1st Maghreb Regulatory Conference

Event #14113
24-25 November 2014
Algiers, Algeria

Programme Committee & Programme Advisors

This conference is being developed with key contributions by Programme Committee members representing pharmaceutical companies and associations as well as Programme Advisors from ministries of health in the Maghreb Region, representing:

- Algeria
- Morocco
- Tunisia
- Libya

EXHIBITION OPPORTUNITIES

For more details, please contact Roxann Schumacher, Exhibits Manger 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.

Topics will include

- Regulatory processes in the region
- Pre-marketing
- Post-marketing
- Intellectual property/data exclusivity
- Additional topics to be identified

Who will attend

The conference offers the opportunity for key stakeholders active in the Maghreb 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.

Representatives of health authorities, 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.

Simultaneous translation in French and English will be available.

Adjacent Event: 26-27 November 2014

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

- 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

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MONDAY, 24 NOVEMBER 2014
DAY ONE

08:00-09:00 Registration and Welcome Coffee

09:00-09:30 Opening Session
Welcome

Key note address

Introduction to the conference; scope and main topic highlights of the conference

09:30-11:00 Session 1
Current Regulatory Landscape and Initiatives in the Maghreb Region

Regulatory Practice with Registration

Industry Perspective

11:00-11:30 Refreshment Break & Networking with Participants and Exhibitors

11:30-13:00 Session 1 continued
Regulatory Convergence and Harmonisation - Why and how?

International Cooperation: The ideas of ICH and PIC/S

Panel Discussion

13:00-14:30 Lunch & Networking with Participants and Exhibitors

14:30-15:30 Session 2: Clinical Trials
Why Develop Common Ground and Clinical Trials in the Maghreb Region?

Experiences with Clinical Trials in the Maghreb Region

Patient Safety in Clinical Trials: Current practice and possibilities for the future

Role of Ethics Committee

How to Develop Common Ground and Clinical Trials in the Maghreb Region?

15:30-16:00 Refreshment Break & Networking with Participants and Exhibitors

16:00-17:00 Session 3: Biosimilars

17:00-17:30 Recap of Day One

17:30-19:00 Networking Reception in Exhibition Area

19:00 End of Day One

TUESDAY, 25 NOVEMBER 2014
DAY TWO

09:00-09:15 Introduction to Day Two

09:15-10:30 Session 4: Pharmacovigilance
Post-marketing Surveillance and Life-cycle Management: State of art in the region

Adverse Reactions Reporting and Registries: How to be most efficient?

Case Studies and Examples of Safety Incidents and their Handling

10:30-11:00 Refreshment Break & Networking with Participants and Exhibitors

11:00-12:00 Session 4 continued
How to Advance Pharmacovigilance Guidelines to include Global Best Practices?

12:00-13:30 Lunch & Networking with Participants and Exhibitors

13:30-14:15 Session 5
Data Exclusivity and Intellectual Property: What are the challenges?

14:15-15:00 Session 6: OTC status

Non-drug registration

15:00-15:30 Refreshment Break & Networking with Participants and Exhibitors

15:30-16:45 Session 7
How to Advance a Common Strategy to Support the Development of Talent and Human Resources in the Region?

Building partnerships, expertise and capacity

Improving Access to Medicines and Therapies in the region: The way forward

16:45-17:15 Closing Session: Conference Summary

17:15 End of Conference

Exhibit at this Conference

This DIA conference gives the opportunity to a limited number of organisations to present themselves to the key stakeholders in the field through mini-booths on a small and intimate exhibition space.

Exhibitors are granted a unique opportunity to meet attendees before and after sessions and during all breaks. As there are only a very limited number of booths available, high visibility can be guaranteed. The mini-booths will be positioned to fit naturally into the flow of conference traffic, so the opportunities to engage with attendees are ensured.

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

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 interdisciplinary 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 headquartered in Washington, DC, USA with the European, Middle East & African office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

About Algiers

Sometimes nicknamed El-Behdja or alternatively Alger la Blanche ("Algiers the White") for the glistening white of its buildings as seen rising up from the sea, Algiers is situated on the west side of a bay of the Mediterranean Sea. The modern part of the city is built on the level ground by the seashore; the old part, the ancient city of the deys, climbs the steep hill behind the modern town and is crowned by the casbah or citadel, 122 meters above the sea.

DIA EUROPE, MIDDLE EAST & AFRICA CONFERENCES & WORKSHOPS 2014

- **Achieving Improved Regulatory Efficiency within the current Framework: Lessons from the Escher Project – jointly organised by DIA and TOPRA**
  18 September 2014 | Brussels, Belgium
- **8th Annual European Medical Information and Communication Conference and Exhibition**
  23-24 September 2014 | London, United Kingdom | ID 14103
- **Clinical Trials Workshop I – Translating the New Clinical Trials Regulation into Practice**
  23-24 September 2014 | London, United Kingdom | ID 14111
- **Clinical Trials Workshop II – Translating the New Transparency Requirements into Practice**
  24-25 September 2014 | London, United Kingdom | ID 14116
- **Joint DIA/FIP European Workshop Biorelevant Performance Testing of Orally Administered Dosage Forms**
  24-25 September 2014 | Amsterdam, the Netherlands | ID14109
- **EFGCP/DIA/EMA Annual Conference on Better Medicines for Children – Exploring ways to enhance collaboration between key players**
  30 September – 1 October 2014, EMA Headquarters, London, United Kingdom
- **Joint DIA/ICOS Conference on Cardiac Toxicity Resulting from Cancer Chemotherapy: Strategies for Early Detection, Risk Mitigation and Clinical Prevention and Exhibition**
  9-10 October 2014 | Prague, Czech Republic | ID14108
- **4th African Regulatory Conference and Exhibition**
  22-23 October 2014 | Dakar, Senegal | ID 14105
- **Workshop on HTA and Access to Medicines Status and Future**
  End October 2014 | location to be confirmed | ID14102
- **Joint DIA/AEMPS Statistics Workshop**
  10-11 November 2014 | Barcelona, Spain | ID 14107
- **Maghreb Regulatory Conference and Exhibition**
  November 2014 | Algiers, Algeria | ID 14113
- **ISPE/DIA Workshop on Computer Science Compliance "Maintain Data Integrity to Reduce Risk for the Patient"**
  6-7 November 2014 | Basel, Switzerland | ID 14112
- **15th Conference on European Electronic Document Management (eDM) and Exhibition**
  1-3 December 2014 | Berlin, Germany | ID 14110
- **Biosimilars Conference**
  2-3 December 2014 | Berlin, Germany | ID 14115
- **27th Annual EuroMeeting and Exhibition**
  13-15 April 2015 | Paris, France | ID 15101
- **8th Annual Clinical Forum and Exhibition**
  14-15 April 2015 | Paris, France | ID 15103

For more information and a complete listing of all DIA conferences and training courses, please visit:
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Call DIA Europe on +41 61 225 51 51 or email: diaeurope@diaeurope.org