2nd EMEA- EGA INFO DAY

Generic and Biosimilar Medicines in the Centralised Procedure

For EGA Members Only

DATE:	**Friday 3 October 2008 at 09.30-16.15**
VENUE:	**EMEA (Room 2A),** 7 Westferry Circus, Canary Wharf, London, E14 4HB Tel + 44 207 418 8400
CHAIRS:	
Patrick Le Courtois,	Head of Unit, Pre-Authorisation of Medicines for Human Use Unit, EMEA
Michael Banks,	Head of European Regulatory Affairs, TEVA Pharmaceuticals Europe & Chair of EMEA-EGA Working Group
Suzette Kox,	Senior Director Scientific Affairs, EGA

PROGRAMME

MORNING SESSION: CHAIRED BY PATRICK LE COURTOIS

TIME	TOPIC	
9:30	**Welcome and general introduction** **Thomas Lönngren**, Executive Director (EMEA)	**10 min**
9:40	**Presentation of the Generic and Biosimilar Medicines Industry** **Greg Perry**, Director General, (EGA)	**10 min**
9:50	**Centralised Procedure for generic medicinal products: lessons learned and further guidance** **Jose Ramon Cozar** Scientific Administrator, Quality of Medicines Sector, Pre-Authorization Evaluation of Medicines for Human Use (EMEA) **Evangelos Kotzagiorgis** Scientific Administrator, Quality of Medicines Sector, Pre-Authorization Evaluation of Medicines for Human Use (EMEA)	**20 min**
10:05	**Experience gained so far by the generic medicines industry** **Michael Banks**, Head of European Regulatory Affairs, TEVA Pharmaceuticals Europe and Chair of EMEA-EGA Working Group	**20 min**
10:25	**Referrals** **Thomas Larsson**, Scientific Administrator, Safety & Efficacy Sector, Pre-Authorization Evaluation of Medicines for Human Use (EMEA)	**15 min**
10:40	**Questions & Answer** **Michael Berntgen, Zaide Frias, Thomas Larsson, Michael Banks, Jose Ramon Cozar, Evangelos Kotzagiorgis**	**20 min**
11:00	**COFFEE BREAK**	

TIME	TOPIC	
11:15	**Lessons learned so far with biosimilar medicines in the Centralised Procedure**	**20 min**
	Peter Richardson, Scientific Administrator, Quality of Medicines Sector, Pre-Authorization Evaluation of Medicines for Human Use (EMEA)	
11:35	**Experience gained so far by the biosimilar medicines industry**	**20 min**
	Maria Saurwein-Teissl, Head Regulatory Affairs Group Biopharmaceuticals Sandoz **Ingrid Schwarzenberger,** Global Head Regulatory Affairs Biopharmaceuticals Sandoz	
11:55	**Questions & Answers**	**30 min**
	Peter Richardson, Falk Ehmann, Valentina Stamouli, Maria Saurwein-Teissl, Ingrid Schwarzenberger	
12:30	**BUFFET LUNCH**	**1 hour**

AFTERNOON SESSION: CHAIRED BY MICHAEL BANKS AND SUZETTE KOX

TIME	TOPIC	
13:30	**Use patents in the Centralised Procedure and Related Issues**	
	Arielle North, Executive Support, (EMEA)	**10 min**
	Suzette Kox, Sr Director Scientific Affairs (EGA)	**10 min**
	Discussion	**15 min**
14:05	**Centralised Procedure GMP Inspections**	
	Francois-Xavier Lery, Scientific Administrator**,** Inspection Sector (EMEA)	**10 min**
	Julie Maréchal, Senior Manager Regulatory Affairs (EGA)	**10 min**
14:25	**Centralised Procedure GCP Inspections**	
	Ana Rodriguez, Scientific Administrator**,** Inspection Sector (EMEA)	**10 min**
	Panel discussion and Q&A on GMP/GCP **Francois-Xavier Lery, Ana Rodriguez Beato, Julie Maréchal**	**15 min**
14:50	**COFFEE BREAK**	
15:05	**Transparency and Communication**	
	Laurent Brassart, Scientific Administrator, Medical Information Sector (EMEA)	**10 min**
	Beata Stepniewska, Director Regulatory Affairs (EGA)	**10 min**
	Discussion	**10 min**
15:35	**EudraVigilance and other Pharmacovigilance Issues**	
	Petracek Jan, Scientific Administrator, Pharmacovigilance and Risk Management Sector Post-Authorization Evaluation of Medicines for Human Use (EMEA)	**10 min**
	Wendy Huisman, QP Pharmacovigilance Teva Europe and Chair of EGA Safety & Pharmacovigilance Working Group	**10 min**
	Discussion	**15 min**
16:10	**Closing remarks by the Chairs**	
	Patrick Le Courtois, Michael Banks, Suzette Kox	
16:20	**END OF INFO – DAY**	

For registration or any additional queries, please contact Susie Lyddon/EGA at
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