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?

New - read insights from the Region:
Lebanon: http://engage.diaglobal.org/Interview-01.html
Jordan: http://engage.diaglobal.org/EMEA_ME_2017-05-03.html
Iraq: http://engage.diaglobal.org/EMEA_ME_2017_06_08.html
Egypt: http://engage.diaglobal.org/EMEA_ME_07_12.html

The 12th DIA Middle East Regulatory Conference (MERC), 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 2017 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

HEALTH AUTHORITY ADVISORS
Dr Sarah Maqseed, KFDC, Kuwait
Dr Donia Al Bastaki, KFDC, Kuwait
Dr Hassaan Alwohaibi, SFDA, Saudi Arabia
Dr Ahlam Abdelaziz, JFDA, Jordan

MERN REPRESENTATIVES
Greg Jordinson
EFPIA Middle East Regulatory Network Chairperson
Janssen R&D, United Kingdom

Nadine Otin
LEEM, France

Marijke van Bruggen
F. Hoffmann-La Roche Ltd., Switzerland

Paul Dearden
AbbVie, United Kingdom

Kerstin Ahrndt-Söltner
Biotest AG, Germany

Hany Gamal
Boehringer Ingelheim, United Arab Emirates

Inas Chehimi
Novartis Pharma Services AG, United Arab Emirates

LOCAL NETWORK CHAIRS
Adele Choueiry
Regulatory Working Group Chair, Novartis, Lebanon

Mounay Khafaja
Iraqi Regulatory Working Group Chair, Merck, Iraq

Haitham Al-Zuhair
Representative of Saudi Arabia Regulatory Working Group, Janssen-Cilag, Saudi Arabia

Samia Farhan
Egypt Regulatory Affairs Working Group Chair
Abbvie, Egypt

Ihab Al-Attia
Gulf Regulatory Affairs Working Group Chair
Eli Lilly Suisse S.A., United Arab Emirates

Tamara Al Rabi
LEVANT Jordan Pharma lead
Pfizer, Jordan
WHO WILL YOU 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
  - Regulatory affairs, Policy, Government Affairs, Access
  - Pharmacovigilance

To get a feel for the conference view the final programme from the 2015 MERC

WHO SHOULD 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:

- 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

FOR VISA INFORMATION:

1. Participants with European passports and GCC residents can obtain their e-Visa online [https://evisa.moi.gov.kw/evisa/home_e.do](https://evisa.moi.gov.kw/evisa/home_e.do) and collect it upon arrival at Kuwait Airport. 3 KWD in cash is required for the visa issuance at the airport.
2. Nationals of other countries, kindly submit the copy of your passport together with the registration form or afterwards if registered online. In order to obtain visa on time, the passport should be submitted by 15 October latest.

Kindly contact Isabelle Nguyen for questions at isabelle.nguyen@diaglobal.org

DISCLOSURE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.
Middle East Regulatory Conference

| DAY ONE | TUESDAY, 21 NOVEMBER |

07:30  REGISTRATION AND WELCOME REFRESHMENTS

08:30  OPENING OF THE CONFERENCE
Representative of the Ministry of Health, Kuwait
Greg Jordinson, EFPIA MERN Chairperson, Associate Director, Global Regulatory Affairs, Janssen R&D, United Kingdom
Inka Heikkinen, Head of Scientific Content Development, DIA Europe, Middle East and Africa

09:00  BREAK

09:30  SESSION 1, PART 1
GOOD REGULATORY PRACTICE
Session Chair: Paul Dearden, Head of Emerging Markets, Regulatory Policy & Intelligence, AbbVie, United Kingdom

Patients are demanding faster access to new medicines, especially in areas of high unmet medical need, ineffective and inefficient regulatory systems can be a barrier to access to safe, quality medical products. This session focuses on the key principles in regulatory systems (good regulatory practices) to provide sufficient flexibility to enable innovation and ensure agencies’ resources are efficiently utilised.

Speakers will describe related international guidances and regulators will share their experiences implementing good regulatory practices and optimised registration procedures. Finally, interactive panel discussions will address the question “can we do more to improve systems and align with these principles?”

Update on Global Developments Regarding Good Regulatory Practices and Collaborative Procedures
Stuart Walker, Centre for Innovative Regulatory Science, UK

Industry Perspective on Reliance & Expedited Pathways in Emerging Markets
Inas Chehimi, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

OPTIMISING REVIEW PROCESSES
Examples from SFDA, JFDA and EDA on Verification and Abridged Registration Procedures
Bandar Al Hammad, Director of Benefit-Risk Assessment Department, Executive directorate of Pharmacovigilance, Drug Sector, SFDA, Saudi Arabia
Rasha Zeyada, President, Pharmaceutical Affairs Directorate, Egyptian Drug Authority, Egypt
Dr Ghadeer Sheik Salem, Regulatory Affairs Specialist, JFDA, Jordan
Gulf Health Council Central Registration - a new Beginning
Hajed Hashan, Deputy of General Director, Gulf Health Council

11:00  BREAK

11:30  SESSION 1, PART 2 - PANEL DISCUSSION
Stakeholders’ Experience Regarding Reliance Procedures
Panelists:
All speakers

12:15  LUNCH

13:45  SESSION 1, PART 3
MEETING THE UNMET NEED OF THE PATIENTS
A view from Europe – Successes and Challenges of Early Access Tools
Tomas Salmonson, EMA CHMP Chair, Senior Assessor, Swedish Medicines Agency, Sweden

14:30  SESSION 1, PART 4 - PANEL DISCUSSION
Panelists:
Dr. Donia Al Bastaki, Head of Registration Department, Pharmaceutical and Herbal Medicines Registration and Control Administration, Drug and Food Control, Ministry of Health, Kuwait
Inas Chehimi, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates
Stuart Walker, Centre for Innovative Regulatory Science, UK
LIFE CYCLE MANAGEMENT
Session Chair: Sylvie Meillerais, Director Global Regulatory Policy, MSD Europe, Belgium

Post-approval changes (PAC) to the registered information of authorised medicinal products are introduced routinely worldwide to enhance the robustness and efficiency of the manufacturing process; improve quality control techniques; respond to changes in regulatory requirements; and upgrade to state-of-the-art facilities. The regulatory landscape for PAC varies dramatically across health authorities globally, also within the Middle East region countries have variable regulations with regard to requirements and approval timelines for changes. Implementing simple changes globally can take up to 5 years. There is a need to globally harmonize the post approval regulations to ensure continuous supply of high quality, compliant drugs to patients globally with a flexible supply chain. ICH and WHO are taking a leading role to establish key concepts that can be leveraged globally to drive global regulatory convergence regarding regulatory requirements for PACs. The session will explore the current landscape for PACs globally and specifically in ME, the challenges being faced and recommendations for improvement.

EFPIA Position Papers on Life Cycle Management (CMC, Safety Labelling)
Susanne Ausborn, EFPIA CMC Working Group member, Head Regulatory Policy & International Operations EEMEA, Hoffmann-La Roche, Switzerland
ICH Q12 Guideline
Frank Montgomery, ICH Working group member, Global Head, Regulatory CMC, AstraZeneca, UK

Questions and Answers

RAPID FIRE SESSION - DEVELOPMENTS WITHIN THE REGION
Moderator: Dr. Donia Al Bastaki, Head of Registration Department, Pharmaceutical and Herbal Medicines Registration and Control Administration, Drug and Food Control, Ministry of Health, Kuwait

The session will give floor to authorities in the region to present the recent developments and updates in their country as a rapid update.

Presentations will focus on life cycle management.

Developments in Kuwait
Dr Donia Al Bastaki, Head of Registration Department, Pharmaceutical and Herbal Medicines Registration and Control Administration, Drug and Food Control, Ministry of Health, Kuwait

Developments in UAE
Ihab Attia, Regulatory Director - Middle East Affiliate, Eli Lilly Suisse S.A., United Arab Emirates - Gulf Regulatory Affairs Working Group (RAWG) Chair

Developments in Jordan
Dr Ahlam Abdelaziz, Head of Generic Unit, Senior Registration Affairs Pharmacist, Drug Registration Department/ Drug Directorate, JFDA, Jordan

Developments in Oman
Oman Ministry of Health representative invited

Developments in Saudi Arabia
SFDA representative invited

17:45 NETWORKING RECEPTION

18:45 END OF DAY ONE
Looking into the future and laying the path forward

08:30  REGISTRATION AND WELCOME REFRESHMENTS

09:00  SESSION 4

PHARMACOVIGILANCE

Session Chair: Magnus Ekelo, Pharmacovigilance Officer, Uppsala Monitoring Centre, World Health Organisation

Topics to be addressed and discussed:

- The implications, differences in terms of implementation in the region
  - what are the benefits from this legislation – Health Authority perspective
  - opinion sharing on harmonisation
  - reflection on and benefits of the new Pharmacovigilance legislation – Health Authority perspective
  - Pharmacovigilance Rest of World group – overlap between systems and data

Common Arab guidance – updates
Prof. Amr Saad, Professor, Founder of The Egyptian Pharmacovigilance Center (EPVC) & Former Associate Minister of Health for Pharmaceutical Affairs, Egypt

Regional implementation – Trends and challenges for future
Dr Reem Al-Essa, Senior Pharmacy Specialist, Drug Inspection Administration, Drug and Food Control, Ministry of Health, Kuwait

Pharmacovigilance in the rest of the world
Esteban Herrero-Martinez, Director, Regulatory Policy & Intelligence, Abbvie, United Kingdom

Panel discussion

10:30  BREAK

11:00  SESSION 5

BARCODING/SERIALISATION

Session Chairs: Hany Gamal, Regional Drug Regulatory Affairs Head, Middle East, Turkey & Africa, Boehringer Ingelheim, United Arab Emirates
Adele Choueiry, Regulatory Affairs Head, GDD | LEVANT, Novartis Pharma Services Inc., The ME countries are implementing barcoding and serialisation in different ways for different reasons, why are they doing this and what do they want from such implementation?
What are the practical implications for industry, how can industry pro-actively work with regulators to converge on mutually acceptable targets. Wider impacts to payers. New regulations in almost all countries, GS1 to talk about standardization, learnings from countries who have implemented it.

Global standards for barcoding & serialisation
Geraldine Lissalde Bonnet, Director Public Policy, GS1, Belgium

EFPIA expert group
Dirk Van Den Wouwer, Serialisation Business Senior Manager, Janssen Pharmaceutical companies of J&J, Belgium

Example of implementation from Jordan
Dr Aham Abdelaziz, Head of Generics, Drug Registration Department/ Drug Directorate, JFDA, Jordan

Example of implementation from Saudi Arabia
Dr Abdullah Fahad Al-Meshal, Director of Drug Informatics Department, Drug Sector, SFDA, Saudi Arabia

Example of implementation from Egypt
Dr Yasin Affy, Head of Technical Office, Central Administration for Pharmaceutical Affairs, Egyptian Drug Authority, Egypt

Questions & Answers
All speakers
Dr Lina Abou Mrad, National E-health Program Director, Ministry of Health, Lebanon

12:30  LUNCH
13:40 SESSION 6

PARALLEL WORKSHOPS

WORKSHOP 1

eCTD

Moderators:
Alastair Nixon, Director, Publishing, GSK, UK
Dr Hajed Hashan, Deputy of General Director, Gulf Health Council, Saudi Arabia

Workshop overview
• Benefits and pitfalls of the implementation process; problems that have arisen during the implementation.
• Validation issue and interoperability of the systems
• How to keep the life cycle ongoing (too many sequences ongoing unless aligned)

WORKSHOP 2

PHARMACOVIGILANCE

Moderator:
Dr Sarah Maqseed, Registration and Release Superintendent, Pharmaceutical and Herbal Registration and Control Administration, Kuwait Ministry of Health

Workshop overview
The workshop will invited pharmacovigilance authorities to work together on capacity building in the region. The workshop will touch upon:
- Experience in benefit/risk assessment
- Basis for decision making
- Data utilisation
- Use of case examples

WORKSHOP 3

CASE STUDIES OF BIOSIMILARS

Moderator:
Dr Mai Allam, Technical Manager, National Organization for Research & Control of Biologicals, Egypt

Workshop overview
This sessions starts with a brief re-cap on how to assess biosimilar dossiers and the key steps in the development of these type of products. Thereafter, we will make it more concrete, by jointly reviewing some case examples of biosimilar applications. We will review the data packages of these ‘hypothetical cases’ and discuss whether or not the data presented is sufficient to conclude biosimilarity. If not, we will discuss what should be done differently, to be able to draw a conclusion on biosimilarity.

14:40 BREAK

15:15 SESSION 7

INNOVATION IN THE PHARMACEUTICAL SECTOR

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

Topic Leads: Nadine Otin, Consultant for Regulatory Affairs & Market Access, LEEM, France
Inas Chehimi, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

This session will present the value of innovation from different perspectives:
• Discuss the value of innovative medicines based on new studies done in countries around the world, including emerging market and EEMEA countries (patient quality of life, cost effectiveness, disease burden management/hospitalisation, social impact, competitiveness ).
• Present how the regulatory environment operates as a central pillar in any country’s competitiveness, a critical element of success if Middle East countries want to get into the P-20 or be more competitive and successful in the healthcare sector.
• Experience from the region in the RWE (Real Word Evidence)

Value of Innovation
Frank Lichtenberg, Courtney C. Brown Professor of Business, Columbia University, United States

Competitiveness, innovation and investment
Jeffrey P. Kemprecos, Executive Director Emerging Markets Public Policy, MSD, United Arab Emirates

Panel discussion
All speakers
Dr Hend al-Hussiany, Head, Egyptian Drug Information Centre, Egypt
Dr Hajed Hassan, Deputy of General Director, Gulf Health Council, Saudi Arabia

17:00 WRAP-UP OF BREAKOUT SESSIONS AND CLOSING REMARKS

Greg Jordinson, EFPIA MERN Chairperson, Associate Director, Global Regulatory Affairs, Janssen R&D, United Kingdom

17:30 END OF CONFERENCE
CONTINUING EDUCATION

SwAPP Credits
DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for applicable credits.

This conference has been accredited with 12.25 credits.

EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference via email.

ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on www.diaglobal.org.

- Presentations are made available to full conference attendees only (Attendee, Exhibitor, Speaker, and Press badges).
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NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with their presentation. Updated versions of the slides will be made available shortly after the conference.

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CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be provided on onsite to pre-registered attendees. Those who registered onsite will receive it electronically after the conference. Please note certification requires full attendance.

For more information please liaise with our DIA Contact Centre on Basel@DIAglobal.org or call +41 61 225 51 51.
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