EUROPEAN GENERIC MEDICINES ASSOCIATION

12th EGA Regulatory and Scientific Affairs Conference

Increasing Challenges of the Regulatory Environment

17 - 18 January 2013

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

Thursday 17 January 2013 | **EGA Regulatory and Scientific Affairs Conference**

08:00 Registration and networking coffee

09:00 Opening Session - **How to respond to the increasing challenges of the regulatory environment**
Chair | ***Gudbjorg Edda Eggertsdottir***, *President, European Generic medicines Association (EGA), Actavis*

Changing the legal and regulatory environment to fulfil public health needs while managing implementation by stakeholders
- Challenges related to on-going processes of implementation of new legislation - how to make it viable for all actors?
- Impact of globalisation on regulators and industry activities
- Lessons learned and the way forward

Exchange of experience and observations from various actors:
- **Generic Medicines Industry** | ***Beata Stepniewska***, *EGA*
- **European Commission** | ***Andrzej Rys***, *DG SANCO, EC*
- **Heads of Medicines Agencies (HMA)** | ***Aginus Kalis***, *MEB (NL)*
- **European Medicines Agency (EMA)** | ***Guido Rasi***, *EMA*

Panel Discussion composed of session speakers and ***Peter Bachmann***, *Chair of the CMDh* | ***Michael Banks***, *Chair EGA Regulatory and Scientific Committee, Teva* | ***Caroline Kleinjan***, *Deputy Chair EGA Regulatory and Scientific Committee, Sandoz for industry*

10:30 Networking coffee break

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

11:00 Session 2 - **Handling consistency in scientific evaluation of generic medicines between similar/identical dossiers authorised via the CP/DCP/MRP/National Procedures**
Chairs | ***Michael Banks**, Teva and **Christer Backman**, MPA (SE)*

Improve consistency on evaluation of generic dossiers

- **Exchange of information between the EMA and EU MSs on the same/similar dossier of generic medicinal products submitted in CP/DCP/MRP/National Procedures. Dialogue between authorities and the industry: *Zaide Frias**, EMA | ***Peter Bachmann**, Chair of the CMDh | **Anna Geist**, Teva Pharmaceuticals Europe for industry*

How to facilitate assessment of the same Active Substance Master File (ASMF) and to harmonise decision making and reducing regulatory burden on the ASMF and MA holders? | ***Paul Marshall**, MHRA*

Panel Discussion composed of session speakers

12:30 Networking buffet lunch

13:45 Session 3 - **How to implement new elements of the Pharmacovigilance legislation into regulatory practice?**
Chairs | ***Kora Doorduyn-van der Stoep**, MEB (NL) and **Beata Stepniewska**, EGA*

Implementation of new elements of the Pharmacovigilance legislation - impact on variations. Dialogue between authorities and the industry | ***Susanne Winterscheid**, BfArM (DE) and **TBN** for industry*

- Switch to PSMF
- Summary of the PhV system
- New QRD template
- Amendments to the SmPC, package leaflet and labelling as a result of the PSUR assessment

Risk Management Plan (RMP) as a regulatory document | ***Kora Doorduyn-van der Stoep**, MEB (NL)*

- RMP for existing authorisations in view of the RUP
- Maintenance of the RMP
- Transparency of the RMP for an originator product in view of a generic MAH's commitment to follow

Panel Discussion composed of session speakers

15:15 Networking coffee break

15:45 Session 4 - **Changes in the regulatory environment - impact on a company's operational activities**
Chair | ***Michel Mikhail**, Fresenius Kabi and **Ray Brooks**, Hydrogen*

Changes in the regulatory environment - impact on a company's operational activities | ***Caroline Kleinjan**, Deputy Chair EGA Regulatory and Scientific Committee, Sandoz and **Elke Grooten**, Sandoz Belgium for industry*

- Dynamic relationship between headquarters and national affiliates
- New dimension of the dialogue between Regulatory and Pharmacovigilance departments within a company

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

- Need for new competences of regulatory staff | ***Ray Brooks**, Hydrogen*

Panel Discussion composed of session speakers

17:00 Closure of the day

19:30 Conference buffet dinner | Informal Attire

Friday 18 January 2013 **EGA Regulatory and Scientific Affairs Conference**

08:00 Welcome coffee

TWO parallel technical tracks (please advise choice when registering)

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

09:00 Session 5A – **International cooperation as a key enabler to regulatory efficiency**
Chairs | ***Emer Cooke**, EMA, and **Mechthild Sander**, AET*

Implementation of the Quality Aspects of the Falsified Medicines Directive
- **Managing API sourcing from 2 July 2013 onward** | ***Geoff Ansell**, Glenmark*
- **National transposition and compliance with new requirements for API GDP, excipient GMP, QP declaration and activity registration** | ***Gerald Heddell**, MHRA*

09:50 **Transatlantic dialogue. Exchange between authorities and the industry** | ***Emer Cooke**, EMA & **Julie Maréchal-Jamil**, EGA*
- Possible way forward to a Single Development Programme and Harmonisation of Data Requirements for Approval of Generic Medicinal Products in the EU and the US
- Mutual Recognition of Compliance Inspections between Europe and the USA

11:00 Q&A Session with a panel composed of session speakers

11:00 Networking coffee break

11:30 Session 6A – **Recent political developments impacting regulatory processes in the longer term**
Chair | ***Paul Fleming**, BGMA (Association UK)*

How to better inform about medicines?
- **EC studies on the readability of the PIL and SmPC - possible impact on the future revision of information on medicinal products** | ***Beata Stepniewska**, EGA*
- **Learning from current experience - did readability tests improve the quality of information and satisfy patients' needs?** | ***Jörg Fuchs**, PAINT-Consult*
- **New way of thinking and possible use of new communication tools** | ***Stella Aliadis**, Mylan on behalf of FGL (Swedish Generic Association)*

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

12:20 **Pharmaceuticals in the Environment (PIE): how could this emerging issue influence the current regulatory framework?** | ***Henry Stemplewski**, MHRA & **Paul Fleming**, BGMA (Association UK)*

- EC SANCO report on PIE: recommendations
- EMA Environmental Risk Assessment Guideline: looking back on 6 years of implementation and future evolution/revision?
- Carbon footprinting - the UK experience in developing guidance for medicines

Q&A Session with a panel composed of session speakers

13:00 Networking buffet lunch

TRACK TWO – LATEST DEVELOPMENTS IN THE ELECTRONIC SUBMISSION ENVIRONMENT

09:00 Session 5B – **Initiatives to improve the regulatory environment by effective use of electronic tools**

Chair | ***Remco Munnik**, Chair of the EGA Telematics WG, Combinopharm*

Experience with new validation criteria for electronic submissions and the leading role of the RMS. Dialogue between authorities and the industry moderated by *Karin Grondahl, MPA (SE)* and ***Wolfgang Rieckert**, Helm*

EMA update on on-going projects | ***Luc Verhelst**, EMA*

- Gateway, Central Repository, eAF

Common European Submission Platform (CESP) dialogue between authorities and the industry | ***Kevin Horan**, IMB (IE) and **Remco Munnik**, Combinopharm for industry*

- Implementation by the National Authorities
- Industry experience
- CESP demo with Industry and Agency's role play

Q&A Session with a panel composed of session speakers

11:00 Networking coffee break

11:30 Session 6B – **Technical aspects of submission of information on medicinal products in the EVPRM format**

Chair | ***Javier Monvoisin**, Deputy Chair of the EGA Telematics WG, Teva Europe*

Submission of information on medicinal products in the EVPRM format in accordance with Art 57 of the new pharmacovigilance legislation | ***Sabine Brosch**, EMA*

- Overview of the submission process and dealing with pending issues
- How will the validation of data be performed and feedback communicated to the MAHs?
- How will the maintenance of information be dealt with?
- What are the next steps towards implementation of international standards for identification of medicinal products?
- What is the perspective of the NCA/EMA data sharing for databases (XEVMPD)?

Industry's practical experience related to the submission of information to the EMA | ***Anjana Pindoria**, Mercury Pharma and **Geraldine Moore**, Arrow Generics*

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

- Submission of EVMPD by Gateway and by EVweb
- Observations related to the maintenance process
- Future strategy for large, medium and small sized companies on how to deal with the maintenance and development of the system

Q&A Session with a panel composed of session speakers

13:00 Networking buffet lunch

13:00 – 14:30 - SPECIAL WORKING LUNCH
ON THE LATEST DEVELOPMENTS IN SOUTH EAST EUROPEAN COUNTRIES
Chaired by Vesna Koblar, RAPHARM (www.rapharm.eu)
With the kind participation of the authorities from SEE countries: Croatia, Serbia
To confirm your attendance at this special working lunch please send an e-mail to info@gpaconferences.com by the 9 January 2013. Otherwise, for the others, the networking buffet lunch is organised in the foyer outside the main conference room.

14:30 Session 7 - **Ask your questions to the Regulators**
Chairs | ***Peter Bachmann**, Chair of the CMDh and **Caroline Kleinjan**, Sandoz*

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 and should be sent 2 weeks in advance to beata@egagenerics.com

Q&A Session with representatives from the EU authorities | ***Christer Backman**, MPA (SE)* | ***Marta Marcelino**, INFARMED (PT)* | ***Joan Boye**, DHMA (DK)* | ***Kora Doorduyn-van der Stoep**, MEB (NL)* | ***Susanne Winterscheid**, BfArM (DE)* | ***Keith McDonald**, MHRA (UK)* | ***Zaide Frias** (EMA)*

16:00 End of conference and 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 9 January 2013 & are subject to availability.

Event Sponsor

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