6 July 2023
EMA/293652/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

6 July 2023, from 13:00 to 16:00 (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 WP meeting held on 16 June 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) Feedback for Q2 2023 Meeting from Global Regulatory Working (WG) Group on Drug Shortages
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
4.	**Ongoing critical shortages reported by the SPOC WP:**
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim; Urokinase NAP
	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
	d) Methotrexate IV NAP.
5.	Presentation of the **Pharmaceutical Pricing and Reimbursement Information** (PPRI) Network **shortage survey** results
6.	Update from EC **DG HERA**

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

© European Medicines Agency, 2023. Reproduction is authorised provided the source is acknowledged.

Item	Topic
7.	**HMA/EMA Task Force on Availability of authorised medicines:** • EU list of critical medicines – methodology, outline of the process for establishing the list and impact to Medicine Shortages (SPOC) Working Party
8.	**Update on the EMA extended mandate implementation**: • ESMP product development status and plan for Q3 2023
9.	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 on-going 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).