

2nd AFRICAN REGULATORY CONFERENCE

A forum for regulatory authorities and the pharmaceutical industry

March 2-3, 2010 | The Misty Hills Country Hotel, Johannesburg, South Africa



In collaboration with



European Federation of Pharmaceutical
Industries and Associations



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 2,200 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 people of Southern Africa."

Conference Chairperson

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

Conference Co-chairperson

Mr. Joseph Mthetwa, Senior Programme Manager for Health and Pharmaceuticals,
SADC Secretariat

Programme Committee

Ms. Valérie Abondo, sanofi-aventis, France

Ms. Engela Dedwith, Eli Lilly, South Africa

Ms. Muriel Dona-Fologo, Biogen Idec Limited, UK

Mr. Salieu Jalloh, Novartis Pharma AG, Switzerland

Mr. Igor Knezevic, Bayer Schering Pharma AG, Germany

Mr. Peter J. Krol, Schering-Plough, The Netherlands (EFPIA-IRAG ARN Deputy Lead)

Ms. Gina Partridge, Abbott Laboratories, South Africa

Mr. Niklaus Puppato, Hoffmann-La Roche Ltd, Switzerland

Ms. Florence Roizard, Merck Sharp & Dohme, France (EFPIA-IRAG ARN Lead)

Ms. Danielle Tobin, Pfizer Ltd, UK

Ms. Claire Tshilumba, Merck Sharp & Dohme, South Africa

Ms. Gina Weston, Glaxo Smith Kline, UK

Programme Advisors

Ms. Val Beaumont, Executive Director, Innovative Medicines South Africa (IMSA)

Ms. Delese Mimi Darko, Head, Drug Evaluation & Registration, Food and Drugs Board,
Ghana

Ms. Mandisa Hela, Registrar, Medicines Regulatory Agency, South Africa

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Zimbabwe

Mr. Apollo E. Muhairwe, Executive Secretary/Registrar, National Drug Authority, Uganda

Ms. Esnart Mwape, Director General, Pharmaceutical Regulatory Authority, Zambia

Ms. Kirti Narsai, Head, Scientific and Regulatory Affairs, Pharmaceutical Industry
Association of South Africa (PIASA)

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Background

This is the second 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-International Regulatory Affairs Group (IRAG). EFPIA (European Federation of Pharmaceutical Industries and Associations) represents the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 44 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,200 companies committed to researching, developing, and bringing to patients new medicines that improve health and the quality of life around the world.

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 2nd African Regulatory Conference will focus on access to safe, effective, quality and affordable medicines in the Region. It will offer the opportunity to:

- Foster collaboration between African Regulatory Authorities and the Pharmaceutical Industry
- Share information and best practices, and identify potential workable solutions which meet the needs of the Region
- 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 panel discussions to maximize contributions around the key topics.

Key Topics

- Regulatory Harmonisation: How Can It Improve Access to Medicines?
- The Role of Research and Development in Patient Access to Medicines
- How Do Changes in the Global Regulatory Environment Impact Africa?
- Regulatory Challenges to Access
 - Capacity Building
 - Speed to Market
 - Management of Variations
- Ensuring Patient Safety
- Product Quality Update, Including GMP, Site Inspections, and Anti-counterfeiting Strategies

Target Audience

Regulatory Affairs Professionals, Regulatory Authorities and other professionals involved in or interested in the aspects surrounding registration and control of medicinal products and regulatory harmonisation initiatives in the African region.

**Online registration will be available soon.
Monitor DIA's website – www.diahome.org**