15 May 2018
EMA/195267/2018

Agenda – Industry stakeholder platform on research and development support

18 May 2018 10:30 – 17:00, Meeting room 03-F

Chair: Michael Berntgen

Item	Agenda	Time
1.	**Welcome / Introductions** Overview of the agenda *Enrica Alteri, EMA*	15 min
2.	**Exchange on experience with the implementation of the Orphan notice** Experience and developments based on the reviews by COMP over the first year *Kristina Larsson, EMA* Challenges from industry perspective, particularly for the reassessment in the context of an extension of indication *Maren von Fritschen and James Barnes, EUCOPE* Discussion	30 min
3.	**Targeting "histology-independent indications" and resulting challenges in the context of orphan designations** Experience from developers when discussing such development programmes *Isabelle Stöckert, EFPIA* Discussion, including update from the workshop as well as COMP experience *Francesco Pignatti and Kristina Larsson, EMA*	30 min

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4.	**Introduction to the upcoming rollout of the new technology to support orphan designation procedures (S-REPS)** Presentation of the new CRM tool including live demo *Paolo Tomasi, Sylvie Beausuroy and Bob Coggins, EMA* Feedback from industry representatives from the user group *Olaf Mengels and Danuta Wawrzak, EBE-EFPIA* Discussion	45 min
5.	**Experience with the review of digital technology proposals in medicine development programmes** Orientation and overview of developments in this field and needs for future engagement with regulators and other decision makers *Mark Hope and Chris Walker, EFPIA* Experience in scientific advice and qualification, and initial learnings for future activities *Spiros Vamvakas and Francesca Cerreta, EMA* Discussion on priorities for upcoming exchange in this space *(also involving Marisa Papaluca and Alison Cave, EMA)*	45 min
	Lunch	**60 min**
6.	**Evolving framework for the co-development of medicinal products with companion diagnostics** Status update on the developments in the implementation activities of the MDR/IVDR *Armin Ritzhaupt, EMA* Scientific proposals coming into the regulatory system: Identified critical issues for the (co-) development of companion diagnostics and medicinal products *Falk Ehmann, EMA* Considerations from developer's perspective on the opportunities for alignment of development between drugs and diagnostics *Christine Mayer-Nicolai and Claudia Dollins, EBE-EFPIA* Discussion *(with participation of Oliver Bisazza and Petra Zoellner, MedTech Europe, as observers)*	45 min

7.	**Understanding which technologies are coming into the healthcare systems** Considerations from discussions across decision makers (regulator, HTA, payer) *Michael Berntgen, EMA, together with Cláudia Furtado, INFARMED, Ingvil von Mehren Sæterdal, NIPH, as well as Ad Schuurman, Wytse Bruinsma, and Niels Speksnijder, ZIN* Discussion *(also with Enrico Tognana and Marisa Papaluca, EMA)*	20 min
8.	**Focus group "Post-licensing evidence generation"** Scope and methodology to progress with this focus group *Jane Moseley, EMA / Emma Du Four, EFPIA*	20 min
9.	**Follow-up from the EC/EMA workshop on paediatrics** Summary of the outcome and next steps; recent experiences in the field of paediatrics with regard to extrapolation and international collaboration *Ralph Bax, EMA* Industry reflections on the workshop and priority areas Industry *Angelika Joos and Genevieve Le Visage, EFPIA* Discussion	30 min
10.	**Update on PRIME** Overview of updated guidance based on experience and learnings after 2 years of operation of the scheme *Jordi Llinares and Zahra Hanaizi, EMA*	30 min
11.	**Summary of follow-up items** Close of meeting *Michael Berntgen, EMA*	15 min