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Highlight report 8th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

27th June 2022

Role	Name
Chair:	Alberto Gañán Jiménez
Present:	**Industry: AESGP:** Klavdija Kmetic and Mihai Ionita. **Alliance for Regenerative Medicine (ARM):** Andrea Braun, Jacquelyn Awigena-Cook, Mimi Choon-Quinones, Sarah Higham, Sibylle Herzer, Simone Biel and Stuart Beattie. **EFPIA:** Aimad Torqui, Almath Spooner, Amanda Matthews, Anne de Bock, Emma Du Four, Markus Goese, Pär Tellner and Patrick Middag. **EUCOPE:** Bianca Tan, Lars Hyveled-Nilsen, Lucia D'Apote, Marcelo Milano, Maren von Fritschen and Roberta Bernadelli. **EUROPABIO:** Bettina Doepner, Esteban Herrero Martinez, Jill Morrell, Kara Daly, Laura Liebers, Pedro Franco and Seán Byrne. **EUROPHARM:** Alain Verrijdt. **MEDICINES FOR EUROPE:** Anabela Godinho, Beata Stepniewska, Britt Vermeij, Dora Halmai, James Kim, Juliette Omtzigt, Klaudija Marijanovic Barac, Przemyslaw Reszka and Špelca Jenko. **MPP Association:** Anja Bührer, Mike Wallenstein, Shayesteh Fürst-Ladani, Samuel Gavillet and Stephan Affolter. **VACCINES FOR EUROPE:** Agnes Legathe, Anna Czwarno, Helena Ardebrant, Muriel Paste, Stephane Callewaert and Susanne Heiland-Hunath. **EMA:** Alberto Gañán Jiménez, Alexios Skarlatos, Alexis Nolte, Christelle Bouygues, Efstratia Vatzaki, Eftychia-Eirini Psarelli, Enrico Tognana, Francesca Day, Karl Hamilton, Marcia Rueckbeil, Marie-Helene Pinheiro, Martin Harvey Allchurch, Pascal Venneugues, Pedro Pina Ferreira, Robert Bream, Silvy Da Rocha, Thomas Castelnovo, Thomas Girard, Veronika Jekerle Victoria Palmi Reig and Virginia Rojo. **EMA scientific committees and working parties:** Martina Schüßler-Lenz **European Commission:** Sara Rafael Almeida and Nada Alkhayat. **Trade Associations:** Dr. Hans Ulrich Burger, Christoph Gerlinger, Olivier Leconte and Sascha Ahrweiler

This was the 8th EMA-Industry stakeholder centralised platform meeting developed by the Agency between regulators and representatives of industry stakeholder organisations aiming to foster a constructive exchange with these stakeholders on general updates and more focused discussions on specific processes and issues to support continuous improvement. The purpose of the platform is to provide an opportunity for both general updates and more focused discussions on specific processes or issues to support continuous improvement, and generally to foster a constructive dialogue with industry stakeholders.

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1. EMA's Raw Data project - Information on upcoming proof-of-concept pilot

The Agency presented EMA's plans regarding an upcoming proof-of-concept (PoC) raw data pilot which will be conducted as part of EMA's raw data project and stems from one of the priority recommendations issued by the joint HMA-EMA Big Data Task Force. See presentation here.

Following detailing of the project's background and mandate, the presentation focused on the raw data PoC pilot's details including timelines and scope, integration of pilot with the assessment process, terms of pilot participation as also next steps.

The PoC pilot aims to clarify the benefits and practicalities of access to individual patient data from clinical studies (raw data) in the assessment of medicines. The pilot will comprise ten centralised procedures submitted to EMA and will fully comply with data protection legislation requirements. Applicants and Marketing Authorisation Holders (MAHs) may participate in the pilot on a voluntary basis if their marketing authorisation or post-authorisation application submitted to EMA meets the pilot's selection criteria.

The pilot will start in September 2022 and run for up to two years. Learnings from the proof-of-concept pilot will help the EU medicines regulatory network to make an informed decision on the place of raw data in regulatory decision-making. Finally, it was mentioned that an Industry Focus Group will be formed in due course in order for Industry representatives to share their views on specific PoC pilot aspects.

Industry presented their views in relation to the upcoming proof-of-concept raw data pilot, highlighting concerns but also opportunities from industry perspective, while also offering to contribute to learnings defining the process of raw data submission. It was highlighted that EMA should start the PoC pilot with retrospective pilots before running pilots in parallel to an ongoing assessment and that the complexity and variability between electronically submitted data should not be underestimated.

Conclusion and follow-up actions:

- It was confirmed that procedures selected for the PoC pilot will include a 'data submission meeting' in which the Applicant/MAH will introduce the data analysts from EMA to the key characteristics of the raw data files and accompanying documentation from their submission;
- The EMA will not start the PoC pilot with retrospective pilots as suggested by Industry;
- The EMA will continue to engage with Industry during all phases of the PoC raw data pilot especially through the Industry Focus Group for which a call for nominations was shared with trade associations on 30 June.
- On 12/07/2022, EMA published the pilot project in a news item and a document with specific information for industry.

2. Update on the implementation of the new Working Parties Governance

The Agency presented the progress on the step-wise implementation of the new Working Parties (WPs) model. See presentation here.

The implementation of Phase 1 started with the reorganisation of the WPs from the non-clinical, methodology and clinical domains. Expertise-based membership of the WPs as well as chairs have already been nominated. Expertise in the WPs was diversified across the MS and experience was retained, with majority of experts selected having been members of previous WPs/Committees.

A 3-year rolling workplan at domain level has been introduced with yearly operational workplan. End of Phase 1 is planned in August 2022 with a lessons learned exercise that will support the launch of phase 2 to reorganise the quality domain from Dec 2022.

The European Specialist Experts Community (ESEC) was launched with an Oncology ESEC pilot in May 2022. These experts will be contributing to the regulatory systems. Training through Awareness session and knowledge sharing envisaged.

Conclusion and follow-up actions:

- Industry representatives were updated on the status of the implementing of the new Working Parties Governance. Further updates to be considered for a future Industry stakeholder platform meetings.

3. Information on EMA new Quality Innovation Group (QIG)

The Agency presented the plans for the new Quality Innovation Group, the vision for how this group will work, and the anticipated timelines including when industry can expect the first product/technology interactions. EMA also presented a summary of the findings from a survey to stakeholders to identify the most presenting topics in the quality innovation field. See the presentation here.

Listen and learn platforms are planned for Q4 2022 to further refine these topics, identify priorities, and set a workplan for the group once constituted.

Industry representatives then gave a summary of their priorities. For the most part, these are aligned with the findings of the survey and the EMA conclusions. The EMA noted that some of the industry proposals are not in the remit of the QIG, for example, any changes to legislation. The QIG is a scientific group aimed at facilitating implementation of novel beneficial technology.

Conclusion and follow-up actions:

EMA will continue with the implementation of the QIG and will organise listen and learn platforms in Q4 2022. Further information will be directly communicated to the relevant industry associations.

4. Updates on EMA's implementation of the Medical Device Regulation

The Agency presented their 1-year experience since the entry into application of the medical device regulation (MDR). The Agency shared their observations based on actual cases and challenges encountered with the transitioning from the medical devices directive to the medical devices regulation. In that regard, the Agency reported on challenges and inconsistencies in the qualification of some medical devices/medical device parts with impact on evidence of MDR conformity provided, MAHs seeking advice to EMA on lifecycle management of integral device changes and how to address device labelling requirement for co-packaged devices. See presentation here.

Industry representatives gave as well a presentation highlighting the need for clarification on significant changes during product lifecycle management, the need for clarification on role of MAH for co-packaged combined products. Industry also flagged some concerns on the need for harmonisation of the terminology for drug device combination used in the various guidelines and the need for an integrated pathway.

The EMA noted that some of the industry proposals are not in the direct remit of the EMA, for example, the limited notified body availability, defining changes to the device component that would require an update of the NBOp, approach for platform technologies, clarifications on roles of economic operators for co-packaged combined products.

Conclusion and follow-up actions:

EMA will continue with the implementation of the MDR and to collaborate with the various stakeholders to develop further guidance

5. International OPEN project pilot next steps and industry feedback

EMA presented a one-year review of the OPEN pilot, which was launched in December 2020 as an international collaboration framework of parallel or near-concurrent review among international regulators. OPEN allowed non-EU regulators from Australia, Canada, Japan and Switzerland and WHO, to collaborate in the scientific evaluation of the CHMP assessment of COVID-19 vaccines and therapeutics and participate in the discussions of the COVID-19 EMA pandemic Task Force (ETF), while maintaining their scientific and regulatory independence. All the COVID-19 vaccines and therapeutics evaluated since the launch of the pilot were assessed under OPEN, from the moment the rolling review started, this included the initial MA but also extension of indications, major variations or inspection issues. This collaboration facilitated the assessment of similar data by multiple authorities, reducing duplication of work and allowing the release of scarce resources to other critical areas. OPEN also facilitated alignment and fewer labelling differences and accelerated assessment and access to patients outside the EU. The EMA Management board endorsed the continuation of the pilot in a permanent collaboration framework. See presentation here.

Industry supports EMA's proposal to continue the OPEN initiative in a more structure procedure, however, Industry would like to discuss the strategy with EMA of their submissions to create more awareness of the program, maximize the consolidation of LoQ and responses, recognition of inspections and acceleration of approvals. Industry supports OPEN not only in IMA but also major post-authorization approvals and expanding the program, if possible to other countries, like EU-accession countries and ORBIS partners.

Conclusion and follow-up actions:

- EMA is engaging with all stakeholders to better consolidate the pilot's operation, strengthen further the collaboration, increase visibility of the initiative and plans to expand the framework to identified areas in a stepwise approach, AMR, Cross-regional collaborative assessment of CMC aspects, some PRIME medicines or medicines responding to future health threats or public health emergencies.

6. Updates on IRIS Platform

Industry presented on a number of aspects of particular interest to Industry Associations with regard to the evolution of the IRIS platform. This included feedback on a number of issues being experienced since the launch of GMP Inspections on IRIS and lessons learned. The prestation included feedback since the launch of Marketing Status on IRIS. See presentation here.

The presentation also included questions on how EMA's new Agile governance will affect the delivery of work on IRIS, in particular how the value streams will operate to ensure strategic industry engagement, advance notice of changes affecting industry and how appropriate user testing will be ensured.

Questions were raised in particular as to how silo working will be avoided and how IRIS fits into the network IT strategy to deliver digital transformation.

The Agency presented an update on the Agile Transformation and his this specifically affects the delivery of IRIS as a strategic platform. The presentation explained how the implementation of value streams will optimise the delivery of different products/projects and are designed to ensure scalability of delivery and process optimisation.

In the context of the value streams, it was explained that the EMA is pursuing Agile to eliminate silo working by linking work, setting clear priorities and having shared planning events with delegated decision making. Five value streams were established, with three of them having a key role in the development of specific but integrated products/projects related to regulatory procedure management. These are the 'Research and Development', 'Product Lifecycle Management' and 'Monitoring' value streams.

The presentation included an explanation as to why it has become necessary to adapt the way processes are delivered on IRIS, taking into account lessons learned. It was explained how the platform has evolved from relatively standalone processes to increasingly integrating with SPOR master data, while needing to work with legacy architectures and systems. It was also emphasised that to ensure an appropriate digital transformation, it is necessary to optimise how IRIS integrates with eSubmissions processes and systems to enable more connected processes.

Examples were given of pieces of work that have been brought together within their respective value streams, i.e. Initial Marketing Authorisations, Variations, Transfers, Renewals / GxP Inspections, Shortages of Medicines). Cross-value stream roles were also pointed out, including a Lead Process Manager and various Architects, who ensure consistency across implementations.

Change Management has also been significantly stepped up and will be further strengthened at value stream level to ensure a more consistent and optimised approach towards all affected stakeholders.

With respect to industry engagement specifically, EMA acknowledges and understands industry requests to provide input on prioritisation choices regarding the development of products/projects in IRIS. As such, different engagement levels were presented where Industry participate and can influence product development as appropriate. These range from formal engagement structures, such as subject matter expert nominations and ceremonies, to specifically targeted workshops and meetings.

Finally, brief status updates on the Inspections processes and Marketing Status on IRIS were provided, with high emphasis on expected delivery dates for on-going issues that are affecting MAHs. A short update was also given on the upcoming user acceptance testing and release plan for DADI.

Conclusion and follow-up actions:

- All relevant issues on Inspections and Marketing Status are either being analysed/planned or designed/developed for the upcoming Program Increment (PI) Planning events;
- The EMA will continue to update the IRIS Forum for all relevant updates (i.e. upcoming releases of new software, relevant information for users);
- EMA will provide the forum with available information about the protocol nomination process for subject matter experts for Agile.
- The points raised by Industry on points raised by industry on IRIS GXP raised before the meeting (including those from EFPIA letter of 4th April 2022) have been addressed either at the centralised platform meeting or the latest IRIS GVP inspection system Demo of 30th June 2022. On 13th July

2022, EMA sent clarification to the questions raised during the meeting regarding Iris Marketing Status.

7. Proposed changes to the RMP publications in EPARs

Industry presented the background and the case on the need for RMPs to be regularly published in order to facilitate the future generic applications. The decision taken by the EMA Management Board in December 2021 for increased transparency on the safety information in the form of RMP publications (main body, Annex 4 and Annex 6) was largely based on the positive feedback on the publication of RMPs in the EPARs of the Covid-19 related products during the pandemic situation. Industry as well pointed that products that are reaching maturity and are going to lose their market exclusivity soon may be considered as the next cohort for publication purposes. The request was also made for a way to easily identify the products with newly published RMPs, for ease of reference.

EMA responded with a plan of action for the immediate term, where the RMP (main body, Annex 4 and Annex 6) of products authorised as new active substances under Article 8.3 of the directive 2001/83/EC at the time of EPAR publications. Once a RMP is published, any further updates of the document will also be published in order to always have the most up-to-date information available. In addition, RMPs of earlier authorised products that have already been released to the public domain by EMA following requests to Access to Documents, will also be published and making them widely available. See presentation here.

Conclusion and follow-up actions:

- EMA will go ahead with the publication of RMPs of newly authorised products starting with products receiving a positive CHMP opinion in July 2022. Their EPAR publication which will include the RMP after having received the Commission Decision.
- Further discussions in identifying different cohorts of products for RMP publication will take place in the future.

8. Predictability on marketing authorisation submissions

EMA presented data showing the current poor predictability of initial MAA submissions. This poor predictability is a problem for the European network because it makes planning and resourcing of available assessment teams very difficult, at a time when resources are strained. EMA therefore solicited partnership from Industry to find possible solutions that would promote better planning from applicants, avoiding delays and as a consequence allow better planning at NCA level. See presentation here.

Industry endorses the need for a root cause analysis for the delays of MAAs and also referred to consider the impact on other procedures (e.g. variations). EMA welcome Industry suggestion to develop a survey on the root causes of variability of delays.

Conclusion and follow-up actions:

- The consensus was that a focus group should be set up to look at potential solutions.