14 December 2023
EMA/557090/2023
European Medicines Agency

Meeting Summary - Medicine Shortages (SPOC) Working Party

20 November 2023, 10:00-13:30, WebEx

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

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. 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 topics in the agenda of the meeting, the SPOC WP Secretariat 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 26-27 October 2023** The Vice-Chair informed that the minutes of the meeting held on 26-27 October 2023 had been distributed one week prior the meeting. Comments were received from EC DG HERA and the minutes were updated to reflect their interventions. Minutes were adopted with the abovementioned amendments.
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 preparedness activities EMA presented the feedback from various stakeholders, the intervention at the PCWP/HCPWP, and the ongoing public awareness campaigns. Furthermore, EMA provided an update on the outcomes of the matching of supply and demand exercise and informed that the next steps will include interactions with alternative antibiotic manufacturers.

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	Agreed action: • SPOC WP to continue reporting critical and non-critical shortages to EMA for antibiotics under monitoring and to inform EMA how the shortage situation compares to last year.
	b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) One SPOC WP member reported that there are ongoing shortages of paracetamol IV formulation and also of a combination diphtheria, tetanus, pertussis and poliomyelitis vaccine. Comments raised Some SPOC WP members noted that supply tensions of this combination vaccine have also been observed in other MSs. **Agreed action:** • SPOC WP members with critical shortage issues to report the information to the SPOC WP Secretariat for further action.
	c) Impact of the Israel-Hamas war on medicines availability in EU/EEA markets EMA presented the latest feedback from the SPOC WP, industry associations, and MAHs of CAPs on the supply of medicinal products with manufacturing steps in Israel. Currently, no impact on supply has been identified. **Agreed actions:** • SPOC WP members to report to EMA any impact of the Israel-Hamas war at the national level. • MAHs and Industry Associations to continue providing feedback on any potential impact on products and early signals to EMA.
	d) Update on impact of BREXIT on medicines availability SPOC WP member provided an update with regards to the implementation of new labelling and packaging requirements for medicinal products for human use following agreement of the Windsor Framework. As of January 2025, UK packaging will carry a UK-specific label to be allowed onto the UK market, including in Northern Ireland. These products will only be able to be sold in the UK and will not be available on the market in the EU. SPOC WP member informed that packs that are shared with the UK are widely used in their Member State therefore interactions with MAHs and national Industry Associations are ongoing to understand the impact. Comments raised One SPOC WP member informed that impact on their Member State is currently under evaluation. **Agreed action:** • SPOC WP to continue monitoring the situation and keep the topic in the agenda for upcoming meetings.

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4.	**Ongoing critical shortages reported by the SPOC WP:** **a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim** EMA provided an update on the current status of the thrombolytics shortages in the EU/EEA, including the status of planned shortage mitigation activities such as distribution of additional Actilyse vials and a new manufacturing site.
	b) 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. EMA provided an overview of the shortage of GLP-1 receptor agonists and presented preliminary estimates for the proportion of reimbursed and non-reimbursed prescriptions of Ozempic as provided by certain EU/EEA countries. EMA also provided an overview on the criticality of the shortages and the mitigation measures undertaken in EU/EEA countries for Ozempic and Victoza based on the feedback collected from the SPOC WP members. Comments raised SPOC WP member highlighted – and EMA confirmed – that shortage of Ozempic 1 mg strength will continue into 2024. Intermittent shortages are expected throughout 2024. **Agreed actions:** • SPOC WP to brief their respective MSSG members on the situation with GLP-1 receptor agonists ahead of the MSSG meeting on 23 November 2023.
	c) Integrilin CAP (eptifibatide) – MAH: GlaxoSmithKline (Ireland) Limited EMA presented the ongoing actions to ensure future availability of eptifibatide containing medicinal products in the EU/EEA after Integrilin's withdrawal from the market, and provided feedback received from manufacturers of alternatives. Comments raised SPOC WP members confirmed that tirofiban is also considered as an alternative and is authorised in their countries. EMA informed that interactions with manufacturers of alternative products have taken place and supplies are available, if needed. **Agreed actions:** • EMA to share the details of available alternative products. • EMA to support the interactions with CMDh as appropriate with regards to marketing authorisation of tirofiban containing medicinal products.
	d) Abraxane CAP (paclitaxel) – MAH: Bristol-Myers Squibb Pharma; Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH EMA provided an update on the availability of paclitaxel, including the mitigating actions by Bristol-Myers Squibb to increase their supply following the withdrawal of Pazenir, and the CHMP positive opinion for Naveruclif (paclitaxel) from the MAH Accord Healthcare.

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	Agreed actions: • SPOC WP to inform EMA if they receive any feedback from Ratiopharm on supply situation for 2024 in individual EU countries.
	e) Attention deficit hyperactivity disorder (ADHD) medicine shortages EMA provided an update on the mitigating measures undertaken to address ADHD medicine shortages and provided the feedback from recent interactions with key methylphenidate manufacturers in Europe. Comments raised SPOC WP member expressed their concerns and asked for details on the number of MSs reporting critical shortages.
5.	**Ad-hoc gap analysis: Lessons learned from the pilot procedure for supporting MSs on shortages management** EMA presented the lessons learned from a pilot ad-hoc gap analysis conducted in 2023 to support Member States considering importing unauthorised product in the context of a critical shortage. EMA provided an overview of the high-level feedback received from the SPOC WP on the impact and usefulness of the data generated through this exercise, as well as general feedback received on the process itself.
6.	**Derogation for import of foreign packs in case of a shortage** SPOC WP member presented an overview of the derogations for import of medicinal products in foreign packaging to mitigate shortages, including the criteria and conditions to be met at a national level, such as (non-)availability of therapeutic alternatives and (non-) availability of medicinal products from alternative MAHs, amongst others.
7.	**HMA/EMA Task Force on Availability of authorised medicines: EU list of critical medicines** EMA provided an update on the development of the Union list of critical medicines and informed the SPOC WP that the planned communication activities for December 2023 include the publication of the methodology and the list, as well as a joint EMA/HMA press release with dedicated Q&A document and EMA website update.
8.	**European Shortages Monitoring Platform (ESMP) update: ESMP Industry Workshop on Interoperability** EMA provided feedback from the workshop with industry Subject Matter Experts on the interoperability between the ESMP and industry systems which was held in November 2023. The workshop focused on the process for data submission, data elements, and availability of national and industry IT systems where the relevant data is collected. EMA informed that the next joint workshop with both industry and NCA representatives is expected to be held in January 2024, focusing on potential IT solutions to enable interoperability. EMA also informed that a webinar with national IT directors and the SPOC WP is planned for 14 December 2023, where this will be explained in more detail.

Item	Topic
9.	**Conclusions and next steps** The agreed actions are detailed above.

Next meeting: 14 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).