

7th EGA Regulatory & Scientific Affairs Conference

| 31st January - 1st February 2008 |

Radisson SAS Royal Hotel
47, rue du Fossé-aux-Loups - 1000 Brussels, Belgium

Thursday 31st January 2008

EGA Regulatory & Scientific Affairs Conference

- 08:00 Registration and Networking Coffee
- 09:00 **Opening Session - Development of an efficient regulatory system in Europe**
Chairs | *Jytte Lyngvig (DK), Chair of the Heads of Agencies Management Board and Greg Perry, Director General, EGA*
- 09:00 **Opening Speeches**
- Priorities for the Generics Industry | *Greg Perry, Director General, European Generic medicines Association*
 - Priorities for the Regulatory Authorities | *Jytte Lyngvig (DK), Chair of the Heads of Agencies Management Board*
- 09:30 **Development of an efficient regulatory system in Europe**
- Point of view of the national competent authorities | *Jean Marimbert, Director of AFFSAPS (FR)*
 - Point of view of the EMEA | *Thomas Lönngren, Executive Director, EMEA*
 - Point of view of the European Commission | *Martin Terberger, Head of the Pharmaceutical Unit, DG Enterprise, European Commission*
- 10:30 **Panel discussion** composed of session speakers and other representatives of the EU National Authorities | *Aginus Kalis (NL) and Susan De Stasio, Arrow Generics for the industry*
- 11:00 Coffee Break



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- 11:30 **Session 2 - Decentralised procedures for generic medicines**
Chair | Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics
- **What are the lessons learned so far?**
 - Key advice from the CMD(h) after two years' experience
 - **Withdrawal and referrals during the procedure**
 - *CMD perspective* | Christa Wirthumer-Hoche (AT)
 - *The Generic Industry's perspective* | Maïke Lubomierski, Tiefenbacher
 - **What is the perspective of electronic submission for national procedures? Interplay with the EMEA system**
 - e-CTD, non-e-CTD electronic submission and Product Information Management (PIM) | Miguel Bley (FR)
 - *The Generic Industry's perspective* | Remco Munnik, Sandoz
- Q&A Session** with a panel composed of session speakers and other CMD members | Peter Bachmann (DE)
- 13:00 Buffet Lunch
- 14:15 **Session 3-1 - The centralised procedure for generic & hybrid applications**
Chair | Suzette Kox, European Generic medicines Association
- **Guidance for generic and hybrid applications** | Zaïde Frias and Anthony Humphreys (EMEA)
 - Latest update of the guideline
 - Experience with the generics applications gained so far
 - Naming and the fees proposal in case of use patent
- Q&A Session** with a panel composed of session speakers and Jonathan Rousell, TEVA for the industry
- 15:45 Coffee Break
- 16:15 **Session 4 - Regulatory and legal interplay**
Chairs | Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics and Emilce Vega, sj berwin
- **Legal and regulatory challenges in the revised Directive 2001/83** | Gareth Morgan, Taylor Wessing and Peter Feldschreiber, Four New Square (UK)
 - **Product liability. Issues particularly related to generic medicines** | Peter Feldschreiber, Four New Square (UK)
- Panel discussion** composed of representatives of the EU Authorities | Christer Backman (S) | Peter Bachmann (DE) | Anthony Humphreys (EMEA)
- 17:00 Closure of the Day
- 19:30 Conference Buffet Dinner | Informal Attire



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Friday 1st February 2008

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09:00

Session 5 - New guidelines under revision

Chair | *Kevan Cassidy, Generics (UK)*

Session 5-1 - Future developments of the Bioequivalence guidelines

- **Bioequivalence Guidelines under revision** | *Jan Welink, MEB (NL)*
- **Conclusion of the EGA- CMD Workshop on Bioequivalence study design, working to the GCP and interpreting the guidelines (Lisbon 24 October 07)** | *Susana Almeida, Tecnimed*

Panel discussion with session speakers and representatives from the EU authority: *Truus Janse de Hoog (NL)*

Session 5-2 - Genotoxic impurities

- **Genotoxic impurities:** | *Michael Wierer (EDQM)*
 - *Impact on EP monographs*
 - *Consequences for the Generic Industry*

Q&A Session with session speaker and *Jean Louis Robert, Chair of the QWP (LU)*

10:30

Coffee Break

11:00

Session 6 - Revision of the variations regulation

Chairs | *Christa Wirthumer-Hoche (AT) and Beata Stepniewska, European Generic Medicines Association*

- **Latest development of ICH Q8, Q9, Q10 - impact on the variations** | *Jean Louis Robert, Chair of the QWP (LU)*
- **The new proposal of the EC for the variations system** | *Nicolas Rossignol, Pharmaceutical Unit, DG Enterprise, European Commission*
 - *Generic Industry Perspective* | *Graham Powell, Generics (UK)*
 - *National Competent Authority's perspective* | *Sandra Kruger (NL)*
- **Changes to the current variations guideline in the quality area: generics industry proposal** | *Harm Peters, Tiefenbacher*
- **Changes in the CEP - impact on variations** | *Corinne Pouget, EDQM*

Panel discussion with session speakers and *Mike Teiler, TEVA* for the industry

13:00

Networking Buffet Lunch



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- 14:15 **Session 7 - Ask your questions to the Regulators**
Chairs | *Truus Janse de Hoog, Chair of the CMD(h) and Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics*
- **An opportunity to ask 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 | *Christa Wirthumer-Hoche (AT) | Christer Backman (S) | Peter Bachmann (DE) | Antoine Sawaya (FR) | Joan Boye (DK) | Urszula Scieszko-Fic (PL) | Anthony Humphreys (EMA)*
- 15:00 End of Conference with Networking Coffee

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

www.gpaconferences.com or www.egagenerics.com

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Registrations close officially on 15th January 2008 & are subject to availability