



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 March 2025
Regulatory Science and Innovation Task Force

Agenda - Medicine Shortages (SPOC) Working Party

18 March 2025, from 09:30 to 13:15 (CET), Webex

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 18 February 2025
3.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) -led activities:
	a) Feedback from the MSSG meeting on 26 February 2025
	b) MSSG Working Group on VSM and Policy: Feedback from WG meeting on 27 February 2025
4.	Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:
	a) Availability of antibiotics – preparedness for autumn/winter 2024-2025
	b) Re-activation of the SPOC WP Subgroup on crisis monitoring and preparedness
	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) Fludarabine containing medicinal products
	b) Medicinal products from MAH: Cheplapharm
	c) Shortage and discontinuation of insulin containing medicinal products

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5.2	Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)
	a) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk b) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH c) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer d) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists e) Medicinal products containing salbutamol (inhalation use) f) Medicinal product containing quetiapine g) Menopur NAP (menotropin) – MAH: Ferring h) Availability of perfusion solutions following hurricane Helene
6.	European Commission DG SANTE update
7.	European Commission DG HERA update
8.	Joint Action on shortages (CHESSMEN) <ul style="list-style-type: none"> Work Package 6 – demand forecasting at national level: survey results and next steps
9.	SPOC WP satisfaction survey outcomes and next steps
10.	SPOC WP F2F April meeting – presentation of draft agenda and call for proposals of agenda topics
11.	Update on revised rules on handling of competing interests of scientific committee members and experts ('Policy 0044')
12.	AOB
13.	Conclusions and next steps

Next meeting: 10–11 April 2025, F2F EMA Office + Webex

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).