02 February 2011
Doc. Ref.: EMA/90390/2011
Human Medicines Development and Evaluation

Agenda - Workshop on Antibacterials

7-8 February 2011: European Medicines Agency, London, United Kingdom

Co-chairs: Jaap van Dissel and Marco Cavaleri
Rapporteur: Mair Powell

Time	Item / Presentation title	Presenter, affiliation
09:00	Registration and coffee	
10:00	Welcome and Opening	Patrick Le Courtois, European Medicines Agency
10:15	Non-inferiority studies and indication-specific primary endpoints Regulatory consideration Discussion on specific indications: HAP/VAP	Mair Powell, MHRA, United Kingdom Jean Chastre, Group Hospitalier Pitie-Salpetriere, France Robert Fromtling, MSD, USA Paul G. Ambrose, Institute for Clinical Pharmacodynamics, USA
11:30	Coffee Break	
12:00	Discussion on specific indications: cSSTI	M Dryden, Royal Hampshire County Hospital, United Kingdom John Rex, AstraZeneca UK Limited United Kingdom
13:00	Lunch Break	
14.00	Discussion on specific indications: Regulatory consideration AECB (ABECB), AOM/ABS	Mair Powell, MHRA, United Kingdom Francois Boer, Abbott laboratories Limited, United Kingdom Robert Cohen, French Health Products Safety Agency, France Solange Rohou, AstraZeneca UK
16:00	Coffee Break	

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Time	Item / Presentation title	Presenter, affiliation
16:30	Evaluating new agents for rare and/or MDR pathogens: Possible study designs and possible scenarios depending on total spectrum and indications granted/sought	Angelos Pefanis, National Health System, Sotitia Hospital, Athens, Greece Mark Goldberger, Abbott laboratories Limited, United Kingdom
18:30	End of Session	

Tuesday, 8th February

Time	Item / Presentation title	Presenter, affiliation
08:30	Consideration of some other specific indications: Regulatory consideration Bacteraemia Elimination of carriage	Mair Powell, MHRA, United Kingdom Harald Seifert, University of Cologne; Mark Kunkel, Pfizer, United States Antoine Andremont, Hospital Bichat-Claude Bernard, France; Keith Barker, GSK, United Kingdom
10:30	Coffee Break	
11:00	Reflection of in-vitro and in-vivo activity in the SmPC Section 5.1 Regulatory consideration	Mair Powell, MHRA, United Kingdom
12:00	End of Workshop	