

17 June 2025
European Medicines Agency

Agenda — Medicine Shortages (SPOC) Working Party

17 June 2025, from 09:30 to 13:00 (CEST), TEAMS

Chair: Monica Dias (EMA), Vice-Chair: Magdalena Rychter (GIF, Poland)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 13 May 2025
3.	Administrative topic: meeting transition to MS Teams
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
	c) 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:
5.1	Ongoing shortages
	a) Shortage and discontinuation of insulin containing medicinal products
	b) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists
	c) Moventig CAP (naloxegol) – MAH: Grünenthal
	d) Biltricide NAP (praziquantel) – MAH: Bayer
	e) Venlafaxine containing medicinal products:
	<ul style="list-style-type: none">• Outcome of the voluntary solidarity mechanism (VSM) procedure• Presentation on national shortage mitigating measures

Item	Topic
5.2	Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)
	<ul style="list-style-type: none"> 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)
6.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 21 May 2025
	b) Draft Recommendations of the MSSG to address anti-D immunoglobulin supply vulnerabilities
	c) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology
	d) Feedback from the MSSG WG on Voluntary Solidarity Mechanism and Policy
7.	Global Regulatory Working Group on Drug Shortages: Q2 meeting
8.	AOB
9.	Conclusions and next steps

Next meeting: 14 July (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).