



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 March 2026
EMA/38413/2026
Regulatory Science and Innovation Task Force

Meeting Summary - Medicine Shortages SPOC Working Party

Tuesday, 20 January 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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Item	Topic
1.	<p>Welcome, declaration of interest, adoption of draft agenda</p> <p>The Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party (WP). The Chair welcomed the CY SPOC WP member as the new rotating Vice-Chairperson under the Cypriot Presidency of the Council of the EU.</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 a reminder for SPOC WP members to complete a medicines shortage communication (MSC) survey, noted under AOB.</p>
2.	<p>Adoption of draft minutes of the SPOC WP meeting held on 9 December 2025</p> <p>The Vice-Chair informed that the minutes of the meeting held on 9 December 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>Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:</p>
	<p>a) Feedback from the SPOC WP subgroup on crisis monitoring and preparedness</p> <ul style="list-style-type: none">Update on geopolitical situation <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>Agreed actions:</p> <ul style="list-style-type: none">SPOC WP subgroup to continue meeting on a biweekly basis and monitor the impact of geopolitical situation on the supply and availability of medicinal products in EU/EEA countries.Availability of antibiotics: update on preparedness activities <p>EMA presented feedback received from SPOC WP 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.</p> <p>Agreed actions:</p> <ul style="list-style-type: none">EMA to follow-up with Member States (MSs) experiencing antibiotic supply disruptions and provide support if needed.SPOC WP members to inform EMA in case critical shortages of antibiotics occur or any ongoing shortages deteriorate.

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	<ul style="list-style-type: none"> EMA to continue monitoring the availability of antibiotics via information from MAHs, SPOC WP, international regulators and ECDC epidemiology reports to identify early warning signals.
4.	<p>Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)</p> <p>A SPOC WP member reported a shortage of an antineoplastic agent, due to a temporary production halt and a short-term interruption in product release. EMA has circulated a survey to assess the situation across EU/EEA countries. As a next step, EMA will contact the MAH to obtain further details regarding the supply situation.</p> <p>Another SPOC WP member reported a potential shortage of an antineoplastic agent due to withdrawal of the product from the market and a quality defect affecting the last two batches. EMA has contacted the MAH to obtain additional information and will share any updates with the SPOC WP as soon as they become available. The SPOC WP member further noted the availability of an alternative product, with the MAH indicating its capacity to compensate for the anticipated shortfall pending potential regulatory support. EMA will examine the potential for regulatory support activities to mitigate the risk of a potential shortage.</p> <p>One SPOC WP member reported a shortage of an antidepressant medicinal product due to a manufacturing issue. EMA has circulated a criticality survey to understand the situation in other EU/EEA countries and will follow-up with the SPOC WP member once more information is available.</p> <p>A SPOC WP member informed about anticipated shortages of some insulin preparations, including Insulin Lispro Sanofi 100 U/ml. While there are other short-acting insulins available, the SPOC WP member expressed concerns that switching patients to other insulin products may cause significant inconvenience. EMA is closely monitoring the supply of insulins. An MSC on Insulin Lispro Sanofi (cartridges and pre-filled pen) was recently published to inform health care professionals of expected shortages in 2026, including suggested mitigation measures. EMA will liaise with the SPOC WP member to assess whether engaging with alternative MAHs could help identify options to support the MS.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> SPOC WP members to submit critical shortage notifications to EMA (if not previously done) for circulation to the SPOC WP if the abovementioned shortage situations in their territories deteriorate.
5.	<p>Critical shortages escalated to the SPOC Working Party:</p>
5.1	<p>Ongoing shortages</p>
	<p>a) Medicinal products manufactured by Pharmathen International site</p> <p>EMA informed SPOC WP that Pharmathen International has voluntarily halted the manufacturing of prolonged release injectables. This is affecting the availability of several long-acting injectables products in EU/EEA (lanreotide, octreotide, paliperidone, and risperidone).</p>

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	<p>Lastly, EMA presented the outcomes of the criticality survey, revealing ongoing shortages in MSs for several long-acting injectable products and outlined the next steps.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> The critical shortage of paliperidone prolonged release suspension for injection was escalated to SPOC WP for EU coordinated action. As part of the shortage mitigation activities, EMA will contact both the impacted MAH and alternative MAHs to have an overview of the whole supply situation and to identify shortage mitigation measures. A shortage catalogue entry will be published on the EMA website. SPOC WP agreed to invite Pharmathen International to the face-to-face SPOC WP meeting in March for an oral explanation. EMA to continue engagement with Pharmathen International via biweekly meetings. SPOC WP members to share information about critical shortages of products manufactured by Pharmathen International.
	<p>b) Medicinal products from MAH Cheplapharm</p> <p>EMA provided an update on the ongoing critical shortages of Visudyne and Zypadhera, noting that additional stocks will be distributed. Additionally, EMA updated the group on the progress of ongoing regulatory procedures with Visudyne.</p> <p>A SPOC WP reported an ongoing shortage of an antihypertensive medicinal product in their country. SPOC WP members noted that the product is either not marketed or that no shortages are reported in their countries.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> EMA to follow up with the respective SPOC WP member to understand the situation and provide support if needed. EMA and SPOC WP to continue monitoring the supply situation of Cheplapharm medicinal products via the reactivated SPOC WP subgroup on Cheplapharm.
	<p>c) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists</p> <p>EMA provided an update on supply situation of GLP-1 RAs with a focus on Ozempic (semaglutide). It was noted that the situation has significantly improved, and, as a result, it was proposed that the shortage catalogue entry for Ozempic will be closed.</p> <p>Lastly, EMA provided a brief update on the progress of the DARWIN EU drug utilisation study about GLP-1 RAs, informing the group that study protocol has been recently finalised.</p> <p><u>Discussion</u></p> <p>SPOC WP members confirmed a stable supply of Ozempic in their countries and agreed to close the shortage catalogue entry for Ozempic.</p> <p>One SPOC WP member noted that controlled distribution for Saxenda remains in place in their country.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> EMA to close the shortage catalogue entry for Ozempic.

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	<ul style="list-style-type: none"> EMA, with SPOC WP, to continue monitoring the supply situation of other GLP-1 RAs.
5.2	<p>Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)</p>
	<p>a) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk</p> <p>b) Biltricide NAP (praziquantel) – MAH: Bayer</p> <p>c) Medicinal products containing salbutamol (inhalation use)</p> <p>d) Shortage and discontinuation of insulin containing medicinal products</p> <p><u>Discussion</u></p> <p>SPOC WP members discussed ongoing issues in sourcing praziquantel.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> EMA to seek clarification with relevant MAHs and continue collaboration with MSs regarding the availability of praziquantel and to understand the use of alternative products in other jurisdictions.
6.	<p>The value of ISO IDMP PhPID in clinical healthcare – within a country, cross border and in-hospital use</p> <p>A representative from NOMA presented the concept of the Pharmaceutical Product Identifier (PhPID) and its use in cross border clinical healthcare. A fictitious case involving a Dutch patient receiving treatment abroad was used to illustrate how ISO IDMP standards and the PhPID framework can facilitate safe and accurate continuity of medication management across national systems.</p> <p><u>Discussion</u></p> <p>The speaker noted that EC guidelines specify ISO IDMP data as the common framework for the cross-border identification and exchange of medication information within the European Health Data Space (EHDS).</p>
7.	<p>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:</p>
	<p>a) Feedback from the MSSG meeting on 17 December 2025</p> <p>A SPOC WP member provided a high-level update on the points discussed at the MSSG meeting in December 2025. These included an update on supply and availability of Zypadhera, followed by a presentation from the MAH Cheplapharm. The meeting also covered the annual review methodology of the Union list of critical medicines, an update from the European Commission (EC) on the Critical Medicines Act and the new pharmaceutical legislation, as well as progress on the Vulnerability Assessment Methodology.</p>
	<p>b) MSSG WG on the Voluntary Solidarity Mechanism and Policy</p> <ul style="list-style-type: none"> Union list of critical medicines - launch of 2026 annual review <p>EMA provided an update on the annual review methodology for the Union list, which was adopted by MSSG at its meeting in December 2025. It was further noted that the 2026</p>

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	<p>annual review was launched and MSs were invited to submit requests for review or removal of medicines from the Union list.</p> <p>Agreed actions:</p> <ul style="list-style-type: none"> EMA to regularly update the SPOC WP and MSSG throughout the process of the annual review.
8.	<p>EC DG SANTE update</p> <p>DG SANTE representative provided an update on the new pharmaceutical legislation with focus on both sections of Chapter X – monitoring and management of shortages, and security of supply.</p>
9.	<p>Drug Shortages Global Regulatory Working Group – update</p> <p>EMA informed the SPOC WP about topics discussed in the Q4 meeting held in December 2025.</p>
10.	<p>AOB</p> <p>EMA reminded SPOC WP members to complete the MSC survey.</p>
11.	<p>Conclusions and next steps</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: 17 February 2026, TEAMS

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 20 January 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	
Sybill 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 Velik	Czechia	Member	No interest declared	
Michaela Kosová	Czechia	Alternate	No interest declared	
Mathilde Moe Møldrup	Denmark	Member	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	
Theoni Kousteni	Greece	Member	No interest declared	
Thomas Brouwers	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	
Hafdís Birna Baldursdóttir	Iceland	Alternate	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	
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	
Susana Penedo Alves	Portugal	Member	No interest declared	
Alina Iordache	Romania	Member	No interest declared	
Erik Mokroš	Slovakia	Alternate	No interest declared	
Saša Martinc	Slovenia	Member	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	
Maria Criado	Spain	Expert	No interest declared	
Patricia Rodríguez Molla	Spain	Expert	No restrictions applicable to this meeting	
Ramiro Casamiro	Spain	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.