

14 October 2025
European Medicines Agency

Agenda — Medicine Shortages (SPOC) Working Party

14 October 2025, from 10:00 to 18:00 (CEST), hybrid meeting — F2F + TEAMS

15 October 2025, from 09:00 to 16:00 (CEST), hybrid meeting — F2F + TEAMS

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

Tuesday, 14 October 2025 (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 10 September 2025
3.	Updates from Member States
	a) SPOC WP lightning round — most critical issues at national level
	b) Danish presidency of the EU: initiatives on medicine shortages for H2 2025
	c) Status update on any new strategic measures implemented at national level (e.g., critical medicines lists, stockpiling requirements)

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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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
	b) 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 containing salbutamol (inhalation use) <ul style="list-style-type: none"> Update on current situation in EU/EEA countries DARWIN EU salbutamol drug utilisation study report
	b) Medicinal products from MAH: Cheplapharm
	c) Medicinal products containing quetiapine <ul style="list-style-type: none"> Outcome of the voluntary solidarity mechanism (VSM) procedure France — National perspective on the VSM procedure
	d) Medicinal products manufactured by Pharmathen International site: <ul style="list-style-type: none"> Outcome of the survey to identify critical shortages of products manufactured by Pharmathen Sweden: critical shortage of risperidone prolonged-release suspension for injection
	e) Bronchitol (mannitol) CAP, MAH: Pharmaxis Europe Limited
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
	b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk
	c) Oncology medicinal products – MAHs: Teva, Accord
	d) Medicinal products from MAH Viatris

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7.	European Commission DG SANTE
8.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 24 September 2025
	b) Feedback from the MSSG WG on Voluntary Solidarity Mechanism and Policy
	c) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology
9.	Drug Shortage Global Regulatory Working Group: <ul style="list-style-type: none">• Feedback from Ad hoc meeting on supply chain vulnerabilities on 17 September 2025• Update on current activities of the WG
10.	Outcome of ECA audit on critical shortages of medicines

Item	Topic
11.	Technical topics
	a) Root cause classification: SPOC WP Subgroup proposal for harmonisation
12.	Shortage management systems:
	a) Germany — Time-series demand forecasting project & dashboard
	b) Austria — Shortage management system Pharos
	c) Denmark — IT tool supporting stockpile obligations in DK
	d) European Shortages Monitoring Platform (ESMP) update
13.	EDQM: Progress of the EDQM initiatives on shortages
14.	Joint Action on Antimicrobial Resistance and Healthcare-Associated infections (EU JAMRAI-2):
	• Work Package 9 — intervention proposals to improve availability of selected antibiotics
15.	Joint Action on Shortages (CHESSMEN): findings from the Work Packages
	a) Work Package 1 — Coordination, management and evaluation
	b) Work Package 2 — Communication, dissemination and exploitation
	c) Work Package 3 — Evaluation
	d) Work Package 4 — Sustainability
	e) Work Package 5 — Root causes of observed shortages of medicines
	f) Work Package 6 — Best practices to address medicine shortages
	g) Work Package 7 — Digital Information Exchange for Monitoring and reporting medicine shortages
	h) Work Package 8 — Shortages preventive and mitigation strategies
16.	Exchanges on (inter-)national practices:

Wednesday, 15 October 2025 (09:00–16:00)

Item	Topic
	a) Health Canada: shortage management initiatives
17.	Medicine Shortage Communication (MSC) pilot update
18.	AOB
19.	Wrap-up and next steps
20.	Closing remarks

Next meeting: 11 November (TEAMS)**Note on access to documents**

Some documents mentioned in the agenda 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 ongoing 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).