



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 June 2026
EMA/128036/2026
Regulatory Science and Innovation Task Force

Meeting Summary - Medicine Shortages SPOC Working Party

Tuesday, 12 May 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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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 (WP). 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.
2.	Adoption of draft minutes of the SPOC WP meeting held on 15 April 2026 DK SPOC WP member informed that the minutes of the meeting held on 15 April 2026 had been distributed one week prior to the meeting. No comments were received before and during the meeting and the minutes were adopted.
3.	Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market: Update on the geopolitical situation EMA provided feedback from the latest SPOC WP subgroup on crisis monitoring and preparedness meeting, including updates on the potential impact of the ongoing conflict in the Middle East on the availability of medicines in the EU. Regarding the Middle East conflict, only limited isolated risks were identified, which are being managed at national level. Industry associations reported no significant disruptions; however, continued cost increases and logistical challenges were noted. Supply chains remain operational but are increasingly reliant on mitigation measures such as rerouting, buffer stocks, and operational flexibility. <u>Discussion</u> A SPOC WP member shared initial findings from the national assessment of the potential impact on medicines and medical devices supply should the situation in the Middle East remain unchanged over the next four to six months. The findings indicate that a prolonged conflict could lead to a limited to moderate impact on the supply of medicines, and a moderate to high impact on the supply of medical devices. Agreed actions: - EMA, in collaboration with the SPOC WP subgroup on crisis monitoring and preparedness, will continue to closely monitor the ongoing situation in the Middle East, and its potential impact on the availability of medicines in the EU/EEA. - SPOC WP members are requested to report to EMA any observed impact of the situation in the Middle East on the availability of medicines in their territories.
4.	Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member reported a shortage of a beta-blocking agent due to manufacturing issues. No alternatives or import options are currently available in the jurisdiction. As a mitigation measure, distribution has been restricted, and the shortage is expected to be

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	resolved by December 2026. Most Member States (MSs) are not affected as the product is not marketed in their countries. One SPOC WP member reported a shortage of an antiepileptic medicinal product expected to last until end of June 2026, with limited alternative options. Initial feedback suggests that the shortage issue is primarily national in scope as most MSs reported minimal or no impact. EMA has not been notified of this shortage.
5.	Critical shortages escalated to the SPOC Working Party:
5.1	Ongoing shortages
	a) Ifosfamide containing medicinal products and cyclophosphamide containing medicinal products, MAH: Baxter EMA provided an update on the ongoing critical shortages of ifosfamide and cyclophosphamide, including information received from MAH Baxter and its contract manufacturing organisation (CMO) and outlined current and planned mitigation measures. EMA also informed the group about activities of Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) relating to these medicines. <u>Discussion</u> SPOC WP discussed ongoing efforts to encourage both Baxter and their CMO to improve and secure the supply of these critical medicines. Further, a SPOC WP member raised concerns regarding delays and lack of transparency in communication from the MAH/ CMO. EMA is aware and has raised the issue with the MAH. Agreed actions: • EMA, together with SPOC WP subgroup on ifosfamide and cyclophosphamide shortages, will continue monitoring the shortages, including tracking the implementation of MSSG recommendations with Baxter, and continue communication with both, the MAH and CMO as well as potential alternative suppliers.
	b) Gastrografin and Urografin NAP (sodium amidotrizoate, meglumine amidotrizoate), MAH: Bayer EMA presented an update on the ongoing shortages of Gastrografin and Urografin, including the outcome of the criticality survey for Urografin and updates from the current and an alternative MAHs. The root cause of the shortage is due to a voluntary recall of the medicines initiated by the MAH due to nitrosamine-related impurities. A SPOC WP member provided an overview of the shortage situation in their territory, including available alternatives. Agreed actions: • EMA to continue monitoring the shortage.
	c) Topamax NAP (topiramate), MAH: Johnson and Johnson

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	EMA presented an update on the critical shortage of Topamax, including ongoing work on the development of the Medicine Shortage Communication (MSC). EMA noted that once revised supply outlook will be provided by the MAH it will be shared with MSs. Agreed actions: • EMA to continue monitoring the shortage. • Shortage catalogue entry and MSC (following MSSG adoption) to be published on EMA website.
	d) Fibclot NAP (human fibrinogen), MAH: Laboratoire français du Fractionnement et des Biotechnologies S.A. (LFB) A SPOC WP member informed the group about the critical shortage of Fibclot in their territory and the mitigation measures in place, including controlled distribution. The product is indicated to treat and prevent bleeding in patients with rare blood disorders and to support the management of severe, uncontrolled bleeding. EMA presented an overview of the responses from the criticality survey and feedback received from the MAH. EMA also noted that alternative MAHs have been identified and discussions are ongoing to explore mitigation options.
	e) Mycobutin NAP (rifabutin), MAH: Pfizer B.V. EMA presented a new shortage case of Mycobutin due to manufacturing issues, following signals shared by a SPOC WP member in the April SPOC WP meeting. EMA presented the outcome of the criticality survey, with several MSs reporting shortages and noting concerns, and provided information received by the MAH on mitigation measures. Agreed actions: • Agreement to develop and publish a shortage catalogue entry. • Availability issues of anti-tuberculosis medicinal products to be discussed in future SPOC WP meetings.
	f) Praziquantel containing medicinal products EMA presented an update on the distribution developments for Bermoxel (praziquantel), MAH Medochemie. EMA requested MSs to provide feedback and to discuss national annual needs directly with Medochemie as soon as possible, if there is an interest to receive the product. Agreed actions: • MSs to facilitate their national decision-making related to the purchasing of the product, taking into account the feasibility of ordering their annual needs and to discuss with Medochemie accordingly. • Agreement to close EU-level coordination activities on praziquantel containing medicinal products.
5.2	Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)
	a) Medicinal products containing salbutamol (inhalation use)

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	b) Medicinal products affected by fire incident at Viatris manufacturing site c) Medicinal products from MAH Cheplapharm <u>Discussion</u> Regarding the status of medicinal products containing salbutamol, EMA proposed to pause EU-level activities, including monitoring, over the summer period, as the situation is currently considered stable. EMA will update the shortage catalogue entry accordingly and proposed reconvening for a supply status review in autumn 2026, if necessary. It was also noted that no updates will be requested from the relevant MAHs during this period however SPOC WP members may continue to report any critical shortages to EMA as needed.
6.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 24 April 2026 EMA provided high-level feedback on the discussions held at the MSSG meeting in April 2026. This included updates from the European Commission (EC) DG HERA on the Medical Counter Measures Strategy and from DG SANTE 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, among other topics, the progress on the Vulnerability Assessment exercise and update on the ongoing conflict in the Middle East and its impact on the availability of medicines in EU/EEA. b) Feedback from the MSSG WG on Vulnerability Assessment Methodology, including update on Shortage Prevention Plans (SPPs) EMA provided an update of the key outcomes of the latest meeting of the MSSG Working Group on the Vulnerability Assessment Methodology. The update covered the progress of the Shortage Prevention Plan template and guidance in line with the new pharmaceutical legislation to support implementation by MAHs, discussions on the supporting guidance and tools to complete the vulnerability assessment exercise, and an overview of the agreed next steps. c) Union list of Critical Medicines and Union long list – update EMA provided an update about the ongoing 2026 annual update activities of the Union list of critical medicines including lessons learned from the data consolidation exercise. Further, EMA informed the group on ongoing activities to agree the Union long list. The purpose of the Union long list is to identify critical medicines subject to obligations in case of market withdrawal, with updates to be managed through annual review cycles.
7.	SPOC WP subgroup on shortage definitions – Update on proposal of harmonised root cause classification EMA in collaboration with CHESSMEN WP 5 lead provided an update on the ongoing work on the proposal of the harmonised shortage root cause classification, including feedback gathered from the industry consultation which closed on 7 May 2026. No structural proposals were received from industry. Agreed actions:

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	The final proposal to be presented at the next SPOC WP meeting in June 2026 for SPOC WP endorsement.
8.	European Shortages Monitoring Platform (ESMP) update ESMP Network Product owner provided an update on the recent release of a new functionality related to voluntary solidarity mechanism submissions in the ESMP. The functionality will be released to all NCAs for testing in the second half of May. It was noted that the ESMP should not be used for real VSM submissions until EMA completes the full transition of VSM submissions to the ESMP.
9.	SPOC WP F2F June meeting — presentation of draft agenda and call for proposals of agenda topics EMA presented the current draft agenda for the face-to-face (F2F) SPOC WP meeting on 16–17 June 2026. EMA invited SPOC WP members to share their proposals or ideas on any topics or concerns they would like to bring to the group's attention at the F2F meeting. Agreed action SPOC WP members to share proposals for topics for the upcoming F2F SPOC WP meeting in June.
10.	AOB No comments were raised.
11.	Conclusions and next steps 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.
Next meeting: 16-17 June 2026, F2F EMA office (Amsterdam) + TEAMS	

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 12 May 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	
Vasileios Loutas	Cyprus	Vice-Chair	No interest declared	
Anna Gerhartl	Austria	Member	No restrictions applicable to this meeting	
Andrea Kugi	Austria	Alternate	No interest declared	
Sybilie Schotte	Belgium	Member	No interest declared	
Sanne Vandelanotte	Belgium	Alternate	No interest declared	
Emilia Stoyanova	Bulgaria	Member	No interest declared	
Radoslav Ruitchev	Bulgaria	Alternate	No interest declared	
Mateja Mervić	Croatia	Member	No restrictions applicable to this meeting	
Stela Lilek	Croatia	Alternate	No restrictions applicable to this meeting	
Jakub Velík	Czechia	Member	No interest declared	
Michaela Kosová	Czechia	Alternate	No interest declared	
Mathilde Moe Møldrup	Denmark	Member	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	
Minna Myllyntausta	Finland	Alternate	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Flore Demay	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	
Linda Holtkamp	Germany	Alternate	No interest declared	
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	
Margrét Lilja Heiðarsdóttir	Iceland			
Ellen McGrath	Ireland	Member	No interest declared	
Lisa Recchia	Italy	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 Olechnovič	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	
Martyna Jakubowska	Poland	Alternate	No interest declared	
Helena Ponte	Portugal	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
Susana Alves	Portugal	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	
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.				