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Highlight report 7th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

1st December 2021

Role	Name
Chair:	Alberto Gañán Jiménez
Present:	**Industry: AESGP:** Klavdija Kmetic, **Alliance for Regenerative Medicine (ARM):** Michael Werner, **EFPIA:** Aimad Torqui, Emma Du Four, Genevieve Le Visage, Pär Tellner, Patrick Middag, François Bouvy. **EUCOPE:** Joao Duarte, Jörg Plessl, Laura Liebers, Lucia DÁpote, Maren von Fritschen, Roberta Bernardelli. **EUROPABIO:** Esteban Herrero Martinez, Francesca Buttigieg, Kara Daly, Laura Liebers, Marcello Milano, Pedro Franco, Sean Byrne. **EUROPHARM:** Alain Verrijdt, Parminder Kaur. **MEDICINES FOR EUROPE:** Ayman Ibrahim, Beata Stepniewska, Audrey Masserot-Coquard, Britt Vermeij, Dora Halmai, Karen Jensen, Majbritt Hansen, Navneet Kaur Ubhi, Remco Munnik, Sabrina Conti. **VACCINES FOR EUROPE:** Anna Czwarno, Emilie Demougeot, Karen Jourdan-Brown, Helena Ardebrant, Muriel Paste, Stephane Callewaert, Susanne Heiland-Kunatht. **MPP Association:** Jan Richter, Anja Buehrer, Shayesteh Fürst-Ladani, Tanja Novcovic. **EMA:** Alberto Gañán Jiménez, Alexios Skarlatos, Alexis Nolte, Christelle Bouygues, Elias Pean, Enrico Tognana, Francesca Day, Isabel Chicharo, Kristiina Puusaari, Marie-Helene Pinheiro, Margaux Philippe, Marta Kolb-Sielecka, Paco Peñaranda, Silvy da Rocha Dias, Thomas Castelnovo, Thomas Girard and Virginia Rojo. **EMA scientific committees and working parties:** Ilona Reischl and Harald Enzmann. **European Commission:** Sara Rafael Almeida.

This was the 7th 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.

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

Info on repurposing pilot from EMA

The Agency gave an overview of the medicine repurposing pilot project (see presentation here).

The key aims are to facilitate the regulatory recognition of new indications for well-established, authorised medicines, to outline the process to support not-for-profit organisations and academia and to help champions present their proposed repurposing project to regulatory authorities and receive guidance through scientific advice on the data package. The pilot can also help identifying needs in guidance applicable to repurposing including in the real word evidence / data (RWE/RWD) field. The pilot went live at the end of October and there is a Q&A document on EMAs website here.

Industry presented responses to the following questions provided by EMA:

1/ What can Industry do to help the running of the pilot, including what can Industry do at trade level to help champions finding a potential partners (e.g. contact point to reach out within a company)?

2/ How can Industry MAH support data generation ? Could industry support sharing with academics/non-profit organisations available historical (non)-clinical data for an "off-patent" medicine?

3/ Patients and health system recurrently expressed concerns that drug repurposing may lead to significant increase in drug price/treatment costs and hence limit access to the medicinal product with this new indication. What collaboration models and/or incentives would you see as appropriate/feasible to enhance engagement with other stakeholders pursuing repurposing activities?

Industry proposed to support the pilot by creating a specific area on the websites of the trade associations (including contact within the trade for help to find potential MAH). Industry expects that most data on pilot cases are readily available for a regulatory submission and -if data generation is needed- the use of real world data should be explored. Industry also highlighted the importance to recognise the added-value of a repurposed product.

Conclusion and follow-up actions:

- The outcome of the pilot will be presented at a future Industry stakeholder platform meeting.

Update on Implementation of IRIS Marketing Status

The Agency presented an update on the IRIS platform process expansion related to the reporting of Centrally Authorised medicinal Products (CAPs) Marketing Status which replaces the current reporting system to EMA via email (see presentation here).

The new reporting process was launched on the 26th July 2021 with 3 types of reporting for MAHs available at launch, namely:
- marketing status notification (single),
- marketing status notification (bulk upload), and
- withdrawal/permanent cessation of a medicinal product.

From the date of launch, for CAPs not yet in the market MAHs should report the initial placing in the market and any subsequent updates into the IRIS platform. For CAPs marketed in at least one EU/EEA MS, MAHs can report changes to marketing status/withdrawals by email or *via* the IRIS platform during the first 6 months after launch of the new system (until 31st January 2022). A baseline submission of the current marketing status in all EU/EEA MS for all presentations is required before starting to report any changes of marketing status in IRIS. This baseline should be submitted within 6 months after launch of the IRIS system (31st January 2022).

Industry reporting has been low so far. As per 29th November 2021, 127 IRIS cases have been received for 108 CAPs. Less than 10% of CAPs have had at least one reporting for one presentation in at least one MS.

Some IT issues have been identified for the bulk upload and they are being sorted. No issues identified with the single upload so far.

The IRIS guidance for applicants, other relevant regulatory guidance (e.g. pre-submission guidance documents) and IRIS general webpages in the EMA website are being updated on a regular basis [see links below]. It is very important that Industry consult these webpages regularly to be kept informed of the regular changes.

There have been 3 meetings with the IRIS marketing status Industry volunteers group to discuss technical aspects related to the reporting tool and gather industry feedback, some which have been implemented or will be implemented in the future. A follow-up meeting will be scheduled in January 2022.

Industry presented a list of questions/comments received from different companies and expressed concerns on the capacity of companies to meet the deadline of 31st January 2022 due to both, internal organizational complexities that make difficult to gather the information and problems with the reporting in IRIS. Consideration of the concerns and challenges will be discussed within EMA and further communication (as broad as possible to cover all/majority of all end users) will follow as appropriate.

Useful links were shared:

IRIS guide to applicants (scientific applications) (step by step instructions)

Notifying a change of marketing status | European Medicines Agency (europa.eu)

Questions and answers on Marketing Status reporting submissions · IRIS (europa.eu)

EMA ServiceDesk Portal

Conclusion and follow-up actions:

- The Agency will publish a list of Q&A in the IRIS general webpage (Questions and answers on Marketing Status reporting submissions · IRIS (europa.eu)) to respond to the questions included in the Industry presentation. The regulatory guidance will also be updated to provide more clarity in the topics raised by Industry.
- A follow-up meeting with the Industry volunteers group will be scheduled in January 2022
- The possibility to extend the deadline will be discussed internally in the Agency and the outcome communicated to the Industry Representatives.

Post-meeting note:

- Industry Stakeholders have been informed on 15th December 2021 of the **extension of the timelines in the implementation plan for IRIS marketing status** reporting of medicinal products currently marketed in the EU/EEA MS **from 6 to 9 months**. The **new deadline** for the submission of the Marketing status data for all presentations of each Centrally Authorised medicinal Product in the EU/EEA MSs will now therefore be the **30th April 2022** (prev. 31st January 2022).

Use of master data and IDMP implementation

The Agency and Industry presented separately the use of Master Data and IDMP implementation with a special focus on variations for CAPs, which will be implemented in 2022 with the integration of PMS in DADI and later in IRIS in order to cover end-to-end variation processes (see presentation here). This scope of this project will cover the phase 1 of the Target Operating Model (TOM), as discussed in previous years in the SPOR Task Force and it will be a pilot phase for phase 2 for non-CAPs.

The Agency has used SPOR data in previous projects in the last two years as implementation of Veterinary and Clinical Trials legislations, as well as other internal projects in IRIS as Scientific Advice, Orphans, Inspections, etc. The Agency confirmed that SPOR/IDMP will be used for the TOM and it will be an enabler for multiple business cases to be implemented in the future (e.g. New Mandate). The Agency indicated that DADI project is expected for variations in Q3 2022 and integration in IRIS by end of the year, subject to internal/external discussions and agreements. Industry will be involved in all discussions for the three important elements: DADI, PMS and IRIS. Engagement plan will be prepared and communicated early 2022.

Industry presented their views/concerns about IDMP implementation. Industry has invested heavily in SPOR/IDMP by standardizing RIM/MDM solutions and they are very much interested to bring benefits of this high investment. They provided examples like optimising some regulatory processes (e.g. Type IA variations), eliminating unnecessary processes (e.g. Art 57 XEVMPD) and (re)using SPOR/IDMP data in future business cases. In addition, they emphasized their commitment to the use of SPOR/IDMP and they requested better engagement in present and future projects.

Conclusion and follow-up actions:

- The Agency remains committed to implement SPOR/IDMP into its operating model, as well as other projects for digital transformation of operations.
- The Agency will improve the engagement with Industry with especial focus on the implementation of the TOM, allowing Industry to participate and providing reasonable notice period for any preparation.
- The Agency shares the same view for the benefits of using SPOR/IDMP and it is discussing internally some Industry proposals (e.g. optimising Type IA variations).
- The Agency cannot provide all the details for many questions, as discussions are taking place internally. The Agency will communicate and liaise with Industry on the details and FAQ will be maintained.

An update on EC pilot on Intent to launch of Orphan and Oncology Medicinal products

The European Commission provided an update of level of the industry's participation in the survey included in this voluntary pilot project (see presentation here).

The aim of this survey is to improve regulators' knowledge of market launch intentions and the reasons behind delayed market launches with the ultimate goal of increasing patient access to medicines.

Unfortunately, the recorded data (up to December 2021) shows a very low response rate from marketing authorisation applicants. This low response rate may limit the significance of the results and the derived conclusions of the survey.

EFPIA mentioned that remains neutral vis-à-vis individual companies as regards their decision to (not) participate in the pilot project – it is an individual company decision. The EC reminded that the results of the pilot will be used to inform actions under the Pharma Strategy and reinforced that the chance for voluntary cooperation should be used. Working together on providing evidence will generate a clearer picture.

Upon concerns raised by Industry, the EC clarified that the confidentiality of the responses at individual level is guaranteed. Results will be presented as aggregated data.

EMA will continue inviting MAHs of eligible medicinal products to participate. Industry associations were offered to remind their associates about this opportunity to participate in the pilot project. The project will run until August 2022.

Conclusion and follow-up actions:

- The outcome of the survey will be presented in due time after the finalisation of the pilot.
- Industry associations to remind their associates about this invitation to participate in the survey.

Working Parties project implementation

The Agency presented an update on the implementation of the new model for Working parties (see presentation here).

The new model is based on the organisation of the WPs under five main domains (Quality, Non-clinical, Methodology, Clinical and Veterinary) with a new governance oversight populated by the CHMP, CVMP and SAWP and the WPs chairs and/or vice-chairs. The workplans will be based on a 3-year rolling strategic plans at the domain level linked to the EMRN Strategy and the EMA RSS to 2025. Engagement with stakeholders -including industry- is foreseen at the domain level with at individual working parties and guideline drafting groups.

The new working party model will be expertise-based and experts will be nominated every 3-year. Operational expert groups will provide scientific and product support to core business requests and can be appointed on a temporal basis; Temporary drafting groups are appointed to draft specific guidance, reflection paper or Q&A.

The working parties project was initiated in Sep 2021 and is being implemented in a step-wise approach; it is expected that most WPs become active in 2Q 2022.

The Quality Innovation Group (QIG) will launch a survey to stakeholders in mid-Dec 2021 to identify any new developments as well as the priorities and expertise requirements of the future group. Industry associations are encouraged to reply to the survey.

Conclusion and follow-up actions:

- A follow up to the implementation of the model will be considered in upcoming platform meetings.
- The launch of the QIG survey will be communicated to Industry stakeholders at the time of launch.

Post meeting note

- Industry associations are invited to submit their input to the QIG survey by 11th February 2022.

Measures taken to help the EU regulatory network coping with increased workload. How can industry support?

EMA presented data in relation to the current forecasting of initial Marketing Authorisation Applications (see presentation here). The Agency utilises data from multiple sources, including Eligibility Requests, Letters of Intent, pipeline meetings etc. to try and forecast the numbers of MAA planned for a given year. This data is key in terms of the distribution of resources for the Agency and the network.

The data accumulated show that only around one third of MAAs are received on time. Industry presented some initial possible causes such as the pandemia. More in depth analysis of the data gathered from Industry was required and agreed to be shared after the meeting.

EMA also presented a problem statement related to the misalignment of documentation templates, in particular between Module 2 of the eCTD and the Assessment Reports. Industry representatives were supportive to identify possible templates alignment that would satisfy global requirements. It was proposed that more detailed technical discussions could take place in a dedicated EMA-industry focus group.

Finally, EMA presented a few examples of the numerous queries that Product Leads receive from industry and the need for a better management of these requests from Industry taking into account all available information published on the EMA webpages. It was however acknowledged that the amount of information available on EMA webpage can be difficult to navigate, especially for individuals with less experience or knowledge of EMA regulatory environment and processes. This aspect was proposed to be addressed by the EMA experts and appointed Industry volunteers in the Type II process improvements working group expected to be triggered in I QTR 2022.

Conclusion and follow-up actions:

- Industry to share with EMA final analysis findings of root causes of MAA submissions delays and proposals for mitigations recommendations.
- EMA to inform Industry of follow-up interaction forum to discuss options for eCTD Module 2 and EMA AR templates alignment, taking into account ICH global requirements and EMA scientific and regulatory webpage contents optimisation; these two areas being identified as key potential process efficiency gain for EMA (and Industry) workload simplification and benefits.
- The identification of opportunities for improvements on query management and search for information on EMA website Agency will be discussed Type II process improvements working group expected to be triggered in I QTR 2022.

Changes to Pre-Submission Meeting activities

EMA presented new format of presubmission interactions which was introduced in November (see presentation here). Under the new rules, Applicants send their questions using the "MAA pre-submission interactions form" together with the necessary background documents. The expected briefing package has been significantly simplified. Consolidated written responses will be prepared by the EMA product team and circulated to the Applicant within 3 weeks. In complex cases, this can be followed up with virtual meeting.

The format of presubmission meetings with the Rapporteurs has not been changed and the Applicants are encouraged to request them directly from the National Competent Authorities.

The new process is expected to result in more focused and tailored to the application dialogue. It will also allow Applicants to receive feedback on their questions earlier.

Industry presented a number of comments on the content of presubmission interactions. Among others, industry has mentioned opportunity for enhanced scientific discussions during the pre-submission meetings, Possibility of EMA pre-submission meetings in a post-authorisation and additional flexibility (such as accepting that minor missing information can be provided during validation or with first response to avoid submission delays).

Conclusion and follow-up actions:

EMA will collect industry feedback on the new format of the presubmission interactions in order to see if any further modifications to the process are needed. The experience on this new format pre-submission activities will be reviewed after one year of experience.

Derogation of the Gaelic as an official EU language in January 2022

EMA informed Industry that following the end of the derogation on the use of the Irish language on 31st December 2021, EMA published a practical guide on the impact of this decision to regulatory procedures In summary, EC decisions (+ annexes) addressed to MSs (after 1st January 2022), shall be translated in Irish (certain referrals, PSUSAs or PASSs) (see presentation here).

On the other hand, EC decisions (+ annexes) of CAPs addressed to companies/orphan designation holders established in the Republic of Ireland will be translated in Irish, unless they request a language waiver.

Industry raised a number of clarification questions which were answered post-meeting; a consolidated list of responses was sent to all participants. In addition, the EMA is on the process of updating relevant Q&A to clarify practical questions on the implementation of the lifting of the derogation.

Conclusion and follow-up actions:

EMA to inform all MAH/applicants based in Ireland on the need to submit a waiver should they wish to avoid the translation of annexes into Irish. This action was completed on 06th December 2021.

In particular, companies with opinions in December 2021 to take appropriate measures to comply with the guidance published in respect to the Irish language.

EMA to consider creating a short Q&A to clarify practical questions on the implementation of the lifting of the derogation.

Post-meeting note:

The List of Questions duly answered was sent to all participants and the presentation was amended including this list of questions.