



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 May 2023
EMA/200648/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party meeting

24 May 2023, from 10:00 to 13:00 (CEST), 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 18 April 2023
3.	Future operating model of SPOC Working Party meetings and information exchange: Update on rollout of SharePoint Online
4.	End of the COVID-19 and Mpox public health emergencies: Update on the SPOC Working Party activities under Regulation (EU) 2022/123
5.	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: update on joint EMA/HERA preparedness activities
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
6.	Ongoing shortages reported by the SPOC WP (non-PHE/ME related):
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim; Urokinase NAP
	b) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH
	c) Menopur NAP (menotropin) - MAH: Ferring

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	d) Ozempic CAP and Rybelsus CAP (semaglutide) - MAH: Novo Nordisk
	e) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma EEIG); Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH
	f) Voxzogo CAP (vosoritide) - MAH: BioMarin International Limited
7.	Update from EC DG SANTE
8.	Update from EC DG HERA
9.	Joint Action on Shortages (CHESSMEN)
10.	EU list of critical medicines – feedback from HMA/EMA TF AAM (TWG1)
11.	Implementation of EMA extended mandate: • Status update on implementation activities for Medical Device Shortages; • Shortage Transparency Platform.
12.	European Health Management Association (EHMA) survey to NCAs on hospital data gathering initiative
13.	Conclusions and next steps

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 on-going 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).