

28 August 2025 EMA/141039/2025

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## Agenda – 14th Industry Standing Group (ISG) meeting

30th September 2025, 09:00-13:15 CEST, Webex

Chair: Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

Item	Preliminary draft agenda	Mins		
1.	1. Welcome/Introduction	09:00-		
		09:20		
	1.1: Actions arising from previous meetings and other			
	updates			
Implementation of the extended mandate and shortages related activities				
2.	Update on the Union list of critical medicines (H)	09:20-		
		09:45		
2	Walana Hillian Anna ann an (II)	00.45		
3.	Vulnerability Assessment (H)	09:45- 10:00		
		10:00		
4.	Update on the Shortage Mitigation Plan (SMP)/Shortage	10:00-		
	Prevention Plan (SPP)	10:15		
5.	Update from Medical Devices Expert panels (MD)	10:15-		
		10:35		
Coffee break 15' (10:35-10:50)				
Implementation of the HTA Regulation				
6.	Regulatory/HTA interface under the HTA Regulation	10:50-		
	(H+MD)	11:20		
Other topics of strategic intertest				
7.	EMA activities in support to MDR and IVDR (MD)	11:20-		
		11:45		



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8.	Regulatory Science Research Translation (H)	11:45- 12:10
	Update from the Focus Group Regulatory Science Research Translation (H)	
	Update on the European Platform for Regulatory Science Research	
9.	HMA-EMA Catalogues of real-world data sources and studies (H)	12:10- 12:35
10.	AI research needs in medicines lifecycle survey (H, MD)	12:35- 12:50
11.	Patients Experience Data reflection paper update (H)	12:50- 13:05
12.	Close of the meeting and next steps	13:05- 13:15