



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 January 2023  
EMA/93494/2023  
European Medicines Agency

## Agenda - Medicine Shortages (SPOC) Working Party

18 January 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 SPOC WP meeting held on 13 December 2023
3.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) update: ad hoc meeting held on 11 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
	b) Antipyretic (oral paediatric formulations) shortages, including supply disruptions related to increased RSV infections
	c) Monitoring and preparedness activities related to China's COVID-19 cases surge
	d) Feedback from the "crisis monitoring and preparedness" focus Group
	e) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
5.	Update on ongoing shortages reported by the SPOC WP (non-PHE related):
	a) Ozempic (CAP): update on activities from subgroup
	b) Update on Thrombolytics: Metalyse (CAP) and Actilyse (NAP)
	c) Update on Menopur (NAP) shortages
6.	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](http://www.ema.europa.eu/how-to-find-us)

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

An agency of the European Union



Item	Topics
7.	Major event definition: Criteria for the MSSG to grant a positive opinion on an actual or imminent major event
8.	Joint Action on shortages - Update
9.	Update on the EMA extended mandate implementation
10.	Frequently asked questions (FAQ) document on data exchange between NCAs and other National Health Institutions to meet reporting obligations defined under Regulation (EU) 2022/123 at Member State level
11.	European Commission DG SANTE: general update
12.	European Commission DG HERA: general update
13.	Improving transparency and communication to the public on shortages discussed in the SPOC WP
14.	Conclusions and next steps.

---

**Next meeting:** 15 February 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 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).