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Highlight report from the 15th Industry Stakeholder Platform on Research and Development Support - 4 December 2025

Role	Name
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Participants:	Industry: **AESGP** Paul-Etienne Schaeffer; **ARM** Andrea Braun, Christel Ravesteijn-Verrijt, Monica Veldman, Sibylle Herzer; **EFPIA** Almath Spooner, Cathelijne de Gram, Claudia Popp, Gesine Bejeuhr, Jyo Krishnan, Kirsty Reid, Loeckie De Zwart, Nadege Le Roux, Peggy Sarah; **EUCOPE**, Alison Bond, Bertrand Fournier, Elena Stojanovska, João Duarte, Lucia D'Apote, Marcello Milano, Mariska Mulder, Marta Provencio, Shekhar Natarajan, Simon Bennett; **EuropaBio** Alexa Hunter, Elisabeth Kuhn, Esteban Herrero-Martine, Laura Liebers, Laura Oliveira, Laura Savini, Pedro Franco, Sathej Gopalakrishnan; **Medicines for Europe** Augusto Filipe, Beata Stepniewska, Indiana Castro, Irmela Gabriel, Jávor Judit, Karin Schott, Péter Krisztina Katalin, Sanju Dhawan; **Vaccines for Europe** Marie-Pierre Petitjean, Olivier Thiange EMA: Alberto Ganan, Ana Zanoletty, Carlos Aicardo, Chrissi Pallidis, Demy Vandenhaak, Efthymios Manolis, Jane Moseley, Kevin Cunningham, Kristina Larsson, Massimiliano Sarra, Maria Sheean, Patrice Verpillat, Pieter Colin, Stefano Ponzano, Stiina Aarum, Victor Cojocaru EMA scientific committees and European regulatory network: **COMP** - Frauke Naumann-Winter; **CHMP** – Bruno Sepodes, Outi Mäki-Ikola; **SAWP-H** - Paolo Foggy, Flora Musuamba Tshinanu; **MWP-CP-OEG** - Carolien Versantvoort

This was the fifteenth meeting between regulators and representatives of industry stakeholders to address topics of evidence generation along the medicine's life cycle and related product-development support activities, such as scientific advice and qualification, as well as specifics for paediatric and orphan medicines. The aim 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.

As part of the introduction a review took place of the status of follow-up actions from the last platform meeting. Significant progress was made in accordance with the planned deliverables and timelines, and follow-up discussions took place at the 15th meeting, where required.

Strengthening the delivery of scientific advice to efficiently support development programmes

Update on recent developments

The number of scientific advice procedures started in 2025 was slightly higher than in the previous year and the number of discussion meetings remained at the same level. Submission peaks were noted, as every year, in April and especially in late August / early September and prospective applicants should generally consider avoiding these submission slots, if possible.

Under the SAWP/CTCG pilot 11 applications were successfully concluded. EMA plans to collect and analyse feedback on the clinical trial application if submitted subsequently to the advice provided while the publication of the pilot final report is expected in early 2026. As the pilot will continue towards collection of further experience, applicants are encouraged to continue applying to the pilot even if they have applied previously.

During 2025 applicants experienced challenges with pre-payment for scientific advice requests as legally required by Regulation (EU) 2024/568 since the beginning of the year. EMA is considering making the pre-payment a submission requirement with adjustments to the fee level, as determined during validation of the application, without time pressure in the course of the procedure. In parallel, EMA is developing the necessary IT infrastructure to allow direct debit for payment of invoices for any fee-incurring applications.

Due to low number of applications for parallel scientific advice with FDA, EMA will launch a survey towards industry associations to understand reasons/opportunities for improvement and to reflect on other forms of EMA/FDA interaction. Industry associations prepared in parallel a similar survey and the industry proposal informed the development of the EMA survey which will be conducted in early 2026.

EMA has proposed some updates to the scientific advice briefing document template pertaining to the regulatory registration strategy, special populations and patient representative involvement in scientific advice. At the same time, industry associations would like to propose some further minor amendments for the document to be used more easily in both EMA and FDA submissions. The updated template should be finalised and published in 2026.

Establishment of a Focus group on introducing agility in scientific advice

A Focus Group with representatives from industry, SAWP and EMA will be constituted in 2026 with the aims to consider an opportunities for an agile scientific advice process and explore feasibility and conditions for implementing such process. Deliverables of the Focus Group will be to define scope, submission requirements, assessment resource allocation, timelines and outcome of the agile process, to decide on feasibility of agile process implementation and, depending on it, on the conduct of a pilot.

Broad scientific advice affecting multiple products

Broad scientific advice covers multiple indications of a single medicinal product, multiple products used experimentally in the same indication or affected by the same change (e.g. manufacturing) or a combination of the two.

However, broad scientific advice has been also used occasionally to answer general questions relating to medicines development without reference to specific medicinal products. Industry associations proposed that broad scientific advice could be used to address similar questions sometimes stemming from legislation tangentially relating to medicines, as necessary with the involvement of other relevant EU Agencies, most notably the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA). EMA acknowledged the need for such regulatory interaction and agreed to internally discuss what could be the appropriate regulatory vehicle for such, as necessary inter-Agency, discussions once the revision of the pharmaceutical legislation is finalised.

Follow-up:

Update on recent developments

- Industry to share their proposal for an enhanced briefing book template to enable global development submissions, and follow-up discussions with the sounding board
- EMA to share the EMA/FDA interactions survey with scientific advice sounding board before conducting the survey; results to be reported back at the next platform
- Industry to consider raising practical challenges with the SAWP/CHMP scientific advice at the ACT EU Multi-stakeholder Platform
- EMA to pursue the technical arrangements to enable payment of scientific advice fees at submission

Establishment of a Focus group on introducing agility in scientific advice

- EMA to share the draft objectives / deliverables for comments, alongside the request for nomination of Industry representatives to the Focus Group
- Work of the Focus Group to be initiated in early 2026, with reporting back at the next R&D platform

Broad scientific advice affecting multiple products

- EMA to explore legal and technical/procedural feasibility of extending broad scientific advice scope as proposed by industry

Modernising the Qualification of Novel Methodologies framework

EMA presented a short update on the delivery of the action plan for future-proofing of the framework for qualification of novel methodologies (QoNM). The timelines for delivery were revised due to the substantial amount of work needed. In consequence, the updated general guidance, briefing document templates and the update of the EMA webpages on QoNM are expected by the end of 1Q26 with further topic-specific Q&A documents to be drafted in parallel and later in the course of the year.

Follow-up:

- EMA/industry core team to progress with the delivery of the action plan (including procedural guidance and Q&A, templates, early interaction support and communications)

Translating the experience from the piloting of the new PRIME features into optimised operations

EMA provided an update on the implementation of the new PRIME scheme features (Regulatory Roadmap and Development Tracker, Expedited Scientific Advice (SA), and Submission Readiness Meeting (SRM)). The key findings from the pilot, which were informed by the experience of regulators and PRIME developers, were presented along with the final recommendations for future refinement of the features. The recommendations, which were agreed following consultation with Industry, comprise technical and procedural aspects, as well updates to the published guidance based on the experience gained during the pilot.

EMA also provided an update on the status of the new "Product Development Coordinator" (PDC) role, which was launched as a pilot in July 2025 for a subset of PRIME designated products. The PDC will be a key facilitator of the optimised PRIME scheme features, through their expert development support, procedural stewardship of expedited scientific advice, and experience and knowledge transfer at the submission readiness meeting.

Industry Stakeholders welcomed the implementation of the pilots as standard support features, and the recommendations for their further refinement. Feedback emphasized the need to maximise the impact of PRIME through efficient, iterative and flexible support from early development through to MAA approval, in which all regulatory activities help to build a continuum of knowledge to support the streamlined assessment.

Follow-up:

- Report on the new PRIME features to be published by EMA in 1Q26
- Discussions on the KPIs for the Product Development Coordinator pilot to be finalised with the sounding board, to also reflect the developer's perspective
- Based on the recommendations, further refinements to the features and updated guidance to be prepared, together with the sounding board, and communicated, also in view of the 10th Anniversary and future operations

HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment

The EMA/HMA multi-stakeholder workshop held in October 2025 focused on the qualification and regulatory use of mechanistic models, including PBPK, PBBM, and QSP/QST. The event brought together regulators, academia, industry associations, and software developers to review lessons from EMA's recent PBPK qualification opinion and to discuss uncertainty quantification (UQ), acceptance criteria, and guidance gaps. As a follow-up to the workshop, EMA outlined several key actions. The Agency will consider developing tailored approaches for Model-Informed Drug Development (MIDD) scientific advice and qualification, while exploring a voluntary data submission framework to support MIDD initiatives. The Agency also intends to leverage existing fora and processes to strengthen dialogue on MIDD with international regulators, including opportunities for parallel advice. To maintain effective communication, EMA and industry will identify relevant MIDD contacts and outline a strategic engagement plan. Furthermore, the Agency will advance work on overarching guidance for mechanistic models, update the existing PBPK guideline to incorporate lessons learned from the recent qualification opinion, and prepare a dedicated Q&A on MIDD qualification as an annex to the general qualification guidance.

Industry stakeholders welcomed the Agency's efforts and highlighted opportunities to accelerate the adoption of mechanistic models in regulatory submissions. Feedback focused on expanding contexts of

use (CoUs) to areas such as CYP induction, facilitating early submission of mechanistic models through a "special pathway," and enabling dialogue without delaying marketing applications. There was strong interest in expert-to-expert communication, sharing regulatory review outcomes, and publishing joint perspectives to build confidence in mechanistic modeling. Industry also stressed the importance of clear acceptance criteria and best practices. Data-sharing and establishing approved physiological data sources were identified as key steps to advance mechanistic modeling. Additionally, industry encouraged EMA to provide clarity on resource allocation and training plans for reviewers.

Both the Agency and industry recognised ICH M15 as a cornerstone for strengthening communication and enabling mechanistic models to reach their full potential.

Follow-up:

- EMA to progress the priority actions identified during the workshop (development support, communication with regulators and with stakeholders, as well as guideline activities)
- Industry to disseminate the outcome of the workshop and subsequent publications, to further promote the use of such models, and consider nominating MIDD experts as contact for the Agency to ensure ongoing communication on the follow-up activities.

Proposal for the pilot of a voluntary data submission framework to establish potential alternatives to animal testing in line with the 3Rs principles

EMA provided an update on the Voluntary Data Submission (VDS) pilot project. A summary of the discussions held during the NcWP stakeholder meeting was presented, highlighting the strong interest and engagement from industry and CRO trade associations. In addition, EMA outlined the agenda of an ad-hoc VDS meeting held on 11 December with industry and CROs, which served as a kick-off meeting to co-create the pilot project, together with an indicative timeline for completion of the pilot project.

Follow-up:

- Progress with the co-creation of the pilot for voluntary data submissions with the aim to start the new offering in mid-2026

Progressing the support to paediatric developments

Overview of recent developments

Following the review of the Pediatric Investigation Plan (PIP) Summary Report (SR) and the Key Elements Form (KEF), minor revisions have been introduced to both documents.

The amendments to the SR are intended to strengthen the focus of discussions on critical aspects of extrapolation and to promote the consistent use of the structured guidance.

With respect to the KEF, the clarification underscores that the objective is not to increase the level of detail in the opinion but to provide applicants with clear direction on the type of information required in each section.

Advancements in the prospective design of paediatric development programmes

Participants were informed that the pilot phase for the stepwise PIP (sPIP) has concluded and that the voluntary procedure is now formally established. Updates to the relevant guidance and the associated

Q&A have been published on the EMA website. Applicants are encouraged to continue submitting sPIP applications where appropriate.

Industry representatives highlighted challenges associated with PIPs for rare, pediatric-only diseases, particularly in relation to adaptive trial designs that necessitate frequent modifications.

EMA provided an update on the activities which were ongoing since the implementation of the FDARA Act in the USA (since 2017), which prompted the submission of voluntary mechanism of action driven PIPs in the area of paediatric oncology also in the EU. In response the Non-clinical Working Party conducted a retrospective analysis of the non-clinical assessment process of proof-of-concept data in these PIPs. The results of this analysis were used to draft a Concept Paper on proof-of-concept data supporting the development of anti-cancer products in paediatric patients. The paper proposes a weight-of-evidence approach as a framework for assessment of data in support of clinical studies in paediatric oncology, and it recommends developing a process for involvement of stakeholders in such assessments (including academic and regulatory, when appropriate). Timelines for the consultation process on the Concept Paper were shared.

Follow-up:

- EMA to finalise the draft Concept Paper on proof-of-concept data supporting the development of anti-cancer products in paediatric patients, and subsequent consultation of stakeholders
- Follow-up on the proposal for a PIP Submission in Rare Paediatric-First/Only Diseases to be discussed by the sounding board and to be presented at the next platform meeting
- EMA to consider future arrangements for prospective discussing the Mechanism of Action concept

Identification of product-specific bioequivalence guidelines

EMA presented an update on the current and proposed approach of the selection of products for product-specific bioequivalence guidelines (PSBGLs). The current approach could be viewed as a reactive approach, where products are chosen based on requests from CHMP, CMDh and Scientific Advices, which results in either an advice, a Q&A or a PSBGL. The proposed approach is more proactive by also consulting industry on their view of what products could be of interest. This will be added to the current approach. It is still to be discussed how to shape this planned consultation and a couple of examples were given during the presentation, e.g. a yearly EU survey or yearly open call.

Follow-up:

- EMA to further progress the development of the calls also considering the comments received, and communicate through the platform the final arrangements
- Industry associations to raise awareness of this planned consultation
- EMA to consider strengthening of proactive communication on planned product-specific bioequivalence guidelines

Focus group to explore opportunities for the use of Real-World Data (RWD) and the generation of Real-World Evidence (RWE)

An update of the meeting that took place on September was given. The focus was on getting feedback from the different trade associations on DARWIN EU as part of the on-going exercise on Lessons learned to inform discussions on next DARWIN EU contract. This led to very engaged discussions as often, with positive feedback but also areas for improvement. Clarifications on some of the issues raised may be achieved with the publication of the Q&A which has been already discussed with the focus group but still to be finalised.

Follow-up:

- The Focus Group to consider refining their deliverables in view of translating the fruitful discussions into concrete actions, which can serve as foundation for future engagement as required

Strengthening support to evidence generation for drug-IVD/MD combination products

In follow-up to previous discussion in a focus group, which led to the publication Multistakeholder scientific advice for medicinal products used in combination with a medical device or a companion diagnostic in the EU — summary of a Focus group discussion, industry provided considerations on the importance of scientific advice in advancing the dialogue, focusing on expertise required and on pre-authorisation interactions/dialogue. EMA and industry acknowledged the importance of these discussions and agreed to continue the dialogue also taking into account other legislative and non-legislative initiatives.

Follow-up:

- EMA and industry to continue the dialogue considering the proposals from developers for such advice on combination products, also taking into account other legislative and non-legislative initiatives such as COMBINE