

09 December 2025
European Medicines Agency

Agenda — Medicine Shortages SPOC Working Party

9 December 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 11 November 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 meeting on 2 December 2025
	b) 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) Medicinal products from MAH Cheplapharm Feedback from the SPOC WP subgroup on Cheplapharm
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) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists c) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring d) Medicinal products containing salbutamol (inhalation use) e) Shortage and discontinuation of insulin containing medicinal products f) Medicinal products manufactured by Pharmathen International
6.	Feedback from the SPOC WP Subgroup on Shortage Definition: Root cause classification – proposal for harmonisation
7.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 20 November 2025
	b) MSSG WG on the Voluntary Solidarity Mechanism and Policy Feedback from the Focal Group on Union list of critical medicines
8.	Interchangeability on pharmacy level in case of shortages - European Community Pharmacists (PGEU) - Hungary - Findings of the survey
9.	Leveraging digitalisation and automation for controlled substances management in European hospitals

Item	Topic
10.	European Shortages Monitoring Platform (ESMP) update
11.	AOB
12.	Conclusions and next steps

Next meeting: 20 January, 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).