30 September 2025

European Medicines Agency

Highlights of the 14th Industry Standing Group (ISG)

30th September 2025 - Chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The chair welcomed ISG members and attendees from the regulatory network and medical device authorities to the 14th meeting of the year.

1.1. Actions arising from previous meetings and other updates

The actions arising from the previous meeting were presented briefly. Industry stakeholders were reminded about the key topics requiring action, such as the Product Management Service (PMS) data enrichment, for which the deadlines for submitting the required data have been extended. They were also reminded about the applications for the Portfolio and Technology Meetings (PTMs) for Q1 2026 open until 14/11/2025.

Link to presentation.

2. Implementation of the extended mandate and shortages activities

2.1. Update on the Union list of critical medicines (H)

The ISG was informed of the upcoming update of the Union List of Critical Medicines (ULCM), which was first published in December 2023 with the aim to identify the most critical medicines at Union level to ensure functioning of healthcare systems by ensuring availably of the products.

The latest annual update was initiated with Member States in July 2025 to identify medicines where criticality or availability may have changed. In scope of this revision there are 61 active substance groups where a criticality re-assessment due to reasons linked to history of critical shortages, increased or decreased demand/criticality and change in indication that increased or decreased the previous criticality risk.

From 1st of October to 1st of November stakeholders are expected to further contribute to the assessment before finalisation of the revised ULCM 2.1 by MSSG (Medicines Shortages Steering Group)

and publication in December 2025. It was clarified that stakeholders consultations planned in January 2026 will focus on inclusion or removal of medicines in the ULCR.

Link to presentation.

2.2. Vulnerability Assessment (H)

The ISG was updated on the ongoing work of the working group of the MSSG on the Vulnerability Assessment Methodology aiming at establishing the methodology for the identification of vulnerabilities in the supply chain of critical medicines. The work is the prosecution of the European Commission (EC) structured dialogue on security of medicines supply initiated in 2021 and the Critical Medicines Alliance in 2025.

The methodology proposed was outlined highlighting the ULCM as starting point and stressing the need for industry and member states to avoid data gaps by ensuring PMS data enrichment.

More details were provided on the methodology which includes a phase 1 aiming at establishing the "supply vulnerability index" that can inform the ranking of each substance included on the ULCM. This is followed by a phase 2 consisting in a detailed and specific analysis at the medicinal product level, allowing for identification and clear understanding of specific supply-chain vulnerability.

The ISG was invited to contribute to the vulnerability assessment methodology by providing feedback by the 03rd of October. It was anticipated that a meeting between MSSG and industry stakeholders will take place to discuss the input provided before finalizing the methodology.

Industry stakeholders welcomed the update and the possibility to contribute to the methodology. Proposals were made to ensure inclusion of geographical areas where EU trade agreements are in place and to also consider historical data and the information that could be obtained from the Shortage Mitigation and Prevention Plans. Considerations for specific cases (such as plasma medicines) were also flagged.

The EMA welcomed the comments made and clarified that the initial methodology can be further fine-tuned to ensure fit for purpose.

Link to presentation.

Actions arising:

- ISG to provide feedback on Vulnerability Assessment Methodology by 3rd October 2025.
- EMA to organise an MSSG-Industry meeting.

2.3. Update on the Shortage Mitigation Plan (SMP)/Shortage Prevention Plan (SPP) (H)

Following the publication of the SPMP templates on the 18th of June 2024, a 6-month pilot phase was launched in December 2024 to facilitate implementation of SPMP by marketing authorisation holders and competent authorities. The feedback received from the pilot highlighted the need for more guidance and for refining the templates to ensure that the data provided can be used for the effective identification of supply chain vulnerabilities. A report on the pilot is expected to be published by the end of 2025 and will be shared to Industry accordingly. It was clarified that further amendments to the templates will be considered once the final text of the revised pharmaceutical legislation will be published.

The ISG welcomed the SPMP and proposed further cooperation to shape the improved templates.

Link to presentation

Actions arising:

- EMA to share the report of the pilot phase once published.

2.4. Update from the Medical Devices Expert Panels (MD)

An update was provided on the expert panels advice activities. The ISG noted that ongoing advice to medical device manufacturers which now included observers from Health Technology Assessment (HTA) bodies and there will be the possibility of having a parallel advice with HTA Joint Scientific Consultation (JSC). The low level of applications was flagged, and it was clarified that the expert panel is the only body that can provide scientific clinical advice at centralised level.

The experience with 5 test cases for the ongoing orphan device pilot was provided. The ISG was informed of the expected new panel on paediatric and rare diseases to be linked to this pilot phase.

Additional details, including the criteria for inclusion, were provided on the breakthrough device pilot expected to be launched soon.

It was clarified that the pilots are open to all interested companies including small, medium sized enterprise.

Link to presentation.

3. Regulatory/HTA interface under the HTA Regulation (H+MD)

An update on the activities related to the regulatory/HTA interface when implementing the HTA Regulation was provided confirming the good progress. In terms of the notification of upcoming Joint Clinical Assessment (JCA) procedures, it was emphasised that there are opportunities for improvement in compliance with parallel submissions to EMA and the HTA secretariat and in applicants' responsiveness to reminders. The publication of the Frequently Asked Questions document and the List of ongoing JCA assessment published by the HTA secretariat were noted. Industry was also invited to attend The EU HTA Regulation: Webinar for health technology developers of medicinal products.

Furthermore, the EMA shared the first experience in providing information from the centralised procedure. The principles followed are: alignment with respective remits, sharing appropriate and relevant information only via the secretariats. A review of the 12 months experience on exchanging information will be conducted. In terms of Joint Scientific Consultation (JSC), the update of the applications received for the parallel JSC was noted.

The forecast report for medicinal products and the quarterly report to support the selection of the MD and IVDs were confirmed as ongoing activities from the Agency.

The ISG welcomed the update and expressed their support and availability in working further with their members to resolve the JCA compliance problem. The proposals to have additional discussions in dedicated groups and the importance of having JSC schedule of calls for expression of interest in advance were acknowledged.

Link to presentation.

4. Regulatory Science Research Translation

4.1. Update from the Focus Group Regulatory Science Research Translation (H)

The ISG was updated on the work done by the focus group on regulatory science research translation. The group was formed in September 2023 to address the gap in translating promising research outputs from consortia into practical applications that deliver concrete and impactful solutions for public health. An overview of the recommendations drafted by the group was provided noting the consultation occurred in 2024 and the publication expected by end of 2025.

The ISG acknowledged the positive experience and the important achievement of the group which is now being closed as it delivered its goals. There was a general agreement on the need to keep working on actionable recommendations that could ensure acceleration of science research translation into medicinal products.

Link to presentation.

4.2. Update on the European Platform for Regulatory Science Research (H)

The ISG was updated on the EMA/HMA European platform launched earlier in 2025 to advance research in regulatory science for improved development of medicines.

In addition to the steering group consisting of researchers and regulators and the platform of researchers, it was confirmed that observers from industry, patients and healthcare professionals is envisaged. It was also clarified that additional expertise will be invited to join ad hoc meetings.

The criteria for submitting the nomination were outlined and the ISG was invited to submit their nomination for 1 observer representing industry by the 28th of October.

Link to presentation.

Actions arising:

- Industry to submit 1 nomination for observer to the European Platform for Regulatory Science Research by EOB 28th October.

5. HMA-EMA Catalogues of real-world data sources and studies (H)

The EMA presented the HMA/EMA catalogues launched in February 2024 aiming at providing a transparent overview of existing data sources to enable the use of real world data in regulatory decision making. A short demo was provided showing the information available in the catalogues and how these is linked to studies, data sources and network.

The results of a survey to Industry stakeholder in 2024 on awareness and use of the catalogues confirmed the usefulness of the catalogues in several areas and outlining the improvement made to the system.

To evaluate the impact and effectiveness of the improvements made, an additional survey was circulated in September 2025 to ISG members who were invited to raise awareness about the use of the catalogues and to present the feedback received at the next ISG meeting planned for 11th December 2025.

Link to presentation.

Actions arising:

- Industry to gather the feedback from affiliated member and nominate a speaker to present the consolidated feedback at the next meeting of the ISG in December.

6. Patients Experience Data reflection paper update (H)

An update was provided on the Patients Experience Data (PED) reflection paper which was published for public consultation until the 31 January 2026. The reflection paper discusses types and sources of PED, general principles and elaborates on the use and value of PED across the medicine lifecycle.

The ISG was also invited to provide feedback to the survey on the use of PED in therapeutic areas by the 19th of October 2025.

Industry welcomed the PED reflection paper as a tool to increase predictability of applications. The possibility to have a dedicated workshop to further discuss case studies and experience in applying PED was discussed.

Link to presentation.

Actions arising:

- ISG members to promote industry members contribution to the PED public consultation (by 31/01/2026) and therapeutic areas survey (by 19/10/2025).
- EMA to evaluate a possible workshop after the feedback from the PED reflection paper public consultation.

7. AI research needs in medicines lifecycle survey (H, MD)

The ISG was reminded to contribute to the survey on Artificial Intelligence (AI) research needs issued on the 30th of September. The survey addressed the discussions raised during the 2024 HMA/EMA multi-stakeholder workshop on artificial intelligence (AI). More specifically the feedback received will be used to inform regulatory research priorities for AI in medicines; to inform future prioritisation and update of regulatory requirements and to contribute to a safer, more effective AI ecosystem, in medicines.

The ISG was also informed of the intention to launch a call for nominations for the establishment of the AI focus group which is expected to start its activities on the 7th of November 2025.

Link to presentation.

Actions arising:

- ISG to promote industry members contribution to the survey by EOB 17th October 2025.
- ISG to provide nominations for AI focus group by EOB 24th October 2025.

8. MDR&IVDR related topic (MD)

8.1. Industry Positions on MDR & IVDR related topics

A joint presentation from EFPIA and MPP was provided highlighting industry areas for priority linked to the provisions outlined in the Medical Device Regulation (MDR) and Invitro Diagnostics Regulation (IVDR) and the need to improve the coordination between MDR/IVDR and clinical trials regulation.

Industry (EUCOPE) flagged the need to ensure that relevant expertise in included in the discussions given similarities but also specific ties of MD and IVD and committed to share additional details.

8.2. EMA activities in support to MDR and IVDR

The EMA provided an overview of the activities where support is being provided while waiting for final text of the revised pharmaceutical legislation. The activities include operational support by providing regular guidance to stakeholders and contribution to EU initiatives such as the COMBINE and the MFR/IVDR revision.

The ISG was informed of the establishment of a combination product operational group (COMBO) formed by representatives of NBCG-MED (notified bodies coordination group), device competent authorities, medicinal products authorities, the EMA and the EC and will include 2 subgroups specific for medical device and in vitro diagnostic. Industry involvement will be ensured with a regular dialogue on an ad hoc basis given the important role in the identification of concerns and discussion of solutions.

The ISG welcome the update and the step forward made and expressed support in further contributing to the dialogue. The need to include other areas and expertise was discussed acknowledging the need to ensure alignment with current legislation.

Link to presentation.

9. Close of the meeting and next steps

The chair acknowledged the active contribution of stakeholders and the fruitful discussion on the topics presented and informed about the next meeting of the group taking place in person on the 11th of December 2025.