



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2023
EMA/93334/2023
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

15 February 2023, from 10:00 to 13:00 (CET), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Johan Andersson (SE)

Item	Topics
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the meeting of the SPOC WP held on 18 January 2023
3.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) update: meeting held on 26 January 2023.
4.	Potential impact of the international situation (e.g. Russia-Ukraine War) and energy crisis on the supply of medicinal products for human and veterinary use to the European market.
	a) Antibiotic shortages: - Update on coordinated actions; - Joint EMA/DG HERA proposal for monitoring supply and demand of a set of antibiotics in preparation for 2023/2024 winter's season.
	b) Feedback from the " <i>crisis monitoring and preparedness</i> " focus Group
5.	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) Update on ongoing shortages reported by the SPOC WP (non-PHE related): a) Update on Menopur (NAP) shortages - Closed pre-discussion with SPOC WP Members; - Presentation by Marketing Authorisation Holder: Ferring and discussion on supply and future planning; - Closed post-discussion with SPOC WP Members.
	b) Update on Norditropin Nordiflex (somatropin injection) (NAP) shortages

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
	c) Ozempic (CAP): update on activities from subgroup
	d) Update on Thrombolytics: Metalyse (CAP) and Actilyse (NAP)
	e) Update on Human normal immunoglobulins (IGs) subgroup activities
6.	Major event. Criteria for the MSSG to grant a positive opinion on an actual or imminent major event
7.	Joint Action (JA) on shortages - Update
8.	HMA/EMA Multi-stakeholder Workshop on shortages 1-2 March 2023
9.	Update on the EMA extended mandate implementation
10.	a) Status update on implementation activities for Medical Device Shortages European Commission DG HERA - update
11.	Improving transparency and communication to the public on shortages discussed in the SPOC WP: • Proposal for publication of SPOC WP Meeting Summaries in EMA website; • Proposal to extend EMA shortage catalogue to also include shortages reflected in SPOC WP minutes.
12.	Conclusions and next steps

Next meeting: 21 March 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).