28 March 2025
EMA/66624/2025
European Medicines Agency

Highlights – 12th Industry Standing Group (ISG) meeting

28th March 2025, Chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome/Introductions

The Chair welcomed all participants to the first ISG of 2025 highlighting that the group is now a well-established forum facilitating discussions on strategic topics, including activities to implement the EMA extended mandate and other new legislation.

An overview of follow-up actions arising from the 11th ISG meeting was provided. ISG members were informed of the publication of ICMRA Collaborative assessment pilot report and Collaborative hybrid inspection report and were encouraged to promote participation in the 2025 extended pilots.

ISG members were encouraged to consult the IRIS forum to obtain the updated roadmap and to keep abreast of the latest developments, including the actions required by Marketing Authorisation Holders (MAHs) for the IRIS transition of initial marketing authorisation planned for 2025.

ISG members were also informed on how the topic proposals submitted in the context of 2024 feedback survey will be addressed during the next meetings of the group as applicable.

Link to presentation.

2. Implementation of the extended mandate and shortages related activities

2.1. Update on the development of the European Monitoring Platform (H)

The EMA provided an update on the European Shortages Monitoring Platform (ESMP) following its successful launch in January 2025, ahead of regulatory deadline. The successful collaboration with industry stakeholders was considered paramount for delivering the platform.

The ISG was briefed on the current development objectives, with focus on delivering the Application Programming Interface (API) interoperability and were reminded about the recent workshop for MAHs.

ISG members were invited to participate to the survey to gauge the interest in the API usage by the 25th of April (link).

Given the completion of the key activities for the development of the ESMP, the involvement of Subject Matter Experts will be put on hold until further notice. However, Industry stakeholders will continue to be contacted and updated as necessary.

The ISG was also reminded about the Product Management Service (PMS) updated roadmap and current activities. Significant progress was noted in terms of submitting the required data on packages, manufacturing enrichment and structured package details. Nevertheless, the call to action to MAHs to submit data on packages in XEVMPD, manufacturers and structured pack size data in Product User Interface (PUI)/PMS API is still applicable.

Link to presentation.

Actions arising:

- MAHs to complete submission of packages in XEVMPD by end of May 2025.
- MAHs to complete submission of manufacturers and structured pack size data in PUI/PMS API.
  - For centrally authorised medicines (CAPs): submission not required as data is available, MAHs should confirm that PMS data is correct
  - For non-CAPs included in the union list of critical medicines submission required until end of December 2025.
  - For other non-CAPs submission required until end December 2026.

2.2. Transfer of Task Force on Availability of Authorised Medicines for Human and Veterinary Use activities and the working group of the MSSG on vulnerability assessment methodology (H+V)

The EMA confirmed the transfer of all activities led by the Task Force on Availability of Authorised Medicines (TF-AAM) to the Executive Steering Group on Shortages and Safety of Medicines (MSSG) and the Working Party (WP) on Shortages of Medicines (SPOC). Close collaboration between the different MSSG working groups, SPOC WP subgroups and the Working Group of Communication Professionals will ensure alignment and avoid potential overlap.

The outcomes of the TF-AAM, such as the work on the definition of shortage, guidance and templates on shortage management and communication, will be summarised in a report expected in Q2 2025. The mandate and objectives of the MSSG working groups on the Voluntary Solidarity Mechanism and Policy and the Vulnerability Assessment Methodology were also presented.

The work of the MSSG and the SPOC WP will take into account the future EU pharmaceutical legislation and the Critical Medicines Act to further strengthen the security of supply of critical medicines and the prevention of shortages.

The ISG was reassured that close collaboration with stakeholders will be maintained through the new structures.

Industry stakeholders (PPTA, EFPIA) welcomed the streamlining activities and underlined the need to avoid duplication of work and to involve stakeholders in the vulnerability assessment activities in order to reflect the specificities of certain sector such as plasma derived medicines and vaccines. The EMA confirmed that stakeholders will be informed as the work evolves. It was also clarified that the MSSG WG on the Vulnerability Assessment Methodology will take into account the EC commission Technical Report and the work of the Critical Medicines Alliance set out in the Strategic Report and will identify areas where further refinement is needed in order to provide a reliable methodology.

Link to presentation.

2.3. Cross-industry learnings on Union list of critical medicines (H)

The ISG presented the results of a cross-industry survey on the experience and learnings with the union list of critical medicines. The need to ensure harmonisation and alignment across Member States, to limit the regulatory burden and complexity for industry stakeholders and to consider sector specific aspects was highlighted in order to ensure medicines availability. Recommendations were presented accordingly.

The EMA welcomed the feedback received which will be shared with the MSSG. It was also clarified that the union list of critical medicines was developed using a methodology finalised and commonly agreed by the network and taking into consideration the EC structured dialogue on security of medicines supply performed in 2021. Further analysis of vulnerabilities in the supply chain of critical medicines is expected, as required in the proposed pharmaceutical legislation and the Critical Medicines Act.

It was also noted that national lists will continue to exist in addition to the union list given the need to reflect national needs and interests and that the MSSG will work on a process for reviewing and consolidating the list in line with the proposed legislation.

Industry stakeholders (EuropaBio, Vaccines Europe) would welcome active engagement with the MSSG in order to discuss industry stakeholders' specific needs and potential impacts of the presented provisions.

Actions arising:

- EMA to share the feedback received with the MSSG.

2.4. Medical Devices expert panels (MD)

The EMA provided an update on the expert panel activities, namely on the ongoing orphan medical devices pilot (opinion on orphan device status and clinical data needed for the conformity assessment) and advice to manufacturers (on their clinical development strategy and/or clinical investigation proposals).

The interim report providing an overview of the learnings from the applications received during the pilot on the advice from the expert panels to manufacturers of high-risk medical devices was noted. The pilot informed key process improvements and new measures for the efficient implementation of the standard procedure for advice to manufacturers which is now provided as a regular service.

Companies who participated in the pilot confirmed the benefits of the experience in terms of flexibility of the process, access to experience clinicians and increase in predictability for the expert panels consultations procedures.

Additionally, ISG members were informed about an ongoing project of observership by Health Technology Assessment (HTA) bodies of a limited number of procedures of advice to manufacturers. The experience will inform the implementation of a future parallel Joint Scientific Consultation (JSC) between HTA bodies and expert panels foreseen in the HTA Regulation (HTAR).

The ISG members were encouraged to raise awareness on the beginning of regular service for advice to manufacturers.

Link to presentation.

2.5. Emergency Task Force (H)

The EMA provided information on the extension of the remit of the Emergency Task Forced (ETF) to include antimicrobial resistance related activities.

The ISG noted the overview of the current scientific advice initiatives available for industry stakeholders. In particular, the ETF scientific advice mechanism during a declared emergency as well as during the preparedness phase was outlined. The activities taken to promote harmonisation of clinical trial applications and marketing authorisation applications across Member States (such as appointment of two ETF coordinators, the specific forum of member states concerned and the Ethics Advisory Group) were highlighted.

The relevant sections of the IRIS application form for requesting ETF scientific advice were shown.

The ISG was informed that pre-submission and discussion meetings are also foreseen in the ETF scientific advice process. Industry stakeholders also asked for the possibility to involve the US FDA in the mechanism. The EMA confirmed its continued engagement with international regulators to harmonise regulatory requirements and will continue to reflect on the possibility of coordinated advice.

Link to presentation.

3. Implementation of the HTA Regulation

3.1. Regulatory/HTA interface under the HTA regulation (H+MD)

The EMA provided an update on the implementing activities at the regulatory/HTA interface under the HTA regulation, which is now in application phase.

In terms of the operational aspects of the interface between Centralised Procedure (CP) and Joint Clinical Assessment (JCA), the ISG was reminded of the need for Industry to indicate in the letter of intent whether their upcoming application is in scope of JCA . The importance of submitting the letter of intent in parallel to both EMA and HTA secretariat was stressed.

Update was also provided on the activities for the Joint Scientific Consultation (JSC) for medicinal products. Industry stakeholders were invited to contact the EMA as soon as they received positive feedback from the HTA secretariat about their request for JSC and to register the parallel consultation via the IRIS platform. Industry was also reminded to ensure parallel submission of the briefing package to the EMA and HTA secretariat.

The EMA also provided an overview on the support provided on the expert identification in the context of JCAs and JSCs.

In relation to medical devices, activities are being undertaken in order to revise the parallel JSC briefing document template, on providing forecast activities and assistance of selection of JCA/JCS for medical devices and in vitro diagnostics.

Additional information is published on the European Commission webpage: Implementation of the Regulation on health technology assessment and support can be requested at the following address: SANTE-HTA@ec.europa.eu.

Industry stakeholders welcomed the update and agreed to raise awareness amongst their members.

The HTA secretariat re-confirmed that mechanism to ensure confidentiality are in place, as guided by the legislation.

Link to presentation.

Actions arising:

- Industry stakeholders to ensure parallel submission of letter of intent to both EMA and HTA secretariat was stressed.

4. Other topics of strategic interest

4.1. Cross-industry presentation: Survey results on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative (H)

As agreed during the 11th meeting of the ISG, Industry stakeholders were surveyed on the reasons behind the low participation to the OPEN initiative.

According to the results, although Industry stakeholders welcome this initiative, the operational uncertainty/complexities, the limited scope, the lack of clear incentive and benefits and the potential regulatory divergence amongst OPEN partners represent a barrier. Recommendations were made to raise awareness, including possible linking of OPEN and reliance procedures.

The feedback was welcomed by the EMA who will further reflect in order to understand where improvements could be made. The EMA also confirmed the need to also gain additional knowledge with more products and confirmed the desire from all OPEN partners to align in terms of timelines and list of questions. In order to do so early and parallel submissions should be ensured by applicants.

Actions arising:

- EMA to reflect on the feedback provided by industry stakeholders and provide an update to ISG when possible.
- Industry stakeholders to promote OPEN within their affiliated members.

4.2. Update on ePI (H)

The EMA presented the key learnings and recommendations arising from the electronic Product Information (ePI) pilot (report) done in 2023-2024 on real procedures and that led to the successful creation and publication of ePIs. The ISG noted the overview of pre-implementation work undertaken to finalise PLM portal development and relevant guidance in order to ensure CAP go live ahead of the any foreseen requirement arising from the reformed pharmaceutical legislation.

Industry stakeholders were asked to start considering how to manage ePI technical requirements and how to make ePIs easily accessible to patients and were invited to participate to the public consultation on the Reflection paper on linking to electronic product information (ePI) from EU medicine packages.

The need to ensure an EU wide solution benefiting patients across the EU was stressed.

Industry stakeholders asked for the possibility for companies to submit ePI outside of a regulatory procedure in order to increase adoption. The point was acknowledged and will be considered and communicated as part of the implementation roadmap.

Link to presentation.

Actions arising:

- Industry stakeholders to participate to the public consultation on the Reflection paper on linking to electronic product information (ePI) from EU medicine packages by 30 June 2025.

4.3. Inter-Association Task Force (IATF) for ePI feedback (H)

A cross-industry presentation was given outlining the current thinking on the implementation of the ePI. The benefits of the ePI and the pilot activities were highlighted. Recommendations were made regarding system enhancements (such as links to SPOR and case management tools), multilingual functionality, ensuring applicability across member states and ensure predictability with a clear timeline.

Industry stakeholders confirmed the shared vision of ensuring a simple and single portal that will enable patients to visualise relevant updated safety information.

The Q&A session covered aspects of Industry preparedness and highlight the need of having a solution that fulfils the European requirements for personal data protection.

4.4. Update on EMANS to 2028 (H+V+MD)

The EMA and HMA provided an update on the European Medicines Agencies Network Strategy to 2028 which was recently adopted and published. Details were provided on how the feedback provided by stakeholders during the public consultation was incorporated in the updated strategy.

The ISG was invited to consult the Analysis and summaries of the public consultation results in order to obtain more detail on the comments received.

It was clarified that the EMA and HMA are now defining the key activities to transition the strategy into the EMA and HMA multi-annual workplans and that a mid-year report is foreseen in 2027. It was also o clarified that no specific updates will be made to already released working party workplans; instead, the work will be incorporated to existing activities.

Industry stakeholders stressed the importance of ensuring a horizontal cross-agency work in order to ensure full implementation of the strategy and ensure availability of medicines.

Link to presentation.

5. AOB Industry stakeholders survey on communication and engagement

A call for volunteers was launched in order to establish a drafting group to work on a survey an Industry stakeholders' survey on the Agency's engagement and or communication activities. The initiative is done in line with the Framework for interaction between the European Medicines Agency and industry stakeholders and aims at ensuring effectiveness of and high responsiveness to the Agency's communication and engagement activities.

Link to presentation.

Actions arising:

- Industry stakeholders to submit 1 nomination per trade organisation by the 11th of April.

6. Close of the meeting and next steps

ISG members were informed about the planned dates for 2025 ISG, platforms, quarterly system demos and quarterly strategic portfolio review meetings.