16 June 2023
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European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

16 June 2023, from 10:00 to 13:00 (CEST), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Johan Andersson (SE)

Item	Topics
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 24 May 2023
3.	**Future operating model of SPOC Working Party meetings and information exchange:** • Update on rollout of SharePoint Online
4.	**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: update on joint EMA/HERA preparedness activities
	b) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
5.	**Ongoing shortages reported by the SPOC WP:**
	a) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim; Urokinase NAP b) Visudyne CAP (verteporfin) - MAH: Cheplapharm Arzneimittel GmbH
	c) Ozempic CAP and Rybelsus CAP (semaglutide) - MAH: Novo Nordisk
	d) Insuman CAP (human insulin) – MAH: Sanofi
	e) Abraxane CAP (paclitaxel) - MAH: Bristol-Myers Squibb Pharma EEIG); Pazenir CAP (paclitaxel) – MAH: Ratiopharm GmbH

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Item	Topics
6.	Update from EC **DG SANTE**
7.	**Joint Action** on Shortages (**CHESSMEN**)
8.	**MSSG Recommendations** on shortages of medicinal products toolkit
9.	Update on pilot on shortages reporting by patients and healthcare professionals
10.	Conclusions and next steps

Note on access to documents

Some documents mentioned in the agenda 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).