17 June 2025
European Medicine Agency

Meeting Summary - Medicine Shortages SPOC Working Party

13 May 2025, from 09:30 to 13:30 (CEST), TEAMS

Chair: Monica Dias (EMA), Vice-Chair: Magdalena Rychter (GIF, Poland)

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 (WP). 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 meeting topics, the SPOC WP secretariat announced the applicable restrictions.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 10-11 April 2025** The Vice-Chair informed that the minutes of the meeting held on 10-11 April 2025 had been distributed one week prior to the meeting. One comment was received from EC DG SANTE regarding point 9: 'EC DG SANTE update on the Critical Medicines Act (CMA)'. The minutes were updated. No further comments were received during the meeting and the minutes were adopted with the abovementioned amendments.
3.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG Working Group (WG) on the Vulnerability Assessment Methodology EMA provided feedback from two technical meetings of the MSSG Vulnerability Assessment Methodology WG held on 15 April 2025 and 6 May 2025. EMA informed that the meetings covered a potential stepwise approach to the methodology, possible data sources, a presentation on the national approach to vulnerability assessment in one Member State (MS), as well as proposed next steps.

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	b) Draft recommendations of the MSSG to address anti-D immunoglobulin supply vulnerabilities EMA informed the SPOC WP about the finalisation of the drafting process for the MSSG recommendations aimed at addressing supply chain vulnerabilities for anti-D immunoglobulin. EMA stated that although these recommendations target anti-D immunoglobulins, they may also be relevant for other plasma derived medicinal products (PDMPs). As a next step, the recommendations will be shared with the SPOC WP for review and consultation, followed by endorsement by the MSSG. Comments raised Several SPOC WP members reported that there are no ongoing shortages of anti-D immunoglobulins in their countries and thanked the members of the SPOC WP subgroup on immunoglobulins for their work. EDQM representative also thanked the group for their work on the recommendations and informed that they will support future EDQM activities in the area.
4.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	a) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member raised concerns regarding an increase in sales of normal human immunoglobulins in their country. In response, some MSs indicated that there are currently no shortages of immunoglobulins in their territories. EMA noted that the topic will be further discussed in the SPOC WP subgroup on immunoglobulins. Additionally, the SPOC WP member reported a shortage of venlafaxine. A number of SPOC WP members responded that the supply situation is stable in their countries.
5.	**Presentation from Federation of Veterinarians of Europe (FVE):**
	Availability issues for medicinal products to treat feline infectious peritonitis (FIP) FVE representatives presented that only remdesivir and its breakdown product GS-441524 are currently treatment options for FIP for cats. FVE representatives noted that while remdesivir and its breakdown product (GS-441524) showed positive results in FIP research group, veterinarians in the EU do not have access to these medicines as they are only available outside of the EU. In addition, EMA presented the results of the SPOC WP survey on FIP treatment options which also highlighted the lack of treatments for FIP and indicated overall support for exploring possibilities to authorise a medicine for veterinary use in the EU. Comments raised One SPOC WP member indicated that the sale of an extemporaneous preparation containing GS-441524 for the treatment of FIP is permitted in their country. FVE representative inquired whether the extemporaneously prepared product could potentially be made available to other MSs in need to which EMA responded that this would need to be further explored.

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	Agreed actions: • EMA Veterinary medicines division to explore pathways to EU authorisation of GS-441524 considering feedback received. • SPOC WP members to continue monitoring the situation in their territories.
6.	**Critical shortages escalated to the SPOC Working Party:**
6.1	**Ongoing shortages**
	a) Shortage and discontinuation of insulin containing medicinal products EMA provided an update on the survey to the SPOC WP and EMA's Healthcare Professionals Working Party (HCPWP) related to the discontinuation of selected insulin products by Novo Nordisk and the identification of alternative products. Furthermore, EMA provided an update on ongoing discussions with the MAH Novo Nordisk as well as alternative MAHs on the management of these shortages. Comments raised No major concerns have been raised by SPOC WP members regarding the current situation in their countries.
	b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk This topic could not be taken due to time constraints.
	c) Medicinal products from MAH Viatris EMA provided an update on shortages of medicinal products from MAH Viatris and noted that the results from the SPOC WP criticality assessment indicate that the overall situation is stable and no EU-wide impact is expected. **Agreed actions:** • EMA to continue liaising with alternative MAHs to understand their ability to support any MSs that may experience critical shortages in the future.
	d) Availability of sodium chloride perfusion solutions EMA shared an update on the shortage situation of sodium chloride perfusion solutions together with feedback from the interactions with MAHs, who highlighted the implementation of mitigation measures and noted some improvements in the situation but no resolution yet. Additionally, EMA presented the outcomes of the SPOC WP criticality assessment, highlighting that several countries continue to experience shortages. **Agreed actions:** • EMA to engage with an alternative manufacturer to explore their capacity for additional EU supplies.
	e) Fluorouracil containing medicinal products EMA provided an overview of the shortage situation in the EU/EEA and the results of a SPOC WP criticality assessment that highlighted that multiple countries are impacted.

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	Additionally, EMA shared feedback from recent discussions with the key MAHs in the EU, indicating that one MAH would be able to support countries in need. Lastly, two SPOC WP members provided an update on the situation in their countries. **Agreed actions:** • EMA to contact international alternative suppliers to understand their ability to support MSs in need.
	f) Fludarabine containing medicinal products from MAH Sanofi EMA informed SPOC WP about a shortage of oral fludarabine and noted that the shortage is caused by delays in the manufacturing. EMA also stated that Sanofi is the only MAH for oral fludarabine in the EU, highlighting the importance of close monitoring of the supply situation. Comments raised Majority of the SPOC WP members shared that the situation with oral fludarabine is stable in their countries.
	g) Biltricide NAP (praziquantel) – MAH: Bayer EMA informed SPOC WP about an availability issue of praziquantel which will be withdrawn from the market for commercial reasons in the small number of countries where it is still marketed. In addition, EMA presented the results of the SPOC WP criticality assessment and proposed mitigation measures, such as interactions with alternative MAHs outside of the EU. Lastly, two SPOC WP members presented the situation in their countries and activities at a national level to identify suitable therapeutic alternatives. Comments raised: A number of SPOC WP members highlighted that the withdrawal would impact their territories due to the lack of alternatives and agreed with proposed mitigation measures. **Agreed actions:** • EMA to follow up with impacted MSs and to facilitate interaction with current and alternative MAHs.
6.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments to the written updates)
	a) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH b) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer c) Cyanokit CAP (hydroxocobalamin) MAH: Serb d) Medicinal products from MAH: Cheplapharm e) Medicinal products containing salbutamol (inhalation use) f) Oncology medicinal products from – MAH Teva g) Menopur NAP (menotropin) – MAH: Ferring

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	h) Semintra CAP (telmisartan) – MAH: Boehringer Ingelheim Vetmedica GmbH
7.	**Joint Action on shortages (CHESSMEN)** • **Work Package 6 — demand forecasting at national level: survey results and next steps** Work Package 6 Lead presented the ongoing work on harmonising shortage impact assessments outlining methodology and process. Key criteria of the methodology such as impact on patients, therapeutic alternatives and market share of medicines were presented, as well as determination of a shortage impact levels. As the next step, Work Package 6 Lead will share the draft protocol for monitoring, reporting and managing medicine shortages with the SPOC WP for their suggestions and feedback. Comments raised: EMA Chair asked whether the criteria highlighted by CHESSMEN are reflected in Shortage Mitigation Plans (SMPs) used by MAHs to which Work Package 6 Lead responded that they are not fully aligned. EMA noted that the need to incorporate this information in the SMP template would be discussed by the SPMP drafting group to ensure full alignment.
8.	**AOB** No topics raised under AOB.
9.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 17 June 2025 (TEAMS)

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).

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 13 May meeting, which was held virtually.

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Monica Dias	EMA	Chair	No interest declared	
Magdalena Rychter	Poland	Vice-Chair	No restrictions applicable to this meeting	
Andrea Kugi	Austria	Alternate	No interest declared	
Sybille Schotte	Belgium	Member	No interest declared	
Sanne Vandelanotte	Belgium	Alternate	No interest declared	
Emilia Stoyanova	Bulgaria	Member	No interest declared	
Jakub Velík	Czechia	Member	No interest declared	
Mateja Mervić Stela Lilek	Croatia Croatia	Member Alternate	No restrictions applicable to this meeting No interest declared	
Vasileios Loutas	Cyprus	Member	No interest declared	
Mathilde Moe Møldrup	Denmark	Member	No interest declared	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Julia Lehtinen	Finland	Member	No interest declared	
Flore Demay	France	Member	No interest declared	
Camille Ramahefarivony	France	Member	No interest declared	
Thomas Brouwers	Germany	Member	No restrictions applicable to this meeting	
Gabriele Eibenstein	Germany	Member	No interest declared	
Andrea Stippler	Germany	Alternate	No interest declared	
Inke Reimer	Germany	Member	No interest declared	
Theoni Kousteni	Greece	Member	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petró	Hungary	Alternate	No interest declared	
Hafdís Birna Baldursdóttir	Iceland	Alternate	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Vincenza Giuseppina Azzarà	Italy	Member	No interest declared	
Domenico Di Giorgio	Italy	Member	No interest declared	
Linas Mažeika	Lithuania	Member	No interest declared	
Kristīne Edolfa-Kalniņa	Latvia	Member	No interest declared	
Maxime Salade	Luxembourg	Member	No restrictions applicable to this meeting	
Jessica Zarb	Malta	Alternate	No interest declared	
Eric Hergarden	Netherlands	Alternate	No interest declared	
Guri Wilhelmsen	Norway	Member	No interest declared	
Andreas Sundgren	Norway	Alternate	No interest declared	
Helena Ponte	Portugal	Member	No restrictions applicable to this meeting	
Alina Iordache	Romania	Member	No interest declared	
Viviana Anghel	Romania	Alternate	No interest declared	
Jaroslav Kollárik	Slovakia	Member	No participation in discussions, final deliberations and voting on:	6.1 g) Biltricide NAP (praziquantel) – MAH: Bayer
Simona Paľovčíková	Slovakia	Alternate	No restrictions applicable to this meeting	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Saša Martinc	Slovenia	Member	No interest declared	
Patricia Rodríguez Molla	Spain	Alternate	No interest declared	
Samuel Silkestrand	Sweden	Member	No interest declared	
Karl Högström	Sweden	Alternate	No interest declared	
Rita Rom	Austria	Expert	No interest declared	
Olga Rögelsperger	Austria	Expert	No interest declared	
Edward Bojtor	Netherlands	Expert	No interest declared	
João Simões	Portugal	Expert	No interest declared	
Melita Tovornik	Slovenia	Expert	No interest declared	
Ramiro Casimiro	Spain	Expert	No interest declared	
Laura Marrero Ortiz	Spain	Expert	No interest declared	
Camilla Ledin	Sweden	Expert	No interest declared	
Representatives from the European Commission and EDQM attended the meeting.				
Meeting run with the help of EMA staff.				

Experts' declared interests were evaluated against the agenda topics or activities they participated in.