DIA

1st Regional Conference on Regulatory Harmonisation

27-28 February 2018 | Casablanca, Morocco

PROGRAMME COMMITTEE

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NEMA Region (Near East, Maghreb & Africa),
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Janis Bernat, Director, Biotherapeutics & Scientific Affairs, IFPMA, Switzerland

Bouchra Essaoui, Drug Regulatory Affairs Head, Novartis Pharma, Morocco

Oumkaltoum Lahlou, Head of Regulatory Affairs North & West Africa, Merck, Morocco

Overview

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

The 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 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, 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.

Key Topics

- Regulatory processes and good Regulatory practices in the Region
- Pre-marketing
- Post-marketing
- Biosimilars
- Patient Access
- Safety and Pharmacovigilance Management
- Life cycle management
- Non-prescription medicines

Who Will Attend

- Representatives from health authorities
- Professionals in
  - Regulatory affairs
  - Quality assurance
  - Clinical
  - Safety
  - Research & Development
- And other professionals involved in or interested in the aspects surrounding
  - Registration and life cycle management of medicinal products and
  - Regulatory convergence

Find out more at
DIAglobal.org/RegionReg

DAY ONE I TUESDAY, 27 FEBRUARY

08:00 REGISTRATION AND WELCOME COFFEE (FOYER)

09:00 SESSION 1

CURRENT REGULATORY PROCESSES IN THE REGION

Session Chairs: **Myriam Sedrati**, Regulatory Affairs Director North and West Africa, Merck Sharp & Dohme, Morocco
Oumkaltoum Lahlou, Head of Regulatory Affairs North & West Africa, Merck, Morocco

The focus of the session is to share experience, lessons learnt and best practices related to tremendous progress noticed these last two years in different regulations. The aim is to discuss ways of improving access to medicines and therapies for the citizens and patients.

Morocco: New Decree Related to Marketing Authorization: Implementation in February 2016
Omar Bouazza, Director, Direction du Médicament et de la Pharmacie, Morocco

Meriem El Beghdadi, Head of Visas, Homologations and Authorizations, Direction du Médicament et de la Pharmacie, Morocco

Tunisia: New Guidelines Related To Registrations and Variations Implemented in May 2016
Ines Fradi, Head of Pharmacy and Medicines, Ministry of Health, Tunisia

Algeria: Overview of 2017's Major Reforms in Regulatory Environment
Yacine Sellam, Adviser to Ministry of Health, Assistant General Manager in charge of Vaccines & Sera Development Projects, Pasteur Institute, Algeria

- Regulatory Policies Reform as part of "Vision 2020"
- New Independent Drug Regulatory Agency (ANPP)
- PhRMA Special 301 Submission 2017
- Regulatory reform in the new Health Law

10:30 COFFEE BREAK (FOYER)

11:00 SESSION 2

WAY FORWARD: GOOD REGULATORY PRACTICE'S ROLE IN ACCELERATING PATIENTS ACCESS TO MEDICINES

Session Chair: **Nevena Miletic**, Regulatory Policy Lead – EEMEA (Eastern Europe, Middle East & Africa), F. Hoffmann-La Roche Ltd, Switzerland

Regulators worldwide are developing various pathways to support speeding up drug development and accelerating access to medicines. There are new initiatives arising across the globe, including also development of new WHO guidance and recommendations. Reliance and work-sharing among regulators is heavily encouraged, allowing at the same time their resources and efforts to focus on other important areas in public health that cannot be streamlined.

This session will explore recent developments in the global regulatory landscape, emphasizing on the need for establishing appropriate regulatory pathways for accelerating access to innovation, as well as provide insights into specific region's/countries' experiences.

Global Update on Good Regulatory Practices with the Focus on Facilitated Regulatory Pathways
Samvel Azatyan, Group Lead, Capacity Building, Regulatory Systems Strengthening, World Health Organization, Switzerland *(participating remotely)*

Industry Perspective on Reliance & Expedited Pathways in Emerging Markets
Fabio Bisordi, Global Head International Regulatory Policy, F. Hoffmann-La Roche, Switzerland, (on behalf of IFPMA/EFPIA)

Continental Progress Update on African Medicines Regulatory Harmonization
Paul Tanui, Senior Programme Officer - Technical Support, AMRH Programme, NEPAD, South Africa

Panel discussion & conclusion with all speakers from sessions 1-2

12:30 LUNCH (BRASSERIE LA TOUR)

13:30 SESSION 3

BIOTHERAPEUTIC & BIOSIMILARS

Session Chairs: **Dounia El Maimouni**, Regulatory Affairs Manager NEMA Region (Near East, Maghreb & Africa), JANSSEN (Johnson & Johnson Company), France
Anne Grandjacquot, Sanofi, Head of Regulatory Affairs Africa Region, France

This session will focus on current challenges in biotherapeutics/biosimilars from development to the importance of setting specific regulatory framework. An overview of the existing guidelines and a status of the progress in Maghreb countries will be shared with attendees.

Existing Guidelines
Klara Tiitso, Scientific Administrator, European Medicines Agency, European Union *(participating remotely)*

Algeria: Update on Regulation & Lessons Learnt from Local Experience with Biosimilars
Yacine Sellam, Adviser to Ministry of Health, Assistant General Manager in charge of Vaccines & Sera Development Projects, Pasteur Institute, Algeria

- Biosimilars market landscape in Algeria.
- Examples of local manufacturing projects.
- Uncertainties surrounding biosimilars.
- Updates on biosimilars specific regulations

Morocco: Update on Regulation, Assessment of Biotherapeutics & Biosimilars
Omar Bouazza, Director, Direction du Médicament et de la Pharmacie, Morocco
Mhammed Mouani, Deputy Head of the Biological Assays Laboratory, Laboratoire National de Contrôle du Médicament, Morocco
Wiame Lakhlili, Director, Pharmacist Assessor, Laboratoire National de Contrôle du Médicament, Morocco
Rachida Soulaymani-Bencheikh, Director, Centre Anti Poison et de Pharmacovigilance du Maroc, WHO Collaborative Center, Morocco

Tunisia : Update on Regulation & Lessons Learned from Local Experience with Biosimilars
Sameh Ben Tkhayat, Expert Coordinator in Biosimilar Committee, DPM, Tunisia

Focus on Global Regulatory Pathways and Challenges for Biosimilars
Rebecca Lumsden, Director – EM Regulatory Policy, Pfizer, United Kingdom (on behalf of IFPMA)

15:00 REFRESHMENT BREAK (FOYER)

15:30 SESSION 4

SAFETY & PHARMACOVIGILANCE

Session Chairs: **Myriam Sedrati**, Regulatory Affairs Director North and West Africa, Merck Sharp & Dohme, Morocco
Bouchra Essaoui, Drug Regulatory Affairs Head, Novartis Pharma, Morocco

Post Marketing Surveillance- Adverse Drug Reaction – Reporting and Registries in the Region.

The aim of this session is to provide a platform for experience sharing on Pharmacovigilance and Post Marketing Surveillance activities addressing patient safety.

Pharmacovigilance: Challenges in Africa
Rachida Soulaymani-Bencheikh, Director, Centre Anti Poison et de Pharmacovigilance du Maroc, WHO Collaborative Center, Morocco

Pharmacovigilance Guidelines in Tunisia
Riadh Daghfous, Head of Pharmacovigilance, Centre National de Pharmacovigilance, Tunisia

Global Pharmacovigilance Status
Djoubeir Makhlouf, Regional Head of International Pharmacovigilance EEMEA (Eastern Europe, Middle East & Africa), F. Hoffmann-La Roche Ltd., Switzerland

Use of Mobile Technologies in Different Settings
Mick Foy, Head of Pharmacovigilance Strategy, Vigilance Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

17:00 NETWORKING RECEPTION (FOYER)

18:00 END OF DAY 1

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As a benefit of your registration, presentations are made available on the DIA website.

To access presentations, go to www.diaglobal.org and click on Sign in at the very top. Once you have successfully logged in, click on Welcome on the top, then My Account and on the left, go to My Presentations
No paper copies of the presentations will be provided.

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.

Certificate of Attendance

A Certificate of Attendance will be distributed to you at the end of the conference on Wednesday, 28 February. Alternatively it can also be e-mailed to you after the event. Please note certification requires full attendance to the event

Evaluation

Your comments and views on the content and organisation of the event are highly valued. The English version of the evaluation form will be available online at this link: http://bit.ly/2EJF8uf. The French version of the evaluation form is available at this link: http://bit.ly/2GwPPww

Disclosure Policy

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.

DAY TWO I WEDNESDAY, 28 FEBRUARY

08:30 WELCOME COFFEE (FOYER)

09:00 SESSION 5

LIFE CYCLE MANAGEMENT

Session Chairs: **Hany Gamal**, Drug Regulatory Affairs Head, Middle East, Turkey and Africa Region, Boehringer-Ingelheim, United Arab Emirates
Nevena Miletic, Regulatory Policy Lead – EEMEA (Eastern Europe, Middle East & Africa), F. Hoffmann-La Roche Ltd, Switzerland

The focus of this session is to discuss the 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.
Key concepts, introduced by ICH and WHO, can be leveraged globally to drive convergence regarding regulatory requirements for post-approval changes.
The session will explore the current landscape for PACs globally and in the region, the challenges being faced and recommendations for improvement.

Management of Post-Approval Changes: An Industrial Challenge
Catherine Gulphe, Regulatory Affairs Manager - CMC & Devices, Sanofi, France

New Guidelines on Variation in Morocco
Omar Bouazza, Director, Direction du Médicament et de la Pharmacie, Morocco
Imane Haouach, Head of Quality Assurance, Laboratoire National de Contrôle du Médicament, Morocco

Review of Variations Guidelines in Tunisia
Ines Fradi, Head of Pharmacy and Medicines, Ministry of Health, Tunisia

Global Convergence in Lifecycle Management (ICH Q12 & WHO Guideline)
Kowid Ho, Pharma Technical Regulatory Policy, F. Hoffmann-La Roche, Switzerland

Panel Discussion with Q&A
Moderator: **Dounia El Maimouni**, Regulatory Affairs Manager NEMA Region (Near East, Maghreb & Africa), JANSSEN (Johnson & Johnson Company), France

10:30 REFRESHMENT BREAK (FOYER)

11:00 SESSION 6

NON-PRESCRIPTION MEDICINES: STATUS AND REGISTRATION

Session Chair: **Anne Grandjacquot**, Sanofi, Head of Regulatory Affairs Africa Region, France
Kamal Ubaysi, Chairman of the Middle East North Africa Self Medication Industry and Global Head of Integration projects, Sanofi, France

This session will focus on non-prescription medicines, the status in the region and recent developments.

Pharmacies as a gateway to care - the role of OTC medication
Ema Paulino, Interim CEO, International Pharmaceutical Federation (FIP), The Netherlands

Update on the Middle East OTC Status
Mearal Hussein, Interim CEO, Head of Regulatory Middle East, GSK Consumer Health, Egypt (on behalf of IFPMA)

Panel Discussion with Q&A on Self-Medication
Invited Panellists:
Yacine Sellam, Adviser to Ministry of Health, Assistant General Manager in charge of Vaccines & Sera Development Projects, Pasteur Institute, Algeria
Lotfi Benbahmed, President, National Order of Pharmacists of Algeria, Algeria
Kamal Ubaysi, Chairman of the Middle East North Africa Self Medication Industry and Global Head of Integration projects, Sanofi, France
Saadia Motaouakkil, President, President of Regional Council of Pharmacists of South, Morocco
Mustapha Laaroussi, President, National Order of Pharmacists, Tunisia

12:30 LUNCH (BRASSERIE LA TOUR)

13:30 FINAL PANEL DISCUSSION: KEY TAKE AWAY

Session Chair: **Dounia El Maimouni**, Regulatory Affairs Manager NEMA Region (Near East, Maghreb & Africa), JANSSEN (Johnson & Johnson Company), France

Nevena Miletic, Regulatory Policy Lead – EEMEA (Eastern Europe, Middle East & Africa), F. Hoffmann-La Roche Ltd, Switzerland

Omar Bouazza, Director, Direction du Médicament et de la Pharmacie, Morocco

Yacine Sellam, Adviser to Ministry of Health, Assistant General Manager in charge of Vaccines & Sera Development Projects, Pasteur Institute, Algeria

Paul Tanui, Senior Programme Officer - Technical Support, AMRH Programme, NEPAD, South Africa

15:00 END OF THE CONFERENCE

15:00-15:30 REFRESHMENT BREAK (FOYER)

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

SwAPP Swiss Association of Pharmaceutical Professionals

REGISTRATION FORM | ID# 18114T1

1st Regional Conference on Regulatory Harmonisation
27-28 February 2018 | Hotel Sofitel, Casablanca, Marocco

Registration form for Moroccan citizens.

CATEGORY	Member *	Non-Member*
Industry	€ 950.00 ❑	€ 950.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Please contact DIA in Basel for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

20% Moroccan VAT will be added to the fees (please see invoice confirmation for details of payment)

10% withholding Tax to be paid directly to the authorities. Please send a confirmation of this payment to DIA.

Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

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- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CET.

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