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Highlight report: 14th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

23 June 2025

Role	Name
Chair	Alberto Gañán Jiménez
Present	Industry: AESGP: Aurelie Farfaro, Christelle Anquez-Traxler, Klavdija Kmetic, Stephanie Pick. EFPIA: Almath Spooner*, Andreas Emmendoerffer*, Markus Goese*, Meike Vanhooren, Pär Tellner*, Rodrigo Palacios*, Simon Bennett*. EUCOPE: Bertrand Fournier, Catarina Madanelo, Jörg Plessl, Laura Liebers, Marcello Milano*, Matthew Ondeck, Neila Bendabaji, Roberta Bernardelli, Sean Byrne*, Shekhar Natarajan. EUROPABIO: Alessandra Leone, Emilien Gantelet, Esteban Herrero-Martinez, Isabelle Colmagne-Poulard, Maily Gonzalez, Marcello Milano*, Pedro Franco*. EUROPHARM: Graeme Ladds. IPFA: Francoise Rossi, Linda Hamra, Marine Moreau, Mónica Bejarano, Stéphane Bellec. MEDICINES FOR EUROPE: Audrey Masserot-Coquard, Beata Stepniewska*, Britt Vermeij, Catherine Oleggini, Elisabeth Kapeller*, Lilia Bandeira, Phyllida Duncan*. PPTA: Dietmar Hollensteiner*, Evelina Kozubovska*, Kathrin Dvorak. VACCINES FOR EUROPE: Agnès Legathe, Anna Czwarno*, Aurora Botti, David Pérez Caballero, Evonne Strand, Helena Ardebrant*, Kateryna Khmilevska*, Monica Perea Velez, Rebecca Lumsden. EMA: Alberto Gañán Jiménez*, Alexios Skarlatos, Andrei Catalin Spinei*, Brendan Cuddy, Brian Dooley, Christelle Bouygues*, Eftychia-Eirini Psarelli, Enrico Tognana*, Evangelos Kotzagiorgis, Evdokia Korakianiti*, Francesca Day*, Francisco Penaranda Fernandez*, Glykeria Spyrou, Juan Garcia*, Klara Tiitso*, Lena Marletta, Leonor Enes, Madalina-Cristina Duta-Mare*, Maria Filancia, Pascal Venneugues, Sonia Ribeiro*, Stiina Aarum*, Tarita Toufexi, Thomas Girard*, Veronika Jekerle, Victoria Palmi Reig, Virginia Rojo Guerra*. EMA scientific committees and working parties: Ilona Reischl*, Kieran Breen, Kora van der Stoep, Susanne Winterscheid, Ulla Wändel Liminga. European Commission: Pietro Erba.

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This report summarises the 14th 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. Variations Regulation and guideline implementation

EMA made a presentation on half-year experience in the implementation of the revised Variation Regulation (Reg (EU) 2024/1701) that entered into force in January 2025 focusing on experience in mandatory Type IA annual update and the established measures for flexibility in support of global development, continuous supply and management of shortages, as well as mandatory submissions of same changes across products through worksharing. See presentation.

The revised EN variation classification guidelines was published at EC website in June 2025 and will enter into force on 15 January 2026. The translations will be published on Q3 2025.

EMA presented the principles for the implementation of the new variation classification guidelines. All variations submitted before 15 January 2026 should be based on the current classification guideline. All variations submitted from 15 January 2026 should be based on the revised classification guideline. With regards to Type I submission implemented before 15 January 2026, MAHs are requested to submit them before that date.

Industry shared their experience and asked for clarification on certain aspects like submission of the same changes as part of a WS when the implementation timelines differ. Industry welcomed the flexibility measures that the Agency has established for submission of Type Is.

Industry noted the need to timely publish implementation guidance, adaptation of SPOR to the new variations classification guidelines and availability of revised eAF in support of a smooth transition to the new classification guidelines.

Conclusion and follow-up actions

The Agency published guidance on implementation of the variations classification guidelines on 30 June 2025 and will organise a public webinar on Q3-Q4 2025.

The Agency will continue monitoring the experience on the implementation of the variation regulations including flexibility measures.

2. Streamlining Regulatory Processes: A Discussion on EMA's Simplification Procedures

An industry representative presented on behalf of the industry associations a number of proposals that could potentially streamline and simplify the EU regulatory processes, with a view to accelerating the approval timelines. In particular, the proposals focused on changes that would be implementable in the short term, without the need for legislative changes.

The proposals included, a more flexible validation process, both for initial applications and for variations; the creation of centres of excellence across the regulatory network; optimising pre-submission interactions; the possibility of receiving questions in batches, rather than in bulk; the adoption of the CHMP opinion the same month as the oral explanation; and improving the certificate processing system.

Conclusion and follow-up actions

The proposals were briefly discussed one by one and there was agreement from all sides that a lot is already being done. EMA stressed that the preference from EMA and the network is for complete and mature dossier at the point of submission, rather than flexible validation and opportunity to supplement during the course of the assessment. This would help accelerate approval times, while the submission of data during assessment would have the opposite effect. Work would continue on the pre-submission interactions, via the Pre-SIG group. The Agency also targets to adopt opinions on the same month as oral explanations, except in the rare cases of significant changes in the opinion after an oral explanation requiring additional to ensure alignment of documentation.

3. Ongoing initiatives on the centralised procedure

EMA presented updates from the Revamp Project and from GIREX. The Revamp Project is streamlining the templates on the Marketing Authorisation application within the centralised procedure and is currently concentrating on aligning other templates to the new Overview, which was launched in January 2025. The revision of the templates for line extensions template is concluded and the group is currently working on the templates for Type II to extend the approved indication(s). There are other templates that will have to be updated, such as the generics/hybrids template and the templates use for new active substance or similarity assessments. See presentation.

EMA also presented the current status of the Revamp Pilot (i.e. applicants pre-filling the D80 assessment report templates). All pilots (11) have now started, and the last procedure is expected to reach D80 in September 2025. Following the last product reaching that milestone, a detailed analysis of the amount of text that was retained between the pre-filled templates and the ones shared at D80 will be carried out. A draft report will be shared with all pilot participants by the end of 2025, with the aim of publishing the full final report in Q1 2026.

EMA then presented data from the ongoing efforts to reduce clock stop timelines. This is the work of the GIREX group, which has been actively working since it became apparent in 2022 that clock stops had exceeded the number of active assessment days. Although the CHMP only started being stricter on extensions from July 2024, last year's data already showed a decrease of the average number of days in clock-stop to 182. It is expected that this number will be further reduced in 2025.

EMA informed on the upcoming launch of a 1-year pilot to re-introduce face-to-face oral explanations in the current setting of alternating in-person and remote Committee plenary meetings. The pilot will start as of July 2025 and cover the CHMP, CVMP and PRAC. See presentation

For meetings taking place in person, applicants will be offered the possibility to attend the oral explanation in person or remotely.

For remote meetings, all oral explanations will continue to be held remotely. It was noted that the same rules apply to in-person or remote oral explanations and that the Agency will not accept requests for changes to the timetable of procedures to accommodate in-person oral explanations.

At the end of the pilot, the Agency will review the experience acquired and present the outcome, including any recommendations at a future Industry platform meeting.

Industry representatives welcomed the launch of the pilot.

Conclusion and follow-up actions

It was noted that the excellent collaboration with the various focus groups. Industry welcomed the pilot on face-to-face oral explanations. Further updates will be provided in upcoming platform

meetings.

4. Regulatory challenges for biological medicinal products for human use

EuropaBio & PPTA delivered a presentation on regulatory challenges for biological medicinal products for human use as identified through surveys conducted amongst their members in 2023 and 2025.

The surveys looked to identify the main barriers for not considering EU as a first region for submission of new MAA, what type of regulatory procedures / flexibilities would address these barriers and what could be improved in the EU regulatory system, as well as the level of satisfaction with the support of the EMA SME support. It was noted that the themes were relevant for all types of human pharmaceuticals with specifics noted for biologics where appropriate.

The presentation acknowledged that at the time of the meeting several of the points raised were being addressed via existing initiatives and workstreams led by EMA, EC and HMA and the new regulatory tools and flexibilities developed, piloted and implemented in recent times were welcome.

Conclusion and follow-up actions

The Agency thanked the industry associations for the points identified in the survey and provided feedback on some of the points raised during the presentation.

EMA emphasised that its quality domain operates on an expertise-based model, providing systematic, risk-based input to CHMP and that efforts are ongoing to improve assessment efficiency, build capacity through training, and establish expert groups.

On EU/US regulatory convergence, EMA highlighted active collaboration with the FDA via dedicated communication channels, cluster interactions and ad-hoc initiatives.

Dedicated Investigational Medicinal Products (IMP) guidelines exist for chemicals, biologicals, and ATMPs, offering harmonised guidance for clinical trial submissions. Early access is supported by the toolbox guidance, but sponsors are strongly advised to seek scientific advice on CMC aspects to avoid delays due to poor-quality dossiers.

Concerning GMP requirements for early-phase investigational ATMPs, EMA noted that EU GMP for ATMPs allows flexibility tailored to the product and process, especially in early clinical phases and that inspectors are trained to apply a risk-based approach.

Regarding GMP certificate renewals and EU coordination, it was clarified in the follow-up discussion that issues mainly concern blood and plasma inspections. The GMDP IWG and EMA are working on reliance strategies and coordinating third-country inspections. Companies are encouraged to inform authorities early before application submission on their proposed manufacturers to allow for early inspection planning.

Finally, EMA highlighted the Quality Innovation Group as a platform for early engagement on manufacturing innovation.

5. Follow-up on the clinical study data pilot

The EMA presented an update on EMA's-CHMP ongoing proof-of-concept (PoC) clinical study data pilot, formerly referred to as raw data pilot. The pilot, a key activity of the joint HMA-EMA Network Data Steering Group, aims to assess whether using clinical study data can help speed up and improve the

medicine-evaluation process and enable patients' faster and better-informed access to innovative medicines. See presentation.

Following an update on the pilot's scope, terms of participation and procedures included, the presentation focused on next steps following the pilot's extension as also in preparation of the potential implementation of systematic clinical study data submission as per the New Pharmaceutical Legislation. More specifically, it was shared that during the pilot's extension:

- exploration of systematic use of clinical study data in support of regulatory assessment and decision-making will intensify;
- Information Technology (IT) solutions to support clinical study data receipt, storage and analytics infrastructure for the European Medicines Regulatory Network (EMRN), including automated processes for systematic package characterisation and data validation will be explored;
- change management activities will also intensify, paying particular attention to production/update of process and data guidance but also training to support the preparedness of all stakeholders involved for the upcoming changes.

EMA's highlighted the excellent collaboration with industry via the Industry Focus Group on Raw Data established in 2022 to promote dialogue and offer the opportunity for members to share their views on specific pilot's aspects. Through this collaboration, guidance for industry and a document on the application of EMA's transparency policy during the pilot were developed.

During the second pilot's phase, it was proposed that collaboration with Industry should intensify while focusing on the following four areas: (1) transparency principles, (2) standardised analyses and visualisations, (3) IT/technical development including validation and (4) data standards and submission requirements. As a result, and as agreed with the Industry Focus Group on Raw Data, it was decided to:

- change the group's name into Industry group focused on clinical study data;
- broaden current membership via technical profiles calls to be launched;
- explore creation of subgroups to support the four aforementioned collaboration areas.

EMA's presentation concluded by highlighting once more that the pilot is extended until further notice and that any interested applicants/MAHs can still express their interest in participating.

Industry presented the results of a survey run via EFPIA affiliate companies aimed to understand the key drivers and barriers to Industry's pilot participation. 27% of respondents have participated or are considering participation in the pilot.

Fewer questions/faster approvals, early insights into forthcoming legislation while also building regulatory goodwill with EMA were the top key pilot participation drivers that the survey respondents highlighted. The top barriers preventing Industry from participating in the pilot as reported in the survey were risk of delaying timelines, high workload, protection of CCI, data-privacy/GDPR concerns as also lack of clear incentives. Industry recommended to provide clear guidance and further assurance that participation will not jeopardise review timelines, to publish case studies where the submission of clinical study data reduces questions/review cycles and to convene an ad-hoc bilateral session between the EMA Data-Sharing and industry experts to address data-privacy and CCI safeguards.

Conclusion and follow-up actions

EMA will continue to closely engage and collaborate with Industry during the pilot's extension focusing on the collaboration areas and recommendations suggested by Industry. Discussions will continue to

take place under the industry group focusing on clinical study data while new calls for technical profiles will also be launched in collaboration with existing members.

6. Update on the ICMRA collaborative assessment and hybrid inspection pilots

Managing global supply chains in a constantly evolving pharmaceutical landscape is a complex process. After initial approval, medicines typically undergo numerous post-approval changes to enhance production capacity and strengthen supply chains. These changes may involve introducing new manufacturing sites, improvements in the manufacturing process, updating testing methods, etc.

EMA provided an overview of the ICMRA PQKM collaborative assessment and inspection pilots launched in 2022 key achievements and learnings. See presentation 1, see presentation 2.

By achieving a standardised 120-day review timeline, reducing information requests, and having near-simultaneous approvals across multiple regions, the pilots have proven that meaningful alignment on CMC data expectations is possible despite existing regional regulatory differences. Initiatives such as this allow global regulators to interact during regulatory assessments may help lay the foundations for future regulatory reliance and work-sharing.

Industry thanked EMA and ICRMA for publishing the collaboration assessment and pilot reports, that summaries experience and learnings, and clearly highlight the benefits of these collaborative initiatives for both, regulatory agencies as well as pharmaceutical industry. Industry considers that the benefits of collaborative activities outweigh challenges and hopes these pilots' results become routing practice.

Conclusion and follow-up actions

The pilots have been extended for an additional year and the scope has been widened to also cover generic and biosimilar medicinal products and are open to receive applications (see links to the ICMRA announcement and ICMRA Collaborative Assessment Pilot Summary Report and Collaborative Hybrid Inspection Pilot Summary Report). Industry is encouraged to actively participate by submitting cases in the pilots.

7. Update on implementation of IRIS for lifecycle management of medicinal products

EMA presented an update on the harmonised implementation of start of clock after a final outcome in the IRIS platform. The presentation outlined the legal background, noting the lack of a clear definition for "receipt" in the pharmaceutical legal framework, which previously led to inconsistent clock start times across EMA procedures. See presentation.

To address this, IRIS has adopted a harmonised approach since 2018 for procedures transitioned to the platform: the clock starts when a notification email is sent to the applicant or MAH, indicating that a new document is available in IRIS. This practice has been dispute-free and will apply to all future IRIS processes. Ongoing cases in legacy systems will retain their current practices until completion, and relevant documentation is being updated to reflect the new approach. The presentation was for information only, and the Agency noted that no alternative implementation approaches were feasible. Industry representatives did not raise any comments or objections during the session.

EMA also shared the 2025-2026 roadmap for Regulatory Procedure Management (RPM) in IRIS, focusing on initial Marketing Authorisation Applications (MAAs). Key processes around MAA include eligibility requests, intent to submit, pre-submission meetings, notifications of change/withdrawal, maximum residue limits, accelerated assessment requests, and Advanced Therapy Medicinal Product (ATMP) classification/certification. Engagement with Industry for the implementation will be carried out through Industry SMEs, in the same manner as previous implementations.

Industry Feedback on IRIS for Lifecycle Management

Industry associations presented feedback on their experience with IRIS for lifecycle management since its implementation for post-authorisation procedures starting on or after 20 December 2024. Some comments were made about PIP implementation in IRIS.

Key issues raised included the lack of automatic notifications are sent when ARs are uploaded or when no documents are applicable for a milestone, requiring MAHs to actively monitor IRIS; procedural timetable updates in IRIS do not trigger automatic email notifications; not consistent receipt of all notification by the MAH contact person.

Industry noted challenges in procedure identification as the numbering does not include the procedure as well as the lack of proof receipt after a document is submitted.

Industry also highlighted some improvements to management of PIPs in IRIS that will be shared with the relevant value stream owner.

Industry provided recommendations, including improved user experience through "favourites" functionality and single-button case folder downloads, automatic emails, automatic assignment of contact persons as well as additional EMA Q&A webinars and regular industry interactions to address ongoing concerns.

EMA committed to reviewing the feedback internally, providing a written response, and discussing the issues further in the Industry SME Forum for IRIS. EMA also noted the cancellation of the June e-business pipeline update due to technical developments with IRIS and was invited to clarify this in follow-up communications.

Conclusion and follow-up actions

The harmonised clock-stop implementation in IRIS was noted as a procedural improvement, with no further changes required at this stage. The 2025-2026 roadmap for IRIS regulatory management was acknowledged as a critical step for managing initial MAAs and post-authorisation procedures.

EMA will address the industry's feedback on IRIS through:

An internal review of the issues raised a written response was shared with industry associations as follow up to the meeting.

Discussions in the Industry SME Forum for IRIS to explore solutions collaboratively.

Clarification on the June e-business pipeline update cancellation and future communication plans, including potential Q&A webinars or regular industry meetings.

All parties agreed to continue close collaboration to enhance IRIS functionality and address operational challenges. Industry associations are invited to provide further input through the SME Forum and ongoing engagement with the EMA IRIS project team.

8. Combination products

Industry representatives from EFPIA and Medicines for Europe made a joint presentation presenting the results of a survey among their affiliates on the current challenges of combination products. Although progress has been done during the implementation, the provision NB opinions for integral medicinal products (Art 117) still emphasizes the need for improved communication among NBs and the EMA to better clarify roles and expertise.

Industry stakeholder also noted the need for a legislative framework that facilitates the provision of scientific advice involving the relevant expertise for combination products, as well as for the co-development of CD with medicines.

The Agency published a Q&A in support of labelling challenges for co-pack medical devices with medicinal products. Industry still faces challenges on the provision of batch-related information for co-pack devices cases where is not technically feasible to attach the labelling required by the MDR. Industry is proposing other alternatives like eliminating the need to provide device data to the user on a risk-based approach. Industry also noted the possibility of inclusion of certain information on SmPC/PL instead of a separate IFU to ensure compliance with MDR and minimise confusion on patients.

The Agency made a short presentation informing of recent publication of an update Q&A clarifying that a MAH declaration of compliance of GSPRs can be provided for Class I devices (non-IS, non-IM). This initiative was highly welcomed by industry. See presentation.

Conclusion and follow-up actions

The current challenges presented by industry are acknowledged. EMA in collaboration with the EC is working on the establishment of an operational group on combination products involving representatives of Notified Bodies and national authorities of medicines and national authorities of medical devices. These topics will be proposed for internal discussion on that group.

Industry engagement will continue through dedicated meeting or during follow up meetings of the platform on the Centralised Procedure.