

31 October 2025  
European Medicines Agency

## Meeting Summary — Medicine Shortages SPOC Working Party

10 September 2025, from 09:30 to 13:30 (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)'.

| Item | Topic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| 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, no applicable restrictions were identified.</p> <p>The agenda was adopted with one additional point under AOB — Update on the work of the SPOC WP subgroup on shortage definition regarding a proposal for a revised and harmonised list of shortage root causes and survey covering aspects of shortage notification, critical shortage, shortage management and definition of potential shortage.</p>                                                |
| 2.   | <p><b>Adoption of draft minutes of the SPOC WP meeting held on 14 July 2025</b></p> <p>The Vice-Chair informed that the minutes of the meeting held on 14 July 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><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) Feedback from the SPOC WP subgroup on crisis monitoring and preparedness</b></p> <p>EMA provided feedback from the SPOC WP subgroup written exchanges in August and the subgroup meeting from beginning of September. An update was provided on the EU/US trade agreement reached in July. There is no further analysis ongoing at national level and no new signals nor concerns have been identified.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• SPOC WP subgroup to continue meeting on a biweekly basis and closely monitoring the impact of geopolitical situations on the availability and supply of medicinal products in EU/EEA countries.</li> </ul>                                                                                                                                                                                    |
|      | <p><b>b) Availability of antibiotics: update on preparedness activities</b></p> <p>EMA provided an update on the regulatory support request from a marketing authorisation holder (MAH) to increase the manufacturing of antibiotics in the long-term.</p> <p>EMA further informed the SPOC WP about ongoing and planned activities in preparation for the upcoming autumn/winter season 2025/2026. These include outreach to key 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.</p> <p><u>Discussion</u></p> <p>A SPOC WP member noted that monthly meetings to monitor supply situation of antibiotics have restarted in their country.</p> |

| Item | Topic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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|      | <p><b>c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)</b></p> <p>A SPOC WP member reported shortages of a psycholeptic medicinal product and an antiepileptic medicinal product, noting no availability of marketed alternatives with the same pharmaceutical formulation for both products and few alternatives available for importation as unauthorised products. The SPOC WP member also noted that the shortages are not yet critical in their country. Other SPOC WP members reported no shortages or that the products are not marketed in their countries.</p> <p>A SPOC WP member reported an ongoing shortage of an antiviral medicinal product due to quality issues. Several SPOC WP members confirmed similar issues in their member states; however, these are not considered critical due to the availability of alternative treatments.</p> <p>A SPOC WP member highlighted a shortage of a psychoanaleptic medicinal product. Other SPOC WP members provided feedback on their national situations, noting shortages but with alternatives available or that the product is not marketed in their countries.</p> <p>A SPOC WP member informed of a shortage of an antibacterial medicinal product due to shortages of active pharmaceutical ingredient (API). SPOC WP members noted no shortages or that alternatives are available in their territories.</p> <p>A SPOC WP member raised a long-term shortage of an anticholinergic medicinal product and noted difficulties sourcing it from abroad. Only a few SPOC WP members reported shortages in their countries.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> |
| 4.   | <b>Critical shortages escalated to the SPOC Working Party:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 4.1  | <b>Ongoing shortages</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|      | <p><b>a) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists</b></p> <p>EMA provided a status update on the shortage situation of Ozempic. In addition, EMA provided an update on the GLP-1 RAs drug utilisation study, noting that an expert group has been established for the Darwin EU study to inform on the study design and participate in the review of the study results. Lastly, EMA informed that a second meeting for the international study in collaboration with International Coalition of Medicines Regulatory Authorities (ICMRA) – Drug Shortages Global Regulatory Working Group (DSGR WG) will be held in due course.</p> <p><u>Discussion</u></p> <p>SPOC WP members discussed the availability of Ozempic, with most members informing of no shortages in their countries. One SPOC WP member noted an existing shortage of Ozempic, and that controlled distribution is still in place for this product in their territory.</p> <p>EMA responded that further discussion with the MAH is needed to understand shortage situations in specific countries.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

| Item | Topic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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|      | <p><b>b) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring</b></p> <p>EMA provided an update on the shortage and discontinuation of Beriglobin, highlighting information received from CSL Behring on the timeline of permanent marketing cessation for different countries and current stocks available.</p> <p>Additionally, EMA provided an update on the use of immunoglobulins for hepatitis A prophylaxis included in national clinical guidelines and risk groups related, and interactions with European Centre of Disease Prevention and Control (ECDC) to further understand the prevalence of use and criticality of the unavailability of Beriglobin.</p> <p>EMA also informed SPOC WP that a medicine shortage communication (MSC) is currently being drafted.</p> <p>Representative from National Institute for Public Health and the Environment in the Netherlands (RIVM) informed on the use of Beriglobin for post-exposure prophylaxis of hepatitis A.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|      | <p><b>c) Zypadhera CAP (olanzapine pamoate), MAH: Cheplapharm</b></p> <p><b>Outcome of the voluntary solidarity mechanism (VSM) procedure</b></p> <p>EMA presented the results of the latest VSM procedure on Zypadhera requested by Finland. EMA noted positive responses from Cheplapharm for very limited quantities and that no support was identified from other member states (MSs) due to the prolonged critical shortage in the EU/EEA.</p> <p>EMA proposed to request shortage prevention plan (SPP) for this product to avoid further critical shortages in the future. The SPOC WP agreed with this proposal.</p> <p><b>Finland – National perspective on the VSM procedure</b></p> <p>FI SPOC WP member presented their experience at national level with this VSM procedure, outlining the background of the situation on national level and mitigation measures that were considered. FI SPOC WP member further detailed lessons learned on the national procedure in activating the VSM request.</p> <p><u>Discussion</u></p> <p>A SPOC WP member enquired whether the received products were released to specific sites with the highest need. In response, FI SPOC WP member clarified that stocks were distributed to regular pharmacies, where the most critical shortages were observed, noting that hospitals still have mandatory stock levels.</p> <p><b>VSM Guidance for NCAs - Update proposal</b></p> <p>EMA presented the updated VSM guidance for NCAs, including information reflecting the new procedure and lessons learned from previous cases. The guidance was updated following a request from a SPOC WP member during the SPOC WP meeting in June.</p> |
|      | <p><b>d) Medicinal products containing quetiapine</b></p> <p>A SPOC WP member presented the current supply situation of quetiapine, which remains critical and that the criticality assessment undertaken by EMA showed that shortages have been identified in several countries. The SPOC WP member also informed about their request for a VSM. Finally, the SPOC WP member noted that according to the</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

| Item | Topic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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|      | <p>manufacturer, normalisation of supply is only expected by Q1 2026 with reduced supply until then.</p> <p><u>Discussion</u></p> <p>EMA provided details on the VSM request highlighting ongoing pre-launch VSM activities. EMA explained that the VSM will be launched, once the pre-launch activities are completed, if no further support can be identified.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 4.2  | <p><b>Status update on other critical shortages escalated to the SPOC WP</b> (only comments relating to previously circulated written updates)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|      | <p>a) Ecalta CAP (anidulafungin) and Dynastat CAP (parecoxib) – MAH: Pfizer</p> <p>b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk</p> <p>c) Biltricide NAP (praziquantel) – MAH: Bayer</p> <p>d) Oncology medicinal products – MAH Teva</p> <p>e) Medicinal products containing salbutamol (inhalation use)</p> <p>f) Shortage and discontinuation of insulin containing medicinal products</p> <p>Regarding oncology products in shortage by MAH TEVA, a SPOC WP member highlighted a potential critical shortage of an oncology medicinal product, with no alternatives available, though the situation is not yet critical but will be closely monitored. EMA responded that TEVA will be contacted to understand the current shortage situation.</p> <p>A SPOC WP member highlighted that a shortage end date of a fluticasone containing medicinal product has been extended and inquired whether other SPOC WP members had any further insights on this extension and its root cause. EMA confirmed previous communication with the MAH on fluticasone products shortages and the need to clarify the causes of the shortage and the reason for this extension. Insufficient information has been received from MAH thus far.</p> |
| 5.   | <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 23 July 2025</b></p> <p>The Vice-Chair provided feedback on the topics discussed during the MSSG meeting in July 2025 highlighting recent developments from the MSSG Working Groups (WGs), a presentation by DG HERA on Medical Countermeasures (MCM) Strategy, and an update from the SPOC WP subgroup on crisis preparedness and response.</p> <p>The Vice-Chair also informed that the MSSG discussed supply and availability of GLP-1 RAs, the outcome of the latest VSM procedure, and a joint EMA-EC pilot for extension of shelf life for stockpiled medicines in preparedness for health treats.</p> <p><b>b) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology</b></p> <p>EMA provided feedback on the written exchanges during August 2025, as well as from the meeting of the WG on 4th September 2025, where discussion on phase 1 indicators and medicines requiring an adapted or additional approach were held. In addition, it was</p>                                                                                                                                                                                                        |

| Item | Topic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
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|      | <p>confirmed that a survey will be circulated to industry associations, building upon the input already provided during the Critical Medicines Alliance.</p> <p><u>Discussion</u></p> <p>A SPOC WP member asked about activities to improve availability of data, to which EMA noted ongoing efforts to encourage MAHs to populate PMS data. EMA highlighted the importance of access to standardised data to allow for smooth implementation of the vulnerability assessment methodology. In addition, data from shortage prevention plans (SPPs) and shortage mitigation plans (SMPs) will be needed, in line with the revised pharmaceutical legislation.</p>                                                                                                                                                                                                                                                                  |
| 6.   | <p><b>Establishment of GMDP IWG Drafting Group on inspections of MAH</b></p> <p>EMA presented information on the establishment of a drafting group within the GMP/GDP Inspectors Working Group (GMDP IWG) to address MAH compliance with reporting obligations, including a pilot inspection programme on shortages and nitrosamine reporting obligations. The kick-off is planned for 2026, with results to be reported back to the drafting group and relevant committees to inform future harmonisation of inspection principles.</p> <p><u>Discussion</u></p> <p>EMA noted that the pilot is also linked to a paper developed by the SPOC network on consultation of supervisory authorities for information gathering, answering and possibility of conducting inspections for medicine shortages of high public health impact in June 2021, and thanked SPOC WP for volunteering as participants of the drafting group.</p> |
| 7.   | <p><b>Drug Shortage Global Regulatory Working group — update</b></p> <p>EMA presented the agenda for the Q3 meeting of the group scheduled for October 2025, the agenda of an ad-hoc meeting of the group scheduled in September 2025 to exchange information on supply chain vulnerabilities, and a brief overview on the progress related to the international drug utilisation study on GLP-1 RAs in collaboration with the ICMRA Working Group on Real-World Evidence for Public Health Emergencies.</p> <p>In addition, feedback on the establishment of an international best practice document on shortages was provided. The best practice document covers topics such as shortage reporting, signal detection and prevention. SPOC WP members are invited to suggest additional topics for inclusion in the document.</p>                                                                                                |
| 8.   | <p><b>Shortage Prevention and Mitigation Plans (SPP/SMP) pilot update</b></p> <p>EMA provided an update on the SPMPs pilot's preliminary results, detailing its scope, participation, initial findings, and proposed next steps. These include the closure of the pilot, publication of the report and plans for ongoing improvements to templates and procedures in early 2026.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 9.   | <p><b>European Shortages Monitoring Platform (ESMP) update</b></p> <p>This topic could not be taken due to time constraints and was postponed to the SPOC WP meeting in October.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

| Item | Topic                                                                                                                                                                                                                                                                                                                                                                                           |
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| 10.  | <p><b>SPOC WP F2F October 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 14–15 October 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>AOB</b></p> <p>EMA informed on the ongoing activities of the SPOC WP subgroup on shortage definition. The subgroup's proposal for a revised and harmonised list of shortage root causes and draft descriptions will be brought for further discussion at the face-to-face SPOC WP meeting in October 2025.</p>                                                                            |
| 12.  | <p><b>Conclusions and next steps</b></p> <p>The agreed actions are detailed above.</p>                                                                                                                                                                                                                                                                                                          |

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**Next meeting:** 14–15 October, F2F EMA office (Amsterdam) + TEAMS

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## List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 10 September meeting, which was held virtually. 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                              |                                               |
| Martina Unteregger          | Austria                     | Member     | No restrictions applicable to this meeting        |                                               |
| Andrea Kugi                 | Austria                     | Alternate  | No interest declared                              |                                               |
| Sanne Vandelanotte          | Belgium                     | Alternate  | No interest declared                              |                                               |
| Mateja Mervić               | Croatia                     | Member     | No restrictions applicable to this meeting        |                                               |
| Vasileios Loutas            | Cyprus                      | Alternate  | No interest declared                              |                                               |
| Michaela Kosová             | Czechia                     | Alternate  | No interest declared                              |                                               |
| Anita Tuula                 | Estonia                     | Alternate  | No restrictions applicable to this meeting        |                                               |
| Camille Ramahefarivony      | France                      | Member     | No interest declared                              |                                               |
| Laurent Fabry               | France                      | Alternate  | No interest declared                              |                                               |
| Theoni Kousteni             | Greece                      | Member     | No interest declared                              |                                               |
| Thomas Brouwers             | Germany                     | Member     | No restrictions applicable to this meeting        |                                               |
| Inke Reimer                 | Germany                     | Member     | No interest declared                              |                                               |
| Kinga Csécsei               | Hungary                     | Member     | No interest declared                              |                                               |
| Veronika Horváth            | Hungary                     | Member     | No interest declared                              |                                               |
| Gyöngyi Petró               | Hungary                     | Alternate  | No interest declared                              |                                               |
| Marta Reining               | 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                              |                                               |
| Linus 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                              |                                               |
| Andreas Sundgren            | Norway                      | Alternate  | No interest declared                              |                                               |
| Martyna Jakubowska          | Poland                      | Alternate  | No interest declared                              |                                               |
| Susana Penedo Alves         | Portugal                    | Member     | No interest declared                              |                                               |
| Alina Iordache              | Romania                     | Member     | No interest declared                              |                                               |
| Viviana Anghel              | Romania                     | Alternate  | No interest declared                              |                                               |
| 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        |                                               |
| Samuel Silkestrand          | Sweden                      | Member     | No interest declared                              |                                               |
| Anna Gerhartl               | Austria                     | Expert     | No restrictions applicable to this meeting        |                                               |
| Rita Rom                    | Austria                     | Expert     | No interest declared                              |                                               |
| Olga Rögelsperger           | Austria                     | Expert     | No restrictions applicable to this meeting        |                                               |
| Minna Myllyntausta          | Finland                     | Expert     | No interest declared                              |                                               |
| Willem Woldring             | Netherlands                 | Expert     | No interest declared                              |                                               |

| Name                                                                        | Member State or affiliation | Role   | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|-----------------------------------------------------------------------------|-----------------------------|--------|---------------------------------------------------|-----------------------------------------------|
| Sónia Gomes                                                                 | 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        |                                               |
| Representatives from the European Commission and EDQM attended the meeting. |                             |        |                                                   |                                               |
| Meeting run with the help of EMA staff.                                     |                             |        |                                                   |                                               |