

5th Annual EGA
Regulatory Affairs Conference

Time of Changes

| 2nd - 3rd February 2006 |

Hotel Radisson SAS Portman
22 Portman Square - London W1H 7BG, UK

THURSDAY 2nd February 2006

Regulatory Affairs Conference

08:00 Registration and Networking Coffee

09:00 **Opening Session - A Look to the Future**

Chair | *Greg Perry, Director General, EGA*

- **Opening Speech: Generic Industry's Priorities** | *Greg Perry, Director General, European Generic medicines Association*
- **The Achievements of the UK Presidency** | *Margaret Jackman, Medicines and Healthcare Products Regulatory Agency (MHRA), UK*
- **Priorities for the Heads of Agencies** | *Jytte Lyngvig, Chair of the Heads of Agencies Management Board, DK*
- **European Commission Priorities for the Pharmaceutical Sector** | *Irene Sacristan Sanchez, DG Enterprise, European Commission*

10.30 **Issues at the National Level Following Implementation**

Panel discussion with representatives from EU national authorities | *Vasco Maria (PT)* | *Tamas Paal (HU)* | *Patricia Vella-Bonanno (MT)*

11:00 **Coffee Break**

11:30 **Session 2 - New Registration Procedures for Generics - A Choice?**

Chair | *Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics*

- **Mutual Recognition Procedure (MRP)/Decentralised Procedure (DCP)**
 - *CMD(h) perspective* | *Truus Janse de Hoog, Chair of the CMD(h), NL*
 - *Generic Industry perspective* | *Harm Peters, Alfred E. Tiefenbacher*
- **Centralised Procedure for Generics**
 - *EMEA perspective* | *Patrick Le Courtois, EMEA*
 - *Generic Industry's perspective* | *Michael Banks, Ivax*

Q&A Session with panel composed by sessions speakers, and other EU national authorities / Jitka Sabartova (CZ)

13:00 Lunch Buffet

14:15 Session 3 - Patient Benefits from Regulatory Developments for Generics Medicines
Chair | *Susan De Stasio, Chair of the EGA Regulatory and Scientific Committee, Arrow Generics*

Better Information for Patient

- Harmonised Patient Information
- QRD template, mock-ups and Blue Box requirements
- New requirements on PIL Readability in view of the revised guideline - when applicable for generics?

Presentation of the issues | *Peter Bachmann (DE)*

- Industry experience with readability testing | *Paul Fleming, Alpharma*

Impact of the Second Medical Use Patents on Patient Information Leaflet and SmPC of Generics

- Increase of patients' access to indications not covered by use patent
- The impact of the use patent clause on regulatory procedures- practical approach
- Impact on reimbursement and substitution rules

Presentation of the issues | *Christer Backman (S)*

Panel discussion with session speakers and representatives from the EU authorities:
| *Anthony Humphreys, EMEA* | *Shirley Norton (UK)* | *Antoine Sawaya (FR)* | *Suzette Kox, EGA for industry*

15:45 Coffee Break

16:15 Session 4 - Chair | *Susan De Stasio, Chair of the EGA Regulatory and Scientific Committee, Arrow Generics*

New Transparency Measures Versus Confidential and Commercially Sensitive Information - How to Strike a Balance?

- Regulatory Authority Point of View | *Rita Purcell (IE)*
- EMEA Point of View | *Anthony Humphreys, EMEA*
- Company Point of View | *Mary Smillie, Teva*

Panel discussion with session speakers and representatives from EU authorities: | *Jussi Holmalahti (FI)*

Increase of Patient's Access to Generics through the European Reference Product

- Legal framework of the European Reference Product
- Cooperation between Competent Authorities- which documentation is shared?
- Choice of SmPC and Reference Product for bioequivalence studies
- First experience with ERP

Presentation of the issues by | *Milan Smid (CZ)*

Panel discussion with representatives from the EU authorities: | *John Lisman (NL)*
| *Shirley Norton (UK)* | *Patricia Vella-Bonanno (MT)* | *Beata Stepniewska, EGA for industry*

17:45 Closure of Day

19:00 Departure to Conference Dinner

19:30 Conference Dinner | *Informal Attire*

08:00 Networking Coffee

TRACK I: Scientific/Technical Track

08:30 Session 5-I - ICH Harmonisation Process – Impact on Generics Industry

Chair | *Suzette Kox, Senior Director Scientific and Regulatory Affairs, EGA*

- Regulatory acceptance of harmonised monographs in accordance with ICH Q4B
| *Costin Camarasu, Biovail*
- Future Pharmaceutical Development in the context of ICH Q8 Guideline
| *Geoff Ansell, Niche*
- ICH Q9 and Q10 - Guidance on Quality Risk Management and on Quality System
| *Jan Moors, Pharmachemie*

10:00 Coffee Break

10:30 Session 6-I - GMP Compliance for Starting Materials

Chair | *Howard Rosenberg, Chair of the EGA APIs Working Group, Merck Generics*

- What are the ways of verifying that only GMP compliant APIs are used?
- What is the status of the GMP data base and who gets access?
- Which third party audit organisations are accepted by the Health Authorities?
- What is the status of the list of certain excipients for which GMP principles apply?
- How to prevent that inspection delays may block registrations?

Presentation of the issues | *Emer Cooke, EMEA*

Panel Discussion with Geoff Ansell (Niche) and Howard Rosenberg (Merck Generics, UK) representing industry

Chair | *Beata Stepniewska, Director of Regulatory Affairs, EGA*

New Rules of Validity of Marketing Authorisation

- Which documentation is required for renewal process?
- Does the implementation of sunset clause cover generics' specificity?

Presentation of the issues by | *Truus Janse de Hoog (NL)*

- Industry Point of View | *Caroline Kleinjan, Sandoz*

Panel discussion with session speakers and representatives from the EU authorities:

| *Jussi Holmalahti (FI)* | *Tamas Paal (HU)*

12:30 Buffet Lunch

TRACK II: The New Pharmacovigilance Environment

Session 5-II - Chair | *Philip Wood, EGA Member of Eudravigilance Steering Committee (ESC)*

8:30 Pharmacovigilance in the ICH process: impact on and contribution of the generics industry | *Jackie Conant, Apotex*

9:00 The Eudravigilance Project: Practical and Operational Implementation Aspects
| *Victoria Newbould, EMEA*



Making Medicines Affordable

9:30 Company's Experience with the Electronic Reporting | Wendy Huisman, Pharmachemie

10:00 Coffee Break

Session 6-II - Co-Chair | Suzette Kox, Senior Director Scientific and Regulatory Affairs, EGA

10:30 Update on PSUR Work Sharing and Harmonised Birthday Initiative | Pim van der Giesen, Medicines Evaluation Board (NL)

11:00 European Product Liability | Peter Feldschreiber, Four New Square (UK)

11:30 Preparing for Pharmacovigilance Inspection

- Authority's Point of View | Lindsay Watt (UK)
- Generic Industry's Perspective | Philip Wood, Teva

12:30 Buffet Lunch

COMMON TRACK

Session 7 - Chair | Susan De Stasio, Chair of the EGA RSA Committee, Arrow Generics

13.45 Applying the New Data Exclusivity Requirements

- "Global Marketing Authorisation" concept in practice.
- "Significant Clinical Benefit in Comparison to Existing Therapies" in the context of "8+2+1" DE

Panel discussion with representatives from the EU authorities | Peter Bachmann (DE)
| Anthony Humphreys, EMEA | John Lisman (NL) | Gary Clapp, PLIVA for industry

15:15 End of Conference

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

www.gpaconferences.com or www.egagenerics.com

T: +377-93 501348 - F: +377-93 501348 - E: info@gpaconferences.com

Registrations close officially on 21 January 2006 & are subject to availability