10th Middle East Regulatory Conference (MERC) 2013

Collaboration, Partnership and Interaction: Authority and Industry

Event #13102
24-25 September 2013
Shangri-La, Muscat, Sultanate of Oman

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Professor Stuart Walker, Founder of Centre for Innovation in Regulatory Science (CIRS), United Kingdom

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Emad Bassiouny, Abbott Laboratories, RAWG Chairperson, United Arab Emirates
Dr Sawsan Ahmed Jaffar, Director General of Pharmaceutical Affairs & Drug Control, Ministry of Health, Sultanate of Oman
Dr Bahaa Eldin Fateha, Chief Executive, National Health Regulatory Authority (NHRA), Kingdom of Bahrain
Dr Hajed M. Hashan, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
Dr Hassan Mohamed Abd El Aziz Lashin, Ministry of Health, Egypt
Dr Hayel Mohamad Obeidat, Director General, Jordan Food and Drug Authority, Jordan
Nevine Raafat, Janssen, Chairperson Egypt

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.

Middle East Regulatory Network

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TUESDAY I 24 SEPTEMBER 2013

07:30-08:30 **CONFERENCE REGISTRATION**

08:45 **CONFERENCE OPENING AND WELCOME ADDRESS**
Minister of Health, His Excellency (H.E.)
Dr Ahmed Bin Mohammed Al Saidi

DIA Opening Remarks
Dr Jytte Lyngvig, Director DIA Europe, Switzerland

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 Regulatory 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 Barasain, 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

Panellists:

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 Mohamad 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 Pharminvent Services, Czech Republic

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

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.

16:15 **Session 4**

THE CONCEPT OF BIOTECH MEDICINE AND BIOSIMILARS

Session Chair:
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 I 25 SEPTEMBER 2013

.09:00 **Session 5**

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
Maître 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/visaonarivals.asp

For further information on visa requirements and visa application, please visit the website of the Royal Oman Police:
http://www.rop.gov.om/english/index.asp

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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- 14 pre-conference tutorials
- Student and professional posters
- A whole range of networking events
- More than 170 exhibiting companies
- Student and young professional events
- Hot-topic sessions
- Patient Fellowship Programme

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REGISTRATION FORM

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

DIA www.diahome.org

ID #13102

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)*

€ 1'550.00 ❑

FEES (after 12 August 2013)

	Member*	Non-Member*
Industry	€ 1'750.00 ❑	€ 1'865.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 875.00 ❑	€ 990.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

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 avaibility – 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.

TOTAL AMOUNT DUE: _____

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(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

Card N°

Exp. Date /

Cardholder's Name

❑ **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.**

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	Signature

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.

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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