

**Portfolio Committee on Economic Development
the dti's involvement in the State's procurement of
ARV's**

**Directorate: Pharmaceuticals and Medical Devices
NATIONAL DEPARTMENT OF TRADE AND
INDUSTRY
28 June 2017**



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Overview of the South African Pharmaceuticals Industry



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Key Statistics: Pharmaceuticals

Variable	Contribution in 2014/15
Global market	Estimated to reach \$400 mil per annum – 2019
SA market	Approximately ZAR 45 bn
Contribution to GDP	Approximately <1%
SA share of global market	0.4% (value) and 1.0% (volume) - Deloitte, 2016
CAGR (SA)	4.5% from 2015 TO 2020
Employment	9,500 in the industry 25,000 downstream (specialized logistics, retail and hospital pharmacies)
Trade balance	ZAR 1.5 billion (Chapter 30 - Pharmaceuticals) Active pharm. ingredients (APIs) est. - R 4.9 billion
Biologics – SA market	Estimated ZAR 4 bn (biologics and vaccines)
Estimated multiplier	1.35 (Deloitte, 2016)

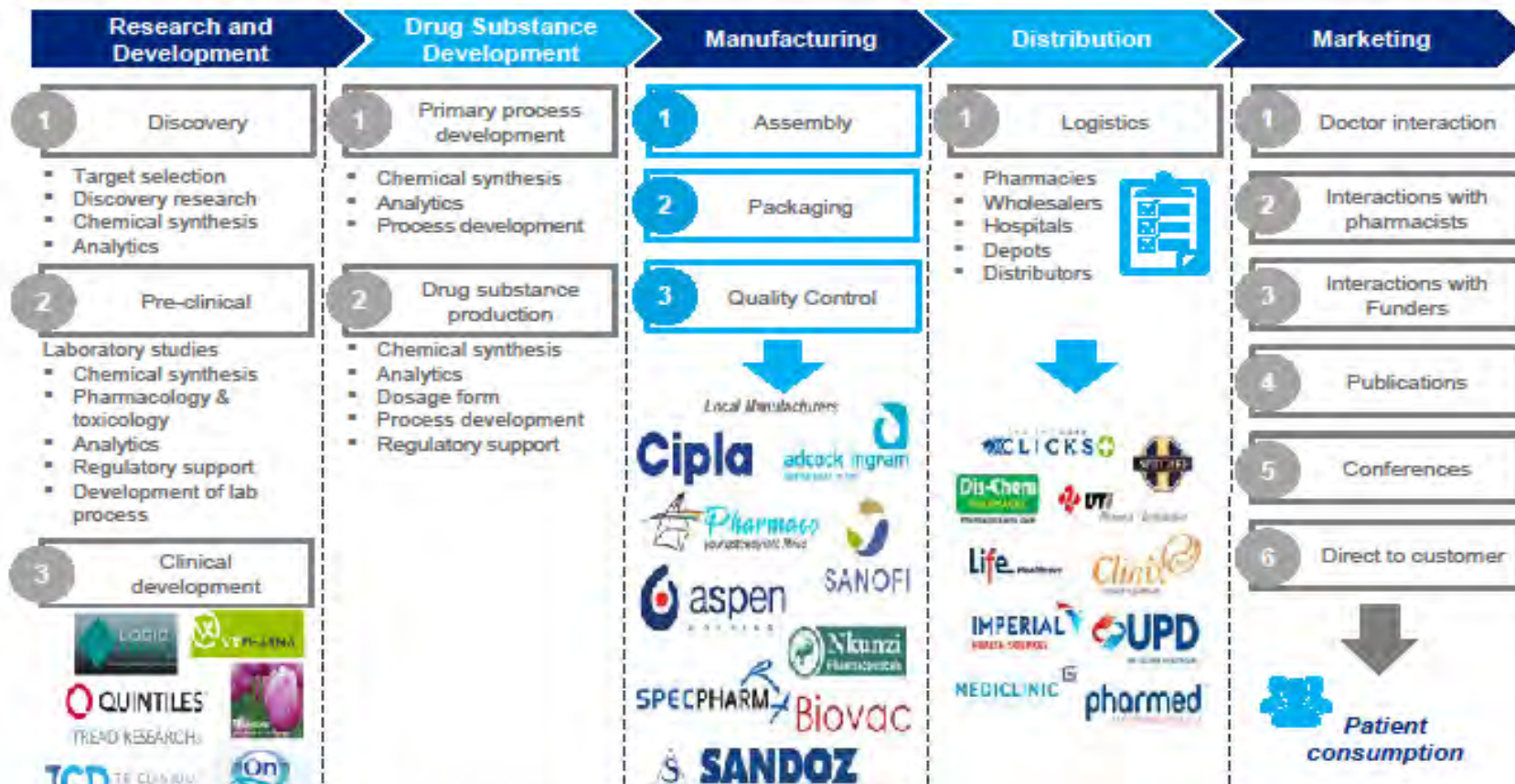


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Players in the South African value chain

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



27 Note: 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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Broad profile of the SA pharmaceutical manufacturing industry

- The pharmaceutical market in SA was valued at approximately R45 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 import, manufacture, distribute 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%

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)/SAHPRA, The South African National Accreditation System (SANAS), South African Bureau of Standards (SABS), Medicines Pricing Committee
 - 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.



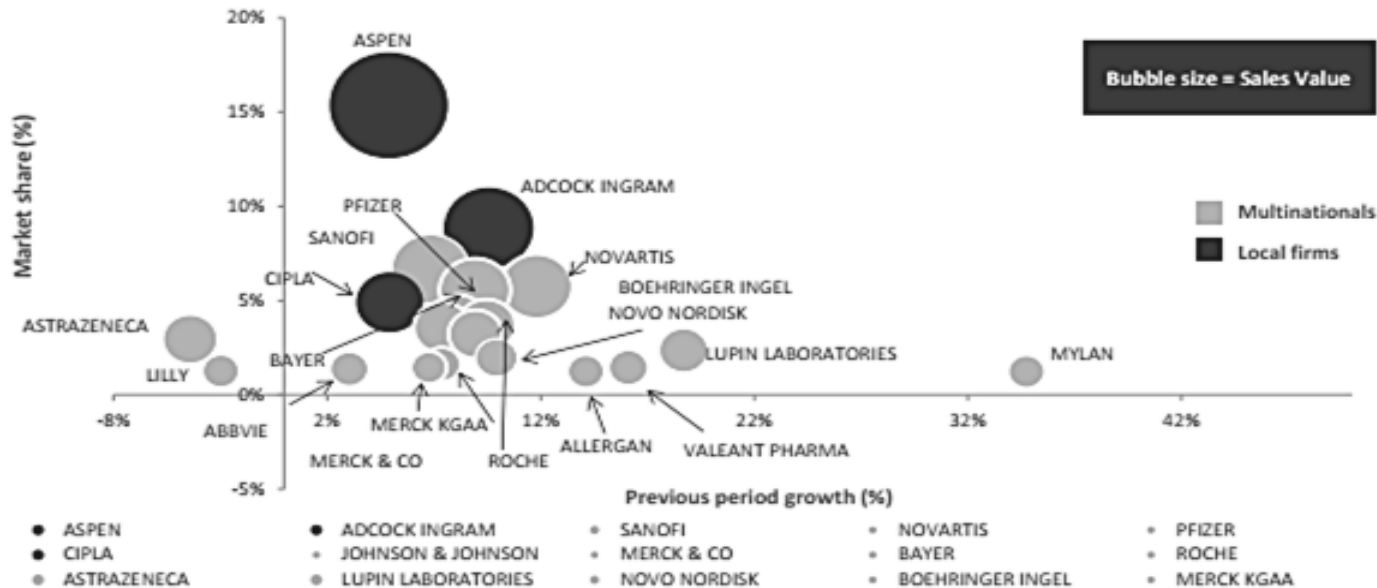
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Key Players (Performance):

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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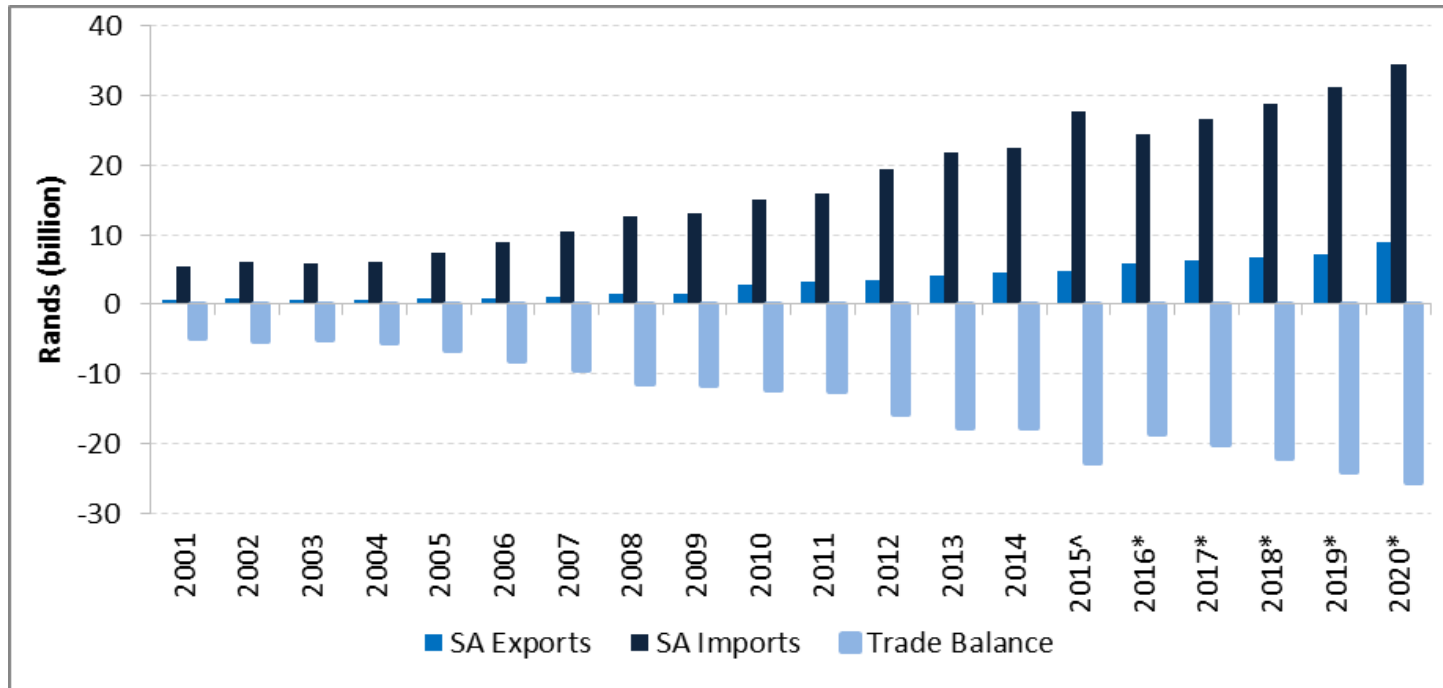
Top 10 Global Exporters of Pharmaceutical Products

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%
46	South Africa	4 642	11,7%	0,1%
TOTAL EXPORTS		5 524 474	18,3%	100,0%

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%
42	South Africa	22 407	2,6%	0,4%
TOTAL IMPORTS		5 698 997	19,0%	100,0%

South Africa's Trade in Pharmaceutical Products



- Note: **BMI Forecasted Values*
- [^]*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*

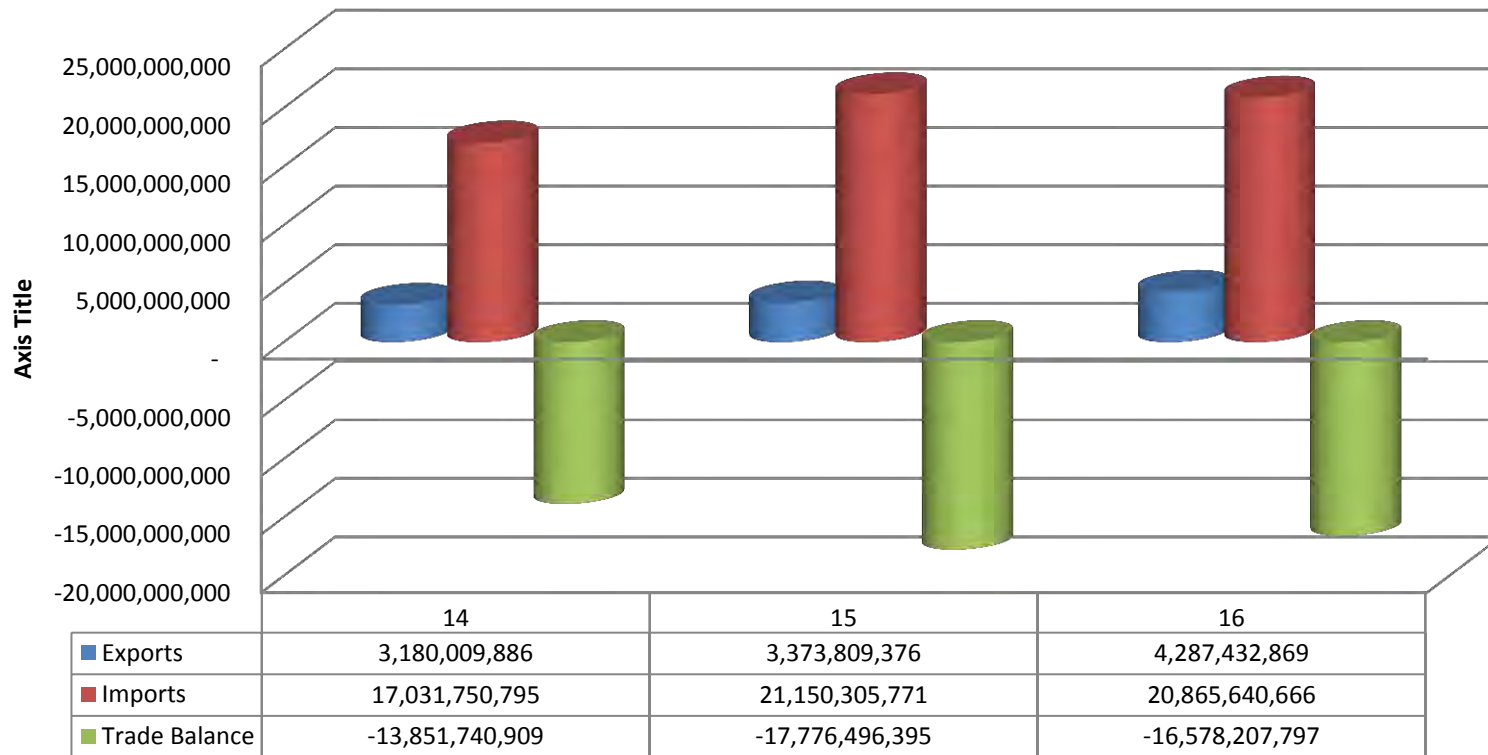


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Pharma trade 2016

Finished dosage form (H3004) trade balance



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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%
Total Imports		22 446	27 615	100,0%	23,0%	12,6%

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%
Total Exports		4 474	4 827	100,0%	7,9%	12,8%



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Data Extracted from: Quantec, 2016

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

SWOT Analysis cont...

- ***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

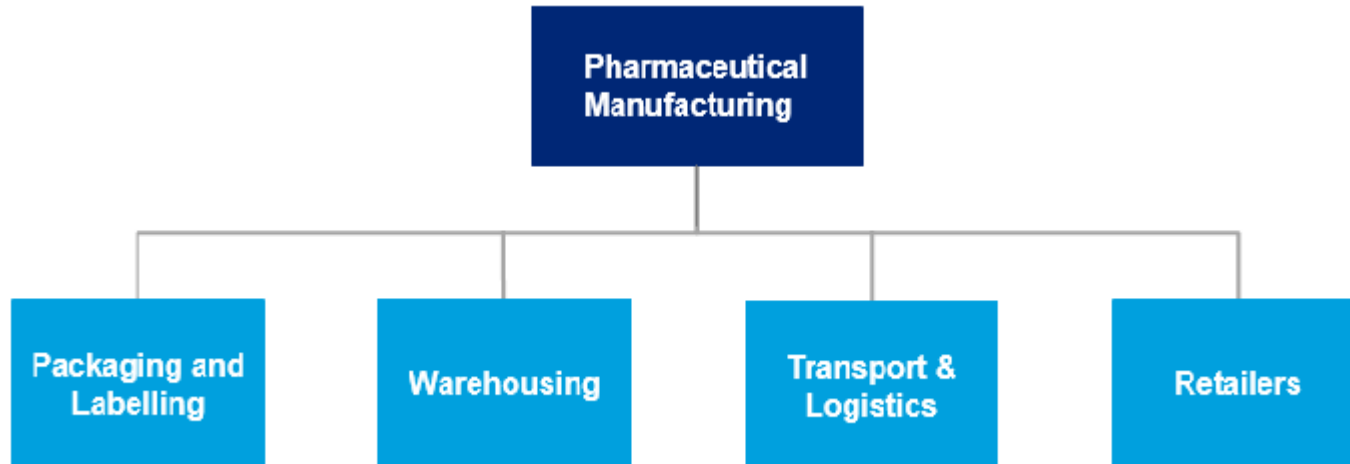
- Absence of integrated plan between relevant Government Departments re local production of pharmaceuticals
- Efficiencies within regulatory bodies
- Price controls – Single Exit Price – increasing cost base – R/\$ fx volatility – contributes to higher than normal API costs
- Uncertainty in policy environment i.e. IP Policy, tender timeframes
- Growing trade deficit in pharmaceuticals
- Lack of adequate incentives across the pharmaceutical value chain
- Tariff protection for local manufacturers



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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



CONSIDERATIONS - 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 5th 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)

- Strategic projects:
 - Pharmaceutical Industry Development Plan
 - Roadmap for API production
 - “Biovac” –vaccine manufacturing project, a 48%-52% jv SA Govt - private consortium, pursued since 2003
 - Support for Biotech projects in SA e.g. Sabi Pharm etc.
 - Various private sector projects in pharmaceutical formulation
 - Aurobindo, Mylan, Cipla etc.



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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.), to the Global fund and the UN procurement agencies such as Unicef, UNDP, UNAIDS
 - 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 transfer arrangements, investment incentives, tariff protection, expedited regulatory approval processes, NIPP etc.
3. 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).



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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

Local ARV production capabilities

- Adcock, Aspen, Cipla, Sonke/Sun Pharma, Specpharm
- Systematic understanding of local production capability for all molecules manufactured in SA
- Approximately 40% progress made, and about 30% completion on database
- Preparation for upcoming ARV tender in 2019

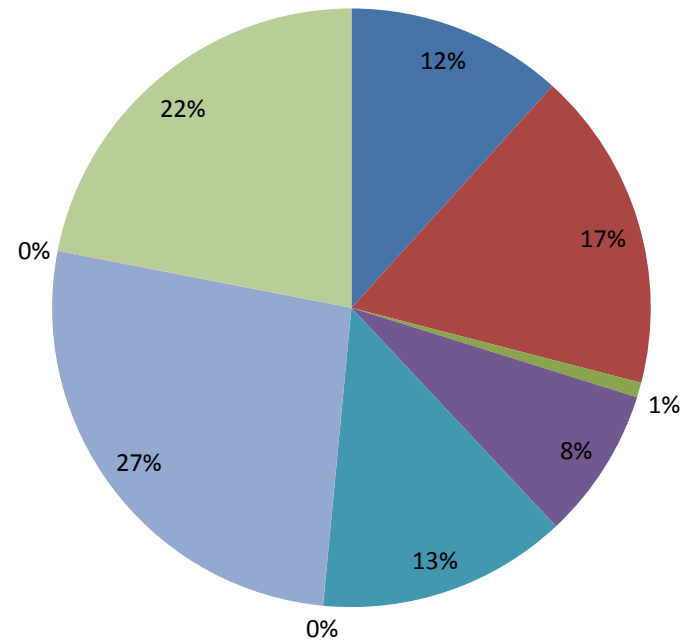
Collaboration with the dti re Designation of HP13 2015

- Local manufacturing info provided to NDoH in lieu of Designating the tender.
- Points allocation: 90/10 rule as per PPPFA
- Preference for local manufacturers
- Pricing – no price premium in place however the PPPFA allowed for negotiations with local manufacturers for those whose bids were within 10% of the price of the highest points scorer
- Local manufacturers awarded approximately 62% by value at the time of contract award i.e. est. R8.7 bn of total award

HP13 ARV allocation by volume

Volume

- Adcock
- Aspen
- Aurobindo
- Abbot/Abvie
- Cipla
- MSD
- Mylan
- Mylan (via GFF)
- Sonke (Ranbaxy)

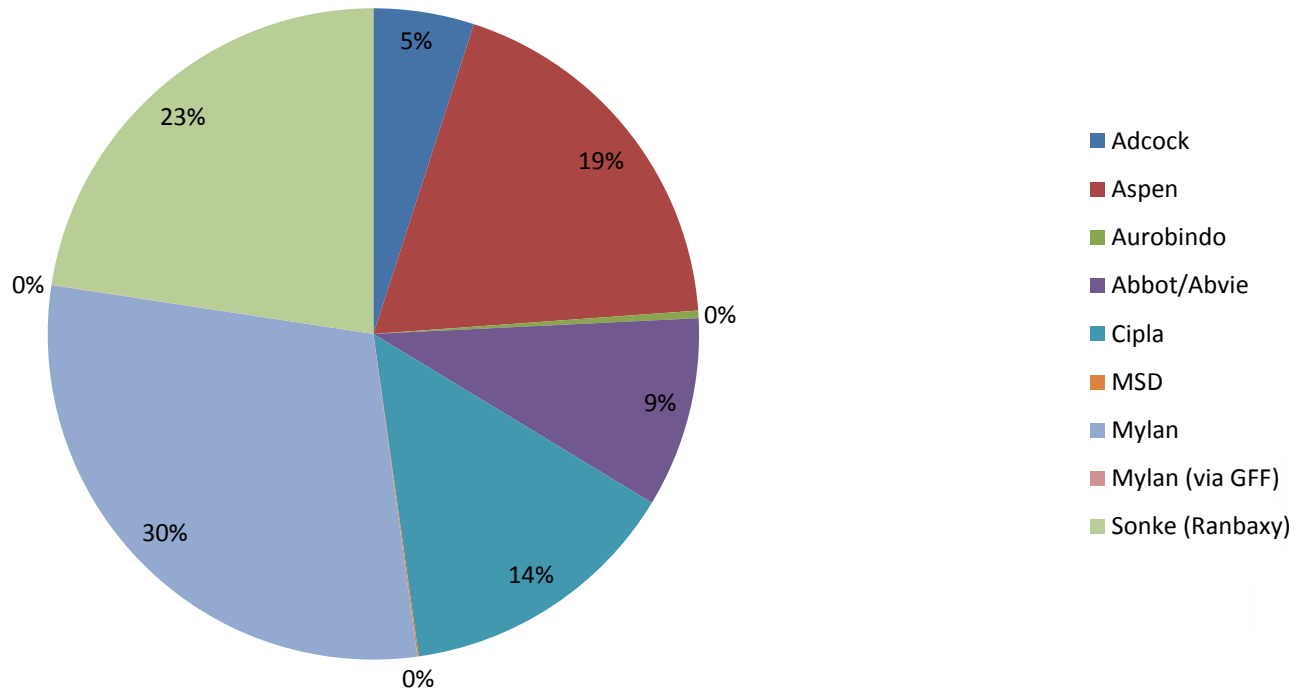


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HP13 ARV allocation by value

Value

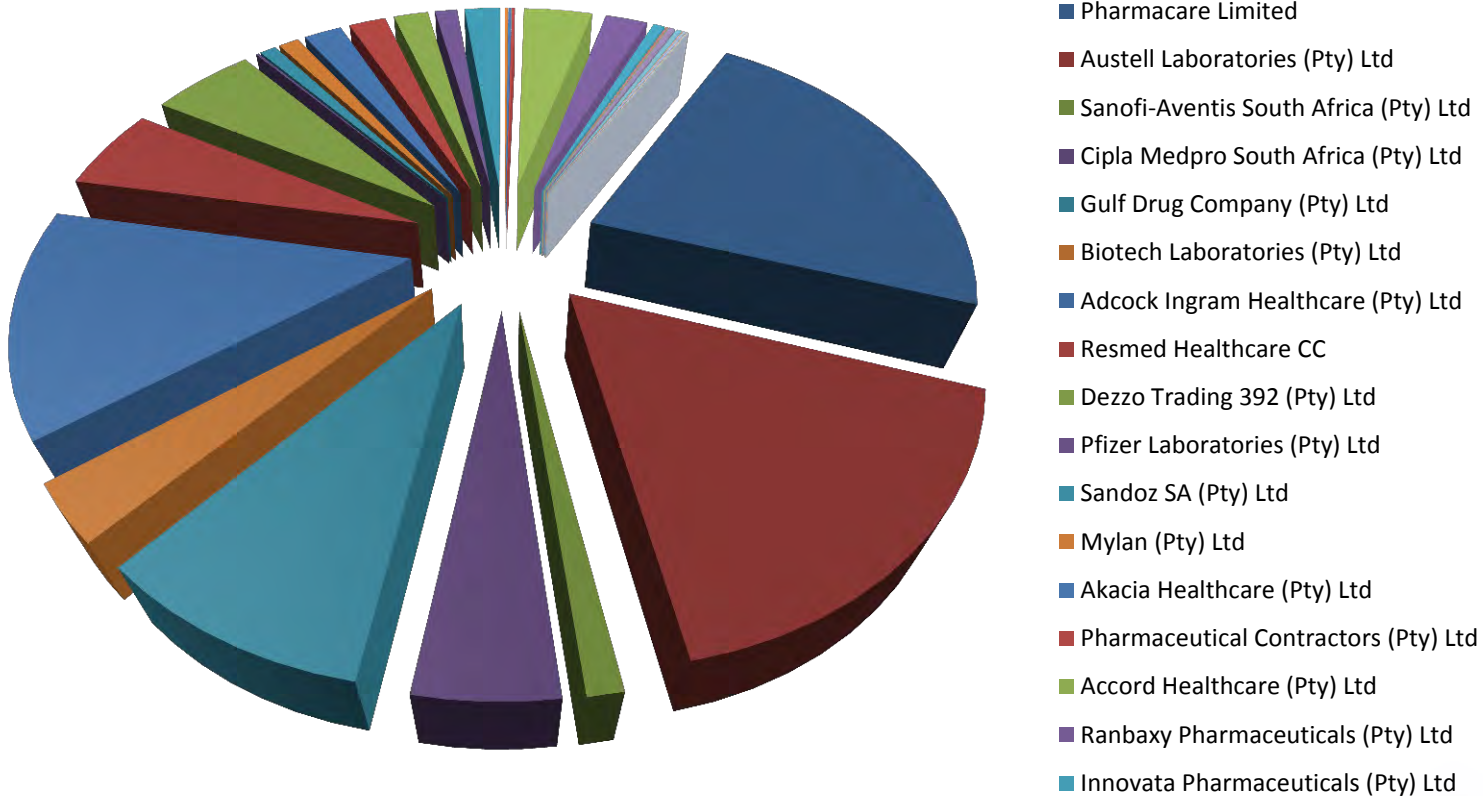


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HP09 award by volume

Sum of Quantity Awarded

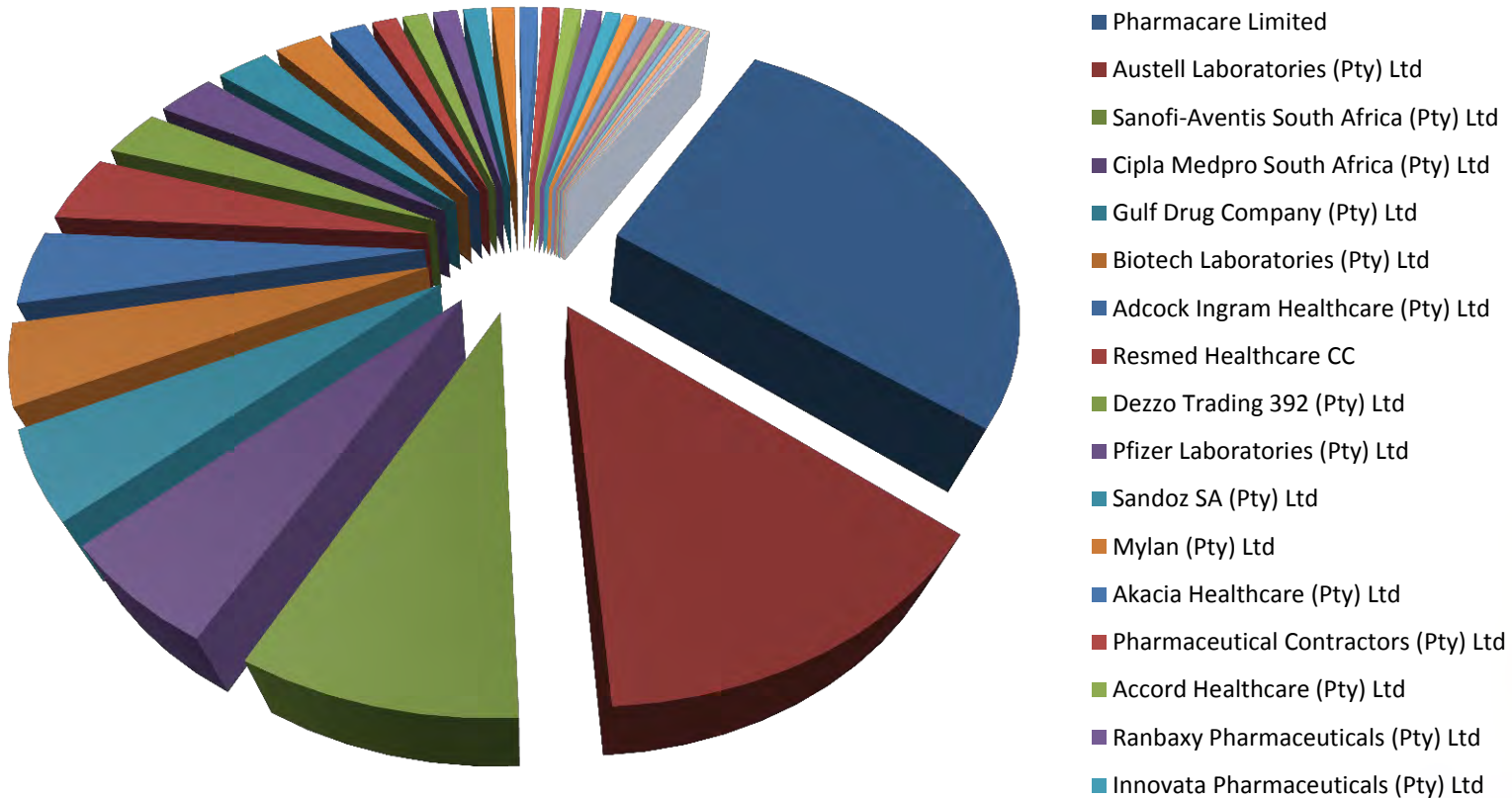


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HP09 award by value

Sum of Value



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Condom manufacturing industry

- 2018 tender estimated to be valued at ?
- Collaboration with NT to understand local manufacturing capacity and phase in a preferential procurement mechanism
- Current 2 bona fide local manufacturers, 2 additional to come on-line by 2018, the dti and DFI support – local industry creation
- Collaboration with NT around possible tech transfer for local manufacture of female condoms

Thank You!!

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