

14 July 2025
European Medicines Agency

Agenda — Medicine Shortages SPOC Working Party

14 July 2025, from 09:30 to 13:40 (CEST), 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 17 June 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
	b) Availability of antibiotics: update on preparedness activities
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
4.	Critical shortages escalated to the SPOC Working Party:
4.1	Ongoing shortages
	a) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists, MAH: Novo Nordisk, Eli Lilly
	b) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring
4.2	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) Medicinal products from MAH: Cheplapharm
	d) Medicinal products containing salbutamol (inhalation use)
	e) Moventig CAP (naloxegol) – MAH: Grünenthal GmbH
	f) Biltricide NAP (praziquantel) – MAH: Bayer

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	g) Medicinal products from MAH Viatriis
5.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology
	b) Feedback from the MSSG WG on Voluntary Solidarity Mechanism and Policy: Focal Group on Union list of critical medicines - Annual update of the Union list of critical medicines
6.	European Shortages Monitoring Platform (ESMP) update
7.	Collaborative assessment program for critical medicines
8.	EMA-EC Pilot for extension of shelf life for medicines stockpiled in preparedness for health threats
9.	EC DG SANTE
10.	Global Regulatory Working Group on Drug Shortages: Q2 meeting
11.	AOB
12.	Conclusions and next steps

Next meeting: 10 September (TEAMS) (placeholder 12 August)

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).