Industrial Policy and Incentives for Pharmaceutical and Medical Devices Sector

IDD PHARMACEUTICAL AND MEDICAL DEVICES

DEPARTMENT OF TRADE AND INDUSTRY, SOUTH AFRICA

SAPC 4 OCTOBER 2019







Slide 1

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Windows User, 10/24/2018

INDUSTRY OVERVIEW: PHARMACEUTICAL

- Trade balance deficit over almost two decades
 - Less than 1% of GDP
- More recently imports constitute approximately 60-70%
- Predominantly Asian and European imports
- Pharmaceutical exports gradual increase
 - Efficiency of manufacturing firms
 - weakness of the exchange rate makes exports attractive.
- Market value R45bn in 2016.
- 276 companies (different activities) licensed by SAPHRA
- Local manufacture, valued at R 4.9bn in 2015, dominated by local companies.
- SA companies #1 overall market share, Pharmaceuticals only and OTC only in 2017



INDUSTRY OVERVIEW: MEDICAL DEVICES

- Domestic medical device industry underdeveloped,
 - Imports <u>90</u>% of the market by value.
 - Trade deficity
 - SA market ranks amongst the 30 largest globally
- 2016-2021 CAGR = 8.4% in local currency terms
- Market value = ZAR24.2bn by 2021
- Imports increase by 6% to USD2.1bn in 2017
- >60% of all imports are sourced from 5 countries (2017)
 - half from the top three.
 - USA remains the dominant supplier, in value terms, 22%
 - Germany with 14%.
 - China's increase to 13%



POLICY DIRECTIVES

- Industrial Policy Action Plan (IPAP)
- Economic Sectors, Employment and Infrastructure Development (ESEID) cluster
- Structural change, by encouraging the development, growth and increased competitiveness of the manufacturing (Value Added) sector
- Overall policy and plans to address the key challenges of economic and industrial growth and race based poverty, inequality and unemployment
- Reindustrialisation for inclusive growth (2019) i.e. Masterplan
- Encourage sustainable investment in South Africa
- Identify employment opportunities
- Identify national, regional, broader international possibilities
- Identify opportunities to deepen industrialisation (cross sector linkages)



PHARMACEUTICAL AND MEDICAL DEVICES DESK

Industrial Development Division (Policy development and implementation)

Chemicals, Cosmetics, Pharmaceutical and Plastics

Pharmaceutical and Medical Devices



INDUSTRIAL POLICY OBJECTIVE W.R.T LOCAL CONTENT REQUIREMENTS

- Leverage public expenditure
- Develop and enhance local manufacturing capacity and capabilities
- Support industrial innovation and technological developments
- Create employment and sustain jobs
- Boost exports and ensure suppliers are integrated into OEMs global value chains
- Support broader economic empowerment through the creation of black industrialists



INDUSTRIAL POLICY OBJECTIVE W.R.T LOCAL CONTENT REQUIREMENTS

- ➤ Preferential Procurement Policy Framework Act (PPPFA) was enacted in 2000, and its Regulations promulgated in 2001
- Local Content Regulations came into effect on 7 December 2011 through the 2011 PPPFA
- Amended Regulations applicable from the 2018 Public Procurement cycle onward
- Section 8: Local Production and Content



PROCUREMENT LEVERS

- Designation: Local Production and Content
- Sectoral In depth analysis establish local production capacity and public procurement opportunities.
- Section 8 of Preferential Procurement Policy Procurement Act (PPPFA)
 - empowers the dti to designate specific industries/sectors for local procurement by organs of state supporting industrialization
- Establish capacity database in both pharmaceutical and medical devices to inform designation recommendations
 - ARV, TB, OSD



PROCUREMENT LEVERS

- National Industrial Participation Programme (NIPP)
- Applicable to all government procurement,
- Imported Content => US\$10 million
- Direct NIPP
 - projects where there is potential to develop or support strategic industries
- Indirect NIPP
 - projects where there is no potential or opportunities for local manufacturing in procured industries
- Other include Defense Industrial Participation Programme (DIPP) and CSDP



POLICY INSTRUMENTS: INCENTIVES

Broadening Participation

- Incubation Support Programme (ISP)
- Support Programme for Industrial Innovation (SPII)

Competitiveness Investment

- Manufacturing Competitiveness Enhancement Programme (MCEP) – Suspended due to oversubscription
- Export Marketing Investment Assistance (EMIA)
- Sector Specific Assistance Scheme (SSAS)
- Capital Projects Feasibility Programme (CPFP)

Manufacturing Investment

- 12I Tax Allowance Programme
- Automotive Investment Scheme (AIS)
- Aquaculture Development and Enhancement Programme (ADEP)

Services Investment

- Film & TV Production Incentive
- Business Process Services (BPS)

Infrastructure Investment

- Critical Infrastructure Programme (CIP)
- Special Economic Zones (SEZ)



POLICY INSTRUMENTS: INCENTIVES

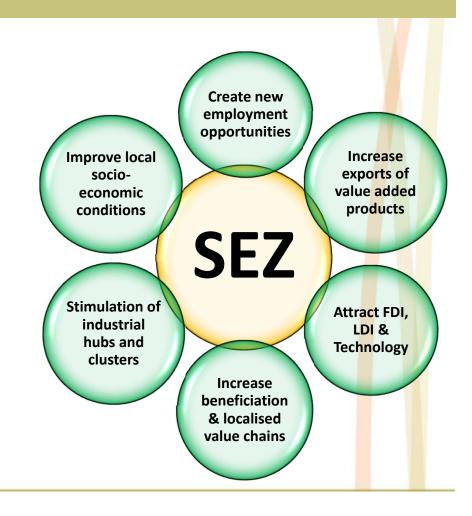
- Black Industrialist Scheme (BIS)
 - Launched 2016
 - 100 per annum
 - Address transformation
 - Development of industrialists in core sectors
 - Successful recipients
 - Condom manufacturers
 - Other healthcare support to be determined



POLICY INSTRUMENTS: INCENTIVES -SEZ's

Special Economic Zones (SEZs) are geographically designated areas of a country set aside for specifically targeted economic activities to promote rapid industrial development.

Zones are supported through special arrangements and support systems to attract and retain targeted industrial investors.





INDUSTRIALISATION AND LOCALISATION

- OSD 2012 70% volume, 2014>60%, 2016 50% value & volume, 2018
- Family Planning 2013 50% value, 2018 50% value (oral)
- ARV 70% value 2013, 2015 >60% value, 2019 69.7% local
- Medical textiles currently designated 100% under the Textiles designation importers require exemption letter
- ➤ Condoms 2015/18 cycle only 1 manufacturer, 2018/2021 cycle 3 manufacturers (Section 8(4)(a) to boost localization)
- Anti-TB 2017 > 67% local
- Intravenous tubes and catheters localized using PPPFA



INDUSTRIALISATION AND LOCALISATION

- Surgical sutures 3 local manufacturers, 2017 Section 8(4)(a) to award >80% local
- ➤ Wheelchairs 2 domestic manufacturers, 2017/20 bulk awarded using Section 8.4(a) of the revised PPPFA Regulations.
- Gloves 1 domestic manufacture, localizing using PPPFA, increase exports, new site commissioned. 2nd re-establishing local manufacture Sep 2019
- New 500 bed Hospital in KZN furnishings of almost R1bn to be localized
- Medical refrigeration 2 local manufacturers, 1 awarded bulk using Section 8(4)(a)
 - > 3 quote system used by the procurers and successfully negotiated for the prioritisation of the local manufacturers

OTHER INITIATIVES

- Cluster Development Program
 - > Pheroid Cluster
 - Medical devices Cluster
- Chemical incentive
 - > Approval pending



THANK YOU

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