



## ANNOUNCING THE EGA LEGAL AND REGULATORY EVENTS FOR 2006

LONDON 1 FEBRUARY 2006

2<sup>nd</sup> EGA LEGAL AFFAIRS FORUM 2006

### PRESENTATIONS COVERED

- Update on the Interpretation of the European 'Bolar' Provision after its Implementation in National Legislation
- Harmonization of Data Exclusivity Periods in Europe and Worldwide
- Application of New Intellectual Property Requirements in the New EU Member States, Particularly in Relation to Bolar, SPCs and Data Exclusivity
- EU Regulation on Medicinal Products for Paediatric Use
- EU Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems
- Injunctions and Cross-Undertakings
- Update on Member State Implementation of Directive 2004/48/EC on the Enforcement of Intellectual Property Rights
- New EU Proposal for a Directive on Criminal Measures to Enforce IP Rights
- Patent Linkage to Regulatory Approval
- AstraZeneca Case

### SPEAKERS CONFIRMED FOR THE FORUM ON FEBRUARY 1

Ewan Livesey, IVAX | Mariusz Kondrat, Office of the Committee for European Integration Poland | Nadene McClay, Director of Policy EGA | Elisabeth-Marie Coleman, European Commission | Anna McKay, English Solicitor Consultant | Daniel Fontanaud, European Commission | Veronica Lowe, Mayne Pharma UK | Suzette Kox, Senior Director Scientific Affairs, EGA

LONDON 1 FEBRUARY 2006

PRE-CONFERENCE SEMINAR

Organised in conjunction with  **INFOTEHNA** HOLDING AN ESSENCE.  **BillevPharma**.aps

**HOW TO APPROACH ELECTRONIC SUBMISSIONS WITH eCTD?**  
Practical Experience on the Benefits of using Document Management System and preparing Electronic Submissions in eCTD format

**A MUST ATTEND EVENT!**

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CONFERENCES

LONDON



LONDON 2 - 3 FEBRUARY 2006

5<sup>th</sup> EGA REGULATORY AFFAIRS CONFERENCE 2006

**PRESENTATIONS COVERED**

**A Look to the Future**

- Priorities of the European Commission, the EU Member States and the Generic Medicines in the Healthcare and Pharmaceutical Sectors

**Issues at the National Level Following Implementation**

**New Registration Procedures for Generics - A Choice?**

- Mutual Recognition Procedure (MRP)/ Decentralised Procedure (DP)
- Centralised Procedure for Generics

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

**How to Use the European Reference Product in Practice?**

**Patient Gains from Regulatory Developments for Generics**

- New Rules of Validity of Marketing Authorisation
- Better Information for Patient
- Applying SmPC Exemptions to Generics for Patented Indications and Dosage Forms

**Applying the New Data Exclusivity Requirements**

- Interpreting the 'Global Marketing Authorisation' Concept
- Understanding 'Significant Clinical Benefit in Comparison to Existing Therapies' in the New Guideline

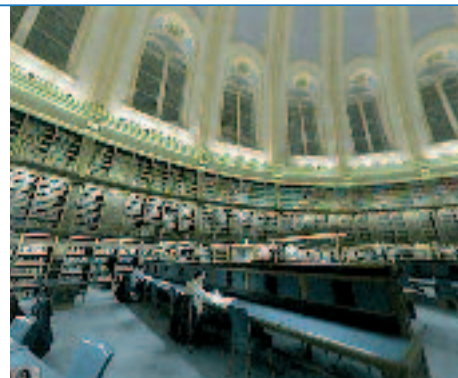
**The New Pharmacovigilance Environment**

- The Eudravigilance Project: Practical and Operational Aspects of Implementation
- Update on PSUR Work-Sharing and Synchronisation
- Preparing for Pharmacovigilance Inspection

**ICH Harmonisation Process - The Impact on Generic Medicines**

**GMP Requirements for Starting Materials**

**e-CTD - Where are We with Electronic Submissions in the EU?**



| British Museum - The reading Room



| Eye of London



| Marble Arch

| Radisson SAS Portman Hotel London



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More info and registration on [www.gpaconferences.com](http://www.gpaconferences.com)  
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Registrations close officially the 20<sup>th</sup> January 2006  
& are subject to availability