



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 **Opening Speech**

Vision 2015 - New European Regulatory framework for generic medicines | *Greg Perry, Director General, European Generic medicines Association (EGA)*

- o How to improve the legal and regulatory environment for generic medicines to ensure access to generic medicines in a timely manner?
- o 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, EMEA* | *Truus Janse de Hoog, MEB (NL), Chair of the CMD(h)* | *Cristina Avendaño, AGEMED (ES) (inv)* | *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

- o The industry's observation on CP/DCP Marketing Authorisation processes | *Caroline Kleinjan (Sandoz) and Tom Manussen (Disphar)*

Panel composed of representatives from the EU Authorities | *Truus Janse de Hoog, MEB (NL), Chair of the CMD(h)* | *Zaide Frias (EMEA)* | *Peter Bachmann, BfArM (DE)* | *Alban*

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 50, B-1000 Brussels, Belgium
T: +32-(0)2-736 8411 F: +32-(0)2-736 7438
E: info@egagenerics.com www.egagenerics.com
VAT: BE 0449 332 209

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Dhanani, AFSSAPS (FR) (inv) | Michael Banks, Chair of the EGA- EMEA 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

- o **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?
- o **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: **Zahra Hanaizi, EMEA (inv) and (TBN) 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

- o **SPC paediatric extension | Gareth Morgan, Taylor Wessing**
 - Recent decision of the national courts on granting “zero SPC” - impact on the launch of generic medicines
- o **Use Patent - Latest experience with carving out of patented indication | Jane Trevanion, Mylan**
- o **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) | Rita Purcell, IMB (IE) (inv)**

17:00 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 | *Susanne Keitel*, Director, the European Directorate for the Quality of Medicine & HealthCare (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?
 - Industry's perspective | *TBN*
 - Competent authorities' perspective | *Christer Backman, MPA (SE)*
- Regulatory consequences of suspension of the CEPs
 - Industry's perspective | *Hanno Binder, Sandoz*
 - Competent authorities' perspective | *Paul Sexton, IMB (IE) (inv)*
- Regulatory implications of the interpretation of the definition of "starting materials" involved in the API route of synthesis and their description in ASMF
 - Industry's perspective | *TBN*
 - Competent authorities' perspective | *TBN*

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

- **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: **Truus Janse-de Hoog**, MEB (NL), Chair of the CMD(h) and **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 and representatives from the EU authority: **EMEA representative**

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** | **Claire Holmes**, EMEA
- 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?** | **Claire Holmes**, EMEA

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, EMEA | Shirley Norton, MHRA (UK) | Susanne Winterscheid, BfArM (DE) | Alban Dhanani, AFSSAPS (FR) (inv)*

15:30 End of Conference with Networking Coffee

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

www.gpaconferences.com or www.egagenerics.com

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

Registrations close officially on 11 January 2010 & are subject to availability