12 September 2023
European Medicines Agency

# Meeting Summary - Medicine Shortages (SPOC) Working Party

6 July 2023, from 13:00 to 16:00 (CEST), WebEx

**Chair: Monica Dias (EMA), Vice-Chair: Maria Criado (AEMPS, Spain)**

| 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 Medicine Shortages SPOC Working Party meeting. EMA Chair welcomed the ES SPOC WP member as the new rotating Vice-Chairperson under the Spanish Presidency of the Council of EU.<br><br>SPOC WP Secretariat reviewed members' and experts declared interests in accordance with the Agency's policy on handling declarations of interests (DoI) of Scientific Committees applicable to members and experts of the SPOC WP and announced the relevant restrictions.<br><br>Changes to the SPOC WP membership were announced. The agenda was adopted with an additional point under AOB on the solidarity mechanism. |
| 2. | **Adoption of draft minutes of the SPOC WP meeting held on 21 June 2023**<br><br>The Vice-chair informed that the minutes of the meeting held on 21 June 2023 had been distributed on 3 July 2023 for adoption via written procedure. |
| 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:** |
| | **a) Antibiotic shortages: update on joint EMA/HERA preparedness activities**<br><br>EMA presented the state of play of the exercise in relation to the supply data from the MAHs and the preliminary outcomes of matching supply/demand.<br><br>EMA informed that the outcome of the exercise will be presented to MSSG on 14 July 2023, where recommendations for measures to be undertaken proactively by all stakeholders will be discussed. |

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| | **b) Feedback from the Q2 2023 Meeting from the Global Regulatory Working Group (WG) on Drug Shortages**<br><br>EMA provided an update from the meeting of the Global Regulatory WG on Drug Shortages, held on 22 June 2023. EMA informed that the guidance for industry on preventing shortages of medicines was presented to the group, and the members shared updates from the jurisdictions on medicine shortages of concern. |
| | **c) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)**<br><br>SPOC WP members noted availability issues of a muscle relaxant and shortage issues of specific antibiotics, antineoplastic and diuretic medicines.<br><br>**Agreed actions:**<br><br>• SPOC WP members with critical shortage issues to report the information to the SPOC WP Secretariat. |
| 4. | **Ongoing shortages reported by the SPOC WP (non-PHE/ME related):** |
| | **a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim; Urokinase NAP**<br><br>EMA provided an update on activities to address shortages of thrombolytics.<br><br>EMA provided a status update on the availability of an additional batch of Actilyse, together with an update on the long-term measures. |
| | **b) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH**<br><br>EMA provided feedback from the subgroup discussions with the MAH, including the topics of transparency in the allocation process and the effectiveness of shortage mitigating measures undertaken by the company. The next subgroup meeting will be dedicated to discussing more general issues related to shortages of medicines for which Cheplapharm is the MAH. |
| | **c) Glucagon-like Peptide-1 (GLP1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide); MAH: Eli Lilly**<br><br>EMA presented the feedback from the meeting with the MAH (Novo Nordisk) and highlighted their supply outlook for semaglutide-containing medicinal products in the second half of 2023. Additionally, EMA informed that interactions with MAH Eli Lilly are ongoing to understand their supply plans for their GLP-1 agonist.<br><br>**Agreed actions:**<br><br>• SPOC WP to inform EMA of any concerns to be looked into within the dedicated SPOC WP subgroup. |
| | **d) Methotrexate IV NAP**<br><br>EMA provided an overview of the supply situation of methotrexate NAPs in EU/EEA. Additionally, EMA informed that following the MSSG agreement, shortages of methotrexate will be monitored at the EU level, and potential mitigating actions will be investigated. |

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| 5. | **Presentation of the Pharmaceutical Pricing and Reimbursement Information (PPRI) Network Shortage Survey results**<br><br>PPRI representative presented global measures to manage, reduce or prevent medicine shortages in PPRI member countries from a financial standpoint, following the compilation of the PPRI Network shortage survey. Those, amongst others, can include economic sanctions for shortage non-reporting, financial measures for non-supply or non-compliance with stockpiling requirements, and financial incentives.<br><br>Comments raised:<br><br>SPOC WP discussed the possible impact of financial measures and noted the feedback from the industry on pricing issues. PPRI representative highlighted that impact is evaluated on a case-by-case basis, and any data from the MSs is helpful; differences in pricing practices between countries were also noted. |
| 6. | **Update from EC DG HERA**<br><br>EC DG HERA provided an update on the EU Multi-Country Pull incentives to improve antibiotic access. HERA informed that the process for identifying candidate antimicrobials is ongoing and will target newly developed and approved ones.<br><br>Furthermore, HERA provided an update on the ongoing activities to improve access to tuberculosis medicines for children. |
| 7. | **HMA/EMA Task Force on Availability of authorised medicines:**<br><br>• **EU list of critical medicines – methodology, outline of the process for establishing the list and impact on SPOC WP**<br><br>EMA presented the high-level methodology, roadmap, and process to set up a Union list of critical medicines, which the Steering Committee of the HMA/EMA TFAAM adopted on 29 June 2023.<br><br>The process for establishing the Union list will follow a phased approach: the release of the first version is expected in Q4 2023 based on published national lists of critical medicines or lists currently under development, followed by a second phase with subsequent versions prioritising review by therapeutic groups of major interest. |
| 8. | **Update on the EMA extended mandate implementation**:<br><br>• **ESMP product development status and plan for Q3 2023**<br><br>EMA informed that Programme Increment (PI) planning took place at the end of June 2023, where ESMP objectives for the next three months – from the development and the analysis perspectives – were agreed upon. EMA presented those objectives the IT development teams have committed to achieving by the end of September 2023. |
| 9. | **AOB**<br><br>EMA informed that in light of the ongoing activities towards developing a solidarity mechanism, the existence of national safety stocks will be investigated, and a request for information will be distributed to the SPOC WP. |

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| 10. | **Conclusions and next steps**<br><br>The agreed actions are detailed above. |

**Next meeting**: 12 September 2023, virtual

**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).