur or any ongoing shortages deteriorate.</li> </ul>
4.	<p><b>Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)</b></p> <p>Some SPOC WP members raised availability issues of an anthelmintic medicinal product following its discontinuation and it was agreed to explore the possibility of EU coordinated actions to resolve the issue.</p> <p>A SPOC WP member reported a worsening shortage situation for quetiapine-containing medicinal products in their country, with several other MSs noting shortages in their countries. EMA is engaging with the manufacturer Pharmathen and will keep SPOC WP members informed once clarification on the supply situation from them is available.</p> <p>A SPOC WP member raised concerns about availability of an enzyme replacement medicine used in digestion disorders due to high demand. While some localised non-critical shortages have been reported, the majority of SPOC WP members noted no ongoing shortages of the product in their territories. EMA will follow up with the respective SPOC WP member and the MAH to better understand the situation and assess options to mitigate the shortage.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP if the abovementioned shortage situations deteriorate.</li> </ul>
5.	<p><b>Critical shortages escalated to the SPOC Working Party:</b></p>
5.1	<p><b>Ongoing shortages</b></p>
	<p><b>a) Medicinal products from MAH Cheplapharm</b></p> <p>EMA provided an update on the current supply situation and mitigation activities conducted for Visudyne and noted that it will remain in close contact with the MAH, SPOC WP and the Rapporteurs/Co-Rapporteurs.</p> <p>EMA also presented the supply outlook for Zypadhera and provided feedback from the SPOC WP subgroup on Cheplapharm, which included actions to manage and prevent shortages of medicinal products from this MAH. It was noted that Cheplapharm will attend the MSSG in person meeting in December to provide an update on the ongoing and planned mitigation measures.</p> <p><b>Agreed actions:</b></p>

Item	Topic
	<ul style="list-style-type: none"> <li>EMA, with SPOC WP, will continue monitoring the supply situation of medicinal products from Cheplapharm, via its dedicated SPOC WP subgroup.</li> </ul>
5.2	<p><b>Status update on other critical shortages escalated to the SPOC WP</b> (only comments relating to previously circulated written updates)</p>
	<p>a) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk</p> <p>b) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists</p> <p>c) Beriglobin NAP (human normal immunoglobulin) – MAH: CSL Behring</p> <p>d) Medicinal products containing salbutamol (inhalation use)</p> <p>e) Shortage and discontinuation of insulin containing medicinal products</p> <p>f) Medicinal products manufactured by Pharmathen International</p> <p><u>Discussion</u></p> <p>No comments were raised during the meeting.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>EMA to continue monitoring the ongoing shortages listed above and to keep SPOC WP informed about latest developments.</li> </ul>
6.	<p><b>Feedback from the SPOC WP Subgroup on Shortage Definition:</b></p> <ul style="list-style-type: none"> <li><b>Root cause classification – proposal for harmonisation</b></li> </ul> <p>Members of the SPOC WP subgroup presented amendments to the report on the proposal for harmonising the classification of the root causes of shortages, reflecting the oral and written feedback received from the SPOC WP since the face-to-face meeting in October 2025. They also outlined the proposed next steps, which include industry consultation and presentation to the MSSG for endorsement.</p> <p><u>Discussion</u></p> <p>SPOC WP agreed to discuss the implementation of the proposal once endorsed by MSSG.</p>
7.	<p><b>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:</b></p>
	<p><b>a) Feedback from the MSSG meeting on 20 November 2025</b></p> <p>The SPOC WP Vice-Chair provided feedback on the topics discussed during the MSSG meeting in November 2025 which included the 2025 annual update of the Union list of critical medicines, preparedness activities for the autumn/winter season concerning antibiotics, VSM for Quetiapine prolonged-release tablets and an update on the MSSG written procedure to adopt the Vulnerability Assessment Methodology.</p>
	<p><b>b) MSSG WG on the Voluntary Solidarity Mechanism and Policy</b></p> <ul style="list-style-type: none"> <li><b>Focal Group on Union list of critical medicines</b></li> </ul>

Item	Topic
	<p>EMA outlined the proposed changes to the procedure for the annual update of the Union list. The revised methodology will be presented to the MSSG in December 2025 and circulated in writing for adoption. Once adopted, the methodology will be published on the EMA website.</p> <p><u>Discussion</u></p> <p>A SPOC WP member inquired on whether timelines for review by MSs would be extended which was confirmed by EMA.</p>
8.	<p><b>Interchangeability on pharmacy level in case of shortages</b></p> <ul style="list-style-type: none"> <li>• <b>European Community Pharmacists (PGEU)</b></li> </ul> <p>PGEU representative presented findings from a survey carried out in 2024 with community pharmacists on the impact of medicine shortages in Europe as well as PGEU’s policy recommendations to improve the availability of medicines in Europe. The PGEU representative also provided insights into various approaches to interchangeability at pharmacy level in case of shortages.</p> <ul style="list-style-type: none"> <li>• <b>Hungary - Findings of the survey</b></li> </ul> <p>HU SPOC WP member presented results of a SPOC WP survey on national approaches to pharmacy-level substitution during shortages, covering approaches that extend beyond standard generic substitution with the same active substance, strength and dosage form. HU SPOC WP member noted that while most MSs have developed a legal framework or standardised approach, there is currently no harmonised approach across EU/EEA countries.</p>
9.	<p><b>Leveraging digitalisation and automation for controlled substances management in European hospitals, European Health Management Association (EHMA)</b></p> <p>An EHMA representative presented the organisation’s work on digitalisation and automation of controlled substance management in European hospitals, with a particular focus on a recently <a href="#">published report</a> on the topic. The EHMA representative presented key findings from a survey conducted in collaboration with National Competent Authorities on challenges in managing controlled substances and provided EHMA’s key recommendations.</p>
10.	<p><b>European Shortages Monitoring Platform (ESMP) update</b></p> <p>EMA informed the group that the implementation of shortage mitigation plans in the ESMP will be deprioritised in the current epic, and national competent authorities (NCA) critical shortage reporting will be built in the ESMP instead.</p>
11.	<p><b>AOB</b></p> <p>No topics raised under AOB.</p>
12.	<p><b>Conclusions and next steps</b></p> <p>The Chair and Vice-Chair thanked the SPOC WP for their participation in the meeting and contribution to the discussions. The agreed actions are detailed above.</p>

**Next meeting:** 20 January, TEAMS

## List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 9 December meeting, which was held virtually.

Based on the review of the conflict of interests, no restrictions were identified.

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	
Mathilde Moe Møldrup	Denmark	Vice-Chair	No interest declared	
Andrea Kugi	Austria	Alternate	No interest declared	
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 restrictions applicable to this meeting	
Stela Lilek	Croatia	Alternate	No restrictions applicable to this meeting	
Vasileios Loutas	Cyprus	Member	No interest declared	
Jakub Velik	Czechia	Member	No interest declared	
Michaela Kosova	Czechia	Alternate	No interest declared	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Julia Lehtinen	Finland	Member	No interest declared	
Minna Myllyntausta	Finland	Alternate	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Laurent Fabry	France	Alternate	No interest declared	
Theoni Kousteni	Greece	Member	No interest declared	
Thomas Brouwers	Germany	Member	No restrictions applicable to this meeting	
Andrea Stippler	Germany	Alternate	No interest declared	
Veronika Horvath	Hungary	Member	No interest declared	
Petro Gyongyi	Hungary	Alternate	No interest declared	
Hafdis Birna Baldursdottir	Iceland	Alternate	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Oscar Cruciani	Italy	Alternate	No interest declared	
Linas Mazeika	Lithuania	Member	No interest declared	
Maura Olechnovic	Lithuania	Alternate	No interest declared	
Maxime Salade	Luxembourg	Member	No restrictions applicable to this meeting	
Hanneke Mulder	Netherlands	Member	No interest declared	
Erik Hergarden	Netherlands	Alternate	No interest declared	
Guri Wilhelmsen	Norway	Member	No interest declared	
Rebwar Saleh	Norway	Alternate	No interest declared	
Magdalena Rychter	Poland	Member	No restrictions applicable to this meeting	
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	
Simona Palovcikova	Slovakia	Member	No restrictions applicable to this meeting	
Erik Mokros	Slovakia	Alternate	No interest declared	
Sasa Martinc	Slovenia	Member	No interest declared	
Mara Esplugues Argente	Spain	Member	No restrictions applicable to this meeting	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Samuel Silkestrand	Sweden	Member	No interest declared	
Karl Högström	Sweden	Alternate	No interest declared	
Anna Gerhartl	Austria	Expert	No restrictions applicable to this meeting	
Rita Rom	Austria	Expert	No interest declared	
Verena Hofer	Austria	Expert	No interest declared	
Isabelle Barabas	Romania	Expert	No interest declared	
Melita Tovornik	Slovenia	Expert	No interest declared	
Laura Marrero Ortiz	Spain	Expert	No interest declared	
Maria Criado	Spain	Expert	No interest declared	
Patricia Rodríguez Molla	Spain	Expert	No restrictions applicable to this meeting	
Andreas Sundgren	Sweden	Expert	No interest declared	
<p>Representatives from the European Commission and EDQM attended the meeting.  Observers from pre-accession countries attended a non-sensitive portion of the meeting.  Meeting run with the help of EMA staff.</p>				