AFRICAN REGULATORY CONFERENCE
A forum for regulatory authorities and the pharmaceutical industry

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

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

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

Programme Advisors
Mr. Joseph Mthetwa, SADC, South Africa, Senior Programme Manager for Healthcare and Pharmaceuticals
Ms. Lebogang Lebese, SADC, South Africa, 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.

To register online please visit http://www.redballoon.biz/DIA/register.php
To register via fax or email, please see pages 3 and 4.

www.diahome.org www.efpia.eu
Monday, February 4, 2008
18:00– Registration
20:00

Tuesday, February 5, 2008
07:30 Registration and Welcome Coffee
08:30– OPENING SESSION
09:40 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, South Africa, Senior Programme Manager for Healthcare and Pharmaceuticals
   Dr. Yves Julliet, LEEM (Les Entreprises du Médicament)/IFPMA, France, Senior Advisor; DIA Board Member
   Mr. Sheel Talwar, GlaxoSmithKline, UK, Regulatory Director; ARN Representative

09:40– SESSION 1
10:10 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– Coffee Break
10:40– SESSION 1 continued
11:10 Role of Africa in Clinical Development – Regulatory Implications
   Dr. Lynn Katsoulis, Cato Research, South Africa, Associate Director, Drug Development

11:10– Lunch Break
12:00– SESSION 2
13:30 GLOBAL REGULATORY ENVIRONMENT
   Session Objectives: Changes in the global regulatory environment of relevance to Africa will be presented.
   EU Regulatory Assessment Using Article 58
   Dr. Marie Hélène Pinheiro, EMEA, EU, Scientific Administrator, Human Unit Regulatory Affairs Section

13:30– Who's Prequalification Scheme
   Dr. Lembit Rägo, WHO, Switzerland, Coordinator, Quality Assurance and Safety Medicines, Department of Medicines Policy and Standards

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

14:30 Panel Discussion
15:00– Coffee Break
15:30– SESSION 2 continued
16:30 Update on ICH-GCG and Interface with Regional Harmonisation Initiatives
   Dr. Yves Julliet, LEEM (Les Entreprises du Médicament)/IFPMA, France, Senior Advisor

16:50 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, South Africa, 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.)
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 ☐ Halal ☐ Other ________________________________
Physical disability needs (please specify): ______________________________________________________

Registration Details

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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 – PLEASE COMPLETE THE FOLLOWING INFORMATION
Credit Card Type: ☐ Visa ☐ Mastercard ☐ American Express 
Card #: ____________________________________________ Exp. Date: ________
Name printed on card: _______________________________ CVV (three digits on back of card):_____
Signature: ____________________________________________________________________

☐ BANK TRANSFER – I REQUIRE AN INVOICE WITH BANKING DETAILS

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 FORWARDER TO YOU. SHOULD YOU NOT HAVE RECEIVED THIS CONFIRMATION WITHIN 48 HOURS OF REGISTRATION, PLEASE CONTACT RIPCORD PROMOTIONS ON dia@ripcord.za.com

Ripcord Promotions
P.O. Box 91989, Auckland Park 2006
SOUTH AFRICA

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