EUROPEAN GENERIC MEDICINES ASSOCIATION

11th EGA Regulatory & Scientific Affairs Conference

Meeting New Challenges of the Regulatory Environment

19 - 20 January 2012

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

Thursday 19 January 2012 — **EGA Regulatory & Scientific Affairs Conference**

08:00 Registration and networking coffee

09:00 Opening Session - **Are we moving in the same direction to improve the European regulatory framework for generic medicines and increase patient access to affordable medicines?**
Chair | ***Greg Perry**, Director General, European Generic medicines Association (EGA)*

- **Implementation of the EGA Vision 2015 - one year on** | ***Greg Perry**, EGA*
- **Implementation plan of the HMA strategy 2011-2015** | ***Aginus Kalis**, MEB (NL)*
- **The EMA's way forward to achieve the objectives of Road Map 2015** | ***Guido Rasi**, EMA*

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

10:30 Networking coffee break

GOAL: TO IMPROVE PATIENT ACCESS TO GENERIC MEDICINES THROUGH BETTER REGULATION AND TO REINFORCE REGULATORY HARMONISATION

11:00 Session 2 - **Ideal marketing authorisation procedure: can a dream come true?**
Chairs | ***Truus Janse de Hoog**, MEB (NL) and **Maike Lubomierski**, AET*

Achieving the HMA's objective to make the DCP more attractive for applicants. Dialogue between authorities and the industry | ***Christa Wirthumer-Hoche**, AGES (AT) and **Caroline Kleinjan**, Sandoz*

- **The leading role of the RMS in technical and administrative validation**
- **Timely restart of the clock stop**

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- **Possible solutions to speed up the national phase**
- **Optimal MA duplication process in CMS**

Addressing the drivers for progress and change for generics medicines in the Centralised Procedure. Dialogue between authorities and the industry | ***Zaide Frias**, EMA and **Jonathan Rousell**, Teva Pharmaceuticals Europe*

- **CHMP proposal for peer review of generic medicines application**
- **Naming of duplicates on use patent grounds**
- **Possible solutions for duplicate applications?**

New QRD template: how is it going to be implemented in both the CP and the DCP world?

Panel of speakers with ***Rocio Salvador Roldan**, Unit D3, Pharmaceuticals, DG Health & Consumers, EC*

12:30 Networking buffet lunch

13:45 Session 3 - **Regulatory and legal interplay: impact of some instruments of IP law on regulatory procedures**
Chairs | ***Mary Smillie**, Bird & Bird LLP and **Peter Bachmann**, Chair of the CMDh*

- **The status of the ongoing update of Chapter 1 of the Notice to Applicants** | ***Christer Backman**, MPA (SE), **Peter Bachmann**, Chair of the CMDh and **Rocio Salvador Roldan**, Unit D3, Pharmaceuticals, DG Health & Consumers, European Commission*
- **Latest update on patent linkage in Portugal and Italy** | ***Beata Stepniewska**, EGA*
- **Practical consequences of the recent court cases on regulatory practice**
  - Linking the SPC to the Global MA | ***Marleen van den Horst**, BarentsKrans N.V.*
  - SPC for fixed combination product | ***Mary Smillie**, Bird & Bird LLP*

Panel Discussion composed of session speakers *and **Marta Marcelino**, INFARMED (PT)*

15:15 Networking coffee break

15:45 Session 4 - **Regulatory implications regarding implementation of the new EU Pharmacovigilance legislation**
Chairs | ***Peter Arlett**, Head of Sector for Pharmacovigilance and Risk Management, EMA and **Beata Stepniewska**, EGA*

Update on the implementation of the Pharmacovigilance legislation | ***Peter Arlett** and **Ilaria Del Seppia**, EMA*

The CMDh proposal how to handle administrative simplifications, particularly related to the change of QPPV | ***Peter Bachmann**, Chair of the CMDh, BfArM (DE)*

How to be compliant with new requirements? | ***Remco Munnik**, Combinopharm*

- **Possible company strategies to deal with a complex exercise and challenging timeline**

Panel Discussion composed of session speakers and ***Anjana Pindoria** (Goldshield) and **Javier Monvoisin** (Teva Europe) for industry*

17:15 Closure of the day

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19:30 Conference buffet dinner | Informal Attire

Friday 20 January 2012 **EGA Regulatory & Scientific Affairs Conference**

TWO parallel technical tracks (please advise choice during registration)

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

GOAL: TO ENHANCE THE COMPETITIVENESS OF THE GENERIC MEDICINES INDUSTRY BY ENSURING GLOBAL COMPETITION ON A LEVEL PLAYING FIELD

09:00 Session 5A – **Early supply chain: expanding the regulatory oversight**
Chairs | ***Riccardo Luigetti**, EMA and **Jan Moors**, Vice chair of the EGA Quality & Compliance WG, Teva*

Global API supply chain: update on recent EU and international initiatives

- **EMA GMDP IWG collaboration on international GMP agreements with regulatory partners and implementation of the EU Falsified medicines directive | *Riccardo Luigetti**, EMA***
- **Harmonisation of the requirements for the Qualified Person (QP) declaration | *Sean Jones**, MHRA (UK)***
- **Industry perspective on EU developments on the API supply chain and on the impact of the EU falsified medicines directive | *Julie Maréchal-Jamil**, EGA***

10:30 Q&A Session with a panel composed of session speakers

11:00 Networking coffee break

GOAL: TO ACHIEVE BETTER REGULATION AND TO REINFORCE REGULATORY HARMONISATION

11:30 Session 6A - **Early supply chain developments in regulatory harmonisation on API starting materials**
Chairs | ***Jean-Louis Robert**, Chair of the QWP at EMA and **Mechthild Rösner**, Chair of the EGA Quality & Compliance WG, AET*

Are we heading towards an EU harmonised regulatory policy on API starting materials?

- **EU Member State experience with API SMs | *Maryam Mehmandoust**, AFSSAPS***
- **EDQM - presentation on new EDQM policy on API SMs description in CEP applications | *Hélène Bruguera**, EDQM***

Q&A Session with a panel composed of session speakers and ***Sean Jones**, MHRA (UK)* | ***Riccardo Luigetti**, EMA*

Revision of the variations regulation: what will be changed following the outcome of the public consultation in 2011? | ***Maria-Angeles Figuerola-Santos**, Unit D3, Pharmaceuticals, DG Health and Consumers, EC*

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- **The extension of the scope of the variations regulation to purely national MAs**
- **The adjustment of the procedures and operational aspects**

Industry's expectation of the next revision of the variations regulation | ***Nienke Rodenhuis**, Disphar*

Q&A Session with a panel composed of session speakers

13:00 Networking buffet lunch

TRACK TWO - LATEST DEVELOPMENTS IN THE ELECTRONIC SUBMISSION ENVIRONMENT

GOAL: TO IMPROVE THE REGULATORY ENVIRONMENT BY EFFECTIVE USE OF ELECTRONIC TOOLS

09:00 Session 5B - **Initiatives to improve the regulatory environment by effective use of electronic tools**
Chairs | ***Remco Munnik**, Chair of the EGA Telematics WG, Combinopharm*

Experience with new validation criteria for electronic submissions | ***Karin Grondahl**, MPA (SE)* and ***Wolfgang Rieckert**, Helm*

EMA update on on-going projects | ***Remco Munnik**, Combinopharm*
- **Gateway, Central Repository, eAF**

Common European Submission Platform (CESP):
- **The results of testing of the Proof of Concept and next steps** | ***Kevin Horan**, IMB (IE)*

Road Map on mandatory eCTD | ***Remco Munnik**, Combinopharm*
- **Presentation of the results of eCTD industry readiness questionnaire and suggestion of the way forward**

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 | ***Paolo Alcini** & **Ilaria del Seppia**, EMA*
- **How to create the message in the EVPRM format?**
- **Practical examples of how to populate the EVPRM for various data elements**
- **The EMA tool available to submit data to the EMA**
- **Validation of data and feedback to the MAHs**

Industry's practical comments related to submission of information to the EMA | ***Anjana Pindoria**, Goldshield and **Vito Strasberger**, Billev Pharma*

Q&A Session with a panel composed of session speakers

13:00 Networking buffet lunch

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Making Medicines Affordable

TWO PARALLEL SESSIONS (free access for registered delegates)

SPECIAL SESSION - PROVIDERS OF IT TOOLS

14.15 **Presentation of technical solutions facilitating the submission of information in the EVPRMS format to the EMA by vendors:**

NANOKINETIK introducing: READY!™ for Article 57 - *Vito Strasberger*

Lorenz LIFE SCIENCES GROUP *How to meet the EVMPD challenge with LORENZ drugTrack - Sebastian Knieps*

samarind RMS regulatory management software *Live demonstration of Samarind's EVMPD solution - Phil Turner*

15:30 End of conference with networking coffee

SPECIAL Q&A SESSION

14:15 Session 7 - **Ask your questions to the Regulators**
Chairs | ***Peter Bachmann**, Chair of the CMDh and **Caroline Kleinjan**, Deputy Chair EGA Regulatory and Scientific Committee, Sandoz*

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

Q&A Session with representatives from the EU authorities | ***Christer Backman**, MPA (SE)* | ***Marta Marcelino**, INFARMED (PT)* | ***Joan Boye**, DMA (DK)* | ***Zaide Frias**, EMA* | ***Christa Wirthumer-Hoche**, AGES (AT)* | ***Truus Janse de Hoog**, MEB (NL)*

15:30 End of conference networking coffee

Programme Committee

Maike Lubomierski (AE Tiefenbacher) - **Gillian Latham** (Arrow) - **Remco Munnik** (Combinopharm) - **Tom Manussen** (Disphar) - **Michel Mikhail** (Fresenius Kabi) - **Jane Trevanion** (Mylan) - **Caroline Kleinjan** (Sandoz) - **Michael Banks** (Teva) - **Suzette Kox**, **Julie Maréchal-Jamil** and **Beata Stepniewska** (EGA)

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