11th Middle East Regulatory Conference (MERC) 2015

Regulatory Science and Best-Practices Bringing Innovative Medicines to Patients

Celebrating 20th Anniversary of MERC

17-18 November 2015
Riyadh, Kingdom of Saudi Arabia

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Dr Samah Rageb Ibrahim, Egyptian Drug Authority
Dr Hayel Mohamad Obeidat, Jordan Food and Drug Authority(JFDA)
Dr Faisal Al Ani, Ministry of Health, Kuwait

Conference Moderator

Professor Trevor M Jones CBE, King's College London, former Director General ABPI, United Kingdom

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM).

The MERC conference will be honored with 12 credits for pharmaceutical medicine. All participants are eligible for these credits.

OVERVIEW

This is the 11th DIA Middle East Regulatory Conference (MERC) in partnership with the Middle East Regulatory Network (MERN).

The MERN is a 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 in line with international standards.

This Conference marks an important milestone – it will celebrate the 20 year anniversary of MERC and will reflect on the significant progress made over that period. And, for the first time in that 20 year period, MERC is being co-hosted by a regulatory authority – Saudi Food and Drug Authority (SFDA)

As an important forum related to the provision of healthcare in the region, it will continue to discuss the opportunities to achieve further improvements for faster access to new, 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.

OBJECTIVES

This year's conference will explore advances in regulatory science and discuss the benefits of regulators collaboration & best practices. It will reflect on how this can be put into practice to meet the challenges of assessing innovative medicines.

WHO WILL ATTEND

The conference offers the opportunity for key stakeholders active or interested in this diverse and changing region, including representatives from regulatory agencies, 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.

co-hosted by SFDA "Saudi Food & Drug Authority"

SFDA
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

DIA DEVELOP INNOVATE ADVANCE

KEY TOPICS

> SHARING PROGRESS AND LEARNINGS FROM LOCAL REGULATORY ENVIRONMENT

- Focus on sharing best practice, experience and learnings from a number of recent, positive changes that have been implemented by Middle East Regulators.

> PROGRESSIVE REGULATORY PATHWAYS – THE WAY AHEAD

- Share new developments in regulatory science - how innovative regulatory pathways can strengthen regulatory review.

> ENSURING QUALITY THROUGH COMPLIANCE

- Deliver the right drug at the right place at the right time - key quality aspects of manufacturing, analytical testing, release and distribution. Promoting global harmonisation of standards for regulators, industry and patients.

> eCTD AND PRACTICAL EXPERIENCE SHARING

- Experiences, best practices, challenges and opportunities.

> REGULATORY PRACTICES ADDRESSING SCIENTIFIC AND THERAPEUTIC INNOVATION

- Review paradigm shifts in research and development - how changes in disease understanding are influencing regulatory pathways.

> DILIGENT ASSESSMENT OF BIOSIMILARS ENSURING PATIENT SAFETY

- Ensure timely accessibility of high quality efficacy and safety profile bio-therapeutics to patients of the Middle East.

> PHARMACOVIGILANCE

- Share information on pharmacovigilance infrastructure, reporting and pre- & post-approval.

CONTINUING EDUCATION

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honored with credits for pharmaceutical medicine. All participants are eligible for these credits.

ABOUT DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, global nonprofit organization based in Washington, DC, USA, with regional offices representing the Americas (Horsham, PA, USA); Europe, the Middle East, and Africa (Basel, Switzerland); and Asia (Beijing, China; Mumbai, India; and, Tokyo, Japan). For more information, visit our website at www.DIAGlobal.org or contact us via Twitter @DrugInfoAssn, LinkedIn or on Facebook

Discover more opportunities at www.DIAglobal.org

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TUESDAY | 17 NOVEMBER 2015

08:00 CONFERENCE REGISTRATION

09:00 SESSION 1

Welcome Address
H.E. Professor Mohammed Almeshal, CEO Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia

DIA Opening Remarks
Jytte Lyngvig, Senior Vice President and Managing Director, DIA Europe, Middle East & Africa, Switzerland

Opening Remarks from MERN Chairperson
Greg Jordinson, MERN Chairperson Regulatory Manager, Global Regulatory Affairs, Janssen Research & Development, Janssen-Cilag Ltd, United Kingdom

Recognising 20 years of MERC Progress - Welcome by MERC Programme Advisory Chair
Paul Dearden, MERC PAC Chairperson, Director Regulatory Policy & Intelligence, AbbVie, United Kingdom

Introductory Remarks by Conference Chairperson – Reflection on the MERC Journey
Professor Trevor M. Jones, CBE, King's College London, former Director General ABPI, United Kingdom

09:30 REFRESHMENT BREAK

10:00 SESSION 2

LOCAL REGULATORY ENVIRONMENT

Session Moderator:
Professor Trevor M. Jones, CBE, King's College London, former Director General ABPI, United Kingdom

This session will allow regulators to share best practice, experience and learnings from recent changes in the Middle East regulatory environment.

Saudi Food & Drug Authority (SFDA)
Dr Ibrahim A. Aljuffali, VP for Drug Sector, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia

Jordan Food & Drug Administration (JFDA)
Dr Maha Al Jaghbeer, Pharmacist, Head of Drug Registration Unit, JFDA, Jordan

Egyptian Drug Authority
Dr Samah Ragab Ibrahim, Director of Pharmaceutical Registration, Ministry of Health, Egypt

Kuwait Ministry of Public Health (MoPH)
Dr Hamza Garashi, Pharmacist, Drug Registration and Control, Kuwait Ministry of Public Health

Panel Discussion and Questions & Answers
All Presenters and Greg Jordinson, MERN Chairperson, Johnson & Johnson, United Kingdom, Ihab Attia, RAWG Chair, Eli Lilly, United Arab Emirates, Abdulrahim Al-Yahya, SARA Group Chair, Abbvie, Kingdom of Saudi Arabia, Wadiah Batarseh, JRWG Group Co-Chair, Bayer Jordan, Samia Seleem, Egypt Group Chair, AbbVie, Egypt

12:05 LUNCH BREAK

13:15 SESSION 3

REGULATORY INNOVATION AND CHALLENGES

Session Moderator:
Professor Trevor M. Jones, CBE, King's College London, former Director General ABPI, United Kingdom

The objective of this session is to share new paradigms in regulatory science and current developments. To facilitate registration of medicinal products & increase efficiency (through collaboration, work-sharing and implementation of global norms and standards).

Global Overview of Work-sharing, Good Review Practice and Regulatory System Strengthening

WHO Perspective
Dr Lembit Rägo, Head, Regulation of Medicines and other Health Technologies Essential Medicines and Health Products, World Health Organization, Geneva, Switzerland

Industry Perspective
Florence Roizard, Associate Vice President, Regulatory Affairs International, Regional Regulatory Affairs Lead, Europe, Middle East and Africa (EMEA), Merck Sharp & Dohme, France

The Saudi Food and Drug Authority: An Evaluation of Registration Procedures & Good Review Practices in Saudi Arabia in Comparison with Australia, Canada & Singapore
Dr Hajed M. Hashan, Executive Director, Licensing Executive Directorate, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia

A Structured Approach to the Benefit-Risk Assessment of Medicines: Key to Improving Decision Making in Drug Development and the Regulatory Review in the Gulf Region
Professor Stuart Walker, Founder, CIRS - Centre for Innovation in Regulatory Sciences, United Kingdom

Questions & Answers - with all presenters

14:30 SESSION 4

QUALITY THROUGH COMPLIANCE – PART I: COUNTERFEIT

Session Moderator:
Prof. Saleh A. Al-Suwayeh, Professor of Pharmaceutics
College of Pharmacy, King Saud University, Riyadh, Saudi Arabia

This session will focus on ensuring uninterrupted access and delivering the right drug at the right place at the right time. Promoting global harmonization of standards for regulators, industry and patients.

Saudi FDA Role in Combating Pharmaceutical Counterfeiting
Dr Mohammed A. Dahhas, Executive Director, Inspection & Law Enforcement Directorate, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia

Challenges with Counterfeits and Experience with Serialization Implementation

- Dr Ziad Nassour, Member of French Academy of Pharmacy, ex-President of the Lebanese Order of Pharmacists, ex- President EMROPHARM-Forum, WHO, ex- Vice President of the International Conference of Francophone (C.I.O.P.F), Lebanon
- Mathieu Aman, Program Manager Supply Chain F. Hoffmann-La Roche Ltd, Pharma Division, representing EFPIA, Switzerland

TUESDAY
17 NOVEMBER 2015

Panel Discussion and Questions & Answers
All presenters, Dr Lembit Rägo, Head, Regulation of Medicines and other Health Technologies Essential Medicines and Health Products, World Health Organization, Geneva Switzerland
Egyptian Drug Authority I invited

16:00 REFRESHMENT BREAK

16:30 SESSION 4

QUALITY THROUGH COMPLIANCE – PART II: POST-APPROVAL CHANGES

Session Moderator:
Florence Roizard, Associate Vice President, Regulatory Affairs International, Regional Regulatory Affairs Lead, Europe, Middle East and Africa (EMEA), Merck Sharp & Dohme, France

This session will focus on ensuring uninterrupted access and delivering the right drug at the right place at the right time. Promoting global harmonization of standards for regulators, industry and patients.

Global Challenges of Handling Post-approval Changes and Examples of Agency Collaborations
- Susanne Ausborn, Pharma Technical Regulatory CMC Policy EEMEA, F. Hoffmann-La Roche AG, Switzerland
- Dr Moheb M. Nasr, VP, CMC Regulatory Strategy, Global Affairs, (GRA), GlaxoSmithKline, United States

Panel Discussion and Questions & Answers
All presenters and Dr Lembit Rägo, Head, Regulation of Medicines and other Health Technologies Essential Medicines and Health Products, World Health Organization, Geneva Switzerland, Dr Ali M. Al Homaidan, Executive Director, Product Evaluation Executive Directorate, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia, Dr Maha Al Jaghbeer, Pharmacist, Head of Drug Registration Unit, JFDA, Jordan, and Egyptian Drug Authority I invited

17:30 SUMMARY OF CONFERENCE DAY

Professor Trevor M. Jones, CBE, King's College London, former Director General ABPI, United Kingdom

17:45 - 19:30 NETWORKING RECEPTION

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WEDNESDAY
18 NOVEMBER 2015

08:15 SESSION 5

REGULATORY PRACTICES ADDRESSING SCIENTIFIC AND THERAPEUTIC INNOVATION

Session Moderator:
Inas Chehimi, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

The focus of this session will be to review some of the paradigm shifts in technical research and development; "How changes in the scientific understanding of disease are influencing changes in regulatory pathways."

Introduction
Professor Trevor M Jones CBE, King's College London, former Director General ABPI, United Kingdom

Regulatory Pathway / Share Experience
Dr Balazs Sarkadi, Head of Biomembrane Research Group, Research Centre for Natural Sciences, Hungarian Academy of Sciences, Hungary

Gene Therapy / Regulatory Pathway
Dr Ramy S. Behbehani, Drug Registration and Release Superintendent, Kuwait Drug & Food Control Administration, Ministry of Health Kuwait

Industry R&D Overview / FDA Regulatory Pathways and EU Industry
Mikkel Oestergaard, Medical Affairs Biomarker Leader, Hematology-oncology, F. Hoffmann-La Roche AG, Switzerland

Panel Discussion and Questions & Answers

10:00 REFRESHMENT BREAK

10:30 SESSION 6

eCTD & PRACTICAL EXPERIENCE SHARING GLOBALLY, REGIONALLY & LOCALLY

Session Moderator:
Dr Hajed M. Hashan, Executive Director, Licensing Executive Directorate, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia

In this session presenters will share experiences and best practices and discuss challenges and opportunities from regulators and industry.

ICH – Increasing Use, Trends
Joerg Schnitzler, Head of Regulatory Affairs Operations, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Definition of Readiness / Challenges, Considerations
- Dr Mohannad El Khider, Parmacist, Registration Sectioni, Drug Control Department, Ministry of Health, Oman
- Dr Pieter Van Keerberghen, Head of AFMPS Development & Projects, FAGG-AFMPS, Belgium

Panel Discussion "Why Collaborate" and Questions & Answers
All presenters

12:00 LUNCH BREAK

13:00 SESSION 7

DILIGENT ASSESSMENT OF BIOSIMILARS ENSURING PATIENT SAFETY

Session Moderator:
Keith Watson, Director, Global Regulatory Affairs, Biologics Strategic Development, AbbVie United Kingdom

Ensure timely accessibility of high quality efficacy & safety profile biosimilar to patients of the Middle East region. Building capabilities at Health Authorities end and faster access to patients.

WHO Experience – *via webex*
Dr Ivana Knezevic, Scientist, Technologies, Standards and Norms Team, Group Lead, Norms and Standards for Biologicals, Department of Essential Medicines and Health Products (EMP), Health Systems and Innovation (HIS) Cluster, WHO, Switzerland

EU Regulator Assessments
Dr Seàn Barry, Executive Pharmaceutical Assessor (Acting), Health Products Regulatory Authority, Ireland

Biosimilars Regulation in the Region – A Case Study
- Dr Ali M. Al Homaidan, Executive Director, Product Evaluation Executive Directorate, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia
- Dr Mona Mohamed Abdelhamed Saleh, Director of Biological Registration Directorate, Central Administration of Pharmaceutical Affairs, Egyptian Drug Authority
- Dr Ramy S. Behbehani, Drug Registration and Release Superintendent, Kuwait Drug & Food Control Administration, Ministry of Health Kuwait

IFPMA Perspective
Fabio Bisordi, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd., Switzerland

Panel Discussion and Questions & Answers
All presenters and Jordan Food & Drug Administration (JFDA) I Dr Maha Al Jaghbeer, Pharmacist, Head of Drug Registration Unit, JFDA, Jordan

15:00 REFRESHMENT BREAK

15:15 SESSION 8

ENSURING COMPLIANCE WITH NEW PHARMACOVIGILANCE REGULATIONS

Session Moderator: Dr Hisham Aljadhey, Interim Dean, College of Pharmacy, Supervisor of Pharmacy Services at Medical City, King Saud University, Kingdom of Saudi Arabia

The main aim of this session is to provide marketing authorization holders (MAHs) with background information on current pharmacovigilance regulations and how to improve their capabilities in order to comply with the requirements of good pharmacovigilance practices.

Update on Pharmacovigilance Regulations in Middle East
Dr Adel A. Alharf, Executive Director, Vigilance and Crisis Management Executive Directorate, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia

Adverse Drug Reactions: The Role of Causality Assessment Scales in Pharmacovigilance
Dr Tariq Alhawassi, College of Pharmacy, King Saud University, Kingdom of Saudi Arabia

Practical Considerations in Benefit-Risk Assessment
Dr Syed Rizwanuddin Ahmad, Consultant, National Medicines Regulatory Authorities, Associate Professor (adjunct), Rutgers School of Public Health, United States, Ex-Consultant, U.S. FDA

Questions & Answers

16:30 CONFERENCE SUMMARY AND DIRECTION FOR THE NEXT 20 YEARS

- Paul Dearden, MERC PAC Chairperson, Director Regulatory Policy & Intelligence, AbbVie United Kingdom
- Greg Jordinson, MERN Chairperson Regulatory Manager, Global Regulatory Affairs, Janssen Research & Development, Janssen-Cilag Ltd, United Kingdom
- Dr Adel A. Alharf, Executive Director, Vigilance and Crisis Management Executive Directorate, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia
- Jytte Lyngvig, Senior Vice President and Managing Director, DIA Europe, Middle East & Africa, Switzerland
- Professor Trevor M. Jones, CBE, King's College London, former Director General ABPI, United Kingdom

17:15 END OF CONFERENCE

CONFERENCE VENUE

The conference will take place at the:

Riyadh Marriott Hotel
King Saud Road, Ryiadh-11464, Saudi Arabia
Phone: 966 11 4779300 | Fax: 966 11 4779089 | www.riyadhmarriott.com

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