28 January 2026
EMA/387702/2025

Highlights of the 15th Industry Standing Group (ISG) meeting

11/12/2025 – chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The chair welcomed ISG members to the last meeting of the year.

An update on the actions arising from the 15th ISG meeting was provided. It was confirmed the intention to start the vulnerability assessment pilot phase in Q1 2026 with concerned Marketing Authorisation Holders (MAHs) to be directly approached by the Agency.

It was also confirmed that the Union list of Critical Medicines v2.1 will be shared with ISG members under embargo before its publication.

The ISG members were reminded of the upcoming quarterly system demo meeting (16/12/2025) and the recently launched call for Product Management Service (PMS) call for four Subject Matter Experts (SMEs) ending on the 30th January 2026.

Link to presentation.

2. Agency approach to the implementation of the revised pharmaceutical legislation and stakeholders' engagement

In preparation to the publication of the revised pharmaceutical legislation, and in the view of the political agreement reached by the European Commission, the European Parliament and the Council of the European Union on the comprehensive reform of the EU pharmaceutical legislation, an overview of Agency's approach to the implementation phase was provided.

The importance of engaging with stakeholders during the implementation phase was recognised, with the ISG confirmed as the main point of reference for industry stakeholders, enabling strategic discussions and regular updates. Additionally the intention to host a multi-stakeholder workshop and to

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allow operational discussions with the established industry stakeholder platforms and other groups were noted.

The ISG was also informed about the plans to launch in 2026 a dedicated webpage on the Agency corporate website and an industry newsletter with the intent to keep relevant companies informed throughout the implementation.

Industry welcomed the update and asked for more clarity on timelines, priorities and guidance needs.

Link to presentation.

Action arising:

- The Agency to update ISG with more details on the implementation when available.

3. Regulatory/HTA interface under the HTA Regulation

A status update was provided by the EMA and HTA secretariat on the activities done in 2025 and planned for 2026 to implement the Health Technology Assessment Regulation (HTAR).

The ISG noted the adoption of the last procedural rule for Joint Scientific Assessment (JCA) of medical devices and in vitro diagnostic medical devices. The rules governing the sharing of information between the EMA and the HTA, adopted in October 2024, were highlighted to the group.

It was flagged that, to facilitate companies' compliance with the parallel submission of the letter of intent, as of January 2026 the HTA secretariat mailbox will be in copy to applicants' reminders. It was also clarified that the exchange of information between the two secretariats will continue and will be revised after 12 months.

The progress on the parallel Joint Scientific Consultation (JSC), including 2026 plans, was shared and industry was invited to familiarise with the parallel scientific advice procedure, the relevant Scientific Advice Working Party meetings and submission timelines for 2026 and the timetable for the joint scientific advice to medical device manufacturers by the Expert Panels.

The importance of the collaboration between the HTA bodies and the EMA (link to joint HTAb-regulatory perspectives paper) in terms of developing a shared understanding while respecting each other scopes was flagged.

The HTA secretariat provided clarifications on the role of the HTA unit in DG Sante' and provided an overview of the annual work programme for 2026. Regular meetings of the coordination group with the health technology associations in the HTA Stakeholder Network, as well as biannual meetings with the Agency, were noted. The ISG was invited to monitor the HTA website for updates.

The industry welcomed the update and asked about the possibility of ensuring company readiness by updating them on the expected acceptability of JSC eligibility. Further discussions were arranged with the HTA secretariat. It was also clarified that only information on major objections is shared between the secretariats via a secure IT platform that ensures confidentiality.

The need for more coordination on methodology guidance was recognised and already captured under the ACT EU initiative.

Link to EMA presentation

Link to EC presentation

Action arising:

- Industry to ensure compliance with the parallel submission of the letter of intent.
- Industry to follow up directly with HTA secretariat to further discuss companies' needs on the eligibility requests overview.

4. Publication of information on CVMP agenda and minutes

The ISG was informed of the intention to start publishing certain information on the CVMP (Committee for the Veterinary Medicinal Products) agendas and minutes to ensure alignment with Agency transparency policies already in place for the human scientific committees' agendas and minutes.

As of January 2026, the international non-proprietary name (INN) and proposed indication for initial marketing authorisation applications, the proposed indication for extension of indications and the INN and proposed indication for accelerated assessment request will be published.

Link to presentation.

5. Updates on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative

Following a consultation with ISG members on how to enhance the use of the OPEN initiatives (11th ISG meeting), the OPEN framework was broadened to include ATMPs (Advanced Therapies Medicinal Products), other medicines targeting unmet medical needs and post-authorisation procedures. Additionally some process improvements were noted, and the Questions and Answers document was updated.

The Agency confirmed its intention to explore the expansion of the OPEN Framework to other international authorities and asked Industry to express interest in a potential inclusion of veterinary applications.

The industry stakeholders were invited to raise awareness within their affiliated members on the improvements made and encourage participation to the OPEN framework.

The ISG welcomed the update in the scope and procedural aspects.

Actions arising:

- The EMA to update the Q&A with the agreed clarifications. Update 20/01: Q&A published: Questions and Answers on the Pilot Project 'OPEN' - phase 3 - current version
- Industry stakeholders to raise awareness within their members and encourage participation in the OPEN framework.
- Industry to provide feedback on the interest in having veterinary applications in the scope of this procedure.

Link to presentation

6. Cross-Industry feedback on HMA-EMA Catalogues of real-world data sources and studies

Following the initial discussion during the 14th ISG meeting, industry presented the outcome of a survey to better understand companies' awareness and use of the HMA-EMA catalogues of real world data sources and studies.

The awareness, usefulness of the catalogues and the positive impact of recent improvements were acknowledged. Nevertheless the need to further refine the advanced search functionality and to ensure the availability of high quality and up to date metadata for better usability were flagged.

Industry suggestions to further collaborate on the improvements to the search functionality and on exploring ways to enable knowledge sharing on the existing data sources were noted.

Actions arising:

- The EMA to reflect on how to integrate the recommendations made.

7. Update on Product Management Service (PMS)

The ISG members noted the updates to PMS activities since June 2025, as well as the ongoing work to integrate PMS data with all regulatory processes throughout the lifecycle of medicines. They also noted the transition to submitting both investigational and medicinal product master data in the ISO IDMP/FHIR format via the PMS API or User Interface, rather than in the XEVMPD format.

The ISG was also informed that the PMS working arrangement document is currently being drafted. This document will clarify the roles and responsibilities of sponsors, industry and regulators in the management of investigational, pending and authorised product master data in PMS. This work will be complemented by a feasibility study from the Regulatory Optimisation Group (ROG), which will reflect the different levels of preparedness of National Competent Authorities and provide clearer implementation timelines.

Industry suggested the importance of a possible consultation to ensure clarify and a fit for purpose process.

The roadmap was revised. Industry was informed about the ongoing work to release the capabilities to enable the PMS Public API (Application Programming Interface) read and was reminded of the need to submit the following data.

- Enrichment of Manufacturer's data & structured pack size for non-CAPs (ULCM) by June 2026.
- Enrichment of Manufacturer's data for all non-CAPs on the company's portfolio by December 2026.
- Enrichment of pack sizes for all non-CAPs & structured pack sizes on the company's portfolio by June 2027.
- Optional submission of data carrier ID for non-CAPs by June 2027.

The need to ensure data quality before it reached the public was confirmed to be a priority for 2026 activities (including PMS data quality framework and ROG interlinks).

The Agency will further reflect on the points raised and will consult industry stakeholders via the Subject Matters experts and the ISG.

Actions arising:

- The Agency to reflect on industry consultation on the working arrangement documents and on the PMS data quality and keep industry updated.
- Industry stakeholders to follow up on:
  - Enrichment of Manufacturer's data & structured pack size for non-CAPs (ULCM) by June 2026.
  - Enrichment of Manufacturer's data for all non-CAPs on the company's portfolio by December 2026.
  - Enrichment of pack sizes for all non-CAPs & structured pack sizes on the company's portfolio by June 2027.
  - Optional submission of data carrier ID for non-CAPs by June 2027.

Link to presentation.

8. Report on Industry stakeholders survey on communication and engagement

Following the announcement at the 12th ISG meeting, the results of the survey and interviews with industry stakeholders regarding the Agency's engagement and communication activities were presented. Overall, positive feedback was received, confirming the value of current practices in ensuring effective communication and active stakeholder engagement. Recommendations were presented to further enhance clarity and engagement. Industry was invited to reflect on how to contribute to addressing some points relating to the relevance of activities and events communicated by updating their areas of interest in the Agency's Stakeholder Database and Industry Liaisons, as well as raising awareness amongst nominees contributing to Agency activities of the importance to keep the relevant trades updated.

The cooperation of Industry in this exercise was recognised.

Industry welcomed the initiative, acknowledged the results and asked to ensure better practices in terms of timelines of certain engagement requests to ensure adequate contribution.

Link to presentation

Link to the report

Actions arising:

- EMA to implement the recommendations and provide regular updates.

- ISG to keep up to date Agency's Stakeholder Database and Industry Liaisons with the areas of interest.
- ISG to raise awareness within their nominees contributing to Agency activities of the importance to keep the relevant trade updated.

9. Close of the meeting and next steps

The meeting was an opportunity to ensure the strategic dialogue with industry stakeholders on key topics linked to legislative requirements and supporting activities for companies.

The ISG was confirmed to be the main forum for discussing the implementation of the new pharmaceutical legislation in addition to other strategic topics.

The proposed revised agenda template and the dates for 2026 were presented:

- 31.03.2026 (13:00-17:30 CEST, hybrid)
- 29.06.2026 (09:00-13:30 CEST, virtual)
- 29.09.2026 (09:30-13:30 CEST, hybrid)
- 07.12.2026 (09:30-13:30 CEST, virtual)

Note: meetings may be subject to change. This includes dates, times and modalities.