



11 September 2024  
European Medicines Agency

## Meeting Summary - Medicine Shortages (SPOC) Working Party

17 July 2024, virtual meeting – WebEx

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

Item	Topic
1.	<p><b>Welcome, declaration of interest, adoption of draft agenda</b></p> <p>The Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party (WP). EMA Chair welcomed the HU SPOC WP member as the new rotating Vice-Chairperson under the Hungarian Presidency of the Council of EU.</p> <p>The 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 meeting topics, the SPOC WP secretariat announced the applicable restrictions.</p> <p>Changes to the SPOC WP membership were announced.</p> <p>The agenda was adopted with no additional points under AOB.</p>
2.	<p><b>Adoption of draft minutes of the SPOC WP meeting held on 20 June 2024</b></p> <p>The Vice-Chair informed that the minutes of the meeting held on 20 June 2024 had been distributed one week prior to the meeting.</p> <p>No comments were received before or during the meeting. The minutes were adopted.</p>
3.	<p><b>Presentation of findings from a Pharmaceutical Pricing and Reimbursement Information (PPRI) Network query: Tackling medicine shortages during and after the COVID-19 pandemic</b></p> <p>PPRI representative presented the <a href="#">findings on government policies to address medicine shortages</a>, based on a survey to public authorities involved in the PPRI Network in 2023 and building on 2020 survey data. It was identified that the most commonly used policies to address medicine shortages were linked to regulatory and financial aspects; PPRI representative also noted that the COVID-19 pandemic led to significant policy changes shifting from shortage management to shortage mitigation and prevention.</p>

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	<p><u>Comments raised</u></p> <p>EMA Chair welcomed the findings of the study and asked whether the impact of the policies presented is planned to be analysed. PPRI representative responded that while this activity is currently not part of the PPRI workplan, it is important for policies to be supported by evidence. PPRI representative added that as part of the study recommendations, policymakers were encouraged to evaluate the policies in parallel to their execution.</p> <p>A SPOC WP member highlighted the work undertaken under Joint Action (JA) CHESSMEN Work Package 8 and noted the importance of national impact assessments to ensure that effective measures (incl. those linked to pricing and reimbursement) can be implemented across the EU/EEA. PPRI representative highlighted the need for continuous cooperation between regulatory bodies and pricing and reimbursement bodies on the impact evaluation.</p>
4.	<p><b>European Shortages Monitoring Platform (ESMP): status update</b></p> <p>EMA presented an update on the main development milestones, highlighting the features and go-live dates for the marketing authorisation holders' (MAHs) and national competent authorities' (NCAs) Medicine Shortages Steering Group (MSSG)-led preparedness and crisis reporting activities, as well as routine shortage reporting for centrally authorised products (CAPs).</p> <p>Additionally, EMA presented the outcomes of the user acceptance testing (UAT) of the platform by industry subject matter experts (SMEs), the feedback received from the <a href="#">ESMP webinar</a> for MAHs, as well as the planned communication activities accompanying the release of the platform. It was also noted that a major update of the ESMP webpage on the EMA website is imminent, including publication of documents such as the ESMP Implementation Guides for MAHs and NCAs, prototypes of the templates for the submission of data in the platform, a document with frequently asked questions, and more.</p> <p><i>Post meeting note: <a href="#">The ESMP webpage on the EMA website was updated</a> and the above listed documents were published.</i></p> <p><u>Comments raised</u></p> <p>One SPOC WP member asked whether there will be a pilot testing phase for NCAs once the MSSG-led preparedness and crisis reporting activities are live, which EMA confirmed.</p> <p>Another SPOC WP member asked whether reporting activities for veterinary medicines are considered to be included in the ESMP. EMA explained that in line with the Regulation (EU) 2022/123 the reporting activities within the ESMP are foreseen for human medicines only. Once the ESMP is fully operational in February 2025, internal discussions on how to further improve the platform and whether its functionalities could be expanded to other areas will take place.</p>
5.	<p><b>Demonstration of national IT system:</b></p>
	<p><b>a) Belgium – Stock monitoring tool</b></p> <p>BE SPOC WP member presented the Belgian national stock monitoring tool, which aims to support the NCA in anticipating and managing the risks of shortages of medicines for human use. BE SPOC WP member informed the SPOC WP members that different data sets are collected from different stakeholders and explained the data submission and analysis process.</p>

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6.	<b>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:</b>
	<p><b>a) Feedback from the <a href="#">MSSG multistakeholder workshop on shortages of GLP-1 receptor agonists</a></b></p> <p>EMA highlighted that the MSSG multistakeholder workshop focused on three areas – clinical impact of shortages, mitigation measures and communication. The participants discussed challenges for different stakeholder groups, shared experiences on ongoing mitigation actions and identified additional activities to better manage the situation.</p> <p>Workshop participants concluded that everyone has a role to play and gave their commitment to engage in further concrete actions, such as guidelines on prioritising patients during shortages and to ensure that treatments are allocated fairly and efficiently across patient populations. Lastly, EMA informed that a workshop report is currently being drafted and will be published on the EMA website.</p>
7.	<b>Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:</b>
	<p><b>a) Impact on the supply of medicines of the takeover of three Catalent sites by Novo Holdings</b></p> <p>EMA informed the SPOC WP that the feedback on the potential impact was received from all relevant MAHs, however, some companies expect to have a better understanding of the situation in the coming months.</p> <p>Additionally, EMA provided an update on a potential shortage of an antibiotic medicine. While the medicine is manufactured at one of the impacted sites, this potential shortage is not caused by the takeover of three Catalent sites by Novo Nordisk. EMA, together with the SPOC WP continues to work with the MAH and alternative manufacturers to prevent this shortage and any impact on EU patients in the long-term.</p>
	<p><b>b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)</b></p> <p>One SPOC WP member informed about a shortage of an adrenaline autoinjector (AAI). The SPOC WP received feedback that alternative manufacturers are also experiencing an unexpected increase in demand.</p> <p>EMA added that a national Healthcare Professional (HCP) organisation approached EMA in early July 2024 with information about a local shortage of AAIs, however it was not further escalated to the SPOC WP as there were alternatives available on the national market.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>SPOC WP members to submit critical shortage notifications to EMA if the abovementioned shortage situation in their territories deteriorates.</li> </ul>
8.	<b>Critical shortages escalated to the SPOC Working Party:</b>
8.1	<b>Ongoing shortages</b>
	<b>a) Shortages of Glucagon-like Peptide-1 (GLP-1) Receptor Agonists</b>

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	<p>EMA provided an overview of the current supply and availability situation of GLP-1 Receptor Agonists (RA) and presented the updated Direct Healthcare Professional Communication (DHPC) for Ozempic CAP (semaglutide) and Victoza CAP (liraglutide).</p> <p>Additionally, EMA provided feedback from meetings with MAHs.</p>
	<p><b>b) Shortages of oncology medicinal products from MAH: Accord Healthcare B.V.</b></p> <p>EMA presented the results of the SPOC WP criticality assessment on the shortages of cisplatin and fluorouracil and informed that the root cause is linked to capacity constraints and manufacturing issues of the main supplier in the EU/EEA.</p> <p>Additionally, EMA provided feedback from alternative MAHs on their ability to support MSs experiencing critical shortages by increasing their supply of cisplatin and fluorouracil.</p>
	<p><b>c) Mimpara CAP (cinacalcet) – MAH: Amgen Europe B.V.</b></p> <p>EMA provided an overview of the ongoing shortage of Mimpara. EMA also presented the results of the SPOC WP criticality assessment and noted that further data is required to agree on suitable mitigation measures.</p> <p><u>Comments raised</u></p> <p>One SPOC WP member informed that the shortage of Mimpara tablets is becoming critical and further national efforts are being undertaken to agree on mitigating measures. Another SPOC WP member explained that there are generic alternatives for certain formulations. A number of SPOC WP members exchanged further information on the shortage situation in their territories.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>• SPOC WP member to provide feedback on the efforts undertaken at a national level in a future SPOC WP meeting.</li> </ul>
	<p><b>d) Thrombolytics update: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim</b></p> <p>EMA provided an update on a new manufacturing site and the company’s manufacturing and supply plans. EMA informed the SPOC WP that no further supply restrictions for Metalyse or Actilyse will be expected.</p> <p>EMA informed the SPOC WP that the situation will be closely monitored to ensure a smooth transition and acknowledged the support from the SPOC WP members in the management of this shortage.</p>
8.2	<p><b>Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)</b></p>
	<p>e) Shortages of medicinal products from MAH: Cheplapharm</p> <p>f) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris</p> <p>g) Shortages of medicinal products containing salbutamol (inhalation use)</p> <p><u>Comments raised</u></p> <p>One SPOC WP member noted that the supply situation of Creon NAP may deteriorate in the coming months due to changes in their <a href="#">national treatment guidelines</a> and asked about the</p>

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	<p>possibilities to import the product from third countries. EMA responded that it is not possible to import product from abroad, but measures are being undertaken by the company to increase supply.</p> <p>No comments or concerns were raised on other abovementioned critical shortages.</p>
2.	<p><b>Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities (continued):</b></p>
	<p><b>a) Shortage communication activities: Medicine shortage communication (MSC) template and process</b></p> <p>EMA explained that MSCs will be used as a communication tool to inform HCPs about shortage situations without quality, safety, or efficacy issues, while all other communications related to quality, safety, or efficacy that also impact supply and availability will continue through the existing Direct Healthcare Professional Communication (DHPC) process. EMA presented the proposed MSC template and informed that as a next step, MSC template and process will be presented to the MSSG for endorsement.</p> <p><u>Comments raised</u></p> <p>The group discussed the legal basis for the MSC and its link to aspects on medicines availability described in <a href="#">GVP module XV</a>, MSC endorsement under the governance of the MSSG and the need to be cautious in the template wording on the measures and potential alternatives proposed by companies.</p> <p><b>Agreed actions:</b></p> <ul style="list-style-type: none"> <li>EMA to launch the written SPOC WP consultation on the MSC template and process.</li> </ul>
	<p><b>b) Update from MSSG meetings held on 26 June and 1 July 2024</b></p> <p>The topic could not be taken.</p> <p>Topics included in the agendas of both MSSG meetings had been already presented in the previous meetings or had dedicated slots at the SPOC WP meeting in July 2024.</p>
9.	<p><b>HMA/EMA Task Force on Availability of Authorised Medicines:</b></p>
	<p><b>a) Union list of critical medicines</b></p> <p>EMA provided an update on the rollout of Phase 2 and presented the status of Batch 2 categorisation activities by the MSs, which was due on 15 July 2024. EMA informed that Batch 3 is now available for review, with a deadline for completion by 13 September 2024.</p> <p><u>Comments raised</u></p> <p>EMA Chair acknowledged the efforts of the SPOC WP and their colleagues in the Ministries of Health in this exercise, which will allow the finalisation of the list by the end of the year.</p> <p>One SPOC WP member asked for clarity on how the list will be updated after its publication at the end of 2024. EMA explained that currently there is no fixed date for annual updates and that a proposal for this process is expected to be finalised this autumn.</p>
10.	<p><b>Update from Global Regulatory Working Group meeting held on 26 June 2024</b></p>

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	EMA informed that the topics discussed during the meeting included a presentation by the WHO on shortage definition and monitoring tools, and a reflection on the pilot for a subgroup on GLP-1 RA shortages.
11.	<p><b>EC SANTE update</b></p> <p>EC DG SANTE provided the feedback from the ad-hoc Pharmaceutical Committee meeting held on 9 July 2024 on contingency stocks. EC DG SANTE explained that MSs shared information on national contingency stock measures that are in place or are being considered, which was followed by a discussion on common principles on contingency stock requirements.</p> <p>EC DG SANTE noted that coherence with other initiatives and the need for proportionality of these measures to avoid an impact on other MSs was highlighted during the meeting. Lastly, EC DG SANTE highlighted the role of the SPOC WP in monitoring any events linked to these types of measures that could subsequently impact the supply of medicines in the EU/EEA.</p>
12.	<p><b>EC HERA update</b></p> <p>EC DG HERA provided an update on the Critical Medicines Alliance (CMA) working groups, noting that the two working groups would be further split into sub-groups, and which will advance their respective activities on a technical level and draft policy recommendations.</p> <p><u>Comments raised</u></p> <p>EMA Chair noted the importance of distinguishing the long-term activities of the CMA on industrial policy and the SPOC WP and the MSSG on short to mid-term regulatory measures.</p>
13.	<p><b>Conclusions and next steps</b></p> <p>SPOC WP secretariat informed that a letter from the CMDh on the impact of serialisation on multilingual packaging was received and a survey will be circulated to the SPOC WP to investigate the potential impact on medicines' availability.</p> <p>The agreed actions are detailed above.</p>

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**Next meeting:** 11 September (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)