



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2025
EMA/14552/2025

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Draft agenda – 12th Industry Standing group (ISG) meeting

28th March 2025, 09:00-14:00 CET, meeting room 1A, Webex

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

Item	Preliminary draft agenda	Mins
1.	1. Welcome/Introduction 1.1 Follow up actions arising from previous meeting 1.2 Overview of 2024 feedback survey and topic proposals Q&A	09:00-09:25
Implementation of the extended mandate and shortages related activities		
2.	Medicine and medical devices shortages (H+MD) 2.1 Closure of Task Force on Availability of Authorised Medicines for Human and Veterinary Use and MSSG vulnerability assessment methodology (H+V) Q&A 2.2 Update on the development of the European Shortages Monitoring Platform (H) Q&A 2.3 Cross-Industry learnings on union critical medicines list (H) Industry speaker tbc Q&A	09:25-10:55

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3.	Medical Devices expert panels (MD) 3.1 Update on Orphan programme 3.2 Update on regular programme 3.3. HTA observer-ship Q&A	10:55-11:20
4.	Emergency Task Force (ETF) (H) Q&A	11:20-11:45
Coffee break (11:45-12:05 - 20')		
Implementation of the HTA Regulation		
5.	5.1 Regulatory/HTA interface under the HTA Regulation (H+MD) Q&A	12:05-12:35
Other topics of strategic interest		
6.	Cross-industry presentation: Survey results on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative (H) Q&A	12:35-13:00
7.	Update on ePI (H) Q&A	13:00-13:25
8.	Update on EMANS to 2028 (H+V+MD) Q&A	13:25-13:50
9.	Close of the meeting and next steps	13:50-14:00

Legend:

H: Human

V: Veterinary

MD: Medical Devices