



11 September 2024  
European Medicines Agency

## Agenda - Medicine Shortages (SPOC) Working Party

11 September 2024, from 09:30 to 13:40 (CEST), Webex

**Chair: Monica Dias (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 17 July 2024
3.	Executive Steering Group on Shortages and Safety of Medicinal Products ( <b>MSSG</b> )-led <b>activities:</b>
	a) Solidarity Mechanism: feedback from the etoposide case
4.	<b>Potential impact of the international situation</b> on the supply of medicinal products for human and veterinary use to the European market:
	a) Impact of tightened espionage laws in China
	b) Suspension of API manufacturing site EuroAPI in Brindisi
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
5.	Activities under Joint Action on Shortages ( <b>CHESSMEN</b> ) work package 8:
	<ul style="list-style-type: none"><li>• <b>Export bans and parallel trade</b></li><li>• Other planned <b>mitigation and preventive measures</b></li></ul>
6.	Impact of <b>serialisation</b> on multilingual packaging
7.	<b>Critical shortages escalated to the SPOC Working Party:</b>
7.1	<b>Ongoing shortages</b>
	a) Oncology medicinal products from Accord Healthcare B.V.
	b) Chenpen NAP (epinephrine) – MAH: Bioproject Pharma; Jext NAP (epinephrine) – MAH: Alk-Abello



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	c) Synulox NAP (amoxicillin/clavulanic acid) – MAH: Zoetis
	d) Mimpara CAP (cinacalcet) – MAH: Amgen Europe B.V.
	e) Medicinal products containing atomoxetine
	f) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists
	g) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk
	h) Medicinal products from Cheplapharm
7.2	<b>Status update on other critical shortages escalated to the SPOC WP</b> (only comments to the written updates)
	a) Medicinal products containing salbutamol (inhalation use)
	b) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris
8.	<b>HMA/EMA Task Force on Availability of Authorised Medicines:</b>
	a) Union list of critical medicines
	b) Shortage prevention and mitigation plans (SPP/SMP)
9.	Survey on <b>national approaches to shelf life extension</b> of medicines stockpiled in preparedness to health threat
10.	EC <b>HERA</b> update
11.	AOB
12.	Conclusions and next steps

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**Next meeting:** 7-8 October 2024 (hybrid – F2F+Webex)

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