



INDO-AFRICA PHARMA BUSINESS MEETING

Hyderabad, india

25 – 27 September, 2009

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PRAZ

What is PRA

The Pharmaceutical Regulatory Authority is a government agency responsible for medicines regulation and control in Zambia:

- It is established as a statutory body under the Pharmaceutical Act (No.14) of 2004;
- It is mandated to ensure that pharmaceutical products being made available to the Zambian people consistently meet the required standards of quality, safety and efficacy

Functions & duties of the PRA(1)

- Registration of pharmaceutical products
- Registration, licensing and inspection of pharmaceutical establishments for purposes of manufacture, import/export, sale and supply of pharmaceutical products
- Regulation and control of medicines promotion and advertising;
- Carry out Post marketing surveillance activities
- Regulation and control of the conduct of clinical trials;
- Quality control of pharmaceutical products to ensure adherence to quality standards;
- Conduct pharmacovigilance activities
- Administer the Pharmaceutical Act and perform duties and exercise powers which are imposed to the Authority by the Act

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Organisation and management of the PRA

- Board appointed by Minister responsible for Health;
- There is a PRA Secretariat with four major directorates:
 - General Administration
 - Registration
 - Inspectorate and licensing
 - Laboratory services

The Pharmaceutical Industry

- Relatively small
- Pharmaceutical manufacturers (06)
- Importers and wholesale dealers (>100)
- Reatilers (<100)

Scope of products regulated by PRA

- Medicines including herbal medicines
 - for herbal medicines regulation is limited to those that are formulated and packaged for placement on the market
- Allied substances including food supplements, medical devices, condoms, cosmetics

N.B. Most products on the Zambian market are imported (~90%) and largely from India

Regulatory Challenges

Our major challenges include:

- Insufficient funds
- Inadequate human resources and Zambia has not been spared in terms of brain drain or what in SADC is referred to as brain circulation
- Infrastructure such as office accommodation and laboratory
- Transport
- Centralised regulatory system

Challenges (2)

- some of the regulations to support the effective implementation of the Pharmaceutical Act are yet to be done and we need to build regulatory capacities to deal with the new areas
- Counterfeits and substandard medicines

OPPORUNITIES

- International collaboration and collaboration such as these forums which provides an opportunity for information sharing and networking
- Harmonisation initiatives in SADC and COMESA countries

Conclusion...

- It is my considered view that Zambia has great investment opportunities in the pharma industry;
- Zambia is politically stable and a peaceful nation
- Government is making efforts to create an enabling environment for business through various licensing reforms
- We as regulators will do our utmost to reduce the regulatory burdens on pharma industry but we also wish to see our local pharma industry especially local manufacture flourish

Questions???

THANK YOU FOR YOUR
ATTENTION.....