



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 October 2024
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

7 October 2024, from 10:00 to 18:00 (CEST), F2F + Webex

8 October 2024, from 09:00 to 16:00 (CEST), F2F + Webex

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

Monday, 7 October 2024	
Item	Topic
1.	Welcome, declarations of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 11 September 2024
3.	SPOC WP information exchange : refresher on shortage notifications, requests for information and voluntary solidarity mechanism
4.	EC DG SANTE update
5.	EC DG HERA update
6.	Update on EDQM shortage initiatives
7.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG meeting on 18 September 2024
	b) Feedback from the MSSG WG on Solidarity Mechanism
8.	Tour de table : exchange of best practices on import licences
9.	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 takeover of Catalent by Novo Holdings on the supply of medicines
	c) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)

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Item	Topic
10.	Critical shortages escalated to the SPOC Working Party:
10.1	Ongoing shortages
	a) Oncology medicinal products from MAH: Accord Healthcare B.V.
	• Overview of the overall shortage situation • Presentation delivered by MAH: Accord Healthcare B.V., followed by a Q&A session • Debrief on next steps/actions
	b) Supply and availability of Novo Nordisk medicinal product portfolio
	• Effectiveness of shortage mitigating measures – Hungarian experience • Overview of the supply and availability situation • Discussion and next steps
	c) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH
	• Overview of the overall shortage situation • Presentation delivered by MAH: Pharmaand GmbH, followed by a Q&A session • Debrief on next steps/actions
	d) Nakom NAP (levidopa/carbidopa) – MAH: Sandoz
	e) Medicinal products containing salbutamol (inhalation use)
	f) Medicinal products containing doxycycline
	g) Chenpen NAP (epinephrine) – MAH: Bioproject Pharma; Jext NAP (epinephrine) – MAH: Alk-Abello
	h) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk
10.2	Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)
	i) Medicinal products from Cheplapharm
	j) Semintra (telmisartan) CAP – MAH: Boehringer Ingelheim Animal Health
	k) Veklury CAP (remdesivir) for cats to treat Feline Infectious Peritonitis (MAH: Gilead Sciences Ireland UC)
	l) Synulox (amoxicillin/clavulanic acid) NAP - MAH: Zoetis
11.	GMP/GDP Inspectors Working Group:
	• Implementation of revised ICH Q9 R1 guideline on quality risk management (including product availability risks arising from quality/manufacturing issues) in GMP guideline

Tuesday, 8 October 2024

Item	Topic
12.	European Shortages Monitoring Platform (ESMP) update
13.	Presentations from SPOC WP Members:
	a) Italy – Stock traceability system
	b) Czechia – New measures and systems for availability monitoring
	c) Bulgaria: • Shortage monitoring system (SESPA) • Defining shortages through empirical and real world data
14.	Definition of medicine shortage
	a) Drug Shortages: definitions across different market types
	b) Status update on the activities of the SPOC WP subgroup
15.	Presentation from International Society of Pharmaceutical Engineering (ISPE): Drug Shortages Initiatives
16.	Improving access to plasma derived medicinal products (PDMPs): recommendations from the SUPPLY project
17.	Joint Action on Shortages (CHESSMEN): general update and findings from the Work Packages:
	a) WP 2 – Communication, dissemination and exploitation
	b) WP 5 – Shortage root causes
	c) WP 6 – Best practices to address medicine shortages
	d) WP 7 – Digital Information Exchange
	e) WP 8 – Shortages preventive and mitigation strategies – results from the survey on export restrictions
18.	European Medicines Agencies Network Strategy (EMANS) to 2028
19.	Medicine Shortage Communication (MSC) update
20.	HMA/EMA Task Force on Availability of Authorised Medicines (TF-AAM)
	a) Thematic Working Group 2: Update on communication activities
	b) Thematic Working Group 1: Union list of critical medicines
21.	Hungarian presidency of the EU: initiatives on medicine shortages for H2 2024
22.	Status update on any new strategic measures implemented at national level
23.	AOB
24.	Wrap-up and next steps

Tuesday, 8 October 2024

Item	Topic
25.	Closing remarks

Next meeting: 6 November 2024 (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).