14 March 2024
European Medicines Agency

Meeting Summary - Medicine Shortages SPOC Working Party

14 February 2024, 09:30-13:00 (CET), WebEx

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

Item	Topic
1.	**Welcome, declaration of interest, adoption of draft agenda** The Chair and Vice-Chair welcomed participants to the virtual 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. Based on the topics in the agenda of the meeting, the SPOC WP Secretariat announced the applicable restrictions. 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 22 January 2024** The Vice-Chair informed that the minutes of the meeting held on 22 January 2024 had been distributed one week prior the meeting. 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:** **a) Antibiotic shortages: Update on preparedness activities** EMA provided an update on the current status of antibiotic shortages reported by the SPOC WP and informed that no signals were reported by industry associations, patients and consumers, or healthcare professionals' organisations. Additionally, EMA informed that the feedback from one MAH is awaited. <u>Comments raised:</u> SPOC WP members shared that there are ongoing shortages of certain antibiotics and explained the situation at a national level.

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	Agreed actions: • SPOC WP members to continue reporting all current and expected shortages (critical and non-critical) of the set of antibiotics in scope of this exercise to EMA. • EMA to follow up with some SPOC WP members to better understand the national situation.
	b) Impact of the takeover of Catalent by Novo Holdings on the supply of medicines EMA informed the SPOC WP about the acquisition of the contract manufacturer Catalent Inc. by Novo Holdings and that Novo Nordisk will be acquiring three of Catalent's production sites. The impact of this acquisition on the availability of medicinal products manufactured at the Catalent sites will be assessed.
	c) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets EMA presented an update on the impact of the Israel-Hamas war on the supply of medicinal products with manufacturing steps in Israel. Although some constraints have been identified the current situation is considered to be stable. EMA informed the SPOC WP that the scope of the monitoring has been expanded to include potential issues as a consequence of the current tensions in the Red Sea. **Agreed actions:** • SPOC WP members to notify EMA as soon as they become aware of any signals of shortages or availability issues related to the situation in Israel or the Red Sea.
	d) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) Three SPOC WP members expressed concerns about the availability of a parenteral mucolytic acetylcysteine. SPOC WP members shared that one MAH does not expect shortages for their product, however another MAH faces production issues and no alternatives are available in one Member State. Another SPOC WP member reported a shortage of etomidate, an IV anesthetic. Furthermore, a shortage of an antibiotic was reported. **Agreed actions:** • SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP.
4.	**Ongoing critical shortages reported by the SPOC WP:**
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim EMA presented an update on the status of ongoing shortage management activities including the distribution of Actilyse vials and the proposed new manufacturing site. Additionally, EMA informed SPOC WP members about the launch of a new strength and indication of Metalyse.

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	b) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide), Victoza CAP (liraglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide) – MAH: Eli Lilly Nederland B.V. EMA provided an update on the supply and stock situation of GLP-1 receptor agonists. Furthermore, EMA informed the SPOC WP about an upcoming joint EMA/FDA meeting with Novo Nordisk, an upcoming joint HCPWP/PCWP meeting, and a survey on national communication campaigns on Ozempic that was recently circulated to the Working Group of Communication Professionals (WGCP). Comments raised SPOC WP discussed the details of supply chain aspects and shortages in individual countries. **Agreed actions:** • Further discussion on supply chain and shortages aspects will take place at the next EMA and the SPOC WP subgroup meeting with the MAH.
	c) Supply and availability of IV/SC human normal immunoglobulins in the EU/EEA • **Overview of the shortage situation of immunoglobulins** EMA provided an overview of the current supply and availability of human normal immunoglobulins and informed about recent interactions with MAHs for CAPs. In addition, EMA presented feedback from the IPFA/EBA symposium on plasma collection and supply which took place on 7-8 February 2024 in Leiden, the Netherlands. • **Update on the revision of CHMP position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products** An update on the revision of the CHMP position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products was provided.
	d) Shortages of medicinal products from MAH: Cheplapharm EMA presented an update on the ongoing shortages of Visudyne and informed the SPOC WP about the batches to be allocated to the EU/EEA in 2024. Furthermore, EMA provided an update on the ongoing shortages of Zypadhera and that the supply situation has improved. EMA will continue monitoring the situation until the supply of Zypadhera is stabilised.
	e) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited EMA shared the outcomes of the recently held meetings with alternative MAHs of eptifibatide and tirofiban. EMA informed SPOC WP of the positive feedback from an alternative manufacturer who could potentially supply MSs that may experience critical shortages.
	f) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH EMA presented the outcomes of the recent interactions with the MAH. EMA informed the SPOC WP that while improvement is expected in most EU/EEA countries from June 2024, in two countries availability issues are expected to last until January 2025.

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	Comments raised: A number of SPOC WP members expressed concerns regarding the situation in their countries.
	g) Emend CAP (aprepitant) - MAH: Merck Sharp & Dohme B.V. EMA provided an update on the shortage of Emend oral suspension and presented the results of the criticality assessment and proposed mitigation measures. EMA asked impacted SPOC WP members whether there are any national activities (e.g. the use of magistral formulations) foreseen to mitigate the shortage or if additional support is required, such as the solidarity mechanism. Comments raised: SPOC WP member responded that the solidarity mechanism is not required at the moment as they are looking into other measures first.
	h) Creon (pancrelipase) - MAH: Viatris Italia S.R.L and Creonipe (pancrelipase) - MAH: Viatris Healthcare Limited SPOC WP member presented an overview of the ongoing critical shortage of Creon and Creonipe in their country, including mitigation measures already taken and planned. SPOC WP member also stated that the root cause of this shortage is related to production issues and high demand. Comments raised: Several SPOC WP members reported that they are also experiencing shortages of Creon and Creonipe in their countries. **Agreed actions** • EMA to assess the criticality of this shortage across the EU/EEA.
5.	**Update from MSSG meeting held on 29 January 2024** The Vice-Chair provided a high-level update on the points discussed at the 29 January 2024 meeting of the MSSG, such as critical medicine alliance, solidarity mechanism procedure and preparedness activities. The Vice-Chair informed that the first meeting of the Critical Medicine Alliance will be scheduled in April 2024 and the strategic action plan adoption is expected in Q4 2024. The Vice-Chair also provided brief update on the HERA/GROW workshop on the vulnerability analysis for the first tranche of medicines from the Union list of critical medicines held on 10 January and the HERA Board meeting held on 16-17 January 2024.
6.	**EC DG HERA update** DG HERA presented the criteria to select the first tranche of medicines, the proposed methodology to conduct the supply chain vulnerability assessment, the roadmap and the list itself. The first tranche of critical medicines will be used as a pilot to test the methodology to assess the vulnerabilities in the supply chain. DG HERA also informed the SPOC WP about timelines for the pilot exercise.

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7.	**Update on the Joint Action on Shortages (CHESSMEN) coordination activities** An update on the JA CHESSMEN activities and participation at the kick-off meeting of the Joint Action on Antimicrobial Resistance & Healthcare-Associated Infections (EU-JAMRAI 2) was provided. Additionally, SPOC WP was informed about an upcoming CHESSMEN meeting in Lisbon that will take place on 17 and 18 June 2024.
8.	**HMA/EMA Task Force on Availability of authorised medicines**
	Union list of critical medicines – Phase 2 "go-live" EMA explained the process of the data collection by MS which will be done in three batches, each to be completed in three-months' time. EMA also informed that Phase 2 will be launched shortly as the preparatory work for the first batch is being finalised.
9.	**Update on the Solidarity Mechanism procedure** EMA clarified the conditions that need to be met in order to launch the solidarity mechanism and confirmed that the procedure is ready to be used as soon as a MS requires support for the mitigation of a critical shortage. EMA also highlighted that the lack of candidates for the pilot exercise demonstrates that the existing structures are adequate, and the coordinated actions put in place have had a positive impact in mitigating shortages. **Agreed actions**: • SPOC WP members to inform EMA in case there is a suitable candidate for the pilot exercise.
10.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 14 March 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).