

Vaughn Harrison

Spotlight on South Africa

Regulatory Landscape and Business Opportunities

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—
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South African Medical Device Industry

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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

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Industry

Innovation and Initiatives

- 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

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South African Medical Device Industry

Localisation – Medical Devices Supplier Development Programme

- Department of Trade and Industry (DTI) launched the Industrial Policy Action Plan 2017/2018 – 2019/2020
- 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

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South African Medical Device Industry

Localisation – Medical Devices Supplier Development Programme

- 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")

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Broad-Based Black Economic Empowerment ("BEE")

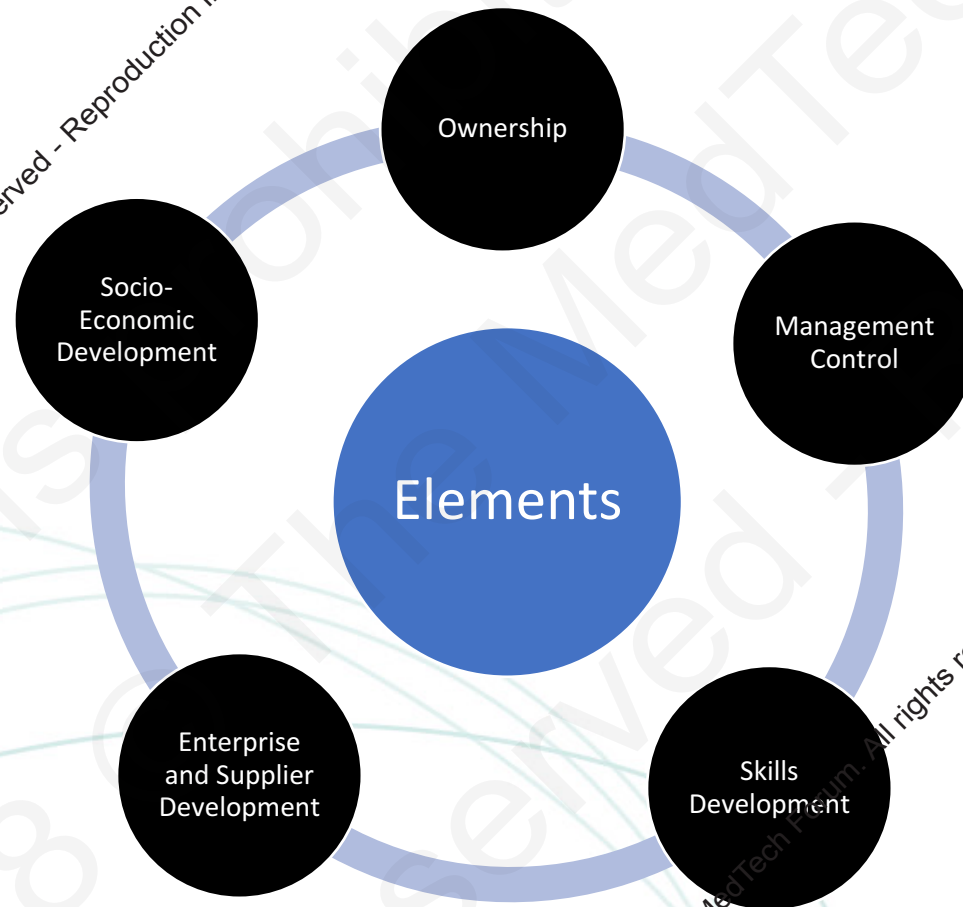
Introduction

- 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

Broad-Based Black Economic Empowerment ("BEE") Continued

- 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



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Life Sciences Commercial & Regulatory Team

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Life Sciences Commercial & Regulatory Team Attending MedTech Forum 2018



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