EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Experience with the R&D stakeholder platform

5th Industry Stakeholder Platform on R&D support

16 November 2020

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Evolution of the industry stakeholder platform on research and development support

Since its inception, four R&D platform meetings were held:

1st R&D platform meeting - 25.04.2017

2nd R&D platform meeting - 15.11.2017

3rd R&D platform meeting - 18.05.2018

4th R&D platform meeting - 23.11.2018

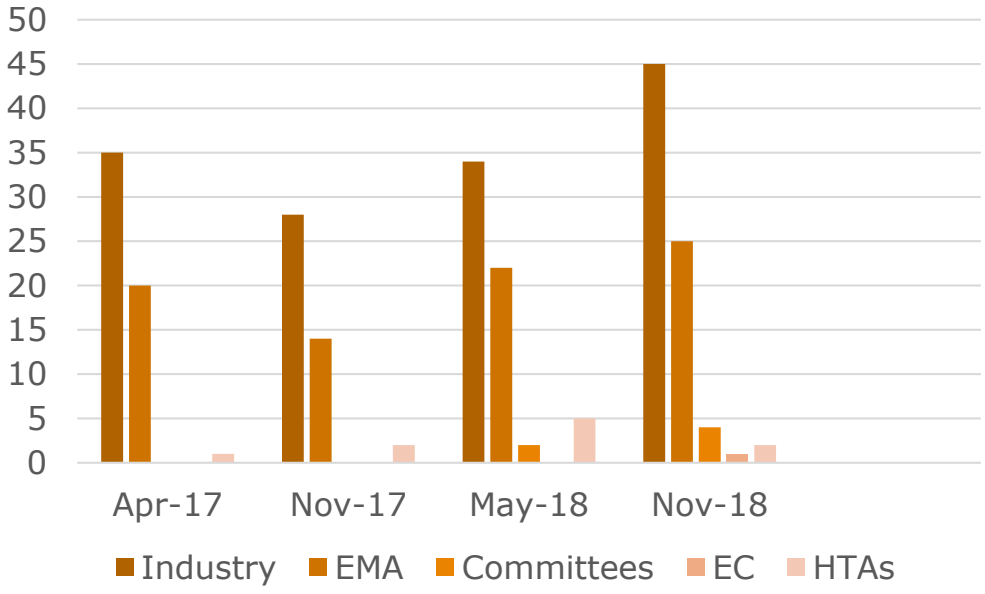
(note: platforms were paused in 2019 due to business continuity considerations)

Scope: all areas of product-development support, from scientific advice, through specifics for paediatric and orphan medicines, to innovation support

Focus: general updates and more focused discussions on specific processes or issues to support continuous improvement

Transparency: Highlight reports and EMA presentations published on the website

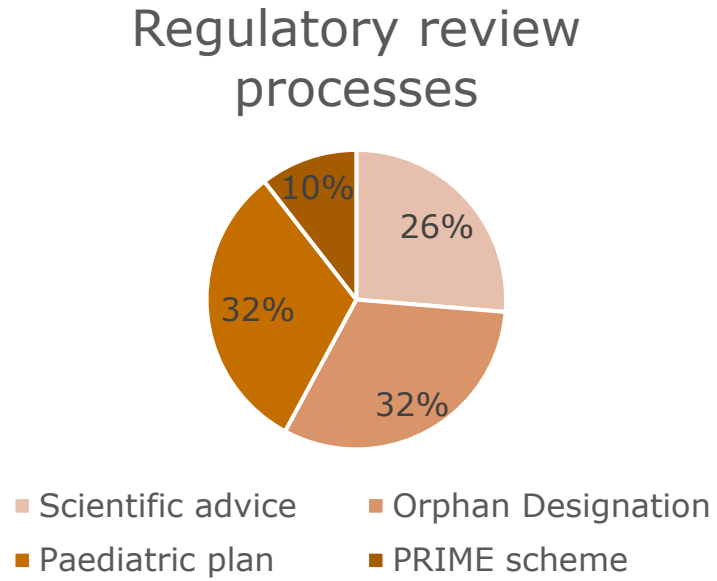
Participants at the platform meetings



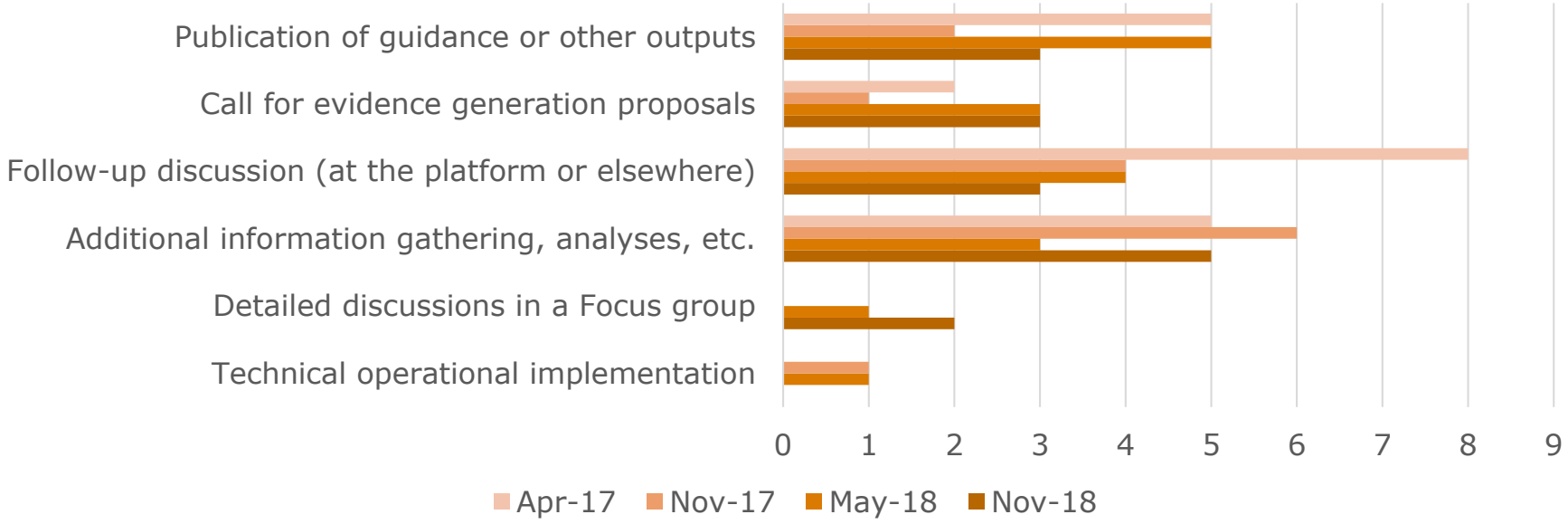
- Aim to maintain a constructive working environment:
  - Industry associations coordinate their participants
  - EMA contributors depending on the agenda items
- Committee chairs as well as European Commission invited
- Additional attendees possible (e.g. HTA bodies)

Topics for the platform discussion

- Usually 8 topics on the agenda of a 1-day meeting, of which 4-5 are for detailed discussion and the remainder shorter updates
- Scope is either related to regulatory review processes [N=19] or more general evidence generation approaches (e.g. real world evidence, digital technologies) [N=10]; rarely pure operational topics are discussed
- Break-out sessions on conceptual topics were tried at the last meeting



Follow-up actions from the discussions

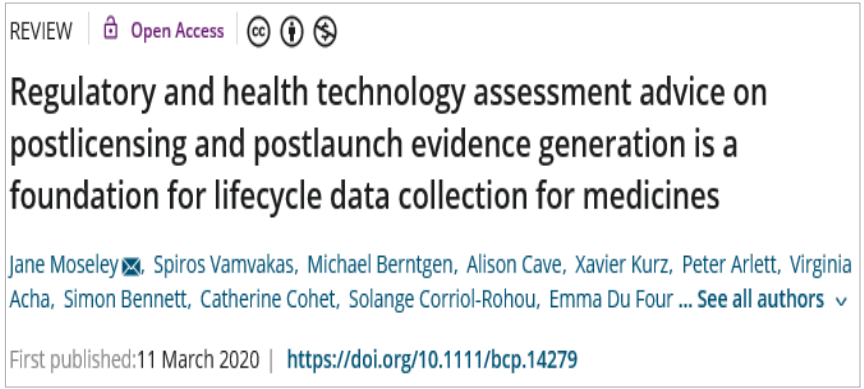


Focus group "Post-licensing/launch evidence generation"

Objectives:

- To identify issues and barriers to seeking scientific advice on PLEG, and discuss potential solutions.
- To discuss several key areas in the context of seeking scientific advice on PLEG including approaches for questions on which scientific advice is sought.

Output:


REVIEW | Open Access

Regulatory and health technology assessment advice on postlicensing and postlaunch evidence generation is a foundation for lifecycle data collection for medicines

Jane Moseley, Spiros Vamvakas, Michael Berntgen, Alison Cave, Xavier Kurz, Peter Arlett, Virginia Acha, Simon Bennett, Catherine Cohet, Solange Corriol-Rohou, Emma Du Four ... See all authors

First published:11 March 2020 | https://doi.org/10.1111/bcp.14279

British Journal of Clinical Pharmacology

Advice involving different decision makers aims to optimise the PLEG plan to address remaining uncertainties after licensure and launch

Focus group "Qualification of digital technologies"

Objectives:

- To summarise circumstances where digital technologies are expected to enable some steps of the product development process
- To describe the scope and process of a digital technology's qualification procedure
- To develop points to consider for the preparation of a high-quality request for qualification dossier

Output:

Digital technologies for medicines: shaping a framework for success

Francesca Cerreta[1]✉, Armin Ritzhaupt[1], Thomas Metcalfe[2], Scott Askin[3], João Duarte[4], Michael Berntgen[1] and Spiros Vamvakas[1]

Regulatory agencies can provide advice to support developers of digital technologies for medicines use, but what are the best strategies to maximize the chance of a successful regulatory interaction? Here, EMA and industry representatives comment on the experience so far.

Nature Reviews Drug Discovery

Questions and answers: Qualification of digital technology-based methodologies to support approval of medicinal products

Status as of June 2020

Qualification of digital technology-based methodologies

Focus group "Integrated R&D product support"

Objectives:

- To map current interaction opportunities, and how they are being used in practice
- To describe principles and limitations of such interactions
- To develop ideas to ensure a continuum of interactions along the development life-cycle including relevant enablers and boundaries

Output:

1/ Analysis of **existing engagement platforms** describing their use in development programmes, strengths/limitations as well as familiarisation from developer's perspective

- Basis for further EMA communication material

2/ **Multi-stakeholder discussion** at DIA Europe

3/ Establishment of **design principles** for enhancing the development support ecosystem

- Discussed in session 3 "Evolution of the scientific advice framework"

Take home messages

- The European regulatory system is constantly evolving in scientific, regulatory and technical aspects relevant for medicines development and evaluation
- The R&D stakeholder platform has been established as a collaborative forum for progressing relevant topics in terms of development support from regulatory perspective, and beyond, as well as evidence generation concepts
- Achievements from the R&D platform can contribute to the implementation of strategies such as the RSS to 2025 as well as the EMAN strategy