AFRICAN REGULATORY CONFERENCE

A forum for regulatory authorities and the pharmaceutical industry

FEBRUARY 5-6, 2008 | INDABA HOTEL, FOURWAYS JOHANNESBURG, SOUTH AFRICA

About the Drug Information Association (DIA)

With almost 20,000 members worldwide, the Drug Information Association (DIA) is the premier member-driven organization encompassing the full continuum of disciplines in the pharmaceutical and related industries. The mission of DIA is to serve and develop members by providing a neutral, global forum that promotes the exchange of information critical to their professional performance and achievement. The goal of DIA is to be the most effective means for members to obtain the knowledge they need to advance their career, their profession, and their organization.

About the European Federation of Pharmaceutical Industries & Associations (EFPIA)

EFPIA is the voice of the pharmaceutical industry in Europe. Through its membership, EFPIA represents 2,100 companies committed to researching, developing, and bringing to patients new medicines that improve health and quality of life around the world. The mission of EFPIA is to improve the competitiveness of the research-based pharmaceutical industry in Europe in a regulatory and political environment, which above all stimulates R&D and rewards innovation.

About the Southern African Development Community (SADC)

SADC consists of 14 Member States (approximately 200 million people): Angola, Botswana, the Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe. SADC's clear mission statement is "To promote sustainable and equitable economic growth and socio-economic development through efficient productive systems, deeper co-operation and integration, good governance, and durable peace and security, so that the region emerges as a competitive and effective player in international relations and the world economy". This mission is anchored on the common values and principles and the historical and cultural affinities that exist between the peoples of Southern Africa."

DIA Drug Information Association

efpia European Federation of Pharmaceutical Industries and Associations

SADC Southern African Development Community – Towards a Common Future

Conference Chairperson

Prof. Trevor M. Jones, CBE, Kings College London, UK; Recently WHO Commissioner CIPIH

Programme Committee

Ms. Engela Dedwith, Eli Lilly, South Africa, Area Regulatory Advisor
Ms. Fabienne Hanser, Hoffmann-La Roche Ltd, Switzerland, Regulatory Manager
Mr. Afschin Khodaverdi-Afaghi, Bayer Schering Pharma AG, Germany, Regulatory Head
Ms. Lynne Scarlett, AstraZeneca UK Limited, UK, Associate Regulatory Director
Mr. Jonothan Shaw, (Co-chairperson), Pfizer Ltd, UK, Associate Regulatory Director
Mr. Sheel Talwar, (Chairperson), GlaxoSmithKline, UK, Regulatory Director
Ms. Visda Vaghayenegar, sanofi-aventis, France, Regulatory Head
Mr. Colin Vickers, Pfizer Ltd, UK, Head, International Regulatory Affairs

Programme Advisors

Mr. Joseph Mthetwa, SADC, Senior Programme Manager for Healthcare and Pharmaceuticals
Ms. Lebogang Lebese, SADC, Technical Advisor for Health

Background

This is the first DIA/SADC co-sponsored African Regulatory Conference in partnership with the Africa Regulatory Network (ARN). The ARN is an ad hoc regional network of EFPIA. The ARN works in partnership with regulatory authorities and the pharmaceutical industry in Africa to develop legislation and regulatory practices that enable patients to have access to good quality medicines, including innovative medicines.

Themes and Objectives

This first conference offers the opportunity to:

- Promote partnerships between African regulatory authorities and the pharmaceutical industry
- Facilitate open discussion on current topics important to the region
- Raise awareness of the regulatory environment and promote exchange of information
- Share views on expectations, benefits and challenges to regulatory harmonisation

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

Key Topics

- R&D industry and its role in providing access to new medicines
- Updates on global and regional regulatory developments
  - Recent developments in EU regulations
  - International Conference on Harmonisation Global Cooperation Group (ICH GCG)
  - SADC Harmonisation
- Quality Risk Management and the Pharmaceutical Inspection Co-operation Scheme
- Certification – The CPP and its role in earlier patient access to medicines
- Anti-counterfeiting initiatives

Target Audience

Regulatory Affairs Professionals, Regulatory Authorities and other professionals involved in or interested in the pharmaceutical regulatory aspects of Quality/GMP, Anti-counterfeiting, and Harmonisation initiatives in the African region.

The final programme agenda will be available on DIA's website www.diahome.org and EFPIA's website www.efpia.eu in early November 2007. Please check these websites for additional information and registration.

Monday, February 4, 2008

18:00–20:00 Registration

Tuesday, February 5, 2008

07:30 Registration and Welcome Coffee

08:30–09:40 **OPENING SESSION**
Session Objectives: Conference opening and statement of meeting objectives.

INTRODUCTORY REMARKS BY CONFERENCE CHAIRPERSON
Prof. Trevor M. Jones, CBE, Kings College London, UK

KEYNOTE ADDRESS
Speaker Invited

WELCOME BY CO-SPONSORS/ARN
Mr. Joseph Mthetwa, SADC, Senior Programme Manager for Healthcare and Pharmaceuticals
Dr. Yves Juillet, LEEM (Les Enterprises du Médicament)/IFPMA, France, Senior Advisor; DIA Board Member
Mr. Sheel Talwar, GlaxoSmithKline, UK, Regulatory Director; ARN Representative

09:40–10:10 **SESSION 1**
PHARMACEUTICAL R&D INDUSTRY GOING FORWARD
Session Objectives: The contribution to world health by the pharmaceutical industry and the challenges going forward will be discussed.

The Importance of Pharmaceutical R&D
Prof. Trevor M. Jones, CBE, Kings College London, UK

10:10–10:40 Coffee Break

10:40–12:00 **SESSION 1 *continued***

10:40 **Role of Africa in Clinical Development – Regulatory Implications**
Dr. Lynn Katsoulis, Cato Research, Associate Director, Drug Development

11:10 **Accelerating Access of Medicines to Address Diseases of Public Health Importance**
WHO Speaker Invited

11:40 **Panel Discussion**

12:00–13:30 Lunch Break

13:30–15:00 **SESSION 2**
GLOBAL REGULATORY ENVIRONMENT
Session Objectives: Changes in the global regulatory environment of relevance to Africa will be presented.

13:30 **EU Regulatory Assessment Using Article 58**
Dr. Marie Hélène Pinheiro, EMEA, EU, Scientific Administrator, Human Unit Regulatory Affairs Section

13:50 **WHO Prequalification Scheme**
Dr. Lembit Rägo, WHO, Switzerland, Coordinator, Quality Assurance and Safety Medicines, Department of Medicines Policy and Standards

14:10 **Biosimilars**
Dr. Eugene Corretge, sanofi-aventis R&D, France, Head, Cardiovascular Axis II, Regulatory Development Department

14:30 **Panel Discussion**

15:00–15:30 Coffee Break

15:30–17:00 **SESSION 2 *continued***

15:30 **Update on ICH-GCG and Interface with Regional Harmonisation Initiatives**
Dr. Yves Juillet, LEEM (Les Enterprises du Médicament)/IFPMA, France, Senior Advisor

15:50 **Experience and Successes of EU Accession**
Dr. Marie Hélène Pinheiro, EMEA, EU, Scientific Administrator, Human Unit Regulatory Affairs Section

16:10 **Update on SADC Including the Perceived Benefits and Challenges of Harmonisation**
Mr. Joseph Mthetwa, SADC, Senior Programme Manager for Healthcare and Pharmaceuticals

16:30 **Panel Discussion**

17:00 **End of Day 1**

18:00 **Networking Dinner**
(The dinner will be an additional fee and we kindly ask you to register in advance.)

Wednesday, February 6, 2008

07:30 Welcome Coffee

08:30–09:45 **SESSION 3**
ASSURING PRODUCT QUALITY
Session Objectives: The goal of this session is to raise awareness of risk-based approaches to quality and to reinforce understanding of GMP and the role of PIC/S.

08:30 **ICH Quality**
Industry Speaker Invited

09:00 **Quality Risk Management**
Mr. Malcolm Brian Holmes, GlaxoSmithKline, UK, Director, Quality Assurance

09:45–10:15 Coffee Break

10:15–11:45 **SESSION 3 *continued***

10:15 **GMP and the Pharmaceutical Inspection Cooperation Scheme (PIC/S)**
Mr. Robert Wayne Tribe, Bob Tribe Consultancy, Australia, GMP Consultant; Consultant to PIC/S; Former Chairman of PIC/S

10:45 **Journey into PIC/S**
Dr. Joey Gouws, South African Department of Health, Director: Inspectorate & Law Enforcement

11:15 **Panel Discussion**

11:45–13:00 Lunch Break

13:00–14:30 **SESSION 4**
CERTIFICATION – THE CPP AND ITS ROLE IN EARLIER PATIENT ACCESS TO MEDICINES
Session Objectives: This session aims to reinforce the value of the CPP in order to facilitate and accelerate the review process.

13:00 **WHO Certification Scheme**
Dr. Lembit Rägo, WHO, Switzerland, Coordinator, Quality Assurance and Safety Medicines, Department of Medicines Policy and Standards

13:30 **The Place of the CPP in Guaranteeing Quality, Safety, and Efficacy**
Mr. Adrian Waterson, AstraZeneca UK Limited, UK, Regional Regulatory Director

14:00 **Panel Discussion**

14:30–15:00 Coffee Break

15:00–16:30 **SESSION 5**
ANTI-COUNTERFEITING MEASURES
Session Objectives: The purpose of this session is to provide an update and sharing of experiences.

15:00 **The Roles of the WHO IMPACT Groups**
FDA Speaker Invited

15:20 **Industry Perspective of Counterfeits – Regulatory Implications**
Mr. Kevin Moore, Eli Lilly, UK, Investigation Manager, Europe, Middle East, Africa

15:40 **Addressing the Counterfeit Issue**
Prof. Dora Akunyili, National Agency for Food and Drug Administration and Control (NAFDAC), Director General; Vice Chair, WHO IMPACT Group

16:10 **Panel Discussion**

16:30–17:00 **CONFERENCE CLOSING**
Session Objectives: Conclude the session and look at the next steps.

Wrap-up and Next Steps
Prof. Trevor M. Jones, CBE, Kings College London, UK

17:00 **CONFERENCE ADJOURNED**

African Regulatory Conference
Indaba Hotel Fourways, Johannesburg, South Africa
5-6 February 2008

A forum for regulatory authorities and the pharmaceutical industry

Please complete all sections of this form, and email to dia@ripcord.za.com or fax (international) +27 11 4822836 or local (South Africa) 0866 161575

Personal Details

Title:_____ Surname:_____First Name:_____.
Preferred name for name Badge:_____
Position:_____
Organisation:_____
Postal Address:_____
Suburb/Town:_____Postal Code:_____State:_____
Country:_____
Phone:_____ Fax:_____
Mobile Phone:_____ E-Mail:_____
Dietary requirements: □ Vegetarian □ Halaal □ Other_____
Physical disability needs (please specify):_____

Registration Details

Registration Costs		
Early Bird fees are applicable to registrations received on or before 15 January 2008		Please check relevant box and insert fee
□ Early Bird – Government	R 1,420.00	
□ Early Bird - Industry International	R 13,490.00	
□ Early Bird - Industry Regional - African Countries	R 3,550.00	
□ Early Bird - Non-profit organization	R 2,665.00	
These fees are applicable to registrations received after 16 January 2008		
□ Government	R 1,635.00	
□ Industry – International	R 13,705.00	
□ Industry Regional - African Countries	R 3,765.00	
□ Non-profit organisation	R 2,880.00	
□ Conference Dinner:	R 200.00	

Total: _____

Accommodation

Standard single room R735 per night, bed and breakfast, excluding 1% Tourism Levy
Arrival date:…….. Departure date:…… No of nights:…….
SHOULD YOU WISH DOUBLE/SHARING ACCOMMODATION, PLEASE CONTACT RIPCORD PROMOTIONS ON dia@ripcord.za.com

Travel

FLIGHT INFORMATION:
Arrival date:…….. Arrival day:…….. Arrival time:……Flight number:……
Departure date:…….…. Departure day:……. Departure time:…… Flight number:……

PLEASE NOTE THAT THE ABOVE INFORMATION IS REQUIRED TO ARRANGE THE COMPLIMENTARY TRANSFER FROM THE AIRPORT TO THE HOTEL. SHOULD YOU NOT HAVE MADE TRAVEL ARRANGEMENTS YET, PLEASE ADVISE ONCE YOU HAVE DONE SO.

Additional information

□ I am interested in a Pre or post conference tour – please contact me for details

PAYMENT INFORMATION:
Credit Card Type: □ Visa □ Mastercard □ American Express
Card #: _____ Exp. Date: _____

Name printed on card: _____ CVV (three digits on back of card):_____

Signature: _____

CANCELLATION POLICY: On or before January 28, 2008
Administrative fee will be withheld from the refund amount: Industry = R1330 RAND, Regional/Local Industry = R500, Full-time Government = R170, Non-profit = R335

Cancellations must be in writing and be received by the cancellation date above. Cancellation notices should be emailed to ellen.diegel@diahome.org and dia@ripcord.za.com. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

Signature, accepting terms of cancellation policy (emailed forms will be deemed to be signed)_____

TRAVEL AND HOTEL:
OR Tambo International Airport is about 25 miles from the Indaba Hotel and Conference Centre. Attendees should make airline reservations as early as possible to ensure availability.

All hotel reservations will be at the Indaba Hotel and Conference Centre. Reservations will be made under the name used to register for the program, and will be made by Ripcord Promotions. Payment / Reservation must be guaranteed with a credit card. The card used to cover your registration fee will be used to guarantee your hotel reservation.

MEETING INFORMATION:
USA: Contact Ellen Diegel at the DIA office by telephone +1-215-442-6158
Fax +1-215-293-5965 or email: ellen.diegel@diahome.org.
All Registrations will be processed by Ripcord Promotions.

South Africa and other countries:
Ripcord Promotions – Phone: + 27 11 4822835
Email: dia@ripcord.za.com

ONCE YOUR REGISTRATION FORM HAS BEEN RECEIVED, AN EMAIL CONFIRMATION WILL BE FORWARDED TO YOU. SHOULD YOU NOT HAVE RECEIVED THIS CONFIRMATION WITHIN 48 HOURS OF REGISTRATION, PLEASE CONTACT RIPCORD PROMOTIONS ON dia@ripcord.za.com

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