20 July 2026
EMA/149042/2026
European Medicines Agency

Highlights - 17th Industry Standing Group meeting

29/06/2026 - chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The Chair welcomed all members of the Industry Standing Group (ISG). A status update on the actions arising from the 16th ISG meeting was provided highlighting the progress made, specifically with the industry stakeholders consultation on the top 10 priorities for the implementation of the reformed pharmaceutical legislation and with the consultations on the priorities for shortages root cause terminology.

The ISG was informed about key milestones (such as the planned launch of pre-submission activities in IRIS) and publications.

Link to presentation.

2. Update from the EMA on the implementation of the revised pharmaceutical legislation (H)

The Agency expressed its appreciation to industry stakeholders for sharing their priorities for the implementation of the revised pharmaceutical legislation. Industry indicated that, for both cross-industry and sector-specific priorities, key considerations included planning, timelines, the impact on operational activities across multiple sectors, and the need for clarity and guidance. The importance of ensuring predictability, preparedness, and alignment across the different parties, including with the CMDh, was also highlighted to support successful implementation.

EMA presented the initial version of the masterplan programme, which incorporates the input provided by industry stakeholders, along with the corresponding enablers mapped to the established delivery workstreams. It was noted that the masterplan will be further refined to include more detailed deliverables and activities for each topic. The ISG highlighted the need for additional detail on the planned activities as implementation progresses.

The ISG was confirmed as the overarching forum for providing regular updates on cross-cutting topics, as well as an overview of planned engagement activities and key achievements. More detailed, topic-

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specific discussions will take place through existing industry platforms and ad hoc meetings. An overview of upcoming engagement activities was also shared.

The European Commission provided a brief update on the legislative process and indicated the intention to organise a multi-stakeholder conference on 7 December, subject to the publication of the legislative text in the Official Journal of the European Union, expected by end of 2026.

Industry stakeholders welcomed the presentation and requested greater visibility on timelines, milestones, consultations, and workshops to facilitate internal resource planning and expert participation. The importance of continued coordination between EMA, the EC, national authorities, and relevant stakeholder platforms was also emphasised.

The Agency, the EC, and CMDh acknowledged these points and reaffirmed the importance of alignment across authorities, including at national level. It was also confirmed that a joint Questions & Answers (Q&A) document will be developed to support implementation. The feedback received will be used to further refine the masterplan and enhance clarity.

Link to presentation.

3. Roll-out ePI vaccine Q4 2026 (H)

EMA provided overview of ePI implementation roadmap. ePI is expected to become mandatory in 2028. An update on the ongoing activities, including the planned initial rollout with vaccines and the user acceptance testing (UAT) were presented. It was confirmed that national implementation will be progressed through close collaboration of EMA and national competent authorities.

An overview of all available and future guidance was provided. Industry was invited to familiarise with guidance and take advantage of the UAT to familiarise with the tool and environment.

Industry stakeholders welcomed the update and flagged the importance of including relevant committees and group into the discussion.

Link to presentation.

4. Harmonisation of shortages root cause terminology (H)

An update was provided on development of harmonized shortage root-cause classifications which included incorporated the feedback received from Industry stakeholders. The root-cause terminology is expected to be adopted in July by the Executive Steering Group on Shortages and Safety of Medicines (MSSG) and Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN) will coordination the integration at national level. It was flagged that this works aligns with annex 4 of the revised pharmaceutical legislation.

Industry stakeholders were pleased to see its feedback incorporated into the final proposal and asked for more clarity on the intended next steps.

Link to presentation.

5. Medical Devices expert panels (H+MD)

EMA presented an update on the activities of the expert panels highlighting the current call for experts.

The progress of the overview of the pilot on orphan medical devices was provided confirming the including of 13 designation procedures and 2 advice procedures. It was confirmed that the pilot was converted into a regular service applicable to all device classes and fixed timetables.

Details were shared for the breakthrough devices pilot launched in April 2026. The programme is currently limited to 5/6 procedures of devices class III and IIb AARMP targeting paediatrics and cardiology with the intention to expand the scope to all medical devices and all In-vitro diagnostics in 2027.

Industry stakeholders asked to consider guidance enhancing clarity of the submission status available on the portal currently used.

Link to presentation.

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

The progress of the 18 months implementation of the Health Technology Assessment (HTA) regulation was reviewed.

ISG welcomed the increased compliance rate from applicants on the simultaneous submissions of the letters of intent to EMA and the HTA Unit. Also, the increased of marketed authorisation applications in scope of Joint Clinical Assessment (JCA) was commented upon with acknowledgment of the publication of the first JCA report.

A brief overview was provided on the ongoing parallel Joint Scientific Consultation (JSC) procedures and the 2027 Scientific Advice working party meeting dates and submission deadline were highlighted.

In the context of the collaboration between the EMA, HTA coordination group and HTA unit, details were shared on the enhanced cooperation on transparency, data publication processes and expert identification.

The ISG was invited to consult the Frequently asked questions about the publication of the Joint Clinical Assessment report, the Health Technology Assessment – Member State Coordination Group adopts guiding principles on data transparency and the Questions and Answers on general methodological and procedural issues for joint clinical assessments.

Industry stakeholders were also invited to prepare for the publication of the call for evidence and public consultation HTA-Evaluation of rules.

The ISG welcomed the update and flagged the need to consider alignment with the reduced timelines for marketing authorisation applications foreseen in the reformed EU legislation, to have more clarity on how experts are selected and how to manage discontinued JCA applications.

Link to EMA presentation.

Link to EC presentation.

Actions arising:

- Industry to participate to HTA evaluation of rules consultation.
- EMA/HTA secretariat to reflect on additional guidance for extension of indication in scope of JCA.

7. Update on COMBO (H+MD)

The EMA provided an update on the Combination Products Operational Group (COMBO), outlining its scope and objectives. It was clarified that the group includes dedicated expertise in medical devices and in vitro diagnostics.

ISG took note of the planned interested parties meeting in Q4 2026 and highlighted the need for simplification, including consideration of risk-based approaches for Notified Body Opinions (NBOs).

Link to presentation.

Actions arising:

- COMBO to reflect on simplifications and NBOs risk-based approaches.

8. Instrument for Pre-accession Assistance (IPA) plans with candidate countries (H+V)

European Commission has signalled that new Member States may be joining the EU in the coming years and therefore it is important to support the readiness of EU candidate countries. EMA supports this process under the Instrument for Pre-accession (IPA) programme, supporting capacity building in 10 EU candidate countries. The support includes organization of dedicated trainings, access to EU Network Training Centre (EU NTC) and observer-ship at EMA's WPs-WGs, including for example the Patients' and Consumers' Working Pary (PCWP). Proposals for future activities include candidate countries participation as observers in the next BEMA cycle, support for candidate countries' participation in the EMA/WHO post-authorisation changes pilots, alignment of marketing authorisation dossiers and close cooperation on implementation of the reform of the EU pharmaceutical legislation.

Industry stakeholders were asked to provide feedback on the following questions:

1. Based on your experience, what were the main challenges faced by candidate country National Regulatory Authorities (NRAs) in preparing for EU accession and their alignment with EU acquis and how could these challenges be better addressed in future enlargement rounds?
2. Reflecting on your experience, how effective was EMA's support (e.g. guidance, training, joint activities) in facilitating NRA and industry preparedness, and how could this support be improved or adapted going forward?
3. Looking ahead, which specific areas of regulatory alignment or capability should EMA prioritise to better support NRAs and industry and ensure a smooth and efficient transition at accession?

ISG flagged importance of early planning (regulatory alignment and operational readiness), alignment of dossiers with practical guidance, and improved data interoperability and digital harmonisation, as well as the value of twinning programme.

Link to presentation.

Actions arising:

- Industry stakeholders to provide feedback to EMA on their experience with candidate countries.

9. AOB: Revision of Framework for interaction with industry stakeholders and related documents (H+V+MD)

ISG was informed of the planned revision of the Framework for interaction between the European Medicines Agency and industry stakeholders (EMA/591272/2014), the Criteria to be fulfilled by industry stakeholder organisations involved in EMA activities (EMA/323235/2016), and the associated eligibility application form.

The revision aims to reflect key developments since 2015, including the inclusion of the medical devices industry, the establishment of the Industry Standing Group (ISG), and the evolution towards more strategic engagement, including with senior leaders from the pharmaceutical industry.

The draft revised documents will be circulated to ISG for consultation in due course.

Link to presentation.

Actions arising

- EMA to circulate revised documents for consultation.

10. End of the meeting

The Chair thanked all attendees for the active participation and informed about the time change for the next meeting of the group to ensure that interested colleagues could join the workshop on sandboxes scheduled in the afternoon of the same day:

- 21st September 09:00-12:30 CEST, hybrid.