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Highlight report: 16th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

15 June 2026

Role	Name
Chair	Alberto Ganan Jimenez
Present	Industry: AEGP: Klavdija Kmetic*, Christelle Anquez-Traxler, Paul-Etienne Schaffer, Aurelie Farfaro. EFPIA: Pär Tellner*, Rebecca Lumsden*, Meike Vanhooren*, Stefan Schwoch*, Agnes Legathe*, Simon Bennett, Koen Nauwelaerts*, Susanne Ausborn. EUCOPE: Marcello Milano*, Marta Provencio*, Shekhar Natajaran, Kara Daly, Judit Corderroure, Catherine Lunny, Yvonne Udenwa, Roberta Bernardelli, Bharti Navsariwala, Marianne Poulmaire, Emma du Four. EUROPABIO: EUROPABIO: Sara Gul, Laura Savini, Pedro Franco*, Pauline Roudot, Esteban Herrero Martinez, Laura Liebers*. MEDICINES FOR EUROPE: Beata Stepniewska*, Britt Vermeij, Andrew Modley, Phyllida Duncan, Catherine Oleggini, Lilia Bandeira, Audrey Masserot-Coquard, Sahra Iqbal, Spelca Jenko, Cristina Sola, Katja Pecjak, Ramakrishna Srikakulapu*. MPP Association: Mike Wallenstein. VACCINES FOR EUROPE: Anna Czwarno*, Kateryna Khmilevska, Alessandra Luperto*, Monica Perea Velez, Bart Barefoot, Beatrice Huret, Laura Pintado, Susanne Heiland-Kunath, Raffaella Brandi, Ylenia Runci. PPTA: Evelina Kozubovska, Sebastian Paveza, Eva Perez Palomar, Anna Sorelli. EMA: Andrei Spinei*, Caroline Pothet*, Christelle Bouygues, Cristina Pepato, Elizabeth Scanlan*, Francesca Day*, Juan Garcia, Kristiina Puusaari*, Madalina-Cristina Duta-Mare*, Maria Boulos, Maria Filancia, Melania Fanari*, Michael Vogl, Monica Buch, Nuria Semis-Costa, Paola Samassa, Rosa Gonzalez-Quevedo, Simona Griniene*, Thomas Castelnovo*, Thomas Girard*, Victoria Palmi, Virginia Rojo*, Zahra Hanaizi*. EMA scientific committees, working parties and NCAs: Iola Reischl-Kok (CAT Chair), Liana Martirosyan (PRAC Vice-chair), Marta Marcelino (CMDh Chair), Susanne Winterscheid (CMDh Vice-chair), Menno van der Elst (MEB), Denis Lacombe (EORTC, EMA MB member), Beatrix Horvath (EMA MB member). European Commission: Antonios Rodiadis, Barbara Mentre, Pietro Erba.

* In-person attendance

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This report summarises the 16th EMA-Industry stakeholder centralised platform meeting. These meetings are set up by the Agency as an exchange platform between regulators and representatives of industry stakeholder organisations aiming to foster a constructive exchange on general updates and more focused discussions on specific EMA centralised processes and issues to support continuous improvement.

1. Implementation of the New Pharmaceutical Legislation (NPL)

- **EMA update on NPL activities in stream 1, 5, 6**
- **Industry NPL considerations and priorities**
- **Variations and annex II**

EMA gave an overview on the HMA/EMA established governance for the implementation of the new pharmaceutical legislation based on EMA/HMA NPL Oversight Group, a programme management team and six delivery streams. The implementation will be supported by existing IT governance structures (see presentation).

The near-term objective is to review the final legislative texts, assess impacts, define actions and deliverables, identify EMA/network resources, and prioritize project planning. Industry engagement will happen through a multi-stakeholder workshop, the Industry Standing Group, and topic-specific industry platforms (CP and R&D).

The main delivery focus areas highlighted are Centralised Procedure and Committees, Quality and Manufacturing, and Other Regulatory & Legal topics. Current priorities include initial marketing authorisation, EMA reform/experts, TEVs for priority antimicrobials, Annex II updates, regulatory data protection, product information, and emergency/exceptional authorisation pathways.

In a joint presentation, Industry association supports implementation of the NPL and asked EMA for further clarity, coordination and more information on practical timelines and early engagement to timely input and prevent regulatory uncertainty.

Industry advocates for a clear, pragmatic and risk-based EMA implementation roadmap. Industry is seeking structured engagement mechanisms, including consultations, workshops, Q&A processes, written feedback routes, and potentially a dedicated NPL inbox. The main priorities vary among the trade associations. Common priorities across include: the centralised procedure, ERA, Annex II, ePI/labelling and variations.

Industry also provided some views for consideration on Annex II that aim for simplification to support innovation, align with ICH guidance and lifecycle management principles, and avoid locking detailed technical requirements into legislation.

With regards to Antimicrobial Voucher (TEV), industry welcomes the scientific guidance to provide clarification on eligibility for priority antimicrobials, timelines and the EMA/Commission roles and the required evidence with regards to supply and financial obligations.

Conclusion and follow-up actions

Further engagement on the topic will take place on the Industry Standing Group. The EC is considering a workshop.

EMA is working on the priorities. Any engagement required until next platform meeting will take place through the established representatives of industry association for this NPL topic in the platform and the EMA industry liaison.

2. Variations implementation feedback from industry

Industry associations are overall highly satisfied with new variations classification guidelines implemented in January 2026. Industry requested clarification on certain aspects of the Variations Regulation (worksharings), Variations classification guidelines, PLCM Q&As and use of the eAP for variations.

They also presented an overview of the state of international alignment with the revised EU classification guidelines and requested support in the communication of changes to the EU regulation to authorities from third countries.

EMA provided an oral reply to Industry comments and questions, including clarifications on the use of PLCMs as tool for global harmonization and to summarize the lifecycle of the product within the constraints of the Variation classification guidelines and current EU framework; clarification on the requirements for mandatory worksharings (same change, same outcome, no need for product specific assessment), expectations on the submission of pending IA variations implemented with the old classification guidelines, and advice on using the PLM portal online form for large submissions. EMA also acknowledged the errors still remaining in the eAP and requested companies to keep raising ServiceDesk tickets when a mistake is spotted and include explicit confirmation that all conditions and documentation are met if they are not listed correctly in the eAP. EMA also confirmed its commitment to support reliance for lifecycle management.

Conclusion and follow-up actions

With regards to PLCM EMA guidance, Industry will seek further clarifications on the next interested parties meeting at QWP and BWP. Industry proposed EMA support on communications strategy in outreach to non-EU regulators on the changes to the variations classification guideline. EMA confirmed its commitment to support reliance for lifecycle management on any activity agreed within the EMA/Industry working group on Reliance.

As follow up to the meeting, EMA did not identify any pending reported issues related to the variations eAF. MAHs to keep raising ServiceDesk tickets when a mistake is identified.

3. Centralised Procedure topics:

EMA presented an overview of the focus group on predictability constituted in H2 2023. The group monitored the EMA submissions for MAAs that resulted in 2 published reports and organised an EMA DIA info day. The submissions on time improved from 48% to 57% during the period. The findings of the work of the drafting group were published on a final report. The mandate of the drafting has finalised (see presentation).

EMA also presented the final report on Revamp pilot that tested whether pre-filled D80 assessment report templates and early clarification questions would save assessor time or reduce D120 questions. Results revealed that both core pilot hypotheses were negative. On the other hand, assessors found pre-filled tables helpful.

Applicants found the process resource-intensive, especially aligning report content, tables, and timelines and queried about potential use of AI assisted tools to generate this data.

Industry was also reminded of the recent launch of the revamped ways of working for the product information, for which guidance is available in the response template for applicants to follow (see presentation). In terms of upcoming activities, EMA highlighted the launch of enhanced report (overview) template with IRIS go-live for initials (from September onwards), and implementation of a revamped template/ways of working for extension of indications, expected in the second half of the year. In relation to the co-authoring pilot recommendations for provision of pre-populated tables, EMA took notes of the Industry feedback and will reach out the Industry focus group for REVAMP regarding future implementation of such proposal.

Conclusion and follow-up actions

The focus group on predictability is closed. Any follow up discussions on this matter will take place within the pre-SIG working group or as part of NPL activities.

Industry to refer to guidance available in the response template for addressing comments on the product information.

For the provision of pre-populated tables, Industry focus group for REVAMP will discuss the co-authoring pilot recommendations for consideration of future implementation of such proposal.

4. Pre-submission Interactions Group (PreSIG)

EMA presented PReSIG, a Joint Committee–EMA–Industry working group, covering its objectives, its proposal to pilot a revised pre-submission interaction model for initial marketing authorisation, ongoing activities and next steps, and preliminary information on the intended pilot phase (timing, duration, eligibility and participation criteria) (see presentation).

PreSIG is finalising the revised EMA PSI form, a new list to support participants in preparing for the joint Pre Submission Meeting, and guidance on the new model to support participants during the pilot phase.

Industry provided feedback on the proposal, welcoming strengthened pre-submission interactions and the proposed pilot as meaningful steps toward high-quality submissions and viewed the upcoming pilot as valuable preparation for implementation of the NPL. Industry's key considerations for a successful pilot were presented. Two main topics were debated: the mechanism for defining next steps when no agreement is reached on the submission date, and the criteria for defining dossier maturity. EMA clarified that current legislation applies during the pilot phase and agreed that dossier maturity cannot be defined through a single universal checklist, but rather through a framework supported by guiding parameters that assessors and applicants consider together during the PSM.

Conclusion and follow-up actions

PReSIG activities will continue to finalise the necessary documentation to enable the pilot phase to start, targeting September. Documents will be made available to all stakeholders on the EMA website before the pilot launch.

5. Roll-out ePI vaccine Q4 2026

EMA presented the ongoing pre-implementation activities on ePI including the recently published roadmap. The roadmap outlines the plan for ePI go-live beginning with centrally authorised vaccines (see presentation).

An NCA readiness assessment is ongoing with the intention to define timelines for NCA implementation. EMA described an industry User Acceptance Testing later in the year for industry participants. EMA provided updates on how country-specific/paper-specific information will be handled in ePI. This does not preclude post-processing by medicines information providers.

Vaccines Europe summarised the results of a survey of its members on their interest in participating in ePI go-live. Responses were positive and many companies intend to submit ePI despite some remaining uncertainties that should be resolved with publication of planned guidance on the business process. It is not yet defined how ePI will reach patients. The EMA-HMA FHIR repository will be a trusted source for creating the leaflet. There are many ongoing initiatives and third-party providers.

Industry associations advocate that a central EMA HMA repository should also include member-states specific information of the ePI (e.g. national links for adverse effects reporting, local reps).

Conclusion and follow-up actions

Collaboration between EMA and industry will be needed to enable a user-friendly ePI ecosystem in the EU.

6. Post-authorisation changes reliance pilot

EMA on behalf of the EMA/Industry working group on reliance provided a snapshot of the pilot programme on post authorisation procedures, with 44 pilots initiated using EMA as reference authority by May 2026. A mid-pilot review, based on 9 finalised and 8 ongoing pilots (cut-off end 2025), shows broad global engagement (involving 77 regulatory authorities) and clear benefits: most NRAs reported faster approvals alongside resource savings and, in around half of cases, no additional questions (see presentation).

Built trust in EMA assessment reports has enabled reliance in practice, while convergence of submission requirements has proven feasible and greater predictability has helped mitigate supply risks. Overall, the pilot is contributing to normalising reliance as an efficient way of working, with end-to-end gains observed across submission, review, and implementation. However, benefits depend on how reliance is applied, with key priorities identified as strengthening predictability and convergence, building capacity and practical guidance, and maintaining a strong focus on efficiency.

Conclusion and follow-up actions

EMA, the industry subgroup and WHO will analyse data available by the end of the year to agree on next steps for embedding the pilot into routine practice.

7. Update on digitalisation initiatives affecting CP submissions

EMA provided a presentation to updates Industry stakeholders on EMA digitalisation changes affecting the Centralised Procedure submissions in 2026 (see presentation).

The MAH management on contact points for products under centralised procedure moves into IRIS from 15th June and all pre-submission activities moves into IRIS on 16th August. The management of new MAAs is expected to move to IRIS in September.

Human MAA eAF v1.28.0.0 aligns forms with the ISO Identification of medicinal products (IDMP) and supports testing/rollout towards its use on MAAS from 1st September 2026.

PLM web-based eAF becomes mandatory for human CAP variations from 1st September 2026. PDF eAF use will be rejected except for justified technical reasons.

The optional use of eCTD v4.0 for new CAP MAAs was launched 22nd December 2025; pilots and testing continue, with mandatory CAP use not expected before late 2027.

Conclusion and follow-up actions

Dedicated communication and guidance will be posted on EMA website on the referred digitalisation initiatives.