

11 November 2025
European Medicines Agency

Agenda — Medicine Shortages (SPOC) Working Party

11 November 2025, from 09:30 to 13:30 (CET), TEAMS

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

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 14-15 October 2025
3.	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 • Availability of antibiotics: update on preparedness activities
4.	Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
5.	Critical shortages escalated to the SPOC Working Party:

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5.1	Ongoing shortages
	a) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring
	b) Medicinal products from MAH Cheplapharm
	c) Medicinal products manufactured by Pharmathen Risperidone NAP, powder and solvent for prolonged-release suspension for injection medicinal products
5.2	Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)
	a) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk
	b) Bronchitol CAP (mannitol) – MAH: Pharmaxis Europe Limited
	c) Medicinal products containing salbutamol (inhalation use)
	d) Shortage and discontinuation of insulin containing medicinal products
5.3	Supply and availability of veterinary medicinal products Medicinal products to treat feline infectious peritonitis (FIP)
6.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 20 October 2025
	b) MSSG WG on the Voluntary Solidarity Mechanism and Policy - Feedback from Focal Group on Union list of critical medicines - Shortage Prevention and Mitigation Plans (SPMPs) pilot update
7.	European Shortages Monitoring Platform (ESMP) - ESMP/EMVS Gap analysis final report - ESMP update

Item	Topic
8.	Drug Shortage Global Regulatory Working group — update
9.	AOB
10.	Conclusions and next steps

Next meeting: 09 December, TEAMS
