22 May 2024
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

15-16 April 2024, hybrid meeting – F2F + WebEx

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

Monday, 15 April 2024	
Item	**Topic**
1.	**Welcome, declarations 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 and 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 14 March 2024** The Vice-chair informed that the minutes of the meeting held on 14 March 2024 had been distributed one week prior 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): General update on March and April 2024 meetings** The Vice-Chair provided an overview of the discussions at the MSSG meetings in March and April 2024 including an update on the development of the ESMP, MSSG recommendations to strengthen supply chains of critical medicinal products, an update on the Union list of critical medicines and a high-level overview of preparedness activities on antibiotics and shortages of GLP-1 RAs.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Monday, 15 April 2024	
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	Additionally, the Vice-Chair provided a brief update on the pilot solidarity mechanism procedure, updates on discussions regarding Mpox and COVID-19, and the status of the supply chain vulnerability assessment by HERA/GROW and the Critical Medicines Alliance (CMA). Lastly, Vice-Chair informed the SPOC WP that an ad-hoc MSSG meeting dedicated to the outcomes of the supply chain vulnerability assessment by HERA/GROW will take place on 23 April 2024.
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) Impact of the takeover of Catalent by Novo Holdings on the supply of medicines EMA updated the SPOC WP about an ongoing assessment of the impact of the takeover of three Catalent manufacturing sites by Novo Holdings on the supply of medicines manufactured at those sites. Furthermore, EMA informed about a potential shortage of an antibiotic medicine manufactured at one of the impacted sites and the next steps to mitigate the potential impact.
	b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) Comments raised EMA informed that despite the increased tensions in Israel the situation is considered to be stable. No critical ongoing shortages were reported by the SPOC WP members.
5.	**Critical shortages escalated to the SPOC Working Party:**
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim EMA provided an update on the current supply situation including the launch of a new strength and indication for Metalyse and an update on a new manufacturing site.
	b) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited EMA presented the feedback from the meetings with alternative eptifibatide manufacturers, and informed that a launch of a new eptifibatide containing medicinal product is planned.
	c) Shortages of medicinal products from MAH: Cheplapharm EMA provided an update on the ongoing shortage of Visudyne and informed the SPOC WP about the batches to be allocated to the EU/EEA in coming months. Furthermore, EMA provided an update on the ongoing shortages of Zypadhera, the feedback from the meeting with the MAH and next steps. Comments raised One SPOC WP member noted the lack of communication on shortage mitigation by the company.

Monday, 15 April 2024	
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	Agreed action: • EMA to flag to Cheplapharm the need to liaise with the impacted SPOC WP member.
	d) Emend CAP (aprepitant) – MAH: Merck Sharp & Dohme B.V. EMA informed the SPOC WP about the root cause of the shortage and noted that the shortage is expected to last until the end of July 2024. EMA also highlighted the possibility to use a magistral formulation as one of the possible alternatives, as presented in previous meetings. Additionally, EDQM presented the work conducted by the European Drug shortage Formulary Working Party (EDSForm WP) to develop technical recommendations on unlicensed pharmaceutical preparations that could be used to cover for the ongoing shortage of Emend. *Post-meeting note: the **Expert opinion** of the EDSForm WP was published on 23 April 2024.*
	e) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris EMA presented the latest information received from Viatris regarding the supply situation of pancrelipase containing medicinal products as well as proposed mitigation measures. In addition, EMA informed about the outcome of the meetings with alternative MAHs and the positive feedback from one manufacturer who could potentially support MSs that may experience critical shortages. Comments raised A few SPOC WP members noted the need for a more streamlined communication by the MAH. Additionally, SPOC WP members shared experiences on the shortage criticality in their countries and alternatives available. EMA explained that a number of EU/EEA countries have alternatives marketed. **Agreed actions:** • SPOC WP members interested in additional supplies of pancrelipase containing medicinal products to contact the alternative manufacturer. • EMA to highlight to Viatris the need to improve communication with EU/EEA countries.
	f) Fluracedyl NAP (fluorouracil) – MAH: Teva Pharma Belgium S.A.; Fluorouracil Accord Healthcare NAP (fluorouracil) – MAH: Accord Healthcare B.V SPOC WP member presented the shortage situation of Fluracedyl in their territory together with the results of the survey circulated to the SPOC WP members. Comments raised The group discussed the types of stocks that may be used to mitigate critical shortages and a SPOC WP member suggested to look at different national stockpiling mechanisms and share best practices within EU/EEA countries. Additionally, SPOC WP noted the need for industrial policy measures for low-priced generic medicines.

Monday, 15 April 2024	
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	g) Methotrexate IV NAP (methotrexate) – MAH: Teva Sante EMA presented background information on the shortage of methotrexate injections and actions taken to address it as well as the feedback received from the SPOC WP members on the criticality of the shortage. EMA also proposed to restart the methotrexate subgroup of the SPOC WP and to contact alternative MAHs to investigate their ability to increase supply, if needed. Comments raised A SPOC WP member reported that this shortage is considered critical and asked whether the import of methotrexate from other EU/EEA countries would be possible. EMA will contact alternative MAHs to explore the possibilities to increase their supply. **Agreed action:** • EMA to inform the SPOC WP once information from alternative MAHs is available.
	h) Ventolin NAP (salbutamol sulfate) – MAH: GlaxoSmithKline EMA presented the results from the survey on Ventolin availability circulated to the SPOC WP members. Additionally, EMA explained the measures taken to address the supply disruptions, provided the feedback from the meeting with the MAH and informed of the proposed next steps.
	i) Shortages of medicinal products containing cisplatin A SPOC WP member informed the group about an ongoing critical shortage of products containing cisplatin and asked about the situation in other MSs. The SPOC WP member noted that a solidarity mechanism for this critical shortage will be launched. Comments raised SPOC WP members shared the feedback on the supply situation in their territories and availability of alternatives. One SPOC WP member confirmed that the situation at national level will be evaluated and the possibility to provide support though the solidarity mechanism will be assessed.
6.	**Availability issues for veterinary medicines:**
	a) Remdesivir for cats to treat Feline Infectious Peritonitis EMA informed the SPOC WP about CVMP's conclusion to use remdesivir for treatment of feline infectious peritonitis. However, the medicine is not accessible to veterinarians as it is only distributed to hospitals.
	b) Drug shortages in zoological parks in the US EMA informed the SPOC WP about ongoing shortages of opioid analgesics and neuroleptics in zoological parks in the US. EMA noted that none of the mentioned products are authorised for the use in zoo animals or wildlife in the EU.
	c) Shortages of veterinary vaccines for dogs, cats and horses

Monday, 15 April 2024	
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	A SPOC WP member presented the details about a potential impact on stock availability in EU countries for vaccines for use in dogs, cats and horses.
7.	**Availability of antimicrobials:**
	a) Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI-2): Work Package 9 on access to antimicrobials EU-JAMRAI-2 representative provided an overview of JAMRAI-2 and presented ongoing activities and objectives of Work Package (WP) 9, with a focus on improving access to antimicrobials. <u>Comments raised</u> EMA welcomed the initiatives under WP9 and asked for clarification about Global Drug Facility (GDF). Representative of EU-JAMRAI-2 explained that the GDF is an international organisation working to improve the accessibility and affordability of tuberculosis (TB) treatments, particularly to low- and middle-income countries. Lastly, cooperation between JA CHESSMEN and JAMRAI-2 was noted, and EU-JAMRAI-2 representative noted the interest to work together with EMA and the SPOC WP on improving access to antimicrobials.
	b) Antibiotic shortages: • **General update on preparedness activities** EMA informed the SPOC WP members that no signals of supply disruptions were reported by Industry associations or Patients and Consumers and Healthcare Professionals organisations in the past month. Additionally, EMA shared the feedback on actions by an MAH to mitigate shortages in a few MSs. • **Presentation delivered by MAH: Sandoz, followed by Q&A session** Sandoz presented an overview of the supply situation and their proposed long-term shortage mitigation measures. <u>Comments raised</u> The group discussed aspects linked to Sandoz proposals and asked for clarity on the production capacity and safety stocks. The group welcomed the improved communication at local affiliate level with NCAs. Additionally, a few shortages of concern were highlighted by SPOC WP members.
	c) Debrief on next steps/actions for antibiotic shortages ("Closed session" for SPOC WP members) The SPOC WP debriefed on the presentation and discussion with the MAH.
8.	**European Shortages Monitoring Platform (ESMP)** EMA updated the SPOC WP on the latest developments in the ESMP and the incremental release of the functionalities planned for later this year and in 2025. Additionally, EMA presented the

Monday, 15 April 2024	
Item	**Topic**
	design of the user interface as well as NCA datasets to be used for submission of data during crises and MSSG-led preparedness exercises. Comments raised A SPOC WP member asked for clarity on the MSSG-led preparedness and the process of data submission – EMA explained that MSSG-led preparedness encompasses matching of forecasted supply and demand using information from NCAs and Industry, undertaken during the preparedness phase, as it was done for the joint EMA/HERA antibiotics exercise. Additionally, EMA clarified that it will be possible to submit data manually via the user interface and noted that the format and mechanism for machine-to-machine data exchange are currently being defined. Another SPOC WP member asked whether IT directors from NCAs are involved to which EMA confirmed that they are indeed involved.
9.	**EC DG ECHO – Union Civil Protection Mechanism** DG ECHO presented the Union Civil Protection Mechanism including its capacities such as the European Civil protection pool (ECPP) and the rescEU initiative.
10.	**EC DG HERA update** DG HERA presented an update on the composition of the **CMA** Steering Board, forum and working groups. DG HERA also highlighted that the work of the CMA and the MSSG will be complementary, and coordination will be supported through the MSSG Co-Chairs membership in the Steering Board.
11.	**EC DG SANTE update** DG SANTE presented a general status update on the New Pharmaceutical Legislation and the procurement guidance.

Tuesday, 16 April 2024	
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1.	**Critical shortages escalated to the SPOC Working Party (continued):**
	a) Glucagon-like Peptide-1 (GLP1) 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 a status update on the shortages of GLP-1 Receptor Agonists (RAs) and presented the outcomes of two surveys one on MSs best practices on mitigating measures (conducted by the SPOC WP), and the other on national communication campaigns on shortages of GLP-1 RAs (conducted by Working Group of Communication Professionals). Finally, EMA informed the SPOC WP about a multistakeholder workshop on the shortage of GLP-1 RAs which will take place later this year. Comments raised SPOC WP discussed supply chain aspects and shortages in individual countries.
	b) Supply and availability of IV/SC human normal immunoglobulins in the EU/EEA EMA presented the results of the assessment of the supply and availability situation of Rho(D) immune globulins/ Anti-D immunoglobulins as well as the shortage situation of normal human immunoglobulins in EU/EEA countries. As the next step, EMA proposed to publish a shortage catalogue entry for normal human immunoglobulins. The SPOC WP will be consulted on the draft.
2.	**Presentations from SPOC WP Members:**
	a) Slovenia – National marketing status system – first steps to improve information sharing SI SPOC WP member presented a new notification system implemented in Slovenia to improve information sharing on the marketing status. SI SPOC WP also explained that the system operates through a combination of Microsoft Forms and SharePoint. Comments raised EMA asked whether SI had received any feedback from industry on the new system. SI SPOC WP member confirmed the feedback received has been positive, nonetheless, certain technical aspects of the system still require manual efforts.
	b) Poland – Integrated System for Monitoring the Trade in Medicinal Products (ZSMOPL) PL SPOC WP member presented the monitoring system used in Poland which enables, e.g., monitoring the trade in medicines at retail and wholesale level and transmits this information to the competent authorities. Comments raised Several SPOC WP members discussed the system's capabilities to predict shortages of medicines as well as the data uploading process by the concerned entities.
	c) Greece – Platform for monitoring the pharmaceutical supply chain

Tuesday, 16 April 2024	
Item	**Topic**
	A GR Ministry of Health (MoH) representative presented a system for monitoring pharmaceutical supply chain in Greece (ISPADIF) and explained that the system automatically collects data in (near) real-time from all relevant stakeholders in the supply chain. Additionally, information on system's limitations, challenges and planned next steps was also provided. Comments raised EMA asked whether the system includes the medicines from the Union list of critical medicines and it was clarified that while most medicines from the Union list are included, additional medicines are also included in the system.
3.	**Joint Action on Shortages (CHESSMEN): general update and findings from the Work Packages:**
	a) WP1 – Coordination, management and evaluation WP1 Lead provided an update on the JA CHESSMEN activities including exchange of information and sharing of best practices amongst MSs. Additionally, the SPOC WP was informed about an upcoming CHESSMEN meeting in Lisbon which will take place on 17-18 June 2024.
	b) WP5 – Shortage root causes WP5 Lead presented the results of the analysis of the root causes of medicine shortages extracted from the national registers of shortages - differences between the EU/EEA national notification systems were observed and a higher granularity of the information would enable more detailed understanding of the reasons for medicine shortages. Comments raised EMA proposed to use a unified classification for reporting root causes of medicine shortages and noted that the existing SPOC WP classification system could be revised and implemented by the MSs if required.
	c) WP8 – Shortages preventive and mitigation strategies WP8 Lead presented the ongoing activities and the results of the survey on effectiveness of preventive measures as well as the effectiveness of mitigation measures. The next steps will include the establishment of two subgroups focused on prevention and mitigation, respectively. Additionally, WP8 will collaborate with WP6 to ensure synergies and will attend the workshop on parallel trade and export.
4.	**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 of the Union list of critical medicines. During this phase, the process of the data collection by MSs will be done in three batches – the deadline for MSs to complete the review of Batch 1 is in early May 2024. EMA also highlighted the importance of timely uploads of data by MSs to allow data processing activities. Lastly, EMA provided a general update on the "Union List" Working Group activities.

Tuesday, 16 April 2024	
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	b) Shortage prevention and mitigation plans (SPP/SMP) EMA presented a summary of the consultation on the templates of shortage prevention and mitigation plans, including the comments received from industry associations, and informed the group about the next steps, i.e., the adoption process and publication.
5.	**MSSG-led activities:**
	a) MSSG recommendations for supply chain vulnerabilities EMA presented the toolkit of recommendations MSSG can take to strengthen supply chains of critical medicinal products and the comments received during the SPOC WP and the CMDh written consultations as well as comments received from DG HERA. EMA also informed that the adoption of the toolkit of recommendations will take place via written procedure and the document will be published after adoption. *Post-meeting note: the MSSG recommendations were adopted by the MSSG on 19 April and published on 23 April 2024*
	b) Solidarity Mechanism: feedback from the pilot EMA informed the SPOC WP about the positive outcome of the first solidarity mechanism procedure for 5-fluorouracil. EMA also presented the next steps to be taken and the launch of an additional pilot case for cisplatin. Comments raised The group discussed the particularities of the 5-fluorouracil case in relation to the stocks that were available. **Agreed actions:** • EMA to share the experience and feedback from the 2nd pilot.
6.	**Belgian presidency of the EU: initiatives on medicine shortages** An adviser to the Belgian Deputy Prime Minister and Minister of Social Affairs and Public Health provided an oral update on the initiatives on medicine shortages undertaken in the context of the Belgian presidency of the EU such as the launch of the CMA and the pilot project on pricing and reimbursement of antibiotics. The adviser welcomed the work of the SPOC WP and the MSSG.
7.	**Technical Discussion on Core Topics: Definition of medicine shortage - follow up discussions from the SPOC WP meeting in December 2023** A SPOC WP member presented the background on the definition of a medicine shortage and results of the survey circulated to SPOC WP members. All SPOC WP members agreed that all medicines should be included in the scope of a shortage however differing opinions were expressed regarding at which level of the supply chain the definition should apply. Comments raised SPOC WP members discussed amongst other points the possibility of establishing thresholds and timelines in the context of the definition of medicine shortage.

Tuesday, 16 April 2024	
Item	**Topic**
	Agreed actions: • SPOC WP and the Topic Lead to reflect on the way forward and bring the topic back for discussion at a future meeting.
8.	**Update on EDQM shortage initiatives** EDQM provided an update on their shortage related initiatives including formalisation of Working Group on Medicine Shortages (Methodological guide WG). Furthermore, EDQM informed that the WG will include participation of one representative from the SPOC WP as observer and that the kick-off meeting is planned for 17-18 September 2024.
9.	**Shortage communication activities: Status update on medicine shortage communication (MSC) template** EMA informed the SPOC WP about the need to change the way shortages are communicated to the public and presented the background information, proposed next steps and a new proposed MSC template.
10.	**Presentation from OECD: Securing Medical Supply Chains in a Post-Pandemic World** OECD presented the key findings from the Report on Securing Medical Supply Chains in a Post-Pandemic World Report, focusing on vulnerabilities of medical supply chains, policies for enhancing supply chain security and development of additional crisis capabilities.
11.	**Presentation from WHO EURO: Availability issues of tuberculosis medicines** WHO presented the availability issues of tuberculosis medicines within WHO European region and potential next actions.
12.	**Refresher on shortage notifications and requests for information** The topic could not be taken.
13.	**Wrap-up and next steps** The agreed actions are detailed above.
14.	**Closing remarks** The Chair thanked the SPOC WP for their active participation at the F2F meeting and informed that the next F2F meeting will take place on 7-8 October 2024 at EMA premises in Amsterdam.

Next meeting: 22 May (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).