



Making Medicines Affordable



## 3<sup>rd</sup> 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: 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 and **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 10 min  
**Thomas Lönngren**, Executive Director, EMA

10:10 Generic and Biosimilar Medicines in the EU Healthcare System 15 min  
**Greg Perry**, Director General, EGA

10:25 EMA Road Map to 2015: From Vision to Reality 20 min  
**Noël Wathion**, Head of Unit Patient Health Protection, EMA

10:45 EGA's Vision regarding the Centralised Procedure and Beyond 15 min  
**Suzette Kox**, Sr Director Scientific Affairs, EGA

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 20 min  
**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 20 min  
Pharmaceuticals Europe

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 and **Suzette Kox**, Senior Director Scientific Affairs, EGA

TIME		
13:45	Centralised Procedure for Biosimilar Medicines: What Works Well and Where is Room for Improvement? <b>Claudia Sailer</b> , 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 <b>Falk Ehmann</b> , Scientific Administrator, Section Anti-infectives and Vaccines, Sector Safety and Efficacy of Medicines, Unit Human Medicines Development and Evaluation, EMA	10 min
	<b>Ingrid Schwarzenberger</b> , 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 <b>Katrin Nodop</b> , Principal Scientific Administrator, Head of Sector Support, Sector Compliance and Inspection Section, Unit Patient Health Protection, EMA	15 min
	<b>Julie Maréchal-Jamil</b> , Sr Manager Regulatory Affairs, EGA	15 min
15:45	Approach to Risk Management Plans for Generic Medicines <b>Stella Blackburn</b> , Risk Management Development and Scientific Lead, EMA	15 min
	<b>Wendy Huisman</b> , 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 3 <sup>rd</sup> EMA-EGA Info Day	