9 November 2017
EMA/630645/2017

Agenda – Industry stakeholder platform on research and development support

15 November 2017 11:00 – 16:30, Meeting room 03-F

Chair: Michael Berntgen

Item	Agenda	Time
1.	Welcome / Introductions Overview of the agenda *Enrica Alteri, EMA*	15 min
2.	**Parallel Consultation with regulators and HTAs** **A. The first experience with the newly launched Parallel Consultation platform** *Jane Moseley, EMA & Via TC: Anja Schiel (NOMA) / Chantal Guilhaume (HAS)* *Adam Heathfield, Industry* Plenary discussion **B. Strengthening the prospective discussions on post-licensing evidence generation** *Jane Moseley, EMA & Via TC: Anja Schiel (NOMA) / Chantal Guilhaume (HAS)* *Adam Heathfield, Industry* Plenary discussion	60 min
3.	**Recent update of the guidance for Parallel EMA/FDA scientific advice** *Thorsten Vetter, EMA*	15 min
4.	**Learnings with and further improvements of PRIME** *Jordi G. Llinares / Zahra Hanaizi, EMA* Plenary discussion	15 min

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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	Lunch	**60 min**
5.	**Publication of the Orphan Maintenance Assessment Report** *Kristina Larsson, EMA* • Information on the upcoming publications of COMP assessment reports at time of marketing authorisation • Discussion on the procedure and content of the Orphan Maintenance Assessment Report (OMAR) Plenary discussion	30 min
6.	**Continuous progress in the area of paediatrics** *Claire Hill-Venning / Genevieve Le Visage / Victoria Kitcatt, Industry* *Emilie Desfontaine / Ralph Bax, EMA* • Review of status of the PDCO work plan delivery • Recent experience with scientific multi-stakeholder workshops • Upcoming revocation of class waivers • First exchange on the EC report on the Paediatric Regulation Plenary discussion	75 min
7.	**Follow up on opportunities for integrated R&D product support** *Michael Berntgen, EMA* • Brief overview of exiting engagement opportunities Plenary discussion	15 min
8.	**Upcoming operational advances in development support: Introduction to "Scientific and Regulatory Evaluation Procedure Support (S-REPS)"** *Paolo Tomasi & Valerie Johnson, EMA* Plenary discussion	30 min
9.	Summary of follow-up items Close of meeting *Michael Berntgen, EMA*	15 min