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Highlight report: 15th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

28 November 2025

Role	Name
Chair	Alberto Gañán Jiménez
Present	Industry: AESGP: Christelle Anquez, Mihai Ionita, Stephanie Pick, Amy Mawson. EFPIA: Pär Tellner*, Simon Bennett*, Almath Spooner, Rebecca Lumsden, Michael Rosentreter, Sacha Wissink, Tim Powell*, Susanne Ausborn, Lynsey Flitton. EUCOPE: Marta Provencio, Marcello Milano, Bharti Navsariwala, Roberta Bernardelli, Suzie Henderson*, Laura Liebers, Esteban Herrero – Martinez, Marianne Poulmaire, Jutta Vlasic, Nadege Le Roux, Bertrand Fournier. EUROPABIO: Pedro Franco*, Alessandra Leone*. EUROPHARM: Graeme Ladds. MEDICINES FOR EUROPE: Beata Stepniewska, Britt Vermeij, Phyllida Duncan*, Catherine Oleggini, Lilia Bandeira, Sahra Iqbal, Audrey Masserot-Coquard, Anjana Pindoria, Dmytro Lurye, Beatriz Solanas*. MPP Association: Adrian Sutter, Nathalie Schober-Ladani. PPTA: Dietmar Hollensteiner*, Evelina Kozubovska*. VACCINES FOR EUROPE: Vera Dinis, Agnès Legathe, Susanne Heiland-Kunath, Kateryna Khmilevska. EMA: Alberto Gañán Jiménez*, Alex Barbosa Correia*, Alexios Skarlatos*, Charlotte Hallin, Francesca Day*, Francesco Pignatti, Francisca van Doesum-Wolters*, Francisco Penaranda*, Katre Rugo*, Kristiina Puusaari*, Maria Filancia, Michiel Hendrix, Rosa Gonzalez-Quevedo, Thomas Girard*, Virginia Rojo Guerra*. EMA scientific committees and working parties: Kieran Breen (CAT Vice-chair), Adam Andersson (CMDh).

* In-person attendance

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This report summarises the 15th 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 Classification Guideline on variations

Implementation of the Classification Guideline on variations

The EMA gave a presentation on the experience with the amended Variation Regulation (Regulation (EU) 2024/1701), including statistics on variation and worksharing procedures. Of note, MAHs are reminded that Type IA variations which do not require immediate notification should be submitted as part of an annual update. A justification should always be provided for exceptional individual submissions outside of this, as set out in the EMA guidance. The EMA will continue to monitor the implementation of the amended Variation Regulation and the new EC Variation guidelines (2025). See the presentation (1)

Industry representatives shared their experiences and asked for clarification on certain aspects of the amended Variation Regulation, the EMA post-authorisation guidance and on the variations classification guidelines.

The Agency gave a second presentation addressing some questions raised by Industry representatives regarding the implementation of the EC Variation guidelines (2025) including the cut-off date, the 'End of the year' recommendation and the impact on Plasma Master File (PMF)-holders. The updated to the EMA' post-authorisation guidance was also noted. In addition, the Agency provided an update on the published and upcoming specific guidance. Finally, Industry representatives were informed about the online information session on the EC Variations Guidelines (2025) to take place on 13 January 2026, from 13:00 to 15:00. See presentation (2).

Conclusion and follow-up actions

MAHs are reminded to comply with the updated variations framework and follow the guidance provided. The Agency will continue to monitor the implementation of the updated variations framework. An online information session on the EC Variations Guidelines (2025) is scheduled for 13 January 2026, from 13:00 to 15:00. Further details will be published on the EMA's events webpage.

2. Update on IRIS, eAF and optional submission of CTD 4.0 in the CP

The Agency made a short presentation on the status of IRIS with the following main points See presentation (1)):

- Post-authorisation procedures (variations, renewals, PSURs, etc.) were successfully delivered in IRIS in January 2025 as a Minimum Viable Product (MVP).
- Ongoing work in 2025–2026 focuses on two parallel streams: (1) the continuous improvement of the MVP (bug fixes, usability enhancements, performance) following Agile

methodology and (2) the progressive migration of all remaining centralised procedures currently managed in SIAMED II into IRIS (e.g. initial Marketing Authorisation), with the objective of fully decommissioning SIAMED and having a single platform (IRIS) for all centralised procedures.

- This consolidation will position EMA optimally for the implementation of the New Pharmaceutical Legislation (NPL) in the coming years.
- Long-term vision (post-2026): integration with other EMA portals/tools (PLM portal, Submission Gateway, CESP, CTIS, etc.) is under consideration, but is not a priority for 2026.

The Agency also provided an update on eAF. eAF v.1.28 was published on 28.11.25. The eAF is continuing the work on the 'structured changes' for the implementation for variations and collaborating with the PMS team to solve remaining data issues. See presentation (2).

With regards to eCTD 4.0, the first pilot on technical interoperability was concluded and now the second phase is focusing on analysis and validation aspects and full 'end-to-end' process. The aim is to allow optional use of eCTD 4.0 for new MAA applications for CAPs in Q1 2026.

Conclusion and follow-up actions

Industry concerns on IRIS, eAF and eCTD v.4. were acknowledged and clarified; most issues can be addressed with existing functionality or procedural adjustments. A limited number of follow-up actions were agreed (mainly provision of additional details by industry, as well as Industry to provide their concerns for implementation of variation guideline into IRIS) and EMA will provide more information in 2026 concerning user journey proposals for Industry.

3. Ongoing initiatives on the centralised procedure

EMA presented updates from the focus group on submission predictability, the Revamp Project and from the Pre-SIG group. See presentation.

The focus group on submission predictability has just concluded the close monitoring exercise for the second half of 2025, in which they tracked all planned submissions of initial MAAs (i.e. with letter of intent submission date in H2 2025) and compared them to the actual submissions received. The results were not presented at this meeting, since it was in advance of the last submission deadline, but they were instead presented at a dedicated DIA Info Day, held on 3 December 2025.

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 and the generics/hybrids template.

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 completed. Following the last product reaching the D120 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 an update from the Pre-SIG group, a multi-stakeholder group, with industry participation, which is looking at improving the pre-submission interactions process, in particular with

in mind the revision of the pharma legislation. The group has been working throughout 2025 and has come up with a proposal that was then presented to the CHMP and CAT. The group is now assessing the feedback received from the committee members and will continue working to refine the proposal.

EMA informed industry that the quality of translations seems to have deteriorated in recent months. There is an increasing number of corrections to opinion packages (pre EC decision) and corrigenda (post EC decision). This causes a lot of work, can lead to protracted exchanges during the translation phase and has led to delays in EC decisions. Their plea is for applicants to ensure translation accuracy since correct translations are key to the correct and safe use of medicines.

EMA also informed industry of a gradual increase in the number of interactions during the redaction process pre EPAR publication. EMA reminded industry that the redaction process concerns CCI and PPD identification only and that EMA will be much clearer in communications going forward that only CCI/PPD redaction or, exceptionally, data error corrections will be accepted.

Finally, EMA clarified the timelines for request of clock-stop extension.

Conclusion and follow-up actions

It was noted the good collaboration with the various focus groups. Further updates will be provided in upcoming platform meetings.

4. Instrument for Pre-accession assistance (IPA): Update on EMA activities and regulatory challenges

The European Commission's Instrument for Pre-accession Assistance (IPA) programme supports EU enlargement by helping candidate countries align with EU pharmaceutical standards. EMA has been involved since 2008, with the current cycle (IPA III) running from 2024 to 2026 with a budget of €600,000. The programme aims to strengthen collaboration with national competent authorities and prepare them for integration into the European medicines regulatory network. See presentation.

Beneficiaries include Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, Serbia, and Türkiye. Georgia, Moldova, and Ukraine also participate in activities but without dedicated funding. The programme focuses on capacity building for medicinal product assessment, fostering scientific cooperation, and harmonising regulatory frameworks with EU acquis. Achievements so far include training hundreds of experts and improving legislative alignment, supported by regular quarterly meetings with candidate countries.

Under IPA III, activities are structured around three pillars. First, training sessions are organised based on candidate country needs, delivered through face-to-face and hybrid seminars and online courses. Second, candidate countries participate in selected EMA working groups in areas such as inspections and antimicrobial resistance. Third, candidate countries have been granted access to EMA's Learning Management System with over 250 users benefitting from a catalogue of more than 120 courses which is continuously expanded.

Challenges of the programme implementation include balancing uniform programme rules with individual country needs, aligning legislation amid ongoing EU pharmaceutical law revisions, and limited funding for newer candidates. Looking ahead, planning for IPA IV (2027 onwards) is underway. EMA aims to deepen cooperation and continue providing a needs-based training offer.

Industry presented their view on engagement with EU candidate countries and stressed that regulatory divergence between EU standards and those in candidate countries creates complexity and delays.

Limited adoption of reliance mechanisms and country-specific requirements, such as mandatory local batch release testing, add to inefficiencies. While digitalisation is progressing, most systems are not yet eCTD-ready.

Industry calls for further cooperation, prioritizing accelerating regulatory convergence, embedding reliance throughout the product lifecycle, and strengthening digital infrastructure to support harmonisation.

Conclusion and follow-up actions

EMA will take into account the input and background information shared by stakeholders when shaping future activities under the IPA programme and preparing for the next cycle. The Agency remains committed to maintaining close engagement with industry and will place particular emphasis on advancing reliance practices with candidate countries.

5. Update on SEND proof of concept study

EMA presented an update on the ongoing Standard for Exchange of non-clinical data (SEND) proof-of-concept (PoC) study. The PoC aims to evaluate the feasibility and advantages of adopting the SEND datasets in the assessment of initial centralised marketing authorisations. See presentation.

With 27 iMAA submissions that have included SEND data in 2025, the objective of the PoC to include between 10-20 Applications has been met. As several of these iMAAs are still under evaluation, the results of the PoC will be reported in the course of 2026.

From January 2026, EMA will continue to stimulate voluntary submission of SEND data by Applicants, continue to support and provide training to non-clinical assessors to gain experience with using SEND data visualisation software and extend this to more member states. Feedback and suggestions on the use of SEND data in MAA evaluations by EMA remain welcome on send@ema.europa.eu

Conclusion and follow-up actions

The results of the PoC will be reported in the course of 2026. Applicants of iMAAs in the centralised procedure are encouraged to participate in the study.

6. Update on review of QRD template

EMA provided an update on the revision of the QRD template.

In first instance, the possibility of inclusion of a new 'Key information section' was released for external consultation until 21 May 2025. 567 comments were received from representatives of patients, health care professionals, industry and academia with very split views and different justifications towards supporting or objecting to its inclusion. Industry expressed concerns on its inclusion during the meeting and highlighted the need for long implementation timelines and consideration only for new products, should the proposal go ahead. See presentation.

Comments to the proposed changes of the revised QRD template were received by 21 August 2025. Proposed changes include a simplification and reorganisation of the information in the package leaflet to enhance patient-friendliness. More than 800 comments were received from 40 stakeholders that are

currently under review. Finalisation is expected by Q2 2026.

Conclusion and follow-up actions

Engagement with industry following the review of comments received on the revision of the QRD template will take place through the established framework of the QRD/industry platform meeting.

7. Patient experience data

The Agency reminded industry trade associations on the ongoing consultation on the Patient Experience Data (PED) reflection paper, and the timelines for submission of comments until 31 January 2026. See presentation.

Industry presented the preliminary feedback consolidated across the trade organisations, including more clarity on the PED definition, the scope and value of patient engagement, and the request for a multi-stakeholder workshop before finalisation of the reflection paper. A proposal for a focus group on transparency and the updated CHMP assessment template with dedicated PED sections was also discussed.

Conclusion and follow-up actions

The Agency acknowledged the points raised by industry and will carefully consider all feedback received from all stakeholders once this is submitted formally when the consultation is closed. A decision on the workshop and further engagement activities will be taken once the analysis of the consultation has taken place.

8. Update on Cancer medicines pathfinder industry focus group

The Cancer medicines pathfinder industry focus group was established to explore opportunities for engagement during the centralised procedure that would lead to a faster, more efficient regulatory system in support to innovation.

An update of the focus group was provided. They explored two proposals of establishing clarification teleconferences with applicants at the time of circulation of the draft AR and a voluntary structured debrief process after the conclusion of the MAA to capture learnings of the procedure.

CHMP to consider proposal for structured debrief and resource implications.

The group proposed to continue exploring opportunities, including to broaden its focus to regulatory/development aspects like benefit/risk communication and treatment optimization.

Conclusion and follow-up actions

Updates about the activities of the focus group will be provided in upcoming platform meetings.