14 March 2024
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

14 March 2024, from 09:30 to 13:00 (CET), WebEx

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

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 14 February 2023
3.	**Potential impact of the international situation** on the supply of medicinal products for human and veterinary use to the European market:
	a) Antibiotic shortages: update on preparedness activities
	b) Impact of the takeover of Catalent by Novo Holdings on the supply of medicines
	c) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets
	d) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
4.	**Critical shortages escalated to the SPOC Working Party:**
	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
	c) Shortages of medicinal products from MAH: Cheplapharm
	d) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris
	e) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH
	f) Cyclogyl NAP (cyclopentolate) – MAH: Alcon SA-NV

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	g) Ventolin Inhaler N NAP (salbutamol sulfate) - MAH: GlaxoSmithKline (Ireland) Limited
	h) Impact of Colistimethate sodium referral
5.	Presentation from **GIRP** (European Healthcare Distribution Association (About GIRP | GIRP) on shortages reporting
6.	EC **DG HERA** update:
	a) progress update on the supply chain vulnerability assessment
	b) update on call for TB paediatric medicine
7.	**HMA/EMA Task Force on Availability of authorised medicines:**
	a) Union list of critical medicines – launch of **Phase 2** and SPOC Working Party input
	b) presentation of the **MSSG recommendations** to strengthen supply chains of critical medicinal products
8.	Conclusions and next steps

Next meeting: 15-16 April 2024 (hybrid – F2F+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).