

5 December 2024
European Medicines Agency

Agenda — Medicine Shortages (SPOC) Working Party

5 December 2024, from 09:30 to 13:30 (CET), Webex

Chair: Monica Dias (EMA), Vice-Chair: Veronika Horvath (NNGYK, Hungary)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 6 November 2024
3.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) -led activities:
	a) Feedback from the MSSG meeting on 19 November 2024
	b) MSSG recommendations to address the vulnerabilities in the supply chain
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) Impact of the hurricane over US territory on availability of medicinal products in Europe
	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) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists
	b) Insulin containing medicinal products
	c) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH
	d) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris
	e) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk

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	f) Medicinal products from Cheplapharm
5.2	Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)
	a) Medicinal products containing salbutamol (inhalation use) b) Oncology medicinal products from Accord Healthcare B.V. c) Nakom NAP (levidopa/carbidopa) – MAH: Sandoz d) Chenpen NAP (epinephrine) – MAH: Bioproject Pharma; Jext NAP (epinephrine) – MAH: Alk-Abello e) Synulox NAP (amoxicillin/clavulanic acid) - MAH: Zoetis
6.	European Shortages Monitoring Platform (ESMP) update
7.	HMA/EMA Task Force on Availability of Authorised Medicines (TF-AAM)
	a) Union list of critical medicines b) The closure of the HMA/EMA TF-AAM
8.	Communication on shortages: feedback from EMA media seminar
9.	EC DG SANTE update
10.	EC DG HERA update
11.	AOB
12.	Conclusions and next steps

Next meeting: 21 January (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).