10 September 2025
European Medicines Agency

Meeting Summary - Medicine Shortages SPOC Working Party

14 July 2025, from 09:30 to 13:40 (CEST), 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 being brought to the SPOC WP meetings.

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

Chair: Monica Dias (EMA), Vice-Chair: Mathilde Moe Møldrup (DKMA, Denmark)

Item	Topic
1.	**Welcome, declaration of interest, adoption of draft agenda** The Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party (WP). The Chair welcomed the DK SPOC WP member as the new rotating Vice-Chairperson under the Danish 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. The agenda was adopted with one additional point under AOB – Update on CHESSMEN Work package 8 by a SPOC WP member.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 17 June 2025** The Vice-Chair informed the group that the minutes of the meeting held on 17 June 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 informed the SPOC WP that the subgroup continues to monitor a number of ongoing geopolitical situations and no coordinated action at EU level is currently required. **Agreed actions:** • SPOC WP subgroup to continue close monitoring of the impact of geopolitical situations on the availability and supply of medicinal products in EU/EEA countries.
	b) Availability of antibiotics: update on preparedness activities EMA provided an update on the regulatory support request from one MAH to increase the EU supply of their antibiotics in the long term. Further, and given the current situation in Member States on the availability of antibiotics, EMA concluded that a supply-demand matching exercise for the upcoming autumn/winter season is not needed at the moment. **Agreed actions:** • SPOC WP members to continue monitoring the supply situation for antibiotics in their territories.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member reported a shortage of an anticoagulant medicinal product noting that no alternatives are available in their country. EMA reached out to the MAH of the product and will keep the SPOC WP member informed once information becomes available. SPOC WP members outlined the situation in their territories, confirming no critical issues due to short durations of the shortage or alternative methods to procure the product being available.

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	A SPOC WP member raised a critical shortage of Prostin E2 (dinoprostone). Other MSs noted that the product is either not marketed in their countries or that they are not experiencing shortages of Prostin E2. A SPOC WP member reported an ongoing critical shortage of Atgam (anti-human T-lymphocyte immunoglobulin), noting that there are no suitable alternatives available in their country for treatment of aplastic anaemia and that discussions with the MAH are ongoing. Other MSs confirmed that they do not have the product marketed or are not experiencing shortages of the abovementioned product. A SPOC WP member reported an ongoing shortage of injectable oxycodone medicinal products noting that alternative opioids are available in their country and a resolution is expected in the next two weeks. Other MSs where injectable oxycodone is marketed are not experiencing shortages. **Agreed actions:** • 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.
4.	**Critical shortages escalated to the SPOC Working Party:**
4.1	**Ongoing shortages**
	a) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists EMA informed the SPOC WP about current activities related to exploring the feasibility to conduct a global GLP-1 RAs drug utilisation study. The International Coalition of Medicines Regulatory Authorities (ICMRA) working group on public health emergencies together with the Drug Shortages Global Regulatory Working Group are currently exploring the feasibility to conduct a global GLP-1 RA drug utilisation study. This study could further strengthen international collaboration and provide novel insights in the use of GLP-1 RA. Brief feedback on proposed research objectives and discussions that took place in a first meeting of interested regulatory authorities on 30 June 2025 were presented. In addition, EMA presented the current supply and availability situation of GLP-1 RAs and informed about the planned publication of a Medicine Shortage Communication (MSC) for Victoza as well as an update to the shortage catalogue entries for Saxenda and Trulicity. <u>Discussion:</u> One SPOC WP member reported a shortage of Trulicity with an expected end date at the end of September 2025. Another SPOC WP member noted that the upcoming marketing cessation of Victoza does not appear to be a concern as patients are being switched to other therapies in their country. **Agreed actions:** • EMA to share the MSC for Victoza with SPOC WP members for their review. • EMA to continue monitoring the supply situation of GLP-1 RAs across EU/EEA countries.
	b) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring EMA provided an update on the permanent market cessation and related potential and ongoing shortages of Beriglobin and noted that Beriglobin is currently the only

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	immunoglobulin in EU/EEA countries authorised for post-exposure prophylaxis of hepatitis A. The product is authorised in 4 MSs and other EU/EEA countries import the product. SPOC WP members provided updates on the national situation regarding Beriglobin in their territories. Discussion SPOC WP members exchanged information on the situation in their countries, highlighting the criticality of the situation. SPOC WP members further discussed the need to find alternatives for post-exposure prophylaxis of Hepatitis A and noted that coordinated EU level action on this shortage would be welcome. **Agreed actions:** • EMA to contact manufacturers of normal human immunoglobulins and requesting further information. • EMA to engage with impacted countries and coordinate further actions.
4.3	**Status update on other critical shortages escalated to the SPOC WP** (only comments relating to previously circulated written updates)
	a) Ecalta CAP (anidulafungin) and Dynastat CAP (parecoxib) – MAH: Pfizer b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk c) Medicinal products from MAH: Cheplapharm d) Medicinal products containing salbutamol (inhalation use) e) Moventig CAP (naloxegol) – MAH: Grünenthal GmbH f) Biltricide NAP (praziquantel) – MAH: Bayer g) Medicinal products from MAH Viatris Discussion A SPOC WP member highlighted a critical supply situation regarding medicinal products containing salbutamol. The SPOC WP member is in contact with alternative MAHs for possible imports. EMA will follow up with the impacted SPOC WP member in writing to better understand the situation and possibly provide support.
5.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology EMA presented an update on the progress made in the working group, including presentations from Member States, outcome of discussions and agreement on indicators and a composite supply vulnerability index, based on the indicators. In addition, the outcome of the recently completed pilot, to test elements of the methodology was presented which included exploring data sources, examining the ease of access to the necessary data and suitability of the indicators selected.

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	Additionally, EMA presented an update on the planned next steps focusing on finalisation of the draft vulnerability assessment methodology in advance of the October MSSG meeting.
	b) Feedback from the MSSG WG on Voluntary Solidarity Mechanism and Policy: Focal Group on Union list of critical medicines - Annual update of the Union list of critical medicines EMA presented the procedure for the periodic update of the Union list of Critical Medicines which was adopted by MSSG via written procedure on 4 June 2025. Linked to the periodic update, EMA informed about the reactivation of the focal group on Union list of Critical Medicines now operating under the MSSG WG on Voluntary Solidarity Mechanism (VSM) and Policy, following the closure of HMA/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary use (TF-AAM). Lastly, EMA reminded SPOC WP members that the deadline for submitting requests to update the Union list is 15 July 2025.
6.	**European Shortages Monitoring Platform (ESMP) update** EMA presented plans for future development of ESMP which will allow reflecting VSM, shortage mitigation plans (SMPs), and outcome of medicines' supply chain vulnerability assessment. EMA informed that a call for interest for Subject Matter Experts (SMEs) and a Network Product Owner (Network PO) is currently open for applications and SPOC WP members were invited to submit their nominations until 25 July 2025. <u>Discussion</u> A SPOC WP member inquired whether the planned functionality developments would include critical notifications by NCAs and whether the shortage prevention plans (SPPs) would be integrated into the platform. EMA clarified that neither NCA critical shortage management nor SPPs are currently foreseen but will be considered in future expansions.
7.	**Collaborative assessment program for critical medicines** EMA provided an overview of the ongoing ICMRA Collaborative Assessment Pilot concerning Post Approval Change Management Protocols (PACMPs), highlighting key achievements such as near simultaneous approvals across jurisdictions. The pilot focuses on medically important treatments for chemical and biological products but does not include vaccines. In addition, EMA presented the pilot's objectives, the experience gathered and the challenges for the future. The pilot has been extended for one additional year and applications for inclusion into the pilot are welcome. <u>Discussion</u> The SPOC WP discussed the potential use of the pilot for shortage situations. EMA clarified that the pilot is designed as a pro-active mechanism for industry use in situations where potential issues in the supply chain are anticipated. These issues may not necessarily be linked to medicine shortages, although the pilot can be applied in such cases.

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	Lastly, EMA clarified that the pilot is not limited to medicines on the Union list of critical medicines. Each application is individually assessed by the ICMRA WG and must meet predefined eligibility criteria, which include criticality amongst others.
8.	**EMA-EC Pilot for extension of shelf life for medicines stockpiled in preparedness for health threats** DG HERA representative together with EMA presented a joint initiative focused on the extension of shelf life for medicines stockpiled in preparedness for health threats. The pilot builds on findings from the SPOC WP survey on national approaches to shelf-life extension conducted in autumn 2024. The presentation also covered medicines included in the pilot, its timeline and outlined its main objectives. These included identifying policy and technical pathways, identifying and engaging relevant actors and exploring opportunities for long-term solutions.
9.	**DG SANTE update** DG SANTE representative provided an update on the progress of the revised pharmaceutical legislation negotiations, noting that the Council of the European Union and the European Parliament have both adopted their positions and that trilogues are ongoing. Additionally, DG SANTE representative updated the SPOC WP on the status of the proposed Critical Medicines Act which complements the pharmaceutical legislation and for which the co-legislators are currently developing their respective positions.
10.	**Global Regulatory Working Group on Drug Shortages: Q2 meeting** This topic could not be taken due to time constrains. *Post-meeting note: Update distributed in writing with post-mailing on 15 July 2025.*
11.	**AOB** A SPOC WP member provided an update on CHESSMEN Work package 8 and informed the SPOC WP about next steps including preparation of a position paper.
12.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 10 September 2025 (TEAMS) (placeholder 12 August 2025)

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 14 July meeting, which was held virtually. Experts' declared interests were evaluated against the agenda topics or activities they participated in.

Experts' declared interests were evaluated against the agenda topics or activities they participated in.

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	
Sybille Schotte	Belgium	Member	No interest declared	
Sanne Vandelanotte	Belgium	Alternate	No interest declared	
Ruitchev Radoslav	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	
Vasileios Loutas	Cyprus	Member	No interest declared	
Jakub Velík	Czechia	Member	No interest declared	
Michaela Kosová	Czechia	Alternate	No interest declared	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Lehtinen Julia	Finland	Member	No interest declared	
Gabriele Eibenstein	Germany	Member	No restrictions applicable to this meeting	
Linda Holtkamp	Germany	Alternate	No restrictions applicable to this meeting	
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	
Oscar Cruciani	Italy	Alternate	No interest declared	
Kristīne Edolfa-Kalniņa	Latvia	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	
Magdalena Rychter	Poland	Member	No restrictions applicable to this meeting	
Martyna Jakubowska	Poland	Alternate	No interest declared	
Susana Penedo Alves	Portugal	Member	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	
Jaroslav Kollárik	Slovakia	Member	No participation in discussions, final deliberations and voting on:	4.3 g) Biltricide NAP (praziquantel) – MAH: Bayer
Simona Paľovčíková	Slovakia	Alternate	No restrictions applicable to this meeting	
Saša Martinc	Slovenia	Member	No interest declared	
Maria Esplugues Argente	Spain	Member	No restrictions applicable to this meeting	
Myllyntausta Minna	Finland	Expert	No interest declared	
Nuno Simões	Portugal	Expert	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Isabelle Barabas	Romania	Expert	No interest declared	
Melita Tovornik	Slovenia	Expert	No interest declared	
Patricia Rodríguez Molla	Spain	Expert	No restrictions applicable to this meeting	
Laura Marrero Ortiz	Spain	Expert	No interest declared	
Eva Pettersson	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.				