



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 November 2024
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

6 November 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 7-8 October 2024
3.	EC DG HERA update
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) Supply and availability of radioisotopes
	<ul style="list-style-type: none">Status update on supply and availability of radioisotopes in EU/EEAEuropean Observatory on the supply of medical radioisotopesNuclear Medicine Europe – Emergency Response TeamDiscussion
	b) Insulin containing medicinal products
	c) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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	d) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris
	e) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer
	f) Medicinal products from Cheplapharm
	g) Medicinal products containing salbutamol (inhalation use): <ul style="list-style-type: none"> Potential impact of F-gas regulation on the availability of metered-dose inhalers
5.2	Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)
	a) Oncology medicinal products from Accord Healthcare B.V.
	b) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH
	c) Nakom NAP (levidopa/carbidopa) – MAH: Sandoz
	d) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk
	e) Semintra (telmisartan) CAP – MAH: Boehringer Ingelheim Animal Health
6.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Voluntary Solidarity Mechanism (VSM) : Presentation of the latest VSM procedures
7.	Survey on national approaches to shelf life extension of medicines stockpiled in preparedness to health threat: Key results of the SPOC WP survey
8.	Scientific article on the activities of the Medicine Shortages SPOC Working Party – 5 year review
9.	AOB
10.	Conclusions and next steps

Next meeting: 5 December (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).