



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 December 2025

...

Agenda – 15th Industry Standing Group (ISG) meeting 11th December 2025; 09:00-13:00 CET

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

| Item | Preliminary draft agenda | Mins |
|---|---|-------------|
| 1. | 1.1 Welcome/Introduction <i>Juan Garcia Burgos (EMA)</i> 1.2 Actions arising from previous meeting and other updates Q&A | 09:00-09:20 |
| Implementation of legislative requirements | | |
| 2. | Agency approach to the implementation of the revised pharmaceutical legislation and stakeholders' engagement Q&A | 09:20-09:55 |
| 3. | Regulatory/HTA interface under the HTA Regulation (H, MD) Q&A | 09:55-10:25 |
| Other topics of strategic interest | | |
| 4. | Publication of information on CVMP agenda and minutes (H, V) Q&A | 10:25-10:45 |
| Coffee break 10:45-11:10 | | |
| 5. | Update on Product Management Service (PMS) (H) Q&A | 11:10-11:35 |
| 6. | Cross-Industry feedback on HMA-EMA Catalogues of real-world data sources and studies (H) | 11:35-12:00 |

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 | Preliminary draft agenda | Mins |
|------|--|-------------|
| 7. | Updates on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative (H) Q&A | 12:10-12:25 |
| 8. | Report on Industry stakeholders survey on communication Q&A | 12:25-12:50 |
| 9. | End of the meeting | 12:50-13:00 |