



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2022
EMA/93474/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party meeting

13 December 2022, from 10:00 to 13:15 (CET), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Jakub Velik (CZ)

Item	Topics
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 18 November 2022
3.	Update on ongoing shortages reported by the SPOC WP (non-PHE related):
	a) Ozempic (CAP): • presentation of the results of the survey (EMA); • presentation of MAH: Novo Nordisk.
	b) Update on Thrombolytics: Metalyse (CAP) and Actilyse (NAP)
	c) Menopur (NAP) shortages
	d) Antiepileptics shortages (NAPs) – outcome of survey to NCA SPOCs
4.	Potential impact of the situation in Ukraine and energy crisis on the supply of medicinal products for human and veterinary use for the European market
	a) Feedback from the " <i>Ukraine and energy crisis</i> " focus Group, primarily antibiotic shortages monitoring
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
5.	Update on monitoring of the supply and demand for the ongoing PHEs (COVID-19 and Monkeypox) in EU/EEA

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	Topics
6.	Shortage definition - Follow up on shortage definition tour de table and next steps
7.	Interplay of various Shortage and Availability governance structures in the Regulatory Network
8.	Joint Action on shortages - Update
9.	Update on the EMA extended mandate implementation
	a) Update from the Core Group
	b) ESMP status update
	c) Relevant updates from NCAs on electronic reporting systems
	d) Status update on implementation activities for Medical Device Shortages
10.	European Commission DG HERA: general update
11.	Improving transparency and communication to the public on shortages discussed in the SPOC WP
12.	AOB
13.	Conclusions and next steps

Next meeting: 18 January 2023

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).