DIA

# North Africa Regulatory Conference

The collaborative platform for connecting Regulatory experts in North Africa

16-17 October 2019 | Royal Maxim Palace Kempinski, Cairo, Egypt

## PROGRAMME COMMITTEE

**Hala Abu-Ghazalah**
Head of Regulatory Affairs Africa and Middle East, GRA- International, Pfizer Biopharmaceuticals Group, United Arab Emirates

**Sarah Adam**
Head of Regulatory Science Policy - Africa, IFPMA, Switzerland

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

**Samia Beddek**
Head of Regulatory Affairs/ Qualified Person, Sanofi, Algeria

**Sanaa Cherradi**
Regulatory Affairs Head MTL, Novartis Pharma Maroc, Morocco

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

**Smail Nahmed**
Regulatory Affairs Manager North and West Africa, Merck, Morocco

**Jasmin Badcock**
Associate Director, EMEA Emerging Markets Regulatory Liaison, Johnson & Johnson, UK

**Kawaldip Sehmi**
CEO, International Alliance Of Patients' Organizations (IAPO), UK

**Myriam Sedrati**
Regulatory Affairs Director North and West Africa, MSD, Morocco

## Overview

The aim of the North Africa 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 Region.

North Africa 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 different 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.

## Who Will Attend

The conference is directed at key stakeholders that are active or 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:

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

## Key Topics

- Regulatory System Strengthening
- Good Regulatory Practices in the North Africa Region and Beyond
- Biotherapeutic Products and Biosimilars
- Medical Devices and in-vitro diagnostics
- Safety and Pharmacovigilance
- Sub-standards and Falsified Medicines
- Innovative Approaches in Medicine Developments

# DAY ONE | WEDNESDAY, 16 OCTOBER 2019

08:00 REGISTRATION

08:45 OPENING REMARKS

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

09:00 SESSION 1

## REGULATORY SYSTEM STRENGTHENING: A GLOBAL PERSPECTIVE

**Session Chairs:**

**Nevena Miletic,** Regulatory Policy Lead – EEMEA (Eastern Europe, Middle East & Africa), F. Hoffmann-La Roche Ltd, Switzerland
**Jasmin Badcock,** Associate Director, EMEA Emerging Markets Regulatory Liaison, Johnson & Johnson, United Kingdom

**Regulatory System Strengthening: WHO Activities**

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

- Global Benchmarking Tool
- Global Coalition of Partners
- Collaborative Registration Procedures

**CIRS: Good Reliance Practices**

**Remote Presentation: Neil McAuslane,** Director, Center for Innovation in Regulatory Science (CIRS), UK

**Collaboration, Convergence & Work Sharing in African context, based on reliance**

- Regulatory Harmonisation for all products & AMRH updates: 10 years anniversary

**Remote Presentation: Margareth Ndomondo-Sigonda,** Head of Health Programs at the African Union-New Partnership, Africa's Development (NEPAD), South Africa

- Collaboration. Convergence and Work Sharing in African Context. ZAZIBONA

  **Tariro Makamure Sithole,** Chief Regulatory Officer Evaluations and Registration, Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwe

**Industry perspective on Reliance abstract**
**Paul Dearden**, Senior Director, Global Regulatory Policy, Biogen, UK

Panel Discussions with Q&A

10:30 COFFEE BREAK

11:00 SESSION 2

## GOOD REGULATORY PRACTICES IN THE NORTH AFRICA REGION AND BEYOND

**Session Chairs:**

**Smail Nahmed,** Regulatory Affairs Manager North and West Africa, Merck, Morocco
**Myriam Sedrati,** Regulatory Affairs Director North and West Africa, MSD, Morocco

**Good Regulatory Practices Guidelines: Current Status**
**Samvel Azatyan,** Group Lead, Regulatory Networks and Harmonization, World Health Organization (WHO), Switzerland

**Updates on the processes on the implementation of Good Regulatory Practices from:**

- Morocco
  **Haouach Imane,** Head of Quality Assurance, Laboratoire National De Contrôle Du Médicament, Morocco
- Tunisia
  **Wassila Ouerghi,** Head of Legal Affairs at the Legal Department, Ministry of Health, Tunisia

**Feedback on fast-tracking**
**Heba Nabil,** Head of Drug Registration Directorate, CAPA, Egypt

**Patients Perspective on Convergence and Reliance**
**Remote Presentation: Kawaldip Sehmi,** CEO, International Alliance Of Patients' Organizations (IAPO), UK

Panel Discussions with Q&A

12:30 LUNCH

14:00 SESSION 3:

## BIOTHERAPEUTIC PRODUCTS AND BIOSIMILARS

**Session Chairs:**
**Myriam Sedrati,** Regulatory Affairs Director North and West Africa, MSD, Morocco
**Susanne Ausborn,** Lead Technical Regulatory Policy Eastern Europe, Middle East, Africa at F. Hoffmann-La Roche, Switzerland

**WHO Guidelines**
**Remote Presentation: Hye-Na Kang,** Scientist, Technologies, Standards and Norms Team, Department of Essential Medicines and Health Products, World Health Organisation (WHO), Switzerland

**Patients' Perspective on Biosimilars**
**Remote Presentation: Kawaldip Sehmi,** CEO, International Alliance Of Patients' Organizations (IAPO), UK

**Updates from the Region:**
- Tunisia
  **Houda Ben Khedija,** Directeur de l'Inspection Pharmaceutique – Ministère de la santé publique, Tunisia

**Interchangeability and Extrapolation**
**Virginia Acha,** Executive Director, Global Regulatory Policy, MSD, UK

Panel Discussions with Q&A
Additional Panellist:
**Peter Pitts,** MERC 2019 Chair & President, Center for Medicine in the Public Interest, US

15:30 COFFEE BREAK

16:00 SESSION 4

## SAFETY AND PHARMACOVIGILANCE

**Session Chairs:**
**Rachida Soulaymani-Bencheikh,** Director, Centre Anti Poison et de Pharmacovigilance du Maroc, WHO Collaborative Center, Morocco
**Sean Burke,** EEMEA Regional Lead, Pharmacovigilance, MSD, UK

**WHO 3S Initiative: From Pilot to Programme – What Happens Beyond**
**Shanthi Pal,** Group Lead, Medicines Safety, Safety & Vigilance, World Health Organization, WHO, Switzerland

**North Africa updates on PV**

- **Tunisia**
  **Sarah Kastalli,** Centre National de Pharmacovigilance, Tunisia
- **Algeria**
  **Remote Presentation: Nadjat Loumi – Mededjel**, Directrice générale, Centre National de Pharmacovigilance & Matériovigilance, CNPM, Algeria
- **Morocco**
  **Rachida Soulaymani-Bencheikh,** Director, Centre Anti Poison et de Pharmacovigilance du Maroc, WHO Collaborative Center, Morocco

Panel Discussions with Q&A

17:30 END OF DAY ONE

## 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.

## 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 | THURSDAY, 17 OCTOBER 2019

09:00 SESSION 5

## MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

**Session Chairs:**
**Sanaa Cherradi,** Regulatory Affairs Head MTL, Novartis Pharma Maroc, Morocco
**Smail Nahmed,** Regulatory Affairs Manager North and West Africa, Merck, Morocco

**WHO Model Framework**
**Samvel Azatyan,** Group Lead, Regulatory Networks and Harmonization, World Health Organization (WHO), Switzerland

**Medical Devices Regulation in Morocco**
**Hanane Moul El Bab,** Pharmacist, Medical Device Department, Ministry of Health, Morocco

Panel Discussions with Q&A

10:30 COFFEE BREAK

11:00 SESSION 6

## SUB-STANDARDS AND FALSIFIED MEDICINES

**Session Chairs:**
**Adi Al Nuseirat,** Technical Officer, WHO EMRO, Egypt
**Sérgio Cavalheiro Filho,** Assistant Manager, Regulatory Affairs, IFPMA, Switzerland

**WHO Activities**
**Remote Presentation: Pernette Bourdillon-Esteve,** Intelligence Analyst, Safety and Vigilance Team, WHO, Switzerland

**Best practices sharing from Tunisia**
**Houda Ben Khedija,** Directeur de l'Inspection Pharmaceutique – Ministère de la santé publique, Tunisia

**Other examples: GS1**
**Ahmed ElKalla,** CEO, GS1, Egypt

Panel Discussions with Q&A
Additional Pannelists Invited

12:30 LUNCH

14:00 SESSION 7

## INNOVATIVE APPROACHES IN MEDICINE DEVELOPMENTS

**Session Chairs:**
**Hala Abu-Ghazalah,** Head of Regulatory Affairs Africa and Middle East, GRA- International, Pfizer Biopharmaceuticals Group, UAE
**Nevena Miletic,** Regulatory Policy Lead – EEMEA (Eastern Europe, Middle East & Africa), F. Hoffmann-La Roche Ltd, Switzerland

**Importance of Innovation for Patients - Patient Perspective**
**Remote Presentation: Kawaldip Sehmi,** CEO, International Alliance Of Patients' Organizations (IAPO), UK

**Regulatory Environment for Gene therapy**
**Remote Presentation: Keith Wonnacott,** Executive Director for Advanced Therapy Medicinal Products in Global Regulatory Affairs, Pfizer Biopharmaceuticals Group, USA

**RWE in regulatory decision making**
**Gracy Crane,** Senior Principal Data Scientist, RWD Policy, PHC Data Science, Hoffmann-La Roche Ltd, UK

**Digitalisation in Regulatory Systems: Industry Perspective**
**Rodrigo Palacios,** PTR Global Head for Business Systems, Regulatory Technology Policy Lead, F. Hoffmann-La Roche Ltd, Switzerland

Panel Discussions with Q&A

15:30 COFFEE BREAK

16:00 SESSION 8

**FINAL PANEL DISCUSSION: KEY TAKE AWAY**

**Session Chairs:**

**Nevena Miletic,** Regulatory Policy Lead – EEMEA (Eastern Europe, Middle East & Africa), F. Hoffmann-La Roche Ltd, Switzerland
**Myriam Sedrati,** Regulatory Affairs Director North and West Africa, MSD, Morocco

**Panellists:**

**Samvel Azatyan,** Group Lead, Regulatory Networks and Harmonization, World Health Organization (WHO), Switzerland
**Houda Ben Khedija,** Directeur de l'Inspection Pharmaceutique – Ministère de la santé publique, Tunisia
**Paul Dearden**, Senior Director, Global Regulatory Policy, Biogen, UK
**Haouach Imane,** Head of Quality Assurance, Laboratoire National De Contrôle Du Médicament, Morocco
**Rachida Soulaymani-Bencheikh,** Director, Centre Anti Poison et de Pharmacovigilance du Maroc, WHO Collaborative Center, Morocco

17:30 END OF THE CONFERENCE

## Group Rates

Register 3 individuals from the same company and receive a 50% discount for a 4th!

All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate. To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact
Zsofia.Molnar@diaglobal.org for a custom group rate.

## 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.