24 May 2023
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European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

18 April 2023, from 10:00 to 17:00 (CEST), hybrid meeting – F2F + 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 F2F meeting of the Medicine Shortages SPOC Working Party at EMA premises in Amsterdam. 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, 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 21 March 2023** The Vice-chair informed that the minutes of the meeting held on 21 March 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 WP Meetings and information exchange** EMA presented the future operating model of the SPOC WP on information exchange (via SharePoint Online) which will gradually replace email messaging regarding shortages case notifications, requests for information, and meeting document management from Q2 2023. EMA will keep the SPOC WP members informed on the change management activities which will also include dedicated training to assist during this transition.

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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: general update on preparedness activities - EMA/HERA exercise for a subset of antibiotics EMA presented the state of play of the joint EMA/HERA exercise aimed at identifying any gaps between the supply and demand of a set of antibiotics for the next autumn/winter season. DG HERA presented their activities related to antibiotics and possible actions to be undertaken after the exercise, if necessary. Comments raised SPOC WP members noted the various approaches that could be used to forecast the demand for the next autumn/winter season at a national level.
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) No new emerging information was raised.
5.	**Update on 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
	• **Update on thrombolytics availability** EMA provided a general update on the activities related to the ongoing shortages of thrombolytics including the distribution of vials and the discussions related to urokinase with EU and non-EU suppliers. **Agreed actions** • EMA to share further details from the alternative urokinase manufacturers with the SPOC WP, once received.
	• **Country case study (Belgium): addressing urokinase shortage locally** BE SPOC presented an overview of the management of the critical shortage of urokinase, the interplay between EMA's shortage management activities and the activities taken at national level, as well as support from other MSs. Comments raised NCA SPOCs noted their experience with applying controlled distribution at national level.
	b) Visudyne CAP (verteporfin) – MAH: Cheplapharm Arzneimittel GmbH EMA presented the approach for shortage mitigating actions proposed by the drafting group, and asked for agreement by the SPOC WP. EMA also presented the feedback from the meetings with the MAH and alternative MAHs on the possible importation from other markets and increasing the manufacturing capacity as well as long-term measures to address this global shortage.

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	Agreed actions: • SPOC WP agreed to the actions proposed by the drafting group related to importation and delivery timelines. EMA to request updated information on the shortage criticality in EU/EEA from the SPOC WP.
	c) Menopur NAP (menotropin) - MAH: Ferring EMA presented an update on the current supply situation and the ongoing shortage mitigation measures. EMA presented an update on the DHPC finalisation and dissemination, and the next steps related to interactions with the MAH and MAHs of alternative products, amongst others. **Agreed actions:** • EMA to reduce the meeting frequency with the MAH due to stability of the current situation. • SPOC WP subgroup to draft lessons learned from the case management of Menopur shortage, for internal WP use.
	d) Ozempic CAP (semaglutide) - MAH: Novo Nordisk EMA presented the latest update on the discussions between the SPOC WP subgroup and the MAH, impact on availability of alternative GLP-1 receptor agonists, and the feedback from international regulators. The SPOC WP discussed the impact on alternative oral GLP-1 receptor agonists, as well as the latest media reports over breaches of some codes of practice. **Agreed action:** • SPOC WP to share with EMA the information available at national level on the off-label use.
	e) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH EMA presented an update on the supply situation and the discussion between EMA, affected NCAs and the MAH including the mitigating measures related to supply resumption and reallocation.
	f) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma EEIG); Pazenir CAP (paclitaxel) - MAH Ratiopharm GmbH EMA presented an ongoing shortage of two medicinal products containing paclitaxel formulated as albumin bound nanoparticles, caused by an increased demand. EMA noted the current supply situation in the MSs and globally, as well as communication and regulatory measures initiated to alleviate the situation. **Agreed action:** • SPOC WP agreed to set up a subgroup focusing on these shortages.

Item	Topics
	g) Rivotril NAP (clonazepam) - MAH: Cheplapharm Arzneimittel GmbH NCA SPOC presented the results of the survey to the SPOC WP regarding the supply situation of Rivotril in the EU/EEA which confirmed a shortage. NCA SPOC highlighted the impact in their territories and presented possible mitigating measures, including sourcing of additional supplies. <u>Comments raised</u> • SPOC WP members highlighted the need for a coordinated approach to improve cooperation from companies.
6.	**EC DG SANTE update** The EC provided a general overview of the upcoming revision of the pharma legislation in the area of security of supply and shortages.
7.	**EC DG HERA update** DG HERA presented an update the medical counter measures (MCM) prioritisation exercise for supply chain monitoring and ongoing activities related to avian flu.
8.	**HMA / EMA Task Force on Availability of authorised medicines – update on key workplan deliverables:**
	a) TWG1 (Availability and supply disruptions): • EU list of critical medicines TWG1 presented an update on the activities conducted and the deliverables linked to the setting up of the "EU list of critical medicinal products".
	b) TGW2 (Communications): • Survey to NCAs on public communication of medicines shortages (high-impact shortage cases); TWG2 presented the feedback on the survey to the SPOC WP to assess how EU regulatory authorities have communicated on the recent shortages of the medicines which aims to monitor implementation of the Good practice guidance for communication to the public on medicines' availability issues.
9.	**Joint Action on Shortages (CHESSMEN) – update** At the joint meeting held on April 18th 2023, TF-AAM & CHESSMEN agreed on the way forward to deliver the work together, including the reporting framework (Steering Committee of the TFAAM, Medicine Shortages SPOC WP and/or MSSG). TWGs will contact the leads of WPs to set up the drafting groups and to align on timelines. CHESSMEN will provide regular updates on progress to the Steering Committee of the HMA/EMA TFAAM.

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10.	**Update on the EMA extended mandate implementation**:
	a) ESMP product development status EMA presented the ESMP vision and roadmap, noting that the MSSG ESMP Working Group adopted the ESMP roadmap at the meeting held on 10 March 2023, which was also presented at the Industry Standing Group (ISG) on 21 March 2023 and to other groups involved. The roadmap has also since been formally adopted by the MSSG. EMA presented a progress update on Q1 2023 ESMP product increment (PI) planning based on committed objectives as well as the objectives committed to for Q2 2023. **Agreed action** • New quarterly update to the group scheduled for July 2023.
	b) Updates from NCAs on new information related to national IT systems for monitoring shortages NCA SPOC presented an update regarding new developments in relation to their national IT shortage reporting system.
	c) Status update on implementation activities for Medical Device Shortages An update on the implementation steps since Medical Device Shortages extended mandate became applicable in February 2023 was presented by the EMA.
11.	**EC presentation on affordability of medicines** EC presented the background on the subject of affordability of medicines and explained the mandate and activities of the National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR) group. EC noted the importance of coordination at national level, between SPOC WP members and their respective NCAPR members. Five SPOC WP members presented their experience in liaising with their relevant national counterparts for P&R of medicines, also in relation to practical cases on medicines availability. The group reflected around possible next steps on coordination with P&R decision-makers. **Agreed action:** • SPOC WP and EC agreed on the need to cooperate to collect the evidence on the link between medicine prices and availability.
12.	**EDQM presentation on shortage initiatives** EDQM presented their planned shortage initiatives in times of preparedness for a crisis, such as the Methodological Guide (guide that identifies and selects medicines that can be prepared in pharmacy in shortage situations) and the European Shortages Formulary (a compilation of texts describing methods for the preparation and quality control of standardised unlicensed pharmaceutical preparations that could be used in shortage situations).

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	In crisis situations, initiatives in place relate to certification procedures (fast-tracking of CEPs), support from the OMCL Network, and the use of the aforementioned European Shortages Formulary by pharmacists. EDQM noted the interest to cooperate with the SPOC WP in relation to EDQM's shortage initiatives.
13.	**CAP shortage reporting process in the MSs and EMA:** • **Update from SE on survey to NCAs on reporting of CAP shortages at national level** SE SPOC presented the outcome of the survey to the SPOC WP aimed to gather information on how shortages of CAPs are reported in the Member States, which was conducted in the context of the ongoing review of national legislation around reporting of shortage in Sweden.
14.	**Sterilization of single-use materials and filters:** • **Implementation of X-ray irradiation as an alternative to Gamma irradiation** EMA presented an alternative, new technique in sterilization which will allow to improve the availability of single-use systems and technologies; the sterilised materials are expected to be made available gradually from Q1 2023 through 2025. EMA also presented the feedback from industry and the next steps.
15.	**Country case study (Spain):** • **Presentation on the ARTEMIS pilot project designed to identify early signals of shortages at wholesale distributor level** ES SPOC presented a pilot project with an objective to detect disruptions in the supply chain before the medicine becomes unavailable at pharmacy level, as well as the milestones reached thus far. Lastly, ES SPOC presented the next steps related to the data analysis.
16.	**Conclusions and next steps** The Chairs thanked the SPOC WP for their active participation in the F2F meeting. The Chairs noted that based on the feedback received, the next F2F (planned for Q4 2023) will be extended to two days.

Next meeting: 24 May 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).