6 July 2022
EMA/284940/2022

Agenda – 8th Industry stakeholder platform on research and development support

11 July 2022, 09:30 – 16:15 (WebEx)

Chair: Michael Berntgen

Item	Agenda	Time
1.	**Welcome / Introductions** • Overview of the agenda • Review of status of follow-up actions from the last platform meeting *Michael Berntgen, EMA*	10 min
2.	**Strengthening the ecosystem of engagement platforms for evidence planning**	
	A. Status update in terms of scientific advice capacity and development of proposals moving forward *Iordanis Gravanis, EMA*	30 min
	B. Progress report from the Focus group on review and strengthening the framework for qualification of novel methodologies *Thorsten Vetter, EMA / Claire Hill-Venning, Industry*	15 min
	C. First exchange on the opportunities to synergise EMA scientific advice on drug-device combinations and the Medical Device Expert Panels - Expectations from developer's perspective *Tim Chesworth and Lars Hyveled-Nielsen, Industry*	35 min
	D. Progress with the repurposing pilot – interim feedback *Christelle Bouygues and Anna Tavridou, EMA*	15 min
	E. Experience with the ITF framework for 3Rs and new approach methodologies (NAMs) *Falk Ehmann and Stefano Ponzano, EMA*	15 min
Coffee break (11:30 – 11:40)		10 min

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3.	**Continuous improvement and strengthening of paediatric procedures** A. Progress report from the Focus group on the practical application of principles relevant for the PIP framework *Chrissi Pallidis, EMA / Gesine Bejeuhr, Industry* B. Response to the proposal for modifying the compliance check procedure *Ralph Bax and Peter Karolyi, EMA*	15 min 15 min
4.	**Strengthening patient-centric development** • Information on the planned multi-stakeholder workshop • Updates relevant in preparation of the workshop *Nathalie Bere and Juan Garcia, EMA* *Susan Bhatti, Lucia D'Apote and Isabelle Stoeckert, Industry*	20 min
Lunch break (12:30 – 13:15)		45 min
5.	**Collaboration at the regulatory/HTA interface** A. Progressing parallel Joint Scientific Consultations – experience from the first call and preparation of the second one *Thorsten Olski, EMA, and Antje Behring, EUnetHTA21* *Inka Heikkinen, Industry* B. Opportunities for strengthening information exchange to facilitate sequential decision making (CHMP Opinion and Joint Clinical Assessment) *Ansgar Hebborn, Industry*	30 min 15 min
6.	**Follow-up from the 5-year report on the experience with the PRIME scheme** • Progress update on implementation activities & key areas for engagement with industry stakeholders *Stefanie Prilla and Francesca Cerreta, EMA, together with Bruno Sepodes (CHMP vice-chair) and Martina Schüßler-Lenz (CAT chair)* *Nadege Le Roux, Industry*	30 min
Coffee break (14:30 - 14:40)		10 min
7.	**Follow-up on the "Orphan Maintenance Assessment Report" survey** • Actions taken in response to survey *Kristina Larsson, EMA*	20 min
8.	**Progress with the implementation of the Companion diagnostics framework** A. Update on the final guidance *Ana Trullas Jimeno and Ciska Verbaanderd, EMA* *Panellists for Q&A: Christelle Bouyques, Jörg Engelbergs and Hilke Zander* B. First experiences with CDx procedures *Christine Mayer-Nicolai and Jesus Rueda, Industry*	30 min 10 min

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	C. Insight (e.g. case study) into conformity assessment process at the manufacturer level *Jesus Rueda, Industry*	20 min
9.	**Summary of follow-up items / Close of the meeting** *Michael Berntgen, EMA*	5 min