

8th EGA Regulatory & Scientific Affairs Conference

29 - 30 January 2009

Access to generic medicines through an efficient regulatory system

OKURA Hotel
Ferdinand Bolstraat 333 - NL-1072 LH Amsterdam

Thursday 29 January 2009

EGA Regulatory & Scientific Affairs Conference

08:00 Registration and Networking Coffee

09:00 **Opening Session - Look to the future**

Chairs | *Aginus Kalis, Head of MEB (NL) and Greg Perry, Director General, EGA*

09:00 **Opening Speeches**

- **Priorities for the Generics Industry for the coming years** | *Greg Perry, Director General, European Generic medicines Association (EGA)*
- **Priorities for the EU Regulatory Authorities** | *Jytte Lyngvig (DK), Chair of the Heads of Agencies Management Board*
- **Priorities for the EMEA** | *Arielle North, Scientific Administrator, Directorate European Medicines Agency (EMA)*
- **New legislative initiatives from the European Commission** | *Martin Terberger, Head of Pharmaceutical Unit, DG Enterprise, European Commission*
 - Better regulation initiative
 - Anti-counterfeiting measures
 - Information to patients
 - Pharmacovigilance

10:30 **Panel discussion** composed of session speakers and other representatives of the EU Authorities: *Christina Rångemark Åkerman (SE) | Jean Marimbert (FR)*

11:00 Networking Coffee Break



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

- 11:30 **Session 2 - Achieving an efficient regulatory system in Europe**
Chairs | *Jytte Lyngvig (DK), Chair of the Heads of Agencies Management Board and Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics*
- **Outcome of the discussion at the HMA during the French Presidency on the use of existing resources in the most efficient way** | *Jean Marimbert, Director of AFSSAPS (FR)*
 - Action plans
 - **Contribution from the generic medicines industry to the process of optimisation of resources** | *Georg Stark, Alfred E. Tiefenbacher GmbH*
- Panel discussion** with session speakers and representatives from the EU authority: *Aginus Kalis (NL)* | *Arielle North (EMA)* | *Truus Janse de Hoog, Chair of the CMD(h)*
- 12:45 Networking Buffet Lunch
- 14:00 **Session 3 - Improvement of the variations system**
Chair | *Beata Stepniewska, European Generic medicines Association*
- **Key elements of the revised Variations Regulation** | *Hilde Boone, EMA*
 - What improvements does the new regulation bring to the Authorities and the Industry?
 - When is the implementation expected in practice?
 - **Procedural guidelines under preparation** | *Sandra Kruger (NL)*
 - **Generic medicines industry's comments on procedural aspects of the Variations Regulation** | *Beata Stepniewska, EGA*
- Panel discussion** with session speakers
- 15:30 Networking Coffee Break
- 16:00 **Session 4 - The pharmaceutical sector inquiry on anti-competitive practices**
Chair | *Greg Perry, Director General, EGA*
- **Initial findings from the sector inquiry** | *Benjamin Van Zeveren, DG Competition*
 - **Competitors as a part of your Approval Process- legal perspective** | *Stephen Kon, SJBerwin*
- Panel discussion** composed of representatives from the EU Authorities | *Christer Backman (SE)* | *Joan Boye (DK)* | *Vasco Maria (PT)* | *Hans de Heus, Teva Pharmaceuticals Europe B.V.* and *Georg Stark, Alfred E. Tiefenbacher GmbH for the industry*



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

- 17:30 Closure of the Day
- 19:30 Conference Dinner | Informal Attire

Friday 30 January 2009

EGA Regulatory & Scientific Affairs Conference

- 09:00 **Session 5 - Electronic submissions**
Chairs | *Christa Wirthumer-Hoche (AT) and Remco Munnik, Sandoz*
- **Implementation of eCTD - Survey among authorities and the industry on the readiness of eCTD applications**
 - **Best Practice Guide in MRP/DCP- practical experience with the implementation**
 - **Portals- a need for a more harmonised approach among MS**
 - **The NEES/eCTD submissions**
 - *Industry experience* | *Remco Munnik, Sandoz*
 - *Authorities experience* | *Miguel Bley (FR)*
 - **e-CTD submission at the EMEA: the latest developments** | *Ana Zanoletty Perez, EMEA*
- Panel discussion** with session speakers
- 10:30 Networking Coffee Break
- 11:00 **Session 6 - How to keep the PIL and SmPC of generic medicines up to date in view of changes to the reference product?**
Chair | *Gillian Latham, Glenmark Generics Europe*
- **Impact of the Paediatric Investigation Plan (PIP) and the assessment of paediatric data of reference product on SmPC of generic medicines**
 - **Implementation of the outcome of referrals and SmPC harmonisation**
 - **Impact of the PSUR assessment based on HBD on SmPC of generic medicines**
 - **When and how to update PIL and SmPC of generic medicine?**
 - *Current experience from the industry* | *Caroline Kleinjan, Sandoz*
 - *Key advice from the Authorities* | *Truus Janse de Hoog (NL)*
- Q&A Session** with a panel composed of session speakers and representatives from the EU authority: *Peter Bachmann (DE)*
- 12:30 Networking Buffet Lunch



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

- 14:00 **Session 7 - Ask your questions to the Regulators**
Chairs | *Truus Janse de Hoog (NL), Chair of the CMD(h) and Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics*
- **An opportunity to address questions to the European Regulators on various regulatory issues**
Questions should be formulated rather generally, without reference to a given product/procedure. Questions should be sent 2 weeks in advance to beata@egagenerics.com
- Q&A session** with representatives from the EU authorities | *Peter Bachmann (DE) | Christer Backman (S) | Joan Boye (DK) | Christa Wirthumer-Hoche (AT) | Marjo-Riitta Helle (Finland) | Patricia Vella Bonanno (Malta)*
- 15:30 End of Conference with Networking Coffee

For further information and to register on-line, please visit:

www.egagenerics.com

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

MEDIA SPONSOR

GENERIC
bulletin
www.generics-bulletin.com

 **GENERICSWEB**
THE SEARCH IS OVER

Journal of
**Generic
Medicines**
PALGRAVE JOURNALS

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 50, B-1000 Brussels, Belgium
T: +32-(0)2-736 8411 F: +32-(0)2-736 7438
E: info@egagenerics.com www.egagenerics.com
VAT: BE 0449 332 209

Organised in conjunction with


CONFERENCES

www.gpaconferences.com