3rd African Regulatory Conference (ARC) - Partnering for earlier access to good quality medicines in Africa

Event #12105
3-4 May 2012 | La Palm Beach Hotel, Accra, Ghana

Conference Chair

Mr Fernand Sauer
Former Executive Director of the European Medicines Agency, EU

Programme Committee

Ms Maria Akinla, Amgen, UK
Ms Mercè Caturla, Janssen Pharmaceutical companies of Johnson & Johnson, Belgium
Ms Engela Dedwith, Pharmaceutical Regulatory Affairs Consulting, South Africa
Dr Muriel Delalleau, Sanofi, France
(IFPMA African Regulatory Network (ARN) Chairperson)
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Mr Salieu Jalloh, Novartis Pharma AG, Switzerland
Mr Igor Knežević, Bayer Pharma AG, Germany
Mr Robert Lebeda, Eli Lilly, Austria
Ms Sharmila Parsotam, Pfizer Ltd, UK
Ms Gina Partridge, Abbott Laboratories, South Africa
Dr Dorcas Peta, Merck Sharp & Dohme, South Africa

Programme Advisors

Ms Delese Mimi Darko, Head, Drug Evaluation & Registration, Food and Drugs Board, Ghana
Pr Papa Amadou Diop, Director of Pharmacy & Laboratories, Ministry of Health & Prevention, Senegal
Dr Alexander Dodoo, Director, Centre for Tropical Clinical Pharmacology & Therapeutics, Ghana
Dr Rachelle Duncan, Director of Pharmacy & Medicines, Ministry of Health, Ivory Coast
Ms Monica Eimunjeze, Technical Assistant DG – NAFDAC, Nigeria
Ms Mandisa Hela, Registrar, Medicines Regulatory Agency, South Africa
Dr Ekopimo Ibia, Director, Global Medical & Regulatory Policy, Merck Research Laboratories, USA
Dr Yves Juillet, Senior Vice-President, Industrie Santé, France (DIA President)
Dr Odette Morin, Director, Regulatory & Scientific Affairs IFPMA, Switzerland
Mr Joseph Mthetwa, Senior Programme Manager for Health and Pharmaceuticals, SADC Secretariat, Botswana
Ms Margareth Ndomondo Sigonda, Pharmaceutical Coordinator NEPAD, South Africa
Pr Jean-Baptiste Nikiema, Director of Pharmacy, Medicines & Laboratories, Ministry of Health, Burkina Faso
Dr Safiatou Ouattara, Coordinator of Regulatory Harmonisation & Pharmaceutical Cooperation (CHRCP) UEMOA, Burkina Faso
Dr Lembit Rägo, Coordinator, Quality Assurance and Safety, Medicines, Department of Essential Medicines and Pharmaceutical, Policies, WHO, Switzerland
Dr Stanley Sonoiya, Health Coordinator, East African Community, Tanzania
Dr Emilienne Yissibi, Consultant, HPPN, OCEAC, Cameroon

Background

This is the third DIA African Regulatory Conference co-organised by the DIA and the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) Africa Regulatory Network (ARN) and in partnership with The Bill & Melinda Gates Foundation and The World Bank.

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 1.3 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

The ARN is an ad-hoc network of IFPMA. The association works in partnership with regulatory authorities and the pharmaceutical industry in Africa to encourage greater harmonisation of regulatory requirements on the African continent. This partnership enables patients to gain access to good quality medicines, including innovative medicines.

The African Regulatory Conference offers the opportunity for key stakeholders active on the continent, including representatives from Ministry of Health, local and multinational pharmaceutical companies, to meet to exchange views, discuss topics of interest and identify focus areas for ongoing efforts to increase patient access to new and improved medicines.

Objectives

Following the successful discussions held during the second African Regulatory Conference (ARC) in March 2010 in South Africa, the third ARC intends to build on progress made and to identify further opportunities for stakeholders to work together on the enhancement of healthcare on this continent.

This third African Regulatory Conference will focus on access to safe, effective, affordable, quality medicines for the continent. It will offer the opportunity to:

- Provide a platform to foster collaboration between African regulatory authorities and the pharmaceutical industry
- Share information and best practices
- Openly discuss issues facing African regulatory authorities and industry

Presentations will be given by regional and international speakers, including regulators. The format of the conference will include poster sessions and panel discussions to maximise contributions around the key topics.

Key Topics

- African Medicines Registration Harmonisation (AMRH)
- Management of variations
- Inspections/Good Manufacturing Practice (GMP)/Quality
- Counterfeits/Pharmacovigilance (PV)/Safety
- Transparency/Good regulatory practices
- Dossier evaluation (requirements, frills, samples etc.)
- Clinical Trials

Who Will Attend

Regulatory Affairs professionals, representatives of Health Authorities and other professionals involved in or interested in the aspects surrounding registration of medicinal products and regulatory harmonisation initiatives on the African continent.

Simultaneous translation will be available in French and English.

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 and certificates are available on request from the DIA registration desk.

Co-organised by:

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

DIA® www.diahome.org

In partnership with:

Bill & Melinda Gates foundation

THE WORLD BANK

WEDNESDAY | 2 MAY 2012

18:00-20:00 PRE-CONFERENCE REGISTRATION

DAY 1 – THURSDAY | 3 MAY 2012

07:30 REGISTRATION AND WELCOME COFFEE

08:30 Opening Session

Session Chair:
Mr Fernand Sauer, Former Executive Director of the European Medicines Agency, EU

IFPMA/ARN Introduction
Dr Odette Morin, Director, Regulatory & Scientific Affairs IFPMA, Switzerland
Dr Muriel Delalleau, Chairperson, IFPMA, ARN, Sanofi, France

08:40 **DIA Opening Remarks**
Dr Yves Juillet, President of DIA
Senior Vice-President, Industrie Santé, France
Dr Brigitte Franke-Bray, Director DIA Europe & Global Training Officer, Switzerland

08:50 **Welcome by Partners**
Dr Vincent I. Ahonkhai, Senior Regulatory Officer, Global Health Delivery, Bill & Melinda Gates Foundation (BMGF), USA
Dr Andreas Seiter, Senior Health Specialist, Pharmaceuticals, Health, Nutrition & Population, The World Bank, USA

09:00 **Introductory Remarks by Programme Chair**
Mr Fernand Sauer, Former Executive Director of the European Medicines Agency, EU

09:10 **Welcome Note**
Food and Drugs Board (FDB) Ghana representative invited

09:15 **Keynote Address**
Ministry of Health representative invited

09:30 Session 1

DIFFERENT PERSPECTIVE ON TRENDS IN REGULATORY ENVIRONMENTS

Session Chair:
Dr Lembit Rägo, Coordinator, Quality Assurance and Safety, Medicines, Department of Essential Medicines and Pharmaceutical, Policies, WHO, Switzerland

Session Opening Remarks and Introduction
Dr Lembit Rägo, Coordinator, Quality Assurance and Safety, Medicines, Department of Essential, Medicines and Pharmaceutical, Policies, WHO, Switzerland

09:55 **Agency Experience - Outside Africa**
Dr Huei-Xin Lou, Divisional Director, Health Sciences Authority (HSA), Singapore

10:20 **Regional Economic Community (REC) - African experience**
Mr Hiiti Sillo, Director General, Tanzania Food and Drugs Authority (TFDA), Tanzania

10:40 COFFEE BREAK

11:10 Session 1 continued

Zimbabwe Country Experience
Ms Gugu N. Mahlangu, Director-General, Medicines Control Authority, Zimbabwe

11:30 **Industry Experience (CTD)**
Dr Valérie Faillat Proux, Regulatory Director Access to Medicines, Sanofi, France

11:50 **Panel Discussion** (40 min)
With session speakers and Health Authority representatives

12:30 LUNCH

13:45 Session 2

PRODUCT QUALITY UPDATE

Session Chair:
Prof. Papa Amadou Diop, Director of Pharmacy & Laboratories, Ministry of Health & Prevention, Senegal

Supply Chain Integrity (Quality of API, FP) – EMA perspective
Mr Francisco Peñeranda, Head of Section of Parallel Distribution and Certificates, EMA, EU

14:05 **Supply Chain Integrity (Quality of API, FP) – US FDA perspective**
Government representative invited - via audio link

14:25 **Supply Chain Integrity (Quality of API, FP) – RSA Health Authority perspective**
Ms Mandisa Hela, Registrar, Medicines Regulatory Agency, South Africa

14:45 **Supply Chain Integrity (Quality of API, FP) – Industry perspective**
Dr Georges France, Head of QA & Compliance, EU region, Novartis Consumer Health, Switzerland

15:05 COFFEE BREAK

15:35 Session 2 continued

Counterfeits - The innovative use of cutting-edge technologies in the fight against counterfeit regulated products
Dr Paul Orhii, Director General NAFDAC, Nigeria

15:55 **Strategies against Counterfeits - Industry perspective**
Mr Carl Marsh, Director Regional Economic Security, Sanofi, Kenya

16:15 **Panel Discussion** (55 min)
With session speakers and Health Authority representatives

17:10 **Wrap-up by Programme Chair**
Mr Fernand Sauer, Former Executive Director of the European Medicines Agency, EU

17:25 END OF DAY ONE

19:30 NETWORKING DINNER
(If you would like to attend the networking dinner, please note that an additional fee will be charged. Please kindly register in advance.)

DAY 2 – FRIDAY | 4 MAY 2012

08:30 **Session 3**

REGULATORY HARMONISATION IN AFRICA

Session Chair:
Dr Vincent I. Ahonkhai, Senior Regulatory Officer, Global Health Delivery, Bill & Melissa Gates Foundation (BMGF), USA

NEPAD Update
Ms Margaret Ndomondo Sigonda, Pharmaceutical Coordinator, African Union-NEPAD, South Africa

08:55 **RECs Update**

EAC
Mr Hiiti Sillo, Director General, TFDA, Tanzania

SADC
Speaker invited

Economic Community of West African States (ECOWAS) - West African Health Organisation (WAHO)
ECOWAS representative invited

UEMOA
Dr Safiatou Ouattara, Coordinator of Regulatory Harmonisation & Pharmaceutical Cooperation, UEMOA, Burkina Faso

OCEAC, Health Organisation
Dr Emilienne Yissibi, Consultant, HPPN, OCEAC, Cameroon

10:10 **The African Vaccine Regulatory Forum (AVAREF)**
WHO Regional Office for Africa –
Republic of Congo representative invited

10:30 COFFEE BREAK

11:00 **Session 3 continued**

Economic Development and Harmonisation
Dr Andreas Seiter, Senior Health Specialist, Pharmaceuticals, Health, Nutrition & Population, The World Bank, USA

11:20 **Panel Discussion** (55 min)
With session speakers and Health Authority representatives

12:15 **Session 4**

PARTNERING TO STRENGTHEN AFRICA'S REGULATORY AND ETHICAL PROCESSES

Session Chair:
Prof. Dr Jean-Baptiste Nikiema, Director of Pharmacy and Medicines, MoH, DGPML, Burkina Faso

PQ and CPP as well as Q&A Document
Dr Lembit Rägo, Coordinator, Quality Assurance and Safety Medicines, Department of Essential Medicines and Pharmaceutical, Policies, WHO, Switzerland

12:40 **The Value of CPPs – Presentation from an issuing authority**
Mr Francisco Peñeranda, Head of Section of Parallel Distribution and Certificates, EMA, EU

13:00 LUNCH

14:00 **Session 4 continued**

The Value of CPPs – Presentation from industry perspective
Ms Elaine Whiting, Associate Director Regulatory Policy Intelligence and Labelling, AstraZeneca, UK

14:20 **Good Gx – GMP – Pharmaceutical Inspection Cooperation (PIC) Scheme HA**
Uganda representative invited

14:40 **Good Gx - GMP – Industry perspective**
Dr Georges France, Vice President Global Quality Strategy & Affiliates Quality & Compliance, Pfizer, UK

15:00 **Session 5**

SAFE MEDICINES: HOW TO FURTHER DEVELOP COMMON GROUND FOR PV AND CLINICAL TRIALS IN AFRICA?

Session Chair:
Ms Delese Mimi Darko, Head, Drug Evaluation & Registration, FDB, Ghana

Good Gx – PhV HA
Dr Emilienne Yissibi, Consultant HPPN, OCEAC, Cameroon

15:20 COFFEE BREAK

15:50 **Good Gx – PhV HA**
Dr Jayesh Pandit, Head of PV Department, Pharmacy and Poisons Board, Kenya

16:10 **Good Gx – PhV Industry**
Mr Osama Makram, Head of DSE Pharmacovigilance Operations, Novartis Pharma SAE, Egypt

16:30 **Good Gx - Clinical - How to protect patients in Africa? HA perspective**
Ms Delese Mimi Darko, Head, Drug Evaluation & Registration, FDB, Ghana

16:50 **Good Gx – Clinical Industry**
Addressing patient safety in clinical trials in Africa – Current practice and possibilities for the future
Dr Brian Woodfall, Vice President, Global Clinical Development, Johnson & Johnson, Belgium

17:10 **Panel Discussion**
With session speakers and Health Authority representatives

17:50 **Conference Wrap-up**
Mr Fernand Sauer, Former Executive Director of the European Medicines Agency, EU

18:05 END OF CONFERENCE

About DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal. The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

Travel Information:

Airport
Ghana's Accra International Airport is served by airlines from many world destinations and it is the country's premier airport. The airport is situated 10km (6 miles) north of Accra city centre.

Kotoka International Airport (KIA) http://www.ghanaairports.com.gh

Direct flights to and from Europe include: British Airways (London), KLM (Amsterdam), Lufthansa (Frankfurt) and Ghana Airways the national airline which flies to Rome, London and Dusseldorf.
For general information about Ghana, please visit: http://www.touringghana.com/regions/greateraccra_region.asp

Visas and other Entry Requirements
A valid passport (more than 6 months valid at the time of visa application) is mandatory. Visa requirements are subject to change and should be checked prior to travelling to Ghana, but at the time of writing visas are required by most nationalities and must be acquired in advance at a Ghanaian Embassy or High Commission.

ECOWAS countries are exempted from obtaining entry visas to Ghana.

Check with the Embassy of Ghana for the most updated information and location of Consular offices.

To obtain a tourist visa, please contact your local Embassy of Ghana.

For more information please visit: http://www.touringghana.com/visas.asp or http://www.ghana.gov.gh/index.php/ghana-visa-regulations

Health
Ghana is a malaria endemic country and non-immune visitors are strongly advised to take prophylaxis BEFORE arrival.

Yellow fever vaccination is mandatory and all visitors are encouraged to bring their International Immunisation Cards showing a valid Yellow Fever immunisation.

Conference Venue and Hotel Information:

The DIA has blocked a number of rooms at the:

La-Palm Royal Beach Hotel
Accra, Ghana
1 La Bypass, Accra
Ghana
http://www.gbhghana.net
Tel: + 233 (0) 302 215100 or + 233 (0) 302 215111
Fax: + 233 21771717

at the special rate of:
USD 230.00 for a single room, including breakfast, excluding local VAT

1. Cancellation Policy for rooms
a) A cancellation fee is applicable in the case of a booking being cancelled after 4pm a day prior to the arrival of the guest
b) A one day cancellation fee is applicable in the case of a non guaranteed becoming a NO SHOW. Notification of a cancellation must be made in writing by the guest.
c) Cut off date for room booking is 15 April 2012, reservations received after this date are subject to availability
2. In the event of a late checkout the following additional fees are applicable:
   12:00 – 16:00 $50
   16:00 – 20:00 $75
   After 20:00 nightly charge

Distance to airport: 10 km (complimentary Airport Shuttle will be offered by the hotel)

To make a hotel reservation, please complete the booking form under the following link:
http://www.diahome.org/product/28932/12105HotelBookingForm.pdf

All hotel booking forms should be forwarded to the local agent:

CREATIVE TRENDS (local agent handling hotel & transfer requests):
P.O. Box An 15605
Accra, Ghana
Tel: +233 244 21 41 65
info@creativetrendsgh.com

Important: Please complete your reservation by 15 April 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

Accra offers a wide range of hotel accommodation, please find below a list of additional hotels:

African Royal Beach Hotel
DTD 51 Beach Drive
Nungua, Greater Accra Region,
P.O.Box TN1009,
Teshie Nungua Estate,
Accra, Ghana
http://www.africanroyalbeachhotel.com
Tel: +233 – 302 71 11 11 - 8 Fax: +233 – 302 71 11 10
Email: info@africanroyalbeachhotel.com / info@dutchotel.com
Distance to La Palm Royal Beach Hotel: 100 m, 5 min walking
Distance to airport: 11 km

Labadi Beach Hotel
No. 1 La Bypass, Accra, Ghana.
Tel: +233 302 77 25 01/6 Fax: +233 302 77 25 20
http://www.labadibeach.com
Email: labadi@legacyhotels.com
Distance to La Palm Royal Beach Hotel: 0.6 km, 8 min walking
Distance to airport:10 km

Hotel Novotel Accra City Centre
Barnes Road
P.O. Box 12720
Accra, Ghana
http://www.accorhotels.com/de/hotel-1021-novotel-accra-city-centre/index.shtml
Tel. +233 302 66 75 46 Fax. +233 302 66 75 33
Email: H1021@accor.com
Distance to La Palm Royal Beach Hotel: 8km, 15 min by car
Distance to airport: 7 km

or visit the following website: http://www.touringghana.com/accommodation/accommodation.asp

Please contact our local agent for recommendations and reservations:
CREATIVE TRENDS (local agent handling hotel & transfer requests):
P.O. Box An 15605
Accra, Ghana
Tel: +233 244 21 41 65 info@creativetrendsgh.com

REGISTRATION FORM

3rd African Regulatory Conference (ARC) - Partnering for earlier access to good Quality medicines in Africa | 3-4 May 2012 | La Palm Beach Hotel, Accra, Ghana

ID # 12105

DIA www.diahome.org

CATEGORY	FEE
Industry International (Overseas)	USD 1'700.00 ❑
Industry Regional (African Countries)	USD 680.00 ❑
Government International (Overseas)	USD 340.00 ❑
Government Regional (African Countries)	USD 200.00 ❑
Academia / Charitable / Non-profit International (Overseas)	USD 340.00 ❑
Academia / Charitable / Non-profit Regional (African Countries)	USD 200.00 ❑

TOTAL AMOUNT DUE: $_____

NOTE: PAYMENT IS DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

SME, STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT THE DIA FOR MORE INFORMATION. 12105DIA

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax

Email (Required to receive presentation download instructions)

Please indicate your professional category:

❑ Academia ❑ Government

❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ **Cheques** should be made payable to: DIA and mailed together with a copy of the registration form to facilitate identification to:
DIA Europe, Kuechengasse 16, Postfach, 4002 Basel, Switzerland

❑ Please charge my credit card - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ VISA ❑ MC ❑ AMEX

Card Number

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ **Bank transfers**

Bank:	UBS
Address:	Postfach, 4002 Basel, Switzerland
Account Number:	233 635384.61L
SWIFT:	UBSWCHZH80A
IBAN:	CH63 0023 3233 6353 8461L

Payments in USD should be addressed to "Account Holder: DIA.". Please include your name, company, Event ID# 12105 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer.

CANCELLATION POLICY: All cancellations must be in writing and received with DIA Europe by 17:00 CET on 25 April 2012.

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Industry = USD 150.00. Academia/Government = USD 50.00. If you do not cancel by the date above and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe 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. Substitute attendees will be responsible for the applicable fee. Please notify DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA Europe Postfach, 4002 Basel, Switzerland