

12 May 2026
EMA/77926/2026
Regulatory Science and Innovation Task Force

Agenda — Medicine Shortages SPOC Working Party

Tuesday, 12 May 2026, from 09:30 to 13:35 (CEST), TEAMS

Chair: Monica Dias (EMA), Vice-Chair: Vasileios Loutas (PhS, Ministry of Health, Cyprus)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 15 April 2026
3.	Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market: • Update on the geopolitical situation
4.	Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)

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5.	Critical shortages escalated to the SPOC Working Party:
5.1	Ongoing shortages
	a) Ifosfamide containing medicinal products and cyclophosphamide containing medicinal products, MAH: Baxter
	b) Gastrografin NAP and Urografin NAP (sodium amidotrizoate, meglumine amidotrizoate), MAH: Bayer
	c) Topamax NAP (topiramate), MAH: Janssen-Cilag
	d) Fibclot NAP (human fibrinogen), MAH: Laboratoire français du Fractionnement et des Biotechnologies S.A.
	e) Mycobutin NAP (rifabutin), MAH: Pfizer B.V.
	f) Praziquantel containing medicinal products
5.2	Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)
	a) Medicinal products containing salbutamol (inhalation use)
	b) Medicinal products affected by fire incident at Viatris manufacturing site
	c) Medicinal products from MAH Cheplapharm
6.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 24 April 2026
	b) Feedback from the MSSG WG on Vulnerability Assessment Methodology, including update on Shortage Prevention Plans
	c) Union list of Critical Medicines and Union Long list - update
7.	SPOC WP subgroup on shortage definitions — Update on proposal of harmonised root cause classification
8.	European Shortages Monitoring Platform (ESMP) update
9.	SPOC WP F2F June meeting — presentation of draft agenda and call for proposals of agenda topics

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10.	AOB
11.	Conclusions and next steps

Next meeting: 16-17 June 2026, F2F EMA office (Amsterdam) + TEAMS
