



15 April 2024  
European Medicines Agency

## Meeting Summary - Medicine Shortages SPOC Working Party

14 March 2024, 09:30-13:00 (CET), WebEx

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

Item	Topic
1.	<p><b>Welcome, declaration of interest, adoption of draft agenda</b></p> <p>The Chair and Vice-Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party.</p> <p>SPOC WP Secretariat reviewed members' and experts' declared interests in accordance with the Agency's policy on handling of declarations of interests (DoI) of scientific committees. Based on the topics in the agenda of the meeting, the SPOC WP Secretariat announced the applicable restrictions.</p> <p>Changes to the SPOC WP membership were announced.</p> <p>Agenda was adopted with no additional points under AOB.</p>
2.	<p><b>Adoption of draft minutes of the SPOC WP meeting held on 14 February 2024</b></p> <p>The Vice-Chair informed that the minutes of the meeting held on 14 February 2024 had been distributed one week prior to the meeting.</p> <p>No comments were received before or during the meeting. Minutes were adopted.</p>
3.	<p><b>Potential impact of the international situation (e.g. War in Ukraine) and energy crisis on the supply of medicinal products for human and veterinary use to the European market:</b></p> <p><b>a) Antibiotic shortages: Update on preparedness activities</b></p> <p>EMA informed that no signals of supply disruptions were reported by industry associations, patients and consumers', or healthcare professionals' organisations. EMA informed that a few Member States (MSs) faced difficulties in managing the situation at a national level and that measures are being undertaken to mitigate the impact. Finally, EMA informed that one of the MAHs was invited to present to the SPOC WP at the next meeting and asked SPOC WP members whether the overall situation is still considered stable in the rest of the MSs.</p>



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	<p><u>Comments raised:</u></p> <p>The majority of SPOC WP members confirmed that the overall situation in their countries is stable at the moment. Additionally, a SPOC WP member noted that support provided by EMA in mitigating critical shortages had shown positive results.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• Since the situation was found to be stable, SPOC WP members agreed to discontinue reporting to EMA of all ongoing and anticipated shortages of antibiotics in scope of this exercise as of 1 April 2024. However, they agreed to keep EMA informed in case of any critical shortages.</li> </ul>
	<p><b>b) Impact of the takeover of Catalent by Novo Holdings on the supply of medicines</b></p> <p>EMA informed SPOC WP about the feedback received from the manufacturer Catalent on the products manufactured at the impacted sites. As a next step, the impact of this acquisition on the availability of medicinal products will be assessed.</p>
	<p><b>c) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets</b></p> <p>EMA provided an update on the impact of the Israel-Hamas war on the supply of medicinal products with manufacturing steps in Israel, together with feedback from industry associations. The overall situation remains stable. However, shortages of individual products have been reported in some countries and concerns about increased shipping costs and delivery times have been raised by industry associations.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• SPOC WP members to notify EMA as soon as they become aware of any signals of shortages or availability issues related to the situation in Israel or the Red Sea.</li> <li>• EMA to continue monitoring the situation by liaising with industry associations and the MAHs.</li> </ul>
	<p><b>d) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)</b></p> <p>One SPOC WP member reported a critical shortage of a diuretic from one MAH and the planned mitigation measures. A number of SPOC WP members informed the group that there is no shortage of this product in their countries.</p> <p>Another SPOC WP member reported availability issues of veterinary vaccines for horses, cats and dogs. EMA explained that this shortage is being monitored and suggested to bring this topic for discussion at the next meeting once further information is available.</p> <p>Two SPOC WP members reported a critical shortage of an antiarrhythmic medicine. One SPOC WP member informed that although there are alternatives available, they may not be sufficient to cover the full demand.</p> <p>Several SPOC WP members raised concerns about a potential shortage of salbutamol nebuliser solution and inhalation devices and consulted on practices for flexibilities in labelling and packaging requirements.</p>

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	<p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP if the abovementioned shortage situations in their territories deteriorate.</li> </ul>
4.	<p><b>Ongoing critical shortages reported by the SPOC WP:</b></p>
	<p><b>a) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide), Victoza CAP (liraglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide) – MAH: Eli Lilly Nederland B.V.</b></p> <p>EMA presented a detailed overview of the supply and availability situation of Ozempic and Victoza. Furthermore, EMA provided the feedback from the last meeting of the SPOC WP subgroup on GLP-1 RAs with Novo Nordisk and the joint EMA/FDA meeting with Novo Nordisk.</p>
	<p><b>b) Supply and availability of IV/SC human normal immunoglobulins in the EU/EEA</b></p> <ul style="list-style-type: none"> <li><b>Overview of the shortage situation of immunoglobulins</b></li> </ul> <p>EMA provided the feedback from the survey on human normal immunoglobulin supply situation. Shortages are occurring in several MSs and the publication of a shortage catalogue entry is being considered.</p> <ul style="list-style-type: none"> <li><b>Results of the survey on polyvalent immunoglobulins</b></li> </ul> <p>One SPOC WP member presented an overview of the supply and availability situation of polyvalent immunoglobulins in their country, together with mitigation measures implemented at national level.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>EMA to reach out to the MAHs of CAPs and NAPs to better understand the situation.</li> </ul>
	<p><b>c) Shortages of medicinal products from MAH: Cheplapharm</b></p> <p>The topic was postponed.</p> <p><i>Post-meeting note: an update in writing was provided on 21 March 2024.</i></p>
	<p><b>d) Creon (pancrelipase) - MAH: Viatris Italia S.R.L and Creonipe (pancrelipase) - MAH: Viatris Healthcare Limited</b></p> <p>EMA provided the feedback from the meeting with Viatris and explained that the root cause of the shortage is linked to production problems coupled with a high demand. Furthermore, EMA presented the measures proposed by the company to mitigate this shortage and information received from MAHs of potential alternatives. EMA informed the SPOC WP of the next steps which will include a publication of a shortage catalogue entry and DHPC, amongst others.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>EMA to continue monitoring the situation by liaising with respective MAHs.</li> </ul>

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	<p><b>e) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH</b></p> <p>EMA provided an update on the shortage situation of Ixiaro, including the publication of a shortage catalogue entry and the status on allocation of batches. EMA also updated the SPOC WP about the situation in a few countries where shortages are expected to last until 2025 and suggested possible solutions to mitigate the shortage.</p>
	<p><b>f) Cyclogyl NAP (cyclopentolate) – MAH: Alcon SA-NV</b></p> <p>A SPOC WP member presented an overview of Cyclogyl shortage situation and the measures taken at a national level. The SPOC WP member informed that a few other EU/EEA countries are also experiencing critical shortages of Cyclogyl in their territories.</p>
5.	<p><b>Presentation from GIRP (European Healthcare Distribution Association) on shortage reporting</b></p> <p>GIRP presented an overview and country case-studies on the establishment of reporting channels from wholesalers to NCAs for the prediction of medicine shortages. GIRP noted that these systems could aid in NCA reporting of information to the ESMP in crisis situations.</p> <p><u>Comments raised:</u></p> <p>SPOC WP members welcomed the initiative and asked if products sold via parallel export are reflected in such systems. Additionally, SPOC WP members asked for clarity on the scope of medicines that are being monitored and early warning systems. EMA asked about feasibility of implementing such reporting channels in other MSs.</p> <p>GIRP clarified that parallel exports are reflected as they affect the product availability in warehouses and subsequently influence the supply situation. Additionally, GIRP clarified that medicines for which the reporting channels have been established vary between the MSs, and the shortage predictability in some countries is high. Lastly, GIRP explained that establishment of reporting channels depends on cooperation with wholesalers at a national level, and noted that generally the systems can be established within a short time frame, i.e. two months.</p>
6.	<p><b>EC DG HERA update</b></p> <p>DG HERA provided an update on the supply chain vulnerability assessment including the status of the data collection from MSs and MAHs. Furthermore, DG HERA informed the SPOC WP members on the recently published call for anti-tuberculosis paediatric medicines.</p>
7.	<p><b>HMA/EMA Task Force on Availability of authorised medicines</b></p>
	<p><b>a) Union list of critical medicines – Phase 2 “go-live”</b></p> <p>EMA provided a brief update informing SPOC WP members that Phase 2 has officially been launched and noted that EMA is available to answer any questions that SPOC WP members may have.</p> <p><b>b) MSSG recommendations to strengthen supply chains of critical medicinal products</b></p>

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	<p>The topic was postponed.</p> <p><i>Post-meeting note: an update in writing was provided on 22 March 2024.</i></p>
10.	<p><b>Conclusions and next steps</b></p> <p>The agreed actions are detailed above.</p>

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**Next meeting:** 15-16 April (hybrid – F2F+WebEx)

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**Note on access to documents**

Some documents mentioned in the meeting summary 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 on-going 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).