20 April 2017
EMA/88749/2017

Agenda – Industry stakeholder platform on research and development support

25 April 2017 10:00 – 16:30, Meeting room 03-F

Chair: Michael Berntgen

Item	Agenda	Time
1.	Welcome / Introductions Background and scope of this newly established platform Overview of the agenda *Enrica Alteri, EMA*	10 minutes
2.	**Evidence generation that addresses different decision makers' needs: the experience with parallel HTA / regulatory scientific advice** Experience and ways moving forward from sponsor's perspective *Gesa Pellier, EFPIA* Update on current status of parallel HTA/regulatory scientific advice and expected developments (also in collaboration with EUnetHTA) *Jane Moseley, EMA & François Meyer, Haute Autorité de Santé (HAS) / EUnetHTA JA3 WP5* Plenary discussion (also involving Hannah Brühl, Gemeinsamer Bundesausschuss (G-BA))	10 minutes 10 minutes 25 minutes
3.	**Advances in the co-development process for personalised medicines** Experience in interactions with Notified Bodies and expectations for the implementation of the future framework *Christine Mayer-Nicolai, EBE* Review of experience with scientific approaches to co-development programmes *Falk Ehmann and Efthymios Manolis, EMA* Outlook on the opportunities for interactions between EMA and Notified Bodies *Armin Ritzhaupt, EMA* Plenary discussion	15 minutes 10 minutes 10 minutes 25 minutes

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4.	**Learnings and proposals on incorporation and generation of Real World Evidence within development programmes** Overview of what has been proposed to date by developers in the context of product-specific scientific advice? *Francesca Cerreta and Alison Cave, EMA* Experience, approaches and suggestions from developers to generate and use real-world data in development programmes *Emma du Four, EFPIA* Plenary discussion	 10 minutes 10 minutes 10 minutes
5.	**Optimising the guidance on significant benefit demonstration in the context of protocol assistance** Expectations concerning protocol assistance on the data generation for significant benefit demonstration *Martine Zimmerman, Eucope* Recent developments stimulated through the work of both COMP and SAWP *Matthias Hofer and Spiros Vamvakas, EMA* Plenary discussion	 15 minutes 15 minutes 15 minutes
	Lunch Break	**45 min**
6.	**Implementation of the 2016 Notice on the application of the Orphan Regulation** Approach to the implementation with regard to procedural, regulatory and scientific elements *Kristina Larsson and Laura Liebers, EMA* Opportunities and challenges identified by applicants in the implementation *David King, EuropaBio* Plenary discussion	 15 minutes 10 minutes 15 minutes
7.	**The concept of early dialogue for paediatric development plans** Review of uptake of this concept during the pilot *Gunter Egger, EMA* Experience and proposals for optimising this platform for product-specific dialogue *Geneviève Le Visage, EFPIA* Plenary discussion	 10 minutes 10 minutes 15 minutes

8.	**Facilitating engagement with the FDA to allow shaping paediatric development programmes** Learnings and proposals how to further benefit from EMA/FDA dialogues on paediatric development programmes *Angelika Joos, EFPIA* Experience with the EMA-FDA paediatric cluster, the common commentary and the pilot with joint early paediatric interaction *Irmgard Eichler, EMA* Plenary discussion	10 minutes 10 minutes 15 minutes
9.	**Initiatives concerning optimising the dialogue for paediatric medicines development** Industry reflections regarding optimising the implementation of the Paediatric Regulation and framing paediatric development *Geneviève Le Visage, EFPIA* Plenary discussion, including EMA update on recent initiatives	10 minutes 15 minutes
10.	**Expectations and perspectives to facilitate an integrated product development support** Broader reflections on areas for future engagement based on the discussions of the day and the various areas addressed *Moderator: Michael Berntgen, EMA*	15 minutes
11.	Summary of follow-up items Close of meeting *Michael Berntgen, EMA*	5 minutes

Participants List

EMA	Industry Stakeholder Organisations
Enrica Alteri, Head of Human Medicines Research and Development Support Division	**AESGP**
Michael Berntgen, Head of Product Development Scientific Support Department	Claudine Aziz
Corinne De Vries, Head of the Science and Innovation Support Office	**EBE**
Kristina Larsson, Head of the Orphan Medicines Office	Christine Mayer-Nicolai
Ralph Bax, Head of the Paediatric Medicines Office	Anne Lützhoft Aarbogh
Spiros Vamvakas, Head of the Scientific Advice Office	Isabelle Clamou
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Alison Cave, Scientific Officer	Sonja Pumplün
Armin Ritzhaupt, Regulatory Affairs Officer	Gesa Pellier
Chrissi Pallidis, Scientific Officer	**EFPIA**
Efthymios Manolis, Scientific Officer	Pär Tellner
Falk Ehmann, Scientific Officer	Emma du Four
Francesca Cerreta, Senior Scientific Officer	Geneviève Le Visage
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Irmgard Eichler, Senior Scientific Officer	Agnes Legathe
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	Martine Zimmerman
	Maren von Fritschen
	EuropaBio
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	Vinciane Pirard
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