06 November 2024
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European Medicines Agency

Meeting Summary — Medicine Shortages (SPOC) Working Party

7–8 October 2024, hybrid meeting — F2F + Webex

Chair: Monica Dias (EMA), Veronika Horvath (NNGYK, Hungary)

Monday, 07 October 2024	
Item	**Topic**
1.	**Welcome, declarations of interest, adoption of draft agenda** The Chair and Vice-Chair welcomed participants to the face-to-face (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
2.	**Adoption of draft minutes of the SPOC WP meeting held on 11 September 2024** The Vice-Chair informed the working party that the minutes of the meeting held on 11 September 2024 had been distributed one week prior to the meeting. No comments were received before or during the meeting. The minutes were adopted.
3.	**SPOC WP information exchange: refresher on shortage notifications, requests for information and voluntary solidarity mechanism** EMA Secretariat reminded the SPOC WP of the different types of shortage notifications, their timelines and technical submission details. EMA highlighted the possibility of ad-hoc individual training sessions on technicalities and EMA Secretariat support, in case of queries or technical issues. Additionally, EMA noted that one of the criteria to launch the Voluntary Solidarity Mechanism (VSM) (i.e. prior escalation of the shortage to the SPOC WP) was not fulfilled in recent VSM procedures, and highlighted the importance of escalating critical shortages in a timely manner and before the VSM is triggered.

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4.	**EC DG SANTE update** EC DG SANTE informed the SPOC WP about health-related political guidelines and the incoming Health Commissioner Mission letter, highlighting the Critical Medicines Act and the revision of the Pharmaceutical Legislation.
5.	**EC DG HERA update** EC DG HERA provided feedback from the joint Critical Medicines Alliance (CMA) working group meeting that took place in October 2024, highlighting the strategic recommendations, and the upcoming strategic report. Comments raised A SPOC WP member asked when the strategic recommendations will be finalised, to which EC DG HERA replied that the recommendations will be finalised in November 2024. The respective CMA working groups will consult these strategic recommendations and include them in the strategic report that is planned for release in January 2025.
6.	**Update on EDQM shortage initiatives** EDQM representative presented an update on EDQM shortage initiatives, including an update on milestones of the European Drug Shortages Formulary project, i.e. technical recommendations provided by expert in the European Drug Shortages Formulary working party, and the related next steps. The European Drug Shortages Formulary is a compilation of texts (monographs), describing methods for the preparation and quality control of standardised unlicensed pharmaceutical preparations that could be used as a temporary replacement for potentially unavailable, essential licensed medicines. Feedback from the Methodological Guide Working Group kick-off meeting was provided, which included the discussion about the content and structure of the methodological guide. Comments raised EMA Chair asked whether the Union list of critical medicines will be considered in the context of the activities of the Methodological Guide Working Group and whether the scope of the European Drug Shortages Formulary goes beyond critical shortages. EDQM acknowledged the importance of the Union list of critical medicines, though other lists will also be considered. EDQM confirmed that the primary focus when developing recommendations is medicines in critical shortages, as this tool is meant to be used as a last resort once other options have been exhausted. EMA further asked whether there are any specific pharmaceutical forms for which technical recommendations are being developed. EDQM explained that the focus lies on oral formulations for community pharmacists, whereas recommendations on parenteral formulations could be considered for hospital pharmacists, subject to feasibility.

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7.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG meeting on 18 September 2024 SPOC WP Vice-Chair provided the feedback on the topics discussed during the September meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), highlighting an update on the Mpox outbreak in Africa, the work of the CMA, a European Shortages Monitoring Platform (ESMP) update and EMA's activities to prepare for the upcoming autumn/winter season and follow-up actions on shortages of GLP-1 Receptor Agonists (GLP-1 RAs). Finally, the Vice-Chair noted that the MSSG discussed and endorsed the proposal for the Medicine Shortage Communication (MSC) process and pilot.
	b) Feedback from the MSSG WG on Solidarity Mechanism EMA provided the feedback from the MSSG Working Group (WG) on VSM meeting held in October 2024. EMA explained that discussion focused on international solidarity cooperation, the link between the VSM and the Union Civil Protection Mechanism, identification of barriers to transfer stocks between countries and ways to improve public communication about the procedures. <u>Comments raised</u> One SPOC WP member asked about the flexibility of the VSM conditions and amendment possibilities as for the latest medicine included in the VSM certain conditions were not met. EMA noted that a validation process for the VSM is in place, though there are certain flexibilities to the conditions because the pilot is currently ongoing. Amendments to the conditions have already been made after the first three cases and the procedure will be fine-tuned when the pilot phase ends. In addition, the need to improve communication with MAHs, which are able to support MSs during VSMs was highlighted as other countries beside the triggering MS may also be impacted.
8.	**Tour de table: exchange of best practices on import licences** A SPOC WP member reflected on the lessons learned from the latest VSM procedure, for etoposide, highlighting the effectiveness of a special import license, which allowed for swift product importation of foreign stocks. This was followed by a "tour de table", where SPOC WP members exchanged information on national procedures for import licenses. **Agreed actions:** • EMA to circulate a follow-up survey in writing with some additional questions to compile all the information
9.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	a) Availability of antibiotics — preparedness for autumn/winter 2024–2025 EMA provided an update on the activities undertaken in preparation for the upcoming autumn/winter season, including outreach to key MAHs and manufacturers of certain antibiotics used to treat respiratory infections. Based on feedback from international regulators, signals

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	from the SPOC Working Party, and input from key MAHs, no EU wide shortages are expected at this point in time. Finally, EMA noted the importance of continuing to monitor the situation closely and informed that, as a next step, a social media campaign will be launched. Comments raised Several SPOC WP members informed the working party members about the supply situation for antibiotics in their territories, highlighting national monitoring efforts and noting that the situation seems to be improved compared to last year.
	b) Impact of the takeover of Catalent by Novo Holdings on the supply of medicines The topic could not be taken.
	c) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member informed about a critical shortage of vinblastine, caused by continuous moving shortage end target dates and complicated by hospital pharmacists' inability to import the product. The SPOC WP member noted that the shortage has been reported by a few MSs in the past year and informed about their intent to launch the VSM to address the critical situation. One SPOC WP member noted a shortage of an antiepileptic medicinal product and highlighted the lack of information on the shortage from the company. A SPOC WP member highlighted a critical shortage of a beta blocking agent due to manufacturing issues and increased sales. SPOC WP members exchanged information about the shortages of the abovementioned medicines in their territories. **Agreed actions:** • SPOC WP members to submit critical shortage notifications to EMA for circulation to the SPOC WP if the abovementioned shortage situations in their territories deteriorate.
10.	**Critical shortages escalated to the SPOC Working Party:**
10.1	**Ongoing shortages**
	a) Oncology medicinal products from MAH: Accord Healthcare B.V.
	• **Overview of the overall shortage situation ("Closed session" for SPOC WP members)** EMA presented an overview of the supply situation for Accord's oncology portfolio, highlighting that oncology medicines from Accord were involved in four VSM procedures.
	• **Presentation delivered by MAH: Accord Healthcare B.V., followed by a Q&A session** Accord presented an overview of the supply situation for their oncology portfolio, reasons behind supply constraints as well as mitigation measures and product allocation between countries.

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	Comments raised SPOC WP members called for improved communication from the local affiliates. Stock allocation criteria and possibilities to cooperate with NCAs in this process was discussed. Accord further elaborated on their long term measures to address shortages of oncology medicines. EMA Chair closed the session emphasising the regulators' willingness to support Accord to increase supply and the need to improve communication between HQ and affiliates.
	• **Debrief on next steps/actions ("Closed session" for SPOC WP members)** SPOC WP discussed next steps considering the presentation from Accord. EMA will continue monitoring the supply situation and the mitigation proposals from Accord.
	b) Supply and availability of Novo Nordisk medicinal product portfolio
	• **Effectiveness of shortage mitigating measures – Hungarian experience** HU SPOC WP member provided information on the root cause of the shortages in their territory and reflected on the interactions with stakeholders and mitigation actions and their effectiveness. HU SPOC WP member further reflected on MSSG recommendations and the implementation of various national mitigation measures. Comments raised EMA noted that there may be a need to share information and reflect on the effectiveness of mitigation measures put in place by different MSs in the SPOC WP GLP-1 RA subgroup.
	• **Overview of the current supply and availability situation** EMA provided a summary of the results of a survey with the SPOC WP to assess the criticality of the discontinuation of selected insulin products (Levemir, NovoMix 50, Mixtard 50, Fiasp PumpCart, as well as Penfill, FlexPen, InnoLet presentations for Actrapid, Insulatard, Mixtard 30) over the next two years, until end of 2026. The impact of the discontinuation is still being assessed. As next steps, the impact will be discussed with clinical experts and international partners. Finally, EMA provided an update on the status of the DARWIN EU drug utilisation study on GLP-1 Receptor Agonists.
	• **Discussion and next steps** The SPOC WP discussed the criticality of the discontinuation of certain products, the clinical impact and availability of alternatives, and potential dissemination strategies to patients and HCPs.
	c) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH
	• **Overview of the overall shortage situation ("Closed session" for SPOC WP members)** EMA presented an overview of the supply situation for different strengths of Pegasys in EU/EEA market, outlining the background, root causes, and mitigation actions.

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	• **Presentation delivered by MAH: Pharmaand GmbH, followed by a Q&A session** Pharmaand presented an overview of the root cause of the shortage of Pegasys and its market impact, short and long-term shortage mitigation strategies, and upcoming deliveries and allocation between countries. Lastly, the MAH presented their regulatory strategy. The SPOC WP noted the need for the MAH to align the information on delivery and allocation shared at national and EU level and the need to first, revisit their stock allocation process and second, have flexibility in shifting stocks.
	• **Debrief on next steps/actions ("Closed session" for SPOC WP members).** SPOC WP members debriefed on the presentation and discussion with the MAH and the next steps.
	d) Nakom NAP (levidopa/carbidopa) – MAH: Sandoz A SPOC WP member presented the shortage of Nakom caused by manufacturing issues, the results of the criticality assessment, and the mitigation measures undertaken at national level. The shortage is expected to end in October 2024.
	e) Medicinal products containing salbutamol (inhalation use) The topic was postponed.
	f) Medicinal products containing doxycycline EMA provided an overview on the outcome of the criticality assessment for a shortage of doxycycline. EMA informed the working party that based on the feedback received alternatives were available in most of the impacted MSs. Additionally, EMA informed about an alternative MAH that has additional supplies available for MSs that may experience a critical shortage situation. <u>Comments raised</u> A few SPOC WP members who initially reported critical shortages of doxycycline confirmed that the situation is no longer critical due to upcoming deliveries and availability of alternatives.
	g) Chenpen NAP (epinephrine) – MAH: Bioproject Pharma; Jext NAP (epinephrine) – MAH: Alk-Abello EMA provided an update on the shortage of epinephrine containing medicinal products, including the feedback from meetings with several epinephrine manufacturers. EMA informed that additional supplies are available from alternative manufacturers for the MSs that may experience a critical situation.
	h) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk EMA provided an update on the shortage of NovoSeven by informing about the outcomes of the latest meeting between EMA, some SPOC WP members and the MAH. In addition, EMA informed that while there might be intermittent shortages of other human factor VIII medicinal products there are alternatives available to compensate.

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	As next steps, EMA will monitor the status of the immediate mitigating measures and supplies of NovoSeven.
10.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments to the written updates)
	i) Medicinal products from Cheplapharm j) Semintra (telmisartan) CAP – MAH: Boehringer Ingelheim Animal Health k) Synulox NAP (amoxicillin/clavulanic acid) – MAH: Zoetis l) Remdesivir for to treat Feline Infectious Peritonitis
11.	**GMP/GDP Inspectors Working Group:** EMA provided an update following the IWG meeting in mid-September 2024 on the work to revise two chapters of the GMP guidelines. The updates aim to strengthen the connection between the GMP guidelines and the ICH Q9 R1 recommendations on using quality risk management principles to support the prevention of quality and manufacturing related shortage availability issues.

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12.	**European Shortages Monitoring Platform (ESMP) update** EMA gave a progress update on the development of the ESMP, including the go-live for routine shortage reporting for centrally authorised medicines by MAHs at the end of November 2024. Outcomes from the recent user acceptance testing (UAT) with NCA subject matter experts (SMEs) and MSSG-ESMP WG were presented. EMA invited the participants to volunteer for testing the ESMP in a crisis simulation exercise which is planned to take place in December 2024. Lastly, the design goals and main features of the Monitoring Country Tool (MCT) for monitoring of national supply and demand was also presented. <u>Comments raised</u> SPOC WP discussed Product Management Service (PMS) data. EMA noted that while NCAs are not required to map their local product databases to PMS they are encouraged to do so to prepare for a situation where they will have to report via the ESMP. Lastly, EMA added that a communication strategy has been planned to inform MAHs of their reporting requirements to the ESMP. **Agreed actions:** • EMA to consider involving NCAs in the communication campaign to improve awareness of ESMP reporting requirements among NAP (and CAP) holders.
13.	**Presentations from SPOC WP Members:**
	a) Italy – Stock traceability system IT SPOC WP member presented the national stock traceability system that has been in place since 2001 and can track products throughout the supply chain, from the manufacturer to the patient. IT SPOC WP member reflected on their national experiences using the data to mitigate shortages.
	b) Czechia – New measures and systems for availability monitoring CZ SPOC WP member presented national measures and systems for availability monitoring, introduced in 2024. CZ SPOC WP explained that the reported shortages are being evaluated and flagged, when appropriate, subsequently triggering a cascade of further obligations on MAHs, pharmacies and distributors. CZ SPOC WP member added that the new system required extensive IT solutions for monitoring stock levels, introduction of a new methodology for shortage reporting, and communication activities to all stakeholders in the supply chain.
	c) Bulgaria - Shortage monitoring system (SESPA) and Real-world data to support the shortage definition BG SPOC WP alternate presented an overview of the Bulgarian shortage monitoring system SESPA and its potential as an analytical tool in shortage monitoring. Additionally, the SPOC WP was informed how the use of real-world data could support the harmonised implementation of shortage definition.

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14.	**Definition of medicine shortage**
	a) Drug Shortages: definitions across different market types WHO representative presented on the definition of drug shortages across different markets globally and gave an overview of WHO activities in this area. WHO representative highlighted that a very large number of drug shortage definitions were found, with definitions focussing on both the demand and supply side of the equation. The presenter highlighted that low- or middle-income countries (LMICs) and countries with weaker regulatory capacities generally find managing drug shortages challenging and noted that WHO intends to work further on their drug shortage definitions.
	b) Status update on the activities of the SPOC WP subgroup SPOC WP member leading the subgroup provided an update on the activities, including the kick-off meeting, distribution of the survey, and plan for the work ahead.
15.	**ISPE (International Society of Pharmaceutical Engineering) Drug Shortages Prevention Initiative & Model** ISPE representative presented on the work of the ISPE Drug Shortages Prevention Initiative, outlining specific quality, regulatory, and technical recommendations for pharmaceutical manufacturers to help prevent drug shortages. ISPE presented the potential for regulatory harmonisation opportunities from a global perspective, recommended finding avenues for global collaboration on shortages, and ways to recognise supply resilience. On the latter, ISPE highlighted the ongoing development of a gap assessment tool for industry to assess their performance and their supply resilience. Lastly, ISPE's new risk management guide, aligned with ICHQ9(R1) and including risk management practices for drug shortages, is expected to be published by early 2025. Comments raised The group discussed ISPE support to generic manufacturers, methodology for the supply resilience gap assessment and that it is currently challenging to have an industry-wide overview of how MAHs are progressing in their shortage prevention plans.
16.	**Improving access to PDMPs: recommendations from the SUPPLY project** Representatives from the European Hematology Association (EHA) and European Blood Alliance (EBA) presented the SUPPLY project, which aims to increase and strengthen the resilience of plasma collection in the EU to enable a stable and adequate supply of plasma derived medicinal products (PDMPs). The speakers highlighted that the goals of the project include an understanding on immunoglobulin use, harmonisation on treatment prioritisation during shortages, and collaboration.
17.	**Joint Action on Shortages (CHESSMEN): general update and findings from the Work Packages:**
	a) WP 2 – Communication, dissemination and exploitation PT SPOC WP expert presented the recent activities of the WP2, highlighting recent Joint Action (JA) CHESSMEN meetings, study visits and collaboration with other relevant groups. SPOC WP

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	was informed about the stakeholder engagement plan that aims to raise awareness on JA CHESSMEN, ensure partner engagement, enhance collaboration, and increase transparency.
	b) WP 5 – Shortage root causes ES SPOC WP expert gave an overview of the progress on the shortage root cause analysis deliverables, outlining methodology, preliminary results and the ongoing drafting of a final report. ES SPOC WP expert further presented preliminary findings related to common manufacturing and distribution issues. ES SPOC WP expert concluded that the implementation of a common EU template is crucial to improving future analyses of medicine shortage root causes.
	c) WP 6 – Best practices to address medicine shortages SI SPOC WP expert provided an update on the WP6 deliverables and highlighted that the final report on best practices was shared with the SPOC WP for final comments. SI SPOC WP expert highlighted that following the written consultation, best practices in monitoring, reporting, and managing medicine shortages will be presented at a multistakeholder workshop planned for November 2024. The SPOC WP was additionally informed about the state of play of the deliverables linked to recommendations for the development of national lists of critical medicines and demand forecasting at national level and next steps.
	d) WP 7 – Digital Information Exchange DE SPOC WP member highlighted activities completed and the ongoing work on a framework for a concept platform to monitor and manage medicine shortages which aims to identify ways to enhance national systems and IT tools, standardise data exchange, and boost transparency and information accessibility. Current activities focus on common datasets and identification of data sources, harmonisation on the definitions used and proposals to address data gaps. DE SPOC WP member reassured that activities on harmonisation and standardisation will be compatible with current and future systems for monitoring supply shortages, such as ESMP.
	e) WP 8 – Shortages preventive and mitigation strategies As a follow up to the SPOC WP meeting in September 2024, FI SPOC WP member presented the results of the survey on export restrictions where it was identified that half of surveyed countries had export restrictions. FI SPOC WP member concluded that while most surveyed countries viewed export restrictions as a beneficial critical shortage mitigation measure, it should be used in a duly justified, transparent manner and in line with the principles of European solidarity.
18.	**European Medicines Agencies Network Strategy (EMANS) to 2028** EMA presented an update on the EMANS strategy and its focus areas. EMA presented the approach taken to review and update the strategy and the next steps regarding stakeholder engagement, including public consultation and a multistakeholder workshop. *Post-meeting note: Draft EMANS to 2028 was released for a 2-month public consultation period until 30 November 2024.*

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19.	**Medicine Shortage Communication (MSC) update** EMA informed the SPOC WP that, following the endorsement from the MSSG on 18 September 2024, the new MSSG-led MSC process and template will be rolled out in October through a six-month pilot, until March 2025. EMA added that the scope of the pilot includes all critical shortages for which the root cause is not related to quality, safety or efficacy issues; The MSC process will start following a SPOC WP request. Subject to experience during the pilot, MSSG may adjust the template or process before its implementation.
20.	**HMA/EMA Task Force on Availability of Authorised Medicines** (TF-AAM)
	a) Thematic Working Group 2: Update on communication activities EMA gave an update on the good practice guidance on communication and the good practice guidance on prevention. EMA informed about the ongoing consultation of the update on the good practice guide on communication; EMA will finalise the update by the end of 2024 and will consult with the SPOC WP. A proposal to have a webinar with journalists in November 2024 was also presented. EMA added that for the good practice guide on prevention of shortages, the review and implementation are currently being discussed with patient and healthcare professional representatives. It was suggested to hold a dedicated webinar on this topic for patients and healthcare professionals which will be further discussed and agreed within EMA.
	b) Thematic Working Group 1: Union list of critical medicines EMA updated the SPOC WP on the progress of the second version of the Union list. Before finalising the list, EMA informed on the planned engagement activities with various stakeholder groups and across the regulatory network for Q4 2024. Version 2 of the Union list will be published in December 2024.
21.	**Hungarian presidency of the EU: initiatives on medicine shortages** SPOC WP Vice-Chair presented the medicine shortages initiatives that have been and are planned to be undertaken during the Hungarian presidency of the EU.
22.	**Status update on any new strategic measures implemented at national level (e.g., critical medicines lists, stockpiling requirements)** The topic could not be taken.
23.	**AOB** No AOB topics raised.
24.	**Wrap-up and next steps** The agreed actions are detailed above.
25.	**Closing remarks**

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	The Chair thanked the SPOC WP for their active participation at the F2F meeting and informed that the next F2F meeting will take place in the first half of 2025 at EMA premises in Amsterdam.

Next meeting: 6 November 2024 (Webex)