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Spotlight on South Africa
Regulatory Landscape and Business Opportunities

23-25 JAN. 2018
The EGG
BRUSSELS

The MedTech Forum
bringing HealthTech stakeholders together
South African Medical Device Industry
South African Medical Device Industry

Overview

- Market size worth an estimated ZAR 16.9 billion
- 0.3% of the global market
- Local manufacture is limited
- Industry comprised mostly of imported devices (imports cater for 90% of the market by value)
- Opportunities for exporters of medical equipment (particularly new and innovative equipment)
- Forecasts indicate that the local market will grow by a CAGR of 7.7% in the next 5 years
- Contributing factors to projected growth:
  - the development and upgrade of hospitals
  - the implementation of the National Health Insurance programme
The Technology Innovation Agency (TIA) is a national public entity.

The TIA is placing emphasis on medical device innovation.

Bridges the innovation gap between research and development.

Provides risk funding and support for innovators to progress ideas towards market entry and commercialisation.

Identified key opportunities for medical device sector:
- Increasing local production
- Creation of new export and local markets for local producers
- Developing improved health technology innovation capability
- Geographical location – in relation to Africa
- BRICS status
DTI encourages local supplier development programmes
- Proposes collaboration between local supplier development programmes and the private sector
- Create the opportunity to capture an increasing share of the private sector medical device market
- Facilitate increased local manufacture of medical devices for the domestic market as well as regional and international markets
- Supporting departments/agencies:
  - Economic Development Department
  - National Department of Health
  - National Treasury
Broad-Based Black Economic Empowerment ("BEE")

Introduction

- BEE policy aims to increase participation by previously disadvantaged South Africans in economic activities
- BEE consists of initiatives that aim to:
  - Increase levels of equity ownership by black people in businesses
  - Increase the number of black people in management positions of businesses
  - Improve the skills of black employees
  - Assist small and medium businesses that are majority-owned by black people
  - Procure goods and services from BEE compliant businesses
Organs of state and public entities must apply the BEE Codes when:

- Determining qualification criteria for the granting of licences, concessions or other authorisations in respect of economic activity in terms of any law
- Developing and implementing a preferential procurement policy
- Determining qualification criteria for the sale of state-owned enterprises
- Developing criteria for entering into partnerships with the private sector
- Determining criteria for the awarding of incentives, grants and investment schemes in support of BEE

No Codes issued in the pharmaceutical /medical device sector(s), as yet
Broad-Based Black Economic Empowerment ("BEE")
Measured Elements

- Ownership
- Management Control
- Socio-Economic Development
- Enterprise and Supplier Development
- Skills Development

Elements
Life Sciences Commercial & Regulatory Team