14 February 2024
European Medicines Agency

# Meeting Summary - Medicine Shortages SPOC Working Party

22 January 2024, 09:30-13:00 (CET), WebEx

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

| Item | Topic |
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| 1. | **Welcome, declaration of interest, adoption of draft agenda**<br><br>The Chair and Vice-Chair welcomed participants to the virtual meeting of the Medicine Shortages SPOC Working Party. EMA Chair welcomed the BE SPOC WP member as the new rotating Vice-Chairperson under the Belgian Presidency of the Council of the EU.<br><br>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.<br><br>Agenda was adopted with an additional point under AOB on the definition of a medicine shortage. |
| 2. | **Adoption of draft minutes of the SPOC WP meeting held on 14 December 2023**<br><br>The Chair informed that the minutes of the meeting held on 14 December 2023 had been distributed one week prior to the meeting.<br><br>No comments were received before or during the meeting. Minutes were adopted. |
| 3. | **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:**<br><br>**a) Antibiotic shortages: Update on preparedness activities**<br><br>EMA provided the feedback from international regulators, industry associations, MAHs as well as the SPOC WP crisis monitoring and preparedness focus group on the situation. EMA informed that the situation is currently stable.<br><br>Finally, EMA asked the SPOC WP members if there were any significant changes in the overall availability of antibiotics since the last meeting in December 2023. |

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| | Comments raised:<br><br>A few SPOC WP members informed that there have been no major changes in the past month on the availability of antibiotics and mentioned communication issues with some MAHs of antibiotics. |
| | **b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)**<br><br>SPOC WP member reported a potential supply disruption of an antiviral medicine used for the treatment of HIV infections and informed that discussions are currently taking place at the national level in order to prevent the disruption from occurring.<br><br>**Agreed actions:**<br><br>• SPOC WP members with critical shortage issues to report the information to the SPOC WP Secretariat for further EU coordinated action. |
| | **c) Update on impact of BREXIT on medicines availability**<br><br>SPOC WP member provided an update on the impact of BREXIT on the availability of medicines in their territory. The need for continuous discussion between the Member States affected by the labelling and packaging requirements for medicinal products for human use under the Windsor Framework was highlighted.<br><br>**Agreed actions:**<br><br>• SPOC WP members to bring back the topic on the impact of BREXIT on medicines availability if any new issues are identified. |
| 4. | **Ongoing critical shortages reported by the SPOC WP:**<br><br>**a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim**<br><br>EMA updated the SPOC WP members on the status of the ongoing shortage management activities including the positive CHMP opinion for a new strength and indication of Metalyse. Furthermore, EMA provided an update on the distribution of Actilyse vials, and the new manufacturing site. |
| | **b) Glucagon-like Peptide-1 (GLPO1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide), Victoza CAP (liraglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide) – MAH: Eli Lilly Nederland B.V.**<br><br>EMA presented an overview of Ozempic shortages and stock levels. Furthermore, EMA updated the SPOC WP members on the supply status and outlook for Victoza and Saxenda, and informed that the shortage of Rybelsus has been resolved. |
| | **c) Shortages of medicinal products from MAH: Cheplapharm**<br><br>EMA presented an update on the ongoing shortages of products marketed by Cheplapharm with particular focus on new delay in Visudyne distribution in mid-December 2023. Furthermore, EMA provided an update on the ongoing shortages of Zypadhera whose marketing authorisation is being transferred from Eli Lilly to Cheplapharm. As a next step, EMA will publish a shortage catalogue entry for Zypadhera. |

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| | Comments raised:<br><br>While Cheplapharm has committed to the allocation of Visudyne vials to a particular MS, no further actions have been undertaken by the company in liaison with the respective NCA.<br><br>**Agreed actions:**<br><br>• MAH supply reporting frequency will be updated for EMA and the SPOC WP to be able to identify any new possible delays as early as possible. |
| | **d) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited**<br><br>EMA provided an update on the availability of alternative eptifibatide medicines in the EU/EEA. EMA also presented the recently received information from a tirofiban manufacturer that will slightly increase its supply to EU/EEA countries and support the MSs that may experience a constrained supply situation due to increased demand. |
| | **e) Potential shortage of Simulect CAP (basiliximab) – MAH: Novartis**<br><br>EMA presented an overview of a potential Simulect shortage and the MAH's shortage mitigation strategies. EMA confirmed that discussions with the MAH will continue to take place on a regular basis to prevent the shortage from occurring. |
| | **f) Potential shortage of Brineura CAP (cerliponase alfa) – MAH: Biomarin**<br><br>EMA presented an overview of a potential Brineura shortage and the MAH's proposed short-term mitigation measure. EMA confirmed that discussions with the MAH will continue to take place on a regular basis to prevent the shortage from occurring. |
| | **g) Attention deficit hyperactivity disorder (ADHD) medicines: lisdexamfetamine NAP and methylphenidate NAP**<br><br>EMA presented the feedback from some key manufacturers that expect the supply constraints for lisdexamfetamine and methylphenidate to continue throughout 2024. |
| | **h) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH**<br><br>EMA shared the outcomes of the recent meeting held with the MAH Valneva and the feedback that Ixiaro's supply disruptions are expected to continue in 2024 in several MSs. As next steps, EMA will continue to engage with the MAH, explore the possibilities to provide regulatory support, if required, and will update the shortage catalogue. |
| | **i) Eldisine (vindesine sulphate) – MAH: Stada Group**<br><br>SPOC WP member presented a shortage of Eldisine including the actions taken at national level such as prioritisation of certain groups of patients, communication activities and increasing supply of vindesine containing medicinal products. |
| | **j) Fludarabine NAP – MAH: Teva**<br><br>SPOC WP member provided an overview of shortages of fludarabine in the EU/EEA. SPOC WP member also presented feedback from the interactions with the MAH Teva and alternative pharmaceutical companies as well as mitigation measures taken at national level linked to cooperation between hospitals and import by pharmacists. |

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| | **k) Rabipur NAP (rabies, inactivated, whole virus) – MAH: Bavarian Nordic a.s.**<br><br>SPOC WP member presented an overview of Rabipur shortage and the results of the SPOC WP survey on the situation in the EU/EEA. SPOC WP member also informed that the availability of alternatives is limited. |
| 5. | **EC DG HERA update**<br><br>DG HERA provided feedback from a workshop organised together with DG GROW on 10 January 2024 with representatives from industry, EMA and the Member States on the supply chain vulnerability analysis for the first tranche of medicines included in the Union list. DG HERA informed that the workshop focused on the criteria for the selection of medicines included in the first round of the supply chain analysis, data requests and processes as well as the methodology for the analysis.<br><br>Comments raised:<br><br>SPOC WP members sought clarification on the data that would be requested from the Member States and who would be responsible for providing it. DG HERA explained that these nuances are still being discussed however it will be up to the Member State to nominate the person contributing to the exercise. |
| 6. | **HMA/EMA Task Force on Availability of authorised medicines** |
| | **a) Union list of critical medicines**<br><br>EMA presented the outlook for the Phase 2 rollout including the data sources and the call that was launched to the SPOC WP on any newly published national lists that could be taken into consideration for the new phase.<br><br>EMA explained the practical changes in comparison with Phase 1, the delivery roadmap, and the stakeholder engagement plan, which will include initial consultations with healthcare professionals and learned societies and will be followed by patients and consumers and industry consultation. |
| | **b) Shortage prevention and mitigation plans (SPP/SMP)**<br><br>EMA presented the outcomes of the written consultation with the SPOC WP on the SPP/SMPs drafted by Thematic Working Group 1 – all comments have been implemented with the exception of the medicines in scope of the SPPs which raised divergent views.<br><br>Comments raised:<br><br>SPOC WP members discussed the scope of the SPPs and possibilities to adapt SPP requirements at a national level. EMA explained that SPP template would outline the minimum requirements and noted that SPPs have already been implemented by some companies. Lastly, it was noted that SPP/SMPs would allow all stakeholders to be better prepared to address shortages. |
| 7. | **Update from Global Regulatory Working Group meeting held on 21 December 2023**<br><br>EMA provided an update from the Global Regulatory Working Group meeting and presented the new shortages of concern. Amongst others, the group discussed vindesine sulphate, fludarabine and GLP-1 RA shortages. |

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| 8. | **Update from ESMP interoperability workshop on 16-17 January 2024**<br><br>EMA provided an overall progress update on the ESMP, outlining the committed development, business analysis, and data analytics objectives to be carried out throughout Q1 2024. An updated product roadmap was presented with a focus on efforts for Q1 and Q2 2024 and a high-level plan up to Q1 2025.<br><br>EMA also provided a summary and presented the findings from the third and final ESMP interoperability workshop held on 16-17 January 2024. The workshop was composed of participants from EMA and subject matter experts (SMEs) from NCAs and industry. The main objective of the workshop was to discuss and agree on technical options to ensure interoperability between the various IT systems, including an implementation timeline and plan. The outcomes of discussions were presented, along with short-term next steps. |
| 9. | **AOB**<br><br>SPOC WP Secretariat informed the SPOC WP members of the upcoming call for volunteers to take the lead on the topic on the definition of a medicine shortage. SPOC WP Secretariat summarised the work done at the SPOC WP level and stressed the importance of reaching a conclusion on the implementation of the definition of the medicine shortage. |
| 10. | **Conclusions and next steps**<br><br>The agreed actions are detailed above. |

**Next meeting**: 14 February 2024 (WebEx)

**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).