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European Medicines Agency

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Adaptive pathways workshop agenda

8 December 2016 (EMA Rooms 3A+3M) 8:30 to 17.00

Workshop chair: Tomas Salmonson ([MPA](#) / [EMA CHMP](#))

Introduction – setting the scene		
08.30-08.40	Welcome and meeting objectives	Guido Rasi (EMA)
08.40-08.55	General perspective on early access to medicines	Andrzej Rys (EC DG Sante)
08.55-09.15	The Adaptive Pathways pilot: Complementing the EMA early access tools	Francesca Cerreta (EMA)
09.15-09.30	Adaptive Pathways – Concept and Critical Issues	Hans-Georg Eichler (EMA)
Topic 1: Adaptive pathways: perspectives of patients and healthcare professionals on addressing patient needs		
Session Chair: Tomas Salmonson (MPA / EMA CHMP)		
Rapporteur: Maria Mavris (EMA)		
09.30-09.45	Patients' views on the products selected for the adaptive pathways pilot	Rafał Świerzewski (ECPC / EMA PCWP)
09.45-10.00	The consumer representatives' views on the products selected for the adaptive pathways pilot	Francesca Cattarin (BEUC)
10.00-10.15	HCP representatives' views on the products selected for the adaptive pathways pilot	Rosa Giuliani (ESMO)
10.15-11.15	Floor discussion	
11.15-11.45	Coffee break	



Topic 2: Avenues of knowledge generation throughout a medicine's lifespan

Session chair: Peter Mol ([CBG-MEB](#) / [UMCG](#))

Rapporteur: Andrew Thomson ([EMA](#))

11.45-12.05	Potential Data sources	Alison Cave (EMA)
12.05-12.25	Methodological challenges and the monitoring advantage of Real World Data	Robert Hemmings (MHRA / EMA CHMP / EMA SAWP)
12.25-12.45	The Salford Lung study	Ashley Woodcock (University of Manchester . Clinical lead, Salford lung study) David Leather (GSK , Salford lung study)
12.45-13.45	Floor discussion	
13.45-14.30	Lunch break	

Topic 3: From bench to bed: involvement of all relevant parties in the delivery of medicines for unmet medical needs

Session Chair: Tomas Salmonson ([MPA](#) / [EMA CHMP](#))

Rapporteur: Michael Berntgen ([EMA](#))

14.30-14.45	Adaptive pathways pilot: what has the involvement of other decision makers brought to the discussion?	Sarah Garner (NICE)
14.45-15.00	HTA view	Various HTA representatives
15.00-15.15	MEDEV/Payers view	Ad Schuurman (MEDEV / ZIN)
15.15-15.30	AOK/German payers view	Evert Jan van Lente (AOK Bundesverband)
15.30-16.30	Floor discussion	

Conclusions

16.30-16.50	Overview of today's discussions	Spiros Vamvakas (EMA)
16.50-17.00	Close of meeting	Andrzej Rys (EC DG Sante)