EMA/107723/2026

Agenda - 16th Industry Stakeholder Platform on Research & Development Support

2 July 2026, 12:30 – 17:30 (room 1A)

Co-chairs: Michael Berntgen and Iordanis Gravanis

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 delivery of scientific advice (SA) to efficiently support development programmes** A. Update on recent developments: EMA overview • Statistics, refinement of briefing book template, progress with pre-payment requirements, broad scientific advice, SAWP/CTCG pilot Industry observations and suggestions *EMA: Iordanis Gravanis* *Industry: Esteban Herrero-Martinez (EuropaBio)* *Supportive experts: Alexa Hunter (EuropaBio), Laura Oliveira (EuropaBio), Shekhar Natarajan (EUCOPE), Elena Wolff Holz (Medicines for Europe)* B. Progress of the Focus Group on agility in scientific advice • Overview of achievements so far and next steps *EMA: Milton Bonelli* *Industry: Alexa Hunter (EuropaBio), Laura Oliveira (EuropaBio)* *Supportive experts: Esteban Herrero-Martinez (EuropaBio), Elena Wolff Holz (Medicines for Europe)* C. Pilot on scientific advice specific for Model-informed Drug Development (MIDD-SA) • Scope and expectations for MIDD-SA	25 min 25 min 10 min

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	EMA: Iordanis Gravanis D. Update on activities of the COMBINE workstream 5 focusing on scientific advice for combination developments *EMA: Iordanis Gravanis*	10 min
3.	**Survey on experience and expectations with parallel EMA/FDA development support** • Feedback received and proposed next steps *EMA: Carlos Aicardo, Thorsten Vetter* *Industry: Alexa Hunter (EuropaBio)* *Supportive experts: Esteban Herrero-Martinez (EuropaBio), Susana Almeida (Medicines for Europe)*	25 min
4.	**Continuous evolution of the PRIME scheme** • Update on latest developments with the new features as well as the 10th anniversary of the scheme • Update on ongoing pilot of the new Product Development Coordinator role *EMA: Kevin Cunningham* *Industry: Nadège Le Roux (EFPIA), Christel Ravesteijn (ARM)* *Supportive expert: Pedro Franco (EuropaBio)*	20 min
5.	**Progress update with the action plan on modernising the Qualification of Novel Methodologies** • Recent deliveries from the action plan and overview of upcoming work *EMA: Thorsten Vetter*	10 min
6.	**Role and activities of the R&D stakeholder platform in the implementation of the New Pharmaceutical Legislation (NPL)** • Overview of industry engagement in the context of the NPL implementation • Discussion on priority topics for the R&D stakeholder platform *EMA: Melania Fanari* *Industry: Katarina Nedog (EFPIA), Marta Provencio (EUCOPE), Beata Stepniewska (Medicines for Europe)* *Supportive expert: Pedro Franco (EuropaBio)*	25 min
	COFFEE BREAK	**15 min**

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7.	**Progressing the support to paediatric developments** • Update on embedding the stepwise PIP into practice • Experience exchange on the concept of a Mechanism of Action developments *EMA: Chrissi Pallidis (sPIP), Maria Sheean (MoA)* *Industry: Mariska Mulder - sPIP (EUCOPE) Gesine Bejeuhr – MoA (EFPIA)* *Supportive expert: Pauline Roudot (EFPIA), Andrea Braun (ARM)*	20 min
8.	**Initial considerations on the new concept of a "Regulatory sandbox"** • First exchange on the concept in view of implementation activities • Outline of future engagement opportunities *EMA: Valentina Cordo* *Industry: Nick Sykes (EFPIA)* *Supportive experts: Valentina Mazzanti (EUCOPE), Pedro Franco (EuropaBio)*	30 min
9.	**Focus group to explore opportunities for the use of Real-World Data (RWD) and the generation of Real-World Evidence (RWE)** ▪ Update on the activities including the DARWIN EU Q&A document ▪ Overview of future Focus Group deliverables *EMA: Patrice Verpillat* *Industry: Almath Spooner (EFPIA)* *Supportive expert: Milada Mahic (EUCOPE)*	15 min
10.	**Development of a new guidance for reporting on indirect comparisons** • Updates on the drafting of a Q&A • Insights into a review of indirect comparisons in orphan medicines-related submissions • Experiences and cases from developers' perspective *EMA: Anouk Neven, Artur Lewandowski* *Industry: Shekhar Natarajan (EUCOPE)*	20 min
11.	**Progress update on the launch of the Voluntary Data Submissions (VDS) pilot for 3Rs methodologies** ▪ Feedback from the process development together with industry and expected launch *EMA: Stefano Ponzano*	15 min
12.	**Follow-up discussion on the identification of product-specific bioequivalence guidelines** ▪ Update on the discussion subsequent to the previous R&D stakeholder platform	15 min

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	EMA: Demy van den Haak *Industry: Indiana Castro (Medicines for Europe)*	
13.	**Summary of follow up items / Close of the meeting** *Michael Berntgen (EMA)*	5 min