



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 September 2023
EMA/346780/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party meeting

12 September 2023, from 10:00 to 13:15 (CEST), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Maria Criado (AEMPS, Spain)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC Working Party meeting held on 6 July 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 joint EMA/HERA preparedness activities
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information): Update on NAP shortages and marketing cessations in Austria.
4.	Ongoing critical shortages reported by the SPOC WP:
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim;
	b) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH
	c) 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.
	d) Integrilin CAP (eptifibatide) - MAH: GlaxoSmithKline (Ireland) Limited
	e) Hycamtin CAP (topotecan) - MAH: Sandoz Pharmaceuticals d.d.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Item	Topic
	f) Methotrexate IV NAP – MAH: Medac GmbH, Accord Healthcare, Teva Pharmaceuticals, Sandoz, Viatris, Pzifer, Alfasigma
5.	Update from EC DG HERA
6.	Joint Action on Shortages (CHESSMEN): Update on CHESSMEN questionnaire regarding to the shortage definition
7.	HMA/EMA Task Force on Availability of authorised medicines: EU list of critical medicines – launch of phase 1 (SPOC WP input needed).
8.	MSSG Recommendations on shortages of medicinal products toolkit
9.	Presentation of results of the survey on safety stocks
10.	ESMP status update and interoperability
11.	Presentation of results of the recent surveys on shortages: Feedback from surveys to patients and consumers, HCPs and NCAs on communication practices of recent medicine shortages.
12.	Conclusions and next steps

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).