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EMA/55346/2026
Regulatory Science and Innovation Task Force

Meeting Summary - Medicine Shortages SPOC Working Party

Tuesday, 17 February 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), Vice-Chair: Vasileios Loutas (PhS, Ministry of Health, Cyprus)

Item	Topic
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. The agenda was adopted with two additional points under AOB: • Union List of Critical Medicines – 2026 Annual Review: Reminder for SPOC WP members to submit proposals for adding or removing active substance groups (ASGs). • Reminder to SPOC WP members to update their declarations of interests (DoIs).
2.	**Adoption of draft minutes of the SPOC WP meeting held on 20 January 2026** The Vice-Chair informed that the minutes of the meeting held on 20 January 2026 had been distributed one week prior to the meeting. No comments were received before or during the meeting and the minutes were adopted with no changes.
3.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	a) Feedback from the SPOC WP subgroup on crisis monitoring and preparedness • **Update on the geopolitical situation** EMA provided feedback from the most recent subgroup meeting, noting that there have been no new signals from industry associations indicating potential supply disruptions due to the ongoing geopolitical situation. It was also noted that there is no analysis ongoing at national level, nor have any requests been made for an EU level coordinated assessment. **Agreed actions:** Due to the stability of the situation at the time of the meeting, members of the SPOC WP subgroup agreed to adjust the meeting schedule to a monthly cadence and will continue to closely monitor the impact of geopolitical situations on the supply and availability of medicinal products in EU/EEA countries. • **Availability of antibiotics: update on preparedness activities** EMA presented feedback from Member States (MSs) and marketing authorisation holders (MAHs) indicating that although a few localised supply constraints have been observed, the broader antibiotic supply situation continues to be stable. <u>Discussion</u> SPOC WP members exchanged information on supply of antibiotics in their countries.

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	Agreed actions: • EMA to follow-up with MSs experiencing antibiotic supply disruptions and provide support if needed. • EMA to continue monitoring the availability of antibiotics via information received from MAHs, SPOC WP, international regulators and ECDC epidemiology reports to identify early warning signals. • SPOC WP members to inform EMA in case critical shortages of antibiotics occur or any ongoing shortages deteriorate.
4.	**Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)** A SPOC WP member highlighted a shortage of a medicine used for enzyme replacement therapy and noted related tensions at hospital level. The SPOC WP member also emphasized that the situation is not critical and outlined current mitigation measures. EMA has not been made aware of any shortages of this product. **Agreed actions:** • EMA to liaise with the MAH to understand availability of the medicinal product in the respective MS and to inform the SPOC WP member once further information is available. • SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP if the abovementioned shortage situations deteriorate.
5.	**Critical shortages escalated to the SPOC Working Party:**
5.1	**Ongoing shortages**
	a) Medicinal products manufactured by Pharmathen International site EMA presented an update on the supply situation of medicinal products manufactured by Pharmathen, including oral formulations and long-acting injectables. Additionally, EMA presented the replies received from impacted and alternative MAHs and potential support identified for paliperidone palmitate and lanreotide prolonged-release suspensions for injection. **Agreed actions:** • EMA to continue engagement with Pharmathen International via bi-weekly meetings. • Pharmathen International has accepted the invitation for an oral explanation at the SPOC WP F2F meeting in March. SPOC WP to notify EMA of any specific questions they would like Pharmathen International to address. • SPOC WP members to share information about critical shortages of products manufactured by Pharmathen International and inform EMA in case they need support for paliperidone and lanreotide.

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	b) Oncology medicinal products from Teva, Accord EMA presented the latest information received from TEVA and Accord, noting the supply situation with oncology products from both MAHs has stabilised. **Agreed actions:** • EMA proposed discontinuing further EU-coordinated actions due to the stabilisation of the supply situation, and the SPOC WP members agreed.
	c) Medicinal products from MAH Cheplapharm • **Feedback from the SPOC WP Subgroup on Cheplapharm** EMA provided an update on the supply situation and ongoing and planned regulatory procedures for Visudyne and Zypadhera. EMA noted that a new supply chain for Visudyne is expected to become operational by mid 2026 with production ramping up gradually. The implementation of this new supply chain is expected to restore stable supply by end of 2026. In addition, EMA presented updates on the planned approach to targeted monitoring of certain medicines in Cheplapharm's portfolio and on bimonthly reports and next steps. **Agreed actions:** • EMA and SPOC WP to continue monitoring the supply situation of Cheplapharm medicinal products via the SPOC WP subgroup on Cheplapharm.
	d) Holoxan NAP (ifosfamide), MAH: Baxter A SPOC WP member, together with EMA, presented a new critical shortage of ifosfamide which is currently affecting or expected to affect most EU/EEA countries. Holoxan (ifosfamide) is used to treat various cancers, including sarcomas, lymphoma, testicular cancer, lung cancer, ovarian cancer. The shortage was initially raised at the 2026 January SPOC WP meeting during the oral status update and subsequently escalated for EU-level coordinated action. The root cause of the shortage is linked to technical problem at the manufacturing site and site improvements required after a regulatory inspection. In addition, EMA informed that production of Baxter's cyclophosphamide products is also affected. EMA further noted that a quota distribution system is expected to be in place until the end of 2026. A SPOC WP member presented the national situation on Holoxan shortages, and mitigation measures implemented. EMA presented an overview of the criticality survey results, showing no alternatives containing ifosfamide in most MSs and the ongoing mitigation activities which include engagement with MAH Baxter, and preparation of shortage catalogue entry and medicine shortage communication (MSC) for both products, among others. Additionally, EMA presented information received from identified alternative MAHs in the EU and from third countries for ifosfamide and cyclophosphamide, as well as international regulators. <u>Discussion</u> SPOC WP members informed about the situation at national level and mitigation activities, such as the establishment of an expert task force and emphasised the criticality of the shortage and the need for urgent continued coordinated actions at EU level. EMA proposed

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	setting up a dedicated SPOC WP subgroup on ifosfamide and cyclophosphamide shortages, which was agreed by SPOC WP members, as well as an escalation to the MSSG. **Agreed actions:** • SPOC WP members interested in joining the SPOC WP subgroup on ifosfamide and cyclophosphamide were invited to reach out to EMA. • SPOC WP members to submit demand data for both medicines to EMA. • SPOC WP agreed to escalate the shortage to the MSSG and organise an MSSG meeting with an oral explanation by Baxter on the situation and mitigation measures such as the quota system. • EMA to coordinate drafting and publishing MSCs and shortage catalogue entries for both products.
	e) Praziquantel containing medicinal products EMA provided an update from relevant MAHs regarding the availability of praziquantel containing medicines and information received from international jurisdictions on alternatives. **Agreed actions:** • Ongoing collaboration with MSs and relevant MAHs in sourcing praziquantel was agreed.
	f) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists EMA provided an update on supply situation of GLP-1 Receptor Agonists with a focus on Trulicity (dulaglutide) and Saxenda (liraglutide). It was noted that the shortage of Trulicity can be considered resolved, and, as a result, the closure of the shortage catalogue entry for Trulicity was proposed. <u>Discussion</u> SPOC WP members confirmed a stable supply of Trulicity in their countries and agreed to close the shortage catalogue entry for Trulicity. **Agreed actions:** • EMA to close the shortage catalogue entry for Trulicity. • EMA, with SPOC WP, to continue monitoring the supply situation of other GLP-1 RAs.
5.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments relating to previously circulated written updates)
	a) NovoSeven CAP (eptacog alfa), MAH: Novo Nordisk b) Medicinal products containing salbutamol (inhalation use) **Agreed actions:** • EMA to continue monitoring the ongoing and potential shortages listed above and to keep SPOC WP informed about latest developments.

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6.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG meeting on 30 January 2026 The Vice-Chair provided high-level feedback on the points discussed at the MSSG meeting in January 2026. These included an update from the European Commission (EC) on the Critical Medicines Act and the new pharmaceutical legislation (NPL). The Vice-Chair highlighted that a political agreement on the NPL was reached on 10 December 2025 and that the general implementation period is expected to be 24 months after entry into force, with the following exceptions: – Chapter X, Section I will become applicable 6 months after entry into force. – Chapter X, Section II will become applicable immediately upon entry into force. The MSSG meeting also covered a SPOC WP Flash report presentation, which provides an overview of all critical shortages discussed during the SPOC WP meetings, an update on the Union list of critical medicines, as well as the progress on the Vulnerability Assessment Methodology. • **Vulnerability Assessment Methodology - update** EMA clarified next steps for the vulnerability assessments, based on the approach agreed in the MSSG meeting: Based on a proposal from EC, MSSG agreed to a revised approach to the vulnerability assessment pilot to ensure that by the end of 2026, medicines with supply chain vulnerabilities, identified through formal assessment, can inform policy measures under the Critical Medicines Act and the new pharmaceutical legislation. For the purpose of the pilot, the MSSG agreed to prioritise vulnerability assessments for INNs associated with critical shortages in the last few years, as well as those with known vulnerabilities (including dependencies). It was also agreed that Phase I and Phase II analysis should be done in parallel, since the Supply Vulnerability Index (SVI) is not needed for prioritisation purposes during the pilot. Phase I provides a structured and consistent method to screen for macro-level signals of potential vulnerabilities, while phase II, builds on the Phase I with a detailed product-specific analysis to identify specific vulnerabilities, incorporating information primarily requested from Marketing Authorisation Holders. <u>Discussion</u> EMA clarified that for subsequent assessments beyond this pilot, phase I will be used for prioritisation, also taking into account lessons learned from the pilot. This will inform the basis to proceed to phase II assessment for the remaining INNs on the Union list of critical medicines.
7.	**Urban Wastewater Treatment Directive (UWWTD)** • **Potential impact of UWWTD on the supply and availability of medicines** A representative from Dutch Ministry of Health, Welfare and Sport presented an overview of the Urban Wastewater Treatment Directive (UWWTD), emphasising the implications of the

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	Extended Producer Responsibility (EPR) scheme and its potential impact on the availability of medicines. The speaker also noted that discussions related to UWWTD implementation are ongoing between health ministries across several EU/EEA MSs and encouraged SPOC WP members to involve their respective health ministries in these exchanges. Discussion SPOC WP members shared concerns regarding the potential impact on supply and availability of medicines and stressed the need to act before shortages occur. **Agreed actions:** • The topic of the UWWTD to be brought to future SPOC WP meetings for further discussion.
8.	**EC DG HERA update** A representative from DG HERA presented feedback from the recent meeting of the joint Industrial Cooperation Forum (ICF) and activities of ICF Working Group (WG) 1, highlighting assessment of supply chain vulnerabilities for medical countermeasures (excluding medicines on the Union list of critical medicines). The speaker also outlined the planned next steps for the ICF WG 1.
9.	**SPOC WP F2F March meeting - presentation of draft agenda and call for proposals of agenda topics** This topic could not be taken due to time constraints.
10.	**AOB** EMA reminded SPOC WP members to submit their proposals for adding or removing active substance groups from the current version of the Union list in the context of the 2026 annual update Union list of Critical Medicines. Additionally, SPOC WP Secretariat reminded SPOC WP members to update their declarations of interests (DoIs).
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 March 2026, Hybrid meeting

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 17 February 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	
Sybille Schotte	Belgium	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 Velik	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	
Minna Myllyntausta	Finland	Alternate	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Theoni Kousteni	Greece	Member	No interest declared	
Gabriele Eibenstein	Germany	Member	No restrictions applicable to this meeting	
Andrea Stippler	Germany	Alternate	No interest declared	
Linda Holtkamp	Germany	Alternate	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Petró Gyöngyi	Hungary	Alternate	No interest declared	
Kinga Csécsei	Hungary	Member	No interest declared	
Margrét Lilja Heiðarsdóttir	Iceland	Member	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Lisa Recchia	Italy	Member	No interest declared	
Oscar Cruciani	Italy	Alternate	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	
Jessica Zarb	Malta	Alternate	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	
Alina Iordache	Romania	Member	No interest declared	
Simona Palovcikova	Slovakia	Member	No restrictions applicable to this meeting	
Erik Mokroš	Slovakia	Alternate	No interest declared	
Barbara Razinger	Slovenia	Alternate	No interest declared	
María 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
Marta Casalengua	Spain	Alternate	No interest declared	
Andreas Sundgren	Sweden	Member	No interest declared	
Rita Rom	Austria	Expert	No interest declared	
Verena Hofer	Austria	Expert	No interest declared	
Nuno 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	
Maria Criado	Spain	Expert	No interest declared	
Representatives from the European Commission and EDQM attended the meeting. Meeting run with the help of EMA staff.				