



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 January 2024  
European Medicines Agency

## Agenda of the Medicine Shortages (SPOC) Working Party

22 January 2024, from 09:30 to 13:00 (CET), WebEx

**Chair: Monica Dias (EMA), Vice-Chair: Sybille Schotte (FAGG, 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 December 2023
3.	<b>Potential impact of the international situation</b> 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)
	c) Update on impact of BREXIT on medicines availability
4.	<b>Ongoing critical shortages reported by the SPOC WP:</b>
	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) Shortages of medicinal products from MAH: Cheplapharm
	d) Integrilin CAP (eptifibatide) - MAH: GlaxoSmithKline (Ireland) Limited
	e) Simulect CAP (basiliximab) - MAH: Novartis
	f) Brineura CAP (cerliponase alfa) - MAH: Biomarín
	g) Attention deficit hyperactivity disorder (ADHD) medicines: lisdexamfetamine NAP and methylphenidate NAP

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	h) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH
	i) Eldisine NAP (vindesine sulphate) – MAH: Stada group
	j) Fludarabine NAP – MAH: Teva
	k) Rabipur NAP (rabies, inactivated, whole virus) – MAH: Bavarian Nordic a.s.
5.	EC <b>DG HERA</b> update
6.	<b>HMA/EMA Task Force on Availability of authorised medicines:</b>
	a) Union list of critical medicines
	b) Shortage prevention and mitigation plans (SPP/SMP)
7.	Update from <b>Global Regulatory Working Group</b> meeting held on 21 December 2023
8.	Update from <b>ESMP</b> interoperability workshop held on 16-17 January 2024
9.	AOB
10.	Conclusions and next steps

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**Next meeting:** 14 February (WebEx)

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#### **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).