



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2026
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Regulatory Science and Innovation Task Force

Meeting Summary - Medicine Shortages SPOC Working Party

Wednesday, 15 July 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.	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 Chair welcomed the IE SPOC WP member as the new rotating Vice Chairperson under the Irish Presidency of the Council of the EU. 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, the SPOC WP secretariat announced the applicable restrictions and changes to the SPOC WP membership were announced. The agenda was adopted with one additional point under AOB.
2.	Adoption of draft minutes of the SPOC WP meeting held on 16-17 June 2026 Vice-Chair informed that the minutes of the meeting held on 16-17 June 2026 had been distributed one week prior to the meeting. No comments were received before or 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 an update on the ongoing monitoring of the potential impact of the conflict in the Middle East on the supply of medicines in the EU/EEA, including feedback received from industry associations. Industry associations and marketing authorisation holders (MAHs) reported no significant supply disruptions, although some continued to highlight increased costs and logistical challenges. No signals of supply disruptions were reported by Member States (MSs). • Potential impact of the Super Typhoon Bavi-26 (Inday) on the availability of medicines in EU/EEA EMA informed the SPOC WP of the ongoing monitoring of the potential impact of Super Typhoon Bavi-26 (Inday) on the availability of medicines in the EU/EEA. The typhoon, considered a significant weather event, affected regions of East and Southeast China where a number of pharmaceutical manufacturing facilities are located. EMA has engaged with industry associations and MSs to gather information, assess potential risks, and identify any early warning signals. To date, no signals of supply disruptions have been reported. Agreed actions: • SPOC WP members are requested to report to EMA any signals of medicine supply disruptions in their countries that may be associated with the situations outlined above. • EMA, in collaboration with the SPOC WP subgroup on crisis monitoring and preparedness, will continue monitoring the abovementioned situations and their potential impact on the supply of medicines in the EU/EEA and to provide regular updates to the SPOC WP.

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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 medicine used in diabetes treatment in their jurisdiction since April 2025. It was noted that, despite mitigation measures being implemented, pharmacies have increasingly reported limited availability of the product. Several SPOC WP members provided feedback and confirmed that no supply concerns are currently being experienced in their countries. In addition, EMA has not received any other shortage notifications related to this product. One SPOC WP member reported supply constraints with an antimycobacterial medicine. Feedback from other MSs indicated that this appears to be a localised issue. In addition, EMA has not received any other notifications relating to unavailability of this product.
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 revised supply projections indicating lower forecast deliveries than previously reported. EMA noted that supply remains unpredictable. EMA presented ongoing mitigation measures, including contacts with alternative manufacturers of both ifosfamide and cyclophosphamide to explore possibilities to increase manufacturing capacity of the authorised products, or to source unauthorised products from international sources. EMA also presented the updated MSSG recommendations which were adopted on 15 July and will be soon published on EMA website. <u>Discussion</u> SPOC WP members discussed the importation of unauthorised products from third countries as a potential mitigation measure to address the shortage. In view of the critical supply situation, members also discussed the potential for joint procurement of alternative products. EMA noted that Member States may pursue multilateral procurement arrangements. Agreed actions: • EMA to assess potential joint procurement pathways and to support the identification of potential ongoing national assessments for unauthorised products that can be shared with other SPOC WP members. • EMA to continue monitoring implementation of MSSG recommendations with concerned MAHs through discussions with SPOC WP subgroup. • SPOC WP members are requested to flag critical and potential critical stock situations that cannot be handled by national measures (e.g. import) to EMA as early as possible. b) Brevibloc NAP (esmolol), MAH: Baxter

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	EMA presented the shortage of Brevibloc (esmolol) noting that the shortage is expected to last until the end of 2027. The product is indicated for (1) the short-term control of certain rapid heart rhythms and (2) the control of tachycardia and hypertension during the perioperative period. The root cause of the shortage is due to the discontinuation of manufacturing activities at the active pharmaceutical ingredient (API) supplier. EMA presented long-term mitigation measures proposed by the MAH which includes registration of a new API supplier. In the interim, Baxter intends to seek exemptions to import and supply equivalent product from abroad in affected EU countries until a new API supplier has been approved. Agreed actions: • EMA to continue monitoring the development of the shortage and mitigation measures. • Agreement to develop a shortage catalogue entry to be published on EMA website.
	c) Availability of anti-tuberculosis medicines EMA presented the final results of the survey circulated to MSs on the availability of anti-tuberculosis medicines. The most critical shortage identified is the ongoing shortage of Mycobutin (rifabutin), MAH: Pfizer. Intermittent shortages of rifampicin-containing tablets and capsules marketed by various MAHs were also reported by several MSs. EMA provided an update on the shortage of Mycobutin (rifabutin), including feedback received from Pfizer and alternative suppliers. For rifampicin tablets and capsules, EMA identified several alternative suppliers and shared contact details of companies which may be able to support MSs experiencing supply difficulties. MSs should contact the companies directly. Lastly, EMA informed the SPOC WP that an Article 31 referral procedure for Rifadin (rifampicin) oral suspension and syrup for paediatric use was initiated in June following concerns related to the excipient diethanolamine (DEA). Agreed actions: • MSs to continue sharing any new information or concerns on the availability of anti-tuberculosis medicines with EMA to support ongoing discussions with current and alternative suppliers.
	b) Gastrografin and Urografin NAP (sodium amidotrizoate, meglumine amidotrizoate), MAH: Bayer EMA provided an update on the ongoing shortages of Gastrografin and Urografin following Bayer's voluntary request to withdraw both products due to nitrosamine levels above acceptable limits. <u>Discussion</u> SPOC WP members informed about the discontinuation status of the products in their jurisdictions and provided feedback on the national impact of the shortages. Several MSs indicated that the situation is not considered critical due to the availability of suitable therapeutic alternatives.

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	Agreed actions: • EMA to continue engagement with Bayer to explore potential mitigation options. • SPOC WP members to provide any additional information on the status of and response to withdrawal requests for Gastrografin and Urografin, mitigation measures implemented in response to the discontinuation, and the availability of alternative treatments for the specific indication in meconium ileus.
	c) Albendazole containing medicinal products EMA presented an ongoing shortage of albendazole containing medicinal products, primarily affecting products marketed by one MAH. Albendazole is included in the Union list of critical medicines and is indicated for the treatment of a range of parasitic worm infections. The root cause of the shortage is a significant disruption in the supply of the API from the approved API manufacturer. MAH informed EMA that an alternative API manufacturer has been identified. EMA identified an alternative MAH, which markets albendazole-containing products and indicated that they have sufficient stock available and the capacity to increase production if required. FR representative also presented an overview of the national shortage situation and outlined mitigation measures implemented in France, including a letter issued to healthcare professionals promoting appropriate use of albendazole to regulate prescriptions and importation of WHO stocks, among others. Agreed actions: • SPOC WP members to reach out to the alternative MAH directly to discuss potential to supply alternative product, if needed.
5.2	Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)
	a) Nexobrid CAP (concentrate of proteolytic enzymes enriched in bromelain), MAH: MediWound Germany GmbH b) Azactam NAP (aztreonam), MAH: Delbert Pharma c) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring d) Uromitexan NAP (mesna), MAH: Baxter e) Medicinal products from MAH Cheplapharm f) Insulin containing medicinal products <u>Discussion</u> A SPOC WP member provided an update on ongoing shortage of Azactam highlighting the establishment of a national task force and the implementation of controlled distribution measures in their country. Agreed actions:

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	- Agreement to close Union coordinated actions for Beriglobin (human normal immunoglobulin), MAH: CSL Behring. - SPOC WP to continue monitoring the critical shortages listed above.
6.	Impact of nitrosamines impurities on the availability of medicines - update
	EMA provided an update on the ongoing work concerning the impact of nitrosamine impurities on the availability of medicines. Acceptable intake (AI) limits have been established for nitrosamines and MAHs are required to implement corrective and preventive actions (CAPAs) within agreed timelines. To mitigate the risk of supply disruptions, temporary application of the less-than-lifetime (LTL) approach has been permitted while CAPAs are being implemented. Agreed actions: EMA to keep the SPOC WP informed of relevant developments and provide updates as appropriate.
7.	EC DG SANTE update
	DG SANTE representative provided an update on the new pharmaceutical legislation and the Critical Medicines Act (CMA), including the expected timelines for the entry into force and application. The EC also outlined the main elements of the CMA, focusing on points relevant to the SPOC WP, including new responsibilities related to contingency stock monitoring and reporting. In addition, the EC highlighted overall CMA provisions such as the usage of strategic projects or procurement tools to strengthen the security of supply and availability of critical medicinal products in the EU/EEA. <u>Discussion</u> EMA raised a question whether conditions to initiate the collaborative procurement as outlined in the CMA are cumulative or alternative. DG SANTE representative confirmed that all conditions must apply, including the requirement for a formal request from at least five Member States.
8.	Implementation of the New Pharmaceutical Legislation: Provisions related to shortages and security of supply
	As a follow-up to the discussion at the June F2F SPOC WP meeting, EMA presented the consolidated initial overview of nationally led NPL activities which could benefit from further EU-level coordinated discussion on harmonised approaches to support implementation, based on feedback received from SPOC WP members. EMA proposed that further discussion on these activities could be taken forward within the existing SPOC WP Subgroup on Shortage Definition. A call for expression of interest will be launched for SPOC WP members to join the subgroup.
9.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Union list of critical medicines and Union long list - update

Item	Topic
	EMA provided an overview of the discussions held during the first meeting of the Focal Group following its reactivation. EMA also organised an interactive session to gather information on how Member States assess critical medicines at national level. The aim of the Focal Group is to contribute to the update of the methodology for identifying critical medicines and methodology for the annual review of the Union list, among others. <u>Discussion</u> A SPOC WP member noted the importance of aligning national and EU-level activities related to the methodology for identifying critical medicines in light of the NPL implementation (e.g. stakeholder involvement). It was agreed that the topic will be further discussed at the Focal Group on the Union list of critical medicines. b) Feedback from the MSSG WG on Vulnerability Assessment Methodology, including update on Shortage Prevention Plans (SPPs) EMA provided an update on the ongoing 2026 Vulnerability Assessment exercise, including response rates from MAHs and initial feedback from Rapporteurs. EMA informed the SPOC WP that 197 MAHs had been contacted and that the follow-up would focus on companies with a significant market share whose responses remain outstanding. EMA presented the updated SPP template and corresponding guidance for industry, noting that feedback received from industry associations through the written consultation and a dedicated workshop had been considered in the revision of both documents. <u>Discussion</u> A SPOC WP member inquired whether MAH's self-assessment of risk will be documented in any system other than SPPs (e.g., PMS). EMA clarified that this is currently not foreseen. Agreed actions: • Vulnerability assessment by Rapporteurs ongoing, using the agreed template and guidance. • Updated SPP template and guidance to be adopted by the MSSG at the MSSG meeting on 17 July 2026.
10.	European Shortage Monitoring Platform (ESMP) update EMA provided a brief update on the ESMP, including recent developments related to the voluntary solidarity mechanism (VSM) and critical shortage submission functionalities. EMA also informed the SPOC WP that the ESMP team is launching Epic 3 and is seeking an additional NCA Subject Matter Expert (SME) to support the work. Two SPOC WP members shared their experiences from acting as ESMP SMEs, and they will also be continuing their roles as NPOs (Network Product Owner) and SMEs. Agreed actions: • A call for nomination for an additional ESMP NCA SME to be launched post-meeting.
11.	AOB

Item	Topic
	A SPOC WP member asked members whether any of the MSs plan to attend an upcoming Convention on Pharmaceutical Ingredients (CPHI Milan 2026: Shaping Pharma's Future) taking place in Milan in October 2026 and would be interested in a side event (in context of Critical Medicines Act).
12.	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. The Chair noted that the next SPOC WP meeting is planned for 15 September 2026. A placeholder for 12 August has been scheduled in case there is an urgent issue that would require discussion by the WP.
Next meeting: 15 September (TEAMS) (placeholder 12 August)	

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 15 July 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
Síofradh McMahon	EMA	Stand-in Chair	No interest declared	
Ellen McGrath	Ireland	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	
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	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Minna Myllyntausta	Finland	Alternate	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	
Inke Reimer	Germany	Member	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petró	Hungary	Alternate	No interest declared	
Margrét Heidarsdóttir	Iceland	Member	No interest declared	
Rosemary Heneghan	Ireland	Alternate	No interest declared	
Oscar Cruciani	Italy	Alternate	No interest declared	
Linus 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	
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 Alves	Portugal	Member	No interest declared	
Alina-Titina 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	
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	
Rita Rom	Austria	Expert	No interest declared	
Verena Hofer	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
Lucia Rychvalská	Czechia	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	
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.				