



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2024
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

14 February 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 22 January 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 Nordisk 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) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim
	b) 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.
	c) Supply and availability of IV/SC human normal immunoglobulins in the EU/EEA:
	<ul style="list-style-type: none">• Overview of the shortage situation of immunoglobulins• Update on the revision of CHMP position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products

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	d) Shortages of medicinal products from MAH: Cheplapharm
	e) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited
	f) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH
	g) Emend CAP (aprepitant) - MAH: Merck Sharp & Dohme B.V.
	h) Creon (pancrealipase) - MAH: Viatrix Italia S.R.L and Creonipe (pancrelipase) - MAH: Viatrix Healthcare Limited
5.	Update from MSSG meeting held on 29 January 2024
6.	EC DG HERA update
7.	Update on the Joint Action on Shortages (CHESSMEN) coordination activities
8.	HMA/EMA Task Force on Availability of authorised medicines:
	a) Union list of critical medicines – Phase 2 “go-live”
9.	Update on the Solidarity Mechanism procedure
10.	Conclusions and next steps

Next meeting: 13 March (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).