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

- Review Practices: Efficiencies & Timelines
  - With the objective of improving registration process/timeline of pharmaceutical and biological products. Better predictability of review and approval timelines
- Fast Access to Innovative Medicine for Patients
  - With the objective of discussing challenges with a combined authority and industry panel
- Safety Monitoring and Safe Access to Products
  - With the objective of sharing recent developments in the EU and the ME region including falsified medicine
- The Concept Of Biotech Medicine And Biosimilars
  - With the objective of updating biosimilar requirements and assessments
- Global Health Economics and Market Access
  - With the objective of faster and better accessibility of patients to medicines
- Regulatory Life Cycle Management
  - With the objective of optimising maintenance and product compliance
- Regulatory Data Protection and Patents
  - With the objective of educating stakeholders
- Code of Ethics and Promotion
  - 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.
08:45 CONFERENCE OPENING AND WELCOME ADDRESS
Minister of Health, His Excellency (H.E.)
Dr Ahmed Bin Mohammed Al Saidi

Welcome by MERN Deputy Chair
Dr Visda Vaghayenegar, Global Regulatory Affairs – Intercontinental Region, Turkey Middle East RA Head, Sanofi, France

Introductory Remarks by Conference Chair
Professor Stuart Walker, Founder of Centre for Innovation in Regulotory Science (CIRS), United Kingdom

09:00 Session 1

REVIEW PRACTICES: EFFICIENCIES & TIMELINES
Session Chair:
Maryam Mangoli, Biogen Idec Limited and MERN member, United Kingdom

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 and Ten Years Experience with GCC Centralised Process: Challenges and Opportunities
  Ph. Mohammed Hamdan Al Rubaie, Director, Department of Drug Control, Ministry of Health, Sultanate of Oman
- Fast Track Reviews / Priority Reviews
  Mr Mohammed Barasin, Drug Information Specialist, Deputy Director, National Drug and Poison Information Center (NDPIC), Drug Sector - Saudi Food and Drug Authority, Kingdom of Saudi Arabia
- Harmonisation Initiatives in the Region
  Prof. Saleh A. Bawazir, Vice President for Drug Affairs, Saudi Food and Drug Authority, Kingdom of Saudi Arabia on behalf of GCC

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
Moderator:
Hassan Bibi, Regional Regulatory Affairs Director - Head of Regulatory Cluster (NEWAAT and Pakistan), Janssen, I.R.A.N. and Levant Chairperson, Lebanon

A panel of regulatory and industry representatives will be discussing the following topics:
- Certificate of Pharmaceutical Product (CPP) – future trends
- MAH definition/role
- 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

Panelists:
Middle East Ministries of Health
Prof. Saleh A. Bawazir, Vice President for Drug Affairs, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
Dr Bahaa Eldin Fateha, Chief Executive, National Health Regulatory Authority (NHRA), Kingdom of Bahrain
Dr Hayel Mohammad Obeidat, Director General, Jordan Food and Drug Authority, Jordan
Dr Colette Raidy, Head of Pharmaceutical Inspection Department, MoH Lebanon

Regulatory Networks
Egypt
SARA
Iran/ Levant
RAWG
MERN

IFPMA CPP Network
Marianne Vogt, Manager, Regulatory Operations Certificates and Samples Coordination Center (CSCC) Established Pharmaceuticals, Abbott GmbH & Co. KG, Germany

12:30 LUNCH
14:00 Session 3

PHARMAcOvigilance: Monitoring and Evaluating the Safety Profile of Medicinal Products
Session Chair:
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
Jan Petracek, CEO and Director of Pharmacovigilance, European Pharmsinvent Services, Czech Republic

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

Pharmacovigilance and Safety in the Region
Dr Adel Alharf, Director of the National Pharmacovigilance and Drug Safety Center, Saudi Food and Drug Authority, Kingdom of Saudi Arabia

Falsified Medicines
Dr Bahaa Eldin Fateha, Chief Executive, National Health Regulatory Authority (NHRA), Kingdom of Bahrain

Panel discussion
With session speakers and Dr Sawsan Ahmed Jaffar, Director General of Pharmaceutical Affairs & Drug Control, Ministry of Health, Sultanate of Oman

15:50 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.
The Concept of Biotech Medicine and Biosimilars

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

Current Scientific Challenges on Immunogenicity, Interchangeability, Extrapolation and Nomenclature

Mohammed Abulhasan, Regulatory and Scientific Affairs, Middle East & Pakistan, AbbVie Golf-Levant Region

Biosimilars Quality Requirements

Mourad Farouk, Medical Director, International Development, Amgen Europe

Conclusion and panel discussion with

Dr Hayel Mohamad Obeidat, Director General, Jordan Food and Drug Authority, Jordan, Dr Shahrokh Veisi, Biological Department, Food and Drug Organization of Ministry of Health, Islamic Republic of Iran and Mr Ali Alsamil, Senior Biomedical Laboratory Specialist, PESS Administration, Biologics Evaluation Department - Drug Sector, Saudi Food & Drug Authority, Kingdom of Saudi Arabia

17:45 EXTENDED RECEPTION

19:45 END OF DAY ONE

Wednesday 25 September 2013

Global Health Economics and Market Access

Session Chair: Jeffrey P. Kemprecos, Executive Director, Public Policy & Corporate Responsibility, Merck Sharp & Dohme, Switzerland

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

Health Economics and Market Access - Industry Perspective

Koen Torfs, Vice President Health Economics, Market Access & Reimbursement for Europe, Middle East and Africa, Johnson & Johnson, Germany

Experience with Assessment of Pharmacoeconomic File

Dr Ibraheem Al Abadi, Associate Professor of PharmacoEconomics & Pharmaceutical Marketing, Faculty of Pharmacy, University of Jordan

Questions and Answers

10:15 REFRESHMENT BREAK

10:45 Session 6

Regulatory Life Cycle Management

Session Chair: 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

Dr Hayel Mohamad Obeidat, Director General, Jordan Food and Drug Authority, Jordan

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 Chair: 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

Mr Thomas Heynisch, Deputy Head of Unit, Food and Healthcare Industries, Biotechnology European Commission, Belgium

Industry Perspective in Implementing Intellectual Property Rights in the Region

Reda Bouchenak, E.P.A. Patent Manager, Africa/Middle East and Turkey, Sanofi, France

Implementation of Data Protection in Lebanon

Maitre Walid Nasser, Lawyer of Pharma Association Lebanon

15:05 REFRESHMENT BREAK

15:30 Session 8

Code of Ethics and Promotion

Session Chair: Jeffrey P. Kemprecos, Executive Director, Public Policy & Corporate Responsibility, 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

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.
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: Demand is high for accommodation during the conference
dates, so we encourage you to reserve your hotel room before end of July.
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.

Visa requirements: Arriving passengers who are eligible for Visa on Arrival
are able to obtain and make their visa payments at the Travelex Foreign
Exchange bureau located in the immigration arrivals hall, payment can be
accepted in most currencies or by credit card, an automatic receipt will be
issued to the traveller this receipt is then presented at the immigration desk.
For more details please visit: http://www.omanairports.com/visaonarrival.asp
For further information on visa requirements and visa application, please visit
the website of the Royal Oman Police:

Should you have any question or need assistance, please contact
diaeurope@diaeurope.org

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

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.

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REGISTRATION FORM
10th Middle East Regulatory Conference (MERC) 2013
24-25 September I Shangri-La, Muscat, Sultanate of Oman

ID #13102

ATTENDEE DETAILS
Please complete in block capital letters or attach the attendee’s business card here.

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First Name
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Address
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City
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*(Required for confirmation)

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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.

By signing below, I confirm that I agree with DIA Europe’s Terms and Conditions of booking. These are available from the office or on www.diahome.org/EUTerms

Date
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Cancelation 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.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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Early-bird rates available for members: Register by 12 August 2013
Join DIA now to qualify for the Early-bird member fee! The Early-bird registration form and accompanying payment must be received by the date above.
Early-bird fee applies to industry members only. (www.diahome.org/membership)

FEES (after 12 August 2013)

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Join DIA now to qualify for the member rate

TOTAL AMOUNT DUE: ____________

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to availability – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and meeting material.

Payment is due 30 days after registration and must be paid in full by commencement of the event.