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European Medicines Agency

Highlight report: 13th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

22 November 2024

Role	Name
Chair	Alberto Gañán Jiménez
Present	Industry: AESGP: Christelle Anquez-Traxler, Klavdija Kmetic, Sajjad Jafari, Stephanie Pick. Alliance for Regenerative Medicine (ARM): Michael Werner. EFPIA: Almath Spooner, Amanda Matthews, Koen Nauwelaerts*, Lynsey Flitton, Meike Vanhooren*, Nadège Le Roux, Pär Tellner*, Sacha Wissink*, Simon Bennett*. EUCOPE: Carina Cogan, Joao Duarte, Jörg Plessl, Lucia d'Apote, Marcello Milano, Maren von Fritschen*, Sean Byrne. EUROPABIO: Alessandra Leone, Barbara Nicoletta Cozzi*, Michael Räz*, Pedro Franco. EUROPHARM: Alain Verrijdt, Graeme Ladds. MEDICINES FOR EUROPE: Andrew Modley, Beata Stepniewska, Beatriz Solanas, Britt Vermeij*, Caroline Kleinjan*, Catherine Oleggini, Phyllida Duncan*, Raluca Radu. MPP Association: Andreas Emmendoerffer, Christoph Joosten, Samuel Gavillet. VACCINES FOR EUROPE: Anna Czwarno, Rebecca Lumsden*, Angela Yvonne Kilian, Monica Perea Velez, Anne Bouju, Agnes Legathe, Iain Todd, Evonne Strand. PPTA/IPFA: Evelina Kozuboska*, James Knowles, Linda Hamra, Louise Trouillaud, Stéphane Bellec, Sophie Daninos-Zeghal. EMA: Alberto Gañán Jiménez*, Alex Barbosa Correia*, Alexios Skarlatos, Alexis Nolte, Anne-Sophie Henry-Eude, Constantinos Ziogas, Christelle Bouygues*, Claudia Vicenzi*, Eftychia-Eirini Psarelli*, Elizabeth Scanlan*, Enrico Tognana*, Francesca Day*, Francesco Pignatti*, Juan Garcia*, Karen Quigley, Maria Filancia, Marie-Helene Pinheiro*, Monica Buch*, Silvy da Rocha Dias, Sonia Ribeiro, Stiina Aarum, Thomas Ballotti, Thomas Girard*, Veronika Jekerle, Virginia Rojo Guerra*. EMA scientific committees and working parties: Susanne Winterscheid. European Commission: Kaili Semm.

* In-person attendance

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

This report summarises the 13th 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. Transitional measures to implement the new variation regulation

Several industry associations made a joint presentation on the guidance and transitional measures for the implementation of the amended Variation Regulation (Regulation (EU) 2024/1701 of 11 March 2024) published simultaneously by EMA and CMDh in October 24. Industry noted that additional flexibility regarding the annual update of Type IA variations would have been welcomed, in particular regarding the 3-month submission window and the exception for third countries relying on the proof of acceptance in the EU under certain circumstances.

The Agency made a presentation and addressed some questions raised by industry on the worksharing procedure and further clarifications were provided on the implementation and transition period of the amended Variation Regulation. It was also noted that the date of application of the updated Variations Guidelines is expected to be included in the OJUE publication. See presentation.

Conclusion and follow-up actions

Feedback from industry associations on the guidance and transitional measures for the implementation of the amended Variation Regulation was noted and will be taken into account as appropriate. It was also noted that the guidance could be reviewed, if necessary, in particular in the light of experience with the new framework.

2. ePI Pilots readout, learning and next steps

Industry presented ePI in the context of the entire product lifecycle from the perspective of industry, health authorities, patients and healthcare professionals. The presentation described the current ePI landscape in the EU, including compendia managed by industry and third parties in several Member States, and public-private partnerships working on EU ePI solutions. Next, industry outlined the ecosystem of ePI in the EU, including the EMA-HMA ePI portal, and the healthcare solutions that can use and disseminate ePI data. An EU-level ePI solution for consumers is realisable, as shown by global or EU data ecosystems in other fields, such as railways, weather and flight data solutions. Finally, the IATF (Inter-Association Task Force) position on phasing in of ePI and phasing out of paper package leaflets was presented.

According to the industry presentation, the EMA-HMA ePI portal should be available 1 year after entry into force of the revised pharmaceutical legislation, all key requirements should be in place 2 years after entry into force and the repository should be fully populated 4 years after entry into force. Introduction of ePI should be accompanied by an awareness campaign, and all Member States should adopt the EU ePI Common Standard and use the same repository. According to the IATF position, paper package leaflets should be phased out for products not intended for self-administration and shortly afterwards by other products, with availability of printed copies at the point of dispensing the medicine.

EMA outlined the ePI achievements of the EMA-HMA-EC initiative to date, including the publication of the ePI key principles, the development and adoption of the EU ePI Common Standard, and the development of ePI tooling at the PLM portal. A reflection paper on access to ePI from the medicine package is in preparation. The conclusion of the year-long ePI pilot was mentioned, as well as the upcoming report on pilot outcomes. See presentation.

EMA expressed appreciation of the industry role in recruiting pilot participants and subject matter experts. The presentation highlighted the need for an EU-wide, patient-friendly solution for access to ePI by scanning the data matrix code on the medicine box. The role of the ePI initiative in such a solution was described: the ePI team will annotate ePI with data carrier data and will make archived ePIs available via application programming interface.

During the discussion it was clarified that EMA does not intend to run any further ePI pilots, instead the team will move towards implementation and other activities, such as user acceptance testing, system demos and other communications will be used for engagement. Although the network is moving forward with creation and management of EU-wide ePI, there is as of yet no clear solution by which patients will have access to EU-wide ePI.

Conclusion and follow-up actions

The ePI pilot report will be published in December and ePI team can participate in a follow-up meeting on the topic as required by industry. The ePI product team will continue to consult and involve industry via the standard Agile ceremonies and channels.

The product team is open to hearing about any requirements industry may have regarding developments to enable patient and consumer access to ePI.

3. Focus Group on cancer medicines pathfinder regulatory interactions

EMA gave a short introduction to the Cancer Medicines Pathfinder initiative and presented a proposal to establish an industry focus group to enhance cancer medicines access to patients in Europe. See presentation.

Building on the existing foundation and discussions which have taken place this year within a small group of industry experts, the focus group's key objectives in 2025 will be to discuss piloting activities/centralised evaluation efficiencies proposed to speed up the assessment of promising cancer medicines and identify longer-term strategic initiatives.

Conclusion and follow-up actions

The focus group kick-off meeting will take place in Q1 2025. In this initial meeting the meeting frequency will be discussed and agreed upon. In order to ensure fruitful discussions, the group is expected to consist of about 20 industry participants amongst EU Trade Industry Associations sectors (account of current industry participants should be considered if and as appropriate by relevant EU Trade Associations).

Each EU Industry association is invited to nominate up to 5 industry experts in oncology medicines development (including function and brief summary experience description), who can contribute to discussions and share her/his experience by 6 January 2025.

4. Dynamic Regulatory Assessment

EFPIA made a presentation on the concept of Dynamic Regulatory assessment based on a new way to manage knowledge along medicine development based on data packages building dynamically the submission dossiers.

Conclusion and follow-up actions

The Agency thanked the industry associations for their comprehensive presentation. Many of ideas and concepts are very interesting and shared by all parties. The plan is of course ambitious, and some aspects are reliant on the new pharma legislation. It was agreed that some of the ideas and actions could be considered for trial, or piloting in the work of some of the Focus groups. In particular the two new focus groups that will be formed (Cancer Pathfinder (see point 3) and Pre-submission interactions (see point 5)) will be good fora to discuss some of the concepts.

5. Ongoing initiatives on the centralised procedure

The industry associations made a join presentation with questions to the Agency regarding a number of ongoing initiatives. In particular, there was an interest in receiving feedback on the ongoing Revamp pilot, whereby applicants are asked to pre-fill the factual parts of assessment report templates, and also on receiving more granular statistics on the length and nature of clock-stop extension requests.

EMA presented the current status of the Revamp Pilot. To date, 7 products have been included in the pilot, but only 3 of those have reached post-D80 and have had feedback sessions. Currently, with only 3 products completed, it is difficult to make any firm conclusions. Applicants have reported that the completion of the reports is an onerous exercise, and many of the tables are not "ready-made" in module 2 but had to be constructed from reports. The feedback from the Rapporteurs involved is mixed. In some cases, it was found useful to have the data pre-filled, in others, there was a lot of re-work needed. See presentation.

Overall, it is very useful information for EMA. The pilot continues and will likely only complete towards the middle of 2025. In the meantime, however, there might be updates to the guidance text in the report templates.

EMA also shared more granular data on clock stop extension requests. Unfortunately, the requests were not systematically tracked until mid-2024, but there was some limited information on requests in 2022 and 2023. Since September 2024, once CHMP started to discuss all requests, the data is complete. However, it is only 3 months' worth of data. In that time, 28 requests have been received. Data will continue to be collected and it will be more meaningful by the time of the next platform meeting.

EMA also took the opportunity to launch a call for expression of interest in joining a focus group on pre-submission interactions and to inform MAHs that from Q1 2025, the EPAR page will include a track-changes version of the product information for all authorized innovative products with generics.

Conclusion and follow-up actions

All parties agreed that all the work done to date has been very useful and the collaboration excellent. The Revamp pilot will continue, and a full report will likely be ready in the second half of 2025.

Similarly, the CHMP's approach to clock-stop extensions will continue and data from those will be presented at future meetings. Both EMA and the industry associations are looking forward to continuing to collaborate in the existing and future Focus Groups.

EU Industry associations are invited to nominate participants to the focus group on pre-submission interactions by 6 January 2025.

6. Clinical Study Data Pilot

EMA presented an update on EMA's-CHMP ongoing proof-of-concept (PoC) clinical study data pilot, formerly referred to as raw data pilot, including the pilot's interim results. The pilot is part of EMA's raw data project and stems from one of the priority recommendations issued by the joint HMA/EMA Big Data Steering Group. See presentation.

Following an update on the project's background and mandate, the presentation focused on the pilot's details including scope, timelines and an update on procedures included so far in the pilot. The pilot which started in September 2022, was designed to include clinical study data voluntarily submitted by an Applicant or Marketing Authorisation Holder (MAH) as part of a marketing authorisation or post-marketing authorization dossier for ten centralised procedures. The pilot reached is halfway point in its journey to explore the role of analysis of individual patient data from clinical studies in late 2023 with the inclusion of five procedures in the pilot.

Following this milestone, in December 2023, the cross-Agency's clinical study data pilot ream conducted surveys to gather feedback form all pilot participants (e.g. Rapporteur teams, applicants/MAHs) focusing on four areas: added value for assessment and decision making, capacity and capability, governance and process but also on technical aspects. The pilot's preliminary learnings across the four feedback areas along with recommendations for the second part of the pilot were presented and are compiled in an interim report which is publicly available via EMA's Big Data website. In addition, selected feedback from applicants/MAHs participating in the pilot was also presented protecting the pilot participants' confidentiality. Considering the pilot's interim learnings, clinical study data submission and its use for medicines evaluation, has the potential to reduce overall assessment time, reduce outstanding issues during decision-making and lead to better opinion on indications and warnings. Based on the insights generated so far, EMA and HMA decided to extend the duration of the pilot and continues to accept expressions of interest from applicants/MAHs until further notice.

Finally, EMA concluded with highlighting the excellent collaboration with industry via the Industry Focus Group on Raw Data which was established in 2022 and continues its collaboration with EMA's raw data project team on specific pilot aspects including guidance for industry and application of EMA's transparency policy during the pilot.

Industry presented their views in relation to the interim learnings of the ongoing pilot, highlighting the good interaction with EMA via the Industry Focus group on Raw Data. Industry also noted key challenges including amongst others legal basis for secondary analyses, data privacy and anonymisation, protection of CCI and submission standards while also provided possible future directions to be considered by EMA.

Conclusion and follow-up actions

EMA will continue to closely engage and collaborate with industry during the pilot's extension focusing on areas that were noted as challenging for industry.

The application of EMA's transparency principles to the pilot were once more emphasised, noting that

no access to clinical study data would be given while a product's assessment is ongoing and that any release of data will be anonymised with CCI removed following consultation with the company.

7. Public consultation to review the QRD template for product information

EMA gave an update on the status of the public consultation of the revised QRD template, which is in the internal process flow of the Agency and is likely to be released shortly. EMA confirmed that the agreed 5-month consultation period will be respected. For comments, the same form previously used for other QRD template consultations will be published together with the template.

EMA acknowledged once again all the concerns raised by industry regarding the Key Information Section and invited everyone to reiterate them during the consultation phase and provide further arguments for and/or against.

Conclusion and follow-up actions

The draft review of QRD template is aimed to be released in Q1 25 for external consultation. Industry is invited to provide comments on the text.

8. Lifecycle management of combination products at post authorisation

As a follow up to the previous meeting, MPP made a presentation to further explore regulatory pathways for Connected Combined Products (CCP) and seek clarifications on the variation type and the dossier requirements for the scenario on the optional use of the connected combined product (CCP) without any claimed impact on the safety/efficacy of the benefit/risk of the medicinal product.

EMA also provided a presentation on this topic. On the basis that the choice of variation category is always based on the potential impact on quality, safety, efficacy and the performance of the combined product from the medicinal product perspective, EMA highlighted that a type II variation is expected for the introduction of CCP in the scenario presented by industry, as described above. The reflections shared by EMA on the variation category and dossier content is based on the experience gained so far and this is without prejudice that scientific and regulatory approach is product-specific and should be checked through the appropriate interactions channels with EMA (e.g. scientific advice, pre-submission query). See presentation.

In addition, five industry associations made a joint presentation on industry experience with the application of the MDR Art 117 requirements related to the provision of a Notified Body opinion in the context of a regulatory application for a medicinal product used in combination with a device forming an integral part with the medicine. In their presentation they reflected on findings from a survey conducted to their members relating to: "Consistency of NB Assessments for Art 117 products". This provided insights on their interactions with NBs for obtaining a NB opinion in terms of timeframe and challenges encountered on data in scope of the NB opinion. They also provided positive feedback on the 2024 update of the EMA/CMDh Q&A on MDR/IVDR implementation regarding the guidance provided to clarify when a new or updated NB opinion would be expected during the life cycle management of applications falling under Art 117. Reciprocally, the EMA shared their experience with applications including a Notified Body opinion based on analysis conducted on applications (initial MAA, extensions and variations) submitted between May 2021 and March 2024, findings can be found in the presentation.

As points for consideration, the industry highlighted the following: closer alignment between assessment bodies in relation to scope of assessment for the finished product, compatibility of MAH to fulfil DoC requirement for non-sterile, non-measuring Class I product [i.e. no NBOp/NB involvement] if no regulatory framework for Annex I conformance, legislative framework that supports scientific advice process involving the EMA and medical device bodies.

Conclusion and follow-up actions

The EMA welcomed industry insights and sharing of experience on aspects of the MDR and IVDR implementation which concern medicines used in combination with medical devices. Matters of concern highlighted above by industry are well noted and EMA will continue to closely engage and collaborate with the various stakeholders to provide or contribute to activities and/or guidance to facilitate the interplay between the medicinal products and medical devices frameworks.

9. Clinical Data Publication – next steps consultation

EMA gave a presentation on the proposal to widen the scope of the clinical data publication in line with Policy 0070 following on from the restart in September 2023 which included marketing authorisations for new active substances only. See presentation.

The proposal was initially presented at a dedicated webinar hosted by EMA on 14 November and the documents and recording of that webinar are published on the EMA website.

The proposal is to publish the clinical data for all new marketing authorisations including line extensions and clinical Type IIs from Q2 2025, pending agreement by EMA Management Board in December 2024. Generics, hybrids and biosimilars are excluded from this proposal as they typically do not include clinical study reports and have not been widely viewed on the clinical data portal when previously published.

Access to the legacy products, those clinical data packages not published while Policy 0070 was suspended, is provided for by submitting the standard webform to EMA and the requests for clinical data packages will then be processed by the EMAs clinical data team and published on the portal. Following detailed review, EMA will not publish a listing of these products or initiate publication of these packages apart from on request via the webform. Collaboration with Health Canada continues including a pilot scheme to align publications and avoid duplication of reviews. Updated guidance on preparation of clinical data packages for stakeholders will be published on EMA website prior to the proposed restart in 2025. Publication of clinical data related to medicines for Covid-19 pandemic will continue along with the data for any future public health emergencies.

Conclusion and follow-up actions

General agreement with the proposal was indicated and the next step is to present this proposal to EMA Management Board in December 2024 for endorsement. Once agreed, a start date in Q2 2025 will be announced. A comment was raised on the revision of the biosimilar products guidance and EMA agreed to monitor any changes in the future to the guidance and if clinical studies are included apart from comparability studies.