



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2023
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European Medicines Agency

Agenda of the Medicine Shortages (SPOC) Working Party 20 November 2023, WebEx

Chair: Monica Dias (EMA), Vice-Chair: Patricia Tabernero (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 26-27 October 2023
3.	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)
	c) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets
	d) Update on impact of BREXIT on medicines availability
4.	Ongoing critical shortages reported by the SPOC WP:
	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) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide); MAH: Eli Lilly Nederland B.V.
	c) Integrilin CAP (eptifibatide) - MAH: GlaxoSmithKline (Ireland) Limited
	d) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma; Pazenir CAP (paclitaxel) - MAH: Ratiopharm GmbH



Item	Topic
	e) Attention deficit hyperactivity disorder (ADHD) medicine shortages
5.	Ad-hoc gap analysis: Lessons learned from the pilot procedure for supporting MSs on shortages management
6.	Derogations for import of foreign packs in case of a shortage
7.	HMA/EMA Task Force on Availability of authorised medicines: EU list of critical medicines
8.	European Shortages Monitoring Platform (ESMP) update: ESMP Industry Workshop on Interoperability
9.	Conclusions and next steps

Next meeting: 15 December (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).