



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 March 2026
EMA/58544/2026
Regulatory Science and Innovation Task Force

Agenda - Medicine Shortages SPOC Working Party

16 March 2026, from 10:00 to 18:00 (CET), hybrid meeting – F2F + TEAMS

17 March 2026, from 09:00 to 16:00 (CET), hybrid meeting – F2F + TEAMS

Chair: Monica Dias (EMA), Vice-Chair: Vasileios Loutas (PhS, Ministry of Health, Cyprus)

Monday, 16 March 2026 (10:00-18:00)

| Item | Topic |
|------|--|
| 1. | Welcome, declarations of interest, adoption of draft agenda |
| 2. | Adoption of draft minutes of the SPOC WP meeting held on 17 February 2026 |
| 3. | Updates from Member States |
| | a) SPOC WP lightning round – most critical issues at national level |
| | b) Status update on any new strategic measures implemented at national level (e.g., critical medicines lists, stockpiling requirements) |

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| 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 <ul style="list-style-type: none">• Update on the geopolitical situation• Availability of antibiotics: update on preparedness activities |
| 5. | Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) |
| 6. | Critical shortages escalated to the SPOC Working Party: |
| 6.1 | Ongoing shortages |
| | a) Medicinal products manufactured by Pharmathen <ul style="list-style-type: none">• Overview of the overall shortage situation• Presentation delivered by Pharmathen, followed by a Q&A session• Debrief on next steps/actions |
| | b) Medicinal products from MAH Cheplapharm <ul style="list-style-type: none">• Feedback from the SPOC WP subgroup on Cheplapharm |
| | c) Holoxan NAP (ifosfamide), Endoxan NAP (cyclophosphamide), MAH: Baxter <ul style="list-style-type: none">• Overview of the overall shortage situation• Presentation from MAH Baxter, followed by Q&A session• Debrief on next steps/actions |
| 6.2 | Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates) |
| | a) Dynastat CAP (parecoxib) – MAH: Pfizer |
| | b) Praziquantel containing medicinal products |
| | c) Medicinal products containing salbutamol (inhalation use) |

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| 7. | Drug Shortage Global Regulatory Working Group: feedback from Q1 meeting |
| 8. | Urban Wastewater Treatment Directive <ul style="list-style-type: none">• Presentation from DG ENV• Presentation from Dutch Ministry of Health, Welfare and Sport |
| 9. | Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities: |
| | a) Feedback from the MSSG WG on the Vulnerability Assessment Methodology |
| | b) Union list of critical medicines <ul style="list-style-type: none">• Presentation from members of HCP WP/PC WP |

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| 9. | Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities (continued): |
| | c) Closure of the MSSG WG on Voluntary Solidarity Mechanism and Policy |
| 10. | SPOC WP subgroup on shortage definition — Proposal for update of root cause classification |
| 11. | Impact of the parallel trade on the availability of medicines in EU/EEA |
| | <ul style="list-style-type: none"> • Presentation from Bulgaria • Presentation from Germany • Presentation from Affordable Medicines Europe (AME), followed by a Q&A session • Debrief and closing remarks |
| 12. | Joint Action on Antimicrobial Resistance and Healthcare-Associated infections (EU JAMRAI-2): |
| | <ul style="list-style-type: none"> • France - Regulation governing medicine withdrawals from the market |
| 13. | Joint Action on Shortages (CHESSMEN): update |
| | a) Work Package 1 - Coordination, management and evaluation |
| | b) Work Package 2 - Communication, dissemination and exploitation |
| | c) Work Package 4 - Sustainability |
| | d) Work Package 5 – Root causes of observed shortages of medicines |
| | e) Work Package 6 – Best practices to address medicine shortages |
| | f) Work Package 7 - Digital Information Exchange for Monitoring and reporting medicine shortages |
| | g) Work Package 8 – Shortages preventive and mitigation strategies |
| 14. | EDQM : Update on the EDQM Initiative on Shortages |
| 15. | Shortage management systems: |

Tuesday, 17 March 2026 (09:00-16:00)

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| | a) Croatia – Shortage monitoring tool |
| | b) Finland - PowerBI tool for availability and preparedness |
| | c) European Shortages Monitoring Platform (ESMP) update |
| 16. | AOB |
| 17. | Wrap-up and next steps |
| 18. | Closing remarks |

Next meeting: 15 April 2026 (TEAMS)
