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Highlight report 10th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

27th June 2023

Role	Name
Chair:	Alberto Gañán Jiménez
Present:	**Industry:** AESGP: Klavdija Kmetic, Paul-Etienne Schaeffer and Stephanie Pick. Alliance for Regenerative Medicine (ARM): Michael Werner. EFPIA: Anne de Bock, Alan Hill, Amira Younes, Emma Du Four, Lynsey Flitton, Meike Vanhoren, Pär Tellner, Stefan Schwoch and Susan Bhatti. EUCOPE: Axel Korth, Andrew Gray, Bertrand Fournier, Chantal Le Floch, Corentin Beauchesne, Joao Duarte, Lucia D'Apote, Maren von Fritschen and Nadege Le Roux. EUROPABIO: Bettina Doepner, Francesca Buttigieg, Marcello Milano, Pedro Franco and Valentin Plouchard. EUROPHARM: Alain Verrijdt, Graeme Ladds, Parminder Kaur and Paula Sanchez. MEDICINES FOR EUROPE: Anjana Pindoria, Beata Stepniewska, Britt Vermeii, Caroline Kleinjan, Dora Halmai, Krisztián András Fodor, Marek Surowiec, Susana Almeida and Wonwoo Chung. MPP Association: Barbara Gollob, Carla Sterk, Leïla-Pauline Collet, Samuel Gavillet and Shayesteh Fürst-Ladani. VACCINES FOR EUROPE: Agnes Legathe, Anna Czwarno, Anna Hanzlikova, Iain Todd, Laura Oliveira, Susanne Heiland-Kunath and Tiago Fonseca. **EMA:** Alberto Gañán Jiménez, Alexios Skarlatos, Alexis Nolte, Anne Sophie Henry-Eude, Elizabeth Scanlan, Emil Cochino, Francesca Day, Irene Rager, Juan Garcia, Karen Quigley, Kristina Larsson, Maria Filancia, Maria Mavris, Marie-Helene Pinheiro, Martin Harvey Allchurch, Michael Berntgen, Radhouane Cherif, Rosa Gonzalez-Quevedo, Silvy Da Rocha Dias, Sonia Ribeiro, Thomas Castelnovo, Thomas Girard, Victoria Palmi Reig and Virginia Rojo Guerra. **EMA scientific committees and working parties:** Carla Herberts **European Commission:** Sara Rafael Almeida

This report summarises the 10th EMA-Industry stakeholder centralised platform meeting. These meetings were developed 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 processes and issues to support continuous improvement. Ultimately, platform meetings foster a constructive dialogue with industry stakeholders.

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1. Expansion of OPEN framework to other type of products & Focus group on Regulatory Reliance

OPEN was established by EMA in December 2020 as a framework to increase international collaboration and share scientific expertise on the evaluation of COVID-19 vaccines and therapeutics. It allows regulators from Australia, Brazil, Canada, Japan, Switzerland and the World Health Organization (WHO) to conduct near-concurrent reviews of certain new medicines and exchange their views and reports on the product assessments. A presentation was given on the expansion of the scope of the OPEN initiative from COVID-19 vaccines and treatments to a wider range of medicines that address an unmet medical need. See presentation here.

The new extended scope of OPEN includes marketing authorisation applications and extensions of the therapeutic indication for:

• medicines targeting antimicrobial resistance (AMR);

• medicines supported through EMA's PRIority MEdicines (PRIME) scheme and which do not qualify as advanced therapy medicinal products (ATMPs) and other medicines addressing a high unmet need

• medicines responding to health threats or public health emergencies.

The roles and responsibilities of applicants/OPEN partners/CHMP members/EMA when managing an application which is reviewed as part of the OPEN framework were also presented.

Industry supports EMA’s proposal to continue and expand the OPEN initiative and would like to contribute its experience with other collaborative procedures in the development and enhancement of the OPEN program to ensure operational value.

In the topic of **Reliance**, the results of a survey developed by the EMA-industry Focus Group on Reliance were presented.

The survey highlighted that EMA is broadly used as reference agency to apply reliance, especially for iMAA (although limited for CMC post-approval changes); however, there is no globally agreed unique process for executing reliance and no consistency across documents requested for implementing reliance (number and types of docs required).

The top 6 benefits of reliance from the industry’s perspective were reduction of timelines to approval, reduction of number of questions from the relying agency, aligned product information, predictable review / approval timelines, reduction of country specific requirements/ harmonization with SRA, and capacity building (review and/or resources) amongst regulators.

The ranking of top 6 challenges in reliance were additional administrative requirements/documents, unredacted assessment report required, no clear guideline(s)/guidance with requirements, reliance not practiced, strict interpretation of product sameness prevented reliance or no regulatory framework to support a reliance submission.

Conclusion and follow-up actions:

As follow up to the meeting a Questions and Answers (Q&A) document on the extended scope of OPEN was published on EMA website on 3rd July 2023.

With regards to reliance, several actions where EMA could help in supporting reliance were proposed and agreed. EMA could continue explaining in appropriate forums how ARs are drafted in the EU to further increase the trust by NRAs to rely on them, the process of issuing GMP certificates following a successful performance of an inspection and the role of eCPPs. EMA could also clarify that industry can share directly reports with third parties.

Industry should continue to share practical experience and identify role models and/or consolidate best practices that EMA could help advocating for, including leveraging SRA-CRP model. A dedicated workshop with WHO on CRP could also be organised.

There is high heterogeneity of administrative documents requested by NRAs at local level. Upon provision of a list of documents requested by NRAs by Industry, EMA could support in performing an analysis of the EMA documents that have scientific and regulatory value for reliance purposes compared to those which are not the final documents in the regulatory procedure and/or represent a duplication of information.

These discussions and actions will be followed in the focus group on reliance. The progress and outcomes of the drafting group will be presented in upcoming platform meetings.

2. ePI

A minimum viable product (MVP) for ePI creation and management has been developed in a project including EMA and NCAs and funded by the European Commission. A presentation from industry provided a list of required functionalities and proposed timelines for ePI implementation including voluntary, transitional and mandatory phases. The presentation noted remaining uncertainties about the timelines for implementation and highlighted advanced functionalities including the possibility of submission directly from Regulatory Information Management Systems (RIMS) and the use of ePI during the assessment in regulatory procedures.

EMA noted that the presentation mentioned some requirements that were already in place, some that could be for post-MVP development and some that could be considered further in the future. Features to be developed will be prioritised in line with EMA's Agile project management methodology.

Conclusion and follow-up actions:

EMA is open to receiving specific use cases and requirements from industry via the industry subject matter expert on the ePI team, in addition to details on how RIMS could support ePI submission. A pilot of the MVP is ongoing and the results are expected to inform timelines for implementation. Updates on ePI will be communicated on an ongoing basis through the routine ceremonies and channels.

3. Update on Policy 0070

A presentation on the restart of Policy 0070 with a limited scope, applicable to new active substances with a CHMP Opinion from September 2023 onwards, was provided. This is following the suspension of the policy in 2018. The transparency initiatives put in place during the pandemic for COVID-19 continue in parallel. Reference was provided to the EMA website where the presentations and recording from the recent May 2023 Policy 0070 webinar with detailed information and guidance for applicants is published. See presentation here.

The harmonisation of activities with Health Canada to avoid duplication in the preparation and review of packages was presented. A key message of the restart is that the review of processes to ensure efficiency and standardisation between clinical data publications has been prioritised. Clinical data for new MAAs is intended to be published 120 days after CHMP Opinion and therefore packages for review of anonymisation of personal data and any CCI present need to be prepared early to meet this timeline. A new anonymisation report template (with instructions) has been developed jointly by EMA and Health Canada and will be mandatory for all new publications.

Industry raised the issues around the wider transparency activities, including regarding clinical trials e.g. CTIS and also the access to documents policy. Industry proposed further discussions on cross over between the different initiatives in another forum, which EMA is open to engage.

Conclusion and follow-up actions:

EMA presented the overview on the restart of Policy 0070 and referred to the detailed information following the May 2023 webinar published on our website. EMA welcomed the industry feedback on the broader transparency issues and future direction at EMA and are willing to discuss further the alignment between the different transparency initiatives at a dedicated meeting.

4. Update on CHMP AR revamp project

EMA presented the current status and planned future stages of implementation of the new templates created as part of the CHMP AR Revamp Project. The pilot to test the D80 Clin and non-Clinical templates will take place for procedures submitted from October 2023. Candidate participants are being identified. See presentation here.

There also was a joint presentation from the Industry Associations giving their support for the achievements of the group and their gratitude for the close collaboration thus far. Industry highlighted the importance of the voluntary basis of the participation in the upcoming pilot phase.

Conclusion and follow-up actions:

There is a commitment on both sides to continue the close collaboration as more templates are prepared and released and also for the successful running of the Pilot where the applicant will be asked to pre-fill some the factual parts of the reports.

The EMA industry focus group on AR revamp will continue working in the different steps and streams of the project. Results of the outcome of pilot phase will be presented in the platform meeting on 2024.

5. Scientific Committees organisational aspects post EMA business continuity plan (BCP)

A short presentation was given on the scientific committees organisational aspects post EMA BCP, covering the experience acquired with alternating face-to-face and virtual scientific committees meetings. The experience acquired with remote oral explanations since the start of the COVID-19 pandemic was also presented. Further to feedback received from Applicants that the format of the oral explanations was sub-optimal, the format of oral explanations was recently enhanced to Webex (as of May 2023) and is currently being rolled out to all scientific committees. This new format addresses the issues previously raised and enables an experience closer to a face-to-face setting, as the Applicants can see the slides and the Committee Chairs/Members asking questions. EMA acknowledged the willingness of Applicants to resume face-to-face oral explanations, but expressed concerns on how this could work in an alternating face-to-face/virtual format. See presentation here.

Industry welcomed the actions taken by the Agency to optimise the format of remote oral explanations; however, EFPIA members see high value of in-person interactions and asked EMA not to exclude possibility of face-to-face oral explanations.

During the discussion it was however acknowledged that it would be difficult to have a situation whereby some companies may benefit from a face-to-face oral explanation and others don't, depending on whether the respective Committee meetings is held face-to-face or remotely.

Conclusion and follow-up actions:

For the time being, the Agency would continue working with the new enhanced format of remote oral explanations through Webex. The possibility of in-person oral explanations would be considered at a later stage once further experience is acquired with the new format.

6. Update on RMP publication

Short presentations were provided by EMA and Industry representatives. EMA presented the plans for an update of the RMP publication process focused on post-opinion phase redaction of RMPs. The current arrangements to publish full RMPs for MAAs of new active substances, COVID products and RMPs of authorised products released under access to documents requests remain. See presentation here.

Industry welcomed the initiative to extend the publication process to all products and requested further clarifications before the process is implemented. EMA clarified that when for a product the RMP in full will be publish, the request to publish the RMP Summary will not apply, as the Summary content is included in Part VI of the RMP.

The Industry representatives also commented on the need to better identify publication of RMPs on the EMA website. They also highlighted that there is currently no mechanism to inform MAHs of generic/biosimilars of the withdrawal of reference products. both for CAPs and non-centralised products. This may be relevant in the future depending on the final requirements of the new pharma legislation.

Conclusion and follow-up actions:

EMA will inform Industry when the new process for publication of RMPs for authorised products is finalised.

EMA to improve the display and retrievability of RMPs on EMA webpages and RSS feeds.

7. Update on submission predictability focus group

EMA presented the latest data regarding the poor submission predictability for initial MAAs. Data for the first 5 months of 2023 was presented. The close monitoring that was put in place has not yielded a change in behaviour and no improvement is apparent compared to 2022. See presentation here.

A joint presentation from Industry Associations confirmed these conclusions and made a few proposals that could be put in place. Given that a dedicated meeting of the Focus Group was planned for the following week, a detailed discussion of the proposals was not undertaken at this event.

Conclusion and follow-up actions:

It was agreed that discussions would continue in the dedicated Focus Group on Submission Predictability and outcomes will be reported in upcoming platform meetings.

8. Patient engagement: from a patient centric drug development to authorisation

EMA presented an overview of how patients are engaged in medicines development all across the regulatory lifecycle. Engagement with patients and their organisations has been formalised in a Framework document that was described. Data was presented on the impact and added value of patient input into scientific advice, scientific advisory groups (SAGs) and oral explanations with the CHMP. In addition, the CHMP early contact methodology was mentioned as this is the first time that organisations have been consulted on

medicine specific questions. EMA is developing a Q&A to support the webinar that supports these activities. See presentation here.

EMA also made a presentation on the strategic priority of integrating more systematically Patient Experience Data (PED) in medicines regulation. An update of progress on the actions agreed at the 2022 Patient Experience data workshop was presented, including the two key priorities for 2023: the elaboration of a reflection paper on the EU approach to generating, collecting and analysing PED and on including a dedicated section to reflect PED in the Assessment Report. Further updates will be shared with industry trade associations at future platform meetings. See presentation here.

- Industry proposed multistakeholder focus groups to discuss and identify solutions on PED topics. Industry raised the need for alignment on terminology, use of patient preference methods, requirements of general Clinical outcome assessment, use of different disease specific PED methodologies and increase in transparency of PED in the assessment reports (incl, orphan maintenance and scientific advice) and product information.
- EMA noted that the priority for 2023 remains to deliver the reflection paper and the updated AR. The need for further multistakeholder engagement methodologies (e.g. dedicated focus groups to discuss more methodological aspects with all stakeholders) will be considered following the public consultation of the reflection paper.
- While progress is needed on guidance to industry on how to generate patient experience data, for the time being, the EU approach is to encourage companies to liaise early with regulators during Scientific Advice/qualification, to discuss the best way to generate and collect PED, and have a case-by-case discussion on their specific development plans.

Conclusion and follow-up actions:

Guidance including Q&A on methodology for patient engagement in evaluation phase of MAAs is under development. Industry association will be informed of at the time of publication on EMA website.

EMA is preparing a list of actions and priorities on Patient Experience Data (PED) that will be shared with Industry and presented on the next platform meeting in November 2023.

The reflection paper will be drafted in Q3-4 2023 and a public consultation of the draft reflection paper on PED is expected for publication in Q1 2024. Update on the progress and discussion of best way for engagement with Industry and interested parties to be discussed in the next platform meeting in November 2023.