REGULATORY WORKSHOP

NEW DEVELOPMENTS IN DRUG REGULATION

DATE:

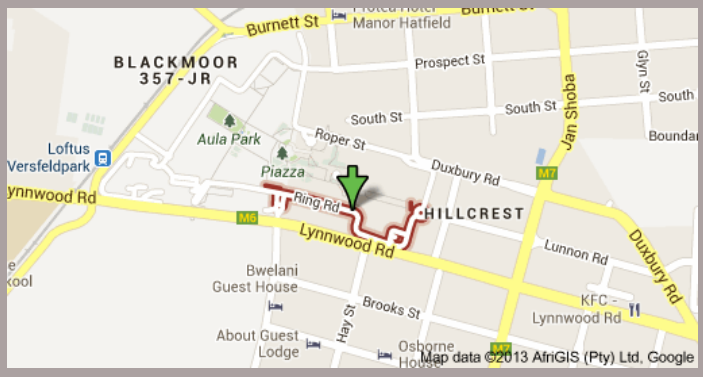
26 – 27 SEPTEMBER 2013

VENUE:

UNIVERSITY OF PRETORIA, SANLAM AUDITORIUM, HATFIELD CAMPUS, OFF RING ROAD

INVITED SPEAKERS:

- **Ekkehard Baader** – Senior Director, Head of EU Regulatory Affairs BP, Teva Pharma GmbH, Germany
- **Peter Bachmann** – Chair, EMA Coordination Group for Mutual Recognition and Decentralized Procedures, CMDh
- **Marc Blockman** – Division of Clinical Pharmacology, University of Cape Town
- **Elwyn Griffiths** – Consultant, World Health Organisation (WHO), United Kingdom
- **Chris Holloway** – Group Director of Regulatory Affairs & Chief Scientific Officer, ERA Consulting Group
- **Ngokoana E Khomo** – Vice-Chair, Medicines Control Council (MCC)
- **Thomas Kirchlechner** – Head Regulatory Emerging Markets Group, Sandoz GmbH, Austria
- **Birka Lehmann** – Bundesinstitut für Arzneimittel (BfArM) and Paediatric Committee (PDCO), Germany
- **Tomas Salmonson** – Chair, EMA Committee for Medicinal Products for Human Use, CHMP, United Kingdom of Sweden
- **Max Wegner** – Vice President, Head Global Regulatory Affairs General Medicine, Bayer AG, Germany
- **Michael Wyand** – Senior Vice President Clinical & Regulatory, Epirus Biopharmaceuticals, USA



ORGANISED BY:

South African Society for Basic and Clinical Pharmacology SASBCP

MCC Medicines Control Council

Fundisa African Academy of Medicines Development

CHAIRS:

- **Bernd Rosenkranz**
  Division of Clinical Pharmacology, Stellenbosch University
  Vice President of South African Society for Basic & Clinical Pharmacology, SASBCP
- **Ngokoana E Khomo**
  Vice-Chair, Medicines Control Council, MCC

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AGENDA

26 SEPTEMBER 2013

09:00 – 9:15	**Introduction by Workshop Chairs**
09:15 – 12:45	**European & African Regulatory Authorities** (Chair: Ngokoana E Khomo)
09:15 – 10:00	European Medicines Agency and CHMP – Tomas Salmonson
10:00 – 10:45	European National Competent Authorities – Peter Bachmann
10:45 – 11:15	Break
11:15 – 12:00	MCC Perspective – Ngokoana E Khomo
12:00 - 12:45	Industry perspective – Ekkehard Baader
12:45-13:45	**Lunch**
13:45 – 17:45	**EU Drug Regulation – New Developments** (Chair: Bernd Rosenkranz)
13:45 – 14:30	Paediatric Regulation – PDCO Perspective – Birka Lehmann
14:30 – 15:15	Paediatric Regulation – Industry perspective – Max Wegner
15:15 – 16:00	Break
16:00 – 17:00	Clinical Trial Directive – Birka Lehmann
17:00 – 17:45	CHMP – New Developments – Tomas Salmonson
17:45 – 18:00	**Panel Discussion**

27 SEPTEMBER 2013

08:30 – 12:30	**Biosimilars & Biopharmaceuticals – EU & WHO Perspective** (Chair: Bernd Rosenkranz)
8:30 – 09:15	Biosimilars – Successes & Failures in Europe – Chris Holloway
09:15 – 10:00	Biosimilars – WHO guideline - Elwyn Griffiths
10:00 – 10:45	Challenges in the development of biosimilar monoclonal antibodies – Chris Holloway
10:45 – 11:15	Break
11:15 – 12:00	Biopharmaceuticals – Experience of a generic drug company in emerging markets – Michael Wyand

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12:00 – 12:30	Biosimilar case studies – From human growth hormone and G-CSF to monoclonal antibodies – Tomas Kirchlechner
12:30 – 13:30	**Lunch**
13:30 – 17:00	**Pharmacovigilance** (Chair: Ngokoana E Khomo)
13:30 – 14:15	National Competent Authority perspective – Peter Bachmann
14:15 – 15:00	PRAC & New Pharmacovigilance legislation – Tomas Salmonson
15:00 – 15:30	Break
15:30 – 16:15	MCC perspective – Marc Blockman
16:15 – 17:00	Industry perspective – Max Wegner
17:00 – 17:45	**Panel Discussion**
17:45 – 18:00	**Closing Remarks – Ngokoana Khomo**

R.S.V.P.
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For further questions:
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CPD ACCREDITED

Registration fees:

- ★ **Regulatory agency members and students:** **Free**
- ★ **Industry delegates:** **R 2500**
- ★ **Other delegates:** **R 1000**