



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 January 2026
EMA/377966/2025
European Medicines Agency

Meeting Summary - Medicine Shortages SPOC Working Party

11 November 2025, from 09:30 to 13:30 (CET), 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)'.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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 one additional point under AOB: EMA informed SPOC WP members about a planned crisis simulation exercise to test EMA's recently adopted Incident Management Plan.
2.	Adoption of draft minutes of the SPOC WP meeting held on 14-15 October 2025 The Vice-Chair informed that the minutes of the meeting held on 14-15 October 2025 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 EMA provided feedback from the SPOC WP subgroup meeting and noted that there have been no new signals indicating potential supply disruptions from industry associations and there is no analysis ongoing at national level. Additionally, there have been no requests for EU level coordinated analysis at this time. Agreed actions: - SPOC WP subgroup to continue meeting on a biweekly basis and closely monitoring the impact of geopolitical situations on the availability and supply of medicinal products in EU/EEA countries. Availability of antibiotics: update on preparedness activities EMA provided an update on the activities it undertakes in the ongoing autumn/winter 2025/2026 season including feedback from key MAHs of a subset of antibiotics indicated for respiratory infections regarding anticipated supply gaps. Additionally, EMA shared a list of MAHs that confirmed availability of additional stocks to assist Member States (MSs) facing shortages of these antibiotics. <u>Discussion</u> 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. Agreed actions: - SPOC WP members to inform EMA in case critical shortages of antibiotics occur, are expected, or if existing shortages deteriorate.

Item	Topic
4.	Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member reported an ongoing shortage of a progestogen containing medicinal product. It was noted that no alternatives with the same active substance and same pharmaceutical form are marketed in the MS. One SPOC WP member indicated a shortage of this product due to a high demand while confirming that alternatives are available in their territory. Other MSs reported that the product is either not marketed or there are no shortages currently in their countries. As a next step, EMA will follow-up with the SPOC WP member regarding the need for any EU coordinated action. A SPOC WP member highlighted a shortage of medicinal products used in treatment of addictive disorders due to a withdrawal of marketing authorisation of these products. Another SPOC WP member also noted that no alternative medicinal products in the same pharmaceutical form are available in their country. The group discussed the withdrawal of these products and a number of MSs raised concerns. Furthermore, EMA confirmed receipt of the planned withdrawal notification for one of these products and noted its inclusion on the agenda of the Committee for Medicinal Products for Human Use (CHMP) meeting in November, for information. To assess the potential impact, a survey was circulated to MSs to collect feedback, and the results will be shared with CHMP. A SPOC WP member reported a shortage of an antimetabolite medicinal product due to a permanent marketing cessation. It was also noted that no alternative medicinal products at ATC level 5 are available in the MS. SPOC WP members reported either no ongoing shortages or that the product is not marketed in their countries. As a next step, EMA will circulate the criticality survey to SPOC WP members to understand the situation in their countries. Agreed actions: • SPOC WP members to provide their feedback on the impact of the withdrawal of the medicinal products used in addictive disorders in the survey circulated by EMA. • SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP if the abovementioned shortage situations in their countries deteriorate.
5.	Critical shortages escalated to the SPOC Working Party:
5.1	Ongoing shortages a) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring EMA provided an update on the shortage and discontinuation of Beriglobin, outlining timelines for permanent marketing cessation in different countries. In addition, EMA noted ongoing interactions with ECDC to further understand the criticality of non-availability of Beriglobin. Lastly, it was noted that the MSC has been adopted by MSSG and published on EMA website together with the shortage catalogue entry. b) Medicinal products from MAH Cheplapharm EMA provided updates on the ongoing critical shortages of Visudyne and Zypadhera and presented the outcomes of the survey circulated to SPOC WP to identify supply issues with other medicines marketed by this MAH.

Item	Topic
	EMA informed that SPOC WP subgroup on Cheplapharm will be reactivated to discuss actions to manage and prevent shortages of medicinal products from this MAH. The group would also meet with the company as needed. SPOC WP members interested in joining the subgroup were invited to reach out to EMA. <u>Discussion</u> EMA and SPOC WP members discussed the need for the MAH to improve and align communication to NCAs and EMA. EMA also noted that the MAH has appointed a new contact point for Visudyne. The group emphasized the importance of providing timely and transparent communication to healthcare professionals, both during periods of critical shortage and when supply resumes. Agreed actions: • EMA to follow up with the MAH to reiterate the need for improved communication. • EMA and SPOC WP to continue monitoring the supply situation of Cheplapharm medicinal products, via the reactivated SPOC WP subgroup.
	c) Medicinal products manufactured by Pharmathen EMA presented updates on the ongoing shortages of quetiapine, venlafaxine, and atomoxetine. EMA informed the SPOC WP that Pharmathen will not have sufficient manufacturing capacity to meet the increased demand for quetiapine until mid-2026. • Risperidone (NAP) powder and solvent for prolonged-release suspension for injection medicinal products EMA presented feedback received from alternative MAHs for risperidone prolonged-release suspension for injection products and provided contact details for those MAHs with capacity to support MSs facing critical shortage with supplies. EMA also shared feedback from other jurisdictions, noting that shortage of risperidone is not currently considered critical. In case of need EMA would coordinate contact with manufacturers in other jurisdictions. Agreed actions: • EMA to continue engagement with Pharmathen International. • SPOC WP members to share information about critical shortages of products manufactured by Pharmathen International. <u>Risperidone:</u> • SPOC WP members to contact alternative MAH in case of support needed and keep EMA informed. • EMA to monitor the supply situation until risperidone is back in supply in all countries. • EMA to publish shortage catalogue entry.
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) Bronchitol (mannitol) CAP, MAH: Pharmaxis Europe Limited c) Medicinal products containing salbutamol (inhalation use)

Item	Topic
	d) Shortage and discontinuation of insulin containing medicinal products <u>Discussion</u> No comments were raised during the meeting. Agreed actions: • EMA to continue monitoring the ongoing and potential shortages listed above and to keep SPOC WP informed about latest developments.
5.3	Supply and availability of veterinary medicinal products
	a) Medicinal products to treat feline infectious peritonitis (FIP) EMA presented outcomes of another survey circulated to SPOC WP on access to treatment options for FIP in cats noting that no changes in availability were reported since the last survey which highlighted the lack of appropriate treatments for FIP. Agreed actions: • SPOC WP members to inform EMA about any further update/development in the availability of medication to treat cats diagnosed with FIP. • EMA to explore possibilities to improve access to appropriate medication for treatment of FIP in cats.
6.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 20 October 2025 The Vice-Chair provided feedback on the topics discussed during the MSSG meeting in October 2025 highlighting the final report of the ESMP/EMVS gap analysis. The draft vulnerability assessment methodology was also presented to the MSSG followed by discussion with industry associations representatives, with the written adoption procedure launched after the meeting. The Vice-Chair also informed that the MSSG discussed the ECA audit report on critical shortages of medicines and the process of issuing clinical recommendations on appropriate alternative medicines. In particular, it was noted that the national competence for clinical recommendations is not always with the NCA. As a next step, MSSG agreed to launch a survey to gather information on best practices at national level.
	b) MSSG WG on the Voluntary Solidarity Mechanism and Policy • Focal Group on Union list of critical medicines EMA outlined the procedure and timeline for the 2025 annual update of the Union list and presented the outcomes of the recently concluded stakeholder consultation. EMA also highlighted next steps which include MSSG adoption of the Union list of critical medicines, and its publication on EMA website. Finally, EMA noted the planned approach for future annual reviews starting from January 2026.

Item	Topic
	• Shortage Prevention and Mitigation Plans (SPMPs) EMA presented findings of the SPMP pilot and noted that it has proven to be a highly valuable exercise, offering important insights into the implementation process and highlighting key areas for improvement to support the effective implementation of the new pharmaceutical legislation. It was noted that the SPP and SMP templates will require further review and update to address the findings of the pilot. The draft SPMP pilot report was shared with SPOC WP members for their information on 4 November 2025. As next steps the SPMP pilot report will be published by the end of 2025 and the templates and guidance for companies will be reviewed in Q1 2026.
7.	European Shortages Monitoring Platform (ESMP) • ESMP/EMVS Gap analysis final report EMA presented the ESMP/EMVS gap analysis report, outlining its objectives, methodology, and conclusions. EMA informed the SPOC WP that while supply data from EMVS cannot replace industry reporting to ESMP, it can complement it, provided that both EMVS supply data and dispensation data are included. A 3-step approach was recommended to include (1) the mapping of EMVS product data to PMS, (2) the consumption of EMVS supply data by ESMP, and (3) the subsequent consumption of EMVS dispensation data. As next steps, the report will be presented to the Directors General of participating industry associations and EMVO Board for further discussion and agreements. • ESMP update EMA provided an update regarding the interim solution for ensuring routine CAP shortage reports from ESMP are accessible to SPOC WP members. As the next step, EMA will distribute an export of the shortages reported via ESMP to SPOC WP members on a monthly basis.
8.	Drug Shortage Global Regulatory Working group – update EMA informed about ongoing activities of the Drug Shortage Global Regulatory Working Group, including feedback from the Q3 meeting, update on the collaborative study on utilisation on GLP-1 RAs, and an exchange of information on shortages of concern.
9.	AOB EMA informed about the crisis simulation exercise planned for the first week of December 2025 to test EMA’s recently adopted Incident Management Plan.
10.	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: 09 December, TEAMS

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 11 November 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	
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 Kosová	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	
Theoni Kousteni	Greece	Member	No interest declared	
Gabriele Eibenstein	Germany	Member	No restrictions applicable to this meeting	
Thomas Brouwers	Germany	Member	No restrictions applicable to this meeting	
Andrea Stippler	Germany	Alternate	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petró	Hungary	Alternate	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	
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	
Rebwar Saleh	Norway	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 Paľovčíková	Slovakia	Member	No restrictions applicable to this meeting	
Saša Martinc	Slovenia	Member	No interest declared	
Barbara Razinger	Slovenia	Alternate	No interest declared	
María Esplugues Argente	Spain	Member	No restrictions applicable to this meeting	
Marta Casalengua	Spain	Alternate	No interest declared	
Samuel Silkestrand	Sweden	Member	No interest declared	
Karl Högström	Sweden	Alternate	No interest declared	
Anna Gerhartl	Austria	Expert	No restrictions applicable to this meeting	
Philip Pöschl	Austria	Expert	No interest declared	
Rita Rom	Austria	Expert	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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	
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	
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.				