6 July 2023
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

16 June 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. EMA Chair thanked the SE Vice-Chair for the successful term and announced that the ES SPOC WP member will take over in July 2023 as new rotating Vice-Chairperson under Spanish Presidency of the Council of EU. 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 agenda was adopted with an additional point on the supply of an antihemorrhagic medicinal product under 4b.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 24 May 2023** The Vice-chair informed the group that the minutes of the meeting held on 24 May 2023 had been distributed via email on 15 June for adoption via written procedure.
3.	**Future operating model of SPOC Working Party meetings and information exchange** • **Update on the rollout of SharePoint (ShP) Online** EMA provided an update in the context of the ongoing ShP features rollout for the SPOC WP meetings and information exchange, noted the timeframe for gradual implementation and showcased to the group the process for navigating in the ShP microsite folders.
4.	**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 a high-level update on the exercise to match supply and demand for a set of antibiotics for the next autumn/winter season. EMA informed the group that

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	supply data from industry is still awaited, which will allow matching the supply and demand for the antibiotics and identify any possible shortfalls. Comments raised The group discussed the need to obtain the data from some MAHs in a timely manner and that while interactions are ongoing, additional actions to ensure cooperation may be required.
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) SPOC WP member noted the potential supply constraints of an antihemorrhagic medicinal product. Comments raised SPOC WP member noted shortages of certain antineoplastic and immunomodulating agents (i.e. hydroxycarbamide and methotrexate). EMA confirmed that situation is being monitored and discussions have taken place with international regulators. **Agreed actions:** • SPOC WP members with critical shortage issues to report the information to the SPOC WP Secretariat.
5.	**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 provided a general update on the activities related to the ongoing shortages of thrombolytics including the distribution of Actilyse 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. In addition, feedback was provided on the discussions regarding mitigating actions related to the shortage of urokinase with EU and non-EU suppliers.
	b) Visudyne CAP (verteporfin) – MAH: Cheplapharm Arzneimittel GmbH EMA provided an update on the supply of Visudyne in the EU/EEA. EMA also provided the feedback from the SPOC WP subgroup discussions on allocation of stocks.
	c) Ozempic CAP and Rybelsus CAP (semaglutide) – MAH: Novo Nordisk EMA presented the feedback from the meeting with the MAH and provided an update on Ozempic supply outlook for the remaining half of 2023. EMA also provided information on the status of the DHPC dissemination in the EU/EEA countries which was adopted in March 2023. EMA highlighted the supply outlook for alternative GLP-1 agonists (Rybelsus and Victoza) and MAHs' measures to meet the increased demand. **Agreed actions:** • EMA together with the SPOC WP to extend the supply monitoring activities to other GLP-1 agonists.

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	d) Insuman CAP (human insulin) – MAH: Sanofi EMA provided an overview of the situation and information received from the MAH, including the proposed approach to mitigate the impact of the discontinuation of certain Insuman presentations and expected impact to EU/EEA countries. Comments raised The group noted the need for timely notifications of marketing cessations. **Agreed actions:** • EMA to continue interactions with the MAHs and discuss possible measures to mitigate impact in the affected Member States. • EMA to update the shortage catalogue entry to reflect the planned discontinuation of Insuman Basal, Rapid, and Comb25.
	e) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma EEIG); Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH EMA provided an update on the supply situation of nab-paclitaxel in the EU/EEA and highlighted the next steps which include updated shortage catalogue entries and close monitoring of the supply situation in the EU/EEA.
6.	**Update from EC DG SANTE** Topic could not be taken and was postponed.
7.	**Joint Action on Shortages (CHESSMEN)** An update on the Joint Action on Shortages was provided in relation to the work package deliverables, communication activities and establishment of an External Advisory Board.
8.	**MSSG Recommendations on shortages of medicinal products toolkit** EMA presented the draft MSSG recommendations ("toolkit") on prevention or mitigation of shortages of medicinal products to ensure preparedness for dealing with shortages of medicinal products, which was based on the experience during COVID-19 and recent cases of critical shortages. EMA informed that the recommendations will be presented to the MSSG on 19 June 2023 and are expected to be adopted by the MSSG in the upcoming months.
9.	**Update on pilot on shortages reporting by patients and healthcare professionals** EMA presented the experience and preliminary insights from the 6-month pilot on reporting of shortages by HCP and patient organisations. EMA highlighted that many of the reported shortages had been already monitored by the SPOC WP, while only a handful was distributed for additional SPOC WP input. **Agreed actions:** • EMA to continue the pilot with adjusted criteria to streamline reports.
10.	**Conclusions and next steps** Agreed actions are detailed above.

Next meeting: 6 July 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).