



Making Medicines Affordable

EGA Annual Regulatory Affairs Conference

12-13 February 2004 - LONDON

CHELSEA VILLAGE HOTEL

Stamford Bridge, Fulham Road, London SW6 1HS

- ***Generic Medicines & the new EU Pharmaceutical Legislation***
- ***How will the Centralised Procedure system work for generic and bio-similar applications***
- ***How will the new Mutual Recognition & Decentralised Procedure systems work for generic applications***
- ***Status of SmPC Harmonisation***
- ***Pricing & Reimbursement Policies in an Enlarged EU: Implications for the registration of generic medicines***
- ***New & Developing Requirements (CTD, e-CTD, Variations' Regulation, Eudravigilance)***
- ***Legal Issues Affecting the Registrations of Generic Medicines***

Organized by



10.00 - 11.30 Generic Medicines & the New EU Pharmaceutical Legislation***Chaired by Greg Perry, Director General, EGA***

- **10.00 Welcome Address**
Patrick Le Courtois, Head of Unit, Pre-authorisation evaluation of medicines for human use EMEA
- **10.10 - 10.40 Status and implementation timetable of the New Pharmaceutical Legislation and key issues affecting generic registrations**
Dr. Philippe Brunet, Head of Unit F2, Pharmaceuticals, Regulatory Framework and Marketing Authorisations, DG Enterprise, European Commission
 - ◊ Bolar
 - ◊ Data exclusivity periods and implementation
 - ◊ “Is marketed” issue and concept of single marketing authorisation
 - ◊ Definition of a generic medicinal product
 - ◊ European Reference product
 - ◊ Provision for bio-similar medicinal products
 - ◊ New procedures: Mutual Recognition, Decentralised and Centralised Procedure
- **10.40 - 11.10 Implications of the Pharma Review on generics in the Acceding Countries**
Dr. Vesna Koblar, Counsellor to the Government, Agency for Medicinal Products, Slovenia
 - ◊ Impact on existing generics
 - ◊ Impact on the registration of generics
- **11.10 - 11.30 Questions & Answers**

11.30 - 11.45 Coffee Break***11.45 - 13.15 How will the Centralised Procedure system work for generic and bio-similar applications******Co-chaired by Susan De Stasio, Chair EGA's Regulatory & Scientific Affairs Committee and John Greenwood, Chair EGA's Working Group on Bio-similar Medicinal Products***

- Opening statements by the Chairpersons
- Presentation by the EMEA - **John Purves**, Head of Sector Quality of Medicines, EMEA
- Panel discussion with **Dr. Philippe Brunet** & EMEA experts **Patrick Le Courtois** and **Anthony Humphreys**

13.15 - 14.15 Lunch***14.15 - 16.00 How will the new Mutual Recognition and Decentralised Procedure systems work for generic applications******Chaired by Susan De Stasio, Chair EGA's Regulatory & Scientific Affairs Committee***

- Viewpoint of Users - **Malcolm Summers**, Kendle; **Michael Banks**, Lek Pharma
- Panel Discussion: **Dr. Philippe Brunet**, **Truus Janse de Hoog** - MEB The Netherlands, **Christer Backman** - MPA Sweden, **Rui Santos Ivo** - Infarmed Portugal

16.00 - 16.30 Coffee Break***16.30 - 18.00 Status of SmPC Harmonisation******Chaired by Susan De Stasio, Chair EGA's Regulatory & Scientific Affairs Committee***

- Status of harmonisation of reference products and Implementation of Article 30 decisions
Suzette Kox, Senior Scientific & Regulatory Affairs Advisor, EGA
- Issues of Implementation of Harmonised SmPCs - Viewpoint of a Member State - **Christer Backman**, MPA Sweden
- Impact of Court Cases on the SmPC harmonisation - **Richard Milchior**, Cabinet Milchior-Smilewitch, Paris

19.30 - 22.30 Conference Dinner: Dress code informal

Break Out Session 1 - Pricing & Reimbursement Policies in an Enlarged EU: Implications for the registration of generic medicines

Chaired by Greg Perry, EGA General Director

- **09.00 - 11.00 Pricing and Reimbursement Policies in the current EU Member States. Implications for generic registrations.**
 - Overview: **Nadene McClay**, EGA Director of Policy
 - Case Studies: **Warwick Smith** - UK, **Stefanie Mevissen** - Germany, **Luc Beaulieu** - France, **Howard Simson** - Sweden

11.00 - 11.15 Coffee Break

- **11.15 - 13.00 Pricing and Reimbursement Policies in the New Member States. Implications for generic registrations.**
 - Overview: **Beata Stepniewska** EGA Accession & Regulatory Affairs Manager
 - Case Studies: **Judit Bidlo** - Hungary, **Cezary Sledziewski** - Poland, **Lumir Krocek** - Czech Republic, **Katja Razinger** - Slovenia

Break Out Session 2 - New & Developing Requirements

Chaired by Suzette Kox, EGA Senior Scientific & Regulatory Affairs Advisor (09:00-10:45) and Paul Fleming, Director Regulatory Affairs, Alpharma (11:15-13:00)

- **09.00 - 10.00 CTD: Lessons learnt from implementation to date**
 - Regulator's perspective - **Diana van Riet**, MEB, The Netherlands
 - Generic industry's perspective - **Gitta Irmer**, Generics [UK]
- **10.00 - 11.00 e-CTD: Readiness and schedule for implementation**
 - Regulator's perspective - **Stan van Belkum**, Medicines Evaluation Board, NL
 - Generic industry's perspective - **Caroline Kleinjan**, Sandoz

11.00 - 11.15 Coffee Break

- **11.15 - 12.15 Experience gained so far with the new Variations' Regulation**
 - Chairman's opening remarks
 - Regulator's perspective - **Anne Ambrose**, MHRA, UK
 - Generic industry's perspective - **Paul Fleming**, Alpharma
- **12.15 - 13.00 Current Status of the Eudravigilance Project with focus on EMEA tools for e-transmission of Individual Case Safety Reports**
 - Dr. **Sabine Brosch**, Deputy Head of Sector for Pharmacovigilance & Post-Authorisations Safety and Efficacy of Medicines, EMEA

13.00 - 14.00 Lunch

14.00 - 16.00 Legal Issues Affecting the Registrations of Generic Medicines

Chaired by Susan De Stasio, Chair EGA's Regulatory and Scientific Affairs Committee

- Review of current and recent court cases affecting the generic medicines industry - **Stephen Kon**, S.J. Berwin
- Case study: "On the legal and regulatory challenges involved in the registration of citalopram" - **Georg Stark**, Alfred E. Tiefenbacher (GmbH & Co. KG)
- Potential loopholes in the Pharma Review - **Stephen Kon**, S.J. Berwin
- Potential loopholes in the Pharma Review. Viewpoint of a Member State - **John Lisman**, Legal Council Medicines Evaluation Board, NL
- Questions & Answers Session

16.00 End of Conference Coffee

EGA's ANNUAL REGULATORY AFFAIRS CONFERENCE

APPLICATION TO REGISTER
To be sent back by fax at +39-02 66804297



MAKING MEDICINES AFFORDABLE

Thursday 12 & Friday 13 February 2004
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Company Job title:
Company VAT No. And Country:
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E-mail: Website:

On day two from 09.00 - 13.00 there will be a choice of break out sessions and I will attend:

- Session 1 - Pricing & Reimbursement Policies in an Enlarged EU: Implications for the registration of generic medicines*
or
 Session 2 - New & Developing Requirements: CTD, e-CTD, Variations' Regulation, Eudravigilance

Please note all prices are inclusive of coffee breaks, lunches & conference dinner and the VAT is compulsory.

- My Company/Association is a Member of the EGA and will pay the Member Fee of £600.00 (+17.5% VAT) = **£705.00**
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Signature Date and Place

If you need any information please contact Cristina Romagnoli E-mail: cristina@gpaconferences.com Tel/Fax: +39-02 66804297

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