People's Democratic Republic of Algeria under the auspices of the Ministry of Health, Population and Hospital Reform

1st Maghreb Regulatory Conference

10-11 February 2015
Hilton Algiers, Algeria

with local collaboration of Arianne Clinical Research Algeria

PROGRAMME COMMITTEE:

Dr Farid Benhammou
EMEA Regulatory Affairs, Maghreb, Africa & Middle East, Bayer Healthcare, Consumer Care, Switzerland

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DRA Head Middle East, Novartis Pharma Services AG, Representative Office Middle East Cluster, Dubai, United Arab Emirates

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Director of Regulatory Affairs, Compliance and Safety for Middle East and Africa for Amgen, Dubai, United Arab Emirates

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Dr Rachid Mounir
Associate Director Country Regulatory Head Morocco & French West Africa, Pfizer, Morocco

Dr Myriam Sedrati
Regulatory Affairs Director North and West Africa, Merck Sharp & Dohme, Morocco

PROGRAMME ADVISORS:
Health Authority/Subject Matter Experts from
- Algeria
- Morocco
- Tunisia
- **Dr Cellia K. Habita**
  President & CEO, Arianne Clinical Research, Algeria
- **Dr Nadine Otin,**
  representing LEEM (Les Entreprises du Médicament), France

EXHIBITION OPPORTUNITIES

For more details, please contact Roxann Schumacher, Exhibits Manager at roxann.schumacher@diaeurope.org or call +41 61 225 51 38.

OVERVIEW

The aim of the 1st Maghreb Regulatory Conference is to bring together key stakeholders and to discuss ways of improving access to medicines and therapies for the citizens and patients in the Maghreb Region.

The Maghreb Region is moving ahead rapidly in playing a major role in innovation and development of new medicines. A local as well as global perspective will support all key stakeholders in exchanging the current state of the art, best practices and future requirements as well as focus on getting guidelines into practice and practice into guidelines.

This regulatory conference will serve as an international and neutral forum for attendees to discuss how the Maghreb countries can play a leadership role in drug development. Speakers from local and international regulatory agencies, industry, and academia will present and will lead the panels and sessions.

The conference offers the opportunity for key stakeholders active in the Maghreb Region including representatives from health authorities, local and multinational pharmaceutical companies, academia, and international governmental and non-governmental organisations to exchange progressive views on key topics of interest and identify focus areas for ongoing efforts aimed to increase patient access to new and improved medicines.

Simultaneous translation in French and English will be available.

TOPICS WILL INCLUDE

- Regulatory processes in the region
- Pre-marketing
- Post-marketing
- Biosimilars
- Over the Counter Products
- Falsified Medicines/Anti-Bribery Laws
- Intellectual Property/Data Exclusivity
- Capacity Building

WHO WILL ATTEND

Representatives from health authorities/subject matter experts, regulatory affairs, quality assurance, medical, safety, research and development professionals, and other professionals involved in or interested in the aspects surrounding registration of medicinal products and regulatory harmonisation.

DIA DEVELOP INNOVATE ADVANCE

DIA Europe, Middle East and Africa
Kuechengasse 16,
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DIA Global Center: Washington, DC, USA | Basel, Switzerland | Beijing, China
Horsham, PA, USA | Mumbai, India | Tokyo, Japan

08:00-09:00 **REGISTRATION AND REFRESHMENTS**

09:00-09:20 **OPENING SESSION**

- Welcome
  Government Representative
- Introduction to the conference; scope and main topic highlights of the conference

09:20-10:40 **SESSION 1**

Regulatory Processes in the Region

Current Regulatory Landscape, Initiatives and Regulatory Practice with Registration
HA/Subject Matter Experts invited

- Algeria
- Morocco
- Tunisia

Current Practices in the EU
European Regulatory Agency speaker invited

10:40-11:10 **REFRESHMENT BREAK**

11:10-12:50 **SESSION 1 CONTINUED**

Regulatory Processes in the Region

Regulatory Convergence, Harmonisation and International Cooperation
Subject Matter Expert from Europe invited
HA/Subject Matter Experts from the Maghreb Region invited

Industry Perspective on Global Life-cycle Management
Industry representative invited

Panel Discussion with all speakers in session 1

12:50–14:00 **LUNCH BREAK**

14:00-15:10 **SESSION 2**

Biosimilars

Overview: Guidelines, Manufacturing and CMC Processes
Subject Matter Experts invited

Quality Requirements & Assessment
Industry representative invited

Panel Discussion with all speakers in session 2, HA/Subject Matter Experts from the Maghreb Region and industry representative

15:10-15:40 **REFRESHMENT BREAK**

15:40-16:40 **SESSION 3**

Over the Counter Products: Status and registration

Classification, Advantages and Regulatory Pathways
HA/Subject Matter Expert from the Maghreb Region invited

Non-prescription Medicines in Europe: Regulatory framework
Industry representative invited

Questions & Answers

16:40-18:10 **SESSION 4**

Data Exclusivity and Intellectual Property

Actual Landscape and Challenges
HA/Subject Matter Expert from the Maghreb Region invited

EU Perspective
Subject Matter Expert from Europe invited

Industry Perspective
Industry representative invited

Panel Discussion with all speakers in session 4 and HA/Subject Matter Experts from the Maghreb Region
Additional Subject Matter Expert invited

18:10-18:15 **CLOSING REMARKS OF DAY 1**

18:15-19:15 **NETWORKING RECEPTION**

Adjacent Event: **12-13 February 2015**
2 day training course on

ICH Endorsed Pharmacovigilance

This training course focuses on ICH international standards related to pharmacovigilance (ICH E2 series). It covers both pre- and post-authorisation pharmacovigilance standards and practical implementation of the ICH guidelines in the international environment. The course includes case studies and examples of challenges and practical solutions. The course is prepared and taught by experienced pharmacovigilance experts. Participants will gain solid knowledge and a clear understanding of international approaches to drug safety pharmacovigilance, as well as the best practices for successful local and global regulatory applications.

Key Topics include:

- ICH E2A Pre-marketing safety
- ICH E2D Definitions and standards for expedited reporting (post–approval)
- ICH E2B (both pre-and post-authorisation) Data elements for electronic submission
- ICH E2F Development Safety Update Report
- ICH E2C (R2) Periodic Benefit Risk Evaluation Report (PBRER) Guideline
- ICH E2E Pharmacovigilance planning

09:00-09:10 **SCOPE OF DAY TWO**

09:10–10:30 **SESSION 5**

Clinical Trials

Clinical Trials Regulations, Regulatory Practice and Role of Ethics Committees in the Region
HA/Subject Matter Experts from the Maghreb Region invited
- Algeria
- Morocco
- Tunisia

Clinical Trials in the Region: Benefit & opportunities of early access to innovative products
CRO Subject Matter Expert from the Maghreb Region invited

Bioequivalence Studies – Algerian Experiences
Industry representative invited

Panel Discussion with all speakers in session 5

10:30-11:00 **REFRESHMENT BREAK**

11:00-12:45 **SESSION 6**

Pharmacovigilance

Post-marketing Surveillance, Life-cycle Management, Adverse Drug Reaction Reporting and Registries in the Region
HA/Subject Matter Experts from the Maghreb Region invited
- Algeria
- Morocco
- Tunisia

International Pharmacovigilance Guidelines and Global Best Practices
Subject Matter Expert invited

Perspective from National Pharmacovigilance centre on Post-marketing
Subject Matter Expert invited

Panel discussion including case studies and examples of safety incidents handling
All speakers in session 6 and industry representative

12:45–14:00 **LUNCH BREAK**

14:00–15:30 **SESSION 7**

Falsified Medicines and Anti-bribery Laws

Actual Landscape, Challenges and Regional Measurements
HA/Subject Matter Experts from
- Algeria
- Morocco
- Tunisia

International Perspective and Global Best Practices
HA/Subject Matter Expert invited

Panel discussion with all session speakers

15:30-16:00 **REFRESHMENT BREAK**

16:00-17:30 **SESSION 8**

Capacity Building and the Way Forward

Building Partnerships, Expertise and Capacity
HA/Subject Matter Experts from the Maghreb Region invited
- Algeria
- Morocco
- Tunisia

Panel discussion on Improving Access to Medicines and Therapies in the Region and the way forward

with HA/Subject Matter Experts from session 8, Government representative, European Regulatory Speaker and Industry representatives

17:30-17:45 **CLOSING REMARKS**

17:45 **END OF CONFERENCE**

REGISTRATION FORM

1st Maghreb Regulatory Conference and ICH Endorsed Training Course on Pharmacovigilance
10-13 February 2015, Hilton Alger, Algiers, Algeria

ID# 15114
ID# 15570

SEND YOUR COMPLETED REGISTRATION FORM TO CREATIVE TRENDS, E-mail: info@creativetrendsgh.com, mabel@creativetrendsgh.com

Registration fees* **	Fees*
1st Maghreb Regulatory Conference, 10-11 February 2015	
Industry International	1'500 EUR ❑
Industry Maghreb	1'150 EUR ❑
Government / Academia / Charitable / Not-for-profit - International	550.00 EUR ❑
Government / Academia / Charitable / Not-for-profit - Maghreb	350.00 EUR ❑
Adjacent Event* **	
ICH endorsed training course on PhV, 12-13 February 2015	
Industry International	990.00 EUR ❑
Industry Maghreb	790.00 EUR ❑
Government / Academia / Charitable / Not-for-profit International and Maghreb	250.00 EUR ❑

***ALL FEES ARE SUBJECT TO THE APPLICABLE ALGERIAN VAT**
**** EUR 25.00 FEE WILL BE ADDED TO ONSITE REGISTRATIONS**
PAYMENT OF REGISTRATION FEES IS DUE 14 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE CONFERENCE.

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

LAST NAME

FIRST NAME

COMPANY

JOB TITLE

STREET ADDRESS / P.O. BOX

POSTAL CODE

CITY

COUNTRY

TELEPHONE

FAX

E-MAIL

VAT Number (Required for Algerian participants)

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

ACCOMMODATION RESERVATION

A limited number of rooms have been blocked at the Hilton Alger, Algiers, Algeria (conference venue) from 10 to 13 February 2015 at the rate of EUR 245.00 per single room per night incl. breakfast, VAT and tourist tax.

Important: The room rate is available until 31 December 2014 or until the group block is sold-out, whichever comes first.

Cancellation policy: No show charges to apply without a notification from the hotel. Bookings cancelled after 31 December 2014 will be charged 100% cancellation fee.

The hotel room must be paid in full when making the reservation.

❑ SINGLE ROOM

❑ DOUBLE ROOM (sharing with)_____

Arrival date: Departure date:

Notice (allergies, disabilities etc.):

PAYMENT METHODS

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Bank transfer:
Payments should be made in EUR to:
Ghana International Bank, 69 Cheapside, P.O. Box 77, London EC2P 2BB, SWIFT Code GHIBGB2L
For the account of: Guaranty Trust Bank (Ghana) Ltd, SWIFT BIC Code GTBIGHAC,
Account Nr. 10118803, EUR IBAN GB09GHIB70061310118803
For further credit of: Creative Trends, Account Nr. 204 1033 41 430
Payments should include your name, company, Meeting ID#15114 as well as the invoice number to ensure correct allocation of your payment.

PAYMENTS MUST BE NET OF ALL CHARGES AND RECIPIENT BANK CHARGES MUST BE DONE BY THE PAYER (EUR 15.00).

Credit cards: 5% charge will be added when paying by credit card.
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.

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CANCELLATION POLICY

Cancellations must be made in writing and be received at the Creative Trends office five (5) working days prior to the conference start.

Cancellations are subject to an administrative fee:
Industry EUR 200.00
Government / Academia / Charitable / Not-for-profit EUR 100.00
Five (5) working days before the conference start registrations are non-refundable.

Registrants who do not cancel five working days prior to the conference start date and do not attend, will be responsible for the full registration fee. Creative Trends reserves the right to alter the venue and dates if necessary. If the conference is cancelled, Creative Trends is not responsible for airfare, hotel or other costs incurred by registrants. Registrants 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. Please notify the Creative Trends office of any such substitutions as soon as possible.

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