9 September 2021
EMA/381927/2021

Highlight report 6th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

30 June 2021

Role	Name
Chair:	Radhouane Cherif
Present:	**Industry: AESGP:** Klavdija Kmetic, Paul-Etienne Schaeffer. **Alliance for Regenerative Medicine:** Michael Werner, Nadege Le Roux, Pauline Roudot, Marcello Milano, Simon Bennett. **EFPIA:** Aimad Torqui, Emma Du Four, Nadege Le Roux, Nick Sykes, Pär Tellner, Patrick Middag, Sharon Gorman, François Bouvy. **EUCOPE:** Bertrand Fournier, David Kane, João Duarte, Lucia D'Apote, Lucy Clayton, Maren von Fritschen. **EUROPABIO:** Francesca Buttigieg, Jill Morrell, Pedro Franco, Violeta Georgieva. **EUROPHARM:** Alain Verrijdt, Paula Sanches, Sonia Ferreira. **MEDICINES FOR EUROPE:** Beata Stepniewska, Britt Vermeij, Dora Halmai, Ekkehard Baader, Martin Schielstl, Navneet Kaur Ubhi, Semy Lee. **VACCINES FOR EUROPE:** Agnes Legathe, Anna Czwarno, Helena Ardebrant, Jacqueline Dias, Michel Stoffel, Muriel Paste, Susanne Heiland-Kunatht. **EMA:** Alberto Gañán Jiménez, Alexis Nolte, Caroline Pothet, Hilmar Hamann, Juan Garcia, Karl Hamilton, Marie-Helene Pinheiro, Nathalie Bere, Paco Peñaranda, Peter Arlett, Radhouane Cherif, Thomas Castelnovo, Thomas Girard, Tony Humphreys, Victoria Palmi Reig, Zaide Frias, Heloise Mignot. **EMA scientific committees and working parties:** Martina Schüssler-Lenz, Sabine Strauss and Harald Enzmann. **European Commission:** Sara Rafael Almeida, Antonios Rodiadis

This was the sixth 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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Accelerated Assessment and Conditional Marketing Authorisation

- The Agency presented an overview of the most recent experience with accelerated assessment and the new template, including the main reasons for ATMPs switching from an accelerated to standard timelines. As part of this overview, key clinical and quality major objections leading to the need to revert to standard timelines included the misalignment between the proposed indication and the studied population, the lack of clinical data originated from the commercial process, issues associated with the potency assay and/or comparability data. Applications that had to switch during assessment were also often linked to discussions around data comprehensiveness.
- The CAT Chair also introduced 9 criteria that assessors should use when reviewing the comprehensiveness of clinical data submitted in marketing authorisation applications; these criteria were recently developed and agreed by the CHMP and CAT to promote alignment during such assessment and are to be incorporated into assessment reports for use by the assessment teams.
- The Agency also presented an overview of the available pre-submission tools, with a specific focus on scientific advice, the PRIME Quality toolbox, and the CAT certification procedure; Lastly, the Agency provided a high-level review of the experience with conditional marketing authorisations (CMA) (see presentation here).
- Industry presented a detailed summary of feedback from companies in relation to their experience with accelerated assessment, conditional marketing authorisations, CAT certification and the PRIME Quality toolbox; For example, the difficulty in maintaining AA, inconsistencies in the determination of data comprehensiveness and limitations in terms of market access for products granted a CMA were amongst the key challenges highlighted; as part of this feedback, Industry also highlighted proposals to enhance pre-submission interactions for products under AA, communication and alignment between stakeholders around CMA (see presentation here). Industry also suggested the creation of a focus group on the procedural improvements of the Agency toolbox.

Conclusion and follow-up actions: EMA welcomed the detailed feedback and proposals which they committed to review in more details ahead of the next platform meeting. The following actions were agreed:

- EMA to review Industry's feedback ahead of the next platform meeting to identify potential areas for improvement and/or for consideration as part of the existing focus groups or via the possible creation of a new focus group on the procedural toolbox to complement the platform meetings.
- EMA to try and enhance SME's awareness of the CAT certification procedure Industry was reminded to send comments by July 30th, 2021 on the PRIME quality toolbox to QWP@ema.europa.eu.

Pilot project 'Market Launch of Centrally Authorised Products' T

- The EC presented the 18-month long pilot project on Market launch Intentions for CAPs launched on 25 March 2021. This initiative aims to improve the regulatory knowledge of the MAA intentions to launch a CAP in the different EU/EEA Member States. Its aim is to get a better understanding of the possible reasons behind delayed market launch and invite companies to explain what are the obstacles for launching their product across the EU, if any. The overall goal is to increase the patients access to medicines (see presentation here).
- All MAHs for orphan designated CAPs or CAPs with an oncology indication are invited to participate at the start of the MAA and/or at the time of positive CHMP MAA opinion.
- Participation through a secure EC online survey is on a voluntary and confidential basis.

- This initiative is supported by the Pharmaceutical Committee under the Pharmaceutical Strategy. MAHs are encouraged to participate and give direct feedback on the issue which will be taken into account in view of the revision of pharmaceutical legislation.
- A link to the secure online questionnaire is added by EMA at the MAA validations letter and the Letter to MAH at CHMP Opinion.
- Applicants are invited to complete the survey preferably within 4 weeks. MAAs of CAPs with opinion/start after March 21 that could not yet complete the survey are still encouraged to provide their feedback.

Conclusion and follow-up actions:

- This pilot is an opportunity for companies to communicate to the Commission any difficulties they are facing in relation to their launch plans and mention the root causes behind any delays.
- An update on the response rate will be provided in the next EMA Meeting of the Industry stakeholder platform on the operation of the centralised procedure for human medicines in 4QTR 2021.
- Applicants are invited to complete the survey within 4 weeks.

Launch of IRIS for reporting changes on Marketing Status

- The Agency presented an update on the new IRIS system for reporting of Marketing Status that will replace the current reporting system to EMA via email, will allow to gather structured marketing status data for a Centrally Authorised Products (CAP) and the creation of a database available to EC/NCAs that will increase transparency on the actual marketing of authorised CAPs (see presentation here).
- EMA will launch the new system in July 2021 with 3 types of submissions available at launch: Marketing status notification (single), marketing status Notification (bulk upload), withdrawal/permanent cessation of a medicinal product.
- EMA news item and regulatory guidance will be published on EMA website on the date of launch. MAHs can report via Service desk (add e-mail service desk) any issue with the new IRIS system after launch. A meeting with the established IRIS marketing status Industry volunteers group will be organised on 16th September 2021 to discuss the any issues with use of the reporting tool.
- EMA notes Industry concerns on duplicate data reporting and preference of a single channel through SPOR/PMS for product information submission. The Agency recognizes that duplicate / potentially inconsistent provision of data is undesirable and is working to ensure harmonisation in data content as well as the interoperability among systems with regards to Marketing status (see presentation here).
- Industry welcomes the EMA plans to roll out a tool to report data on marketing status electronically, instead of the Excel template and the collaboration EMA/industry stakeholders on this matter.
- Industry expressed concerns on the initially proposed 4-month transition phase and the possibility that all functionalities could not be available at launch.

Follow-up actions agreed:
The launch will be communicated to Industry through EMA stakeholders liaison on the date of launch.

A meeting with the Industry volunteers group will be organised on 16th Sep to get feedback on the first weeks of use of the tool.

CHMP Workload and Co-Rapp Involvement

As announced in the EMA website, the EMA presented an overview of the implementation of additional temporary measures to further streamline activities in the European medicines regulatory network to enable experts to deal with an increasing volume of COVID-19-related assessment procedures Additional measures to allow experts to focus on COVID-19 activities | European Medicines Agency (europa.eu).

These measures have been agreed with the EMA Management Board to ensure that the network can continue to dedicate resources to COVID-19 whilst always maintaining the robustness of its scientific evaluations. These measures complement the arrangements prioritising COVID-19 procedures that are already in place under the current phase 2 of the business continuity plan for the European medicines regulatory network, such as maximum flexibility with timetables or temporary changes of rapporteurs for non-COVID-19 procedures (see presentation here).

These measures only affect the preparation of initial assessment reports. They do not change the responsibilities or contribution of rapporteurs, co-rapporteurs or any of the other European experts involved in the assessment of medicines.

Industry welcome the clarifications provided did not express any specific concerns about these procedural changes.

Follow-up agreed: EMA is keeping the measures under review and will amend them if necessary.

Interactions with patients and consumer groups across the product lifecycle

The Agency provided an overview of where patient input is currently solicited along EMA's regulatory product lifecycle; pre-authorisation, evaluation and post-authorisation phases. This included a description of the new CHMP/CAT pilot regarding early dialogue with patient organisations for orphan medicines (see presentation here).

Finally, the future direction of engagement was also highlighted, in line with EMA's RSS and the EMAN strategy to 2025, to expand capacity and network outreach, enrich training and support, exchange methodologies across decision makers (e.g. HTAs), continue to contribute to multi-stakeholder projects (e.g. IMI) and progress patient engagement guidance in a global context (e.g. ICH, CIOMS).

Industry representatives presented an overview of the benefits of patient input throughout product development, proposing considerations and recommendations in two main areas: patient engagement and the "science of patient input"; this included to actively promote patient engagement and enhance EMA's engagement framework to reflect the evolution of patients' contribution, to establish a structured patient network and raise awareness and exchange methodologies and learnings across decision makers (e.g. HTA). They proposed to carry out an industry survey to collect information on patient data submitted to EMA and challenges experienced, and that a multi-stakeholder meeting would be a good way to share key principles and challenges (see presentation here).

Follow up agreed:

EMA agreed overall on all aspects highlighted and confirmed that it would explore the option to hold a multi-stakeholder meeting Q4/2021- 1Q/2022 with the objective to exchange current knowledge, experience and initiatives from the different stakeholder groups, and to look at a potential format for future exchanges.

EMA Strategy on digitalization

The Agency provided an overview of the comprehensive efforts to support digital business transformation and data analytics goals and how these are being enabled by technology capabilities, describing digitalisation as a cross-Agency and cross-network effort. An overview was given of how the Agency has organised itself to accelerate these efforts (see presentation here). Industry highlighted its vision for a "Digital EMA" and presented use cases for the inclusion of SPOR/IDMP data in the CP business assessment (see presentation here).

To advance digital transformation, the Agency is investing in the transformation and optimisation of regulatory processes. The launch of IRIS for reporting changes on marketing status reflects the ongoing investment in integrating and modernising systems and processes that enable and support the centralised procedure and in doing so, better integrate and make use of data. A further project in this transformation is replacing aging PDF electronic application forms with more modern digital interfaces that will enhance structured data capture and integration and increase efficiencies.

Another important focus is adapting the Agency to new legislation, not only to re-use existing processes but to re-think our ways of working. New legal texts such as the Medical Device Regulation and In-Vitro Diagnostics Regulation present opportunities to develop longer-term transformative solutions.

The Agency is also working on scaling up efforts to exploit novel technologies and further apply process analytics and artificial intelligence to improve efficiencies in this intense period and reduce manual interventions in processes. Examples include automating checks for variations and automating the electronic signature of certificates and exposing this information to the EMA website. An update was given on the Agency's investments in enhancing change management as a key enabler of digitalisation to ensure that all stakeholders are ready to take advantage of technology and process enhancements in the most effective way possible. These efforts are already visible in the ongoing programmes and projects discussed. The Agency is also developing a digital skills academy to further develop digital skills across the workforce. The goal of this is to ensure that EMA is well positioned to be able to identify and exploit the opportunities brought by digitalisation, with extension to the Network in a later phase.

In order to enable the transformation from the technology side, it is critical to focus on operational excellence as the foundation with a strong focus on business continuity, information security and data protection compliance as well as on transforming IT delivery and the underlying technology capabilities. The Agency discussed 7 strategic focus areas:

1. Interoperability and Data sharing - creating a data foundation for all pharmaceutical products in Europe and harmonizing product data submission over the medicine's lifecycle, streamlining the exchange of regulatory information with industry and driving the adoption of FHIR as our main exchange standard moving from electronic documents to data.
2. Advanced Analytics Capabilities - Providing the capabilities that help to drive insights and evidence from large amounts of real-world health care data, big data platforms, AI, data lakes etc.
3. Cloud-native Enterprise Architecture – moving to a data-protection compliant and secure cloud infrastructure and taking advantage of innovations from the cloud, AI, big data etc.
4. Modular platforms – using shared, scalable, standard technologies as a principle.
5. Data-driven Solutions – providing solutions that are designed to be data-driven, not designed to move documents.

6. Self-Service / Automation - driving the automation of regulatory processes and moving towards self-service solutions for user registration, resetting passwords or updating organizational data.
7. Agile ways of working – the Agency is currently conducting a pilot of Agile and lean governance and setting up product teams with NCA and industry participation, agile ceremonies instead of steering committees, etc.

Review of EMA Working Parties

The Agency presented a progress report on the EMA's Management Board working group on review of working parties following adoption of a high level implementation plan at the March 2021 Management Board. This plan foresees the introduction of five principal governance domains to strategically direct, prioritise and oversee the work of the working party system namely Quality , Non-clinical, Methodology, Clinical and Veterinary Domains. As well as establishing three year rolling workplans for each Domain in conjunction with the various Scientific Committees, expertise within each domain will be re-organised into more agile flexible structures including European Specialised Expert Communities, operational expert groups , temporary drafting groups and standing working parties which will be adjusted in accordance with workload needs and seek to optimise the use of online collaborative tools in increasing the speed and efficiency of the work done. The new model is designed to deliver the strategic, tactical and operational goals of each domain whilst ensuring sourcing of future-proof expertise and agility to adapt to reflect evolution of science and product development. It also foresees the establishment of various platforms to support the translation of innovation such as a Quality Innovation Group, a repurposed 3Rs and a Methodology working party in their respective Domains. It also envisages an improved outreach to stakeholders to deliver a stronger more managed interaction with relevant stakeholders (i.e. Patients, Learned Societies, Industry and Academia) (see presentation here) .

Type II process improvement - discuss industry involvement

The Agency informed Industry on the revision of post-authorisation activities and mainly type II processes. The objective is to provide a more efficient and lean Type II variation process management. A large and increasing number of queries have being received before the submission of a type II variations. Many of these queries are very specific and justified in order to submit a successful type II variation but many others are standard queries, where the answers can be found in Agency pre-submission guidance and other related documents available in Agency website.

Follow-up Agreed:

The Agency proposed to Industry to create a small group (6 to 8 volunteers) to discuss these 'standard' queries, identify opportunities for improvements and suggest an action plan for reducing non-critical queries. Industry volunteers should have extensive experience in submission of Type II variations, using relevant Agency documentation and sending queries to the Agency. The group should start working with Agency experts in 4Q2021 for a period of 3 to 6 months.