



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

9th EGA Regulatory & Scientific Affairs Conference

Focusing on the Future

21 - 22 January 2010

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

Thursday 21 January 2010

EGA Regulatory & Scientific Affairs Conference

- 08:00 Registration and Networking Coffee
- 09:00 **Opening Session - Vision 2015 New European Regulatory framework for generic medicines Chairs** | *Sir Alasdair Breckenridge, Chairman, Medicines and Healthcare products Regulatory Agency, MHRA (UK) and Greg Perry, Director General, European Generic medicines Association (EGA)*
- 09:00 **Welcome Speech - Didier Barret, President EGA, Mylan**
- Opening Speech: Vision 2015 - New European Regulatory framework for generic medicines** | *Greg Perry, Director General, European Generic medicines Association (EGA)*
- How to improve the legal and regulatory environment for generic medicines to ensure access to generic medicines in a timely manner?
 - How to use the regulatory recommendations in the final report of the pharmaceutical sector inquiry to eliminate barriers to generic competition?
- Panel Discussion** composed of session speakers and other representatives of the EU Authorities: *Jytte Lyngvig, DKMA (DK) | Aginus Kalis, MEB (NL) | Fabienne Bartoli, AFSSAPS (FR) | Thomas Lönngren, EMA | Truus Janse de Hoog, MEB (NL), Chair of the CMD(h) | Martin Terberger, Head of Pharmaceutical Unit, DG Enterprise, European Commission | Benjamin Van Zeveren, Task Force on the Pharmaceutical Sector Inquiry, DG Competition, European Commission and Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics for industry*
- 10:30 Networking Coffee Break
- 11:00 **Session 2 - Choice of procedure as a key element of the Marketing Authorisation strategy Chair** | *Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics*
- Key strategic elements to be taken into consideration in choosing the MA procedure: the CP and the DCP comparison**
- The industry's observation on CP/DCP Marketing Authorisation processes | *Caroline Kleinjan (Sandoz) and Tom Manussen (Disphar)*

EUROPEAN GENERIC MEDICINES ASSOCIATION
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E: info@egagenerics.com www.egagenerics.com
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Panel composed of representatives from the EU Authorities | *Truus Janse de Hoog, MEB (NL), Chair of the CMD(h)* | *Zaide Frias, (EMA)* | *Peter Bachmann, BfArM (DE)* | *Alban Dhanani, AFSSAPS (FR)* | *Michael Banks, Chair of the EGA-EMA WG, Teva for the industry*

12:30 Networking Buffet Lunch

13:45 **Session 3 - Practical Implementation of the new variations system**

Chairs | *Susanne Winterscheid, BfArM (DE)* and *Beata Stepniewska, EGA*

- **Revised Procedural guideline** | *Sandra Kruger-Peters, MEB (NL)*
 - How to report type IA variations?
 - How to group the variations?
 - How to use the worksharing procedure?
 - When to implement the variations in practice?
- **Key Changes in the Classification Guideline** | *Keith Pugh, MHRA (UK)*
 - Construction of the guideline in the context of type IB variations by default
 - Key areas of improvement
 - Changes in the classification guideline important for generic medicines producers

Panel Discussion composed of session speakers and other representatives of the EU Authorities: *Sonia Ribeiro, EMA* and *Nicola Prentice, Arrow Generics for the industry*

15:15 Networking Coffee Break

15:45 **Session 4 - Regulatory and legal interplay - impact of some instruments of IP protection on regulatory procedures**

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

- **SPC paediatric extension** | *Gareth Morgan, Taylor Wessing*
 - Recent decision of the national courts on granting “zero SPC” - impact on the launch of generic medicines
- **Use Patent - Latest experience with carving out of patented indication** | *Jane Trevanion, Mylan*
- **Other on-going legal issues - latest developments** | *Mary Smillie, bird&bird*

Panel Discussion composed of representatives from the EU Authorities | *Joan Boye, DKMA (DK)* | *Shirley Norton, MHRA (UK)* | *Julian Shellard, MHRA (UK)*

17:15 Closure of the Day

19:30 Conference Dinner | Informal Attire



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Friday 22 January 2010

EGA Regulatory & Scientific Affairs Conference

TWO parallel technical tracks (your choice has been made during the registration):

TRACK ONE - REGULATORY IMPLICATIONS OF VARIOUS CHANGES IN THE LEGAL AND OPERATIONAL ENVIRONMENT

09:00

Session 5 - Quality related issues

Chairs | *Hélène Bruguera*, Acting Head, Certification of Substances Division (EDQM) and *Harm Peters*, Chair EGA Quality and Compliance Working Group, Tiefenbacher

- Regulatory implications of up-coming legislation against falsified medicines: Key changes to the existing system for the APIs and excipients?
 - Competent authorities' perspective | *Christer Backman*, MPA (SE)
 - Industry's perspective | *Georg Stark*, Tiefenbacher
- Regulatory consequences of suspension of the CEPs
 - Industry's perspective | *Hanno Binder*, Sandoz
 - Competent authorities' perspective | *Kevin O'Donnell*, IMB (IE)
- Regulatory implications of the interpretation of the definition of "starting materials" involved in the API route of synthesis and their description in ASMF
 - ICH Q11 perspective | *Keith McDonald*, MHRA (UK)
 - Current experience | *Cornelia Nopitsch-Mai*, BfArM (DE)

Panel Discussion composed of session speakers

11:00

Networking Coffee Break

11:30

Session 6 - Pharmacovigilance related issues

Chairs | *Susanne Winterscheid*, BfArM (DE) and *Suzette Kox*, EGA

- Changes related to Safety, Efficacy and Pharmacovigilance in view of the recently revised Variations Regulation
 - How to report changes related to Safety, Efficacy and Pharmacovigilance in line with the revised Variations Regulation? | *Susanne Winterscheid*, BfArM (DE)
- Key elements of the new proposal on the Pharmacovigilance Regulation having an impact on regulatory processes | *Wendy Huisman*, Pharmachemie/TEVA

Q&A Session with a panel composed of session speakers and representatives from the EU authority: *Shirley Norton*, MHRA (UK)

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Session 7 - Bioequivalence related issues

Chair | *Truus Janse-de Hoog, MEB (NL), Chair of the CMD(h)*

- **Regulatory implications of the up-coming revised guideline on Bioequivalence** | *Susana Almeida, EGA Chair of the Bioequivalence Working Group, Tecnimed*
 - What is the current status of the revision process?
 - What are the key changes proposed in the revised guideline and what are their practical implications?
 - How to deal with the studies completed or initiated before adoption of the final revised guidance in the context of the new MA applications

Q&A Session with a panel composed of a session speaker and representatives from the EU authority: *Jan Welink, MEB (NL)*

13:00 Networking Buffet Lunch

TRACK TWO - ELECTRONIC SUBMISSION ENVIRONMENT

09:00 **Session 5 - Recent developments in the electronic submission environment**

Chairs | *Karin Grondahl, MPA (SE) and Anna Geist, ratiopharm*

- **eCTD/NeeS guidance & Validation criteria for eCTD/NeeS** | *Karin Grondahl, MPA (SE)*
 - Industry experience with the validation phase | *Anna Geist, ratiopharm*
- **How to implement the new variations regulation into eCTD reality?** | *Peter Bachmann, BfArM (DE)*
 - Industry observations | *Remco Munnik, Sandoz*

Q&A Session with a panel composed of session speakers

11:00 Networking Coffee Break

11:30 **Session 6 - The future of electronic submission: in which way is the system going to be developed?**

Chairs | *Peter Bachmann, BfArM (DE) and Remco Munnik, Chair of the EGA eCTD Working Group, Sandoz*

- **HMA Road Map on eCTD - are we ready to move into a non-paper world?** | *Miguel Bley, AFSSAPS (FR)*
- **New business model** | *Rob de Haan, MEB (NL)*
 - One central repository- a dream comes true?
 - Electronic Application Form (eAF)
 - Product Information Management (PIM) project
- **eCTD Next Major Version - a revolution in the eCTD concept?** | *Rob de Haan, MEB (NL)*

Q&A Session with a panel composed of a session speaker and representatives from the EU authority: *Karin Grondahl, MPA (SE) and Anna Geist, ratiopharm* for industry

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13:00 Networking Buffet Lunch

COMMON TRACK

14:15 **Session 8 - Ask your questions to the Regulators**
Chairs | *Truus Janse de Hoog, MEB (NL), Chair of the CMD(h) and Susan De Stasio, Chair EGA Regulatory and Scientific Committee, Arrow Generics*

An opportunity to address questions to the European Regulators on various regulatory issues

Questions should be formulated 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 | *Peter Bachmann, BfArM (DE) | Christer Backman, MPA (SE) | Joan Boye, DKMA (DK) | Zaide Frias, EMA | Shirley Norton, MHRA (UK) | Susanne Winterscheid, BfArM (DE)*

15:30 End of Conference with Networking Coffee

PROGRAMME COMMITTEE

Susan De Stasio and Sue Roach (Arrow Generics) - Tom Manussen (Disphar) - Michel Mikhail (Fresenius Kabi) - Jane Trevanion (Mylan) - Caroline Kleinjan and Remco Munnik (Sandoz) - Michael Banks (Teva) - Suzette Kox, Julie Maréchal and Beata Stepniewska (EGA)

For further information

www.gpaconferences.com or www.egagenerics.com

Cristina Romagnoli - T: +377-93-501348 - F: +44-208-0825368 - E: info@gpaconferences.com