17 July 2024
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TRS-SAM

Meeting Summary - Medicine Shortages (SPOC) Working Party

20 June 2024, from 09:30 to 13:30 (CEST), 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. The Chair thanked the Vice-Chair for the successful term and announced that the HU SPOC WP member will take over in July 2024 as the new rotating Vice-Chairperson under the Hungarian Presidency of the Council of the EU. The 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. The agenda was adopted with no additional points under AOB.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 22 May 2024** The Vice-Chair informed that the minutes of the meeting held on 22 May 2024 had been distributed one week prior to the meeting. No comments were received before or during the meeting. Minutes were adopted.
3.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Solidarity Mechanism: lessons learned EMA presented the lessons learned from the first three procedures and the proposal to fine-tune the procedure.

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	EMA noted that further experience with the Solidarity Mechanism is needed before a thorough review of the procedure can be undertaken. As the next step, relevant documents will be updated to incorporate the changes and subsequently proposed to and adopted by the MSSG. Comments raised The Chair noted positive responses from MSs that have made use of the Solidarity Mechanism and highlighted its positive impact on shortages.
4.	**HMA/EMA Task Force on Availability of Authorised Medicines:**
	a) Shortage prevention and mitigation plans (SPP/SMP) EMA informed that SPP/SMP templates were adopted by the HMA/EMA Task Force on Availability of Authorised Medicines (TFAAM) Steering Committee on 24 May 2024 and were subsequently published on EMA and HMA websites. As the next steps, the SPOC WP will be consulted on a proposal for a pilot phase to test the implementation of the SPP/SMP template and following the adoption by the TFAAM Steering Committee the pilot will be launched. Comments raised A few SPOC WP members expressed their interest to participate in the pilot for the implementation of the SPP/SMPs.
5.	**Joint action (JA) CHESSMEN: updates on work packages** IT SPOC WP member presented the feedback from the CHESSMEN mid-term review meeting in Lisbon on 17-18 June 2024, and highlighted the collaboration with the participants and other relevant groups such as the SPOC WP, the approaches undertaken to ensure harmonisation and discussions on best practices and existing mechanisms. Comments raised The Chair reiterated the need for harmonised actions between JA CHESSMEN and the SPOC WP. The Chair informed that the JA CHESSMEN deliverables will be made available to all MSs – through the SPOC WP – beyond those participating in the JA.
6.	**Supply and availability of immunoglobulins**
	a) Is collection of Anti-D plasma in Europe possible? A representative of Sanquin Bloodbank provided an overview of the anti-D immunoglobulins mode of action, plasma collection and supply challenges. The speaker emphasised the need for EU collection as well as the harmonisation and pooling of anti-D plasma in Europe to ensure their availability for patients.
	b) Status update on supply and availability of anti-D immunoglobulins internationally and in EU/EEA EMA provided an overview of the recent activities such as meetings with the dedicated SPOC WP subgroup and MAHs of anti-D immunoglobulins. In addition, EMA provided the feedback from the last meeting of the SPOC WP subgroup on immunoglobulins.

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	EMA informed that throughout the month of June, the topic will be discussed in a joint EDQM/ECDC/EC meeting, the Drug Shortages Global Regulatory Working Group and a teleconference of the Blood cluster.
	c) Presentation delivered by industry: Marketing Research Bureau (MRB) A representative from Marketing Research Bureau provided an overview on the Rho(D) immune globulin market, fractionation and supply of anti-D plasma, anti-D plasma collection and donors, as well as the supply challenges. The speaker noted that the Rho(D) supply is growing slowly, whilst being confronted with an increased demand. The speaker stressed the need for anti-D plasma collection in Europe to avoid future shortages of Rho(D) immune globulin. Comments raised The Chair asked for the reasons for the slow increase in product availability, to which the speaker noted the difficulties in finding the right donors and the dependencies on the population and their characteristics (e.g., a higher rate of Rh-positive cases in Europe and US than in Africa and Asia).
	d) Discussion The Chair concluded the session thanking the speakers and noted that information provided today will be shared with the MSSG for information. In addition, the discussion will continue in the SPOC WP subgroup on immunoglobulins and with the EC and EDQM.
7.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	a) Impact on the supply of medicines of the takeover of three Catalent sites by Novo Holdings EMA provided the preliminary feedback on the potential impact of the takeover of three Catalent manufacturing sites by Novo Nordisk. EMA noted that further clarifications are still required for some medicinal products, and that close interactions with the MAHs will continue. Additionally, EMA provided an update on the potential shortage of an antibiotic medicine and the short and long-term measures to address it in cooperation with the MAH and alternative manufacturers.
	b) Suspension of 12 CEPs at the request of Unimark Remedies Limited, India The topic could not be taken.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) One SPOC WP member informed about a potential shortage of an immunostimulant medicine due to an unexpected increased demand. EMA noted that this potential shortage was discussed at a recent SPOC WP meeting and that the feedback from the MAH and the SPOC WP on the situation in their territories is available.
8.	**Critical shortages escalated to the SPOC Working Party:**
8.1	**Ongoing shortages**

Item	Topic
	a) Shortages of medicinal products containing cisplatin EMA presented the background information on the shortage of cisplatin and the different MAHs impacted. Additionally, EMA provided the feedback from alternative manufacturers.
	b) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists: EMA provided an overview of the shortage situation of GLP-1 Receptor Agonists (RAs). In addition, EMA informed about the adoption of the MSSG recommendations on shortage of GLP-1 RA, an upcoming EMA press briefing scheduled for 26 June 2024 and an ad-hoc MSSG meeting on 1 July 2024 with oral explanations from three MAHs.
	c) Shortages of medicinal products containing salbutamol (inhalation use) EMA provided an update on the mitigating measures undertaken for salbutamol shortages such as the publication of the shortage catalogue entry, communication with the impacted MAHs and the exchange of information with international regulators. As the next steps, EMA will reach out to all MAHs of salbutamol containing medicinal products for inhalation use to understand their marketing status and supply planning. **Agreed actions:** • SPOC WP members to share information on the steps taken at national level.
8.2	**Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)**
	d) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris e) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim f) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH g) Methotrexate IV NAP (methotrexate) – MAH: Teva Sante No comments or concerns were raised on the abovementioned critical shortages. EMA provided a brief status update on the shortages from MAH Cheplapharm which are ongoing for different medicines.
9.	**HMA/EMA Task Force on Availability of Authorised Medicines:**
	a) Union list of critical medicines EMA provided an update on the rollout of Phase 2. The second batch (corresponding to 600 active substance groups) is now available for the SPOC WP review with a deadline for completion by 15 July 2024. EMA informed that the third batch will be made available in two waves starting the second half of June 2024, and will include additional substances highlighted during the stakeholder consultation. EMA thanked the SPOC WP members and colleagues in the Ministries of Health (MoH) for their efforts in this exercise and stressed the need to ensure adherence to the timelines. EMA nonetheless noted the willingness to accommodate extended timelines on a case-by-case basis, if requested.

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10.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Draft MSSG recommendations on supply chain vulnerabilities for the first tranche of medicines EMA presented the proposal for the MSSG to issue recommendations on the first tranche of medicines for which DG HERA/DG GROW has assessed the vulnerabilities in the supply chain (alteplase, amoxicillin, amoxicillin/clavulanic acid, benzathine benzylpenicillin, clonazepam, fludarabine, glucagon, hepatitis B vaccine, rifampicin, verteporfin, vincristine). Furthermore, EMA presented the proposal to include some products for which vulnerabilities in the supply chain are already known. As the next steps, the proposed recommendations will be presented to the SPOC WP for discussion and agreement before they are adopted by the MSSG.
11.	**Impact of new national law on supply of medicinal products and availability of medicines on European market** A SPOC WP member informed that the impact of national stockpiling strategies on the supply to smaller and low-priced markets is perceived as a potential cause of shortages in their MS and is being investigated at a national level. The SPOC WP member informed about additional measures that are planned to be taken at national level on the topic. <u>Comments raised</u> The group discussed the different scopes of the ongoing national investigation and the discussion on stockpiling at the Pharmaceutical Committee which took place at the end of 2023. It was added that discussions on a common strategic approach to stockpiling are being led by DG HERA. **Agreed action:** • To bring the topic back for discussion once the results of the investigation are available.
12.	**EC DG HERA update** DG HERA provided the feedback from the kick off meetings of the Critical Medicines Alliance (CMA) Working Groups (WG). DG HERA informed that the members of the WGs include MSs representatives, industry, civil society, HCPs and patients, EC services and agencies. Chairs for WG 1 include a representative from CZ MoH and a representative of FR Ministry of Economics, Finance and Industry, whereas for WG 2 the Chairs include a representative from DK Business Authority and GR MoH. DG HERA explained that WG 1 will focus on strengthening EU manufacturing capacities for critical medicines and their active pharmaceutical ingredients. For WG 2, the focus will lie on diversifying international partnerships and cooperation. <u>Comments raised</u> It was asked whether medical devices will be considered in the CMA and DG HERA clarified that the current focus of the activities lies on critical medicines.

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13.	**Conclusions and next steps** The Chair encouraged the SPOC WP members to express their interest in taking part in the SPP/SMP pilots. The Chair closed the session reminding that a multistakeholder workshop on GLP-1 RAs will take place on 1 July 2024 and encouraged the SPOC WP members to join. The agreed actions are detailed above.

Next meeting: 17 July (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)