20 November 2023
EMA/497161/2023
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

26 October 2023, from 10:00 to 18:30 (CEST), hybrid meeting
27 October 2023, from 09:00 to 16:30 (CEST), hybrid meeting

Chair: Monica Dias (EMA), Vice-Chair: Patricia Tabernero (AEMPS, Spain)

Thursday, 26 October 2023	
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. Agenda was adopted with no additional points under AOB.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 12 September 2023** The Vice-chair informed that the minutes of the meeting held on 12 September 2023 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: General update on joint EMA/HERA preparedness activities EMA presented the feedback on the supply situation for antibiotics as well as paediatric analgesics, antipyretics and cough syrups received from various stakeholders. EMA updated the group on the outcomes of the matching of supply and demand as well as an overview of antibiotics shortages reported to EMA by the SPOC WP. EMA presented the next steps which will include continuous monitoring of the situation and discussion with key players.

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	DG HERA updated the group on possible short to mid-term mitigation measures discussed at the HERA Board to tackle supply issues of antibiotics beyond ongoing measures. **Agreed action:** • SPOC WP to continue reporting to EMA (critical and non-critical) shortages of the set of antibiotics. • SPOC WP to inform EMA how does the shortage situation compare to the last year. • EMA to continue requesting the MAHs for information on possible changes to their supply forecasts.
	b) Feedback from the Q3 2023 Meeting of the Global Regulatory Working (WG) Group on Drug Shortages EMA provided an overview of the meeting of the Global Regulatory Working Group on Drug Shortages on 21 September 2023, including the preparation for influenza season and current supply of antibiotics and paediatric analgesics, and informed that the members of the Working Group shared updates from their jurisdictions on medicine shortages of concern**.**
	c) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member presented the shortage of flecainide and the mitigating measures undertaken. In particular, the SPOC WP member presented an overview of a dispensing protocol used for a group of patients with a potential life-threatening impact. Comments raised SPOC WP members shared that while some shortages of this antiarrhythmic medicine are occurring in other MSs, the overall situation is relatively stable and mitigating measures are being implemented.
	d) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets EMA presented the feedback collected so far from the SPOC WP, industry associations and MAHs of CAPs on the supply of medicinal products with manufacturing steps in Israel and any potential subsequent impact. Currently, no impact on supply has been identified. **Agreed actions:** • SPOC WP to report any impact of the Israel-Hamas war at the national level for essential medicines. • EMA to monitor new developments in cooperation with Industry Associations/individual MAHs in the context of preparedness activities.
	e) ECHA proposal to ban the use of per- and poly-fluoroalkyl substances (PFASs) EMA informed that ECHA published a proposal for a European ban of per- and poly-fluoroalkyl substances (PFASs). As PFASs are used in the development, manufacturing and supply of medicinal products a ban will have an important impact on human and veterinary medicinal products as well as medical devices. A 6-month consultation with stakeholders ended in September. ECHA's scientific committees are now evaluating the input received

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	during the consultation and a final decision by the EC expected in 2024. EMA's remit is limited in the proposed legislative and policy changes, but EMA is monitoring the process closely and interacting with relevant Industry Associations. Comments raised The SPOC WP discussed the potential impact on availability of medicines (e.g., withdrawals from the market), especially for old medicines with limited alternatives, derogation period and exemptions. SPOC Members shared the concerns of industry and the effect on production in Europe.
4.	**Ongoing critical shortages reported by the SPOC WP:**
	a) Glucagon-like Peptide-1 (GLP1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide); MAH: Eli Lilly Nederland B.V.
	• **Overview of the overall shortage situation ("Closed session" for SPOC WP members)** EMA presented the current supply situation for Trulicity and Rybelsus – where shortages are expected until the end of the year – and Victoza, Ozempic, and Saxenda – where shortages will continue into 2024. Furthermore, EMA presented the feedback from international regulators on the supply situation for GLP-1 receptor agonists. Comments raised SPOC WP members shared an overview of the measures implemented or being considered at a national level.
	• **Presentation delivered by MAH: Novo Nordisk, followed by Q&A session** Novo Nordisk presented the short- medium- and long-term mitigation strategy and a shortage overview. Comments raised SPOC WP members highlighted the pressure on patients and Health Care Professionals (HCPs) and asked, amongst others, questions on the process for allocation of stocks to EU/EEA countries. The group discussed the ongoing mitigation measures and the expected impact. Novo Nordisk explained the challenging situation and their efforts to mitigate the shortages. The MAH elaborated on their allocation criteria.
	• **Debrief on next steps/actions ("Closed session" for SPOC WP members).** The SPOC WP debriefed on the presentation and discussion with the MAH. **Agreed actions:** • Escalate to the MSSG and Novo Nordisk to present at the November 2023 meeting.

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	b) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim; • **Overview of the overall shortage situation ("Closed session" for WP SPOC members)** EMA provided an update on the shortage situation, including ongoing regulatory activities. EMA set the scene for the MAH intervention and informed that the scope of the presentation will include an overview of shortage mitigation activities and 2024 supply plans.
	• **Presentation delivered by Boehringer Ingelheim, followed by Q&A session** The MAH presented its ongoing shortage mitigation plans, including details of the key milestones in the coming year. The MAH also presented the details of their 2024 supply forecast and informed that the overall timeline for the shortage remains unchanged. Comments raised SPOC WP member asked for clarification on the increased demand and the outlook worldwide. Boehringer Ingelheim elaborated on the worldwide increase in stroke prevalence, and the measures implemented to address it. • **Debrief on next steps/actions (*"Closed session" for WP SPOC members*).** The SPOC WP debriefed on the presentation and discussion with the MAH.
	c) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH EMA provided an update on the latest information on shortages of medicinal products marketed by Cheplapharm such as Visudyne, Valcyte (valganciclovir) and Zypadhera (olanzapine). Comments raised One SPOC WP member raised a shortage of sotalol from Cheplapharm. **Agreed actions:** • SPOC WP to inform EMA if shortages of products already identified occur in their respective country or situation worsens. • SPOC WP to communicate new critical shortages of medicinal products marketed by Cheplapharm. • EMA to request Cheplapharm for an overview on sotalol shortage in the EU.
	d) Attention deficit hyperactivity disorder (ADHD) medicine shortages EMA presented the results from the recent Request for Information to the SPOC WP on the supply situation of ADHD medicines in Europe. Furthermore, EMA presented the feedback from international regulators on ADHD medicine shortages in other jurisdictions. Lastly, EMA highlighted that interactions with key manufacturers of ADHD medicines have been undertaken and will continue to take place in the context of shortage management.

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	Comments raised SPOC WP members discussed the multiple shortage root causes for lisdexamphetamine containing medicinal products and reiterated the need for the MAHs to fulfil their obligations to the European patients. **Agreed actions:** • EMA to continue monitoring the situation and liaising with the relevant manufacturers.
	e) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited EMA presented the actions undertaken to mitigate the impact of the withdrawal of Integrilin from the EU/EEA market, such as dissemination of shortage DHPC and interactions with alternative suppliers. **Agreed actions** • EMA to continue liaising with an alternative eptifibatide suppliers.
	f) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma; Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH EMA provided an update on the Pazenir withdrawal from the majority of the EU markets and presented the impact for each affected MS. As next step, EMA will continue to interact with these MAHs to identify mitigating actions. Comments raised SPOC WP members discussed the possible actions to address companies' commercial decisions including possibilities to use of government-owned manufacturing sites. EC noted the revision of the pharmaceutical legislation related to earlier notifications and potential facilitation of marketing authorisation transfers.
	g) Norditropin (somatropin) – MAH (Novo Nordisk) EMA provided an update on the shortage situation of Norditropin Nordiflex and Norditropin FlexPro caused by production capacity issues. EMA presented the feedback on the supply situation of alternative somatropin containing medicinal products and any possibilities to mitigate the impact in cooperation with other key MAHs. **Agreed actions:** • EMA to continue engaging with somatropin MAHs and manufacturers.
5.	**Shortage communication activities:** • **General update on EMA communication activities** EMA provided an update on EMA's communication activities on shortages, how EMA has increased communication through its shortage catalogue and the plans to increase non-product related communication in future. In terms of planned actions in the near future EMA highlighted a social media campaign to promote the rational use of antibiotics as well as dedicated communication materials to support the publication of the Union list of critical medicines.

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	Comments raised SPOC WP highlighted the benefits of involving EMA's PCWP and HCPWP in drafting any communication. EMA confirmed that an update will be presented to these groups in November 2023, and that those groups are involved and consulted in the highlighted activities. A number of SPOC WP members asked for further details on the campaign on antibiotics, including the social media platforms and possibilities to apply the campaign at national level and translate to local languages. EMA clarified that the campaign will be launched through LinkedIn and Twitter social media platforms and while translations have not been planned, the materials can be shared with the MSs for application at national level. • **Feedback on shortage DHPC review experience** EMA presented an overview of the DHPC review process with SPOC WP, including shortage DHPCs published so far and commonly reported challenges. Comments raised SPOC WP members noted the long lead times to get a DHPC agreed and suggested earlier notification as a way to solve this issue and to ask MAHs to more routinely issue DHPCs. A SPOC WP member also noted the fact that GVP Module XV is linked to safety issues and not tailored for shortage DHPCs.
6.	**HMA/EMA Task Force on Availability of Authorised Medicines – update on key work plan deliverables:**
	a) TGW2 (Communications) TWG2 provided an update on the status of the ongoing activities such as monitoring the implementation of good practice guidance for communication to the public on medicines' availability issues and revision of good practice guidance on prevention of shortages. Comments raised SPOC WP requested clarity on whether a good practice guide for industry on prevention/management of shortages of medicinal products for veterinary use is anticipated. EMA clarified that during the HMA/EMA multi-stakeholder workshop on shortages in March 2023 the activity has been agreed to be closed, for the time being.
	b) TWG1 (Availability and supply disruptions) TWG1 provided an update on the ongoing activities and elaborated on the status of the shortage prevention and mitigation plans (SPMP) as well as other activities in the work programme that have been finalised or closed.
	c) EU list of critical medicines EMA presented the milestones for Q4 2023 and the planned communication strategy. EMA explained the method to process the data from the MSs and showed the preliminary outcome of the Batch 1. Lastly, EMA presented the rollout plans for Phase 2, starting in 2024.

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	Comments raised SPOC WP members discussed possibilities to collect the feedback from the MSs on the methodologies for the identification of critical medicines at a national level, the process for updating the list based on vulnerability assessment and the data processing method to set up the initial version of the list. EMA highlighted the need to manage potential implications of the list and to focus on the prevalence of criticality across health care systems in the EU. EMA also alluded to the process in establishing the list of crucial medicines during COVID-19 PHE. Lastly, EMA confirmed that those medicines not meeting the pre-requisites will be under continuous monitoring and may be upgraded upon evaluation.
7.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)** • **General update on September 2023 MSSG** EMA provided a general update on the discussions held at the last MSSG meeting on 22 September 2023, including the publication of the toolkit on recommendations and the rollout of the solidarity mechanism. • **Update on the Solidarity Mechanism procedure** EMA presented the Solidarity Mechanism Procedure, including the conditions required to be met to initiate the procedure, communication, and next steps. Comments raised A SPOC WP member requested clarity on the process for requesting product from more than one Member State, and EMA confirmed that the process will be undertaken as presented.
8.	**European Shortages Monitoring Platform (ESMP)** • **Development status and plan for Q4 2023** EMA provided an update on the progress on the ESMP and the plan for developments in Q4 2023. EMA informed the group that a workshop on interoperability between the ESMP and the NCA systems took place at the beginning of October 2023, and that a subsequent workshop with Industry Subject Matter Experts on interoperability with industry systems is planned for November 2023. • **Submission of data on shortages for CAPs by MAHs to EMA in preparedness** EMA presented the data elements – based on the refined data elements within the Annex I of Guidance on detection and notification of shortages of medicinal products for MAHs in EEA – for the submission of shortage information on CAPs to the EMA through the ESMP.

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1.	**Presentations from SPOC WP Members:** **a) Estonia – Sorbisterit (polystyrene sulfonate): Impact of national stockpiling Agency on shortages management** EE SPOC presented a case study on managing a critical shortage of Sorbisterit (polystyrene sulfonate) by using a medicinal product from the Estonian national stockpile and in cooperation with the Estonian Stockpiling Agency. Comments raised SPOC WP members discussed the aspects of distribution and stock ownership as well as the active pharmaceutical ingredients of medicines in the national stockpile.
	b) Sweden – Financial measures on shortages reporting SE SPOC presented a new law introduced in Sweden on financial measures, i.e., penalties for late shortage reporting. SE SPOC noted the size of the fine has caused some interest by industry and the first case is yet to be evaluated. Comments raised SPOC WP members discussed fines related to non-reporting of shortages, the conditions for industry to receive the highest fine within the established range and publication of information on companies receiving fines. Some SPOC WP members also shared their experiences with fines at national level.
	c) Norway - Nordic Project on the Availability of Medicines for Children NO representative provided an update on a Norwegian project aimed to explore the possibilities for closer Nordic collaboration to ensure better access to authorised and marketed medicinal products for children in the Nordic countries. Comments raised HERA noted the possible use of pull incentives, ensuring a certain annual revenue to the company, covered by both, sales and public funds.
	d) Ireland – Supply/logistic challenges: addressing supply delivery delays IE SPOC member presented the supply and logistic challenges, including manufacturing, shipping, and distributor delays. These contribute to delayed supply resumption and have an impact on health systems.
2.	**Antibiotic shortages**
	• **Presentation delivered by MAH: Sandoz, followed by Q&A session** Sandoz presented an overview of their antibiotic production and supply situation as well as shortage prevention and mitigation actions in the mid- to long- term.

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	Comments raised SPOC WP members discussed shortage reporting and called for overall improvement in the interactions with local affiliates including on the fair distribution of stocks at national level. SPOC WP asked for clarification on product allocation and status on recent market changes. Sandoz elaborated on the current and future production capacity, product allocation criteria and interactions with their partners. Sandoz highlighted the need to work collaboratively with the MSs.
	• **Debrief on next steps/actions ("Closed session" for WP SPOC members).** The SPOC WP debriefed on the presentation and discussion with the MAH. **Agreed actions:** • Escalate to the MSSG and Sandoz to present at the November 2023 meeting.
3.	**Ad-hoc gap analysis: Lessons learned from the pilot procedure for supporting MSs on shortages management** Topic could not be taken and was postponed.
4.	**Availability issues for veterinary medicines** EMA provided an overview of the legal provisions in Regulation (EU) 2019/6 supporting the availability of veterinary medicinal products (VMPS) as well as the outcome of the veterinary breakout session of the HMA/EMA Multi-Stakeholder workshop on shortages held in March 2023. In addition, EMA provided an overview of the state of play concerning the European medicines agencies network strategy to 2025 (EMANS) actions related to VMP availability issues and shortages.
5.	**EC DG SANTE update** EC (SANTE and HERA) presented an update on the EC communication on shortages published on 24 October 2023, which outlined measures to address medicine shortages, including those already in place and set out in the pharmaceutical reform, as well as additional industrial policy solutions. EC highlighted that a dedicated Q&A session on the EC communication will take place at the November 2023 MSSG meeting.
6.	**EC DG HERA update** EC (HERA) presented an update on multiple ongoing programme actions, including medical countermeasures (MCM) prioritisation, AMR incentives, stockpiling initiatives, an update on Advanced Technology for Health Intelligence and Action IT System (ATHINA) development, amongst others.

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7.	**Joint Action on Shortages (CHESSMEN):**
	a) General Update on the JA CHESSMEN coordination activities IT SPOC WP member provided an update on the JA CHESSMEN actions including the current status of various deliverables, key milestones, and potential modifications. IT SPOC WP member noted the October 2023 management board meetings and highlighted that the next F2F JA meeting will take place in Portugal, in June 2023.
	b) Technical Update from CHESSMEN Work Package Leads The various CHESSMEN WP Leads presented the activities for the individual WP deliverables and progress, such as communication, dissemination and exploitation (WP 2), evaluation (WP 3), sustainability (WP 4), shortage root causes (WP 5), best practices to address medicine shortages (WP 6), digital information exchange (WP 7), shortages preventive and mitigation strategies (WP 8). Comments raised A SPOC WP member questioned the launch of a new JA on regulatory flexibilities mentioned in the EC communication and the potential link with the JA on shortages. EC confirmed that the JA on regulatory flexibilities under the EU4Health is separate from the JA on shortages, and SPOC WP noted the need for interconnection between these various joint actions. EMA reiterated the ongoing work in cooperation with the NCA subject matter experts (SMEs) on the common datasets and highlighted the need for alignment at EU level.
8.	**Technical Discussion on Core Topics: Definition of medicine shortage: progress made under JA on shortages and next steps** SPOC WP member presented the interpretations of shortage definition, including the definition included in the EC proposal for the Pharma Revision, with a view of aligning and agreeing within the SPOC WP on what is defined as a shortage. Comments raised SPOC WP members discussed the shortage duration and prescription status in case assessment and recording in internal management systems. The need to distinguish between the shortage definition versus the national shortage reporting and assessment criteria was highlighted. **Agreed actions:** • EMA to bring back the discussion to an upcoming SPOC WP meeting.
9.	**EDQM presentation on shortage initiatives** EDQM presented an update on their planned shortage initiatives in pharmaceutical compounding in "peace-time", such as methodological guide and EU shortages formulary. EDQM informed of its plans to publish a European Shortages Formulary, i.e., a compilation of texts (monographs) describing methods for the preparation and quality control of

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	standardised unlicensed pharmaceutical preparations that could temporarily replace potentially unavailable, essential licensed medicines.
10.	**Wrap-up and next steps** The agreed actions are detailed above.
11.	**Closing remarks**

Next meeting: 15 December 2023 (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).