



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2025
European Medicines Agency

Agenda — Medicine Shortages (SPOC) Working Party

10 September 2025, from 09:30 to 13:30 (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 14 July 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
	b) Beriglobin NAP (human normal immunoglobulin), MAH: CSL Behring
	c) Zypadhera CAP (olanzapine pamoate), MAH: Cheplapharm
	• Outcome of the voluntary solidarity mechanism (VSM) procedure • Finland — National perspective on the VSM procedure • VSM Guidance for NCAs — Update proposal
	d) Medicinal products containing quetiapine

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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) Biltricide NAP (praziquantel) – MAH: Bayer d) Oncology medicinal products – MAH Teva e) Medicinal products containing salbutamol (inhalation use) f) Shortage and discontinuation of insulin containing medicinal products
5.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 23 July 2025
	b) Feedback from the MSSG WG on the Vulnerability Assessment Methodology
6.	Establishment of GMDP IWG Drafting Group on inspections of MAH
7.	Drug Shortage Global Regulatory Working group — update
8.	Shortage Prevention and Mitigation Plans (SPP/SMP) pilot update
9.	European Shortages Monitoring Platform (ESMP) update
10.	SPOC WP F2F October meeting — presentation of draft agenda and call for proposals of agenda topics
11.	AOB
12.	Conclusions and next steps

Next meeting: 14–15 October (EMA office and MS 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).