

EMEA- EGA INFO DAY

Generic and Biosimilar Medicines in the Centralised Procedure For EGA Members Only

DATE:	Friday 24 November 2006, 09.30-16.15
VENUE:	EMEA (Room 3A), 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: GENERAL OVERVIEW, CHAIRED BY PATRICK LE COURTOIS

9:30	Welcome and general introduction Thomas Lönngren, Executive Director (EMEA)	10 min
9:40	Presentation of the Generic Industry Greg Perry, Director General, (EGA)	10 min
9:50	General introduction to the EMEA Anthony Humphreys, EMEA	15 min
10:05	Centralised Procedure for generic medicinal products (pre-authorisation guidance, procedure and post-authorisation issues) Zaide Frias, EMEA	20 min
10:25	Pros and Cons of the Centralised Procedure: Generic Industry point of view Michael Banks, Teva Pharmaceuticals Europe	15 min
10:40	Questions & Answer Anthony Humphreys, Zaide Frias, George Wade, Fergus Sweeney, Michael Banks	20 min
11:00	COFFEE BREAK	
11:15	Centralised procedure for similar biological medicinal products including post-authorisation issues Peter Richardson, EMEA	20 min
11:35	EGA perspective Ingrid Schwarzenberger, Sandoz	20 min
11:55	Questions & Answers Peter Richardson, Marisa Papaluca Amati, Fergus Sweeney, Ingrid Schwarzenberger	30 min
12:30	BUFFET LUNCH Room 3B	1 hour

AFTERNOON SESSION: OUTSTANDING ISSUES, CHAIRED BY MICHAEL BANKS AND SUZETTE KOX

13:30	Naming, packaging, labelling	
	Zaide Frias, EMEA	10 min
	Mary Smillie, EGA	10 min
	Discussion	10 min
14:00	Use patents in the Centralised Procedure	
	Sara Faircliffe, EMEA	10 min
	Suzette Kox, EGA	10 min
	Discussion	10 min
14:30	PUMA (Paediatric Use Marketing Authorisation)	
	Agnès Saint Raymond, EMEA	5 min
	Nadene McClay, EGA	10 min
14:45	COFFEE BREAK	
15:00	Commercially confidential information	
	Isabelle Moulon, EMEA	10 min
	Beata Stepniewska, EGA	10 min
	Discussion	10 min
15:30	Communication on generic and biosimilar medicinal products	
	Isabelle Moulon, EMEA	10 min
	Michael Borek, Sandoz (invited)	10 min
	Discussion	10 min
16:00	Closing remarks by the Chairs	
	Patrick Le Courtois, Michael Banks, Suzette Kox	
16:15	END OF INFO – DAY	

FOR REGISTRATION OR ANY ADDITIONAL QUERIES, PLEASE CONTACT SUSIE LYDDON

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