3rd EMA-EGA INFO DAY
Generic and Biosimilar Medicines in the Centralised Procedure

For EGA Members Only

DATE: Wednesday 10 November 2010 at 10.00-16.30. Registration starts at 08:30

VENUE: Room 2A - EMA, 7 Westferry Circus, Canary Wharf, London, E14 4HB

MORNING SESSION

CHAIRS:
Anthony Humphreys, Head of Regulatory Procedural and Committee Support, Unit Patients Health Protection, EMA
Michael Banks, Vice President Regulatory Affairs Europe, TEVA Pharmaceuticals & Chair of EMA-EGA Working Group and Regulatory & Scientific Affairs Committee

TIME		
08:30	Registration	
10:00	Welcome and General Introduction **Thomas Lönngren**, Executive Director, EMA	10 min
10:10	Generic and Biosimilar Medicines in the EU Healthcare System **Greg Perry**, Director General, EGA	15 min
10:25	EMA Road Map to 2015: From Vision to Reality **Noël Wathion**, Head of Unit Patient Health Protection, EMA	20 min
10:45	EGA's Vision regarding the Centralised Procedure and Beyond **Suzette Kox**, Sr Director Scientific Affairs, EGA	15 min
11:00	Q&A and Discussion	15 min
11:15	COFFEE BREAK	15 min
11:30	Performance Indicators of the Centralised Procedure for Generic Medicines **Michael Berntgen**, Head of Section Rheumatology, Respiratory, Gastroenterology and Immunology, Sector Safety and Efficacy of Medicines, Unit Human Medicines Development and Evaluation, EMA **Jonathan Rousell**, Head of EU Regulatory Competence Centre (UK), Teva Pharmaceuticals Europe	20 min 20 min
12:10	Q&A and Discussion with **Michael Berntgen, Jonathan Rousell, Jose Ramon Cozar (EMA) and Sonia Ribeiro (EMA)**	35 min
12:45	BUFFET LUNCH	1 hour

AFTERNOON SESSION

CHAIRS:
Anthony Humphreys, Head of Regulatory Procedural and Committee Support, Unit Patients Health Protection, EMA
Suzette Kox, Senior Director Scientific Affairs, EGA

TIME		
13:45	Centralised Procedure for Biosimilar Medicines: What Works Well and Where is Room for Improvement? **Claudia Sailer**, Regulatory Affairs Manager, Sandoz Biopharmaceuticals Development	20 min
	Q&A and Discussion	10 min
14:15	Global Development for Biosimilar Medicines in the Light of US Developments	
	Falk Ehmann, Scientific Administrator, Section Anti-infectives and Vaccines, Sector Safety and Efficacy of Medicines, Unit Human Medicines Development and Evaluation, EMA	10 min
	Ingrid Schwarzenberger, Head Global Regulatory Affairs Biopharmaceuticals, Sandoz Biopharmaceuticals Development	10 min
	Q&A and Discussion	10 min
15:00	COFFEE BREAK	15 min
15:15	Impact on the proposed anti-falsification legislation on inspections	
	Katrin Nodop, Principal Scientific Administrator, Head of Sector Support, Sector Compliance and Inspection Section, Unit Patient Health Protection, EMA	15 min
	Julie Maréchal-Jamil, Sr Manager Regulatory Affairs, EGA	15 min
15:45	Approach to Risk Management Plans for Generic Medicines	
	Stella Blackburn, Risk Management Development and Scientific Lead, EMA	15 min
	Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Europe, Chair of EGA Safety & Pharmacovigilance Working Group and EudraVigilance Expert Working Group Member	15 min
16:15	Q&A and Closing remarks by the Chairs	
16:30	End of 3rd EMA-EGA Info Day	