Overview

This is the 10th DIA Middle East Regulatory Conference in partnership with the Middle East Regulatory Network (MERN).

The MERN is an ad hoc regional network of the EFPIA (European Federation of Pharmaceutical Industries and Associations). The MERN works in partnership with regulatory authorities and the pharmaceutical industry in the Middle East to develop legislation and regulatory practices that enable patients to have access to good quality medicines, including innovative medicines.

This Conference has been held every two years since 1996, and has now become an important forum related to the provision of healthcare in the region, with the aim of achieving real improvements in access to new and improved medicines and therapies for the population in the Middle East region. It provides a forum for all participants to contribute to active discussion and identify actions to expedite access of valued innovative medicines to Middle Eastern patients.

Topics will include

- Authority and Industry Panel: Interactive session
  - With the objective of discussing challenges with a combined authority and industry panel
- Regulatory Data Exclusivity (including patents)
  - With the objective of educating stakeholders
- Pharmacovigilance
  - With the objective of sharing recent developments in the EU, WHO and the ME region
- Global Health Economics and Market Access
  - With the objective of faster and better accessibility of patients to medicines
- Biosimilars
  - With the objective of updating biosimilar requirements and assessments
- Regulatory Life Cycle Management
  - With the objective of optimising maintenance and product compliance
- Anti-counterfeiting
  - With the objective of fostering close collaboration and actions by industry and regulators with other stakeholders to help fight against counterfeit medicines and to minimise risks for public health
- Review Practices: Efficiencies & Timelines
  - With the objective of improving registration process/timeline of pharmaceutical and biological products. Better predictability of review and approval timelines
- Pharmaceutical Advertising Regulation
  - With the objective of discussing the implementation in the EU and ME regions and sharing regulators and industry perspective

Who Will Attend

The conference offers the opportunity for key stakeholders active in the region, including representatives from ministries of health, local and multi-national pharmaceutical companies, to meet to exchange views, discuss topics of interest and identify actions to increase patient access to new and improved medicines and therapies.
TUESDAY I 24 SEPTEMBER 2013

08:00  REGISTRATION AND WELCOME REFRESHMENTS

08:45  CONFERENCE OPENING

09:00  Session 1

REVIEW PRACTICES: EFFICIENCIES & TIMELINES
Session Moderator invited

This session will focus on improving the registration process/timeline of pharmaceutical and biological products and better predictability of review and approval timelines.

Update from the Region
- Sharing experiences and best practices
- Fast track reviews / Priority reviews
- Harmonisation initiatives in the region
Middle East regulatory authorities speakers invited

Regulatory Harmonisation and Public Health
Speaker invited

Efficiency and Timelines
Christa Wirthumer-Hoche, Member CMDh, Deputy Head, Austrian Medicines and Medical Devices Agency (AGES), Austria

Questions and Answers

10:40  REFRESHMENT BREAK

11:00  Session 2

REGULATORY/INDUSTRY PANEL INTERACTIVE SESSION:
FAST ACCESS TO INNOVATIVE MEDICINE FOR PATIENTS
Session Moderators:
Hassan Bibi, Janssen, I.R.A.N. and Levant Chairperson, Lebanon
Visda Vaghayenegar, Sanofi, France

A panel of regulatory and industry representatives will be discussing the following topics:
• Certificate of Pharmaceutical Product (CPP) – future trends
• Registration and marketing status in the country of origin
• Alternative/dual sourcing
• Resource optimisation (i.e. laboratory analysis, site inspections)

Followed by an open discussion with audience

Panellists are invited

12:30  LUNCH

14:00  Session 3

PHARMACOVIGILANCE: MONITORING AND EVALUATING THE SAFETY PROFILE OF MEDICINAL PRODUCTS
Session Moderator:
Christa Wirthumer-Hoche, Member CMDh, Deputy Head, Austrian Medicines and Medical Devices Agency (AGES), Austria

Presenters will provide information on the new pharmacovigilance legislation in Europe and the recent developments in the Middle East region for monitoring the safety of the products and reduce the potential risks for public health.

EU Pharmacovigilance Frameworks
Speaker invited

Risk Management Plan (RMP): What it is and when it is required?
Gian Nicola Castiglione, QPPV & Director Corporate Pharmacovigilance, Chiesi Farmaceutici S.p.A., Italy

15:50  REFRESHMENT BREAK

16:15  Session 4

THE CONCEPT OF BIOTECH MEDICINE AND BIOSIMILARS
Session Moderator:
Dr Fernando de Mora, Professor, Department of Pharmacology, Therapeutics and Toxicology, Universitat Autonoma de Barcelona, Spain

This session will provide an overview of biosimilars, its quality requirements and assessments.

A Biosimilar is not a “Generic
Dr Fernando de Mora, Professor, Department of Pharmacology, Therapeutics and Toxicology, Universitat Autonoma de Barcelona, Spain

Biosimilars Quality Requirements
Industry speaker invited

Current Scientific Challenges on Immunogenicity, Interchangeability, Extrapolation and Nomenclature
Mohammed Abulhasan, Regulatory and Scientific Affairs, Middle East & Pakistan, AbbVie Golf-Levant Region

Conclusion and panel discussion with Middle East regulatory authorities

17:45  EXTENDED RECEPTION

19:30  END OF DAY ONE

WEDNESDAY I 25 SEPTEMBER 2013

09:00  Session 5

GLOBAL HEALTH ECONOMICS AND MARKET ACCESS
Session Moderator invited

This session will focus on faster and better accessibility of patients to medicines.

Pharmacoeconomic Evaluation with Practical Examples of Value Proposition
Koen Torfs, Vice President Health Economics, Market Access & Reimbursement for Europe, Middle East and Africa, Johnson & Johnson, Germany

Experience with Assessment of Pharmacoeconomic File
Middle East Regulatory Authority speaker invited

Questions and Answers

10:15  REFRESHMENT BREAK

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of DIA Europe. Speakers and agenda are subject to change without notice.

Recording of any DIA Europe tutorial/workshop/session information in any type of media is prohibited without prior written consent from DIA Europe.
10:45  Session 6  
**REGULATORY LIFE CYCLE MANAGEMENT**  
Session Moderator:  
Nadia Younis, Country Regulatory Head - Gulf & Levant, Pfizer, United Arab Emirates  
In this session presenters will share how to optimise maintenance and product compliance.  

**Regional Perspective on Variations and Experiences**  
Middle East regulatory authorities speakers invited  

**Regional Perspective: Revision of renewal concept**  
Middle East regulatory authority speaker invited  

Current EU System & Annual Report Concept: Review post implementation and lessons learnt  
Christa Wirthumer-Hoche, Member CMDh, Deputy Head, Austrian Medicines and Medical Devices Agency (AGES), Austria  

Questions and Answers

12:15  LUNCH  

13:45  Session 7  
**REGULATORY DATA PROTECTION AND PATENT**  
Session Moderator:  
Haitham Al-Zuhair, Janssen, SARA Chairperson, Kingdom of Saudi Arabia  

The European Community have implemented the TRIPS requirement and it is important to look at the data protection landscape in the Middle East region and what remains to be done.  

Whilst the focus of the session is to remain on RDP, it is felt important that during presentation awareness and knowledge on patency and related regulation is ensured as well.  

Data Protection of Pharmaceuticals in EU  
European Commission speaker invited  

Industry Perspective in Implementing Intellectual Property Rights in the Region  
Industry speaker invited  

Implementation of Data Protection in Lebanon  
Maître Walid Nasser, Lawyer of Pharma Association Lebanon  

15:05  REFRESHMENT BREAK  

15:30  Session 8  
**CODE OF ETHICS AND PROMOTION**  
Session Moderator:  
Jeffrey P. Kemprecos, Director, External Affairs, Merck Sharp & Dohme, Switzerland  

This session will focus on discussing the implementation in Europe and the Middle East regions. Regulators and industry will share their perspective.  

Middle East Industry Perspective  
Linda Daou, Country Manager Near East Area, Eli Lilly and Company, Lebanon  

Local Authority Perspective  
Middle East Regulatory Authority speaker invited  

Code of Ethics and Promotion in Europe  
Speaker invited  

Questions and Answers  

16:50  Closing Remarks  

17:00  END OF CONFERENCE  

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**HOTEL INFORMATION**  
DIA has blocked a limited number of rooms at the following hotel:  

Shangri-La - Barr Al Jissah  
P.O. Box 644  
113 Muscat  
Sultanate of Oman  
Tel.: 00968 2477 6666  
Fax: 00968 2477 6677  
Website: http://www.shangri-la.com/muscat/barraljissahresort/  

at the rate of:  
OMR 70.00 Al Waha Superior and Al Bandar Deluxe Room single occupancy and OMR 80.00 double occupancy inclusive of breakfast buffet, exclusive of service charge and taxes of 17%.  

To make your reservation, please use the booking form available on the DIA website.  

Important: The room rate is available until 21 August 2013 or until the group block is sold-out, whichever comes first. Reservations received after this date will be subject to hotel availability and room rate may vary.  

Cancellation: No show charges to apply without a notification from the hotel. Bookings cancelled after 23 July 2013 will be charged 100% cancellation fee.

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**If you register for both The 10th Middle East Regulatory Conference (MERC) 2013 and The ICH Endorsed Pharmacovigilance Training Course, you will receive 50% off the ICH Endorsed Pharmacovigilance Training Course fee – this offer is only available by emailing diaeurope@diaeurope.org.**  

Please note you have to register for both at the same time to be eligible to receive the discount.

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**About DIA**  
DIA is a neutral global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.  

DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide educational publications.  

DIA’s headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.  

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.
**ATTENDEE DETAILS**

Please complete in block capital letters or attach the attendee's business card here.

- [ ] Prof  
- [ ] Dr  
- [ ] Ms  
- [ ] Mr

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*(Required for confirmation)*

DIA reserves the right to include your name and affiliation on the attendee list.

**PAYMENT METHODS**

**Credit cards:** Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

- [ ] Please charge my [ ] VISA  
- [ ] MC  
- [ ] AMEX

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**Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to “Account Holder: DIA.” Please include your name, company, Event ID #13102 as well as the invoice number to ensure correct allocation of your payment.

- Payments must be net of all charges and bank charges must be borne by the payer.
- If you have not received your confirmation within five working days, please contact DIA Europe.

**CANCELLATION POLICY**

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

**TRANSFER POLICY**

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

**PHOTOGRAPHY POLICY**

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.