Towards Achieving Higher Impact Industrialisation In The Pharmaceuticals And Medical Device Sectors In SA

IDD Pharmaceutical and Medical devices

Department Of Trade And Industry

SAPRAA 12 APRIL 2019

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REPUBLIC OF SOUTH AFRICA

POLICY CONTEXT OF THE IPAP

- Government policy identifies industrial development as one of the key pillars required for inclusive growth with an emphasis, on value-addition, labour intensive sectors and exports

- The IPAP 2018/19-2020/21 is in its 10th iteration and is informed by the vision set out for South Africa's development provided by the National Development Plan and is aligned the Medium Term Strategic Framework (MTSF) and the Medium Term Expenditure Framework, (MTEF)

- It is a product of the Economic Sector and Employment Cluster of Government and its iterative annual format has served as a useful tool to strengthen intra-governmental integration and co-ordination

POLICY CONTEXT OF IPAP

- Address deep structural fault lines in economy requiring longer term solution.

- Identify key constraints to manufacturing growth in the domestic economy.

- Successive annual iterations of IPAP have introduced new themes and focus areas to achieve a higher impact industrial policy.

- Iterations of IPAP highlights adjustment and strengthening of the range of policy instruments at governments

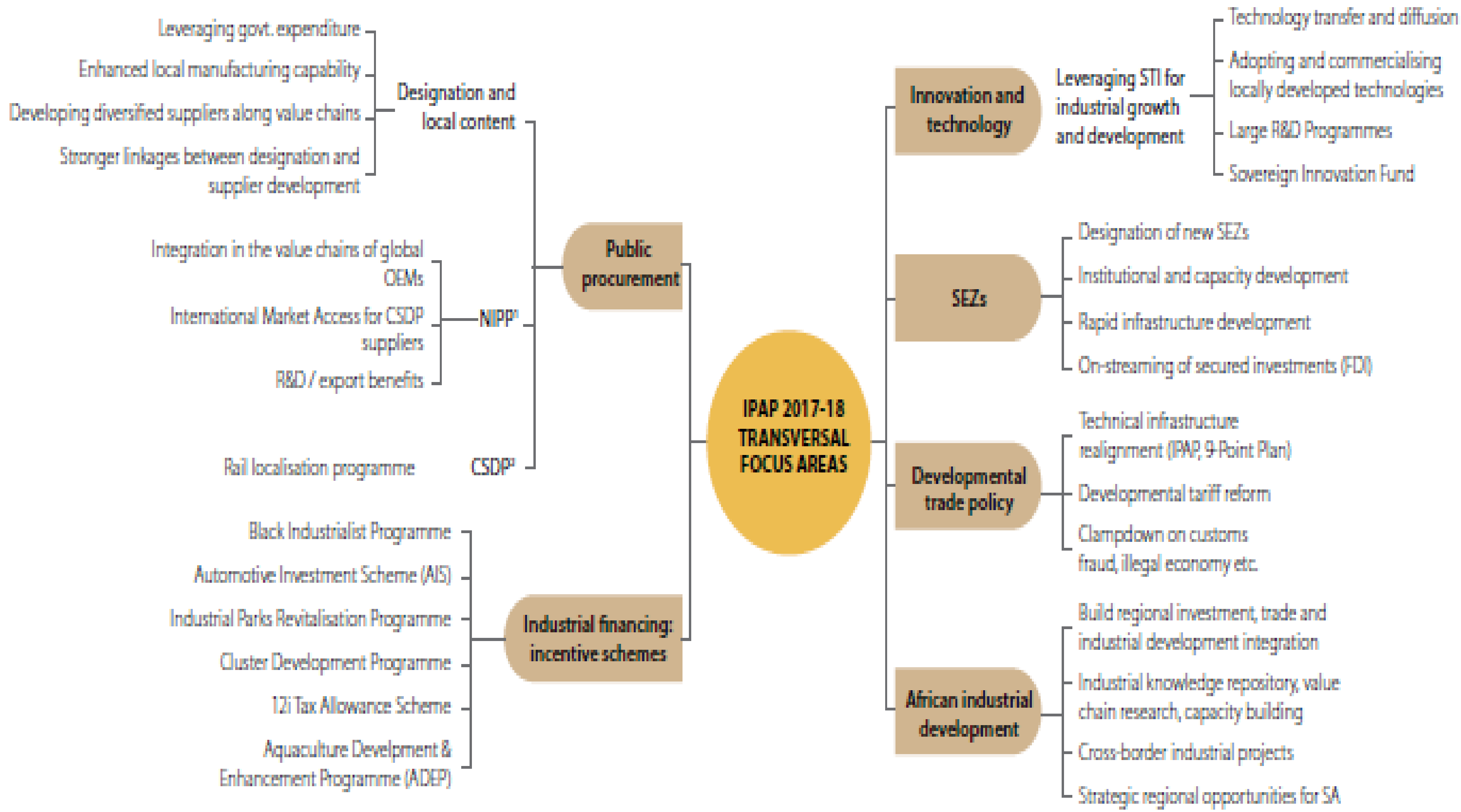
- IPAP 2018/19 –20/21 built upon the successes achieved and lessons learnt and offers opportunity to review the legacy of the past 10 years

  Automotives, Clothing, Textiles Leather and Footwear (CTLF), Business Process Services (BPS), Film Production and Boatbuilding

CORE OBJECTIVES OF IPAP

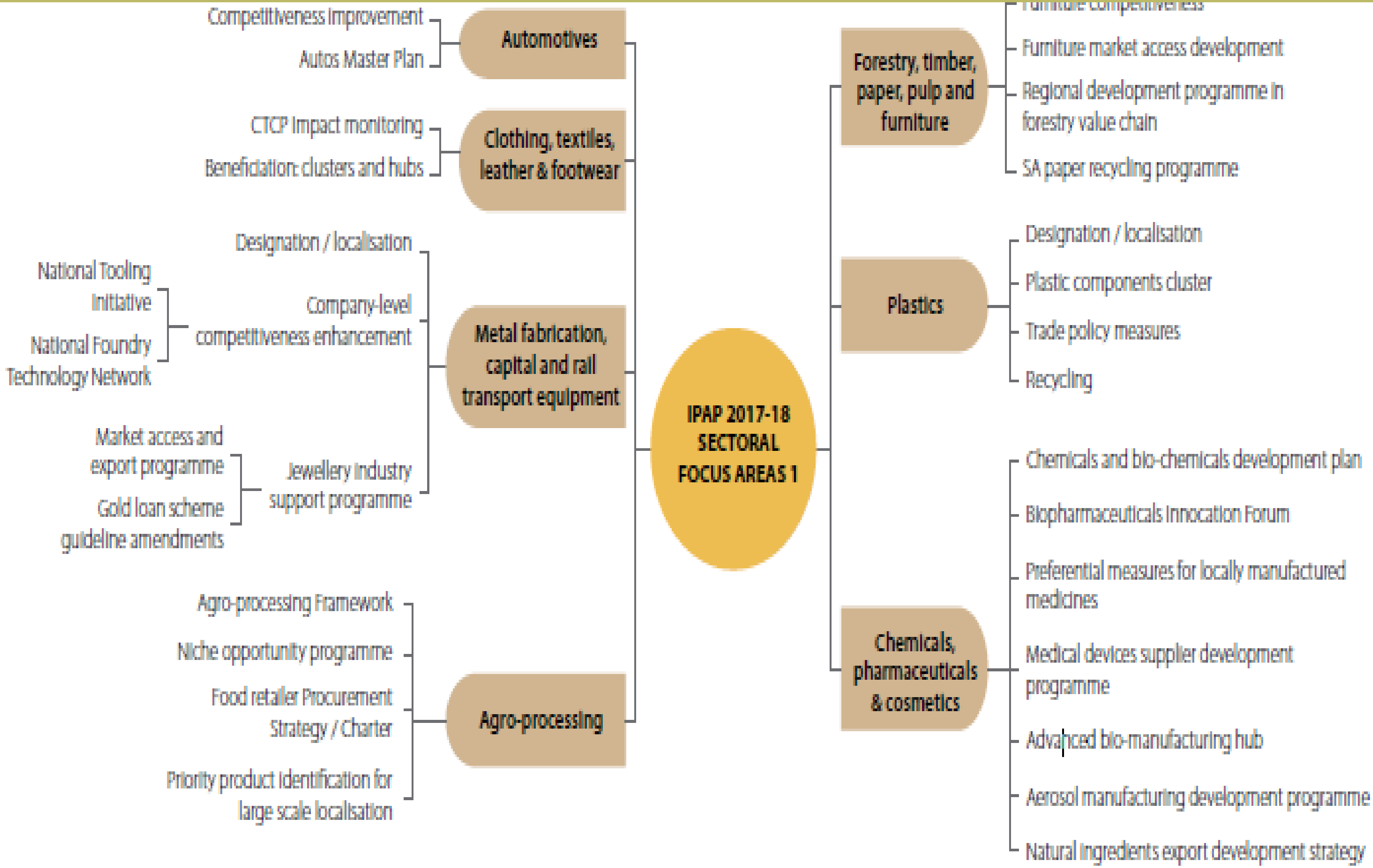
1. **Diversify the economy:** provide strong support for value added manufacturing
2. **Promote labour-absorbing industries**
3. **Industrialisation model focussed on inclusive growth**
4. **Contribute towards industrial development in Africa**
5. **Movement towards a knowledge economy**

IPAP TRANSVERSAL FOCUS AREAS



[1]National Industrial Participation Programme
[2]Competitive Supplier Development Programme

IPAP SECTORAL FOCUS



Pharmaceuticals

PHARMACEUTICAL AND MEDICAL DEVICES DESK

Industrial Development Division

↓

Chemicals, Cosmetics, Pharmaceutical and Plastics

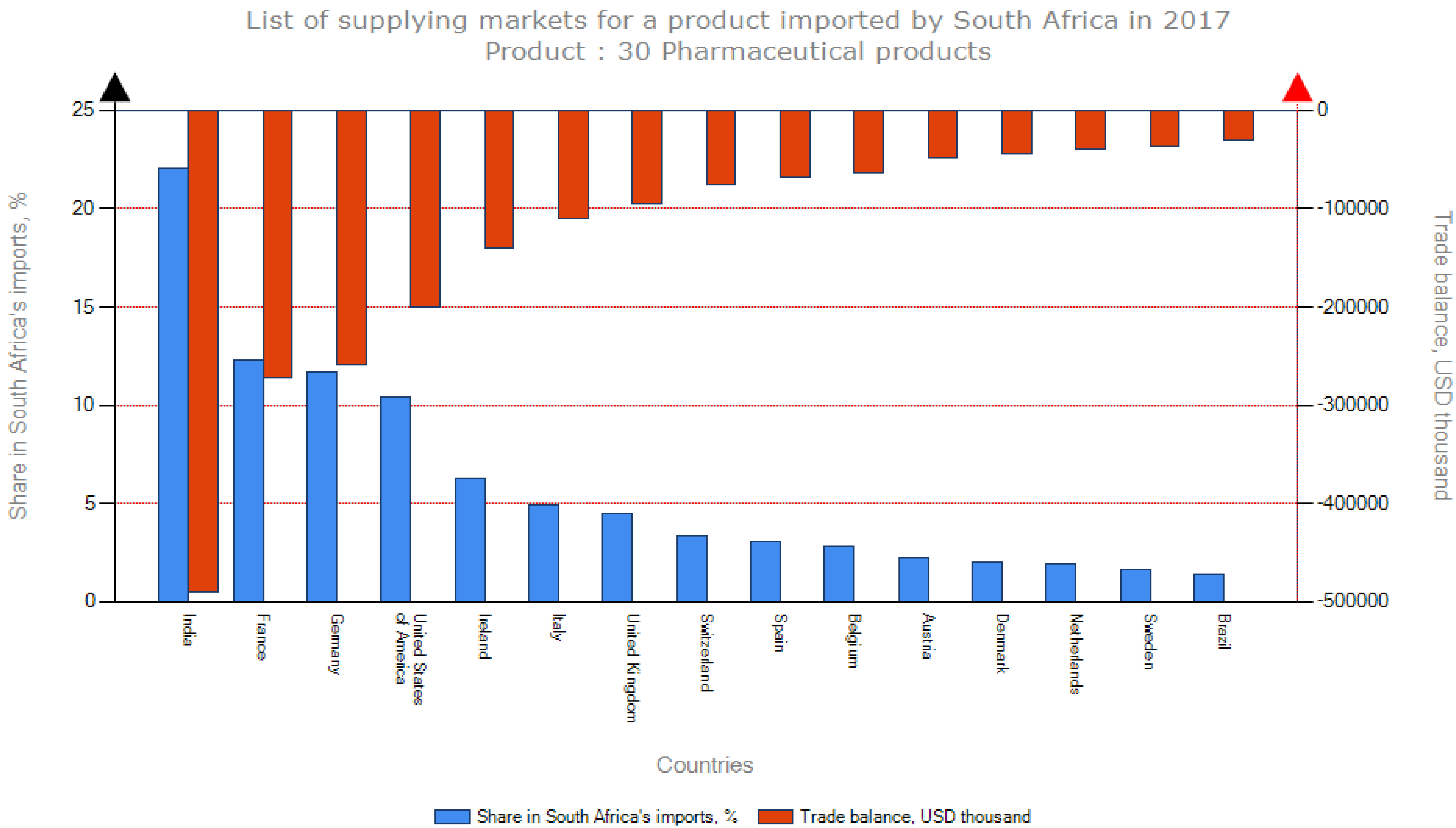
↓

Pharmaceutical and Medical Devices

INDUSTRY OVERVIEW: PHARMACEUTICAL

- Imports exceeds exports, increasing trade balance deficit over almost two decades
- In 2015, imports accounted for **85%** of trade,
- More recently imports constitute approximately 70%
- Predominantly Asian and European imports.
- Pharmaceutical exports gradual increase
- Efficiency of manufacturing firms and weakness of the exchange rate makes exports attractive.
- Market value R45bn in 2016.
- 276 companies 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: PHARMACEUTICAL



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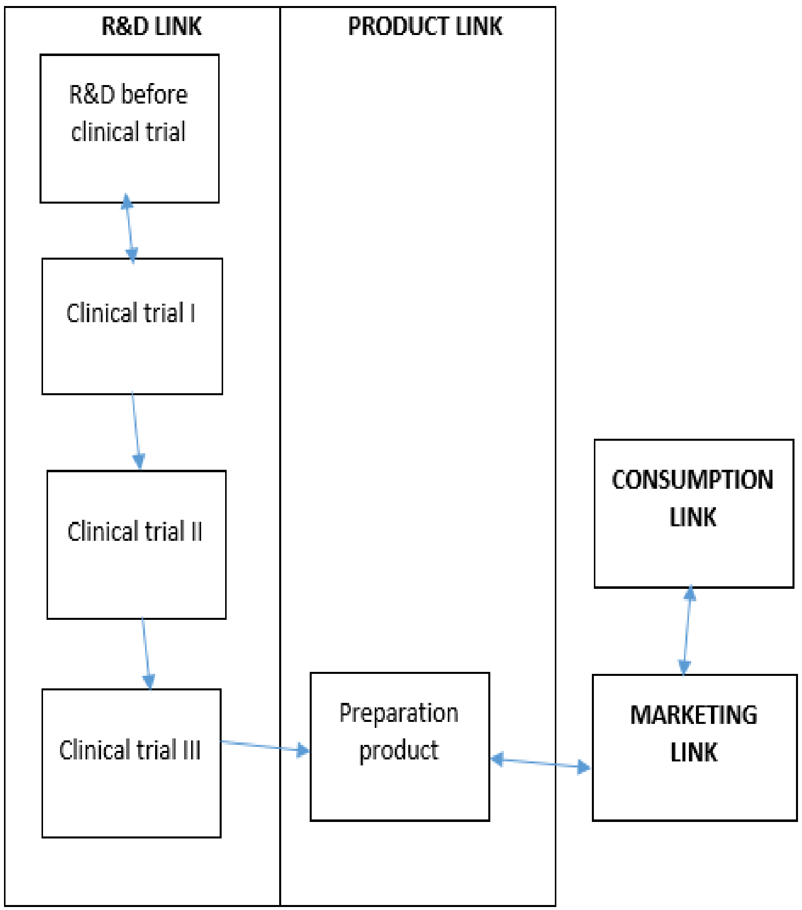
Source: Trade Map, 2018

PHARMACEUTICAL MANUFACTURING VALUE CHAIN



The pharmaceutical value chain is an ‘additive’ value chain. The main activities in the pharmaceuticals industry include:

- R&D and clinical trials
- Manufacturing (Product link)
- Distribution and wholesale
- Retail/sale/marketing

Main activities in SA:

- Tertiary and secondary pharmaceutical manufacturing. Multinationals operate distribution, sales and marketing facilities in SA and contract local manufacturers to package their products
- SA does have specialised clinical trial capabilities

Players in the South African value chain

A variety of companies operate across the pharmaceutical value chain and are all impacted by operational conditions within the country

Research and Development

1 Discovery
- Target selection
- Discovery research
- Chemical synthesis
- Analytics

2 Pre-clinical

Laboratory studies
- Chemical synthesis
- Pharmacology & toxicology
- Analytics
- Regulatory support
- Development of lab process

3 Clinical development

Drug Substance Development

1 Primary process development
- Chemical synthesis
- Analytics
- Process development

2 Drug substance production
- Chemical synthesis
- Analytics
- Dosage form
- Process development
- Regulatory support

Manufacturing

1 Assembly

2 Packaging

3 Quality Control

Local Manufacturers

Distribution

1 Logistics
- Pharmacies
- Wholesalers
- Hospitals
- Depots
- Distributors

Marketing

1 Doctor interaction

2 Interactions with pharmacists

3 Interactions with Funders

4 Publications

5 Conferences

6 Direct to customer

Patient consumption

Note/s: Companies represented are a selection of those operating in South Africa and do not reflect an exhaustive list
References: Deloitte Analysis

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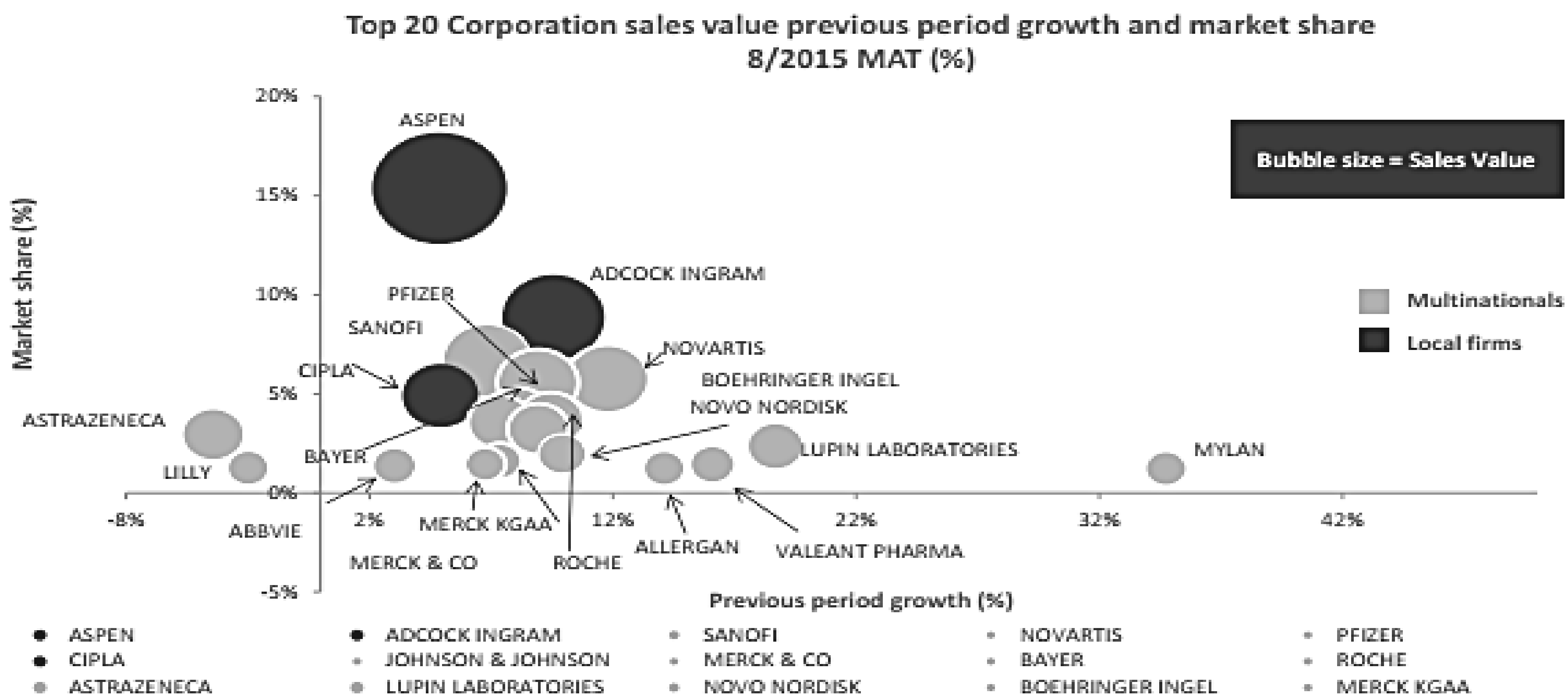
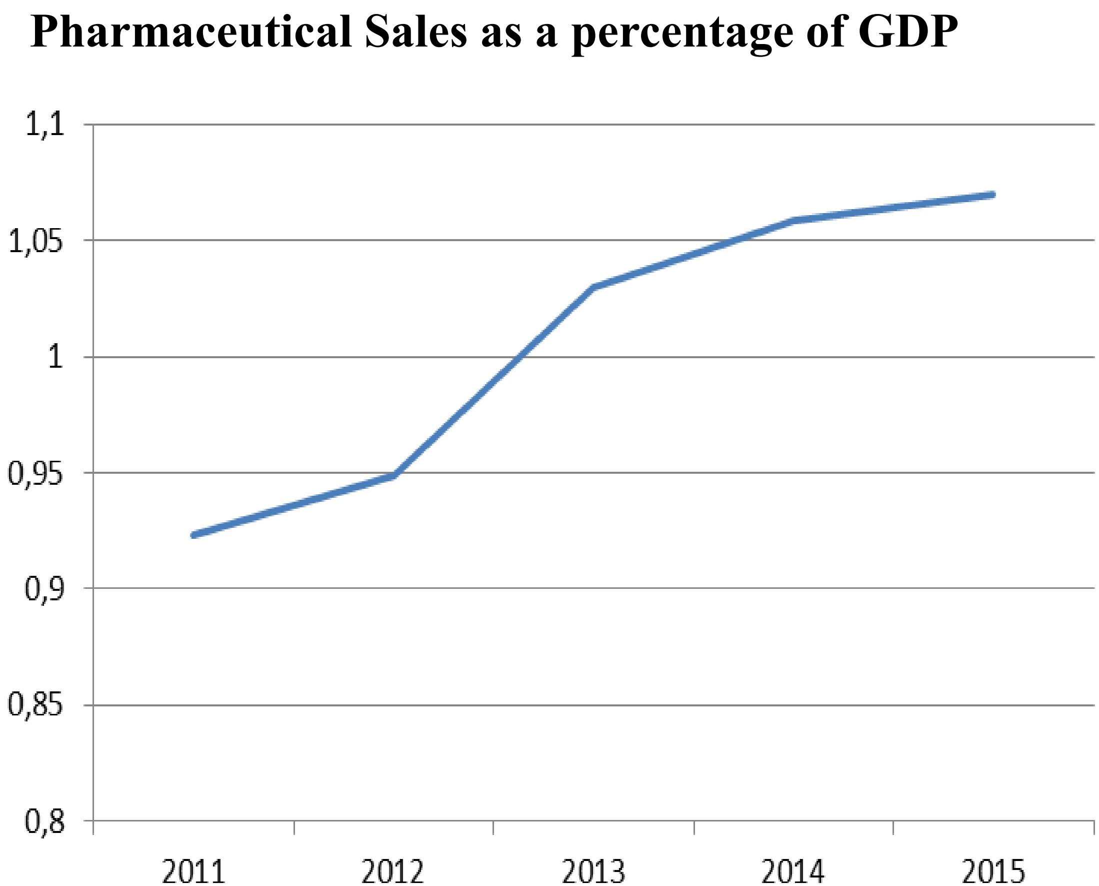
KEY PLAYERS (PERFORMANCE)

Average growth for top 20 corporations is 9%, growth for top performing multinats is 10% while their local counterparts are growing an average of 6%



Source: Utipharma

CONTRIBUTION TO GDP



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Data Extracted from: BMI, 2016

INDUSTRY OVERVIEW: MEDICAL DEVICES

- South Africa's domestic medical device industry remains underdeveloped
- Imports catering for 90% of the market by value
- South African medical device market ranks among the 30 largest in the world.

- 2016-2021 CAGR = 8.4% in local currency terms

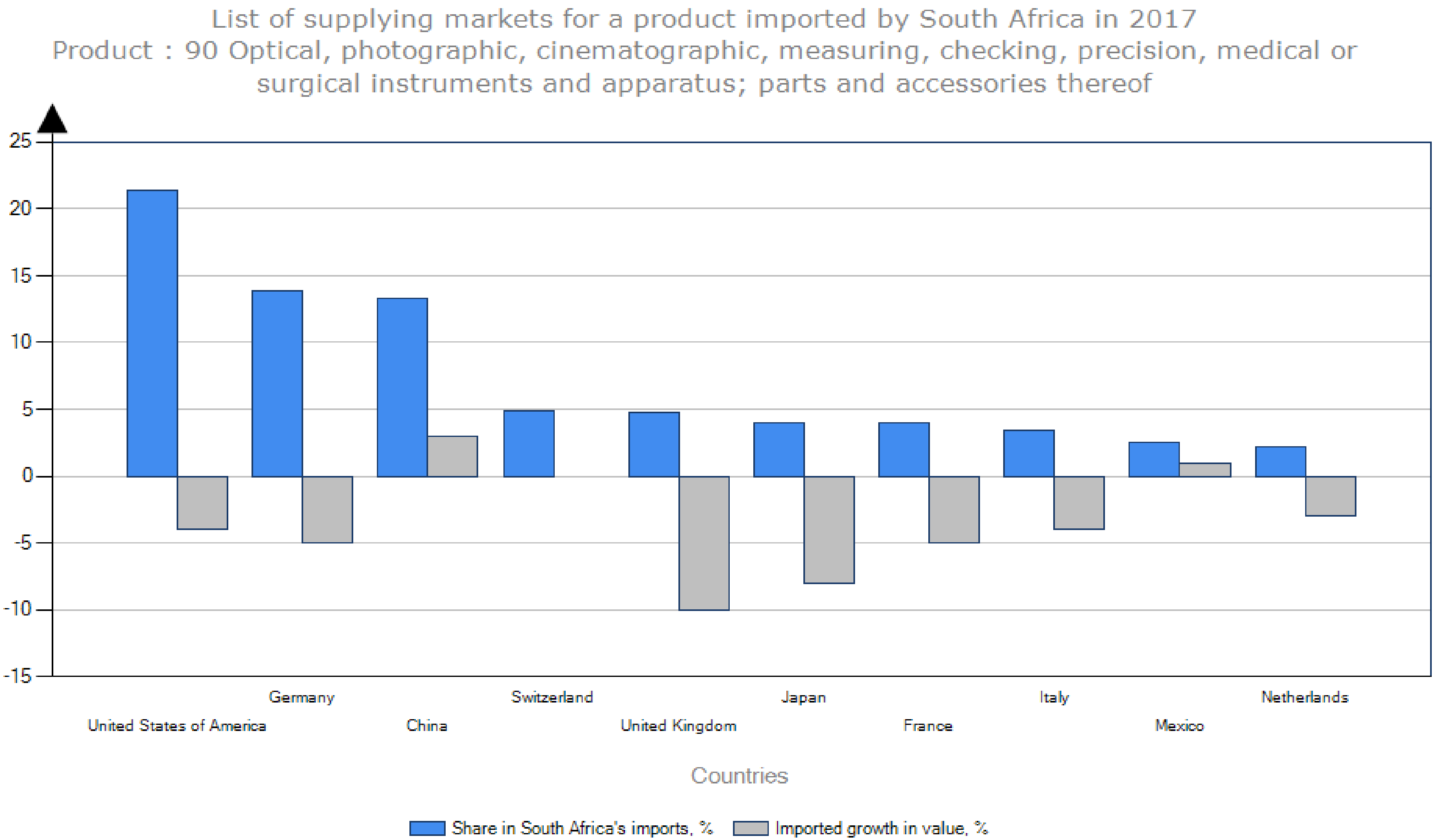
- Market value = ZAR24.2bn by 2021

- Imports rose by 6% to USD2.1bn in 2017

- 90% of devices are imported. Significant contributor to trade deficit

- > 60% of all imports are sourced from 5 countries, half from the top 3.
- USA remains the dominant supplier, in value terms, 22% of imports in 2017
- Gerrmany with 14%.
- China increasing trend 13% in 2017.

INDUSTRY OVERVIEW: MEDICAL DEVICES



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Source: Trade Map, 2018

the dti's INDUSTRIAL POLICY TOOLBOX

- Public procurement
  - -localisation
  - -NIPP
- Industrial Financing, incentives and export support
- Developmental Trade Policy
- SEZ's
- Tariffs
- Cluster Development
- Regional integration

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

PROCUREMENT LEVERS

- **National Industrial Participation Programme (NIPP)**

- Applicable to all government procurement, Imported Content => US$10 million
- **Direct NIPP** is used in projects where there is potential to develop or support strategic industries
- **Indirect NIPP** is used in projects where there is no potential or opportunities for local manufacturing in procured industries

- **Other include Defense Industrial Participation Programme (DIPP) and CSDP**

INDUSTRIALISATION AND PROCUREMENT

- **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 PROCUREMENT

- **Surgical sutures** 3 local manufacturers, 2017 using Section 8(4)(a) to award >80% local
- **Wheelchairs** 2 domestic manufacturers, 2017/20 tender award bulk using Section 8.4(a) of the revised PPPFA Regulations.
- **Gloves** 1 domestic manufacture, localizing using PPPFA, increase exports, new site commissioned. Medtex re-establishing local manufacture June 19
- **New 500 bed Hospital in KZN** furnishings of almost R1bn to be localized
- **Medical refrigeration** 2 local manufacturers, 1 of which was awarded bulk using Section 8(4)(a)
  - **3 quote system** used by the procurers and successfully negotiated for the prioritisation of the local manufacturers

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

PHARMACEUTICAL AND MEDICAL DEVICES OUTPUTS

- Western Cape Medical devices cluster
  - Leverage medical device value chains
  - Enable development of domestic capacity for export
- Pheriod Cluster
  - Optimise use of technology (delivery system) across agriculture, pharmaceutical, cosmeceutical, neutriceutical and other applications
    - Skin care range, food supplement, pharmaceutical creams, fertilizer, etc

PHARMACEUTICAL AND MEDICAL DEVICES OUTPUTS

- Intellectual Policy
  - Pharmaceutical and Geographic Indications prioritised
  - Framework currently being implemented
- Tariffs
  - General review of Chapter 29 and 30
    - Identify incorrect classification
    - Eliminate mis-declaration (new tariff headings)
  - Medical devices (ongoing)
    - Customs data up to 8 digits

PHARMACEUTICAL AND MEDICAL DEVICES OUTPUTS

- Regulatory Interventions
  - Engage SAHPRA and relevant stakeholders regarding appropriate interventions to benefit healthcare and industrial policy
- Medical devices supplier development program
  - Increased procurement of locally manufactured products
  - Domestic and regional/international focus

PHARMACEUTICAL AND MEDICAL DEVICES OUTPUTS

- Technology Innovation Cluster Program
  - With Technology Innovation Agency (TIA)
  - Increase competiveness of domestic medical devices sector
- Technology Innovation Mentorship Programme established as part of the Cluster Programme

PHARMACEUTICAL AND MEDICAL DEVICES OUTPUTS

- Biopharmaceutical study
  - Landscape analysis
  - Identify opportunities to develop locally
- Veterinary pharmaceutical study
  - Landscape analysis
  - Identify opportunities for localisation

PHARMACEUTICAL AND MEDICAL DEVICES OUTPUTS

- Participate in
  - Chieta Pharmaceutical and FMCG Chamber
  - Medicines Pricing Committee
  - DOH Stakeholder Committees
  - API Multi-stakeholder Working Group
  - Association activities (as requested)
  - SABF/NBF Pharmaceutical Working Group

THANK YOU

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