

MEB - EGA Info Day

28 January 2009

OKURA Hotel
Ferdinand Bolstraat 333 - NL-1072 LH Amsterdam

Wednesday 28 January 2009

- 12:00 Registration and Welcome Buffet Lunch
- 13:00 **Opening Speeches:**
- **Welcome Speech** | *Greg Perry, Director General, EGA*
 - **MEB's Strategic Business Plan 2009-2013: Elements Related to Generic Medicines** | *Aginus Kalis, Director General, MEB*
 - **Priorities in the Ministry of Health's Policy - The Place for Generic Medicines** | *Hans van Bijsterveld, Deputy Director Department of Medicines and Medical Technology, Ministry of Health, Welfare and Sport*
- 13:45 **Session 1 - Regulatory Aspects Related to Generic Medicines Applications in the Netherlands**
Chair | *Sipko Mulder, MEB*
- Challenges Related to the Submission of a Generic Medicines Application in the Netherlands**
- **MEB as the RMS in the European Procedures** | *Kora Doorduyn, MEB*
 - MEB capacity as an RMS in the European Procedures
 - MEB experiences: recommendations for the Industry
 - **Optimisation of the MA process** | *Aimad Torqui, MEB*
 - When will backlogs no longer exist?
 - Completion of the national phase of the procedure
 - **Electronic submission in the Netherlands** | *Ricco van den Hoorn, MEB*
 - MEB plans regarding the implementation of the eCTD
 - New portal as a challenge for 2009: status of the creation and roll-out plans
- Q&A Session** with session speakers and representatives of the generic medicines industry:
Caroline Kleinjan, Sandoz and Victor Benjaminsen, TevaPharmachemie
- 15:15 Coffee Break



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

MEDICINES EVALUATION BOARD



15:45

Session 2 - MEB's Key Messages to the Generic Medicines Industry on Various Issues

Chair | Hans van Gompel, MEB

- Quality of the dossier: bioequivalence | Jan Welink, MEB
- Quality of the dossier: Third country manufacturers | Diana van Riet, National Institute for Public Health and the Environment

Q&A Session with session speakers and representatives of the generic medicines industry: Tom Manussen, Disphar International and Mathijs Steegstra, Actavis

Session 3 - MEB Policy on Transparency and Communication

Chair | Truus Janse-de Hoog, MEB

- Information related to generic medicines: patients' expectations | Cees Smit, VSOP/EGAN (European Genetic Alliances Network)
- MEB policy on publication of PAR | Hantzen Stevenson, MEB
- MEB policy on the request for information by third parties | Diederik Slijkerman, MEB

Q&A Session with session speakers and representatives of the generic medicines industry: Sander W.G. Oortgiese, Ratiopharm and Britt Vermeij, TevaNederlands

18:00

End of Info Day and Networking Cocktail

For further information and to register on-line, please visit: www.egagenerics.com

Cristina Romagnoli | T: +377-93-501348 | F: +44-208-0825368
info@gpaconferences.com