



Middle East Regulatory Conference (MERC)

The collaborative platform for connecting
Regulatory experts in the Middle East

14-15 October 2019 | Royal Maxim Palace Kempinski, Cairo, Egypt



PROGRAMME COMMITTEE

HEALTH AUTHORITY ADVISORS:

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Hassaan Alwohaibi, SFDA, Saudi Arabia
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LOCAL NETWORK CHAIRS:

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Representative of Saudi Arabia Regulatory
 Working Group, Abbvie, Saudi Arabia

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Samia Seleem

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 Chair, Abbvie, Egypt

Suha Abdallah

Registration Associate Director
 MSD, Jordan

Overview

DIA provides the unique platform in the Middle East of connecting experts in the region for collaborative discussion.

Every country throughout the Middle East region is formulating improved regulations for pharmaceutical and biopharmaceutical development. What can we all learn from each other?

The 13th DIA Middle East Regulatory Conference (MERC), shaped in partnership with the EFPIA Middle East Regulatory Network (MERN), is built on the premise that collaboration leads to more efficient regulatory system that sustains patient access. This conference, growing in scale every year, brings together health authorities and global stakeholders from across the region and Europe. The conference will discuss country-level progress and challenges, as well as opportunities for increased regional collaboration.

Are you ready to collaborate?

Top 3 Reasons to Attend the 2019 MERC:

1. Collaborate with Health Authorities from many different countries – Don't miss this chance to get exposure to the future of health policy in the region
2. Connect with 300+ participants, representing 27 countries from health authorities and pharmaceutical industry, throughout the Middle East, Europe and globally
3. Establish leading strategies and processes for getting innovative medicines to patients faster

Who You Will Meet

- Regulatory agencies and ministries of health in the region, experts from international organisations
- Thought leaders, global and local stakeholders from both local and multinational pharmaceutical companies who are working in the fields of
 - o Regulatory affairs, Policy, Government Affairs, Access
 - o Pharmacovigilance



| Key Topics

- Regional Developments
- Good Regulatory Practice & Reliance models
- Lifecycle Management & Safety
- HTA Access & Value
- Innovation in the Pharmaceutical Sector
- Pharmacovigilance
- eCTD
- Regulatory Systems
- Biosimilars
- Patient Engagement

| Who Should attend

The conference is directed at key stakeholders that are active or are interested in this diverse and changing region, including representatives from regulatory agencies, ministries of health, local and multi-national pharmaceutical companies. You will have the opportunity to meet and exchange views, discuss topics of interest and identify actions to increase patient access to new and improved medicines and therapies:

- Regulatory Affairs Heads / Officers / Directors / Managers / Specialists
- Scientific Office Managers
- Registration Managers
- Pharmacists
- Patient Safety Managers / Officers
- Drug Safety & Quality Assurance Directors / Managers
- Heads of Market Access
- Patient Advocates

| Conference Venue

Royal Maxim Palace Kempinski Cairo

First Settlement,

11477 Cairo

Egypt

Tel: +20 2 224 95300

Hotel Location

A room block is available at a special DIA rate of USD 175 per night from 13-16 October 2019. This includes: Single Deluxe City View Room VAT – WIFI included.

This special room rate will be available until 13 September 2019 or until the group block is sold-out, whichever comes first.

Please book directly through this [booking link](#) and mention **DIA** to ensure you receive this rate.

In case you wish to extend your stay until 18 October 2019, same rate can be applied (subject to hotel availability). For any extra night extension, kindly contact the [hotel](#) directly.

| About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of 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, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.

| Continuous 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 honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.



| Disclosure Policy

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07:30 REGISTRATION OPEN AND WELCOME REFRESHMENTS

08:30 OPENING OF THE CONFERENCE

Thomas Bols, Senior Vice President and Managing Director, DIA Europe, Middle East and Africa

Inas Chehimi, MERN Chair and Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

Peter Pitts, MERC 2019 Chair & President, Center for Medicine in the Public Interest, US

Rasha Ziada, Head of Central Administration of Pharmaceutical Affairs (CAPA), Ministry of Health, Egypt

09:30 OPENING KEYNOTE

THE PATIENTS' EXPECTATIONS TOWARDS INDUSTRY & REGULATORS

Julie Rihani, Patient, Jordan

10:00 COFFEE BREAK

10:30 SESSION 1

PATIENTS ARE WAITING: HEALTH AUTHORITY REGULATORS, WHO AND INDUSTRY APPROACHES TO ACCELERATE PATIENTS' ACCESS TO INNOVATION

Session chairs:

Jeffrey Kemprecos, Director, Communications Government Affairs & Market Access - Gulf Region, GlaxoSmithKline, Dubai

Catherine Al Ashram, Director Regulatory Affairs ME, MSD, Jordan

Putting Reliance into Practice: WHO's Activities on Regulatory Systems Strengthening

Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization (RNH/RSS), World Health Organization (WHO), Switzerland

The ICH perspective

Lenita Lindström-Gommers, ICH Assembly Chair and Senior Expert, European Commission, EU

Access to Innovative Medicines: Study Comparing Regulatory Timelines in 10 Countries in the Middle East & Africa

Mohamed Omar, Associate Director, IQVIA, Egypt

The Reliance Model implementation in practice: Examples from Jordan, Saudi Arabia and Egypt

Introduction: **Inas Chehimi**, MERN Chairperson, Head RA Middle East & North Africa, Novartis Pharma Services AG, UAE

Panel Discussion with the participation of:

Heba Nabil, Head of Human Drugs Registration Department, CAPA, MoH, Egypt

Wesal Haqaish, Drug Directorate Director, JFDA, Jordan

Bandar Al Hammad, Chief Pharmacist, Regulatory Affairs Department, SFDA, Saudi Arabia

12:15 LUNCH

13:30 SESSION 2

REGULATORY DYNAMICS AND FUTURE VISION ACROSS THE REGION

Session chair: **Peter Pitts**, MERC 2019 Chair & President, Center for Medicine in the Public Interest, US

Session co-chair: **Rasha Ziada**, Head of Central Administration of Pharmaceutical Affairs (CAPA), Ministry of Health, Egypt

During this session, we will discuss the region's regulatory dynamics and future trends. The regulatory environment has been fast evolving in the past few years, with a great number of changes across region. The Health Authorities (HAs) are looking into reforms and to adapting to the recent novelties in regulatory affairs, accelerated pathways, variation guidance, roadmaps and digitalisation. In this session, the region's HAs will be providing their insights, present and future vision, through a brief presentation followed by an interactive Panel Discussion with Q&A.

Sabah Memon, Senior Pharmacist, NHRA, Bahrain

Rasha Ziada, Head of the Central Administration of Pharmaceutical Affairs (CAPA), Ministry of Health, Egypt

Hajed Hashan, Deputy of General Director, Gulf Health Council (GHC), Saudi Arabia

Wesal Haqaish, Drug Directorate Director, Jordan Food and Drug Authority (JFDA), Jordan

Sarah Al Maqseed, Registration and Release Superintendent, Ministry of Health, Kuwait

Mohammed Al Rubaie, Director General, Directorate General of Pharmaceutical Affairs & Drug Control, Ministry of Health, Oman

Adel Al Harf, Executive Vice President for Drug Affairs, Saudi Food and Drug Authority (SFDA), Saudi Arabia



15:15 COFFEE BREAK

15:45 SESSION 3

TURNING FUNDAMENTAL RESEARCH INTO INNOVATIVE TREATMENTS

Session chair:

Greg Jordinson, Associate Director, Global Regulatory Affairs, Janssen R&D, UK

“The Value of the Innovation” – PhRMA Report

Greg Jordinson, Associate Director, Global Regulatory Affairs, Janssen R&D, UK

Patients Driving Innovation

Mathieu Boudes, PARADIGM Coordinator, European Patients' Forum, France

The use of Real World Data in Regulatory Decision Making

Gracy Crane, Senior Principal Data Scientist, RWD Policy, PHC Data Science, Hoffmann-La Roche Ltd, UK

Q&A and Panel Discussion

17:00 SESSION 4

HIGHLIGHTS OF THE DAY AND WRAP-UP

Session chair:

Inas Chehimi, MERN Chair, Head RA Middle East & North Africa, Novartis Pharma Services AG, UAE

“Parking lot” style session and discussion, with the participation of all the Speakers and Panellists from the day.

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

08:30 SESSION 5

HTA 2.0: A GLIMPSE INTO CURRENT USES AND FUTURE TRENDS

Session Chairs:

Mourad Aboubakr, MENA Regional Head Market Access, Novartis, UAE

Noha Salem, Regional Director for Healthcare Policy, EEMEA, MSD, Egypt

Recently, HTA has become one of the most important topics across the region as governments aspire to modernize healthcare systems and adopt contemporary measures for evaluating healthcare interventions. This session will shed light on the past, present and future of HTA through the participation of industry, international bodies, government and academic experts, and the discussion of topics such as lessons from the past, the current state of play and recommendations for moving towards a value-based system and integrating HTA into the broader healthcare context.

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EUnetHTA – Where and Why it Started & Lessons Learned (Remote Presentation)

Ansgar Hebborn, Head – European Access Policy Affairs, F. Hoffmann-La Roche AG, Switzerland

How to get to an international approach in HTA

Video contribution from **Anna-Eva Ampelas**, Head of Unit, Medical products: Quality, Safety, Innovation, European Commission, EU

Health Technology Assessment in Saudi Arabia: Experts Perception on the Creation of a National HTA Entity

Ibrahim Al Juffali, Advisor to the Minister of Health for Pharmaceutical Sector Development & Assistant Professor, Department of Pharmaceutics, College of Pharmacy, King Saud University, Saudi Arabia

Health Technology Assessment: the Innovation Industry Perspective

Mourad Aboubakr, MENA Regional Head Market Access, Novartis, UAE

HTA in the Middle East region – A mapping of the current landscape and options for the future

Panos Kanavos, Deputy Director, LSE Health, London School of Economics, UK

Q&A and Panel discussion: Next steps – Where can we invest and where can we build our capabilities in the ME? With the participation of **Shaimaa Foad**, Pharmacoeconomic Unit, CAPA, MoH, Egypt

10:00 COFFEE BREAK

10:30 SESSION 6

CONVERGENCE AND RELIANCE FOR POST-APPROVAL CHANGES - WHERE DO WE STAND TODAY?

Session Chairs:

Susanne Ausborn, Regulatory Policy Lead, Hoffmann-La Roche Ltd, Switzerland

This session will highlight the progress since the 2017 MERC and the publication of the [EFPIA recommendations](#) for 'Optimising the management of Post-Approval Changes', taking time to reflect on industry and Health Authority perspectives. Furthermore, the session will introduce the newly developed EFPIA position paper on managing post-approval safety labelling updates in the region with industry reflections on the challenges and opportunities that could be realised by global regulatory convergence and reliance.

EFPIA LCM paper – what Progress has been made?

Introduction: **Susanne Ausborn**, Regulatory Policy Lead, Hoffmann-La Roche Ltd, Switzerland

The WHO Perspective

Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization (RNH/RSS), World Health Organization, Switzerland

The National Health Authorities Perspective

Sabah Memon, Senior Pharmacist, NHRA, Bahrain

Shereen M. Abdelgawad, Head of the Technical office, CAPA - Ministry of Health, Egypt

Maha Al Jaghbeer, Head of Registration Department, JFDA, Jordan

Bandar Al Hammad, Chief Pharmacist, Regulatory Affairs Department, SFDA, Saudi Arabia

Industry Reflection on Challenges with Safety Updates in the Region

Introduction: **Catherine Al Ashram**, Director Regulatory Affairs ME, MSD, Jordan

Q&A and Panel Discussion, with the additional participation of:

Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization (RNH/RSS), World Health Organization, Switzerland

Christina Saad Khalil, Pharmacovigilance Committee Rapporteur, Egyptian Pharmaceutical Vigilance Center, Egypt

Sarah Al Maqseed, Registration and Release Superintendent, Ministry of Health, Kuwait

Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe) Inc., Belgium

12:00 LUNCH

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13:30 SESSION 7: PARALLEL SESSIONS 1

SESSION 7A

A ROADMAP FOR eCTD

Session Chairs:

Claudio Shnyder, Senior Global Regulatory Submissions Manager, Novartis, Switzerland

As the ME region faces both challenges and opportunities in the introduction and implementation of eCTD, this session will be a unique opportunity to hear from experts and stakeholders on how the implementation of this technology could be optimized.

eCTD in the EU: The Industry Perspective

Jean Louis Hottart, Senior Specialist, Regulatory Affairs Operations, Lead Publishing EMEA – GRACS, MSD Europe, Inc., Belgium

eCTD in the Middle East

Michael Gessert, Global Agencies Manager, Extedo, Germany

eCTD implementation in the ME: The Roadmap from Oman's Experience

Tarek Essam, Pharmacist, Directorate General of Pharmaceutical Affairs & Drug Control, MoH, Oman

eCTD implementation in the ME: The Roadmap from Jordan's Recent Experience

Maha Al Jaghbeer, Head of Registration Dep., JFDA, Jordan

Q&A and Panel Discussion

SESSION 7B

PHARMACOVIGILANCE

Session Chairs:

Hadir Rostom, Head of Egyptian Pharmaceutical Vigilance Center, Egypt

Reem Al-Essa, Senior Pharmacy Specialist, Drug Inspection Administration, Drug and Food Control, Ministry of Health, Kuwait

Smart Safety Surveillance for Priority Medical Products

Shanthi Pal, Group Lead, Medicines Safety, Safety & Vigilance, WHO, Switzerland

The SFDA Experience – Moving to the Investigation Phase

Mohammed I. Fouda, Head of Signal Detection Department, Saudi Food and Drug Authority (SFDA), Saudi Arabia

Kuwait's Roadmap on Pharmacovigilance

Reem Al-Essa, Senior Pharmacy Specialist, Drug Inspection Administration, Drug and Food Control, Ministry of Health, Kuwait

Q&A and Panel Discussion, with the participation of **Phil Tregunno**, Group Manager, Vigilance, Intelligence and Research Group, MHRA, UK, and **Sean Burke**, EEMEA Regional Lead, Pharmacovigilance, MSD, UK

15:00 COFFEE BREAK

15:30 SESSION 8: PARALLEL SESSIONS 2

SESSION 8B

THE DIGITAL TRANSFORMATION IN REGULATORY AFFAIRS

Session Chair:

Rachelle Ross, Associate Director, Regulatory Affairs, Global Emerging Markets, Biogen, UK

The Digital Future of Regulatory Affairs

Rodrigo Palacios, Regulatory Technology Lead, Hoffmann-La Roche Ltd, Switzerland

Digital Approaches to Labelling and the Relationship to Patient-Centric Healthcare

Ronnie Mundair, Regional Labeling Head – AfME, Canada & LATAM, International Labeling Group & Senior Director, Pfizer, UK

Q&A and Panel Discussion

SESSION 8A

THE USE OF BIOSIMILARS IN THE MIDDLE EAST: IS IT A VICE OR VIRTUE?

Session Chair:

Virginia Acha, Executive Director, Global Regulatory Policy, MSD, UK

Highlights and Analysis of the FDA & EMA Interchangeability Guidelines

Virginia Acha, Executive Director, Global Regulatory Policy, MSD, UK

The Health Authority's Practices

Asmaa Fouad Ismail, Head of Biological Reception Section, CAPA, Ministry of Health, Egypt

Maha Al Jaghbeer, Head of Registration Department, JFDA
Abdulaziz A. AlSayyari, Director for Biological Products Evaluation, SFDA, Saudi Arabia

Biosimilars use in Practice: Challenges and Opportunities

Peter Pitts, President, Center for Medicine in the Public Interest, US

Q&A and Panel Discussion with the additional participation of **Heba Khalil**, Head of the Registration Department, NORCB, Egypt

17:00 WRAP-UP AND CLOSING REMARKS

Peter Pitts, MERC 2019 Chair & President, Center for Medicine in the Public Interest, US

Inas Chehimi, MERN Chairperson and Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

Hadir Rostom, Head of Egyptian Pharmaceutical Vigilance Center, Egypt

Thomas Bols, Senior Vice President and Managing Director, DIA Europe, Middle East and Africa

17:30 END OF THE CONFERENCE