29 October 2026
EMA/226247/2026
Regulatory Science and Innovation Task Force

Summary - Medicine Shortages SPOC Working Party

Tuesday, 15 September 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: Ellen McGrath (HPRA)

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, the SPOC WP secretariat announced the applicable restrictions. 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 15 July 2026** Vice-Chair informed that the minutes of the meeting held on 15 July 2026 had been distributed one and half weeks 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 conflict in the Middle East, noting that no indications of supply disruptions have been reported by industry stakeholders, Member States (MSs), or international regulatory authorities. **Agreed actions:** • SPOC WP members are asked to report to EMA any signals of medicine supply disruptions in their countries that may be associated with the conflict in the Middle East. • EMA, in collaboration with the SPOC WP subgroup on crisis monitoring and preparedness, will continue monitoring the conflict and its potential impact on the supply of medicines in the EU/EEA and to provide regular updates to the SPOC WP.
	a) Availability of antibiotics: update on preparedness activities EMA informed the SPOC WP about ongoing and planned activities in preparation for the upcoming autumn/winter season 2026/2027. These include outreach to key marketing authorisation holders (MAHs) to obtain an overview of the expected supply situation, liaising with the international regulators in the southern hemisphere on the antibiotic supply situation during their autumn/winter season and the re-launch of a social media campaign promoting prudent use of antibiotics. <u>Discussion</u> A SPOC WP member enquired whether any signals had already been identified regarding potential availability issues for antibiotics during the 2026/2027 autumn/winter season. EMA confirmed that no such signals had been identified at this stage. A more comprehensive assessment of the situation will be performed once further information becomes available.

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	Agreed actions: • EMA to continue preparedness activities related to the availability of antibiotics and inform SPOC WP about outcomes.
	b) Seasonal influenza vaccine supply update EMA informed the SPOC WP of anticipated supply delays affecting some egg-based influenza vaccines due to the change of all influenza strains for the current season and delays in the global supply of reagents coordinated by the World Health Organization (WHO). EMA reached out to MAHs of these vaccines and four out of the seven supplying the EU market confirmed that they expect delays. The other three indicated that no significant delays are expected. EMA also presented available mitigation measures, including alternative vaccines that could be used to address urgent demand, and shared the relevant contact details with SPOC WP members. <u>Discussion</u> A SPOC WP member provided feedback on the national situation. **Agreed actions:** • EMA will continue to monitor the situation at EU level and engage with the relevant MAHs to assess the extent of the delays and their potential impact on the supply of medicines across EU/EEA markets. • MSs should provide EMA with information of any new arising shortages or developments.
4.	**Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)**
	A SPOC WP alternate informed the group of an ongoing shortage of an antibiotic which is expected to continue until the end of 2026. The MS is exploring the possibility of importing the product from abroad, although international wholesalers indicated that the import process may take approximately four weeks. Most MSs reported no shortages of the antibiotic, indicating that the shortage is currently localised in the MS concerned.
	A SPOC WP member reported an ongoing shortage of a rabies vaccine. The product is included in the Union list of critical medicines, and the shortage is considered critical in the MS. The shortage is linked to a sustained increase in demand exceeding current supply capacity resulting in recurring supply disruptions. The current supply interruption is expected to continue until 23 October 2026. A second SPOC WP member reported a similar situation in their jurisdiction where a shortage of the rabies vaccine is expected to continue until January 2027. Most SPOC WP members reported no shortages of rabies vaccines in their countries and some MSs noted availability of alternative products.

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	One SPOC WP member reported shortage of an antihypertensive medicinal product with no stock currently available at wholesaler level and no alternative medicinal products available in the MS. No shortages or only limited supply issues were reported in other MSs.
	A SPOC WP member reported ongoing shortages of certain laxatives in their MS. Regular resupply is currently expected in early 2027. The member noted that the availability of foreign-language packs is expected to cover approximately two months of demand however supply beyond this period has not yet been secured. Although one alternative product is available, it is not suitable for all patients and may not be available in sufficient quantities to fully mitigate the impact of the shortages. Several SPOC WP members also reported ongoing shortages of these products with some MSs noting availability of alternatives.
	One SPOC WP member informed the group of the unavailability of a muscle relaxant and noted that product had previously been supplied under a temporary import licence but is no longer supplied. Initial feedback from MSs indicated differences in the availability of the product across EU. Most SPOC WP members reported no ongoing shortage of these medicinal products in their countries.
	Agreed actions: • SPOC WP members to submit a critical shortage notification to EMA should the situation concerning the above-mentioned shortages deteriorate in their countries.
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 activities to mitigate the shortages of ifosfamide and cyclophosphamide products. These included, among others, shared foreign language packs for certain MSs, and additional weekly meetings with Baxter to discuss short and long-term shortage mitigation actions and support the resolution of issues. Additionally, EMA presented the supply plan for the remainder of the year and noted that, although the supply situation had stabilised, a risk of deterioration remains depending on manufacturing operations and planning activities. Discussion SPOC WP members provided updates on the availability of both medicinal products in their territories with many confirming that the supply situation seemed to have stabilised, although it continues to be monitored closely. **Agreed actions:** • Continued monitoring of the supply situation and the implementation of MSSG recommendations.

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	• SPOC WP members to flag any critical and potential critical stock situations that cannot be handled by national measures (e.g. import) to EMA as early as possible.
	b) Emend CAP (aprepitant), MAH: Merck Sharp & Dohme (MSD) EMA informed the group about the MAH's intention to discontinue all presentations of Emend (aprepitant). The timing of the discontinuation will vary by country and presentation, depending on depletion of available supply. Emend is indicated for the prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy. The hard capsule formulation is authorised for adults and adolescents, while the powder for oral suspension is intended for children aged 6 months to 12 years. EMA noted the absence of a suitable alternative for paediatric use and highlighted that the European Directorate for the Quality of Medicines & HealthCare (EDQM) has issued and published guidance on the extemporaneous preparation of an oral liquid formulation using the adult capsules. Discussion SPOC WP members discussed the discontinuation of the product, with some members noting that the paediatric formulation had either never been available in their MS or had since been discontinued. Available therapeutic alternatives for paediatric use were discussed, although options for oral administration were noted to be limited. **Agreed actions:** • EMA shortage catalogue entry and Medicine Shortage Communication (MSC) to be published. • SPOC WP members to provide any relevant updates related to the availability of the product.
	c) Nexviadyme CAP (avalglucosidase alfa), MAH: Sanofi B.V. EMA provided an update on ongoing shortages of Nexviadyme due to delays in the release of product at the Waterford site, Ireland, following an FDA Warning Letter. Several MSs are affected and resolution of the shortage is currently expected by the end of 2026. EMA outlined mitigation measures proposed by the MAH. Discussion A number of SPOC WP members shared information on national mitigation measures. **Agreed actions:** • Agreement to publish an entry in EMA's shortage catalogue for Nexviadyme. • SPOC WP members to provide information of any new arising shortages or developments.
	d) Lenalidomide Mylan CAP (lenalidomide), MAH: Mylan EMA presented a new critical shortage of Lenalidomide Mylan. Lenalidomide is indicated for the treatment of multiple myeloma and follicular lymphoma. The shortage is due to a quality

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	defect that resulted in the recall of affected batches. EMA has identified alternative MAHs and has initiated outreach to explore options to mitigate the shortage. **Agreed actions:** • EMA to monitor the supply situation and update SPOC WP accordingly. • SPOC WP members to inform EMA in case of changes in availability of the product and its alternatives.
5.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments relating to previously circulated written updates)
	a) Brevibloc NAP (esmolol), MAH: Baxter b) Medicinal products from MAH Cheplapharm c) Medicinal products manufactured by Pharmathen International site d) Anti-tuberculosis medicines e) Albendazole containing medicinal products EMA will continue monitoring the ongoing shortages listed above and will keep SPOC WP informed of any developments.
6.	**EC DG HERA update on RAMP UP**
	EC DG HERA representative presented the Rapid Agile Manufacturing Partnership for Union Protection (RAMP UP) Initiative, a voluntary preparedness network established by DG HERA to strengthen Europe's ability to rapidly scale up the production and supply of medical countermeasures (MCMs) in the event of a health emergency. DG HERA representative also informed the SPOC WP that a pilot phase has been launched to engage and onboard stakeholders with portfolios relevant to medical countermeasure preparedness and outlined the associated data collection process. Discussion SPOC WP members inquired about details of the RAMP UP initiative, highlighting the importance of ensuring coherence and alignment with the EMA led vulnerability evaluation exercise and the agreed MSSG methodology. **Agreed actions:** • DG HERA to share updates on RAMP UP initiative as appropriate.
7.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG meeting on 17 July 2026 The SPOC WP Vice-chair provided feedback on the topics discussed during the MSSG meeting in July 2026 highlighting presentation from DG SANTE on the New Pharmaceutical Legislation and Critical Medicines Act and update from MSSG WG on the Vulnerability Assessment exercise and shortage prevention plan (SPP) template and guidance.

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	The Vice-chair also informed that the MSSG discussed the ongoing critical shortage of Visudyne including developments related to the new supply chain, and ongoing critical shortages of ifosfamide and cyclophosphamide.
	b) Voluntary Solidarity Mechanism (VSM): Presentation of the latest VSM procedures • **Tamoxifen** EMA presented the outcome of the VSM procedure initiated by Czechia in July 2026 for tamoxifen-containing medicinal products. EMA informed that several MAHs offered supply support, enabling the procedure to be concluded before its formal launch. CZ SPOC WP member presented the national situation regarding the shortage of tamoxifen and outlined the mitigation measures implemented, including importation of unauthorised product, support through the VSM, and engagement with alternative suppliers, among others. Lastly, CZ SPOC WP member thanked EMA for the coordination, assistance, and support provided throughout the procedure. • **Calcium levofolinate** EMA presented the outcome of the VSM procedure initiated by France in August 2026 for calcium levofolinate-containing medicines. Prior to the launch of the formal VSM procedure, a limited number of MAHs had offered partial support. Following the launch of the procedure, several MAHs and MSs offered potential support with the therapeutic alternatives calcium folinate and disodium levofolinate. EMA also highlighted the ongoing shortages of calcium folinate across multiple MSs. FR SPOC WP member provided a brief update on the current situation, highlighting that two imports had been authorised. FR SPOC WP member also noted that additional supply offers and mitigation measures, including controlled distribution, are being explored.
	c) Union list of critical medicines and Union long list – update • **Union list of critical medicines:** EMA presented the preliminary outcomes of the member state classification exercise for the 2026 annual review. EMA will share the updated draft version of the Union list of critical medicines with the SPOC WP after the meeting. The draft will also be circulated to industry, healthcare professionals and patient stakeholders for their feedback prior to finalisation with MSs expected in November 2026, after which MSSG will adopt and propose it to the EC. • **Union long list:** EMA provided update on the Union long list. The first draft of the Union long list has been circulated to SPOC WP and former Union list of critical medicines focal group members for review. EMA further noted that the first adoption of the Union long list is expected after entry into force of the new pharmaceutical regulation and the related transfer provision becomes applicable from 6 months post entry into force.
	d) Feedback from the MSSG WG on Vulnerability Assessment Methodology EMA presented an update on the progress of the revised SPP template and associated guidance. EMA also informed that the shortage mitigation plan (SMP) guidance and template

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	are currently being reviewed to align with the new pharmaceutical legislation with MSSG adoption and publication expected by the end of 2026. In addition, EMA provided update on the Vulnerability Assessment exercise, which continues to progress well with active participation from Rapporteurs and ongoing support through the Working Group and technical drop-in sessions. Presentation of the outcomes for all INNs to MSSG is planned for December 2026.
8.	**European Shortage Monitoring Platform (ESMP) update** EMA informed the Working Party that following successful testing of the VSM and critical shortage submission functionalities within the ESMP by national competent authorities, the ESMP became the main channel for VSM requests as of 15 September. Submission of VSM requests via the MSSG Secretariat mailbox remains available as a fallback option in case of technical issues or when submission through the ESMP is not possible. Furthermore, as of 1 October, the ESMP will become the primary channel for NCA critical shortage submissions. In addition, EMA informed that the selection process for the ESMP Network Subject Matter Expert is ongoing, with the outcome expected to be communicated soon. <u>Discussion</u> A SPOC WP member asked for clarification regarding the practical use of SharePoint following the migration of critical shortage notification submission to ESMP. EMA clarified that current SharePoint folders will no longer be used however the approach of sharing case-specific documentation is still under discussion, and further clarification will be provided at a later stage.
9.	**SPOC WP F2F October 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 13-14 October 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.
10.	**AOB** SPOC WP members were reminded to complete the survey to collect information on medicine shortage cases at national level that may be linked to nitrosamine-related regulatory measures.
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: 13-14 October, 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 15 September 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	
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	
Vasileos Loutas	Cyprus	Member	No interest declared	
Jakub Velík	Czechia	Member	No interest declared	
Michaela Kosová	Czechia	Alternate	No interest declared	
Mathilde Moe Møldrup	Denmark	Member	No interest declared	
Stine Moliin Bucholdt	Denmark	Alternate	No interest declared	
Julia Lehtinen	Finland	Member	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Laurent Fabry	France	Member	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	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petró	Hungary	Alternate	No interest declared	
Margrét Heidarsdottir	Iceland	Member	No interest declared	
Rosemary Heneghan	Ireland	Alternate	No interest declared	
Oscar Cruciani	Italy	Alternate	No interest declared	
Lisa Recchia	Italy	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	
Jessica Zarb	Malta	Alternate	No interest declared	
Saskia van Dongen	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	
João Simões	Portugal	Alternate	No interest declared	
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	
Marta Casalengua	Spain	Alternate	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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	
Lucia Rychvalská	Czechia	Expert	No interest declared	
Liis Märss	Estonia	Expert	No interest declared	
Carla Maione	Italy	Expert	No interest declared	
Nuno Simões	Portugal	Expert	No interest declared	
Isabelle Barabas	Romania	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.				