21 March 2023
EMA/180631/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

21 March 2023, from 10:30 to 13:30 (CET), virtual meeting 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.	MSSG update: meetings held on 23 February and 15 March 2023
4.	Major event definition: criteria for the MSSG to grant a positive opinion on an actual or imminent major event
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: general update on coordinated actions
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
6.	Update on ongoing shortages reported by the SPOC Working Party (non-PHE/ME related):
	a) Visudyne CAP (MAH: Cheplapharm Arzneimittel GmbH)
	b) Thrombolytics: Metalyse CAP and Actilyse NAP (MAH: Boehringer Ingelheim)
	c) Menopur NAP (MAH: Ferring)
	d) Ozempic CAP (MAH: Novo Nordisk)
	e) Ixiaro CAP withdrawal from the market (MAH: Valneva Austria GmbH)

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7.	Impact of nitrosamines on the availability of medicinal products: • Presentation of FIMEA's position paper on *"Nitrosamine Issues – Risks to Public Health and Proposed Actions for Consideration"* • Update from EMA on coordinated actions on nitrosamines
8.	CAP shortage reporting process in the MSs and EMA
9.	Feedback from HMA/EMA Multi-stakeholder Workshop on shortages 1-2 March 2023
10.	EC DG HERA - update
11.	Update on proposals to enhance shortage communication and transparency to the public
12.	Conclusions and next steps

Next meeting: 18 April 2023, Amsterdam

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).