



2ND REGULATORY WORKSHOP

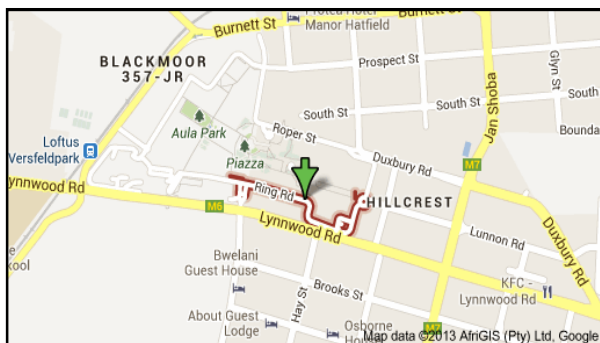
NEW DEVELOPMENTS IN DRUG REGULATION

DATE:

9 - 10 October 2014

VENUE:

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



Registration Fees:

R3000 Industry, CRO & Other Professionals

R1000 Academia

Free MCC Staff & Students

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Programme Committee:

- Prof Bernd Rosenkranz - Head, Division of Clinical Pharmacology, Stellenbosch University and President of Fundisa African Academy of Medicines Development (FAAMD)
- Mandisa Hela - Registrar of Medicines, Medicines Control Council, MCC
- Dr Ekkehard Baader - Senior Director, Head of EU Regulatory Affairs BP, Teva Pharma GmbH, Germany
- Dr Tomas Salmonson - Chair, EMA Committee for Medicinal Products for Human Use, CHMP, Sweden

Invited Speakers:

- ◆ Peter Bachmann (Chairperson of the EMA Coordination Group for Mutual Recognition and Decentralized Procedures, CMDh)
- ◆ Andreas Diacon (CEO, Task Applied Science and Division of Physiology, Stellenbosch University)
- ◆ Mandisa Hela (Registrar of Medicines, MCC)
- ◆ Robyn Howes (Product Specialist, Bioweb Ltd, and EXCO member of South African Laboratory Diagnostics Association, SALDA)
- ◆ Anele Vutha (Manager RAQA, Boston Scientific)
- ◆ Filip Josephson (Member of the Infectious Disease Working Party (IDWP) of the EMA, CHMP, Sweden)
- ◆ Birka Lehmann (Member of the Bundesinstitut für Arzneimittel, BfArM, Germany and of the Pediatric Committee, PDCO; Germany)
- ◆ Yolanda Peens (Teva, South Africa)
- ◆ Sol Ruiz (CHMP; Spanish Medicines Agency (AEMPS), Spain)
- ◆ Patrick Salmon (CHMP; Irish Regulatory Authority (HPRA), Ireland)
- ◆ Tomas Salmonson (Chairperson of the EMA Committee for Medicinal Products for Human Use, CHMP, Sweden)
- ◆ Jaco van Zyl (Medical Executive, Cipla)
- ◆ Joanne van Hermelen (Patent Attorney, ENSafrica)
- ◆ Joy van Oudtshoorn (Member of the Pharmaceutical and Analytical Expert Committee of the MCC)
- ◆ Shabir Banoo (Head, Pharmaceutical Services and Policy Support Division, Right to Care and member of the MCC)
- ◆ Gavin Steel (Chief Director-Sector Wide Procurement, National Department of Health)

ORGANISED BY:

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TIME	SPEAKER	TOPIC
9 October 2014		
Chair: Bernd Rosenkranz		
09:00 – 09:15	Welcome & Introduction – Bernd Rosenkranz & Oppel Greeff	
09:15 – 10:45	Medical Devices	
09:15 – 10:00	Birka Lehmann	Children and Adolescents' Asthma Therapy: Example for EU regulations for medicinal devices and combination medicinal products
10:00 – 10:45	Anele Vutha	Medical Device Regulations – An industry perspective
10:45 – 11:15	Tea Break	
11:15 – 12:45		
In vitro and in vivo Diagnostics		
11:15 – 12:00	Patrick Salmon	EU Regulation of in vivo diagnostics
12:00 – 12:45	Robyn Howes	In vitro diagnostics – a South African perspective
12:45 – 13:45	Lunch Break	
Chair: Tomas Salmonson		
13:45 – 18:30		
Generic Drugs		
13:45 – 14:30	Peter Bachmann	EU Regulation of generic drugs
14:30 – 15:15	Joanne van Harmelen	Generic drugs – Legal issues and patent situation in South Africa
15:15 – 16:00	Tea Break	
16:00 – 16:45	Jaco van Zyl	Generics – The perspective of the South African generics industry
16:45 – 17:15	Yolanda Peens	Generics – An international industry perspective
17:15 – 18:00	Joy van Oudtshoorn	Generic drugs – The MCC perspective
18:00 – 18:30	Panel Discussion	
10 October 2014		
Chair: Mandisa Hela		
09:00 – 12:30		
Anti-infective Drugs		
09:00 – 09:45	Filip Josephson	EU regulatory conditions for novel anti-infective drugs
09:45 – 10:30	Gavin Steel	New anti-infective drugs – Regulatory strategies in South Africa
10:30 – 11:00	Tea Break	
11:00 – 11:45	Andreas Diacon	Novel TB drugs – Medical need & current developments
11:45 – 12:30	Panel Discussion	
12:30 – 13:30	Lunch Break	
Chair: Ekkehard Baader		
13:30 – 14:30		
Advanced-Therapy Medicinal Products (ATMPs)		
13:30 – 14:15	Sol Ruiz	EU regulation of ATMPs
14:15 – 17:00		
The Regulator as Gatekeeper and Enabler for Drug Development		
14:15 – 15:00	Tomas Salmonson	CHMP perspective
15:00 – 15:45	Shabir Banoo	South African perspective
15:45 – 16:45	Panel Discussion	
16:45 – 17:00	Closing Remarks	