

# 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."



### 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 Vaghayenagar**, 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](http://www.diahome.org) and EFPIA's website [www.efpia.eu](http://www.efpia.eu) in early November 2007. Please check these websites for additional information and registration.

## 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, Senior Programme Manager for Healthcare and Pharmaceuticals

Dr. Yves Juillet, 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**

#### **10:10-10:40 PHARMACEUTICAL R&D INDUSTRY GOING FORWARD**

10:10 *Session Objectives:* The promotion of the value and image of the R&D industry and its contribution to access to medicines 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 **SESSION 1 continued**

12:00

#### **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 **SESSION 2**

#### **15:00 GLOBAL REGULATORY ENVIRONMENT**

15:00 *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 Rågo, 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 **SESSION 2 continued**

17:00

#### **15:30 Update on ICH-GCG and Interface with Regional Harmonisation Initiatives**

Dr. Yves Juillet, LEEM (Les Entreprises 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 **SESSION 3**

#### **09:45 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 **SESSION 3 continued**

11:45

#### **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 **SESSION 4**

#### **14:30 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 Rågo, 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 **SESSION 5**

#### **16:30 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**