31 March 2026
EMA/63079/2026
European Medicines Agency

Highlights – 16th Industry Standing Group (ISG) meeting

31/03/2026 - chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The chair and the EMA Executive Director opened the meeting by welcoming members of the Industry Standing Group (ISG) and emphasising the opportunity represented by the revised pharmaceutical legislation to collectively define the future EU regulatory system focused on simplification, innovation, and digitalisation.

2. Revised pharmaceutical legislation

2.1. Opening remarks

The Head of the Stakeholders and Communication Division welcomed the ISG members and highlighted the pivotal moment created by the new pharmaceutical legislation, a major transformation of the EU regulatory framework, aimed at establishing a simpler, more innovation-friendly and increasingly digitalised system. The need for close collaboration to seize this once-in-a-generation opportunity to shape a more connected and efficient regulatory future was underlined.

ISG members were encouraged to maintain open dialogue and share proposals and concerns, if any.

2.2. Update from the EC on the revised pharmaceutical legislation

The European Commission (EC) provided an overview of the key aspects of the reformed pharmaceutical legislation highlighting that that the core principles of safety, efficacy, and quality were maintained while introducing significant changes to support innovation and competitiveness.

Details were shared on the main areas included in the reform: regulatory excellence and simplification, incentives, unmet medical need, access to medicines, measures for orphan and paediatric, security of supply, decentralised manufacturing, inspections, measures against antimicrobial resistance and environmental risk assessment. Additionally, an outline implementation timeline for the new legislation was given, emphasising a two-year transition period for many provisions, with reduced timelines for

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implementation for certain provisions (e.g. availability and security of supply of medicines), the development of a roadmap, and continuous stakeholder engagement through existing platforms and new communication tools.

The ISG welcomed the detailed presentation and raised questions regarding the timing of implementation activities and the need to ensure industry involvement and preparedness by having clear understanding of priorities and timelines.

The EC confirmed that each provision will be prioritised based on the timing for the implementation and that stakeholders will be consulted as needed through all available consultation mechanisms.

Link to presentation.

2.3. Update from the EMA on the implementation of the revised pharmaceutical legislation

EMA provided an update on the activities undertaken in preparation of the implementation phase (i.e. following publication of the final text in the Official Journal) emphasising the important moment of major transformation for the EU regulatory system.

Details on the six delivery streams (centralised procedure & committees, development support, Environmental risk assessment & 3Rs, quality & manufacture, shortages, other regulatory & legal) and the established governance, including members of the EU network, were briefly presented. The intention to use the already established stakeholder platforms, with the ISG as main point of reference was emphasised.

ISG noted the intention to draft a comprehensive roadmap with priorities and timelines by the summer and was invited to flag cross-industry and sector specific priorities.

Additional engagement activities, including a multi-stakeholder workshop (in planning with EC), public consultations, a dedicated webpage and the EMA Industry highlights were indicated as additional tools for stakeholders to be kept updated and to contribute.

ISG expressed support for the roadmap and the consultation on priorities and flagged the importance of clarity on where to discuss horizontal and technical topics.

The Agency confirmed the ISG as main entry point while other groups such as the Industry stakeholders platforms and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) will be used for topic specific discussions.

ISG was informed that a Questions and Answers (Q&A) document is expected to be drafted with all queries received in advance and during the meeting. Additionally the use of Ask EMA was encouraged.

Link to presentation.

Action arising:

- Industry to provide a list of top 10 priorities by mid-May 2026.
- EMA to develop roadmap and keep ISG updated.

3. Implementation of extended mandate and shortages related activities

3.1. Update on Vulnerability Assessment and on the Shortage Mitigation Plan (SMP)/Shortage Prevention Plan (SPP)

EMA provided a summary of the collaborative work carried out since 2022 to draft and pilot the Shortage Mitigation Plan (SMP) and the Shortage Prevention Plan (SPP) guidance and templates, based on the templates shared by industry associations, and feedback received. It was noted that the associated legal provisions become applicable six months after the date of entry into force of the reformed pharmaceutical legislation. EMA confirmed that the SPP template and guidance is being revised to ensure alignment with the legal requirements, taking into account the lessons learned from the pilot, and industry will be consulted as needed. The importance of preparedness was emphasised.

An update was also provided on the activities to implement the Vulnerability Assessment Methodology, which was agreed by MSSG last year following stakeholder consultation. This will inform policy measures under the reformed pharmaceutical legislation and the proposed Critical Medicines Act. As outlined during the Workshop on Vulnerability Assessment (18/03/2026), structured supply chain data will be collected from selected companies to identify structural vulnerabilities and conditional vulnerabilities in the supply chains of those medicines in scope for the 2026 exercise. Following the feedback received at the workshop, a simplified template will be provided to participating companies, and the deadline for data submission has been extended to the 29th of May.

Industry stakeholders were pleased to learn about the improvements made and emphasised the importance of being consulted, in particular with respect to data governance. Stakeholders also noted the need to determine how sector-specific characteristics (such as blood and plasma derived medicines) could be reflected in the template, to enable the identification of appropriate policy measures. The proposal to continue to engage and provide feedback was noted.

The Agency confirmed that the learnings arising from the vulnerability assessment exercise will be key in informing future updates and tailoring the approach. Further engagement with stakeholders will also be considered.

Link to presentation.

3.2. Update on the Union list of critical medicines

EMA provided an update on the 2025 Union List of Critical Medicines (ULCM) which was published in December 2025 following stakeholders and the network consultation. The list was updated in January 2026 to provide a clearer description of the route of administration, thereby improving system operability.

The ISG noted the start of the 2026 revision, for which stakeholder consultation concluded in March. As in previous years, once the analysis of feedback is complete, the list will be updated and shared with stakeholders before finalisation, which is expected in December 2026. It was noted that the final steps will be led by the EC, as set out in the revised legislation.

The ISG requested further clarification on the use of the methodology and the process by which certain products are excluded from the list. The agency confirmed that further clarification will be provided in the form of a Q&A document.

Link to presentation.

Actions arising:

- EMA to provide more clarity on methodology with a Q&A.

3.3. ESMP and harmonisation activities

The EMA provided an overview of a gap analysis exercise performed in the past years, which aimed to identify potential overlaps between European Shortages Monitoring Platform (ESMP) and the European Medicines Verification System (EMVS), and to establish possible interlinks and the potential use of data. The analysis concluded that, while the EMVS cannot replace the ESMP reporting, however some data (such as aggregated dispensation data in conjunction with supply data) could be valuable.

Details were also shared on additional ESMP functionalities, such as the voluntary solidarity mechanism, critical shortage reporting and vulnerability assessment automation. The importance of ensuring Product Management System (PMS) data enrichment was raised.

The ISG also noted the intention to consult stakeholders on the harmonisation of root causes of shortages, with the aim of ensuring consistent terminology is used across member states.

Link to presentation.

Actions arising:

- Companies to ensure PMS data enrichment.
- ISG to contribute to the root cause terminology consultation.

4. Regulatory/HTA interface under HTA regulation

EMA provided an overview of achievements at the regulatory / HTA interface during the first year of application of the Health Technology Assessment (HTA) Regulation, highlighting the continuous learning and experience gained so far. Regarding the parallel processes of Centralised Procedure and Joint Clinical Assessment (JCA), respectively, it was noted that the compliance rate for parallel notification by companies continued to improve, and that for simplification of follow-up the HTA Secretariat is routinely added to reminders. Clarifications were provided by the HTA Secretariat on the JCA eligibility assessment, timelines, and the type of information shared between the EMA and the HTA secretariat, as well as transparency measures.

The completed procedures for the Joint Scientific Consultation (JSC) were summarised high-level, and industry was reminded to first request a slot for JSC if they want to proceed with parallel JSC involving EMA.

The joint focus on evidence needs for different decision making was emphasised, resulting in several activities, including the Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions, HTA contributions to workshops on external controls and patient registries, as well as HTA representation in activities of DARWIN EU, ACT EU and Network Data Steering Group.

Link to presentation.

5. Cross-Industry presentation on PMS Development activities and data quality

The results of a survey on PMS data quality were presented, emphasising the need to resolve certain technical issues affecting the quality of information before the upcoming launch of the PMS public Application Programming Interface (API).

The proposal to further discuss the matter and agree how to address concerns before the scheduled PMS info day was supported.

Action arising:

- The EMA to organise an ad hoc meeting.

6. EFPIA ONE Vision

The EFPIA provided an overview of the 'One Vision' proposal, which establishes a set of principles aimed at modernising the EU regulatory system. The proposal's focus on innovation, integration, interconnectivity and coherence across the regulatory system was noted.

The importance of multi-stakeholder dialogue in realising One Vision, and of alignment with reformed EU legislation and the European Medicines Network Strategy up to 2028, were emphasised.

The EMA encouraged other organisations to present their strategies at future meetings.

7. Actions arising from previous meetings and other updates

The ISG noted the progress on the actions arising from the 15th ISG meeting and the open application for the portfolio and technology meeting (ending on the 30th of April. The EMA Industry highlights newsletter was welcomed.

Link to presentation.

8. End of the meeting

The chair thanked ISG members for the active participation and informed about the ISG meeting schedule noting that meeting time might be extended to provide space for discussion of the EU pharmaceutical legislation implementation activities:

- 29th June 2026, fully virtual;
- 21st September 2026 (instead of 29th September 2026); hybrid.