



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 November 2024
EMA/427165/2024

Draft agenda – 11th Industry Standing Group (ISG) meeting

21th November 2024, 09:30-13:00 CET, meeting room 1C, Webex

Chair: Marie-Hélène Pinheiro, EMA Industry Corporate Liaison

Item	Preliminary draft agenda	Mins
	1. Welcome/Introduction including follow-up actions from last ISG meeting <i>Marie- Hélène Pinheiro (EMA)</i>	9:30-9:35 5'
Implementation of extended mandate and shortages related activities		
	2. Shortages prevention management activities (H) 2.1 Update on release of Union list of critical medicines Version 2 (H) 2.2: Update on Shortage Mitigation Plan (SMP)/Shortage Prevention Plan pilot (SPP) (H) 3. Update on the development of the European Shortages Monitoring platform (H) Q&A session (all)	09:35-10:25
Implementation of HTA Regulation		
	4. EMA HTA regulatory implementation updates(H+MD) Q&A session (all)	10:25-10:55
	Coffee break	10:55-11:10 15'

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Other topics of strategic interest		
5. EMAN strategy to 2028 updates (H+V+MD)		11:10-11:35
Q&A session (all)		
6. Information on Cross EU Agencies One Health Task Force (H+V+MD)		11:35-11:50
Q&A session (all)		
7. Industry stakeholder presentation on cumulative impact assessment of the Green-related files (H)		11:50-12:05
Q&A session (all)		
8. ACT EU and CTIS activities updates (H)		12:05-12:20
Q&A session (all)		
9. EMA update on IT Portfolio Agile transformation key 2025 dates and industry Subject Matter Experts (SMEs) involvement status		12:20-12:35
Q&A session (all)		
10. EMA international activities: Updates on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative		12:35-12:50
Q&A session (all)		
11. Close of the meeting and next steps <i>Marie- Hélène Pinheiro (EMA)</i>		12:50-13:00 10'

Legenda:

H: Human

V: Veterinary

MD: Medical Devices