10 April 2025
European Medicines Agency

Agenda - Medicine Shortages SPOC Working Party

10 April 2025, from 10:00 to 18:00 (CEST), hybrid meeting – F2F + Webex
11 April 2025, from 09:00 to 16:00 (CEST), hybrid meeting – F2F + Webex

Chair: Monica Dias (EMA), Magdalena Rychter (GIF, Poland)

Thursday, 10 April 2025 (10:00-18:00)	
Item	**Topic**
1.	Welcome, declarations of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 18 March 2025
3.	**Member States updates**
	a) SPOC WP **lightning round** – most critical issues at national level
	b) **Polish** presidency of the EU: initiatives on medicine shortages for H1 2025
	c) Status update on any **new strategic measures implemented at national level** (e.g., critical medicines lists, stockpiling requirements)
4.	**Potential impact of the international situation** on the supply of medicinal products for human and veterinary use to the European market:
	a) Feedback from the SPOC WP subgroup on crisis monitoring and preparedness
	b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)
5.	**Critical shortages escalated to the SPOC Working Party:**
5.1	**Ongoing shortages**
	a) Oncology medicinal products from MAH Teva
	b) Medicinal products from MAH Cheplapharm
	• Overview of the overall shortage situation
	• Presentation delivered by MAH: Cheplapharm, followed by a Q&A session
	• Debrief on next steps/actions

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	c) Medicinal products from MAH Viatris
5.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments to the written updates) a) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk c) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer d) Medicinal products containing salbutamol (inhalation use)
6.	Shortage Prevention and Mitigation Plans (**SPP/SMP**) pilot: initial findings
7.	**Revision of EMA policy 0044** on handling of competing interests
8.	**EDQM:** Progress of the European Drug Shortages Formulary and other EDQM initiatives on shortages
9.	European Commission DG **SANTE** update
10.	European Commission DG **HERA** update
11.	Executive Steering Group on Shortages and Safety of Medicinal Products (**MSSG**)-led activities:
	a) Draft procedure for the update of the Union list of critical medicines
	b) Medicine Shortage Communication (**MSC**) pilot update
	c) Feedback from the MSSG meeting on 1 April 2025
	d) Feedback from the MSSG WG on the Vulnerability Assessment Methodology

Friday, 11 April 2025 (09:00-16:00)	
Item	**Topic**
12.	**Shortage management systems**:
	a) Germany – presentation of national system
	b) Belgium – new features in PharmaStatus on unavailability identified by FAMHP
	c) European Shortages Monitoring Platform (**ESMP**) update
13.	**Technical topics**
	a) **Shortage definition**: SPOC WP subgroup proposal for harmonisation
14.	Global Regulators Working Group on Drug Shortages: update from Q1 meeting
15.	**Critical shortages escalated to the SPOC Working Party: ongoing shortages (continued)**
	a) Shortage and discontinuation of selected insulin containing medicinal products
	b) Supply and availability of immunoglobulins
	• Overview of the supply and availability situation
	• Presentation delivered by International Plasma and Fractionation Association (IPFA) and Plasma Protein Therapeutics Association (PPTA)
	• Debrief on next steps/actions.
16.	**Technical topics (continued)**
	b) **Communication** on shortages at EMA: plan for 2025
17.	**Exchanges on national practices:**
	a) Pilot project on English-only common Nordic packages for human medicinal products
	b) Case study: management of shortages of old, life-saving medicines with limited alternatives
18.	**Joint Action** on Shortages (**CHESSMEN**): • Work Package 5 – results of the root cause analysis report
19.	AOB
20.	Wrap-up and next steps
21.	Closing remarks

Next meeting: 13 May 2025 (Webex)

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).