30 June 2025

European Medicines Agency

Highlights of the 13th Industry Standing Group (ISG)

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

1. Welcome and introduction

1.1. Actions arising from previous meetings and other updates

The actions arising from the previous meeting were briefly presented highlighting the upcoming conclusion of the consultation on the Reflection paper on linking to electronic product information (ePI) from EU medicine packages and the ongoing Industry stakeholders survey on communication and engagement.

The ISG was reminded about the ongoing call for ESMP subject matter experts ending on the 25th of July. Additionally the group was informed about the pilot to re-start face to face CHMP oral explanations and was invited to contribute to the public consultation on the ICH M4Q(R2) Guideline on the Common Technical Document for the registration of pharmaceuticals for human use: Quality ending on the 24th October 2025.

Link to presentation.

2. Commission proposal for a Critical Medicines Act

An overview of the measures included in the commission proposal for the Critical Medicines Act (CMA) was presented. The act considers extensive stakeholders feedback obtained through the structure dialogue and critical medicines alliance initiatives. It aims at providing a comprehensive approach to ensure availability of critical medicines and complementing the revised pharmaceutical legislation.

CMA's four main pillars, aiming at strengthening the security of supply and availability of critical medicines and at improving the availability and accessibility of other key medicines, were presented.

The CMA is currently under examination by the European Parliament and the Council of the European Union, after which the legislative process will move to the trilogue stage.

Industry stakeholders welcomed the update and proposed additional guidance and discussion on the future approaches. It was clarified that specific considerations for certain type of products, such as blood

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and plasma derived medicines, were considered in the proposal in order to allow flexibilities at national level.

It was also clarified that the details of the vulnerability assessment methodology will be developed based on the requirements outlined in the CMA and the revised pharmaceutical legislation. These details are intended to be fit for purpose for all medicines included in the Union List of Critical Medicines.

Industry was reminded of the need to ensure that the data on pack size and manufacturing in the Product Management Service are complete in order to reduce duplications and burdens.

Link to presentation.

3. Update on Product Management Service (PMS)

The ISG was informed about the inclusion in the mandate of the Network Data Steering Group (NDSG) of "master data" and "interoperability" as key priorities for advancing product master data and therefore for establishing the PMS as a reference reliable data source. At this regard, an outline of the guiding principles agreed by the Head of Medicines Agency (HMA) in the paper "Medicinal Product master data for better regulation and better health" to ensure the effective delivery of human medicinal product master data was presented.

It was noted that the integration of PMS data into all regulatory submissions covering the entire product lifecycle (from pre- to post-authorisation) will be done in stages and in line with relevant provisions of the revised pharmaceutical legislation.

The ISG noted that no transition period is envisaged for the data transition from XEVMDP to PMS and that close collaboration with Industry stakeholders is planned to ensure alignment of expectations and timelines. This includes also the ongoing engagement with the Regulatory Optimisation Group (ROG) for the feasibility study on data quality.

Link to presentation.

4. Medical Devices expert panels

An update on the activities of the medical devices expert panels in support to innovation was provided noting the publication of the interim report on the Pilot on the Advice from the Expert Panels to Manufacturers of High-Risk Medical Devices, the advice on orphan device status ending at the end on 2025 with possible expansion to paediatric devices and the preparation of a specific pathway dedicated to breakthrough devices.

Industry stakeholders will be updated with more guidance, including clear definitions and details on the scope, on the breakthrough device pathways.

Link to presentation.

Action arising:

- EMA to update ISG with breakthrough device guidance.

5. Regulatory/HTA interface under the HTA Regulation

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 Joint Clinical Assessment (JCA) procedures, the ISG was reminded on the importance for applicants to ensure parallel submission of the letter of intent to EMA and HTA secretariat. Currently only half of the applicants follow the applicable guidance; also responsiveness to reminders is below expectations. Alternative measures might need to be considered to enable efficient working.

More details were provided on the exchange of information between EMA and the HTA secretariat (Article 3 of the Implementing Act on JCA of medicinal products). It was clarified that, in sharing relevant information from the ongoing regulatory assessment to inform JCA production, the following principles will be ensured: respect of separate remits, exchange through secretariat only and information to be appropriate and relevant.

The second Joint Scientific Consultation (JSC) request period was coming to a close and feedback on accepted requests for parallel JSC is expected in the following weeks. Industry stakeholders were reminded to initiate the submission to EMA via the IRIS platform in case of an accepted parallel JSC. Additional guidance is available on the Agency webpage.

Industry stakeholders acknowledged the challenges in ensuring alignment with the parallel submission of the letter of intent.

They also provided feedback on the use of the HTA IT platform and proposals for improvement, which were noted by the HTA Secretariat. Clarification was provided by the HTA Secretariat on document access within the HTA network.

Link to presentation.

Actions arising:

- Industry stakeholders to raise awareness among members on the need to ensure parallel submission of the letter of intent to EMA and the HTA secretariat.

6. REACH impacts on the healthcare industry

Industry stakeholders (EFPIA) representing other associations from human, veterinary and medical technology industries presented an overview of REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation governing the use and manufacturing of chemicals. The impact that this framework has on medicine legislations was highlighted with various case study examples.

The need for all relevant agencies and all concerned stakeholders to ensure engagement and alignment, especially in the view of the upcoming REACH revision process, was stressed.

The Agency welcomed the presentation and confirmed active cooperation with the European Commission and the European Chemicals Agency (ECHA). Industry stakeholders asked EMA to make them aware of substances being considered for new ECHA restrictions. Industry stakeholders were also reminded of their responsibility to stay up to date with ECHA requirements.

Actions arising:

- EMA to facilitate dissemination of information on relevant ECHA regulatory procedures (restrictions, classifications) to industry.
- Industry stakeholders to monitor ECHA requirements.

7. Innovation and reliance

- 2 years of experience with the Quality Innovation Group

The ISG were encouraged to participate to the activities of the Quality Innovation Group (QIG) which, through listen and learn focus group and product specific support meetings, aims at providing a platform for discussion and supporting modernisation of manufacturing and implementation of novel manufacturing processes in Europe.

Industry welcomed the QIG focus on competitiveness and innovations and suggested exploring how to further evolve QIG discussions and discuss regulatory requirements for new technologies.

The proposal was welcomed especially in the view of the future role of the QIG in implementing the Critical Medicines Act by ensuring manufacturing processes modernisation. Industry was encouraged to promote the use of the QIG product specific support meeting.

Link to presentation.

- PQKMS collaborative pilot programs

As presented at the 14th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines, PQKMS (Pharmaceutical Quality Knowledge Management System) collaborative pilot programs (Collaborative Assessment Pilot and the Collaborative Hybrid Inspection Pilots) aim at facilitating implementation of innovation and manufacturing changes across portfolio products at global level.

Industry stakeholders were informed of the recent extension of both pilots and were encouraged to contribute with their applications.

Link to presentation

Actions arising:

- Industry stakeholders to raise awareness on QIG product support meetings and PQKMS pilots.
- EMA to further evaluate how to discuss regulatory aspects with the QIG.

8. Beyond COVID-19 Monitoring Excellence (BeCOME) initiative

Industry stakeholders (Vaccines Europe) presented the recommendations for improving vaccines safety monitoring in Europe arising from the BeCOME initiative.

The need to establish best practices in terms of methodologies and a framework on vaccines safety surveillance, to ensure availability of guidance an update current methodology to boost preparedness for future public health emergencies was acknowledged and further discussion at the level of the Emergency Task Force (ETF) with involvement of relevant pharmacovigilance experts was agreed.

Actions arising:

- Further discuss the topic with the ETF and relevant pharmacovigilance colleagues.

9. Ecosystem information management

- Stakeholders listening pilot: Update on misinformation framework activities

EMA presented two pilots activities aiming at building an information ecosystem management process in order to systematically capture stakeholders needs, expectations, concerns and experience and use them to inform decision making and Agency strategy. The processes in scope of the pilots are misinformation management of acute health events (case study on RSV vaccines) and on stakeholders listening (case study on Long COVID) to anticipate issues and health crises.

Link to presentation.

10. Patient Experience Data reflection paper

The key areas reflected in the Patients Experience Data (PED) paper, expected to be released for public consultation in late 2025, were presented highlighting the importance of considering the use of PED to inform medicines development and decision-making across the medicine lifecycle. Importantly the paper offers EMA support mechanisms (SA, QoNM) as a pathway for applicants who wish to include PED in development programmes and regulatory submissions.

The updated assessment report template including dedicated sections to capture PED data were noted.

Industry stakeholders welcomed the paper and the updated assessment report template. Furthermore, industry invited to also reflect on how patients experience data from social media could be included in regulatory work, highlighting the stakeholder listening pilot on Long COVID as example. EMA highlighted plans to include mention to social media as a potential source of PED in the reflection paper, and also pointed industry to a 2024 report by Big Data Steering Group exploring the use of patient data in social media: https://www.ema.europa.eu/en/documents/other/social-media-data-real-world-evidence-regulatory-decision-making_en.pdf

Link to presentation.

Actions arising:

- EMA to update the ISG upon completion of the pilots.
- EMA to provide an update on the PED reflection paper at the next ISG meeting.

11. European Platform for Regulatory Science Research

The ISG was informed about the EMA/HMA initiative European Platform for Regulatory Science Research aiming at providing a strategic and systematic approach to regulatory science research.

It was noted that the platform fosters collaboration between regulators and academic researchers specifically on questions of common interest. Observer-ship of other stakeholder groups, including industry, is currently being explored and an update will be provided in due course.

Link to presentation.

Actions arising:

- EMA to update the ISG on Industry observer-ship at the European platform for regulatory science research.

12. Close of the meeting and next steps

The chair acknowledged the active contribution of stakeholders and the fruitful discussion on the topics presented.