

# **Towards achieving higher impact industrialisation in the Pharmaceuticals and Medical Device Sectors in SA**

**Directorate: Pharmaceuticals and Medical Devices**  
**DEPARTMENT OF TRADE AND INDUSTRY**



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8



# 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 2016/17-2018/19 is in its eighth 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 the IPAP

- IPAP programmes are underpinned by an understanding that the domestic economy has deep structural fault lines which require longer term solution. IPAP is also informed by a process which seeks identify key constraints to manufacturing growth in the domestic economy and a problem solving, collaborative approach to the solution of these constraints.
- IPAP 2016/17 – 18/19 seeks to build upon the successes achieved and lessons learnt where industrial policy which is well designed; the subject of stakeholder engagement and collaboration and is adequately resourced has been successful – auto's and CTLF
- Successive annual iterations of IPAP have introduced new themes and focus areas to achieve a higher impact industrial policy. e.g. IPAP 2016 introduces an export focus leveraging a devalued currency.
- Successive iterations of IPAP take into account the need to adjust and strengthen the range of policy instruments at governments disposal in a very dynamic global and domestic market



# Core Objectives of the IPAP

**Promote labour-  
absorbing  
industries**

**Contribute towards  
industrial  
development in  
Africa**

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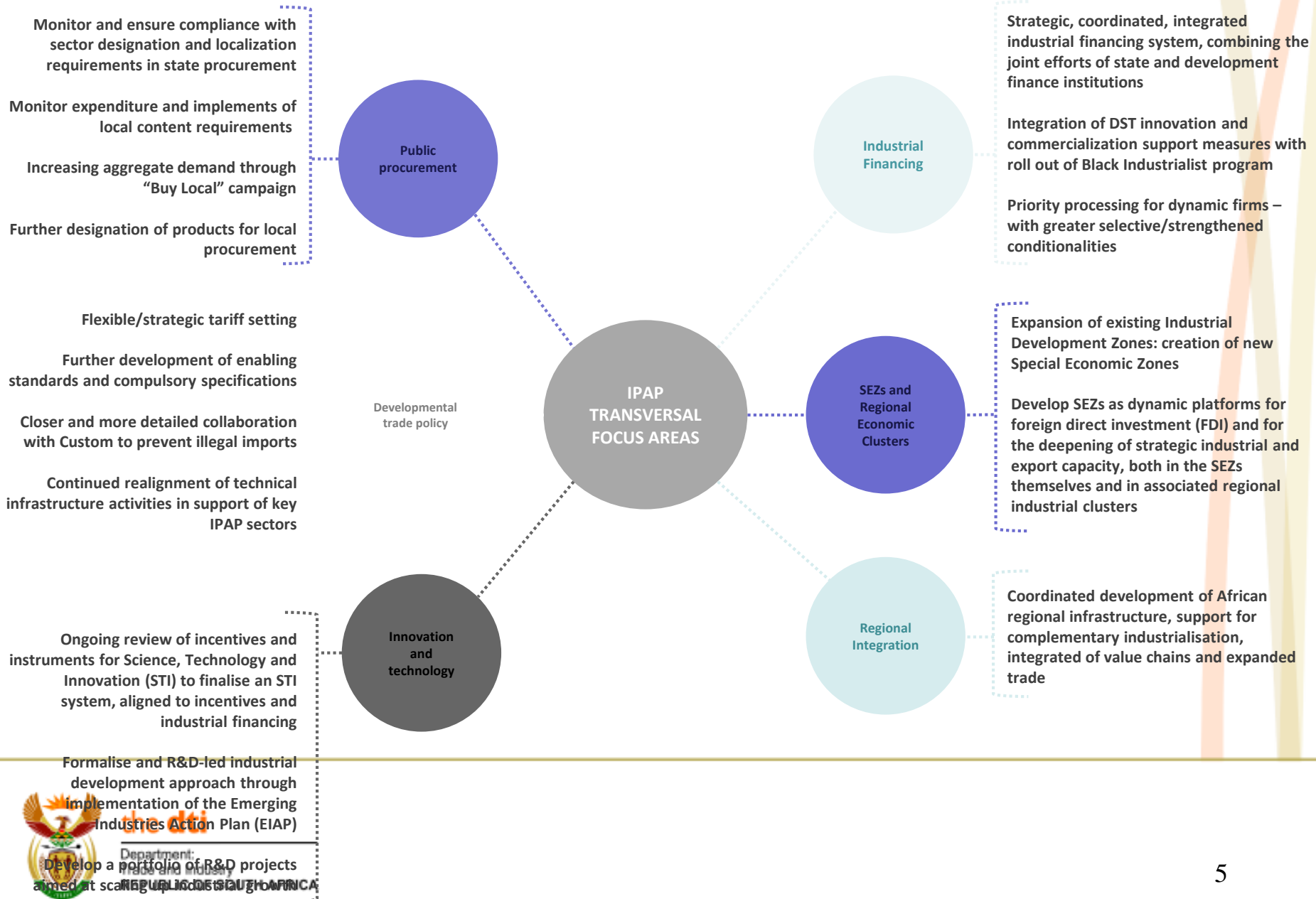
**Diversify the  
economy:** provide  
strong support for  
value added  
manufacturing

**Industrialisation  
model focussed  
on inclusive  
growth**

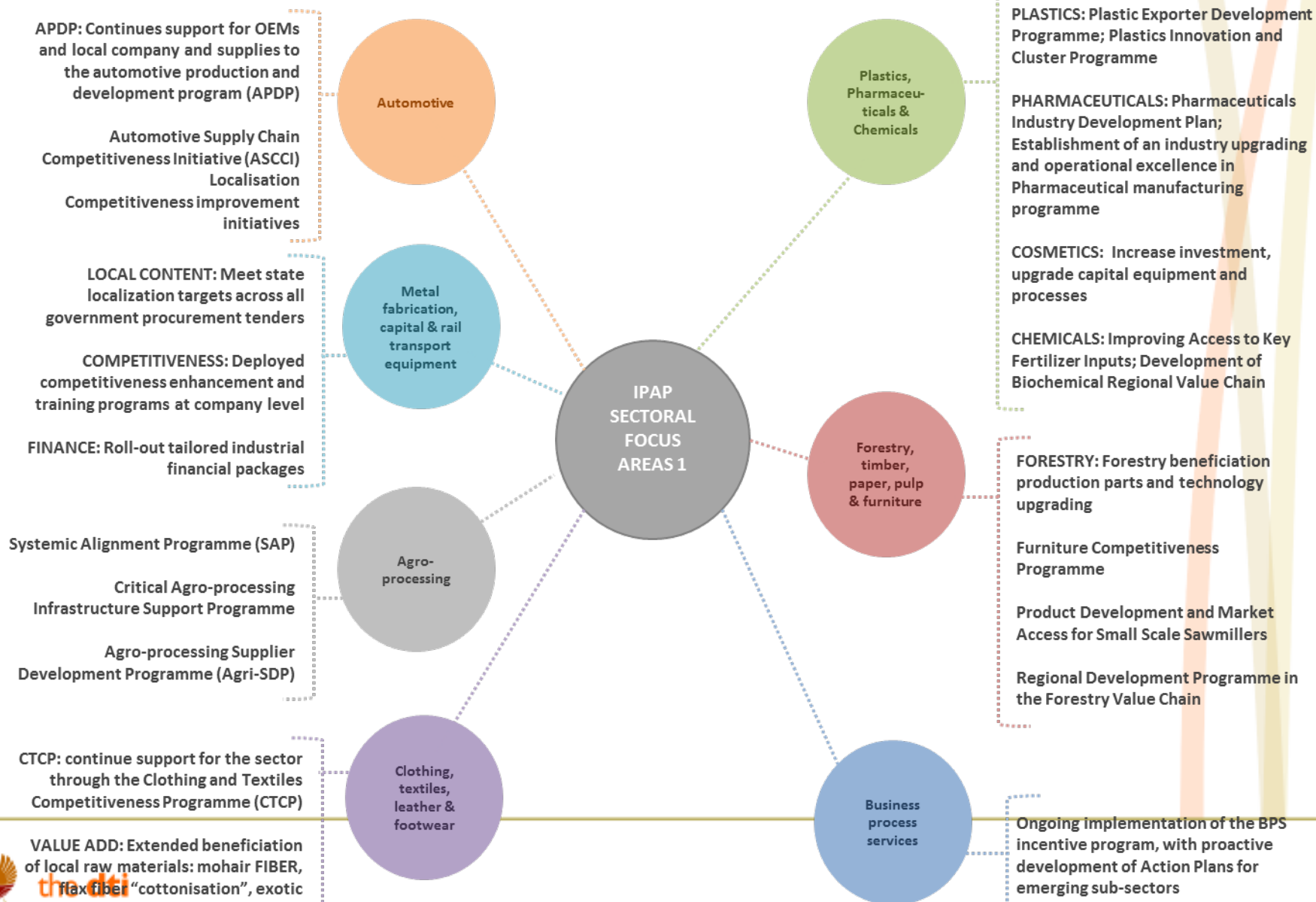
**Movement  
towards a  
knowledge  
economy**



# IPAP 2016/2017 TRANSVERSAL FOCUS AREAS



# IPAP 2016/2017 SECTORAL FOCUS AREAS 1



# PHARMACEUTICALS



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# Key Statistics: Pharmaceuticals

Variable	Contribution in 2014/15
Global market	Estimated to reach \$1 trillion – 2015
SA market	Approximately ZAR 44 bn (US\$ 3.5 bn)
Contribution to GDP	Approximately 1.1 % (2014) - decline noted
SA share of global market	0.4% (value) and 1.0% (volume) - Deloitte, 2016
CAGR (SA)	2.7% revised
Employment	9,500 in the industry 25,000 downstream (specialized logistics, retail and hospital pharmacies)
Trade balance	ZAR 22 billion (Chapter 30 - Pharmaceuticals) Active pharm. ingredients (APIs) est. - R 6 billion
Biologics – SA market	Estimated ZAR 4 bn (biologics and vaccines)
Estimated multiplier	1.35 (Deloitte, 2016)

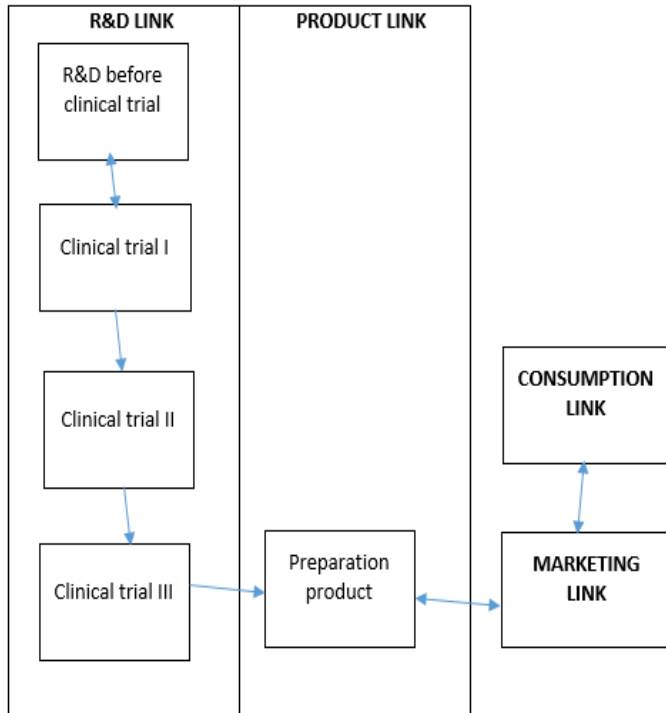


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# Pharmaceutical manufacturing value chain



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

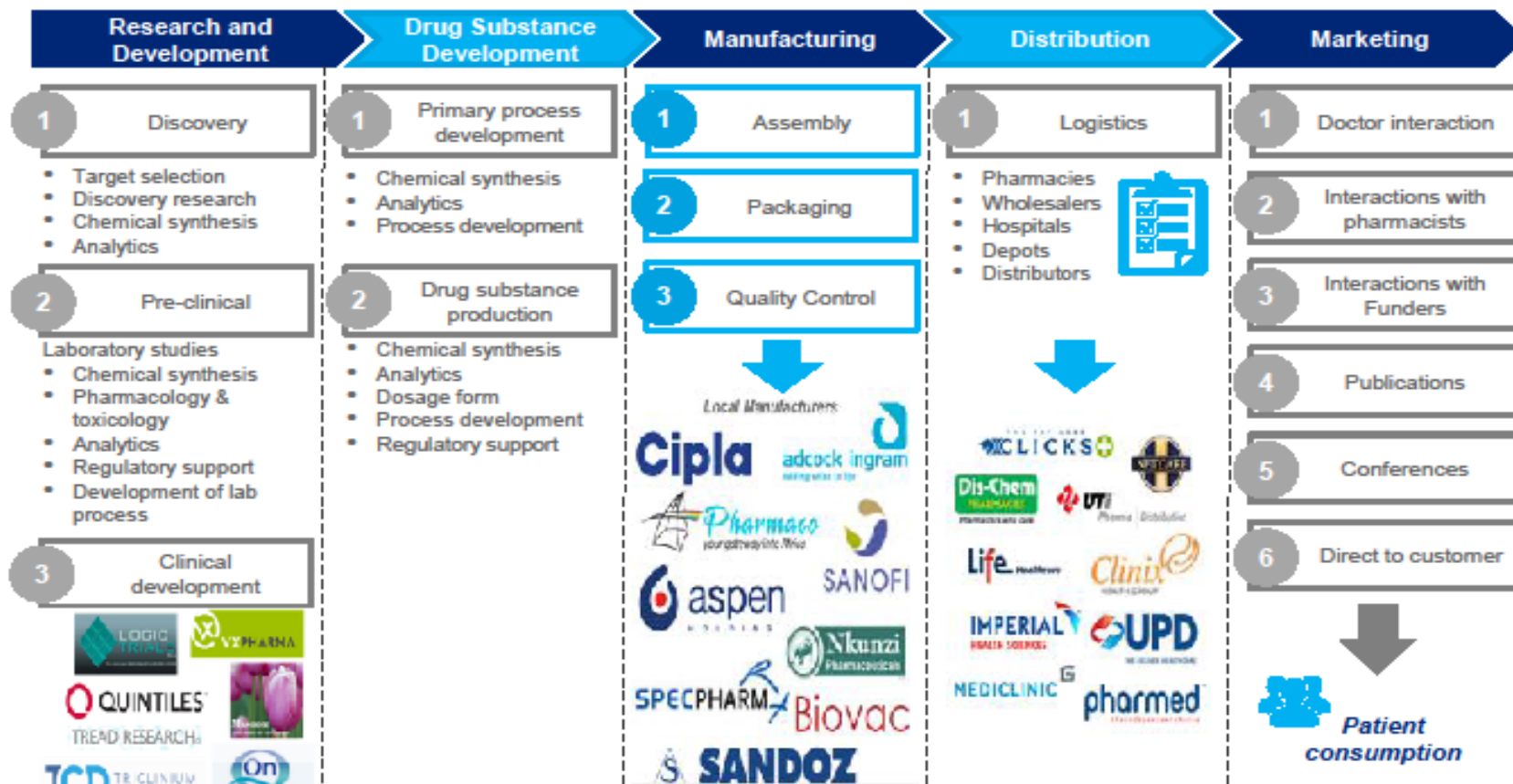


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# Players in the South African value chain

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



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

# Broad profile of the SA pharmaceutical manufacturing industry

- The pharmaceutical market in SA was valued at approximately R44 billion in 2015. The private sector accounted for 84% of the market. The public sector accounted for 16% of the market.
- Approximately 276 companies are licensed by the DoH and the MCC to manufacture or export pharmaceuticals.
- Domestic manufacturing pharmaceutical companies almost exclusively produce generic products. SA pharmaceutical manufacturing companies are import dependent. In 2013, generics accounted for 63% of the private pharmaceutical market and 80% market share in government's pharmaceutical use.
- The value of locally manufactured pharmaceuticals exported in 2015 was R4.9billion.
- Two local pharmaceutical multinational companies dominate the pharmaceutical manufacturing industry.

– As of 2013, Aspen market share = 16,2%; Adcock Ingram market share =8,9%



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# Summary of SA Pharmaceutical manufacturing industry

- **Key players:** Dominant Multinational companies are Local. Aspen Pharmacare, Adcock Ingram, Cipla, Sanofi
- **Key Input:** Active Pharmaceutical Ingredients
- **Market structure:** Few dominant multinational companies that are vertical integrated across the pharmaceutical supply chain but vertical integration not located in SA
- **Key Influencing factors:** Intellectual Property (IP), Single Exit Price (SEP), Medicine selection by patients, registration process for new pharmaceuticals
- **Regulatory bodies governing the industry**
  - The Medicines Control Council (MCC), The South African National Accreditation System (SANAS), South African Health Products Regulatory Authority (SAHPRA)
- **Regulations:**
  - The South African National Policy on Intellectual property (in process of be revised)
  - Technical standards: Trade-related Aspects of TRIPS agreement (e.g. EU Good distribution practices), WTO standards/accreditation
  - Section 15 of the Medicines and Related Substances Amendment Act – enables **DOH** minister to prescribe the registration period for complementary medicines (imported without consent of the patent holder)
  - Department of Health via SEP legislation and Local Procurement framework
  - Although, the industry is subject to **the dti** BBBEE codes the draft charter for the health industry (released in 2005) has yet to materialise.



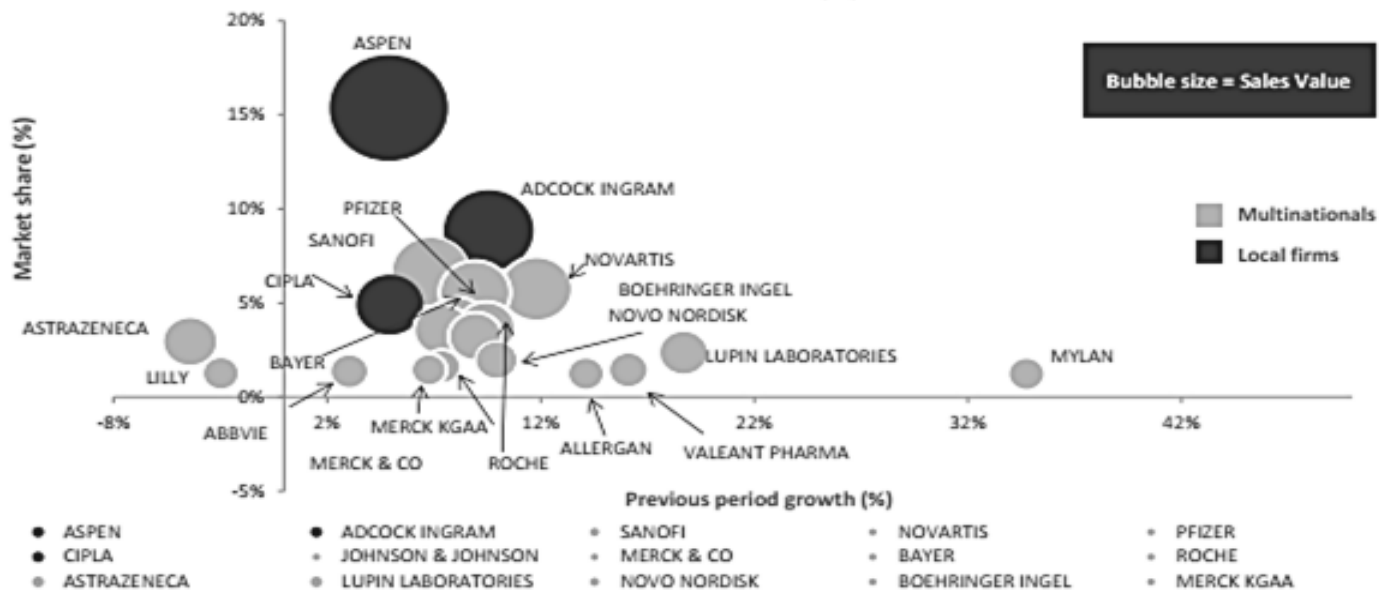
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# Key Players (Performance):

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

Top 20 Corporation sales value previous period growth and market share  
8/2015 MAT (%)



Source: UtiPharma

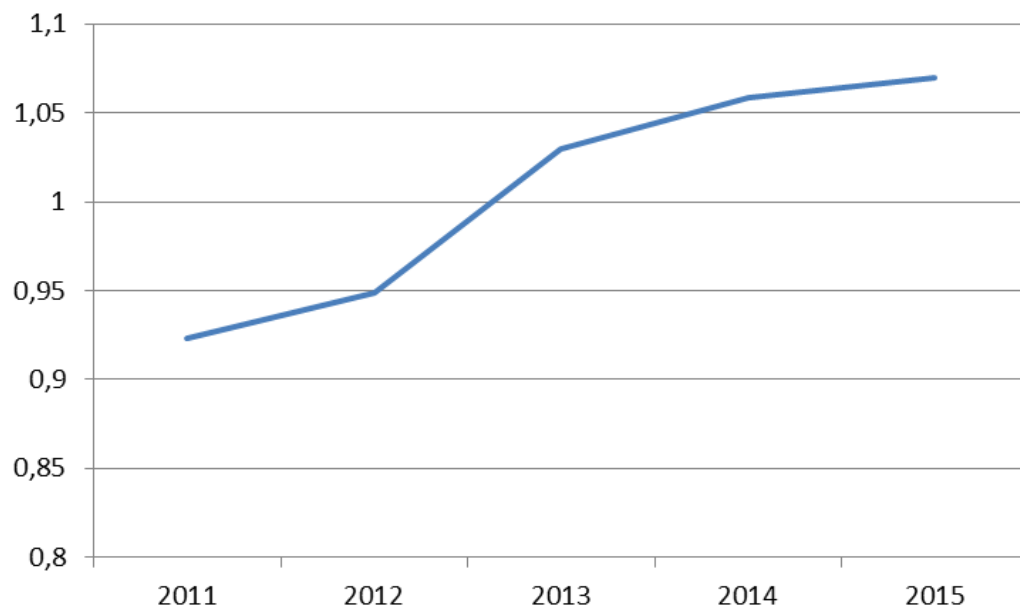


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# Contribution to GDP:

## Pharmaceutical Sales as a percentage of GDP



Data Extracted from: BMI, 2016



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# Top 10 Global Exporters of Pharmaceutical Products

Rank	Exporters	Value 2014 (ZAR million)	% Growth 2014	% Share 2014
1	Germany	862 869	20,1%	15,6%
2	Switzerland	677 686	22,7%	12,3%
3	Belgium	539 656	11,6%	9,8%
4	United States	476 320	24,9%	8,6%
5	France	380 670	7,0%	6,9%
6	United Kingdom	363 419	17,9%	6,6%
7	Ireland	294 806	17,5%	5,3%
8	Netherlands	278 728	28,9%	5,0%
9	Italy	273 553	20,8%	5,0%
10	Spain	137 305	9,7%	2,5%
<b>46</b>	<b>South Africa</b>	<b>4 642</b>	<b>11,7%</b>	<b>0,1%</b>
<b>TOTAL EXPORTS</b>		<b>5 524 474</b>	<b>18,3%</b>	<b>100,0%</b>



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Data Extracted from: Trade Map, 2016

# Top 10 Global importers of pharmaceutical products

Rank	Importers	Value 2014 ZAR million	% Growth 2014	% Share 2014
1	United States	786 012	30,1%	13,8%
2	Germany	533 684	22,9%	9,4%
3	Belgium	426 739	8,5%	7,5%
4	United Kingdom	365 155	37,1%	6,4%
5	France	301 540	20,5%	5,3%
6	Switzerland	254 716	20,0%	4,5%
7	Italy	233 244	14,3%	4,1%
8	Japan	215 438	7,5%	3,8%
9	Netherlands	209 166	28,6%	3,7%
10	China	192 198	32,6%	3,4%
<b>42</b>	<b>South Africa</b>	<b>22 407</b>	<b>2,6%</b>	<b>0,4%</b>
<b>TOTAL IMPORTS</b>		<b>5 698 997</b>	<b>19,0%</b>	<b>100,0%</b>



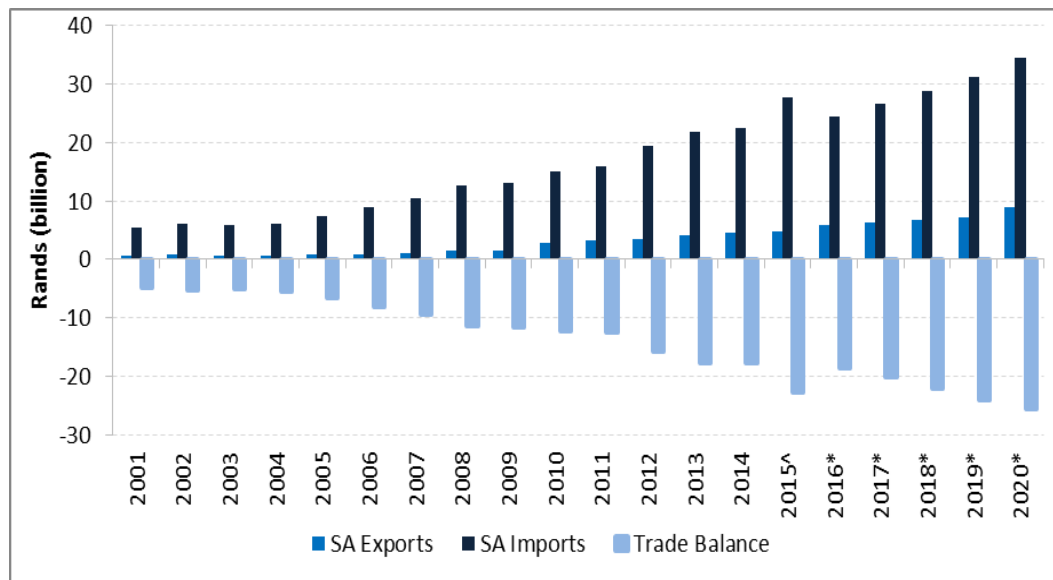
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Data Extracted from: Trade Map, 2016



# South Africa's Trade in Pharmaceutical Products



- Note: <sup>\*</sup>BMI Forecasted Values
- <sup>^</sup>Quantec values
- It is evident that imports are five times more than exports, thus the huge deficit in the pharmaceutical trade

Data Extracted from: *Trade Map, 2016; Quantec, 2016; BMI 2016a & BMI 2016b*



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# South Africa pharmaceutical imports source countries

Rank 2015	Country	Value 2014 ZAR million	Value 2015 ZAR million	% share 2015	% Growth 2015	AAGR (2010-2015)
1	India	3 626	5 895	21,3%	62,6%	29,0%
2	United States	2 629	3 817	13,8%	45,2%	14,6%
3	Germany	2 826	3 321	12,0%	17,5%	11,8%
4	France	2 392	2 495	9,0%	4,3%	8,3%
5	United Kingdom	1 841	1 629	5,9%	-11,5%	6,6%
6	Italy	1 502	1 348	4,9%	-10,2%	3,7%
7	Ireland	772	1 254	4,5%	62,4%	4,4%
8	Belgium	807	995	3,6%	23,3%	11,2%
9	Switzerland	869	781	2,8%	-10,1%	1,4%
10	Spain	537	759	2,7%	41,3%	14,2%
<b>Total Imports</b>		<b>22 446</b>	<b>27 615</b>	<b>100,0%</b>	<b>23,0%</b>	<b>12,6%</b>

Data Extracted from: Quantec, 2016



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# Top 10 South Africa's Pharmaceutical Exports Destination Countries

Rank 2015	Country	Value 2014 ZAR million	Value 2015 ZAR million	% Share 2015	% Growth 2015	AAGR (2010- 2015)
1	Namibia	1 293	1 371	28,4%	6,1%	9,2%
2	Botswana	584	675	14,0%	15,7%	3,0%
3	U.S	282	358	7,4%	26,7%	24,1%
4	Hong Kong	234	318	6,6%	35,7%	78,3%
5	Zimbabwe	230	229	4,7%	-0,6%	26,7%
6	Swaziland	238	220	4,5%	-7,9%	-1,4%
7	Zambia	155	196	4,1%	26,5%	30,9%
8	Kenya	169	153	3,2%	-9,3%	16,5%
9	Australia	144	143	3,0%	-0,7%	25,9%
10	Lesotho	109	138	2,9%	26,9%	6,5%
<b>Total Exports</b>		<b>4 474</b>	<b>4 827</b>	<b>100,0%</b>	<b>7,9%</b>	<b>12,8%</b>

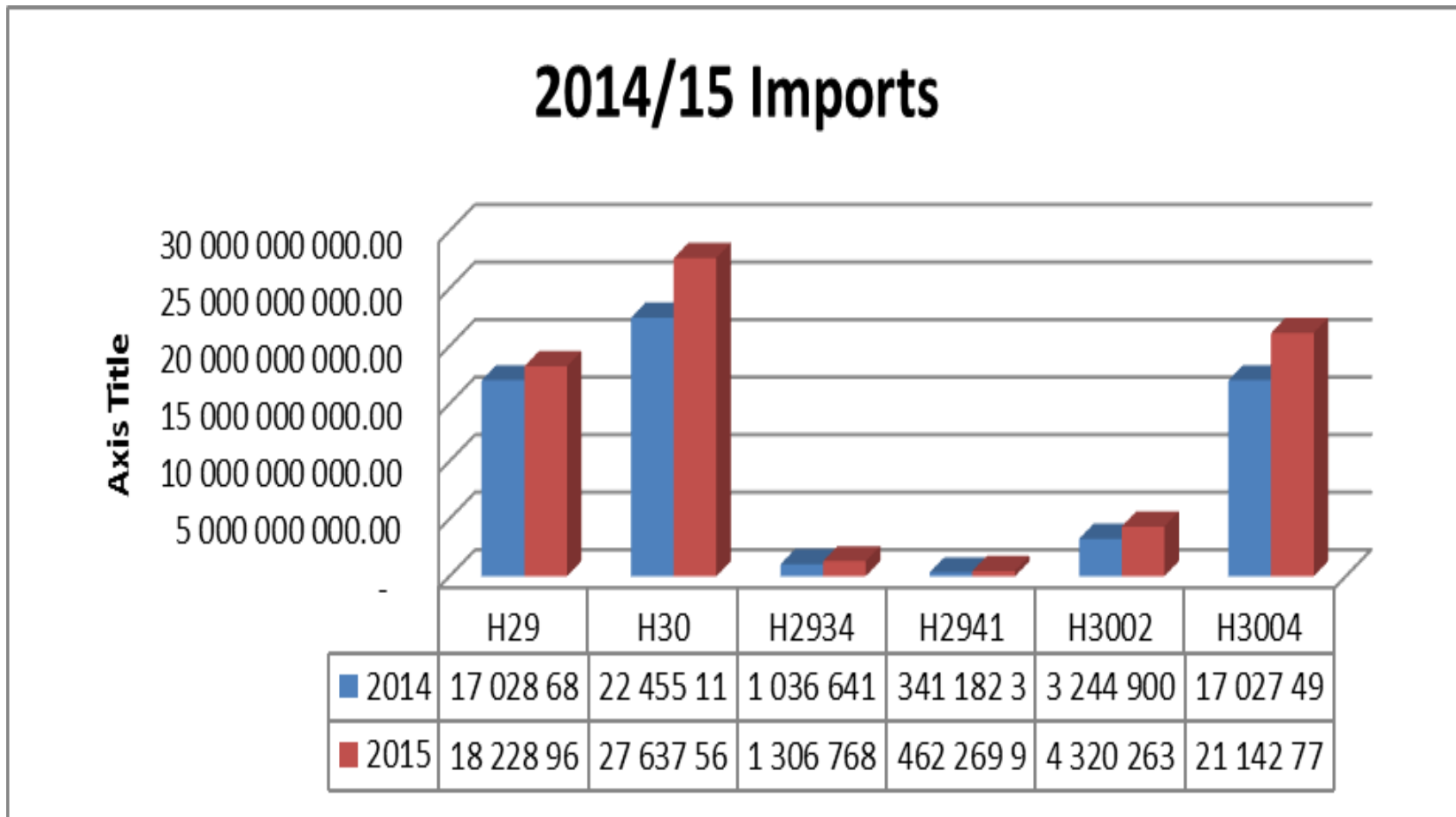


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Data Extracted from: Quantec, 2016

# SA pharmaceutical imports 2014/15

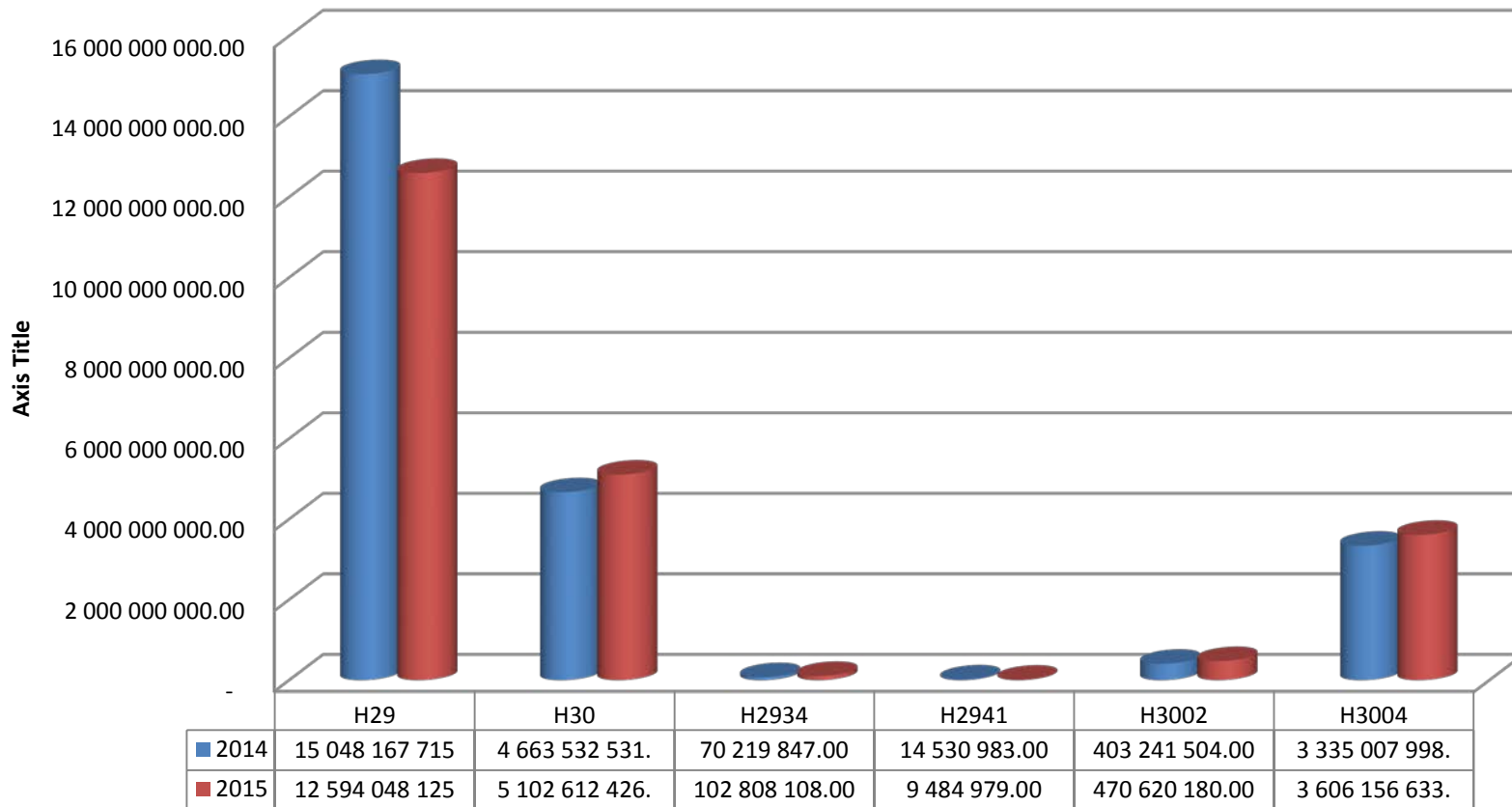


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# SA pharmaceutical exports 2014/15

## 2014/15 Exports



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# SWOT Analysis

- ***Strengths***

- ✓ High demand for pharmaceutical products in SA.
- ✓ Local Manufacturing capabilities in clinical trials, secondary and tertiary manufacturing.
- ✓ A number of different pharmaceutical companies operating in specialised markets operating in SA.
- ✓ API manufacturing sites exist in SA.

- ***Weaknesses***

- ✓ High capital upfront costs required to invest and gain a competitive position within the market, limiting new entry.
- ✓ Significant dependence on imported APIs and finished pharmaceutical products.
- ✓ Dependence on MCC and long registration period of new products – This is due to a shortage in required skills within MCC.
- ✓ The skills shortage (and the cost of specialised skills) also affects the entire pharmaceutical industry supply chain as companies are required to have a supervising pharmacist. It is estimated that SA requires 12 000 pharmacists to meet the international benchmark of 50 pharmacists per 100 000 people



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# SWOT Analysis

- ***Weaknesses***

- ✓ The fragmented nature of the industry, across the private and public sectors has led to difficulties in setting targets for each sub-sector. Incentivising transformation is limited as particular sub-sectors do not rely on government contracts. The fragmented approach to transformation in the industry has entrenched limited transformation of the supply chain.
- ✓ Lack of cohesive policy approach targeting the industry. Legislation governing and influencing the industry is spread across the DoH, NT and **the dti**

- ***Opportunities***

- ✓ Local manufacturing capabilities in niche pharmaceutical sectors can be leveraged to serve growing market demand in the rest of Africa and globally.

- ***Threats***

- ✓ Economic conditions: the volatility of the rand and the relative weakness of the rand means that APIs are more expensive and given the SEP, companies are disincentivised to invest in local production facilities as predicting future profit margins is difficult.



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# Challenges facing further Sector development

- Absence of integrated plan between relevant Government Departments re local production of pharmaceuticals
- Lack of efficiency within regulatory bodies
- Policy uncertainty and unpredictability within public procurement process – PPPFA
- Price controls – Single Exit Price – increasing cost base – R/\$ fx volatility – contributes to higher than normal API costs
- Uncertainty in policy environment – e.g. national IP Policy
- Growing trade deficit in pharmaceuticals
- Lack of adequate incentives across the pharmaceutical value chain

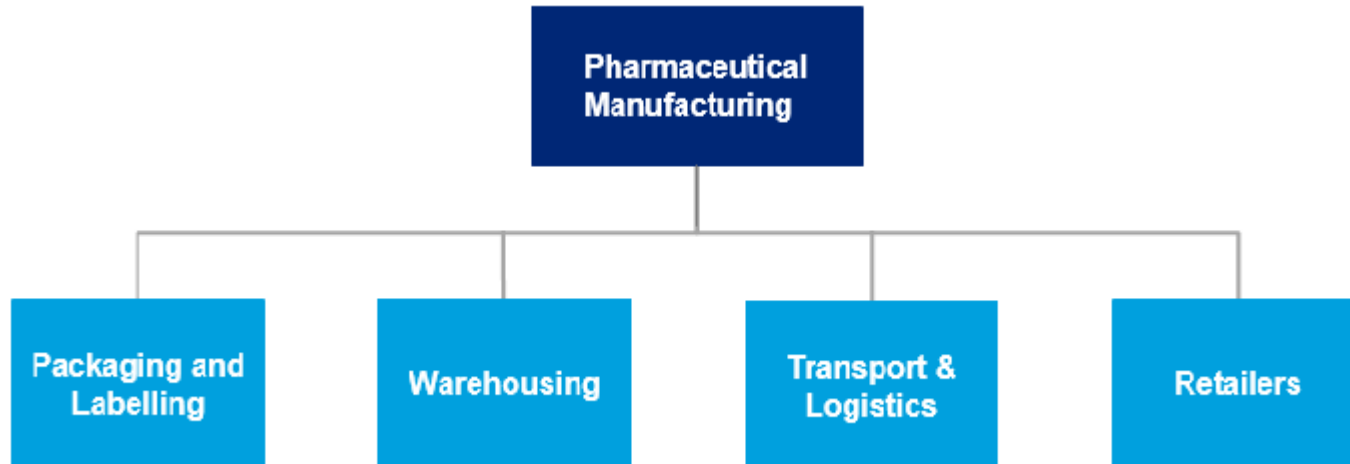


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# Business Case for Local Manufacture of Pharmaceuticals



## Key Multipliers

R1 invested in production  
= R 0.35 in Fiscal Revenue  
= R 1.13 in Value Created  
R1 M invested in production  
= 3 sustained jobs

## Impact on the Economy

- Knowledge economy
- Skills development
- Job creation
- Broader tax base

*Reference: Deloitte 2016*



## 'Vision 2030' for Pharma

- Healthy and productive nation
- Security of supply of essential medicines - NHI
- High rate of economic growth and job creation
- Thriving knowledge economy and investment in R&D
- Local pharmaceutical industry that is globally competitive – DDI and FDI specifically in high growth areas such as biopharmaceuticals
- Highly skilled individuals that are employed within the industry and drivers of further development of the industry
- Key exporter of quality medicines especially to the African market
- Gap in growing trade balance reduced



# STRATEGY FOR THE SA PHARMACEUTICAL INDUSTRY - Formulating industrial policy, a turn-around strategy for the SA pharmaceutical industry.

## Major problem areas

- (i) Divestment by MNC's (37 plants closed down in South Africa over the past 15 years); Low level of domestic investment;
- (ii) Growing reliance on imports
  - Economic burden (medical products are the 5<sup>th</sup> largest contributor to South Africa's trade deficit);
  - Potential risk to security of supply;
  - Stagnant (declining) exports.
- (iii) Structural imbalances (no API production)
- (iv) Widening production capacity and technology gap.

## Responding to national healthcare / public health needs:

- (i) AIDS and TB epidemics
- (ii) Growing burden of non-communicable diseases



# Projects in SA pharmaceutical industry included in Government's Industrial Policy (IPAP)

## ➤ Key action plan:

- “Designation” of pharmaceutical tenders - terms & conditions of government tenders favouring domestic manufacturers (*designated tenders : the 2012 OSD and 2013 family planning*)
- Pharmaceutical projects enjoy preferential access to Government's investment incentives.
- Expedited regulatory approval for local manufacturers

## ➤ Strategic projects:

- “Project Ketlaphela” a US\$ 185 million / R 1.4 billion ARV APIs project in Pelindaba, taking advantage of South Africa's expertise in fluorine technology (*status: Lonza withdrew – new RfP advertized*)
- “Biovac” – R 250 million vaccine manufacturing project, a 48%-52% jv SA Govt - private consortium, pursued since 2003,

Various private sector project in pharmaceutical formulation, capital investment totaling R 4.5 billion, 2008-2013.



## Government procurement of pharmaceuticals: Fast-growing public (tender) segment

Tender	Tender No.	Est. Value
<i>[designated tenders]</i>		
<b>ARVs</b> (Jan/Apr 2013 – March 2015)	HP-13 ARV 2013	R 5.9 billion (US\$ 667 million)
<b>Anti-TB</b> (Sept 2013-Aug 2015)	HP-01 TB 2013	R 890 million
<b>Antibiotics</b> (April 2009)	RT 301-2009 MF	R 750 million
<b>Family planning – contraceptives (June 2013)</b>	HP-03 FP 2013	R 210 million
<b>Oral solids (OSD)</b> (April 2012 – March 2014)	HP-09 SD 2012	R 2.5 billion



# KEY POINTS

## in DTI's Industrial Policy for Pharmaceutical industry

1. Building investors' confidence:
  - I. Using Government procurement to leverage local manufacture.
  - II. Exploring the means (also political) to boost exports (to Africa, to the Least Developed Countries etc.)
  - III. Reasonable approach to the medicines pricing policy.
2. Growing domestic capacity in the manufacture of key APIs (ARVs, anti-TB, biologics, reagents for *in vitro* diagnostics etc.) via technology transfers, investment incentives, preferences in Government tenders, offtake guarantees etc.
3. Preserving and encouraging good relations of SA generic industry with the Big Pharma (through voluntary licenses and technology transfers, joint R&D programmes etc.)
4. Looking beyond simple manufacturing; Establishing alliances in R&D, Promoting clinical R&D, Preparing foundations for the upcoming revolution in pharmaceutical technologies and treatment (biologics, individual therapies).



# 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



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# Price control of medicines in S. Africa

## Price control - important facts & figures:

- Provision for price control (“price transparency”) of medicines in S. 22G of Act 101 (Medicines Control Act).
- Price reform started from prohibition of perverse practices such as bonuses, free samples, volume-related discounts in 2003.
- Price control introduced in May 2004. Applies to private sector.
- “Single Exit Price” (SEP) – definition and rationale.
  - Base price of each product determined by manufacturers in 2003; annual SEP increases allowed once a year by a factor calculated as (70% CPI + 30% Rand exchange rate).
- Phase II of price control
  - International price benchmarking - SA prices vis-à-vis Australia, Canada, Spain and New Zealand; Generally, generics will be exempt from benchmarking.
  - Pharmaco-economic evaluation (PEE) of new medicines.



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# The S. African IP / Patent legislation

- Patents (1)

In S. Africa, patent is granted 20 years from the date of publication of acceptance of the application in the Patent Journal, with no provision for extension. Generally, the patent may only be enforced nine months after grant.

A patent can only be challenged after it has been granted – there is no provision for pre-grant opposition. A patent may be challenged at any time after the grant, by any person, on the grounds that the invention was not new at the date of application or that it was obvious. The Patents Act (Chapter X - Art. 61 to 64) also specifies formal grounds on which a patent may be revoked, such as incomplete disclosure of the invention, insufficient clarity of the claims, fraudulent or false statement or misrepresentation in the application.

The Court of the Commissioner of Patents is the court of first instance in all patent-related matters in South Africa. The Court decision can be appealed, with leave, either to a provincial division of the High Court and thereafter to the Supreme Court of Appeal, or directly to the Supreme Court of Appeal.



# FAQ's - the S. African IP / Patent legislation

- Patents (2).

The South African patent order is often dubbed as a “weak patent system with strong enforcement”. As the substantive examination of patent applications is not carried out in South Africa, the South African patent is intrinsically vulnerable:

- \* The grant of a South African patent does not guarantee that the patented invention is new or non-obvious, that the patent will be valid in other jurisdictions, that the patent cannot be revoked, or that the exploitation of the invention will not infringe on existing patents in South Africa or elsewhere.
- \*\* Abuse of the system (e.g. patent “evergreening”) is possible in the absence of substantive examination.

Solution: New IP / Patent Policy draft for public comments



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# Way Forward

- Framework published on **the dti** website and GG.
- Continuous engagement including roundtables and workshops.
- Draft Policy addressing immediate issues and framework for in-built agenda by 03/17

# Medical Devices



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# Medical Device Stats: SA

Variable	Contribution in 2014/15
Global market	\$ 320 bn
Medical devices – SA market	ZAR 13.4 bn (US\$ 1.22 bn), expected to grow at a CAGR of 7.6% over the next 5 years in local currency terms
SA share of global market	0.4%, 30st <sup>th</sup> largest in the world
CAGR (SA)	7.6% revised
Medical devices - employment	Total 20,000 including manufacturing, marketing and sales, servicing, providing specialized laboratory & diagnostics services.
Medical devices – trade balance	Approximately ZAR 10 bn
Imports	Estimated at 90% (Rand value: approximately R 11.8bn )
Exports into Africa	71% of total exports
Estimated multiplier	1.25



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## Key healthcare market growth drivers in South Africa

- South Africa is among the top 30 most populous countries in the world with an estimated population of almost 54 million in 2014.
- The introduction of the National Health Insurance (NHI) is expected to increase the demand for medical products.
- Fast growing middle class in South Africa and the African region.
- Increasing life expectancy.
- Increasing incidence of non-communicable diseases.

26 of the 54 countries in the continent has achieved middle income status, these countries can now afford to pay for high quality healthcare



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# The size of the South African Medical devices market

The medical devices market size in 2014 was estimated at almost R13 billion. It is among the top 40 largest markets in the world. Per capita spending was R238.48 in 2014; this is more than five times the level of spending in most other parts of Sub Saharan Africa where per capita spending is less than R54.

**Table: Medical Device Market by Product Area, 2014 (ZAR millions)**

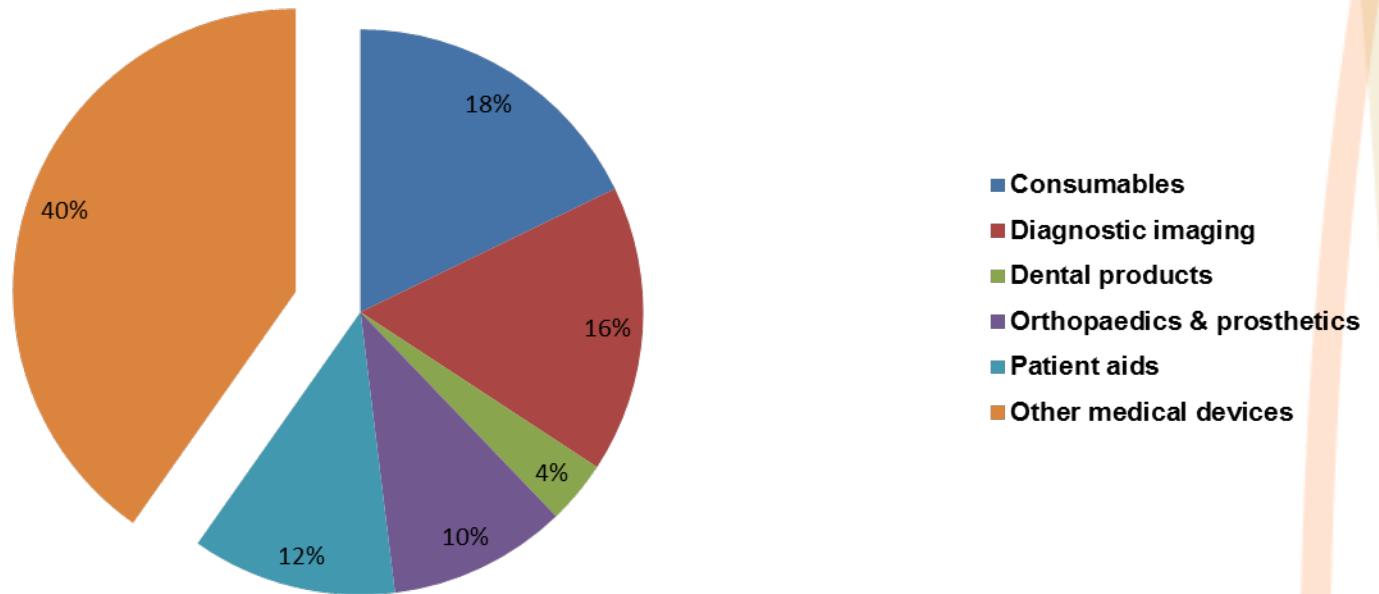
Consumables	2,284.5
Diagnostic imaging	2,107.6
Dental products	467.3
Orthopaedics & prosthetics	1,301.9
Patient aids	1,501.3
Other medical devices	5,156.1
<b><u>Total Market</u></b>	<b><u>12,818.7</u></b>



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# Market share per product area in 2014

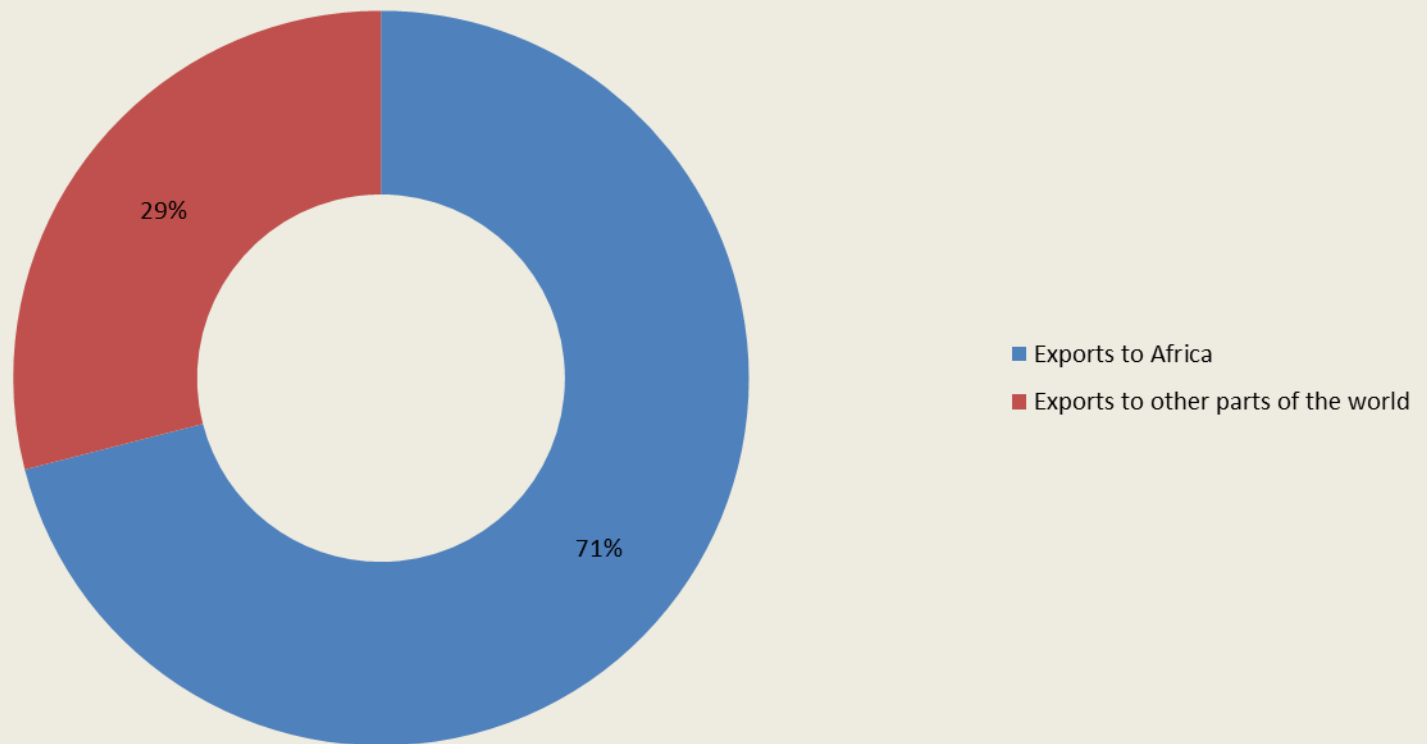


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# Medical Devices Export Destinations 2014



# SWOT Analysis: Medical Devices Sector in SA

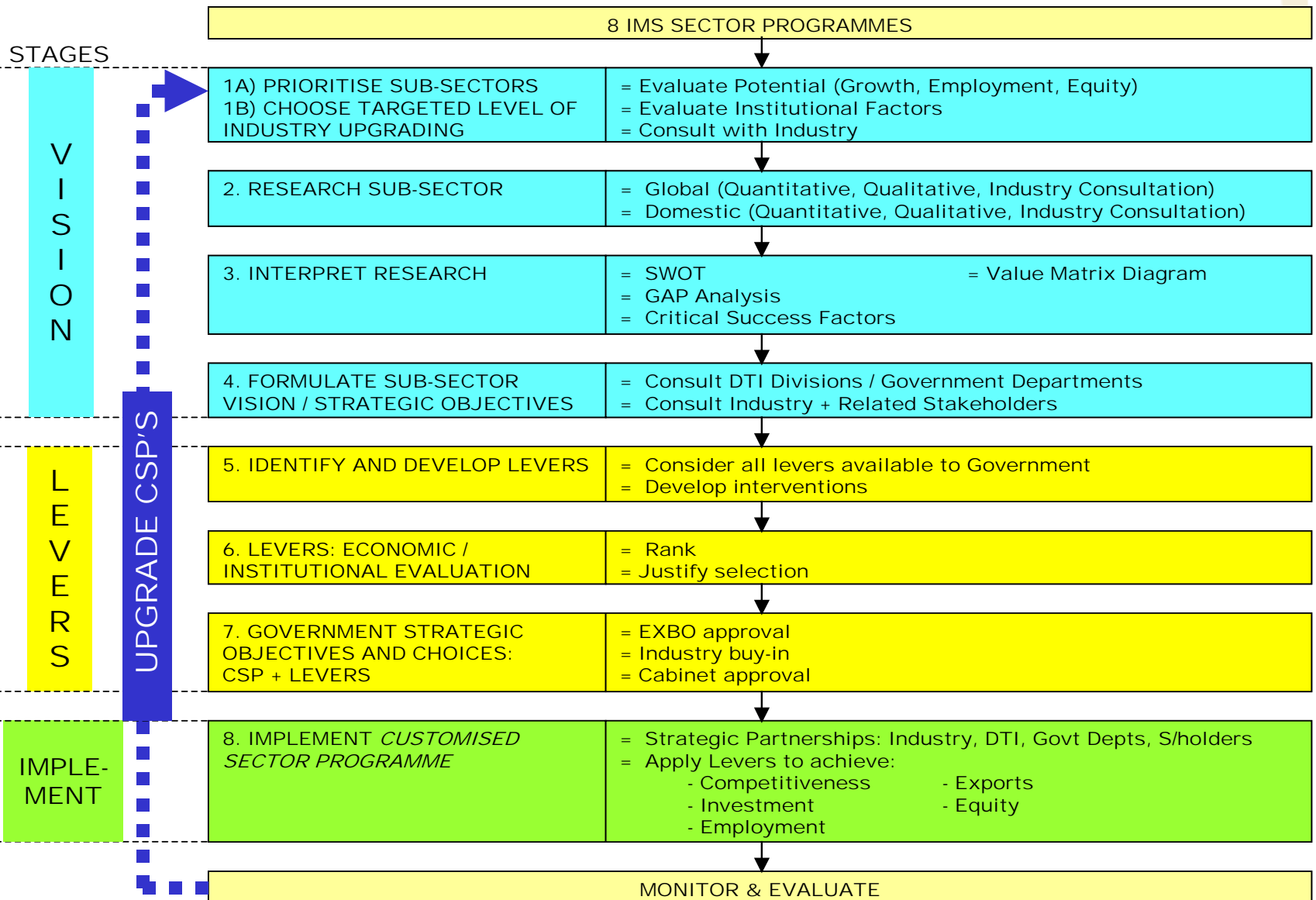
<p><b>Strengths</b></p> <p>Wealthy African economy whose healthcare system is envied by other African nations</p> <p>Strong, sizeable private sector</p>	<p><b>Opportunities</b></p> <p>Public-private partnership growth</p> <p>Imports account for around 95% of market</p> <p>Emergence of affluent, Black middle class</p> <p>Proposed national health insurance scheme which is prompting further investment in the public healthcare system</p> <p>Steady expansion of HIV treatment programme should help reduce pressures on public healthcare system</p> <p>Emergent introduction of SAHPRA</p> <p>Preferential Public Procurement</p>
<p><b>Weaknesses</b></p> <p>Poor infrastructure, particularly in the extensive rural areas, limits efficiency of healthcare delivery as does the chronic shortage of medical personnel</p> <p>Many rural facilities grossly under-used or lying idle due to poor organisation</p> <p>HIV/AIDS patients overburdening the system</p> <p>Private sector out of reach for most of the Black population</p> <p>Purchasing procedures complex and fragmented</p> <p>Lack of Regulatory Standards and Certification to enable exports of products</p>	<p><b>Threats</b></p> <p>No solution in sight to increasing the number of doctors in public sector and preventing them from working in private sector or abroad</p> <p>Depreciating Rand is making imports less affordable</p> <p>Launch of market inquiry into pricing in the private healthcare sector could negatively impact its future development</p> <p>Government moves to centralise certain functions within the National</p>



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# CSP Development Process



# Level of industry upgrading

Upgrading level	Illustrative activities
Basic industry upgrading	<ul style="list-style-type: none"> <li>○ Facilitation of the removal of immediate constraints to the development of the industry, such as:               <ul style="list-style-type: none"> <li>● Infrastructure</li> <li>● Skills</li> <li>● Finance</li> <li>● Legislative / regulatory barriers</li> </ul> </li> <li>○ Facilitation of industry cooperation / clustering</li> <li>○ Investment and export promotion</li> </ul>
Process and product upgrading	<ul style="list-style-type: none"> <li>○ Facilitating increased efficiency of internal processes and / or the introduction of new products within the industry. This is associated with activities such as:               <ul style="list-style-type: none"> <li>● Benchmarking against world best practice</li> <li>● Access to institutions which facilitate process and product improvements</li> </ul> </li> </ul>
Functional upgrading	<ul style="list-style-type: none"> <li>○ Facilitating an increasing value-addition by changing the mix of activities conducted within the industry. This is associated with activities such as:               <ul style="list-style-type: none"> <li>● Moving from assembly to component manufacture</li> <li>● Moving from manufacture to design</li> </ul> </li> </ul>
Industry upgrading / New industry development	<ul style="list-style-type: none"> <li>○ Moving the industry to an altogether new set of activities, e.g. from television monitors to computer monitors, or</li> <li>○ Facilitating the creation of entirely new economic activities within the economy.</li> </ul>



Adapted from Kaplinsky and Morris (2001)

# Critical Success Factors

- Partnerships
- Investment in innovation
- Regulatory framework
- Quality



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# Identify industrial policy levers

- Coordination: achieve higher impact of private sector e.g. Clusters
  - Finance: sector-specific incentives
  - Policy, legislation and regulation: partnership with UNIDO
  - Strategic Partnerships: Internal and external
  - Procurement: leveraging state procurement for medical devices
  - Trade barriers
  - Reciprocal benefits
- \*\*Economic evaluation of levers



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# 4-point plan for Industry Development

## (1)

1. Support for and creation of enabling environment to drive import substitution
  - Establishment of a formal structure for better State-Business relations between key medical device industry stakeholders (Industry, dti, DoH, SABS, DST etc.)
  - Short term targets/Low hanging fruit - low hanging fruit can be defined as products that do not require significant capital investment or rare technical expertise to manufacture. As a result manufacture of such items is often high volume and subject to considerable cost pressure. These types of items are the most appropriate targets for short term intervention in order to address issues surrounding the trade deficit i.e. diagnostics, gloves, syringes, textiles, services such as Health Technology Assessments (dti, DoH, Industry)
  - WC Regional Cluster establishment - shared infrastructure, competitiveness, export development and develop global supply chains (Wesgro, WC Provincial Government, industry, dti, TIA)



# 4-point plan for Industry Development

## (2)

### 2. Establish mechanisms to increase exports

- More attractive incentives for local manufactures – ISO13485 and CE Mark (dti, industry, DST, NIPMO) – requires business case to be developed
- Establish dti recognised Industry Association that would evolve into Export Council (instrument is over-subscribed currently) to target high growth markets through facilitation of access to EMIA and TEO funding (dti, industry)
- Develop sector export Strategy with Regional Heads in Export Promotion (TISA)



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# 4-point plan for Industry Development (3)

3. Support for R&D and Innovation in the sector to increase competitiveness of products

- Establish incubator to support the spin out of medical device companies, products, prototypes from research organisations, universities etc. – investigate whether a multinational could anchor such a programme under equity equivalence, NIPP or supplier/enterprise development (CSIR, DST, dti, industry)
- Develop business case for joint programme of support between TIA and the dti to support innovation in medical devices/diagnostics and equipment (DST, TIA, dti, IDC and industry)

- Leverage the DST SIP funding for industry to direct and conduct relevant RDI (DST, industry, dti)



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# 4-point plan for Industry Development (4)

4. Deploy instruments of industrial policy to support of sector growth

- Introduction of an internationally graded ISO 13485 as a compulsory Quality Management Standard for all local manufacturers (industry, SABS, DoH, dti)
- More attractive incentives for local manufacturers: business case for the subsidisation of certification costs i.e. ISO13485, CE Mark and SABS Mark dti, industry, DFI's)
- Record all customs data to an 8-digit HS level (SARS, industry, DoH, dti) to better manage data within the sector on which future industry development mechanisms will be

hypothesised



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# Thank You!!



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