



19 November 2013
EMA/551358/2013

Agenda of the European Medicines Agency / Health-Technology-Assessment-body workshop on parallel scientific advice in drug development

26 November 2013 – Rooms 2A and 3A

Time	Item	Speaker	Mins
09:00	Welcome address	Guido Rasi	
09:15	Session 1:	Co-chairs	
	Why is this needed?	Regulatory Tomas Salmonson	
	Where do we want to get to?	Academic Ronald Akehurst	
	Patient Advocate View	Yann Le Cam	15 mins
	HTA View	David Barnett	15 mins
	European Commission	Flora Giorgio	10 Mins
	Industry View	Richard Bergström	15 mins
	Discussion	All	20 mins
10.30	Coffee		20 mins
10.50	Session 2:	Co-chairs	
	Science - how can the scientific information needs of both HTAs and regulatory be accommodated in a common development track?	Industry Mel Walker HTA Niklas Hedberg	
	Regulatory View	Robert Hemmings	15 mins
	HTA View	Leeza Osipenko	15 mins
	Industry View	Britta Paschen	15 mins
	Discussion	All	20 mins
12.00-12.50	Lunch		50 mins



Time	Item	Speaker	Mins
12.50	Session 3: Process - Where are we Now? Lessons Learned and Identifying Blocks	Co-chairs HTA Paolo Siviero Industry Judith Creba	
	Industry View – EFPIA survey results	Christine Mayer-Nicolai & Adrian Griffin	20 mins
	EuropaBio SME survey results	Paolo Morgese	15 mins
	HTA View - EUnetHTA	Mira Pavlovic	15 mins
	Regulatory View	Jan Mueller-Berghaus	15 mins
	HTA View	Seren Phillips	15 mins
	Discussion	All	20 mins
14.30	Parallel Breakout Sessions:		1 hour
	Breakout groups on moving forward: 1) Principles and policy Room 4B 2) Science & data Room 2A 3) Process & procedures Room 2G 4) Special areas e.g. (ATMPs /Orphan/Paeds) Room 3A		
15.50	Presentations of breakout sessions and forward plans with short/medium/long term objectives	Co-chairs Industry Richard Bergström HTA Finn Børllum Kristensen	
	Group 1: Principles & policy	Moderators Industry James Anderson Regulatory Tomas Salmonson HTA Seren Phillips	10 mins
	Group 2 Science & data	Moderators Academic Karen Facey Regulatory Rob Hemmings HTA Leeza Osipenko	10 mins
	Group 3 Process & procedures	Moderators Industry Angelika Joos Regulatory Spiros Vamvakas HTA Antje Behring	10 mins
	Group 4 Special Areas e.g. ATMPs /Orphan/Paeds	Moderators Industry Thibaut Du Fayet Regulatory Bertil Jonsson HTA François Meyer	10 mins
	Discussion	All	20 mins
16.50	Wrap up	Regulatory Tomas Salmonson	
17.00	End		