



15 April 2024
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

15 April 2024, from 10:00 to 18:00 (CEST), hybrid meeting – F2F + WebEx

16 April 2024, from 09:00 to 16:00 (CEST), hybrid meeting – F2F + WebEx

Chair: Monica Dias (EMA), Vice-Chair: Sybille Schotte (FAMHP, Belgium)

Monday, 15 April 2024	
Item	Topic
1.	Welcome, declarations of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 14 March 2024
3.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG): General update on March and April 2024 meetings
4.	Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:
	a) Impact of the takeover of Catalent by Novo Holdings on the supply of medicines
	b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)
5.	Critical shortages escalated to the SPOC Working Party:
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim
	b) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited
	c) Shortages of medicinal products from MAH: Cheplapharm
	d) Emend CAP (aprepitant) - MAH: Merck Sharp & Dohme B.V.



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	e) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatrix
	f) Fluracedyl NAP (fluorouracil) – MAH: Teva Pharma Belgium S.A.; Fluorouracil Accord Healthcare NAP (fluorouracil) – MAH: Accord Healthcare B.V
	g) Methotrexate IV NAP (methotrexate) - MAH: Teva Sante
	h) Ventolin NAP (salbutamol sulfate) - MAH: GlaxoSmithKline
	i) Shortages of medicinal products containing cisplatin
6.	Availability issues for veterinary medicines :
	a) Remdesivir for cats to treat Feline Infectious Peritonitis
	b) Drug shortages at Zoological Parks in the US
	a) Shortages of veterinary vaccines for dogs, cats and horses
7.	Availability of antimicrobials :
	a) Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI-2): Work Package 9 on access to antimicrobials
	b) Antibiotic shortages:
	<ul style="list-style-type: none">• General update on preparedness activities• Presentation delivered by MAH: Sandoz
	c) Debrief on next steps/actions for antibiotic shortages .
8.	European Shortages Monitoring Platform (ESMP): a) Status update b) ESMP User Interface design c) NCA datasets for submission in crisis and MSSG-led preparedness
9.	EC DG ECHO - Union Civil Protection Mechanism
10.	EC DG HERA update
11.	EC DG SANTE update

Tuesday, 16 April (09:00-16:00)

Item	Topic
1.	Critical shortages escalated to the SPOC Working Party (continued):
	a) Glucagon-like Peptide-1 (GLP1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide), Victoza CAP (liraglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide) - MAH: Eli Lilly Nederland B.V.
	b) Supply and availability of IV/SC human normal immunoglobulins in the EU/EEA
2.	Presentations from SPOC WP Members:
	a) Slovenia – National marketing status system – first steps to improve information sharing
	b) Poland – Integrated System for Monitoring the Trade in Medicinal Products (ZSMOPL)
	c) Greece – Platform for monitoring the pharmaceutical supply chain
3.	Joint Action on Shortages (CHESSMEN): general update and findings from the Work Packages: <ul style="list-style-type: none">• WP1 – Coordination, management and evaluation• WP5 – Shortage root causes• WP8 – Shortages preventive and mitigation strategies
4.	HMA/EMA Task Force on Availability of Authorised Medicines
	a) Union list of critical medicines
	b) Shortage prevention and mitigation plans (SPP/SMP)
5.	MSSG-led activities:
	a) MSSG recommendations for supply chain vulnerabilities
	b) Solidarity Mechanism: feedback from the pilot
6.	Belgian presidency of the EU: initiatives on medicine shortages
7.	Technical Discussion on Core Topics: Definition of medicine shortage
8.	Update on EDQM shortage initiatives
9.	Shortage communication activities: <ul style="list-style-type: none">• Status update on medicine shortage communication (MSC) template

Tuesday, 16 April (09:00-16:00)

Item	Topic
10.	Presentation from OECD : Securing Medical Supply Chains in a Post-Pandemic World
11.	Presentation from WHO EURO : Availability issues of tuberculosis medicines
12.	Refresher on shortage notifications and requests for information
13.	Wrap-up and next steps
14.	Closing remarks

Next meeting: 22 May (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).