



14 December 2023
EMA/547123/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

Thursday, 14 December 2023, from 10:00 to 13:00 (CET), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Patricia Tabernerero (AEMPS, Spain)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 20 November 2023
3.	MSSG update: meetings held on 23 November and 13 December 2023
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: update on preparedness activities
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) <ul style="list-style-type: none">• Impact of ongoing referral of Synapse Labs Pvt. Ltd. (located in Kharadi, Pune, India) on availability of medicinal products in the EU/EEA
	c) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets
	d) Update on impact of BREXIT on medicines availability
5.	Ongoing critical shortages reported by the SPOC WP:
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim
	b) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited



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	c) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma; Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH
	d) Attention deficit hyperactivity disorder (ADHD) medicine shortages
	e) Visudyne CAP (verteporfin) – MAH: Cheplapharm
6.	Definition of medicine shortage: follow up discussions from the F2F meeting in October 2023
7.	EC DG HERA update
8.	Update on the Joint Action on Shortages (CHESSMEN) coordination activities
9.	HMA/EMA Task Force on Availability of authorised medicines:
	a) Union list of critical medicines
	b) Shortage prevention and mitigation plans (SPMPs)
10.	Conclusions and next steps

Next meeting: 22 January 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 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).