



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 June 2026  
EMA/119443 /2026  
Regulatory Science and Innovation Task Force

## Meeting Summary — Medicine Shortages SPOC Working Party

Wednesday, 15 April 2026, 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).

### Explanatory 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), Stand-in 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 an additional point under AOB:</p> <ul style="list-style-type: none"> <li>Reminder to SPOC WP members to update their declarations of interests (DoIs).</li> </ul>
2.	<p><b>Adoption of draft minutes of the SPOC WP meeting held on 16-17 March 2026</b></p> <p>The Vice-Chair informed that the minutes of the meeting held on 16-17 March 2026 had been distributed one week prior to the meeting. Comments were received from ES SPOC WP representative in relation to point 16. Joint Action on Shortages (CHESSMEN) update - Work Package 5 – Root causes of observed shortages of medicines.</p> <p>The minutes were updated accordingly and adopted as amended.</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>Feedback from the SPOC WP subgroup on crisis monitoring and preparedness</b></p> <ul style="list-style-type: none"> <li><b>Update on the geopolitical situation</b></li> </ul> <p>EMA presented updates on the ongoing situation in the Middle East, including feedback received from Member States (MSs), industry associations and marketing authorisation holders (MAHs) and also feedback from the last MSSG meeting where the topic was discussed. EMA noted that no immediate risks to medicine supply have been identified to date.</p> <p><u>Discussion</u></p> <p>A SPOC WP member updated the group on national monitoring activities, including a request to MAHs of strategic medicines to report any current and potential supply disruptions caused by the conflict.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>EMA, together with SPOC WP subgroup on crisis monitoring and preparedness will continue close monitoring of the ongoing geopolitical situation.</li> <li>SPOC WP members to report any signals related to the conflict in the Middle East to EMA.</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>A SPOC WP member reported a shortage of a meningococcal vaccine, noting that according to the MAH the shortage is caused by higher demand in their territory. EMA confirmed that</p>

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	<p>the criticality survey had been circulated to the MSs. Based on the responses received to date, majority of countries do not anticipate a shortage. In light of this information, the SPOC WP member concluded that the issue is currently national and decided to pause on further action at Union level. EMA will summarise the results of the survey together with the feedback received during the meeting and will share it with the SPOC WP member post-meeting.</p> <p>A SPOC WP member reported a shortage of an antibiotic used in the treatment of tuberculosis due to manufacturing issues. EMA confirmed that a criticality survey had been launched, and that results will be shared once the deadline for responses has passed. It was agreed that shortages of tuberculosis medicines should be assessed together to obtain a comprehensive overview of the availability of these medicines across the EU/EEA.</p> <p>A SPOC WP alternate reported about the planned withdrawal of an oncology medicinal product. Several SPOC WP members noted that an alternative product is available in their countries. EMA also confirmed to be in contact with an alternative MAH to understand their current situation and is awaiting feedback. Furthermore, a criticality survey has been circulated to the SPOC WP.</p> <p>A SPOC WP alternate reported a planned discontinuation of an anticholinergic medicinal product as a company's decision after revision of the F-gas regulation. It was noted that there is high consumption and limited availability of alternative MAHs across MSs. It was agreed to consolidate the information received and bring the topic back for discussion at a future SPOC WP meeting.</p> <p>A SPOC WP member reported a risk of shortage of an antihypertensive medicinal product linked to a shortage of an active substance. EMA confirmed that the criticality survey has been circulated and based on the results received to date, the issue seems to be national. Bilateral exchange with the Member State has been scheduled, and the situation will continue to be closely monitored.</p> <p>A SPOC WP member reported a shortage of an oncology medicinal product due to manufacturing issues. The SPOC WP member noted no suitable alternatives are available in their territory. Several MSs reported that this product is not marketed in their countries. EMA confirmed receipt of the criticality notification and indicated that a criticality survey will be circulated shortly to collect further feedback from MSs.</p> <p>A SPOC WP member reported an ongoing shortage of an antigout medicinal product and no alternative available nationally. The root cause is linked to manufacturing issues. Initial feedback indicated that the product is not marketed in several countries. Other MSs reported the availability of alternative products and no current shortage issues. EMA noted a previous critical shortage notification for a different antigout medicinal product in 2025, linked to manufacturing issues. EMA will review previous information and follow up as appropriate.</p>
5.	<b>Critical shortages escalated to the SPOC Working Party:</b>
5.1	<b>Ongoing shortages</b>
	<p><b>a) Ifosfamide containing medicinal products and cyclophosphamide containing medicinal products, MAH: Baxter</b></p> <p>EMA presented an update on the ongoing shortages of ifosfamide and cyclophosphamide products. This included information received from Baxter on recent and current</p>

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	<p>manufacturing activities and issues, communication actions, supply projections, and feedback from their contract manufacturing organisation.</p> <p>EMA also presented a summary of interactions with healthcare professional organisations and outlined preliminary key findings from the recent criticality survey on the shortages of ifosfamide and cyclophosphamide.</p> <p><u>Discussion</u></p> <p>SPOC WP members discussed ongoing mitigation activities including identification of suitable alternative medicinal products.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• EMA to track the implementation of <a href="#">MSSG recommendations</a> with the concerned MAH.</li> <li>• EMA, together with SPOC WP subgroup on ifosfamide and cyclophosphamide shortages, to continue monitoring the development of the shortage.</li> </ul>
	<p><b>b) Medicinal products affected by fire incident at Viatris manufacturing site</b></p> <p>EMA provided an update on the impact of the recent fire incident at a Viatris manufacturing site. EMA also presented the results of the criticality survey circulated to SPOC WP members, together with an overview of mitigation measures implemented to date. Following the initial assessment, EMA identified a few INNs requiring close monitoring.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• EMA will continue engagement with Viatris and closely monitor shortages of products affected by the fire incident.</li> </ul>
	<p><b>c) Gastrografin and Urografin NAP (sodium amidotrizoate, meglumine amidotrizoate), MAH: Bayer</b></p> <p>EMA provided background information on new ongoing shortages of Gastrografin and Urografin, noting that the shortages are due to a voluntary recall initiated by the MAH due to nitrosamine-related impurities. Additionally, EMA informed the group that a potential alternative MAH had been identified. EMA also outlined potential regulatory approaches proposed by this MAH, some of which aim to increase their production capacity.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• EMA to continue interaction with MAH Bayer and the identified alternative MAH.</li> <li>• SPOC WP members to reach out to the alternative MAH directly for potential supply support.</li> </ul>
	<p><b>d) Praziquantel containing medicinal products</b></p> <p>EMA presented an update regarding distribution developments for a praziquantel containing medicinal product, and results from enquiries with an alternative MAH.</p> <p><u>Discussion</u></p> <p>SPOC WP members discussed the presented distribution developments.</p> <p><b>Agreed actions:</b></p>

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	<ul style="list-style-type: none"> <li>SPOC WP members to reach out to the respective MAH for national needs and practical supply arrangements.</li> <li>SPOC WP members to indicate whether additional support through EMA is needed.</li> <li>Agreement reached by SPOC WP to close the shortage catalogue entry for Biltricide (praziquantel) by MAH Bayer.</li> </ul>
	<p><b>e) Nexobrid CAP (concentrate of proteolytic enzymes enriched in bromelain), MAH: MediWound Germany GmbH</b></p> <p>EMA presented information on a shortage of Nexobrid, which is used to remove dead tissue from areas of the skin such as burn wounds. It was noted that the root cause is linked to quality defect (QD), with EU batches currently on hold pending the outcome of the final investigation report.</p> <p>EMA also presented the results of the criticality survey and outlined ongoing and planned mitigation measures, including the development and publication of a shortage catalogue entry.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>EMA to continue engagement with MAH MediWound and the EMA Inspections Office to monitor the progress of the QD assessment, and to inform SPOC WP accordingly.</li> <li>Shortage catalogue entry to be developed and published on EMA website.</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) Medicinal products containing salbutamol (inhalation use)</p> <p>c) Medicinal products from MAH Cheplapharm</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>Impact of nitrosamines impurities on the availability of medicines</b></p> <p>EMA presented an update on the impact of nitrosamine impurities on the availability of medicines, including the regulatory background and progress on CAPA implementation.</p> <p><u>Discussion</u></p> <p>A SPOC WP member highlighted that overly restrictive nitrosamine requirements may pose a risk to medicine availability, including potential product withdrawals. EMA acknowledged these concerns.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>The topic to be brought to the SPOC WP meeting for further discussion, as appropriate.</li> </ul>
7.	<p><b>EC DG SANTE update</b></p>

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	<p>DG SANTE representative presented the provisions under Article 116(3a) of the new pharmaceutical legislation on the transfer of marketing authorisations in cases of intended withdrawal of critical medicinal products.</p>
8.	<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 23 March 2026</b></p> <p>DK SPOC WP member provided high-level feedback on the points discussed at the MSSG meeting in March 2026. These included an update from the European Commission (EC) covering both the implementation of the new pharmaceutical legislation and the developments in the co-legislative process for the proposed Critical Medicines Act. The MSSG meeting also covered the progress on the Vulnerability Assessment and an update from the MSSG WG on Voluntary Solidarity Mechanism (VSM) which included the closure of the WG. In addition, the Vice-Chair noted presentations on the activities related to shortages of ifosfomide and cyclophosphamide as well as the impact of the ongoing conflict in the Middle East.</p> <p><b>b) Feedback from the MSSG WG on Vulnerability Assessment Methodology</b></p> <p>EMA provided an update on the workshop held with MAHs for the 19 INNs in scope of the exercise, including feedback received from MAHs and industry associations. In addition, the proposed assessment approach was presented.</p> <p><u>Discussion</u></p> <p>A SPOC WP member inquired about timelines of the assessment guidance document for rapporteurs to which EMA confirmed that the work is ongoing with target for completion by end of May 2026.</p> <p><b>c) Union list of Critical Medicines and Union long list – update</b></p> <p>EMA provided an overview of the requests to add or remove medicines from the Union list of Critical Medicines as part of the 2026 annual review, including the number of stakeholders that responded and the estimated number of items to be classified by MSs. EMA further confirmed that the MSs classification phase for the 2026 annual review will start in May with a response deadline of 15 July 2026.</p> <p>Regarding the Union long list, EMA outlined proposed next steps, including further discussions with the EC to clarify the overall approach and structure.</p>
9.	<p><b>Medicine Shortages Communication (MSC) pilot</b></p> <p>EMA presented a summary of feedback received from MSs on the MSC pilot, as well as feedback from the Working Group of Communication Professionals (WGCP) on general shortage communication activities. The proposed next steps were also presented including target dates for the finalisation of the approach to MSCs going forward.</p> <p><u>Discussion</u></p> <p>SPOC WP members discussed the survey feedback highlighting resource constraints and challenges faced by some MAHs in implementing and disseminating them.</p>

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	<p>Different national approaches to the publication and handling of MSCs were also shared, underlining the need for clearer criteria. EMA noted that surveys have been distributed to MAHs, with a survey to Healthcare Professionals (HCPs) to follow in order to gather their feedback. EMA will review the responses and propose updates to MSC process, with any changes to be discussed and agreed by the SPOC WP.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• SPOC WP members to provide any additional feedback to EMA regarding MSC process.</li> </ul>
10.	<p><b>ESMP update</b></p> <p>EMA informed the group that CAP shortage reports will soon be available in SMART and provided an update on the upcoming VSM launch, which is planned for the end of April.</p>
11.	<p><b>AOB</b></p> <p>SPOC WP Secretariat reminded SPOC WP members to update their declarations of interests. SPOC WP Secretariat also noted that start of any academic activities is considered a competing interest and should be declared in the CV and DoI as soon as possible. SPOC WP members were asked to consult <a href="#">Policy 044</a> for more information.</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>

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**Next meeting:** 12 May 2026, TEAMS

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## List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 15 April 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	Stand-in Vice-Chair	No interest declared	
Anna Gerhartl	Austria	Member	No restrictions applicable to this meeting	
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	
Jakub Velik	Czechia	Member	No interest declared	
Michaela Kosová	Czechia	Alternate	No interest declared	
Stine Buchholdt	Denmark	Alternate	No interest declared	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Julia Lehtinen	Finland	Member	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Flore Demay	France	Member	No interest declared	
Theoni Kousteni	Greece	Member	No interest declared	
Thomas Brouwers	Germany	Member	No restrictions applicable to this meeting	
Gabriele Eibenstein	Germany	Member	No restrictions applicable to this meeting	
Andrea Stippler	Germany	Alternate	No interest declared	
Roger Pally	Germany	Alternate	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petró	Hungary	Alternate	No interest declared	
Hafþís Birna Baldursdóttir	Iceland	Alternate	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Oscar Cruciani	Italy	Alternate	No interest declared	
Linas Mažeika	Lithuania	Member	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	
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	
Simona Palovcikova	Slovakia	Member	No restrictions applicable to this meeting	
Erik Mokroš	Slovakia	Alternate	No interest declared	
Saša Martinc	Slovenia	Member	No interest declared	
Barbara Razinger	Slovenia	Alternate	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	
Marta Casalengua	Spain	Alternate	No interest declared	
Andreas Sundgren	Sweden	Member	No interest declared	
Karl Högström	Sweden	Alternate	No interest declared	
Rita Rom	Austria	Expert	No interest declared	
Verena Hofer	Austria	Expert	No interest declared	
João Simões	Portugal	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	
Patricia Rodríguez Molla	Spain	Expert	No restrictions applicable to this meeting	
Camilla Ledin	Sweden	Expert	No interest declared	
Fayeza Suleiman	Sweden	Expert	No restrictions applicable to this meeting	

Representatives from the European Commission and EDQM attended the meeting.

Meeting run with the help of EMA staff.