11 November 2025
European Medicines Agency

# Meeting Summary — Medicine Shortages SPOC Working Party

14-15 October 2025, hybrid meeting (Face-to-face and 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)'.

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

| Tuesday, 14 October 2025 (10:00-18:00) | |
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| **Item** | **Topic** |
| 1. | **Welcome, declarations of interest, adoption of draft agenda**<br><br>The Chair and Vice-Chair welcomed all participants, both those attending in person and those joining online, at the hybrid meeting of the Medicine Shortages SPOC Working Party held at the EMA premises in Amsterdam.<br><br>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, applicable to members and experts of the SPOC WP and announced that according to the topics on the agenda no restrictions are applicable.<br><br>Changes to the SPOC WP membership were announced.<br><br>The agenda was adopted with no additional points under AOB. |
| 2. | **Adoption of draft minutes of the SPOC WP meeting held on 10 September 2025**<br><br>The Vice-Chair informed that the minutes of the meeting held on 10 September 2025 had been distributed on 8 October 2025. No comments were received before or during the meeting.<br><br>The minutes were adopted. |
| 3. | **Updates from Member States** |
| | **a) SPOC WP lightning round – most critical issues at national level**<br><br>SPOC WP members exchanged information on the most critical issues at national level linked to medicines supply and availability, and the measures taken to address these. |
| | **b) Danish presidency of the EU: initiatives on medicine shortages for H2 2025**<br><br>SPOC WP Vice-Chair presented an overview of the work undertaken and planned by Denmark in the area of security of supply under the Danish Presidency of the Council of the European Union (EU). Key priorities were highlighted, including efforts to strengthen the security of medicine supply across the EU.<br><br>The Vice-Chair also shared feedback from the informal ministerial meeting held in Copenhagen in September 2025, with a focus on preparedness, life science and clinical trials. |
| | **c) Status update on any new strategic measures implemented at national level (e.g., critical medicines lists, stockpiling requirements)**<br><br>SPOC WP members exchanged information on new strategic measures at national level, highlighting different amendments to national legislations aimed at improving shortage management and stockpiling requirements. Several SPOC WP members also noted planned or ongoing developments of shortage management systems and tools for monitoring stocks on different levels of the supply chain, as well as work on national lists of critical medicines. |
| 4. | **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** |

| Tuesday, 14 October 2025 (10:00-18:00) | |
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| | EMA provided feedback from the last meeting of the subgroup held in October 2025 noting that no new signals or concerns have been identified by Member States (MSs) or industry associations.<br><br>**Agreed actions:**<br><br>• SPOC WP subgroup to continue meeting on a biweekly basis and closely monitor 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**<br><br>EMA provided an update on the activities undertaken in preparation for the autumn/winter 2025/2026 season, including outreach to key marketing authorisation holders (MAHs) of certain antibiotics for respiratory infections. A high-level overview of their responses was presented.<br><br>In addition, EMA presented feedback received from international regulators in the southern hemisphere on the antibiotic supply situation during their winter season noting that no significant changes in antibiotic usage were identified in their 2025 winter period.<br><br><u>Discussion</u><br><br>A SPOC WP member inquired whether EMA had requested MAHs to notify respective national competent authorities (NCAs) of anticipated shortages of antibiotics. EMA responded that this request was not included in the initial communication but will be addressed in the follow-up.<br><br>A number of SPOC WP members provided updates on the current supply situation in their respective countries noting that the overall situation is expected to be stable in the autumn/winter season 2025/2026.<br><br>**Agreed actions:**<br><br>• EMA to share with MSs the feedback received from MAHs regarding anticipated supply gaps for the autumn/winter season 2025/2026.<br>• SPOC WP to inform EMA in case critical shortages of antibiotics occur or any ongoing shortages deteriorate. |
| 5. | **Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)**<br><br>One SPOC WP member informed that production of all strengths of an analgesic medicinal product will cease in 2026 and asked other MSs about the situation in their countries. MSs discussed the planned cessation and reported that the situation in their territories is currently stable.<br><br>A SPOC WP member reported an ongoing shortage of an analgesic medicinal product used in prophylaxis and treatment of migraine in their territory due to supply disruptions from multiple manufacturers. Furthermore, the SPOC WP member reported an ongoing shortage of an uterotonic medicinal product, expected to last until the second half of 2026 and an ongoing shortage of an antiandrogen medicine. |

| Tuesday, 14 October 2025 (10:00-18:00) | |
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| | SPOC WP members shared information on the situation with above mentioned shortages, with the majority of MSs noting no shortages or non-critical shortages due to alternatives available. Due to the anticipated longer shortage duration, EMA will reach out to the MAH of uterotonic medicinal product to obtain more information on the supply situation and will keep MSs informed of any further information received.<br><br>A SPOC WP member notified an ongoing critical shortage of an antidiarrheal medicinal product due to commercial reasons. Other MSs reported no shortages in their countries.<br><br>**Agreed actions:**<br><br>• SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP if the abovementioned shortage situations in their territories deteriorate. |
| 6. | **Critical shortages escalated to the SPOC Working Party:** |
| 6.1 | **Ongoing shortages** |
| | **a) Medicinal products containing salbutamol (inhalation use)**<br><br>**Update on current situation in EU/EEA countries**<br><br>EMA presented an update on the supply situation of salbutamol containing medicinal products, noting that a number of MSs are affected by intermittent shortages and supply issues are expected to continue until at least the beginning of 2026. As a next step, EMA will update the shortage catalogue entry to reflect the latest developments and continue to monitor the supply situation closely throughout the 2025/2026 autumn/winter period.<br><br>Discussion<br><br>SPOC WP members shared the situation in their countries confirming that the situation is stable at the moment and managed by appropriate mitigation measures.<br><br>**DARWIN EU salbutamol drug utilisation study report**<br><br>EMA presented a summary of the DARWIN-EU study report including study aims, methods, limitations, and results. The findings showed variations in inhaled salbutamol prescription rates across countries, seasons, and years, and highlighted differences in preferred formulation type between countries, populations, and healthcare settings (outpatient vs. inpatient). An upward trend in prescription rates for some alternative inhaled treatments (mainly formoterol + inhaled corticosteroids) was also observed in several countries. The results emphasise the need for proactive strategies to prevent shortages and ensure continuous access to essential respiratory therapies.<br><br>**Agreed actions:**<br><br>• SPOC WP to provide feedback on DARWIN-EU study. |
| | **b) Medicinal products from MAH: Cheplapharm**<br><br>EMA provided an update on ongoing shortages of Visudyne and Zypadhera as well as other medicinal products from Cheplapharm. EMA also informed the group about an ad-hoc meeting held in July 2025 with MSSG Co-Chairs and members, the Rapporteurs for these medicines, and representatives from the MAH (Cheplapharm), with a follow-up letter sent to the MAH. |

| Tuesday, 14 October 2025 (10:00-18:00) | |
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| | Furthermore, EMA presented the planned next steps including the request for a shortage prevention plan (SPP) for Zypadhera, a survey among MSs to identify a targeted group of medicines among those manufactured by Cheplapharm that may require closer follow up, and the continued close engagement between EMA, SPOC WP and the MAH.<br><br>Discussion<br><br>SPOC WP members reiterated the need to ensure clear communication from the MAH.<br><br>Following the letter from MSSG, the MAH has now committed to provide a bi-monthly report covering availability issues relating to the full Cheplapharm portfolio.<br><br>**Agreed actions:**<br><br>• EMA to circulate a survey to MSs.<br>• EMA and SPOC WP to continue monitoring the supply situation of Cheplapharm medicinal products. |
| | **c) Medicinal products containing quetiapine**<br><br>**Outcome of the voluntary solidarity mechanism (VSM) procedure**<br><br>EMA presented the outcome of the recent VSM procedure initiated by France for quetiapine prolonged-release tablets. EMA noted that while network support was identified, it primarily concerned immediate-release formulations, with limited support for prolonged-release tablets.<br><br>**France - National perspective on the VSM procedure**<br><br>FR SPOC WP presented the experience with this VSM procedure at national level and proposed establishing a minimum set of information EMA could request from alternative MAHs in order to facilitate the assessment of the offers. This would include name of the product, MAH, strength, number of packs or units, information about packaging, market of origin, package language, type of marketing authorisation, and availability of stock. EMA noted that some of the information requested by France is already included as part of the set of information collected from alternative MAHs during the pre-launch VSM activities.<br><br>As a follow-up action, EMA will adapt the VSM NCA Guidance to include additional information requested from alternative MAHs based on feedback received from France. |
| | **d) Medicinal products manufactured by Pharmathen International site**<br><br>**Outcome of the survey to identify critical shortages of products manufactured by Pharmathen**<br><br>EMA informed the SPOC WP that the supply situation of products manufactured by Pharmathen International site has deteriorated, impacting the supply of several medicinal products in the EU/EEA. Results from the criticality survey circulated to MSs identified critical shortages of four medicines in the EU/EEA including risperidone.<br><br>**Sweden: critical shortage of risperidone prolonged-release suspension for injection**<br><br>SE SPOC WP member presented results of the criticality survey concerning risperidone noting the number of MSs that are experiencing shortages in their countries. In addition, SE SPOC WP member informed the SPOC WP about available alternatives. |

| Tuesday, 14 October 2025 (10:00-18:00) | |
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| | Lastly, EMA outlined proposed next steps including regular engagement with Pharmathen International until supply stabilises and escalation for EU coordinated action, which was supported by SPOC WP.<br><br>**Agreed actions:**<br><br>• SPOC WP members to share information about critical shortages of products manufactured by Pharmathen International. |
| | **e) Bronchitol (mannitol) CAP, MAH: Pharmaxis Europe Limited**<br><br>EMA informed the SPOC WP of an ongoing shortage and discontinuation of Bronchitol which is affecting several MSs. Bronchitol is indicated for the treatment of cystic fibrosis in adults. The root cause are distribution challenges resulting from a change of distributors and delays at the manufacturing site.<br><br>EMA presented the criticality survey results, a summary of discussions with MAH Pharmaxis and highlighted the development of medicine shortage communications (MSC) and a shortage catalogue entry.<br><br><u>Discussion</u><br><br>SPOC WP discussed the shortage and discontinuation of the product, noting limited usage of the product in their territories, and mitigation measures outlined by the MAH. |
| 6.2 | **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<br><br>b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk<br><br>c) Oncology medicinal products – MAHs: Teva, Accord<br><br>d) Medicinal products from MAH Viatris |
| 7. | **European Commission DG SANTE**<br><br>DG SANTE provided an update on the current negotiations on the revised Pharmaceutical Legislation and a status update on the Critical Medicines Act (CMA) with respective expected timelines. |
| 8. | **Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:** |
| | **a) Feedback from the MSSG meeting on 24 September 2025**<br><br>SPOC WP Vice-Chair provided feedback on the topics discussed during the MSSG meeting in September 2025 which included:<br><br>• update from MSSG Working Groups' on Vulnerability Assessment Methodology, and VSM and Policy.<br><br>• updates on shortage issues from Cheplapharm.<br><br>• VSM procedure on Zypadhera. |

| Tuesday, 14 October 2025 (10:00-18:00) | |
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| | • updated Incident Management Plan for Medicines for Human Use (IMP-H) guidance and the planned connected major event simulation exercise. |
| | **b) Feedback from the MSSG WG on Voluntary Solidarity Mechanism and Policy**<br><br>EMA provided an update on topics discussed at the WG meeting in September 2025, which included:<br><br>• the latest VSM experience and updated VSM Guidance for NCAs.<br><br>• an update on European Medicines Agencies Network strategy to 2028 (EMANS 2028) regarding the availability of medicines.<br><br>• activities of the Joint Action on shortages (CHESSMEN) and veterinary and communication activities related to shortages.<br><br>• updates from the Focal Groups on Shortage Prevention Plans (SPPs) and Shortage Mitigation Plans (SMPs) and Union List of Critical Medicines. On the latter, EMA presented the process and preliminary results of the 2025 annual update, including challenges encountered, and plans for the 2026 and future updates. |
| | **c) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology**<br><br>EMA presented the progress made by the Working Group on the draft methodology for assessing supply chain vulnerabilities of critical medicines, detailing the two-phase approach, indicators, data requirements, and categorisation of vulnerabilities. EMA confirmed that the feedback from industry associations will be taken into account, and the methodology will then be presented to the MSSG for adoption. The methodology will then be tested with available data and further refined as necessary.<br><br>Discussion<br><br>SPOC WP discussed the need for comprehensive data from MAHs and MSs, the potential use of ESMP, and the potential to include data on contingency stocks at MS level. Furthermore, the importance of avoiding duplication in data requests was stressed and detailed explanations on the difference between criteria of market concentration and MAH diversity was provided. Profitability was discussed as a potential criterion, but it was noted that the WG excluded this due to the limited availability of reliable data, and the presence of possible proxy indicators/variables in the proposed methodology. |
| 9. | **Drug Shortage Global Regulatory Working Group:**<br><br>EMA informed about ongoing activities of the Drug Shortage Global Regulatory Working Group, including an *ad hoc* meeting on supply chain vulnerability where the different jurisdictions presented their approaches, the ongoing work on a best practice document, and an exchange of information on shortages of concern. |
| 10. | **Outcome of ECA audit**<br><br>EMA presented main findings of the ECA special report 19/2025 on critical shortages of medicines. The presentation focused on the main findings, recommendations, EMA replies to the report, and next steps. |

| Tuesday, 14 October 2025 (10:00-18:00) | |
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| | EMA will finalise the internal improvement action plan, ensuring alignment with the EU Medicines Agencies Network strategy (EMANS) and will keep the SPOC WP informed. |

| Wednesday, 15 October 2025 (09:00-16:00) | |
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| **Item** | **Topic** |
| 11. | **Technical topics** |
| | **Root cause classification:** SPOC WP Subgroup proposal for harmonisation<br><br>ES SPOC WP expert and EMA presented the subgroup's draft proposal for a harmonised classification of root causes of medicine shortages. Proposed main categories and subcategories for medicine shortages root causes, together with draft descriptions were presented. SPOC WP subgroup discussed the inclusion and exclusion of root cause categories taking into consideration the JA CHESSMEN WP5 analysis report on root causes, and feedback received from stakeholders via EMA Service Desk, AskEMA, webinars and trainings on ESMP.<br><br>Discussion<br><br>SPOC WP discussed various subcategories. As a next step, SPOC WP subgroup will analyse and incorporate feedback received and will circulate a detailed report to the SPOC WP for written consultation.<br><br>**Agreed action:**<br><br>• After completing a second round of discussions of the subgroup and incorporating feedback from the SPOC WP, the SPOC WP subgroup will present the final harmonisation proposal to the SPOC WP. |
| 12. | **Shortage management systems**: |
| | **Germany – Time-series demand forecasting project & dashboard**<br><br>DE SPOC WP member and expert presented their time-series demand forecasting project including an explanation of the methodology and a live demonstration of the tool.<br><br>Discussion<br><br>In response to a question on the data sources used, DE SPOC WP member clarified that the current model relies on historical sales data from both community and hospital pharmacies available through IQVIA. |
| | **Austria – shortage management system Pharos**<br><br>AT SPOC WP member presented an overview of their national shortage management system, Pharos, that includes detailed information about both nationally and centrally authorised medicinal products with a valid or former MA in Austria. AT SPOC WP noted that their shortage catalogue is integrated into this system which allows automated updates when an MAH submits a shortage notification or confirms the end of a shortage. AT SPOC WP member also informed that all submitted shortage notifications are published on the NCA's website.<br><br>Discussion |

| Wednesday, 15 October 2025 (09:00-16:00) | |
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| | SPOC WP discussed the various features of the Austrian shortage management system. |
| | **Denmark – IT tool supporting stockpile obligations in DK**<br><br>DK expert presented an IT tool to support stockpiling obligations in Denmark. DK expert informed the group that the system provides a comprehensive overview of stock levels across the entire distribution chain including MAHs, wholesalers and pharmacies linked to sales data from both the current and the previous year. The system also integrates existing shortage cases and calculates market shares.<br><br>Discussion<br><br>SPOC WP Chair asked whether DK NCA will be able to identify excessive stockpiling at pharmacy or wholesaler level to which DK expert responded that it will be possible to see in the system and react to it.<br><br>SPOC WP and DK expert discussed changes in market dynamics and how it is reflected in the system and managed by DK NCA, as well as sources of data for the system. Additionally, details of the stockpiling regulation that came into effect on 1 July 2024 in Denmark were discussed. |
| | **European Shortages Monitoring Platform (ESMP) update**<br><br>EMA provided an update on the ESMP, including an overview of upcoming expansion features for the VSM, SMPs, and the supply chain vulnerability assessment. In addition, EMA outlined key outcomes from the Q4 PI planning. |
| 13. | **EDQM update - Progress of the EDQM initiatives on shortages**<br><br>EDQM representative provided an update on EDQM's activities related to shortages, including fast-track certification procedures for active substances in shortage, testing of unauthorised medicines, technical reports on supply of plasma and plasma-derived medicinal products, the compounding methodological guide, and developments in the European Drug Shortage Formulary (EDSForm) project.<br><br>Discussion<br><br>A SPOC WP member inquired about the validation process for fast-track assessment procedure requests from NCAs and applicants. EDQM representative clarified that NCA requests are accepted without further validation whereas applicant requests follow a validation process regarding the shortage claim.<br><br>The SPOC WP Chair asked whether the Union List of Critical Medicines is used as a reference when selecting medicines for inclusion in the compounding methodological guide, and the speaker confirmed that it is.<br><br>A SPOC WP member also commented on the importance of national lists as part of the methodological guide activities and stressed the need for MSs to update national lists of critical medicines in the context of the methodological guide for compounding.<br><br>**Agreed action:**<br><br>• SPOC WP is invited to review documents developed by EDQM. |

| Wednesday, 15 October 2025 (09:00-16:00) | |
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| 14. | **Joint Action on Antimicrobial Resistance and Healthcare-Associated infections (EU JAMRAI-2): Work Package 9 – intervention proposals to improve availability of selected antibiotics**<br><br>JA JAMRAI-2 representatives presented the EU-JAMRAI joint action's work on improving availability to selected antibiotics and veterinary vaccines under Work Package 9, describing the identification of focus products, analysis of barriers, and development of tailored interventions in participating countries. Activities for improving access to antibiotics for tuberculosis (TB) and recent activities to improve availability of aztreonam were also presented. Finally, the speakers emphasised the importance of engaging with companies, regulators, and clinicians.<br><br>Discussion<br><br>A SPOC WP member inquired about the potential for further input from MSs, including those not currently participating, to leverage project outputs and share best practices, which was welcomed by the JAMRAI-2 representatives.<br><br>**Agreed action:**<br><br>• SPOC WP and JA JAMRAI-2 representatives to continue collaboration on relevant antibiotic shortage issues. |
| 15. | **Joint Action on Shortages (CHESSMEN): findings from the Work Packages** |
| | **Work Package 1 - Coordination, management and evaluation**<br><br>WP 1 representative provided an update regarding the coordination activities of JA CHESSMEN, noting that the JA is seeking an amendment to extend the project and budget. This is still under discussion with relevant stakeholders and has not yet been confirmed. |
| | **Work Package 2 - Communication, dissemination and exploitation**<br><br>WP 2 representative described ongoing communication activities which includes social media activities, the publication of short videos by WP leads, and the development of communication materials based on approved deliverables from WP 5,6, and 7. WP 2 is currently working with WP 8 to prepare further materials. |
| | **Work Package 3 – Evaluation**<br><br>WP 3 representative outlined the evaluation process of the JA, which involves an External Advisory Board (EAB) conducting evaluations of the deliverables. The board consists of members from various countries and provides independent feedback, with 13 deliverables having been assessed by the EAB so far. The evaluation also includes mid-term and final surveys to gather expectations and advice from JA CHESSMEN members. |
| | **Work Package 4 – Sustainability**<br><br>WP 4 representative reported that the sustainability plan has undergone several revisions and will be delivered at the end of the JA. The plan includes a matrix for systematic assessment of the effectiveness of policy elements to facilitate assessment of deliverables yet to be finalised and to adapt it to future policy elements. |

| Wednesday, 15 October 2025 (09:00-16:00) | |
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| | **Work Package 5 – Root causes of observed shortages of medicines**<br><br>WP 5 representative summarised that WP 5 has completed its three deliverables: definitions, literature review, and analysis report, which underpin a new root cause classification. Currently, WP 5 is focused on dissemination of results and key findings, and ongoing collaboration with the SPOC WP subgroup on shortage definition on the review of root causes classification. |
| | **Work Package 6 – Best practices to address medicine shortages**<br><br>WP 6 representative informed that the reports on common protocols for monitoring, reporting, and managing shortages, and recommendations for developing national lists of critical medicines have been finalised. WP 6 is currently preparing NCA training materials for these two deliverables and is further working on finalising the report on test-case demand forecasting at national level. |
| | **Work Package 7 - Digital Information Exchange for Monitoring and reporting medicine shortages**<br><br>WP 7 representative explained that most deliverables of WP7 have been completed, with the main pending deliverable being a concept platform for monitoring and managing shortages, highlighting outstanding review and feedback implementation activities. |
| | **Work Package 8 – Shortages preventive and mitigation strategies**<br><br>WP 8 representative reported the submission of several deliverables on preventive and mitigation strategies. Planned activities include communicating approved deliverables to relevant stakeholders including the SPOC WP, conducting a survey on the status of measures outlined in the implementation plan deliverable, and preparing a position paper for further activities. |
| 16. | **Exchanges on (inter-)national practices:**<br><br>**a) Health Canada: shortage management initiatives**<br><br>Health Canada representatives outlined national medicine shortage management initiatives, including the Canadian regulatory framework for shortages, shortage case management and signal evaluation processes, stakeholder collaboration, and the development of a critical vulnerable drug list.<br><br>Discussion<br><br>SPOC WP members discussed and shared follow-up questions regarding the shortage notification system and the critical vulnerable drug list methodology. Representatives from Health Canada noted that the finalised critical vulnerable drug list can be shared with the SPOC WP once published. |
| 17. | **Medicine Shortage Communication (MSC) pilot update**<br><br>EMA presented the outcomes and challenges of the MSC pilot, highlighting the number of MSCs published and in development, long development timelines, clinical assessment complexities and the difficulty reflecting complex shortage situations in the MSCs. As a next step, EMA proposed to collect feedback via a stakeholder survey to refine the approach.<br><br>Discussion |

| Wednesday, 15 October 2025 (09:00-16:00) | |
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| | SPOC WP members provided feedback on the MSC pilot and shared their experience on MSC dissemination at national level. SPOC WP members also agreed to the survey to collect further feedback. |
| 18. | **AOB**<br><br>No AOB topics raised. |
| 19. | **Wrap-up and next steps**<br><br>SPOC WP Chair summarised key follow-up actions from the two-day hybrid meeting. The agreed actions are detailed above. |
| 20. | **Closing remarks**<br><br>The Chair and Vice-Chair thanked the SPOC WP for their active participation at the hybrid meeting and informed that the next hybrid meeting will take place in the first half of 2026 at EMA premises in Amsterdam. |

**Next meeting**: 11 November 2025 (TEAMS)

## List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 14-15 October meeting, which was held in hybrid mode (in EMA Office and Microsoft TEAMS).

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 | |
| Mathilde Moe Møldrup | Denmark | Vice-Chair | 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 restrictions applicable to this meeting | |
| Stela Lilek | Croatia | Alternate | No restrictions applicable to this meeting | |
| Vasileios Loutas | Cyprus | Member | No interest declared | |
| Jakub Velik | Czechia | Member | 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 | |
| Flore Demay | France | Member | No interest declared | |
| Laurent Fabry | France | Alternate | No interest declared | |
| Minna Myllyntausta | Finland | Alternate | No interest declared | |
| Theoni Kousteni | Greece | Member | No interest declared | |
| Gabriele Eibenstein | Germany | Member | No restrictions applicable to this meeting | |
| Thomas Brouwers | Germany | Member | No restrictions applicable to this meeting | |
| Linda Holtkamp | Germany | Alternate | No interest declared | |
| Roger Pally | Germany | Alternate | No interest declared | |
| Kinga Csécsei | Hungary | Member | No interest declared | |
| Veronika Horváth | Hungary | Member | No interest declared | |
| Hafdís Birna Baldursdóttir | Iceland | Alternate | No interest declared | |
| Ellen McGrath | Ireland | Member | 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 | |
| Hanneke Mulder | Netherlands | Member | No interest declared | |
| Erik Hergarden | Netherlands | Alternate | No interest declared | |
| Guri Wilhelmsen | Norway | Member | No interest declared | |
| Magdalena Rychter | Poland | Member | No restrictions applicable to this meeting | |
| Martyna Jakubowska | Poland | Alternate | No interest declared | |
| Helena Ponte | Portugal | Member | No restrictions applicable to this meeting | |
| 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 | Member | No restrictions applicable to this meeting | |

| Name | Member State or affiliation | Role | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|---|---|---|---|---|
| Erik Mokroš | Slovakia | Alternate | No interest declared | |
| Saša Martinc | Slovenia | Member | No interest declared | |
| Marta Casalengua | Spain | Alternate | No interest declared | |
| Samuel Silkestrand | Sweden | Member | No interest declared | |
| Karl Högström | Sweden | Alternate | 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 | |
| Carla Maione | Italy | Expert | No interest declared | |
| Frank Blommaert | Netherlands | Expert | No interest declared | |
| Nuno Simões | Portugal | Expert | No interest declared | |
| Sónia Gomes | Portugal | Expert | No interest declared | |
| João Simões | Portugal | Expert | No interest declared | |
| Isabelle Barabas | Romania | Expert | No interest declared | |
| Melita Tovornik | Slovenia | Expert | No interest declared | |
| Laura Marrero Ortiz | Spain | Expert | No interest declared | |
| Maria Criado | Spain | Expert | No interest declared | |
| Patricia Rodríguez Molla | Spain | Expert | No restrictions applicable to this meeting | |
| Ramiro Casamiro | Spain | Expert | No interest declared | |
| Andreas Sundgren | Sweden | Alternate | No interest declared | |
| Representatives from the European Commission and EDQM attended the meeting.<br>Observers from pre-accession countries attended a non-sensitive portion of the meeting.<br>Meeting run with the help of EMA staff. | | | | |