

17 July 2024
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

17 July 2024, from 09:30 to 13:30 (CEST), WebEx

Chair: Joao Ferreira (EMA), Vice-Chair: Veronika Horvath (NNGYK, Hungary)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 20 June 2024
3.	Presentation of findings from a Pharmaceutical Pricing and Reimbursement Information (PPRI) Network query: Tackling medicine shortages during and after the COVID-19 pandemic
4.	European Shortages Monitoring Platform (ESMP): status update
5.	Demonstration of national IT systems :
	a) Belgium – Stock monitoring tool
6.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:
	a) Feedback from the MSSG multistakeholder workshop on shortages of GLP-1 receptor agonists
	SENSITIVE TOPICS
7.	Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:
	a) Impact on the supply of medicines of the takeover of three Catalent sites by Novo Holdings
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
8.	Critical shortages escalated to the SPOC Working Party:
8.1	Ongoing shortages
	a) Shortages of Glucagon-like Peptide-1 (GLP-1) Receptor Agonists

Item	Topic
	b) Shortages of oncology medicinal products from MAH: Accord Healthcare B.V.
	c) Mimpara CAP (cinacalcet) – MAH: Amgen Europe B.V.
	d) Thrombolytics update: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim
8.2	Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)
	e) Shortages of medicinal products from MAH: Cheplapharm
	f) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris
	g) Shortages of medicinal products containing salbutamol (inhalation use)
9.	Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities (continued):
	a) Shortage communication activities: Medicine shortage communication (MSC) template and process
	b) Update from MSSG meetings held on 26 June and 1 July 2024
10.	HMA/EMA Task Force on Availability of Authorised Medicines:
	a) Union list of critical medicines
11.	Update from Global Regulatory Working Group meeting held on 26 June 2024
12.	EC DG SANTE update
13.	EC HERA update
14.	Conclusions and next steps

Next meeting: 11 September (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).