



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 June 2024  
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European Medicines Agency

## Agenda - Medicine Shortages (SPOC) Working Party

20 June 2024, from 09:30 to 13:30 (CEST), WebEx

**Chair: Monica Dias (EMA), Vice-Chair: Sybille Schotte (FAMHP, Belgium)**

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 22 May 2024
3.	<b>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:</b>
	a) <b>Solidarity Mechanism:</b> lessons learned
4.	<b>HMA/EMA Task Force on Availability of Authorised Medicines:</b>
	a) Shortage prevention and mitigation plans (SPP/SMP)
5.	<b>JA CHESSMEN:</b> updates on work packages
6.	<b>Supply and availability of immunoglobulins</b>
	a) Is collection of Anti-D plasma in Europe possible?
	b) Status update on supply and availability of anti-D immunoglobulins internationally and in EU/EEA
	c) Presentation delivered by industry: <a href="#">Marketing Research Bureau</a> (MRB)
	d) Discussion
7.	<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 on the supply of medicines of the takeover of three Catalent sites by Novo Holdings
	b) Suspension of CEP by Unimark Remedies Limited

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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Item	Topic
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
8.	<b>Critical shortages escalated to the SPOC Working Party:</b>
8.1	<b>Ongoing shortages</b>
	a) Shortages of medicinal products containing cisplatin
	b) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists: <ul style="list-style-type: none"> <li>• Ozempic CAP and Rybelsus CAP (semaglutide), Victoza CAP (liraglutide) - MAH: Novo Nordisk;</li> <li>• Trulicity CAP (dulaglutide) – MAH: Eli Lilly Nederland B.V.;</li> <li>• Byetta CAP and Bydureon CAP (exenatide) - MAH: AstraZeneca;</li> <li>• Lyxumia CAP (lixisenatide) - MAH: Sanofi.</li> </ul>
	c) Shortages of medicinal products containing salbutamol (inhalation use)
8.2	<b>Status update on other critical shortages escalated to the SPOC WP</b> (only comments to the written updates)
	d) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris
	e) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim
	f) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH
	g) Methotrexate IV NAP (methotrexate) – MAH: Teva Sante
9.	<b>HMA/EMA Task Force on Availability of Authorised Medicines</b> ( <i>cont.</i> )
	a) Union list of critical medicines
10.	<b>MSSG-led activities</b> ( <i>cont.</i> )
	a) Draft <b>MSSG recommendations</b> on supply chain vulnerabilities for the first tranche of medicines
11.	Impact of <b>new national law on supply of medicinal products</b> and availability of medicines on European market
12.	EC <b>HERA</b> update
13.	Conclusions and next steps

**Next meeting:** 17 July (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).