



4th Annual EGA Regulatory Affairs Conference

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

3rd-4th February 2005

THE EUROPEAN GENERIC MEDICINES ASSOCIATION

Preparing for Change

(PROGRAMME UPDATED 24 JANUARY 05)

THURSDAY 3rd February 2005

Regulatory Affairs Conference

08:00 Registration and Networking Coffee

09:30 Opening Session

Chair | *Susan De Stasio, Chairperson EGA Regulatory & Scientific Affairs Committee*

- **Key Note Speech: Priorities for the UK Presidency in the healthcare and pharmaceutical sector** | *Roy Alder, Head of Executive Support Division, Medicines & Healthcare Products Regulatory Agency, UK*

10:15 Implementation of the new EU Pharmaceutical Law

- **What is the Status of EC Measures foreseen in the Context of the Revised Directive and Regulation?**
Irene Sacristan Sanchez, DG Enterprise, Pharmaceuticals: Regulatory Framework & Marketing Authorisations
- **What is the UK Timetable for Implementation?**
Margaret Jackman, Medicines & Healthcare Products Regulatory Agency, UK
- **Industry Perspectives on Implementation of the new EU Pharmaceutical Law & Priorities in the Healthcare & Pharmaceutical Sector**
Greg Perry, Director General EGA

11:30 Coffee Break



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11:45 Future Challenges for the National Agencies as a Result of the New Pharmaceutical Legislation

- Initiating SmPC harmonisation - identifying public health needs
- Implications of the Bolar provision for national agencies
- Applying the new transparency provisions
- Giving access to information
- Dealing with commercially sensitive information
- Resourcing the new procedures
- Dealing with the legal obligations linked to marketing authorisation extensions
- Dealing with conflicting translations of the revised legislation

Presentation of issues by *John Lisman, Policy Advisor, Medicines Evaluation Board, The Netherlands*, followed by panel discussion with representatives from European Commission - *Prof. Tamas Paál, Hungary* - *Rui Santos Ivo, Portugal* - *Milan Smid, Czech Republic* and *Susan De Stasio representing industry*

13:15 Lunch Buffet

14:15 Future Registration Procedures

Chair | *Susan De Stasio, Chairperson EGA Regulatory & Scientific Affairs Committee*

- **Mutual recognition Procedure (MRP)/ Decentralised Procedure (DP)**
 - A national authority's perspective | *Françoise Portefaix, AFFSAPS, France*
 - Generic industry's perspective | *Gary Clapp, Pliva UK*
- **Centralised Procedure for generics**
 - EMEA perspective | *Patrick Le Courtois, Head of Unit, Pre-Authorisation Evaluation of Medicines for Human Use, EMEA*
 - Generic industry's perspective | *Frank de Vries, Pharmachemie Teva, Chair of the EGA-EMEA Working Group*
- **Q&A session with panel** composed by sessions speakers, *Christer Backman - Sweden, Rui Santos Ivo - Portugal, Rimantas Jankunas - Lithuania*

15:45 Coffee Break

16:15 Applying the New Data Exclusivity Requirements

Chair | *Greg Perry, EGA Director General*

- How will new 8+2+1 data exclusivity work in practice? What has to be understood by the 'global marketing authorisation' concept?
- What is meant by significant clinical benefit in comparison to existing therapies?
- How will the OTC switch apply?
- What is meant by non-cumulative period of one year for well established use substance?
- What is meant by "significant pre-clinical or clinical studies" and who decides?
- What period of data exclusivity is applied to the European Reference product?
- What are the implications of the prospective application of the new data exclusivity law?
- What data is publicly available after the end of the data exclusivity period?

Presentation of the issues by *Suzette Kox, EGA Senior Director Scientific and Regulatory Affairs* followed by panel discussion with representatives from European Commission, *Prof. Tamas Paál, Hungary* - *Rui Santos Ivo, Portugal* - *Milan Smid, Czech Republic* and other EU national authorities, and *Michael Banks, Sandoz, representing industry*



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17:45 Closure of Day

20:00 Conference Dinner: Dress code informal

FRIDAY 4th February 2005

Regulatory Affairs Conference

08:00 Networking Coffee

Track I: The Practical Approach to Implementation & New Regulatory Environment

Chair | *Beata Stepniewska, EGA Senior Manager Regulatory Affairs*

09:00 What are the Practical Implications of General New Provisions?

- Applying the provision on renewals
- Applying the sunset clause - what provisions for generics?
- Applying the SmPC exemptions for generics concerning patented indications and dosage forms
- Applying the readability testing of leaflets
- Applying the Braille requirement
- Applying the terms of the European Reference Product

Member States' approach to implementation: Christer Backman - Sweden, John Lisman - The Netherlands, Shirley Norton - UK, Jitka Šabartová - Czech Republic
Generic industry's interpretation: Laurence Florin, Apotex and Paul Fleming, Alpharma, followed by a Q&A session

10:30 Coffee Break

11:00 What are the Implications of GMP Requirements for Starting Materials on Registrations?

Speaker | *Emer Cooke, Inspection Unit, EMEA*

- What do the new provisions relating to GMP of starting materials say?
- Which excipients fall under the GMP rule?
- What will trigger an inspection?
- Are inspections company, plant, product or process specific?
- Is a GMP certificate mandatory at the time of application?
- What does the certificate cover?
- Do Mutual Recognition Agreements cover APIs?
- Can registrations go ahead while inspection is ongoing?

11:30 How to Become Successful with e-CTD Registrations?

Co-Chair | *Peter de Mayo Billev*

- **Document Management, a must in advance of e-submissions**
Vito Strasberger, Infotehna-Billev, DK
- **Lessons learned from finalised e-MRPs**
Generic company's experience | *Caroline Kleinjean, Sandoz*
- **Lessons learned as RMS with e-submissions**
Regulator's experience | *Stan van Belkum, Medicines Evaluation Board, The Netherlands*

13:00 Buffet Lunch



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Track II: The New Pharmacovigilance Environment

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

9:00 What is the status of the Eudravigilance project?

Sabine Brosch, Deputy Head of Sector for Pharmacovigilance & Post-Authorisations Safety and Efficacy of Medicines, EMEA

9:30 What is the programme & experience of pharmacovigilance inspection?

- Authority's perspective | *Lindsay Watt, Pharmacovigilance Inspection, MHRA, UK*
 - Industry's perspective and experience | *Charlotte Barrett, Merck Generics UK*
- Panel discussion with session speakers and *Maria C. Koster, CEO Vigilex, The Netherlands*

10:30 Coffee Break

11:00 The active substance birth date initiative: towards harmonised PSUR/renewal cycles?

- Member State's perspective | *Pim van der Giesen, Medicines Evaluation Board, The Netherlands*
- Generic industry's perspective | *Mary Smillie, APS Berk Teva, UK*

12:00 What are the future new pharmacovigilance requirements? | *Maria C. Koster, Vigilex, The Netherlands*

12:30 Get prepared and become successful with mandatory electronic reporting of Individual Case Safety Reports (ICSRs)

An EVWEB trainer's viewpoint | *Kim Nordfjeld, Infotehna-Billev, Denmark*

13:00 Buffet Lunch

Common Track

14:00 Round table on Paediatrics

Chair | *Greg Perry, Director General EGA*

- What is the current status of the European Commission's proposed Regulation?
- What is the current need for paediatric indications and formulations in Europe?
- What type of trials will be needed for the development of paediatric medicines?
- How will the PUMA and exclusivity periods operate for generic medicines?
- Will the proposed incentives measures trigger the development of paediatric generic medicines?
- Are the proposed patent extensions for patent products proportional to the costs involved?

Presentation of the issues by *Nadene McClay, EGA Director of Policy* followed by panel discussion with *Julia Dunne - UK, Rui Santos Ivo, Portugal - Susan De Stasio and Warwick Smith*

15:45 End of conference

For more information and to register on-line please visit

www.gpaconferences.com or www.egagenerics.com

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Registrations close officially the 28th January 2005 & are subject to availability