

25 April 2025  
EMA/125235/2025  
Regulatory Science and Innovation Task Force

## Meeting Summary — Medicine Shortages SPOC Working Party

Tuesday, 18 March 2025, from 09:30 to 13:15 (CET), Webex

**Chair: Monica Dias (EMA), Vice-Chair: Magdalena Rychter (GIF, Poland)**

Item	Topic
1.	<p><b>Welcome, declaration of interest, adoption of draft agenda</b></p> <p>The Chair and Vice-Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party (WP).</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, the SPOC WP secretariat announced the applicable restrictions.</p>
2.	<p><b>Adoption of draft minutes of the SPOC WP meeting held on 18 February 2025</b></p> <p>The Vice-Chair informed the WP that the minutes of the meeting held on 18 February 2025 had been distributed one week prior to the meeting.</p> <p>No comments were received before or during the meeting. The minutes were adopted.</p>
3.	<p><b>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:</b></p> <p><b>a) Feedback from the MSSG meeting on 26 February 2025</b></p> <p>The Vice-Chair presented the topics discussed during the MSSG Meeting on 26 February 2025, highlighting updates from the European Commission (EC) on Critical Medicines Act and Critical Medicines Alliance. Furthermore, updates were provided on the mandate and composition of the Working Group (WG) of the MSSG on the Vulnerability Assessment Methodology and the extended scope to policy, revised mandate and next steps for the MSSG WG on Voluntary Solidarity Mechanism and Policy.</p> <p>The Vice-Chair informed that the MSSG also discussed the outcome of the latest voluntary solidarity mechanism (VSM) procedure. Lastly, the MSSG discussed the availability of</p>

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	<p>perfusion solutions, oncology products, insulin products and Glucagon-like Peptide-1 (GLP-1) Receptor Agonists (RA).</p> <p><a href="#">Minutes of the MSSG meeting on 26 February 2025</a> were published on 1 April 2025.</p>
	<p><b>b) MSSG Working Group on VSM and Policy: feedback from WG meeting on 27 February 2025</b></p> <p>EMA Chair provided an update from the first WG meeting on 27 February 2025, highlighted the topics discussed and presented the revised mandate and objectives, which have now been extended to include policy activities related to the availability and supply of medicines. Finally, EMA Chair presented the working arrangements and outlined the next steps.</p> <p><u>Comments raised</u></p> <p>One SPOC WP member asked for further information on the SPOC WP subgroup on European medicines agencies network strategy (EMANS). EMA Chair explained that this subgroup will be responsible for implementing the activities outlined under Goal 1 of Theme 5 on Availability and supply of medicines. The Chair further noted that the scope (with timelines for each activity) will be further discussed and brought to the SPOC WP once established.</p> <p><a href="#">EMANS to 2028</a> was published on 18 March 2025.</p>
4.	<p><b>Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:</b></p>
	<p><b>a) Availability of antibiotics – preparedness for autumn/winter 2024–2025</b></p> <p>EMA provided a brief update noting that since the last meeting no issues with the availability of antibiotics have been reported by the marketing authorisation holders (MAHs) or SPOC WP members.</p> <p><u>Comments raised</u></p> <p>SPOC WP members exchanged information on the situation in their countries, confirming that the supply situation is stable and not critical.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• SPOC WP members to inform EMA if critical shortages of antibiotics occur.</li> </ul>
	<p><b>b) Re-activation of the SPOC WP Subgroup on crisis monitoring and preparedness</b></p> <p>EMA provided an update on the reactivation of the SPOC WP subgroup on crisis monitoring and preparedness. EMA informed that a call for nominations for the SPOC WP subgroup concluded on 14 March 2025.</p>
	<p><b>c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)</b></p> <p>One SPOC WP member raised a critical shortage of ivabradine containing medicinal products due to an increase in demand and commercial reasons, noting that there are shortages from all MAHs that market this product. SPOC WP members provided feedback</p>

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	<p>stating that they were either experiencing no shortages or have sufficient alternatives to mitigate the impact.</p> <p>Another SPOC WP member requested an update on the <a href="#">shortage of Cyanokit CAP</a>, which was monitored through the SPOC WP. EMA responded noting that the situation is expected to improve soon.</p> <p><b>Agreed action</b></p> <ul style="list-style-type: none"> <li>SPOC WP members with critical shortage issues to report the information to the SPOC WP Secretariat for further action.</li> </ul>
5.	<b>Critical shortages escalated to the SPOC Working Party:</b>
5.1	<b>Ongoing shortages</b>
	<p><b>a) Fludarabine-containing medicinal products</b></p> <p>EMA presented a critical shortage of fludarabine caused by multiple factors: issues at the manufacturing site, constraints with the active pharmaceutical ingredient (API) and an increase in demand with a knock-on effect on other suppliers. EMA informed that the impacted MAHs have been requested to submit shortage prevention and mitigation plans as part of the <a href="#">shortage prevention and mitigation plans (SPMP) pilot</a>. Finally, EMA shared the feedback from MAHs of alternatives in the EU and internationally, confirming their ability to provide support to the countries in most critical need, depending on the quantities needed.</p> <p><u>Comments raised</u></p> <p>EMA collected information from MSs regarding the criticality of the situation, noting that the situation is monitored through the SPOC WP subgroup who have requested the MAH to prioritise the manufacturing of fludarabine due to its criticality. Additionally, EMA asked the SPOC WP members to inform them about any additional quantities required, highlighting that EMA will give support in facilitating the allocation of stock from alternative MAHs when possible.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>SPOC WP members with a critical shortage in their country were asked to inform EMA about quantities required.</li> </ul>
	<p><b>b) Medicinal products from MAH: Cheplapharm</b></p> <p>EMA presented an update on the ongoing critical shortages of Zypadhera and Visudyne.</p> <p><u>Comments raised</u></p> <p>SPOC WP members further highlighted the need for the company to improve communication with EMA and SPOC WP members.</p>
	<p><b>c) Shortage and discontinuation of insulin containing medicinal products</b></p> <p>EMA provided an update on the discontinuation of insulin products and feedback from the SPOC WP subgroup meeting with MAH Novo Nordisk on 14 March 2025.</p>

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5.2	<p><b>Status update on other critical shortages escalated to the SPOC WP</b> (only comments to the written updates)</p>
	<p>a) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk</p> <p>b) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH</p> <p>c) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer</p> <p>d) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists</p> <p>e) Medicinal products containing salbutamol (inhalation use)</p> <p>f) Medicinal product containing quetiapine</p> <p>g) Menopur NAP (menotropin) – MAH: Ferring</p> <p>h) Availability of perfusion solutions following hurricane Helene</p>
6.	<p><b>European Commission DG SANTE update</b></p> <p>EC DG SANTE provided an overview on the proposal for a <a href="#">Critical Medicines Act</a>, published on 11 March 2025, which further complements the <a href="#">Extended Mandate of the European Medicines Agency</a> and the proposed <a href="#">reform of the EU Pharmaceutical Legislation</a>.</p> <p>EC DG SANTE further explained that the Critical Medicines Act focuses on strategic projects for critical medicines, public and collaborative procurements, international partnerships and state aid guidelines.</p>
7.	<p><b>European Commission DG HERA update</b></p> <p>EC DG HERA presented the <a href="#">Strategic Report of the Critical Medicines Alliance</a>, published on 28 February 2025, which includes a set of recommendations on supply chain vulnerabilities and investments, frameworks for contingency stocks, procurements and promotion of a level playing field. Lastly, EC DG HERA explained that the Alliance also recommends strengthening partnerships with third countries to bolster supply resilience due to the interconnected nature of pharmaceutical supply chains.</p> <p><u>Comments raised</u></p> <p>A SPOC WP member asked for further information on the recommendation on contingency stocks. DG HERA explained that the recommendation is for industry, MSs and/or the EU to implement a comprehensive, harmonised and balanced framework on contingency stocks to mitigate the potential negative consequences of current national contingency stocks. DG SANTE added that the proposal for the Critical Medicines Act includes obligations for MSs to ensure that national contingency stock requirements are proportionate, respect the principles of transparency and solidarity and have no negative impact on other MSs.</p>
8.	<p><b>Joint Action on shortages (CHESSMEN)</b></p> <ul style="list-style-type: none"> <li>• <b>Work Package 6 – demand forecasting at national level: survey results and next steps</b></li> </ul> <p>A SPOC WP member presented the results of a survey on demand forecasting. They explained that demand forecasting is a new discipline for most national competent authorities (NCAs) and that involvement of dedicated task forces or organisations to support these activities is often needed. Furthermore, demand forecasting activities have</p>

Item	Topic
	<p>primarily been completed on an <i>ad hoc</i> basis and there has been limited verification of demand forecasts versus the real situation.</p> <p><u>Comments raised</u></p> <p>One SPOC WP member added that they use data on stocks and issued/fulfilled prescriptions in their national monitoring activities; currently, there is a focus on establishing algorithms to better predict the demand.</p> <p>EMA noted that the survey results showed that some NCAs do not match supply with forecasted demand and asked for potential reasons. Additionally, EMA asked about possible ways to improve the accuracy of demand forecasts as well as the next steps. The SPOC WP member clarified that there were no clear replies within the survey but it could be linked to supply issues not being persistent or critical. It was noted that the experience with demand forecasting is currently limited, therefore further experience is essential to be able to improve the accuracy; as the next steps, a report will be drafted and shared with EMA and the SPOC WP.</p>
9.	<p><b>SPOC WP satisfaction survey outcomes and next steps</b></p> <p>EMA presented the results of the SPOC WP survey that aimed to take stock of SPOC WP members' overall satisfaction with the monthly meetings and understand how the EMA Secretariat could improve future SPOC WP meetings. EMA noted that there is overall satisfaction with the meeting experience and agendas, however some areas for improvement will include increased time to discuss critical shortages and sharing of more written updates when possible. Some other areas for further improvement focus on elements linked to updates from stakeholders, increased sharing of best practices by MSs, and meeting planning.</p>
10.	<p><b>SPOC WP F2F April meeting — presentation of draft agenda and call for proposals of agenda topics</b></p> <p>EMA presented the current draft agenda for the face-to-face (F2F) SPOC WP meeting on 10–11 April 2025. 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.</p>
11.	<p><b>Update on revised rules on handling of competing interests of scientific committee members and experts ('Policy 0044')</b></p> <p>SPOC WP Secretariat highlighted the revised <a href="#">European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts</a>, which will become effective on 1 May 2025. The SPOC WP was informed that, as a consequence, this will bring changes to the Declaration of Interests (DoI) form in EMA's Experts Management Tool (EMT) and all experts will be requested to submit a DoI in the new format by 1 May 2025.</p>
12.	<p><b>AOB</b></p> <p>No topics raised under AOB.</p>

13. **Conclusions and next steps**

EMA Chair reminded that the SPOC WP April 2025 meeting will be held at EMA premises in Amsterdam. EMA Chair invited the SPOC WP members to share any topics they would like to bring for discussion in April with the SPOC WP Secretariat ahead of the meeting.

The agreed actions are detailed above.

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**Next meeting:** 10–11 April 2025, F2F EMA Office + Webex

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**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).

## List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 18 March meeting, which was held virtually.

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	
Magdalena Rychter	Poland	Vice-Chair	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	
Emilia Stoyanova	Bulgaria	Member	No interest declared	
Mateja MerviĆ	Croatia	Member	No interest declared	
Stela Lilek	Croatia	Alternate	No interest declared	
Vasileios Loutas	Cyprus	Alternate	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	
Anita Tuula	Estonia	Alternate	No interest declared	
Julia Lehtinen	Finland	Member	No interest declared	
Tuija Kainulainen	Finland	Alternate	No interest declared	
Flore Demay	France	Member	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Laurent Fabry	France	Alternate	No interest declared	
Thomas Brouwers	Germany	Member	No interest declared	
Gabriele Eibenstein	Germany	Member	No interest declared	
Andrea Stippler	Germany	Alternate	No interest declared	
Theoni Kousteni	Greece	Member	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petrő	Hungary	Alternate	No interest declared	
Margrét Lilja Heiðarsdóttir	Iceland	Member	No interest declared	
Mary Kinane	Ireland	Alternate	No interest declared	
Vincenza Giuseppina Azzarà	Italy	Member	No interest declared	
Domenico Di Giorgio	Italy	Member	No interest declared	
Oscar Cruciani	Italy	Alternate	No interest declared	
Linās Mažeika	Lithuania	Member	No interest declared	
Maura Olechnovic	Lithuania	Alternate	No interest declared	
Jessica Zarb	Malta	Alternate	No interest declared	
Hanneke Mulder	Netherlands	Member	No interest declared	
Eric Hergarden	Netherlands	Alternate	No interest declared	
Guri Wilhelmsen	Norway	Member	No interest declared	
Andreas Sundgren	Norway	Alternate	No interest declared	
Susana Penedo Alves	Portugal	Member	No interest declared	
Helena Ponte	Portugal	Member	No interest declared	
Alina Iordache	Romania	Member	No interest declared	
Viviana Anghel	Romania	Alternate	No interest declared	
Jaroslav Kollárik	Slovakia	Member	No restrictions applicable to this meeting	
Simona Paľovčíková	Slovakia	Alternate	No restrictions applicable to this meeting	
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	
Patricia Rodríguez	Spain	Alternate	No restrictions applicable to this meeting	
Samuel Silkestrand	Sweden	Member	No interest declared	
Karl Högström	Sweden	Alternate	No interest declared	
Olga Rögelsperger	Austria	Expert	No restrictions applicable to this meeting	
Rita Rom	Austria	Expert	No interest declared	
Stela Lilek	Croatia	Expert	No interest declared	
Frank Blommaert	Netherlands	Expert	No interest declared	
João Simões	Portugal	Expert	No interest declared	
Nuno Simões	Portugal	Expert	No interest declared	
Isabelle-Alexandra Barabas	Romania	Expert	No interest declared	
Melita Tovornik	Slovenia	Expert	Direct interests declared	Competing interest declared resulting in no participation in discussions and decisions with respect to agenda point 3.a
Maria Criado	Spain	Expert	No interest declared	
Laura Marrero Ortiz	Spain	Expert	No interest declared	
Representatives from the European Commission and EDQM attended the meeting.				
Meeting run with the help of EMA staff.				