5 December 2024
EMA/565505/2024
European Medicines Agency

Meeting Summary — Medicine Shortages (SPOC) Working Party

6 November 2024, WebEx

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

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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. 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. The agenda was adopted with no additional points under AOB.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 7–8 October 2024** The Vice-Chair informed that the minutes of the meeting held on 7–8 October 2024 had been distributed one week prior to the meeting. One comment was received before the meeting and the minutes were updated to reflect it. No further comments were received during the meeting and the minutes were adopted.
3.	**EC DG HERA update** EC DG HERA provided an update on the Critical Medicines Alliance (CMA) and outlined that draft recommendations will be consulted by the Steering Board and the CMA forum, followed by adoption in early 2025. <u>Comments raised</u> One SPOC WP member asked whether all subgroups would issue recommendations. EC DG HERA explained that the subgroups' work feeds into the recommendations that will be issued by Working Group 1 — focused on strengthening EU manufacturing capacities for critical

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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	medicines and their active pharmaceutical ingredients — and Working Group 2 — focused on diversifying international partnerships and cooperation. EC DG HERA invited SPOC WP members to reach out to their national counterparts who are participating in the CMA for more information.
4.	**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 informed the group that no new signals of shortages were reported by the marketing authorisation holders (MAHs). EMA highlighted that Member States (MSs) can obtain additional supplies from alternative manufacturers if needed. In addition, EMA noted that no impact on the demand for antibiotics has been observed following the recent floods in Europe. Comments raised Several SPOC WP members informed the WP that the situation with the supply of antibiotics remains stable.
	b) Impact of the hurricane over US territory on availability of medicinal products in Europe EMA provided an update on the impact of Hurricane Helene on the availability of medicinal products in Europe, highlighting the feedback from the impacted manufacturer and alternative suppliers. Additionally, based on the SPOC WP feedback, the availability of sodium chloride solutions is stable with no critical shortages. EMA also presented the situation in other jurisdictions. As the next steps, EMA will continue to engage with the impacted and alternative manufacturers and will continue to monitor the situation. Comments raised The Chair expressed the willingness of EMA and the SPOC WP to provide support to Spain to address medicine supply issues resulting from the recent floods.
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information) No new emerging information was raised.
5.	**Critical shortages escalated to the SPOC Working Party:**
5.1	**Ongoing shortages**
	a) Supply and availability of radioisotopes
	• **Status update on supply and availability of radioisotopes in EU/EEA** There is an ongoing worldwide shortage of medical isotopes, due to the lower available reactor capacity as a result of scheduled maintenance and temporary outages. This caused a delay in the planned re-start of activities of the High Flux Reactor (HFR) in Petten. EMA

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	provided the feedback on the situation in the MSs and feedback from the meetings with MAHs. EMA noted that the reactor has now restarted and that the supply is planned to stabilise in the week commencing 11 November 2024. Lastly, EMA highlighted the lack of visibility on the whole radioisotopes supply chain.
	• **European Observatory on the supply of medical radioisotopes** Euratom Supply Agency (ESA) representative described the European Observatory on the supply of medical radioisotopes. ESA presented the Emergency Response Team (ERT) and communication procedure in cases of supply issues. ESA representative also outlined the HFR situation and confirmed that a normal supply of radioisotope Molybdenum-99 is expected by the week commencing 11 November 2024.
	• **Nuclear Medicine Europe — Emergency Response Team** Nuclear Medicine Europe (NMEU) representative explained the radioisotope manufacturing process and supply chain complexities. NMEU representative detailed the issue with the restart delay of the HFR reactor and measures taken to reduce the impact on patients. Additionally, NMEU representative provided an overview of the role of NMEU's Security of Supply Working Group (SoS WG) and the Emergency Response Team (ETR) in securing supply of medical isotopes.
	• **Discussion** The group discussed plans for the establishment of new reactors. Additionally, EMA asked how the efforts of NMEU and ESA could be supported. The speakers responded that it would be helpful to have an overview of shortages in order to understand the impact. EMA confirmed that information on shortages can be shared and noted the importance of having visibility across the entire supply chain. The Chair closed the session by informing the SPOC WP that this topic is on the agenda of the MSSG meeting on 19 November 2024 to discuss possible recommendations to address the vulnerabilities in the supply chain of radiopharmaceuticals.
	b) Insulin-containing medicinal products EMA presented the results of the SPOC WP criticality assessment and the outcomes of the SPOC WP subgroup meeting with MAH Novo Nordisk. In this meeting, the discontinuation plan for selected insulins (Levemir, NovoMix 50, Mixtard 50, Fiasp PumpCart, Penfill, FlexPen, InnoLet presentations for Actrapid, Insulatard, Mixtard 30), as well as expected clinical impact and possible alternative medicinal products from Novo Nordisk were discussed. EMA provided an overview of the international situation and presented further details on the clinical expert group. As a next step, impact analysis of the discontinuation of selected insulins will be finalised. Additionally, Novo Nordisk will be invited to the MSSG meeting on 19 November 2024. Comments raised SPOC WP members discussed the discontinuation plans and alternative medicinal products. The need to get MAHs commitment to increasing production for identified alternatives of the

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	to-be-discontinued products was highlighted. Discussions with alternative MAHs to increase the supply are already ongoing in some MSs.
	c) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists EMA provided an overview of the current supply and availability situation of GLP-1 Receptor Agonists (RAs), focusing on the situation for Ozempic and Victoza. Meetings with different MAHs will continue to take place. As the next steps, a report on the DARWIN EU Drug Utilisation study on GLP-1 RAs will be finalised.
	d) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris EMA provided a brief update on the pancrelipase-containing medicinal products, noting that some EU countries have started to experience shortages of these medicinal products. EMA requested preliminary feedback from the SPOC WP on the situation in the MSs. Comments raised Several SPOC WP members confirmed shortages of pancrelipase-containing medicinal products.
	e) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer EMA provided an overview of a shortage caused by a manufacturing issue and presented the results of the SPOC WP criticality assessment. EMA also informed about the possible future impact on the supply of other products manufactured on the same line. Comments raised SPOC WP members discussed ongoing shortages of Ecalta and Zirabev in their territories and available alternatives.
	f) Medicinal products from Cheplapharm EMA gave an update on the ongoing shortage of Visudyne, noting that the shortage can continue throughout 2025. Additionally, EMA provided an update on supply challenges for Zypadhera. EMA further informed the group that the MAH is exploring additional mitigation actions to address these shortages.
	g) Medicinal products containing salbutamol (inhalation use): • **Potential impact of F-gas regulation on the availability of meter dose inhalers** EMA provided an overview of the current supply situation, the results of the criticality assessment, and an update from recent interactions with MAHs. Furthermore, EMA provided an update on the DARWIN EU salbutamol drug utilisation study. EMA also presented Regulation (EU) 2024/573 (F-Gas Regulation) which establishes the total elimination of hydrofluorocarbons by 2050, and the potential impact on the availability of metered dose inhalers (MDIs), which contain fluorinated greenhouse gases as propellants in the EU/EEA. EMA highlighted that the Regulation is entering into force on 1 January 2025 with no grace period or extension for implementation foreseen.

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	Comments raised SPOC WP members asked about flexibility options (e.g., extending timelines) for the implementation of the Regulation. EMA explained that national environmental agencies are responsible bodies for the F-gas Regulation.
5.3	**Status update on other critical shortages escalated to the SPOC WP** (only comments to the written updates)
	a) Oncology medicinal products from Accord Healthcare B.V. b) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH c) Nakom NAP (levidopa/carbidopa) – MAH: Sandoz d) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk e) Semintra (telmisartan) CAP – MAH: Boehringer Ingelheim Animal Health Comments raised EMA shared a written update on the shortages of the abovementioned products prior the meeting. The group discussed the shortage of Pegasys and the possibility to arrange a meeting between MAH and concerned countries.
6.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Voluntary Solidarity Mechanism (VSM): Presentation of the latest VSM procedures EMA presented the results of the recent VSM procedures for vinblastine and etoposide launched in October 2024. For both cases, EMA outlined the shortage root cause and current supply situation.
7.	**Survey on national approaches to shelf life extension of medicines stockpiled in preparedness to health threat: Key results of the SPOC WP survey** EMA presented the key outcomes of the survey on the overall use of shelf life extensions, types of products, scope and data used, testing providers and assessment and decision-making bodies. EMA invited any additional MSs who had not yet submitted their responses to share information on national practices.
8.	**Scientific article on the activities of the Medicine Shortages SPOC WP — 5 year review** EMA presented the ongoing work on a scientific publication aimed at informing about the SPOC WP activities during the past five years, its impact on EU shortages management, and its role in implementing and progressing actions outlined under Regulation (EU) 2022/123. EMA presented the workplan and invited SPOC WP members to contribute to the article.
9.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 5 December (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).