22 May 2024
European Medicines Agency

Agenda - Medicine Shortages (SPOC) Working Party

22 May 2024, from 09:30 to 13:15 (CEST), WebEx

Chair: Monica Dias (EMA), Vice-Chair: Sybille Schotte (FAMHP, Belgium)

Item	Topic
1.	Welcome, declaration of interest, adoption of draft agenda
2.	Adoption of draft minutes of the SPOC WP meeting held on 15-16 April 2024
3.	Data Analysis and Real World Interrogation Network (**DARWIN EU**): studies to support shortage monitoring and preparedness
4.	**Potential impact of the international situation** on the supply of medicinal products for human and veterinary use to the European market:
	a) Impact on the supply of medicines of the takeover of three Catalent sites by Novo Nordisk
	b) Suspension of API manufacturing site EuroAPI in Brindisi
	c) Oral status update on availability of human and veterinary medicines in MSs (only for new emerging information)
5.	**Critical shortages escalated to the SPOC Working Party:**
	a) **Solidarity Mechanism**: feedback from the 2nd and 3rd case
	b) Methotrexate IV NAP (methotrexate) – MAH: Teva Sante
	c) Glucagon-like Peptide-1 (GLP-1) Receptor Agonists: Ozempic CAP and Rybelsus CAP (semaglutide), Victoza CAP (liraglutide) - MAH: Novo Nordisk; Trulicity CAP (dulaglutide) – MAH: Eli Lilly Nederland B.V.
	d) Supply and availability of IV/SC human normal immunoglobulins in the EU/EEA
	e) Thrombolytics: Metalyse CAP (tenecteplase) and Actilyse NAP (alteplase) - MAH: Boehringer Ingelheim
	f) Shortages of medicinal products from MAH: Cheplapharm

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Item	Topic
	g) Ixiaro CAP (Japanese encephalitis vaccine) - MAH: Valneva Austria GmbH
	h) Creon NAP and Creonipe NAP (pancrelipase) – MAH: Viatris
	i) Ventolin NAP (salbutamol sulfate) – MAH: GlaxoSmithKline
	j) Menopur NAP (menotrophin) – MAH: Ferring
6.	EC **DG HERA** update (TBC)
7.	Impact of **new national law** on supply of medicinal products and availability of medicines on European market
8.	**HMA/EMA Task Force on Availability of Authorised Medicines:**
	a) Union list of critical medicines
9.	Conclusions and next steps

Next meeting: 19 June (WebEx)

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 ongoing 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).