

22nd March 2024 EMA/125572/2024

Draft agenda – 8th Industry Standing Group (ISG) meeting

25th March 2024, 09.00-13.30 CET Virtual meeting, Webex

Chair: Marie-Hélène Pinheiro

Item	Preliminary draft agenda	Mins
1.	Welcome/Introduction	9:00-9:05
	Marie- Hélène Pinheiro (EMA)	10 min
2.	Medicine shortages and Medical Devices	9:05-9:50
	2.1 Medicines shortages communications update	10 min
	- Union list of critical medicines update	40 .
	Q&A session (all)	10 min
	2.2 Update on the European Shortages Monitoring Platform (ESMP) development progress status.	20 min
	- Update on activities in Q1 2024	
	Q&A session (all)	5 min
3.	Expert panels activities update	9:50-10:20
	- Update on experts panels opinions	5 min
	 Learning from Expert Panels advice pilot and next steps 	10 min
	 Workshop with Notified Bodies on 22 April 2024 focus on clinical assessment alignment. 	5 min
	Q&A session (all)	10 min
4.		10:20-10.40
	Update on the implementation of New Fee Regulation (EU)	10min
	2024/568	10 min
	Q&A session (all)	



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5.	COVID lessons learned - EMA COVID lessons learned published report highlights.	10:40-11:10 20 min
	Q&A session (all)	10 min
6.	European Medicines Agency Network (EMAN) report to 2028 update	11:10-11:30
	 from EMAN mid-term report to 2025 to EMAN report to 2028 	15 min
	Q&A session (all)	5 min
Coffee bre	ak	11:30-11:40 10 min
7.	Misinformation-miscommunication in medicines	11:40-12:10
	 Presentation from (cross-)industry on misinformation- miscommunication experiences and management 	20 min
	Q&A session (all)	10 min
8.	International activities update	12:10-12:50
	 African Medicines Agency: Update on continental medicines evaluation and continental GMP inspections, and other project updates 	10 min
	 Update on the opening procedures at EMA to non-EU authorities (OPEN) 	10 min
	 EU enlargement (Instrument for Pre-accession Assistance [IPA] program implementation): Update on EMA engagement with candidate and potential candidate countries 	10 min
	Q&A session (all)	10 min
9.	Presentation from industry on cross-sectoral legislations and policies affecting EMA and medicines development Q&A session (all)	12:50-13:20 20 min 0 min
10.	Announcement of EMA-Industry Early engagement fostering innovation survey launch	13:20-13:25 5 min
11.	Close of the meeting and next steps	13:25-13:30 5 min