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

To register, see page 5 or CLICK HERE.
For directions, see page 7 or CLICK HERE.

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 15 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, Zimbabwe and Seychelles. 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."

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

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, Botswana

Programme Committee

Ms. Engela Dedwith, Eli Lilly, South Africa

Ms. Muriel Delalleau Biogen Idec Limited, UK (EFPIA-IRAG ARN Deputy Lead)

Ms. Osaretin Jaiyeola, GlaxoSmithKline, Nigeria

Mr. Salieu Jalloh, Novartis Pharma AG, Switzerland

Mr. Igor Knezevic, Bayer Schering Pharma AG, Germany

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

Programme Advisors

Ms. Valérie Abondo, South Africa

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

Ms. Gugu N. Mahlangu, Director, Technical Services, Medicines Control Authority of 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)

Dr. Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines (QSM), World Health Organization, Geneva, Switzerland

continued on page 2

Simultaneous Translation will be available in English, French, and Portuguese

In collaboration with

efpia European Federation of Pharmaceutical Industries and Associations

SADC

DIA® www.diahome.org

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).

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 for patients to safe, effective and quality medicines and 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 Value of Research and Development in Patient Access to Medicines
- How Do Changes in the Global Regulatory Environment Impact Africa?
- Regulatory Challenges to Patient Access to Medicines
  - Capacity Building
  - Speed to Market
  - Management of Variations
- Ensuring Patient Safety through Pharmacovigilance
- Ensuring Patient Safety through 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.

MONDAY, MARCH 1, 2010

18:00-20:00 REGISTRATION

DAY 1 | TUESDAY, MARCH 2, 2010

07:30-8:30 REGISTRATION AND WELCOME COFFEE

08:30-09:30 OPENING SESSION

Session Objective: Conference opening and statement of meeting objectives

INTRODUCTORY REMARKS

Prof. Trevor M. Jones, CBE
Kings College London, UK

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

KEYNOTE ADDRESS:

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

WELCOME BY CO-SPONSORS AND PROGRAM COMMITTEE

DIA

Dr. Yves Juillet
Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises de Médicament (LEEM), France

EFPIA/ARN

Ms. Engela Dedwith
Eli Lilly, South Africa, Area Regulatory Manager, AMEA/CIS-CEE (Non-EU)

09:30-13:00 SESSION 1

Regulatory Harmonization in Africa: Regional and Worldwide Organizations' View, Key Opportunities and Challenges

Session Objective: The question of how ongoing regulatory harmonization initiatives in Africa can improve access to medicines will be discussed

Regulatory Harmonization and Public Health

Dr. Lembit Rägo
Coordinator, Quality Assurance and Safety: Medicines (QSM), World Health Organization, Geneva, Switzerland

New Partnership for Africa's Development (NEPAD): The African Medicines Registration Harmonization (AMRH) Initiative

Prof Eric Buch
Health Adviser, NEPAD. Professor, Health Policy & Management, University of Pretoria, South Africa

10:30-11:00 COFFEE BREAK

Industry Perspective on the Harmonization and Regulatory Environment in Eastern & Central Africa

Dr. William Mwatu
Medical and Regulatory Director, GlaxoSmithKline, Kenya

Economic and Monetary Community of Central Africa Organization, Health Organisation

Mr Jean Jacques Moka
General Secretary, OCEAC, Cameroon

Dr. Emilienne Yissibi Pola
Coordinator, Central African Pharmaceutical Policy Harmonization Program, Cameroon

South African Development Community (SADC)

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

East African Community (EAC)

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

Panel Discussion:

Dr. Lembit Rägo - Coordinator, Quality Assurance and Safety: Medicines (QSM), World Health Organization, Geneva, Switzerland

Prof Eric Buch - Health Adviser, NEPAD. Professor, Health Policy & Management, University of Pretoria, South Africa

Mr. William Mwatu - Medical and Regulatory Director, GlaxoSmithKline, Kenya

Mr. Jean Jacques Moka - General Secretary, OCEAC, Cameroon

Dr. Emilienne Yissibi Pola - Coordinator, Central African Pharmaceutical Policy Harmonization Program, Cameroon

Mr. Joseph Mthetwa - Senior Programme Manager for Healthcare and Pharmaceuticals, SADC Secretariat, Botswana

Ms. Gugu N. Mahlangu - Director, Technical Services, Medicines Control Authorityof Zimbabwe

13:00-14:00 LUNCH BREAK

14:00-15:00 SESSION 2

The Global Regulatory Environment & Opportunities for Africa

Session Objective: To raise awareness of changes in the global regulatory environment and their relevance for Africa.

ICH Update

Dr. Yves Juillet
Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises du Médicament (LEEM), France

New EU Regulatory Trends

Transparency measures, Paediatric Regulations and Pharmacovigilance will be discussed

Dr. Truus Janse-de Hoog
Staff Member Medicines Evaluation Board, European Cluster; Chair of Coordination Group for Mutual Recognition and Decentralization Procedures - Human (CMD(h)), The Netherlands

Panel Discussion:

Dr. Yves Juillet - Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises du Médicament (LEEM), France

Dr. Truus Janse-de Hoog - Staff Member Medicines Evaluation Board, European Cluster; Chair of Coordination Group for Mutual Recognition and Decentralization Procedures - Human (CMD(h)), The Netherlands

Dr. Lembit Rägo - Coordinator, Quality Assurance and Safety: Medicines (QSM), World Health Organization, Geneva, Switzerland

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

15:00-17:15 SESSION 3

The Role of Research and Development in Patient Access to New Medicines

Session Objective: Biological medicines and associated Regulatory features, as well as stimulation of R&D for neglected diseases will be discussed

Biological Medicines – Opportunities and Challenges

Dr Thomas Schreitmueller
Head of Biotech Analytics and Development, Roche, Switzerland

15:45-16:15 COFFEE BREAK

16:15-17:15 SESSION 3 - CONTINUED

R&D for Neglected Diseases

Dr. Arkadius Pichota
Preclinical Development, Novartis Institute for Tropical Diseases, Singapore

Panel Discussion:

Dr. Thomas Schreitmueller - Head of Biotech Analytics and Development, Roche, Switzerland

Dr. Arkadius Pichota - Preclinical Development, Novartis Institute for Tropical Diseases, Singapore

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

Dr. Yves Juillet - Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises du Médicament (LEEM), France

Ms. Margareth Ndomondo-Sigonda - NEPAD Health Pharmaceutical Coordinator

Professor Trevor M. Jones, CBE - Kings College London, UK

17:15-17:30 DAY 1 WRAP-UP

Prof. Trevor M. Jones, CBE
Kings College London, UK

Mr. Joseph Mthetwa
Senior Programme Manager for Healthcare and Pharmaceuticals, SADC Setretariat, Botswana

18:00 PRE-DINNER RECEPTION

19:00 CONFERENCE DINNER

(The dinner will be an additional fee and we kindly ask you to register in advance.)

DAY 2 | WEDNESDAY, MARCH 3, 2010

07:30-8:30 REGISTRATION AND WELCOME COFFEE

08:30-10:30 SESSION 4

Regulatory Challenges to Medicines Access

Session Objective: To review regulatory capacity, speed to market, and management of variations.

How Can Developing Countries Increase Regulatory Efficiency and Maintain Standards without Increasing Costs?

Mrs. Hauwa J. Keri
Director, Establishment Inspection, National Agency for Food and Drug Administration and Controls (NAFDAC), Nigeria

FDA Alumni Association's International Network (FDAAA IN): Opportunity to Partner with National Regulatory Authorities

Dr. Ekopimo Ibia
Director, Global Medical and Regulatory Policy, Merck Research Laboratories, US

Evolving Legislation: the EU Management of Variations System

Dr. Truus Janse-de Hoog
Staff Member Medicines Evaluation Board, European Cluster; Chair of Coordination Group for Mutual Recognition and Decentralization Procedures - Human (CMD(h)), The Netherlands

The Management of Variations in Africa–Regulator View

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

The Management of Variations in Africa–Industry Views and Key Issues

Ms. Florence Roizard
Director, Regulatory Affairs, Middle East and Africa, Merck Sharp & Dohme, France

Panel Discussion:

Mrs. Hauwa J. Keri - Director, Establishment Inspection, National Agency for Food and Drug Administration and Controls (NAFDAC), Nigeria

Dr. Ekopimo Ibia - Director, Global Medical and Regulatory Policy, Merck Research Laboratories, US

Dr. Truus Janse-de Hoog - Staff Member Medicines Evaluation Board, European Cluster; Chair of Coordination Group for Mutual Recognition and Decentralization Procedures - Human (CMD(h)), The Netherlands

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

Ms. Florence Roizard - Director, Regulatory Affairs, Middle East and Africa, Merck Sharp & Dohme, France

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

10:30-11:00 COFFEE BREAK

11:00-12:30 SESSION 5

Ensuring Patient Safety

Session Objective: To discuss elements which contribute securing patient safety, including post-marketing surveillance

Establishing Pharmacovigilance Systems in Africa: Regulators' Perspective

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

Sharing and Managing Post-Marketing Safety Information

Dr. Jayesh Pandit
Head of Pharmacovigilance Department, Pharmacy & Poisons Board, Kenya

Post-marketing Surveillance and Bridge to Label Updates: An Industry Perspective

Dr. Marta Gersberg
Drug Safety, Sanofi-Aventis, France

Panel Discussion:

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

Dr. Jayesh Pandit - Head of Pharmacovigilance Department, Pharmacy & Poisons Board, Kenya

Dr. Marta Gersberg - Drug Safety, Sanofi-Aventis, France

Ms. Esnat Mwape - Director General, Pharmaceutical Regulatory Authority, Zambia

12:30-13:30 LUNCH BREAK

13:30-16:30 SESSION 6

Product Quality Update

Session Objective: To discuss innovations in the Quality arena, GMP, Site Inspections and Anti-Counterfeiting Strategies

Update on Risk-Based GMP Site Inspections

Mr. Deus K. Mubangizi
Technical Officer, WHO Prequalification Program, World Health Organization Geneva, Switzerland

Update on WHO Initiatives Against Counterfeits

Dr. Lembit Rägo
Coordinator, Quality Assurance and Safety: Medicines (QSM), World Health Organization, Geneva, Switzerland

Global Industry Initiatives Update in Anti-counterfeiting Strategies

Dr. Yves Juillet
Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises du Médicament (LEEM), France

15:00-15:30 COFFEE BREAK

15:30-16:30 SESSION 6 - CONTINUED

Product Quality Update

Regulators' Strategies against Counterfeits: The Experience of Ivory Coast

Dr. Parfait Kouassi
President of Ivory Coast Pharmaceutical Association, Abidjan, Ivory Coast

Counterfeits: How Can Regulators Tackle the Issue in Africa?

Mr. Griffith Molewa
Manager Law Enforcement, Department of Health, South Africa

Panel Discussion:

Mr. Deus K. Mubangizi - Technical Officer, WHO Prequalification Program, World Health Organization Geneva, Switzerland

Dr. Lembit Rägo - Coordinator, Quality Assurance and Safety: Medicines (QSM), World Health Organization, Geneva, Switzerland

Dr. Yves Juillet - Chair of Regulatory Policy and Technical Steering Committee at IFPMA, Senior Advisor, Les Entreprises du Médicament (LEEM), France

Dr. Parfait Kouassi - President of Ivory Coast Pharmaceutical Association, Abidjan, Ivory Coast

Mr. Griffith Molewa - Manager Law Enforcement, Department of Health, South Africa

Ms. Esnat Mwape - Director General, Pharmaceutical Regulatory Authority, Zambia

16:30-17:00 CONFERENCE CLOSE

Prof. Trevor M. Jones, CBE
Kings College London, UK

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

Delegate Registration

Please return this form by 22nd February 2010 to:

Ripcord Promotions
Tel: +27(0)11 482 2835 **Fax**: +27(0) 866 161 575
Post: PO Box 91989 Auckland Park 2006 **E-mail:** dia@ripcord.za.com

For Office Use Only:
Date Rec'd: Confirmation: Payment Rec'd: Event Pin:

Please complete in **BLOCK CAPITALS** and tick the appropriate blocks.

DELEGATE DETAILS

Delegate Type:

Surname | First Names

Title (Mr/Ms/Dr) | Preferred name for delegate badge

Company/Association

Position

Postal Address | Code:

Office Tel Code: ( ) | Fax: Code: ( )

E-mail | Cellular

Special Dietary requirements: ☐ Vegetarian ☐ Halaal Other (specify):

Special Disability Needs (please specify)_____ Emergency contact:_____

REGISTRATION FEES

Early Bird registration discounts applicable only to registration forms received on/before **8th February 2010**

Fees are inclusive of VAT at 14%.	EARLY BIRD (RECEIVED BEFORE OR ON 8TH FEBRUARY 2010)	NORMAL (RECEIVED AFTER 8TH FEBRUARY 2010)	
Industry International (Overseas)	R13,660	R15,200	
Industry Regional (South Africa and other African Countries)	R 4,555	R 6,000	
Non –Profit organization / Academic / Research Staff	R 3,035	R 4,500	
Government	R1,515	R 2,500	
Conference Dinner – Tuesday, 2nd March 2010	R265	R 300	
TOTAL			

Delegate Name:

HOTEL ACCOMMODATION

Please note the following important points:

- Accommodation will be allocated on a "first come first served" basis.
- Accommodation rates are subject to availability.
- Accommodation rates include breakfast, but exclude the 1% Tourism Levy on the accommodation portion of the rate. This will be charged as an extra to your hotel bill.
- At check-in, delegates will be required to provide a credit card imprint, or cash deposit, to secure the cost of extras.

	SINGLE (1 OCCUPANT)	DOUBLE (2 OCCUPANTS)
Misty Hills Country Hotel	☐ Bed and Breakfast – R1175	☐ Bed and Breakfast – R850 per person

Arrival Date _____ Departure Date _____ Sharing with: _____

Rate: R _____ X _____ (no of nights) = R _____

☐ Please add accommodation to my total invoice

☐ I wish to settle my accommodation directly with the hotel by credit card

AIRPORT TRANSFERS

☐ I wish to make use of the complimentary airport shuttle

ARRIVAL DATE:…… ARRIVAL TIME:…… FLIGHT NO:……..ARRIVING FROM:……

DEPARTURE DATE:…… DEPARTURETIME:…… FLIGHT NO:……..DEPARTING TO:……

CANCELLATIONS / AMENDMENTS

All cancellations / amendments must be submitted in writing on or before **Monday, 15th February 2010** and will be subject to a cancellation/amendment fee of R500 per registration. Cancellations received after 15 February 2010 will be subject to a cancellation fee of 50% of the full value of the registration. Cancellations received on or after 22 February 2010 will be subject to a cancellation fee of 100% of the full value of the registration.

PAYMENT OPTIONS (registration will only be confirmed upon receipt of payment)

NB: Invoice, DIA banking details and reference number will be sent upon receipt of registration form.

Please provide your VAT number if this is to reflect on the Tax Invoice: _____

☐ Direct Deposit

☐ Please debit my credit card: ☐ Visa ☐ Master ☐ Diners ☐ Amex

Credit Card number: _____

Name on Card: _____

Expiry Date: m m y y CVV Code (Last 3 number on reverse side of card): _ _ _

Payment Option: ☐ Straight ☐ Budget: _____ Months Amount:_____

Signature:_____

PLEASE NOTE: Credit card payments will be processed through the Red Balloon Credit Card Merchant and will appear on your statement as DIA African Regulatory Conference Manual transaction.

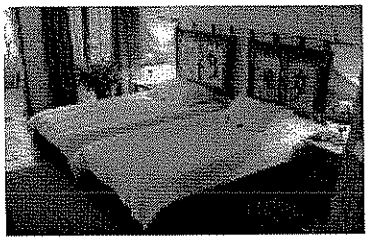
PLEASE RETURN THIS FORM BY 22nd February 2010. Late registrations will incur a R500 administration fee. Confirmation of registration, together with a Tax Invoice, will be sent to you on receipt of your registration. Should you not receive the above documents within 48 hours of registration, please contact Ripcord Promotions to ensure that your registration has been received. For enquiries please contact Ripcord Promotions, Tel. (+2711) 482-2835, Fax 0866 161575 or e-mail dia@ripcord.za.com. When making a direct deposit, please ensure that your name and unique PIN number are reflected on the deposit slip/proof of payment, and forward same to Ripcord Promotions.

RESPONSIBILITY

The Committee of Drug Information Association 2010 (referred to as the "Conference") will do everything possible to ensure that your attendance at the Conference will be as comfortable as possible. The Conference, any member or members of its committee and its appointed agents or sub-contractors, act on the basis that they attend to the arrangements of the Conference for the convenience of the Conference delegates. They perform all tasks on condition that the Conference, any member or members of its committee and its appointed agents or other sub-contractors cannot be held responsible for any loss, personal injury, damage or inconvenience (however arising) experienced by delegates of the Conference; neither can they be held responsible for unforeseen partial or total cancellation of the event for which no refunds can be guaranteed. The programme is subject to change without notice.

By forwarding the Registration Form I agree to the clauses in the Registration Form and I have noted the reservation and cancellation details.

Signature: _____ Date: _____



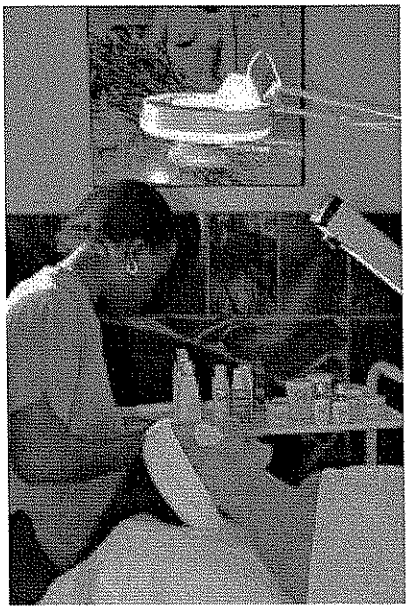
MISTY HILLS
COUNTRY HOTEL
CONFERENCE CENTRE & SPA
★ ★ ★ ★
69 Drift Boulevard, Muldersdrift, 1747
Private Bag 1, Muldersdrift, 1747
Tel: 011 950 6000 / Fax 011 957 3212
Email: sale@rali.co.za
Website: www.rali.co.za

Map to Misty Hills

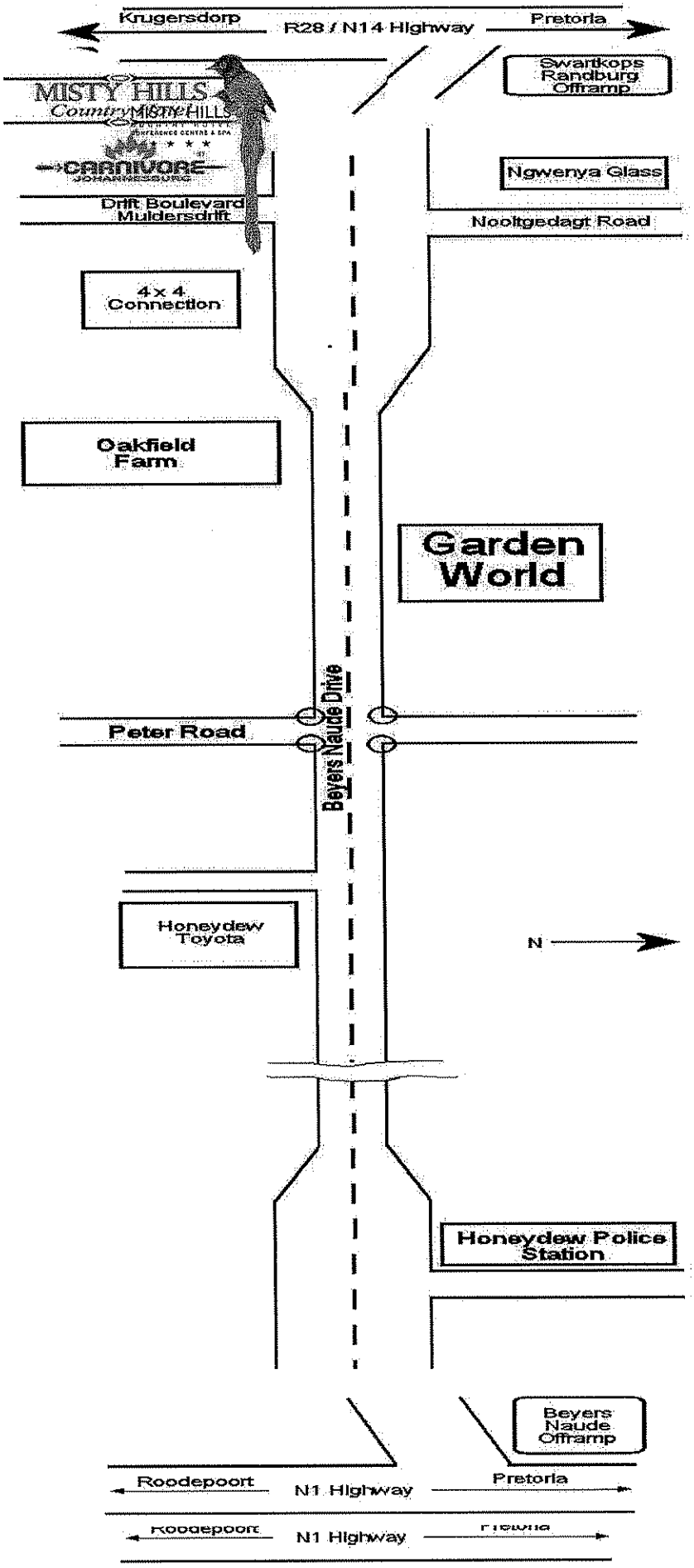
Directions

From OR Tambo International Airport take the Gillooly's intersection N1 highway to Sandton / Roodepoort

- Take the N1 highway to Roodepoort
- Take the Beyers Naude Off ramp and turn towards Honeydew
- The road becomes one lane in each direction, continue past Garden World
- After Garden World and Oakfield Farm, the road becomes 2 lanes again.
- Turn at the first road left into DRIFT BOULEVARD/MULDERSDRIFT (R114)
- The Hotel is about 800 meters on the right hand side.



Member of Recreation Africa



Member of
Recreation Africa