



# 8TH MIDDLE EAST REGULATORY CONFERENCE MERC 2009

January 20-21, 2009 - The Ritz-Carlton Hotel & Spa, Manama, Bahrain



## Background

Since its inception 13 years ago, the Middle East Regulatory Conference has grown to become an important forum for discussion of matters related to the provision of healthcare in the region, with a specific focus on issues around the evaluation and supervision of innovative medicines for human use. 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.

## About the Drug Information Association

With almost 18'000 members worldwide, the Drug Information Association (DIA) is the premier member-driven organisation encompassing the full continuum of disciplines in the pharmaceutical and related industries. The mission of DIA is to serve and develop members by providing a neutral, global forum that promotes the exchange of information critical to their professional performance and achievement. The goal of DIA is to be the most effective means for members to obtain the knowledge they need to advance their career, their profession, and their organisation.

## Conference Chairman

**Prof. Trevor Jones CBE**, WHO Commissioner, CIPIH, UK

## Programme Committee

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**Kerstin Ahrendt-Sölter**, Biotest AG, Germany (Vice-Chair)

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**Dr. Mohamed H. Al Haidari**, Executive Board of the Health Ministers' Council for G.C.C States

**Dr. Easa Ahmed Jakka Al Mansoori**, Ministry of Health, United Arab Emirates

**Dr. Hajed M. Hashan**, Saudi Food and Drug Authority, Saudi Arabia

**Dr. Hakmeh Housseh**, Food and Drug Administration, Jordan

**Dr. Rita Karam**, Ministry of Health, Lebanon

**Dr. Omar Sayed Omar**, Ministry of Health, Kuwait

**Dr. Hamid R. Rasekh**, Ministry of Health, Iran

**Frank Fokkinga**, Genzyme Europe, The Netherlands (EFPIA-IRAG Lead of MERN)

**This is the 8th 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.**

## Themes and Objectives

Following on from successful discussions held during MERC 7 in November 2006 and the workplan issued from the DIA Middle East Regulatory Workshop in November 2007, MERC 8 intends to build on progress made and to identify further opportunities for stakeholders to work together on the enhancement of healthcare in the region. MERC events sets the scene to enable continuing education and networking activities. The conference 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.

## Key Topics Include

- Local Regulatory Authority Views and Key Issues
- Pharmacovigilance
- Pharmacoeconomics
- Counterfeits
- Innovation in the Quality Arena
  - Quality by Design
  - Good Manufacturing Practice Including PIC/S
- Biologics - Medicines of the Future
- Evolving Global Legislation on Medicines
  - Biosimilars
  - Variations Future Trends
  - Common Technical Document and Electronic Submissions

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**JANUARY 19****MONDAY**18:00 - Registration  
19:30**JANUARY 20****TUESDAY**

07:30 Registration and Welcome Coffee

08:30 **DIA OPENING**

Dr. Brigitte Franke-Bray, Director DIA Europe, Switzerland

**INTRODUCTORY REMARKS AND WELCOME**

Prof. Trevor Jones, King's College London; WHO Commissioner CIPIH, UK

**WELCOME ADDRESS**

Local Ministry of Health Representative invited

**KEYNOTE ADDRESS**

Biological Medicines – Opportunities and Challenges

Prof. Trevor Jones, King's College London; WHO Commissioner CIPIH, UK

**Accomplishments since MERC 2006 and Future Developments**

Florence Roizard, Chairperson, EFPIA-Middle East Regulatory Network, Merck Sharp &amp; Dohme, France

10:30 Coffee Break

11:00 **SESSION 1****LOCAL REGULATORY AUTHORITIES VIEWS AND KEY ISSUES****Saudi Food and Drug Authority**

Dr. Hajed M. Hashan, Director of Pharmaceutical Products Registration, Saudi Food and Drug Authority, Saudi Arabia

**Lebanon**

Dr. Rita Karam, Import-Export Department, Ministry of Health, Lebanon

**Iran**

Dr. Hamid Rasekh, Senior Advisor, Deputy Minister for Food and Drug, Ministry of Health, Iran

**Jordan**

Dr. Laila Jarrar, Director of Drug Directorate, Food and Drug Administration, Jordan

**Strategic Planning and Future Vision of Regulatory Systems in the GCC Region**

Dr. Reem Al-Essa, Drug &amp; Food Control, Ministry of Health, Kuwait

**Middle East and Africa Code of Promotional Practices (the 'MEA Code')**

Joe Henein, Managing Director Wyeth - Middle East &amp; North Africa Vice Chair for MEARC LAWG - PhRMA, UAE

**Panel Discussion**

Dr. Reem Al-Essa, Ministry of Health, Kuwait

Prof. Saleh Bawazir, Saudi Food and Drug Authority, Saudi Arabia

Dr. Hajed M. Hashan, Saudi Food and Drug Authority, Saudi Arabia

Joe Henein, Wyeth, UAE

Dr. Laila Jarrar, Food and Drug Administration, Jordan

Dr. Rita Karam, Ministry of Health, Lebanon

Dr. Hamid Rasekh, Ministry of Health, Iran

13:00 Lunch Break



The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102.

DIA is authorised by IACET to offer **1.4** CEUs for this programme.If you would like to receive a statement of credit, you must attend the program, return your evaluation form and complete the online credit request process through My Transcript at [www.diahome.org](http://www.diahome.org). Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

14:30

**SESSION 2****PHARMACOVIGILANCE****Existing Pharmacovigilance Systems Including Post-Marketing Surveillance Across the Globe**

Dr. John Knight, Vice President Strategic and Business Planning, Johnson &amp; Johnson Pharmaceuticals Group, Australia

**Establishing Pharmacovigilance Centers in Saudi Arabia**

Dr. Ghazi S. Saeed, Director, The National Pharmacovigilance Center, Saudi Arabia (invited)

**Panel Discussion**

Dr. Hajed M. Hashan, Saudi Food and Drug Authority, Saudi Arabia

Dr. Hakmeh Housseh, Food and Drug Administration, Jordan

Dr. Ghazi S. Saeed, The National Pharmacovigilance Center, Saudi Arabia (invited)

Dr. Omar Sayed Omar, Head of Drug Inspection Administration, Ministry of Health, Kuwait

Dr. Hamid Rasekh, Ministry of Health, Iran

Dr. John Knight, Johnson &amp; Johnson Pharmaceuticals Group, Australia

16:00 Coffee Break

16:30 **SESSION 3****COUNTERFEIT MEDICINES: COORDINATED PREVENTION AND FIGHT****IMPACT: The WHO Initiative**

Dr. Valerio Reggi, Leader of International Medical Products Anti-counterfeiting Taskforce (IMPACT); Coordinator, Medicines Regulatory Support, Department of Technical Cooperation for Essential Drugs and Traditional Medicine, WHO, Switzerland

**Industry-Coordinated Actions with Other Stakeholders**

Dr. Yves Juillet, Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises du Médicament (LEEM), France

**Industry Strategies to Prevent and Fight Counterfeits:****A Company Perspective**

Kevin Moore, Investigation Manager, Global Product Protection Security Team, Eli Lilly, UK

**Panel Discussion**

Dr. Suresh Aravind, Global Medical Affairs Leader, Johnson &amp; Johnson Pharmaceutical Services, USA

Dr. Yves Juillet, Les Entreprises du Médicament (LEEM), France

Kevin Moore, Eli Lilly, UK

Dr. Omar Sayed Omar, Ministry of Health, Kuwait

Dr. Colette Raidi, Head of Inspection Department, Ministry of Health, Lebanon

Dr. Hamid Rasekh, Ministry of Health, Iran

Dr. Valerio Reggi, International Medical Products Anti-counterfeiting Taskforce (IMPACT); WHO, Switzerland

18:00 End of Day 1

19:30 Dinner

The costs for the dinner are included in the registration fee. We kindly ask you to register in advance.

**JANUARY 21****WEDNESDAY**08:30 **SESSION 4****INNOVATION IN THE QUALITY ARENA****Quality by Design: Background and Objective**

Dr. Fritz Erni, Head Technical Liaison, Group Quality Operations, Novartis, Switzerland

**New Quality Concepts - How to Implement in the CTD?**

Dr. Christa Wirthumer-Hoche, Head of the Unit for Marketing Authorisation of Medicinal Products and Lifecycle Management, AGES PharmMed, Austria

**Quality by Design: Leading by Examples**

Janeen Skutnik, Director/Team Leader Quality &amp; Regulatory Policy, Pfizer Inc., UK

**Good Manufacturing Practice Including PIC/S**

Dr. Joey Gouws, Director, Inspectorate &amp; Law Enforcement South African Department of Health, South Africa (invited)

**Panel Discussion**

Dr. Hakmeh Housseh, Food and Drug Administration, Jordan  
 Dr. Fritz Erni, Novartis, Switzerland  
 Dr. Joey Gouws, South African Department of Health, South Africa (invited)  
 Dr. Hamid Rasekh, Ministry of Health, Iran  
 Janeen Skutnik, Pfizer Inc., UK  
 Dr. Christa Wirthumer-Hoche, AGES PharmMed, Austria

**10:30 Coffee Break**

**11:00 SESSION 5  
 COMMON TECHNICAL DOCUMENT AND ELECTRONIC SUBMISSIONS**

**Opportunities and Challenges of eCTD and e-Submissions in the EU, US and in the Middle East: An Industry Position**  
 Dr. Geoffrey Williams, Roche Products Limited & Chairman of EFPIA eCTD Topic Group, UK

**Implementing Electronic Submissions: A European Regulatory Authority Perspective**  
 Dr. Christa Wirthumer-Hoche, Head of the Unit for Marketing Authorisation of Medicinal Products and Lifecycle Management, AGES PharmMed, Austria

**Panel Discussion**  
 Dr. Hajed M. Hashan, Saudi Food and Drug Authority, Saudi Arabia  
 Dr. Geoffrey Williams, Roche Products Limited, UK  
 Dr. Christa Wirthumer-Hoche, AGES PharmMed, Austria

**12:15 Lunch Break**

**13:30 SESSION 6  
 EVOLVING GLOBAL LEGISLATION ON MEDICINES**

**An Overview of Biopharmaceuticals and Biosimilars**  
 Dr. Suresh Aravind, Global Medical Affairs Leader, Johnson & Johnson Pharmaceutical Services, USA

**New Legal Developments in the EU - Including the Paediatric and Variations Regulations**  
 Dr. Christa Wirthumer-Hoche, Head of the Unit for Marketing Authorisation of Medicinal Products and Lifecycle Management, AGES PharmMed, Austria

**Variations Future Trends - An Industry Perspective**  
 Dr. Mike James, Head of CMC Regulatory Advocacy and Intelligence, GlaxoSmithKline R&D, UK

**ICH Update**  
 Dr. Yves Juillet, Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises du Médicament (LEEM), France

**15:00 Coffee Break**

**15:30 Participation of Regional Harmonisation Initiatives in ICH-GCG**  
 Prof. Saleh Bawazir, Vice President, Head of Drug Sector, Saudi Food and Drug Authority, Saudi Arabia

**Panel Discussion**  
 Dr. Suresh Aravind, Johnson & Johnson Pharmaceutical Services, USA  
 Prof. Saleh Bawazir, Saudi Food and Drug Authority, Saudi Arabia  
 Dr. Hajed M. Hashan, Saudi Food and Drug Authority, Saudi Arabia  
 Dr. Mike James, GlaxoSmithKline R&D, UK  
 Dr. Yves Juillet, Les Entreprises du Médicament (LEEM), France  
 Dr. Omar Sayed Omar, Ministry of Health, Kuwait  
 Dr. Hamid Rasekh, Ministry of Health, Iran  
 Dr. Christa Wirthumer-Hoche, AGES PharmMed, Austria

**16:30 SESSION 7  
 CURRENT AND FUTURE TRENDS - CLOSING REMARKS**

**Health Economics**  
 Xavier Mesrobian, Head of Health Economics and Market Access Intercontinental, sanofi-aventis, France

**Conference Review and Next Steps**  
 Prof. Trevor Jones, King's College London; WHO Commissioner CIPIH, UK

**17:30 Conference Close**

The DIA Europe has blocked a limited number of rooms at:

**The Ritz-Carlton Bahrain Hotel & Spa**

**PO Box 55577  
 Manama  
 Tel.: +973 1758 0000  
 Fax: +973 1758 0948**

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 All rates incl. breakfast, excl. 15% service charge + 5% local taxes**

For online reservations, please visit the course programme page on our website [www.diahome.org/Educational Offerings](http://www.diahome.org/Educational Offerings)>Keyword: 09107

**IMPORTANT: To be assured of accommodation at the Ritz-Carlton Bahrain Hotel & Spa, registrants are recommended to complete their reservation by December 1, 2008.**

**Accommodation Booking Form**

**1 form per reservation**

**Please fax completed form to the**

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 PO Box 55577  
 Manama**

**Tel.: +973 1758 0000 Fax: +973 1758 0948  
 Email: [rc.bahrz.group.reservations@ritzcarlton.com](mailto:rc.bahrz.group.reservations@ritzcarlton.com)  
 by December 1, 2008**

**Guest**

Prof.  Dr.  Ms.  Mr.

Last Name \_\_\_\_\_

First Name & Middle Initial \_\_\_\_\_

Company \_\_\_\_\_

Job Title \_\_\_\_\_

Street Address / P.O. Box \_\_\_\_\_

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*(rates incl. breakfast, excl. 15% service charge + 5% local taxes)*

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Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET, or email diaeurope@diaeurope.org

## REGISTRATION FORM - ID# 09107

**8TH MIDDLE EAST REGULATORY CONFERENCE - MERC 2009**  
**JANUARY 20-21, 2009 - THE RITZ-CARLTON HOTEL, MANAMA, BAHRAIN**

If DIA Europe cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration includes conference material and refreshment breaks for the value of € 250.00.  
Registration will be accepted by mail, fax, email or online at [www.diahome.org](http://www.diahome.org)



Join DIA now to qualify for the early-bird member rate!  
Please mark the box indicated below if you wish to take this option.  
To qualify for the early-bird discount, registration form and accompanying payment must be received by the date below.  € 130.00  
The early-bird rate does not apply to government or academia/nonprofit attendees.

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	FEE	TOTAL	FEE	MEMBERSHIP	TOTAL	FEE
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<input type="checkbox"/> TOTAL AMOUNT DUE: €		NOTE: Payment of registration fees must be received before commencement of the event.				

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09107DIAWEB

Milen Vrabevski Please indicate your areas of professional interest:

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**REGISTRANT**  Prof.  Dr.  Ms.  Mr.

Last Name \_\_\_\_\_

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Company \_\_\_\_\_

Job Title \_\_\_\_\_

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Registrants who do not cancel by the date above, and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel and travel reservations. If an event is cancelled, DIA Europe is not responsible for airfare, hotel or any other costs incurred by registrants. DIA Europe reserves the right to alter the venue and dates if necessary.

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

If you have not received your confirmation letter via fax within five working days, please contact the DIA Europe.