



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 April 2023
EMA/148452/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

18 April 2023, from 10:00 to 17:00 (CEST), hybrid meeting – F2F (EMA office Amsterdam) + WebEx

Chair: Monica Dias (EMA), Vice-Chair: Johan Andersson (SE)

Item	Topics
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 15 February 2023
3.	Future operating model of SPOC WP Meetings and information exchange: <ul style="list-style-type: none">Incoming rollout of SharePoint Online as common, shared platform for meeting management and case reporting
4.	Potential impact of the international situation (e.g. War in Ukraine) and energy crisis on the supply of medicinal products for human and veterinary use to the European market:
	a) Antibiotic shortages: general update on preparedness activities - EMA/HERA exercise for a subset of antibiotics
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
5.	Update on ongoing shortages reported by the SPOC WP (non-PHE/ME related): <ul style="list-style-type: none">a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim; Urokinase NAP
Coffee break	
	b) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH
	c) Menopur NAP (menotropin) - MAH: Ferring
	d) Ozempic CAP (semaglutide) - MAH: Novo Nordisk

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	e) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH
	f) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma EEIG); Pazenir CAP (paclitaxel) - MAH Ratiopharm GmbH
	g) Rivotril NAP (clonazepam) - MAH: Cheplapharm Arzneimittel GmbH
Lunch break	
6.	EC DG SANTE update
7.	EC DG HERA update
8.	HMA / EMA Task Force on Availability of authorised medicines – update on key workplan deliverables:
	a) TWG1 (Availability and supply disruptions): <ul style="list-style-type: none"> • EU list of critical medicines
	b) TGW2 (Communications): <ul style="list-style-type: none"> • Survey to NCAs on public communication of medicines shortages (high-impact shortage cases);
9.	Joint Action on Shortages (CHESSMEN) - update
10.	Update on the EMA extended mandate implementation:
	a) ESMP product development status
	b) Updates from NCAs on new information related to national IT systems for monitoring shortages
	c) Status update on implementation activities for Medical Device Shortages
11.	EC presentation on affordability of medicines
12.	EDQM presentation on shortage initiatives
Coffee break	
13.	CAP shortage reporting process in the MSs and EMA: <ul style="list-style-type: none"> • Update from SE on survey to NCAs on reporting of CAP shortages at national level; • Update from EMA on reporting of CAP shortages in peace-time and during crises.
14.	Sterilization of single-use materials and filters: <ul style="list-style-type: none"> • Implementation of X-ray irradiation as an alternative to Gamma irradiation

Item	Topics
15.	Country case study (Spain): <ul style="list-style-type: none"> • Presentation on the ARTEMIS pilot project designed to identify early signals of shortages at wholesale distributor level
16.	Conclusions and next steps

Next meeting: 24 May 2023

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)