6 July 2023
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

24 May 2023, from 10:00 to 13:00 (CEST), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Johan Andersson (SE)

Item	Topics
1.	**Welcome, declaration of interest, adoption of draft agenda** The Chair and Vice-Chair welcomed participants to the meeting of the Medicine Shortages SPOC Working Party. 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, applicable to members and experts of the SPOC WP. The SPOC WP Secretariat announced the competing interests identified and announced the applicable restrictions for topics on the agenda. Changes to the SPOC WP membership were announced. Agenda was adopted with no additional points under AOB.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 18 April 2023** The Vice-Chair informed that the minutes of the meeting held on 18 April 2023 had been distributed via email one week prior the meeting. No comments were received before or during the meeting. Minutes were adopted.
3.	**Future operating model of SPOC Working Party meetings and information exchange** EMA presented an update on the rollout of SharePoint Online features for meeting management, information exchange related to shortage case management and requests for information, amongst others. EMA noted that the NCA user guide drafting is underway and will be made available in due course.
4.	<u>End of the COVID-19 and Mpox public health emergencies</u> EMA informed that the reporting obligations for NCAs and for Industry for medicines included in the lists of critical medicines for Public Health Emergencies (PHE) under Regulation (EU) 2022/123 ceased to apply upon declaration to an end to the COVID-19 and Mpox PHEs.

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	EMA informed the SPOC WP that the framework for NCA submission of sales and prescription data is being finalised for future reporting. Additionally, EMA will liaise with the i-SPOC networks in relation to the process improvement activities to increase the MAH reporting compliance rates in future PHEs. Comments raised: Chair thanked the SPOC WP members for their cooperation when providing the data as per their reporting obligations which will allow the SPOC WP to be better prepared for any future PHEs or MEs.
5.	**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 EMA presented the current state of play of the joint EMA/HERA exercise to match supply and demand for a set of antibiotics to prepare for the next autumn/winter season. EMA informed that the technical tools to undertake the exercise have been developed, however the supply data from industry is still required. Comments raised: SPOC WP members discussed the possible value of using epidemiological data and whether the data provided by NCAs can cover the EU population and EMA confirmed that both aspects are being evaluated.
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) No new information reported.
6.	**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 EMA presented an update on the ongoing shortage case management activities including the provision of additional Actilyse vials (batches manufactured under a previously approved process and the one-time donation of alteplase vials by another company that markets this product in North America) and interactions with urokinase suppliers outside the EU. Comments raised: The need for detailed supply forecasts including information for 2024 was highlighted and the extension of the duration of shortage until 2025 was also noted. EMA confirmed that the shortage duration has been updated to represent the date when all strengths of Actilyse and Metalyse are expected to be available to patients without restrictions related to the shortage situation.
	b) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH EMA presented the roadmap for activities undertaken to mitigate the shortage thus far including the exchange of information between the MAH and EMA, SPOC WP, MSSG and international regulators. EMA provided an update in relation to importation of vials from US and their allocation in the EU/EEA markets.

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	c) Menopur NAP (menotropin) - MAH: Ferring EMA presented the current status of the activities to mitigate the impact including the adoption of the DHPC, interactions with MAHs of alternative medicines and the availability of their products. While the discussions with the MAHs will continue, the frequency of the MAH interactions will be reduced, and the subgroup will cease activities due to stability of the situation.
	d) Ozempic CAP and Rybelsus CAP (semaglutide) - MAH: Novo Nordisk EMA provided feedback from the joint EMA/SPOC WP subgroup meeting with the MAH of Ozempic and Rybelsus regarding the ongoing shortage of these agents. This also included a discussion on patterns of demand and supply of all GLP-1 agents on the EU/EEA and US markets. <u>Comments raised:</u> NCA SPOC raised possibility to initiate interactions with the MAHs of alternative GLP-1 receptor agonists and EMA replied that the market impact is currently being investigated and interactions with other MAHs are ongoing. SPOC WP discussed how the shortages were reflected in social media and impact of patients, including planned educational activities by some regulators to health correspondents and communication professionals at MSs level. EMA also noted that TF-AAM TWG2 on communication will be discussing the role of media in shortages in an upcoming meeting. **Agreed actions:** • SPOC WP members to share information on initiatives undertaken at national level to address the negative media impact on availability of medicines.
	e) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma EEIG); Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH EMA presented an update on the availability situation of paclitaxel containing CAPs. EMA noted that interactions with the MAHs are ongoing and that a survey to the SPOC WP was ongoing to better understand the situation in the EU/EEA.
7.	**Update from EC DG SANTE** DG SANTE provided an update focused on the proposal for a new Directive and a new Regulation, which will revise and replace the existing general pharmaceutical legislation. EC noted the importance of the work of the SPOC WP and the TF-AAM also in relation to the Chapter 10 of the proposal on availability and security of supply of medicinal products. **Agreed actions:** • SPOC WP members to channel the information on the work undertaken within the WP and the TF-AAM to their national counterparts to inform the discussions that will take place at the European Council.
8.	**Update from EC DG HERA** DG HERA provided an update focused on HERA IT System 'ATHINA' to gather and assess intelligence and inform decision making on medical countermeasures (MCM).

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9.	**Joint Action on Shortages (CHESSMEN)** Topic could not be taken and was postponed.
10.	**EU list of critical medicines – feedback from HMA/EMA TF AAM (TWG1)** TWG1 presented the activities to be undertaken to draft the EU list of critical medicines. TWG1 established a drafting group which will finalise the draft methodology and criteria, and support the development of the list, amongst others.
11.	**Implementation of EMA extended mandate**: • **Status update on implementation activities for Medical Device Shortages** EMA presented an update on the implementation of Medical Device Shortages activities under EMA's Extended Mandate, such as the 1st MDSSG meeting, adoption of the MDSSG Rules of Procedure (RoP) and mandate, along with publication on EMA website. EMA noted that the 1st meeting of the MD SPOC WP will take place on 31 May 2023 to adopt its RoP and the methodology for identification of categories of critical medical devices for PHEs. Lastly, EMA presented the status of the critical medical devices system (CMDS).
12.	**European Health Management Association (EHMA) survey to NCAs on hospital data gathering initiative** European Health Management Association (EHMA) presented that the availability of medicines is one of their strategic priorities considering the complexity of the hospitals' medication management pathways. EHMA plans to launch a survey to NCAs to understand MSs' capacity to gather hospital related stock data to increase visibility of hospital stocks. Interactions will hospital managers and pharmacists will take place as part of the second phase of the research.
13.	**Conclusions and next steps** The Chair thanked the SPOC WP members for their contribution during the meeting and through their participation in various subgroups.

Next meeting: 16 June 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).