



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 October 2023  
EMA/499095/2023  
European Medicines Agency

## Agenda - Medicine Shortages (SPOC) Working Party

26 October 2023, from 10:00 to 18:00 (CEST), F2F + WebEx

27 October 2023, from 09:00 to 16:00 (CEST), F2F + WebEx

**Chair: Monica Dias (EMA), Vice-Chair: Patricia Tabernero (AEMPS, Spain)**

### Thursday, 26 October 2023

Item	Topic
1.	Welcome, declarations of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 12 September 2023
3.	<b>Potential impact of the international situation</b> (e.g. War in Ukraine) and energy crisis on the supply of medicinal products for human and veterinary use to the European market: <ul style="list-style-type: none"><li>a) Antibiotic shortages: General update on joint EMA/HERA preparedness activities</li><li>b) Feedback from the Q3 2023 Meeting of the Global Regulatory Working (WG) Group on Drug Shortages</li><li>c) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information):<ul style="list-style-type: none"><li>• Flecainide shortage in France: elaboration of a specific dispensing protocol.</li></ul></li><li>d) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets</li><li>e) ECHA proposal to ban the use of per- and poly-fluoroalkyl substances (PFASs)</li></ul>
4.	<b>Ongoing critical shortages reported by the SPOC WP:</b> <ul style="list-style-type: none"><li>a) Glucagon-like Peptide-1 (GLP1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide); MAH: Eli Lilly Nederland B.V.<ul style="list-style-type: none"><li>• Overview of the overall shortage situation;</li><li>• Presentation delivered by MAH: Novo Nordisk, followed by Q&amp;A session</li></ul></li></ul>



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	<ul style="list-style-type: none"> <li>Debrief on next steps/actions.</li> </ul>
	b) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim;
	<ul style="list-style-type: none"> <li>Overview of the overall shortage situation</li> </ul>
	<ul style="list-style-type: none"> <li>Presentation delivered by Boehringer Ingelheim, followed by Q&amp;A session;</li> </ul>
	<ul style="list-style-type: none"> <li>Debrief on next steps/actions</li> </ul>
	c) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH
	d) Attention deficit hyperactivity disorder (ADHD) medicine shortages
	e) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited
	f) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma; Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH
5.	g) Norditropin (somatropin) – MAH (Novo Nordisk) <b>Shortage communication activities:</b> <ul style="list-style-type: none"> <li>General update on EMA communication activities;</li> <li>Feedback on shortage DHPC review experience.</li> </ul>
6.	<b>HMA/EMA Task Force on Availability of Authorised Medicines</b> – update on key work plan deliverables:
	a) TWG2 (Communications);
	b) TWG1 (Availability and supply disruptions);
	c) EU list of critical medicines.
7.	<b>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG):</b> <ul style="list-style-type: none"> <li>General update on September 2023 MSSG</li> <li>Update on Solidarity Mechanism procedure</li> </ul>
8.	<b>European Shortages Monitoring Platform (ESMP)</b> <ul style="list-style-type: none"> <li>Development status and plan for Q4 2023;</li> <li>Submission of data on shortages for CAPs by MAHs to EMA in preparedness.</li> </ul>

**Friday, 27 October 2023**

Item	Topic
1.	<b>Presentations from SPOC WP Members:</b>
	a) Estonia - Sorbisterit (polystyrene sulfonate): Impact of national stockpiling Agency on shortages management
	b) Sweden – Financial measures on shortages reporting
	c) Norway - Nordic Project on the Availability of Medicines for Children
	d) Ireland – Supply/logistic challenges: addressing supply delivery delays
2.	<b>Antibiotic shortages:</b>
	• Presentation delivered by MAH: Sandoz, followed by Q&A session
	• Debrief on next steps/actions.
3.	<b>Lessons learned from the pilot procedure for supporting MSs on shortages management</b>
	<b>Availability issues for veterinary medicines:</b>
4.	<ul style="list-style-type: none"> <li>• Outcome of the breakout session on veterinary medicines during the HMA/EMA Multi-Stakeholder workshop in March 2023</li> <li>• Update on the implementation of the EMANS regarding veterinary availability issues/shortages</li> </ul>
5.	EC <b>DG SANTE</b> update
6.	EC <b>DG HERA</b> update
7.	<b>Joint Action on Shortages (CHESSMEN):</b>
	a) General Update on the JA CHESSMEN coordination activities
	b) Technical Update from <b>CHESSMEN Work Package Leads:</b>
	<ul style="list-style-type: none"> <li>• WP2 (Portugal) - Communication, dissemination and exploitation</li> <li>• WP3 (Belgium) - Evaluation</li> <li>• WP4 (Ireland) – Sustainability</li> <li>• WP5 (Spain) – Shortage root causes</li> <li>• WP6 (Slovenia) – Best practices to address medicine shortages</li> <li>• WP7 (Germany) - Digital Information Exchange</li> <li>• WP 8 (Finland) - Shortages preventive and mitigation strategies</li> </ul>
8.	<b>Technical Discussion on Core Topics:</b>
	• Definition of medicine shortage: progress made under JA on shortages and next steps
9.	<b>EDQM</b> presentation on shortage initiatives

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Item	Topic
10.	Wrap-up and next steps
11.	Closing remarks

**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).