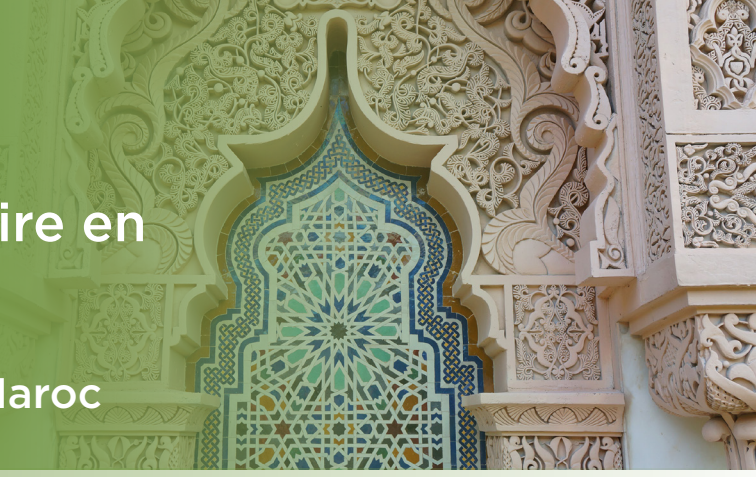
DIA

1ère Conférence Réglementaire en Afrique du Nord

27-28 Février 2018 | Casablanca, Maroc



JOUR 1 | MARDI, 27 FÉVRIER

08:00 ACCUEIL ET ENREGISTREMENT

09:00 SESSION 1

PROCÉDURES RÉGLEMENATIRES ACTUELLES DANS LA RÉGION

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

Maroc: Nouveau Décret lié à l'Autorisation de Mise sur le Marché: Implementation en Février 2016

Omar Bouazza, Director, Direction du Médicament et de la Pharmacie, Morocco
Meriem El Baghadi, Head of Visas, Homologations and Authorizations, Direction du Médicament et de la Pharmacie, Morocco

Tunisie: Nouvelles Directives liées aux Enregistrements et Variations Implementées en Mai 2016

Ines Fradi, Head of Pharmacy and Medicines, Ministry of Health, Tunisia

Algérie: Aperçu des Réformes Majeures sur l'Environnement Réglementaire en 2017

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

- Réforme des politiques de réglementation dans le cadre de "Vision 2020"
  - Nouvelle Agence Nationale des Produits Pharmaceutiques (ANPP)
  - PhRMA Special 301 Submission 2017
  - Réforme de la Réglementation dans la Nouvelle loi sur la Santé

10:30 PAUSE CAFÉ

11:00 SESSION 2

VOIE À SUIVRE: RÔLE DES BONNES PRATIQUES RÉGLEMENTAIRES POUR AMÉLIORER L'ACCÈS DES PATIENTS AUX MÉDICAMENTS

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

Mise à Jour Globale sur les Bonnes Pratiques Réglementaires

Samvel Azatyan, Group Lead, Capacity Building, Regulatory Systems Strengthening, World Health Organization, Switzerland

Perspective de l'Industrie sur les Recours et les Voies Accélérées dans les Marchés Emergents

Fabio Bisordi, Global Head International Regulatory Policy, F. Hoffmann-La Roche, Switzerland, (on behalf of IFPMA/EFPIA)

Mise à Jour des Progrès Continentaux sur l'Harmonisation de la Réglementation des Médicaments en Afrique

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

Table Ronde et Conclusion avec les Orateurs des Sessions 1-2

12:30 DÉJEUNER

13:30 SESSION 3

BIOTHERAPEUTIQUES & BIOSIMILAIRES

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

Directives Actuelles

Peter Richardson, Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), European Union (participating remotely)

Algerie: Mise à Jour sur la Réglementation et Expérience Locale avec les Biosimilaires

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

- Aperçu du Marché des Biosimilaires en Algérie
- Exemples de Projets de Fabrication Locaux
- Incertitudes Autour des Biosimilaires
- Mise à jour sur les Réglementations Spécifiques aux Biosimilaires

Maroc: Mise à Jour sur la Réglementation, l'Évaluation des Produits Biothérapeutiques et Biosimilaires

Omar Bouazza, Director, Direction du Médicament et de la Pharmacie
Mouani Mhamed, Head of LNCM, 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

Tunisie: Mise à Jour sur la Réglementation et Expérience Locale avec les Biosimilaires

Sameh Ben Tkhayat, Expert Coordinator in Biosimilar Committee, DPM, Tunisia

Focus sur les Voies Réglementaires Mondiales et Défis pour les Biosimilaires

Rebecca Lumsden, Director – EM Regulatory Policy, Pfizer, United Kingdom (on behalf of IFPMA)

Find out more at
DIAglobal.org/RegionReg

15:00 PAUSE CAFÉ

15:30 SESSION 4

SECURITÉ & 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

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

Directives de Pharmacovigilance en Tunisie
Riadh Daghfous, Head of Pharmacovigilance, Centre National de Pharmacovigilance, Tunisia

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

Utilisation des Technologies Mobiles dans Différents Contextes
Mick Foy, Group Manager to Head of Pharmacovigilance Strategy, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

17:00 APERITIF & NETWORKING

18:00 FIN DE LA JOURNÉE 1

JOUR 2| MERCREDI, 28 FÉVRIER

08:30 ACCUEIL

09:00 SESSION 5

GESTION DU CYCLE DE VIE DES PRODUITS

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

Convergence Mondiale dans la Gestion du Cycle de Vie (ICH Q12 & Directive WHO)
Kowid Ho, Pharma Technical Regulatory Policy, F. Hoffmann-La Roche, Switzerland

Nouvelles Directives sur la Variation au Maroc
Omar Bouazza, Director, Direction du Médicament et de la Pharmacie
Imane Haouach, Head of Quality Assurance, Laboratoire National de Contrôle du Médicament, Morocco

Examen des Directives sur la Variation en Tunisie
Ines Fradi, Head of Pharmacy and Medicines, Ministry of Health, Tunisia

Implementation desVariations
Catherine Gulphe, Regulatory Affairs Manager - CMC & Devices, Sanofi, France (on behalf of IFPMA)

Table Ronde avec Questions/Réponses

10:30 PAUSE CAFÉ

11:00 SESSION 6

MÉDICAMENTS SANS ORDONNANCE: STATUT ET ENREGISTREMENT

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

Mise à jour sur le statut OTC européen
Ema Paulino, Interim CEO, International Pharmaceutical Federation (FIP), The Netherlands

Mise à jour sur le statut OTC au Moyen-Orient
Mearal Hussein, Interim CEO, Head of Regulatory Middle East, GSK Consumer Health, Egypt (on behalf of IFPMA)

Table Ronde avec Questions/Réponses sur l'Automédication

Intervenants invités:
Ines Fradi, Head of Pharmacy and Medicines, Ministry of Health, Tunisia
Lotfi Benbahmed, President, National Order of Pharmacists of Algeria, Algeria
Yacine Sellam, Adviser to Ministry of Health, Assistant General Manager in charge of Vaccines & Sera Development Projects, Pasteur Institute, Algeria
Kamal Ubaysi, Chairman of the Middle East North Africa Self Medication Industry and Global Head of Integration projects, Sanofi, France
Morocco Representative Invited

12:30 DÉJEUNER

13:30 TABLE RONDE FINALE : POINTS CLÉS À RETENIR

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
Samvel Azatyan, Group Lead, Capacity Building, Regulatory Systems Strengthening, World Health Organization, Switzerland
Yacine Sellam, Adviser to Ministry of Health, Assistant General Manager in charge of Vaccines & Sera Development Projects, Pasteur Institute, Algeria
Ines Fradi, Head of Pharmacy and Medicines, Ministry of Health, Tunisia
Paul Tanui, Senior Programme Officer - Technical Support, AMRH Programme, NEPAD, South Africa
EMA Representative Invited

15:00 CAFÉ

15:30 FIN DE LA CONFÉRENCE

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)

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Date	Signature

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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.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office in Basel of any such substitutions as soon as possible.

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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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