



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 March 2026
EMA/1657/2026

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Draft agenda – 16th Industry Standing Group (ISG) meeting

31 March 2026; 13:00-18:00 CEST; Hybrid meeting

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

| Item | Preliminary draft agenda | Mins* |
|---|---|--------------------|
| 1. | 1.1 Welcome/Introduction | 13:00-13:05 |
| Implementation of legislative requirements | | |
| 2. | Revised pharmaceutical legislation (H) | 13:05-13:10 |
| | 2.1 Opening remarks from Emer Cooke, EMA Executive Director | |
| | 2.2 Update from the EC on the revised pharmaceutical legislation Q&A | 13:10-14:10 |
| | 2.3 Update from the EMA on the implementation of the revised pharmaceutical legislation Q&A | 14:10-14:40 |
| Coffee break (14:40-15:00) | | |
| 3. | Implementation of the extended mandate and shortages related activities (H) | 15:00-15:25 |
| | 3.1 Update on Vulnerability Assessment and on the Shortage Mitigation Plan (SMP)/Shortage Prevention Plan (SPP) Q&A | |
| | 3.2. Update on the Union list of critical medicines Q&A | 15:25-15:50 |

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| | 3.3 ESMP and harmonisation activities Q&A | 15:50-16:25 |
| 4. | Regulatory/HTA interface under the HTA Regulation (H+MD) Q&A | 16:25-17:00 |
| Other topics of strategic interest | | |
| 5. | Cross-Industry presentation on PMS Development Activities and Data Quality Q&A | 17:00-17:20 |
| Industry organisations priorities | | |
| 6. | EFPIA ONE Vision – towards a modernised European regulatory framework Q&A | 17:20-17:40 |
| 7. | Actions arising from previous meetings and other updates Q&A e | 17:40-17:50 |
| 8. | End of the meeting | 17:50-18:00 |

* The order of topics and timing might change during the course of the meeting.