

# **Economic & Socio-economic benefits of the R&D-based multi-national pharmaceutical sector to South Africa**

**A FutureWorld...powered by Deloitte study initiated by Innovative Medicines South Africa (IMSA)**

**Final Report**

13 September 2007

*FutureWorld*<sup>®</sup>

Powered by **Deloitte**.

---

## Purpose of this document

---

FutureWorld...powered by Deloitte was appointed by Innovative Medicines South Africa (IMSA) to determine the *“Economic and Socio-economic benefits of the R&D-based MN pharmaceuticals to the South African economy.”*

This presentation is a summary of the final report and its recommendations. Selected information from the report has been reproduced in this document to outline the salient findings of the study.

Throughout this report, we refer to the multinationals as the “R&D-based multinational (MN) pharmaceuticals sector”. Note: Deloitte references have been omitted since the report is fully annotated and referenced.

This report is solely for the use of client personnel. No part of it may be circulated, quoted, or reproduced for distribution outside the client organization without the prior written approval of Deloitte Consulting (Pty) Ltd. This material was used by Deloitte Consulting (Pty) Ltd for the sole purposes of an oral presentation; it is therefore not a complete record of the discussion nor the final project deliverable.

# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

# The study lasted 4 months and involved the participation of 10 companies and numerous stakeholder groups

## Participating Companies

Companies submitting data

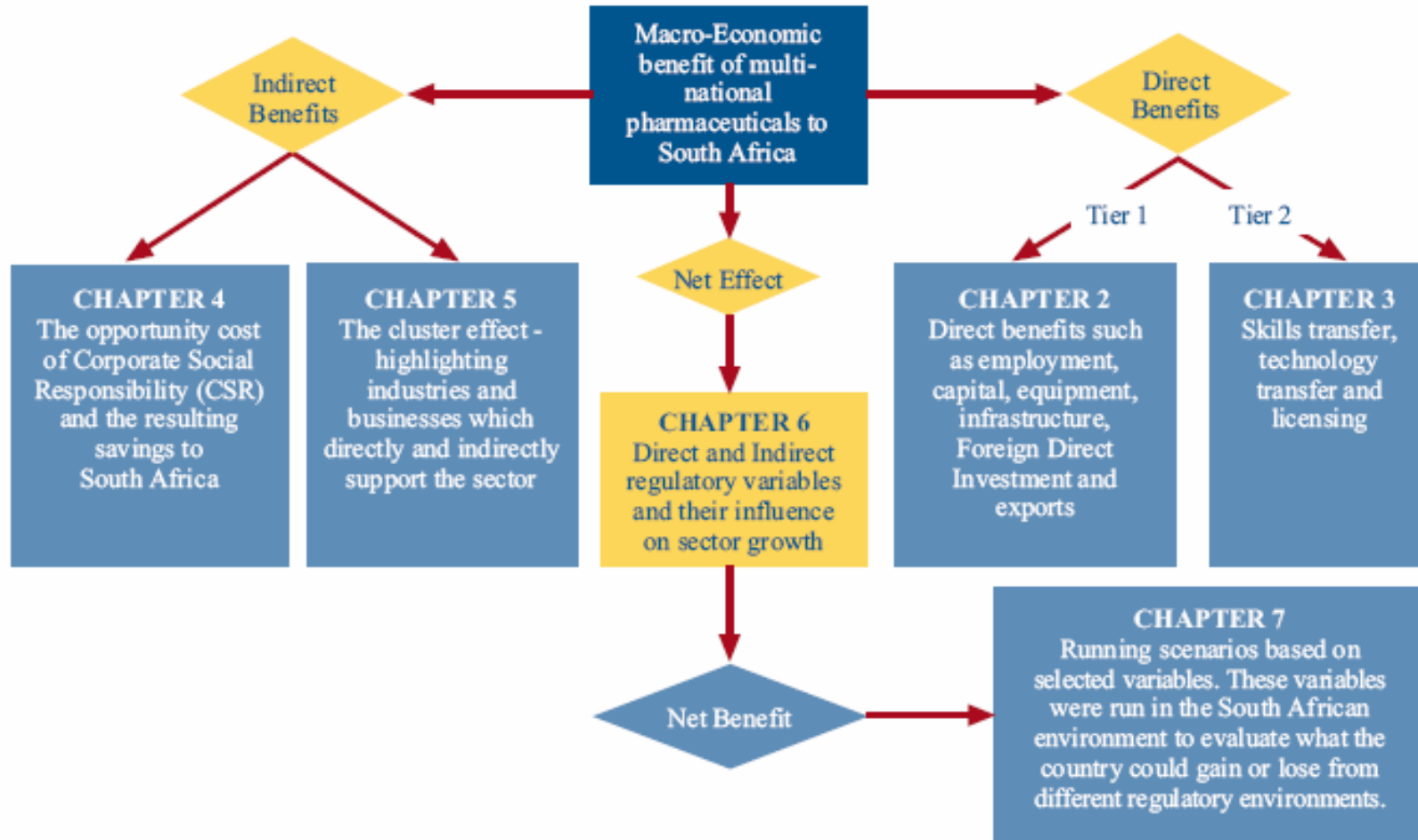


## Key Facts

- The study lasted 4 months
- Ten companies formed the core participating group
  - The group comprised 60% of the total R&D-based MN pharmaceutical sector
  - The group generated sales of approximately R7bn and tax revenues of R340m in 2006
  - Six companies are members of Innovative Medicines South Africa (IMSA) and four are members of the Pharmaceutical Association of South Africa (PIASA)
  - The ten companies employ 3445 employees and the total sector employs approximately 6200 employees
- To understand the industry, a further 6 companies were analysed, although their data was excluded from the study
- Sample data was extrapolated to create an R&D-based multinational pharmaceuticals sector figure

# A structured approach was used to conduct the study and develop the findings

## Project Logic



# The project approach was defined by five hypotheses and tested against data from a set of diverse sources

---

## Hypotheses

- The sector creates **economic value**, which leads to greater return on capital due to access to technology and knowledge transfer.
- The sector cluster leads to the **creation and sustainability of local businesses** that cater to the specialised procurement/supply and service needs of R&D-based MN pharmaceutical companies.
- Apart from ensuring that South Africans have access to innovative medicines, which not only forms the pipeline for the generic industry, the sector also **invests in CSI** which leads to increased access to medicines and social development thus supporting Government imperatives.
- The sector adds socio-economic value to SA which leads to significant savings for SA due to the **utility value of technology transfer** for which the sector is responsible.
- The sector **yields a higher return per Rand** spent leading to little or no opportunity.

## Data Sources

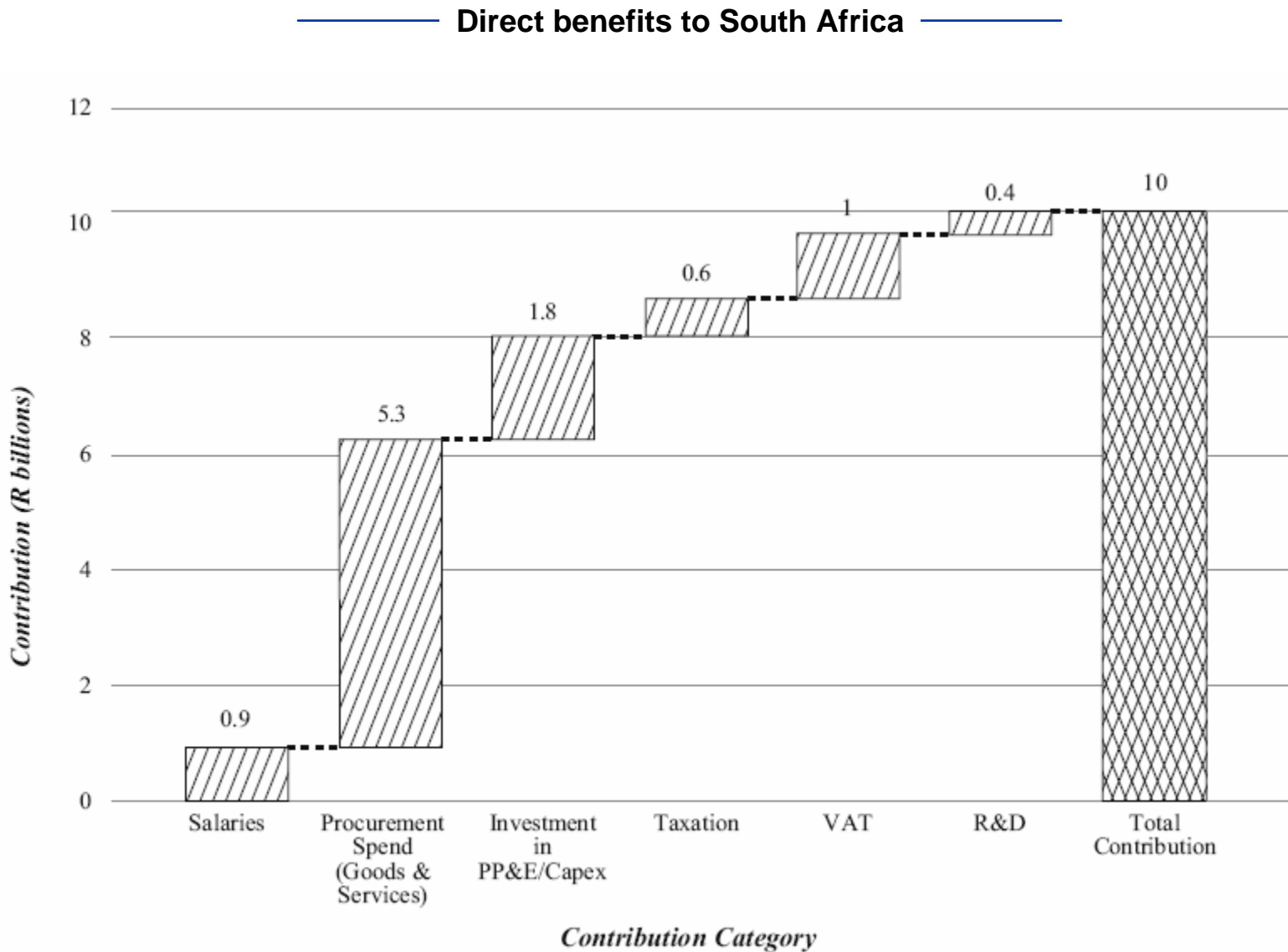
- Data template to collect quantitative information from participating companies.
- Focus interviews to collect qualitative information as well as to better understand the dynamics of the sector.
- Desk-based research/literature review to identify and run scenarios based on best international practices and also to verify the interview commentary.
- Deloitte has used data from multiple sources to conduct the analyses. While we have applied internal process to ensure data accuracy and consistency, we cannot be held responsible for incorrect data.

# Contents

---

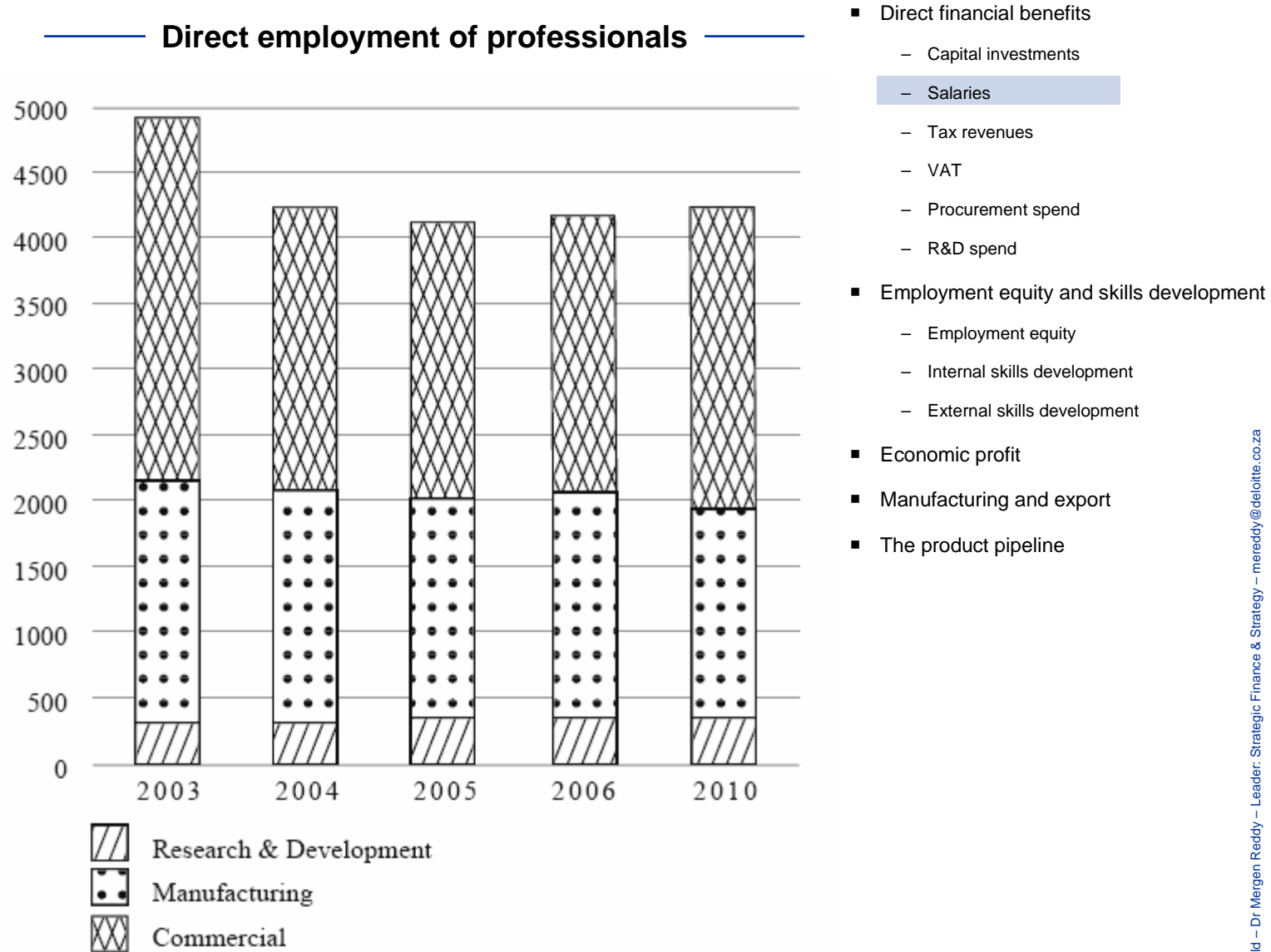
	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

## In 2006, direct benefits to the South African economy equalled R10.0bn

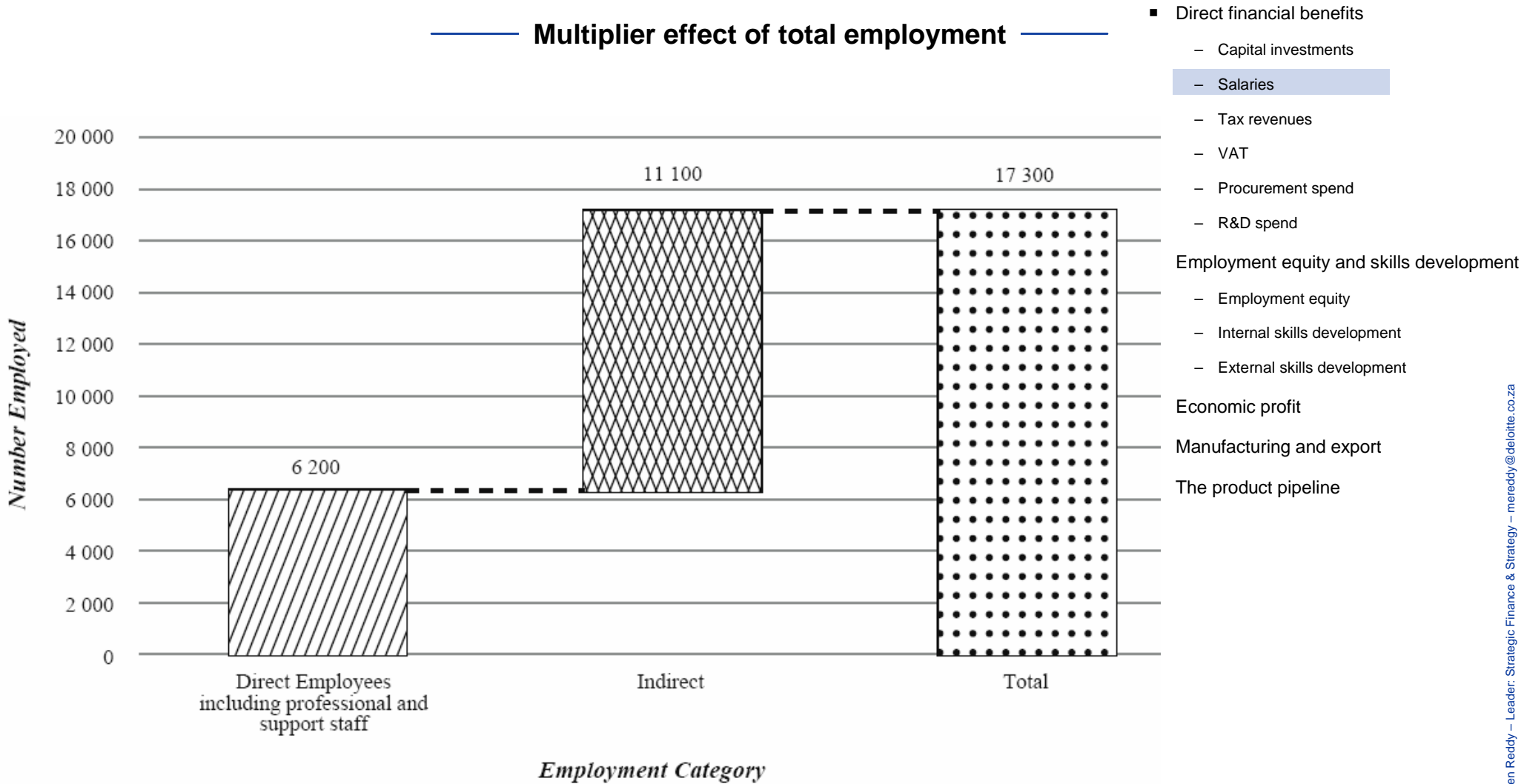




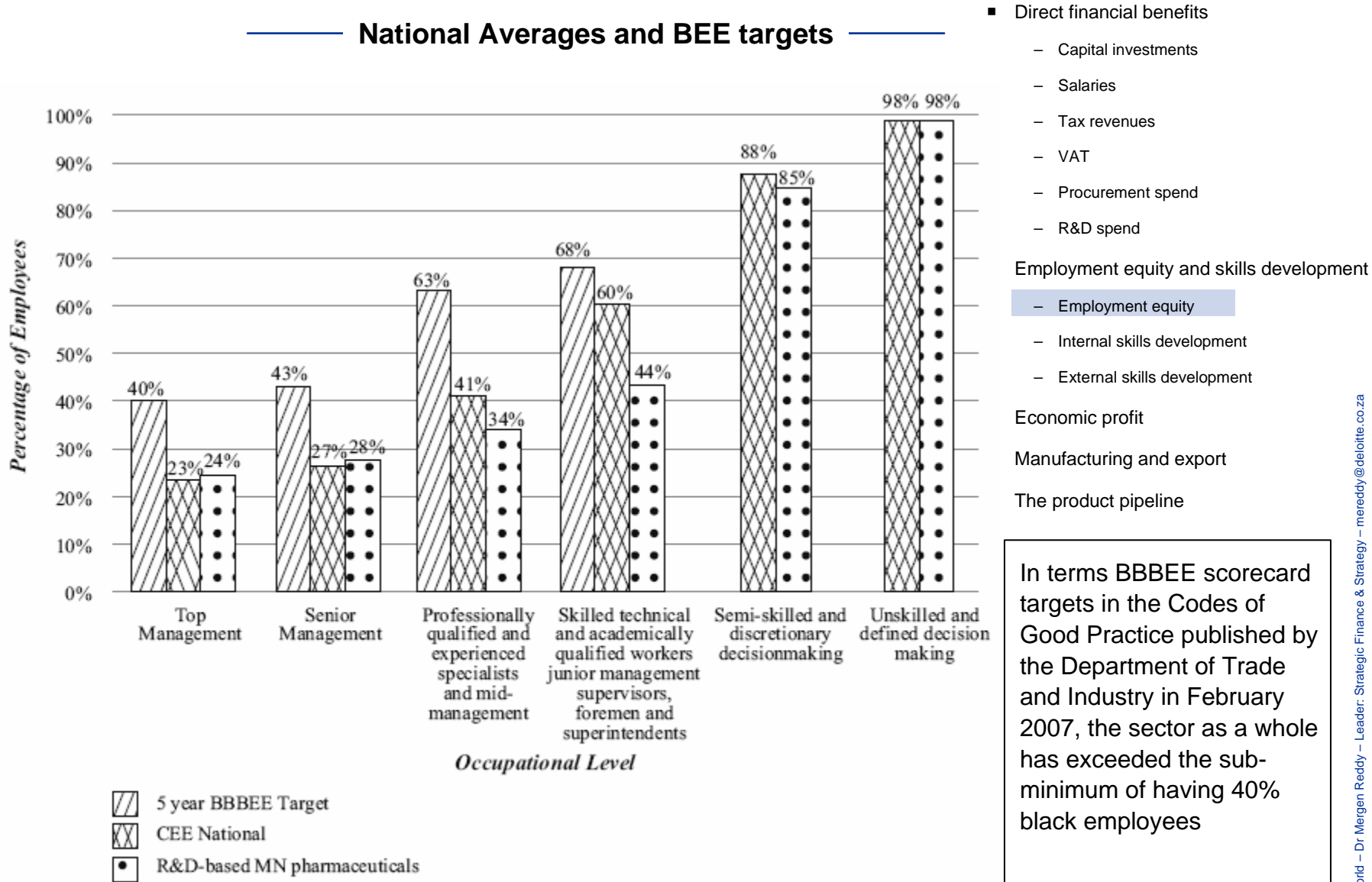
# The sector employed 6200 individuals in 2006 and, over the last 12 months, has reversed the trend of decreasing employment



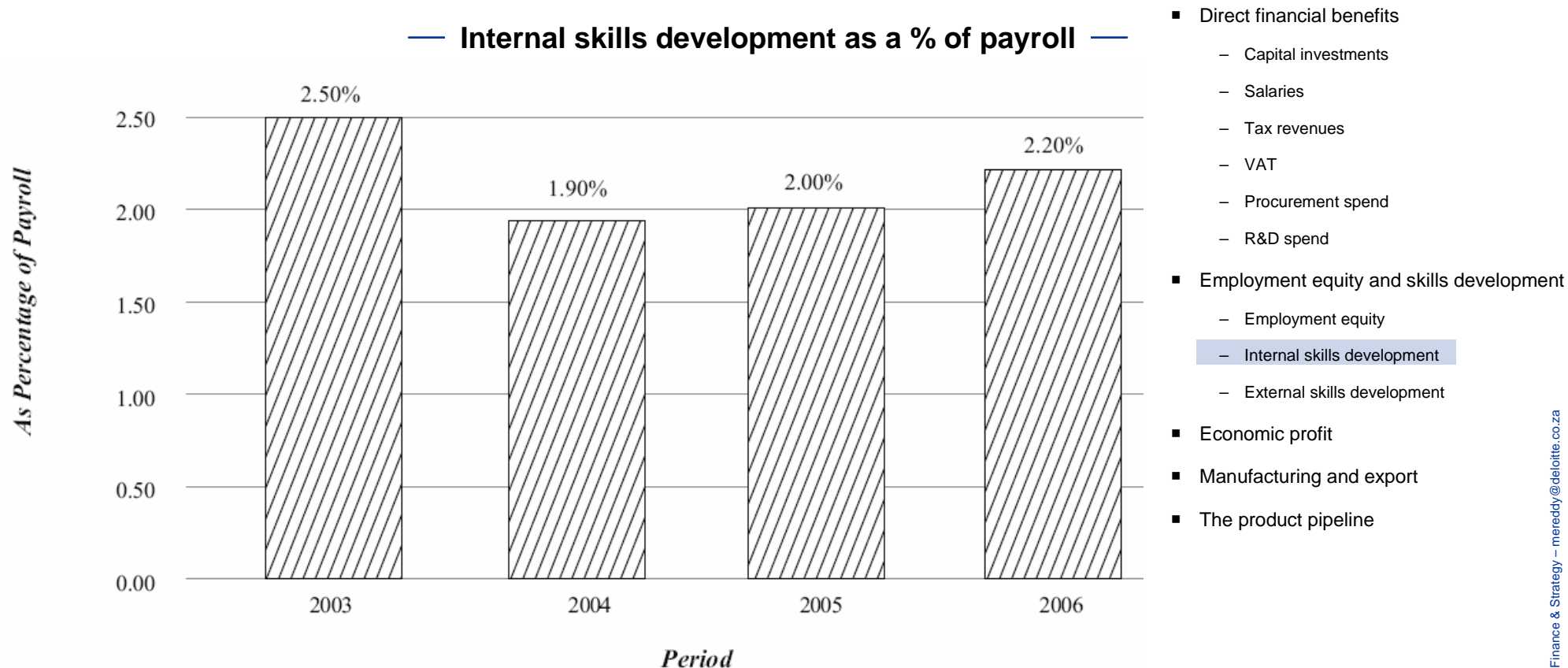
# The calculated sector multiplier of 1.79 suggests that 11 100 indirect jobs were created in 2006



# The sector exceeds the National equity average for the Top and Senior Management levels



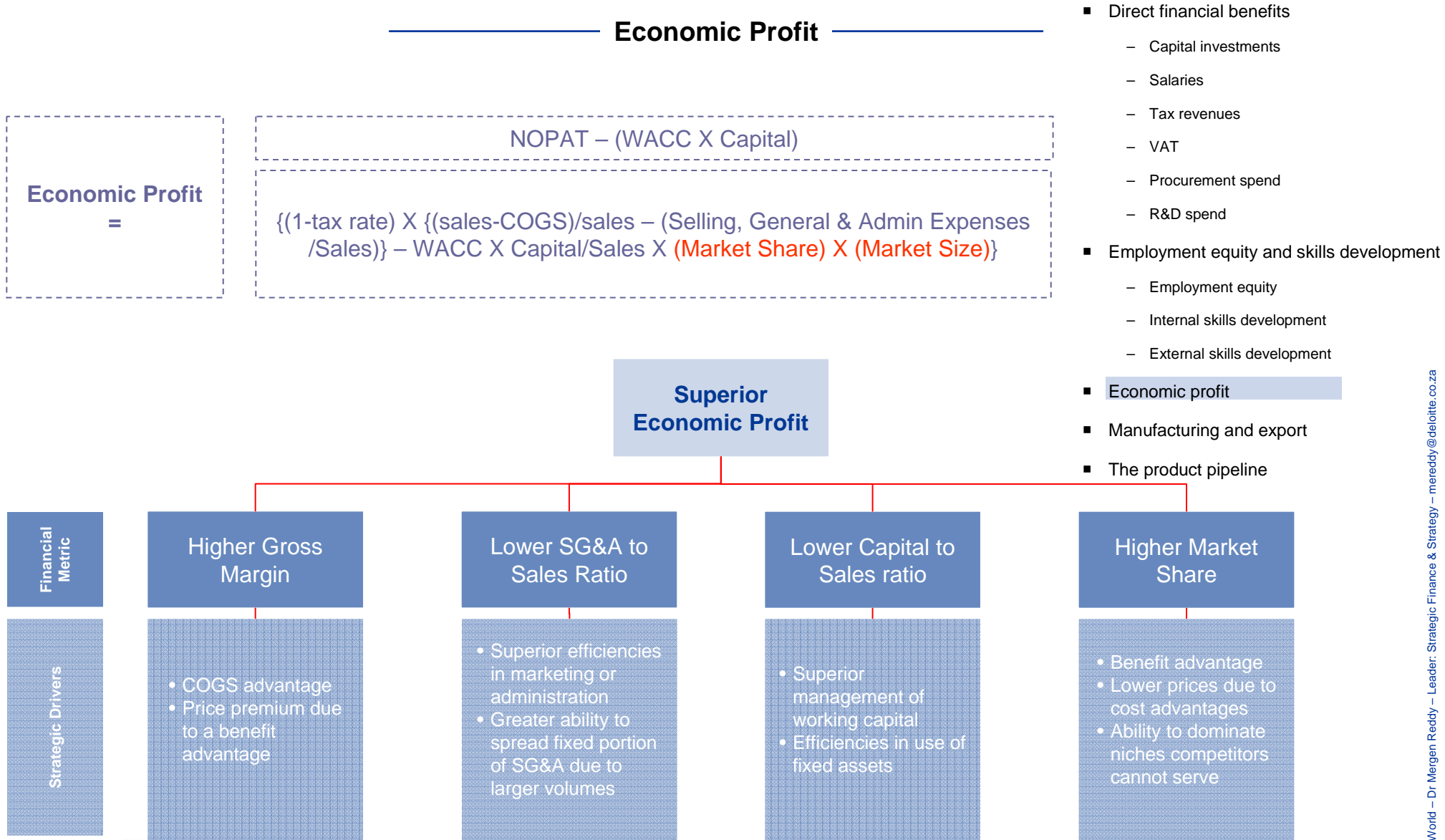
## The sector spends double the statutory requirement of 1% of payroll costs on skills development and sent 2701 employees on training in 2005/06



### Key Points

- Approximately 50% (1326) of the 2701 employees were black
- Skills spend for the 2701 employees was R11.51m to the skills year ended March 2007.
- Approximately 5741 employees were scheduled for training programmes with the priority areas in the year beginning March 2007

# Since true profit must account for the cost of capital, economic profit was used as a measure of performance rather than accounting profit



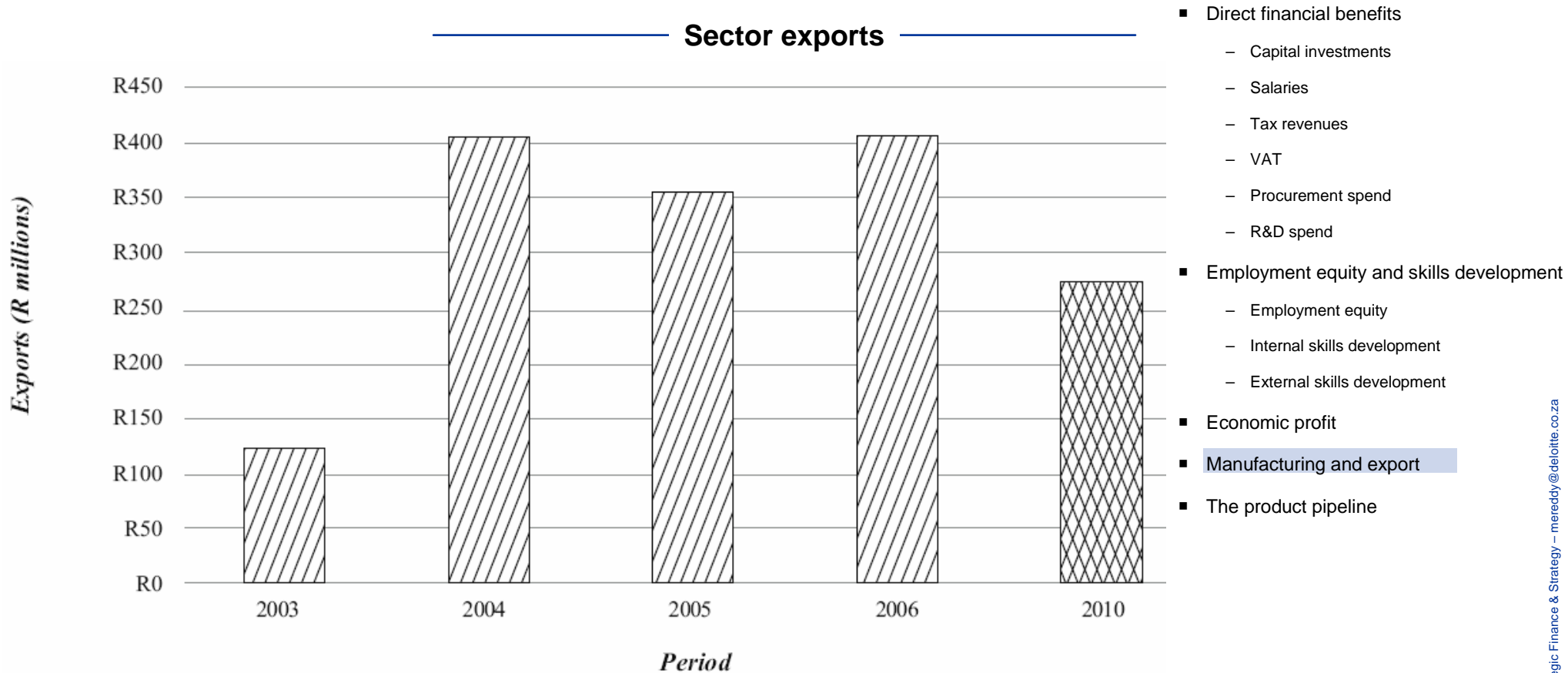
# The sector has consistently earned a positive economic profit since 2003 and is expected to continue doing so until 2010

## Key Points

- The economic profit has consistently been positive and is expected to be positive until at least 2010.
  - Declines in revenue and in one case, a doubling of overhead, led to a decline in the economic profit
  - Due to the positive economic profit, the sector has earned a profit above the cost of doing business in South Africa
  - Sectors with a positive economic profit are attractive to investors since they yield an above average market return
  - Should the sector not earn an economic profit, the participants *could* seek and/or require government support to continue operating in South Africa
- Direct financial benefits
    - Capital investments
    - Salaries
    - Tax revenues
    - VAT
    - Procurement spend
    - R&D spend
  - Employment equity and skills development
    - Employment equity
    - Internal skills development
    - External skills development
  - Economic profit
  - Manufacturing and export
  - The product pipeline

***Despite the challenges it has faced, the sector remains a positive contributor to the economy. With more assistance, it is logical to assume that this contribution could increase.***

# Despite the global consolidation of supply chains, the sector's exports have grown by 240% from 2003 to 2006



*This is primarily due to the focus on niche areas.*

## At least 12 technology transfer and BEE transactions took place across a broad range of areas which added significant value to the recipient

### Selected Activities

Company	Description of Transaction
GSK	Voluntary licensing of ARVs to the following companies: <ul style="list-style-type: none"> <li>• Aspen</li> <li>• Biotech</li> <li>• Cipla Medpro (Pty) Ltd</li> <li>• Feza Pharmaceuticals</li> <li>• Ranbaxy</li> <li>• Adcock Ingram</li> </ul>
MSD	Granted a voluntary licence to Aspen for ARVs
Janssen-Cilag	Manufacturing facility sold to Specpharm Holdings (Pty) Ltd, a BEE company
Eli Lilly	Marketing agreement with Batswadi Pharmaceuticals to the value of R67m, a BEE company who will distribute, market and promote their diabetes medicines Sale of antibiotic products to Ikhambi, a local BEE company Transfer of technology of TB medicines to Aspen to the value of R21m
Roche	Free of charge technology transfer to Aspen to enable local production of HIV medicine for Africa Technology transfer to Aspen for the production of a generic version of Oseltamivir for African countries Empowerment of Holisizwe Medical through enterprise development in the areas of health outcome research
Sanofi-Aventis	Joint venture with Litha Healthcare to form Sisonke Pharmaceuticals, a BEE company who will distribute the TB medicines
Other	Development of operational and financial capacity of small enterprises such as security services, catering services, courier services and car wash services



## Most participating companies engaged in activities across all seven CSI groups valued at 4.8% of NPAT in 2006

Selection of CSI Activities	# Participating companies
<ul style="list-style-type: none"><li>■ Provision of medicines<ul style="list-style-type: none"><li>– Public private partnerships to provide access to innovative medicines</li><li>– Partnerships with NGO's to provide access to medicines and treatment</li></ul></li></ul>	10
<ul style="list-style-type: none"><li>■ Primary healthcare<ul style="list-style-type: none"><li>– Contributions to facilitate improvements in the delivery of care to patients in community hospitals, providing back-up and support for primary healthcare initiatives</li></ul></li></ul>	10
<ul style="list-style-type: none"><li>■ Social development<ul style="list-style-type: none"><li>– Supporting SOS children's homes</li><li>– Immunisation projects</li><li>– Building of clinics and healthcare infrastructure</li></ul></li></ul>	8
<ul style="list-style-type: none"><li>■ Enterprise development<ul style="list-style-type: none"><li>– Assisted in the creation of a black-owned security- and courier firm</li><li>– Assisting in the development of operational &amp; financial capacity of small enterprises, for example cafeteria &amp; carwash facilities</li></ul></li></ul>	2

## Most participating companies engaged in activities across all seven CSI groups valued at 4.8% of NPAT in 2006 ...(cont.)

### Selection of CSI Activities

# Participating companies

#### ■ Education & educational infrastructure

10

- Vehicle provided to Rhodes University to transport students to previously disadvantaged communities for training in the use of pharmaceutical products and compliance
- Opportunity for 20 final year SA Chemistry students to spend a week at a research site in the UK
- 4 Equity individuals received a scholarship to study towards an international MBA
- Dinner and award to Pharmacy Student of the year
- Medical bursaries for medicine and allied medical professions for equity students (MESAB & Manto Tshabalala Msimang Bursary Fund)
- Computer and book donations
- Donations of international standard manuals

#### ■ Burden of disease

8

- TB FREE supports Department of Health's National TB Control Programme (NTCP) by Training Health TB Patient supporters and Implementing TB Mobilization and awareness initiatives
- HIV projects in partnership with NGO's and different clinics
- Contribution to facilitate studies into depression related to pregnancy
- Annual grant given to Diabetes Association
- Trained nurses on Diabetes care and management

## Most participating companies engaged in activities across all seven CSI groups valued at 4.8% of NPAT in 2006 ...*(cont.)*

### Selection of CSI Activities

# Participating companies

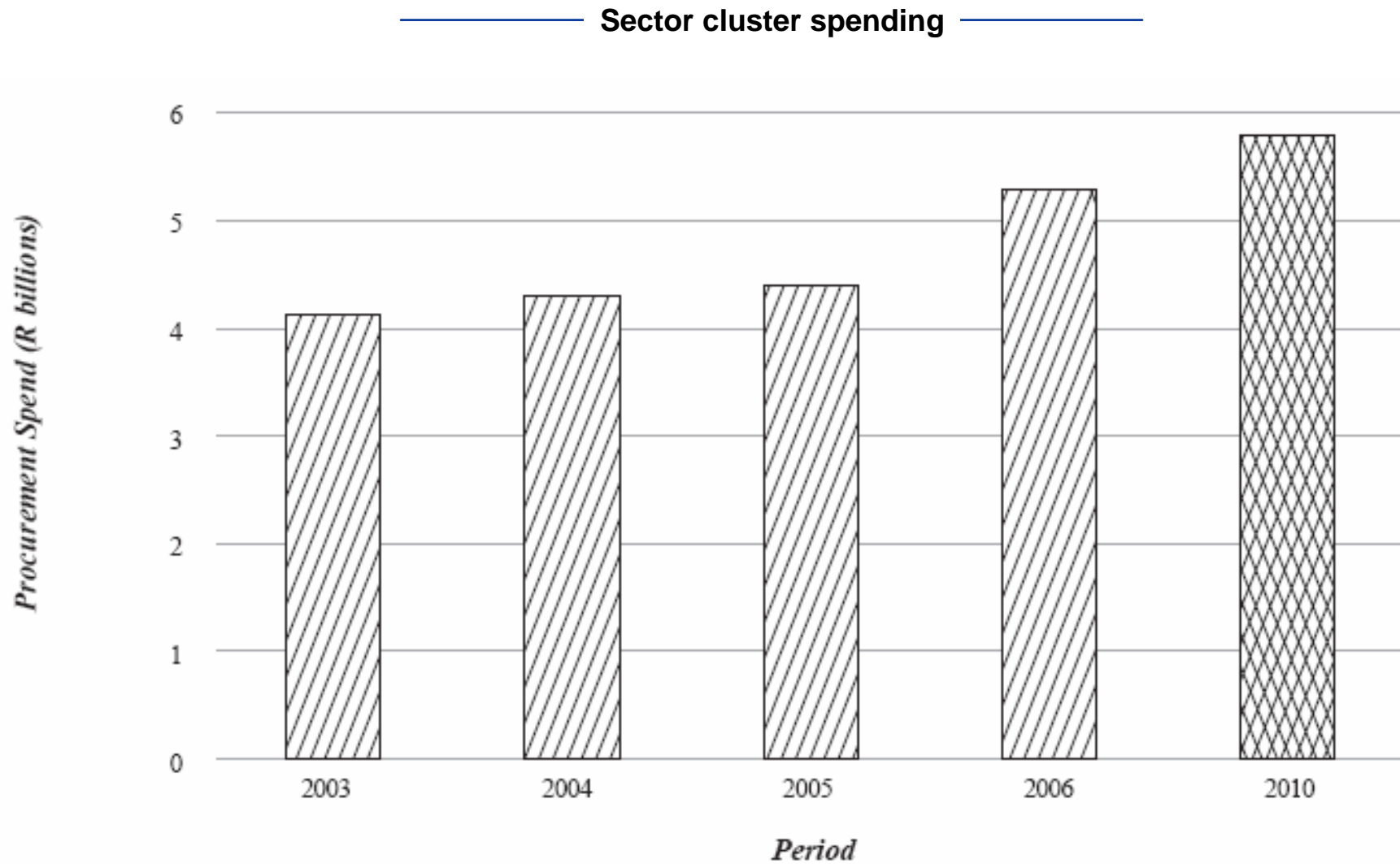
8

#### ■ Training

- Providing on the job training for equity candidates busy with health related studies
- HIV home based care training
- Training to healthcare workers with regards to diabetes, cancer, etc.

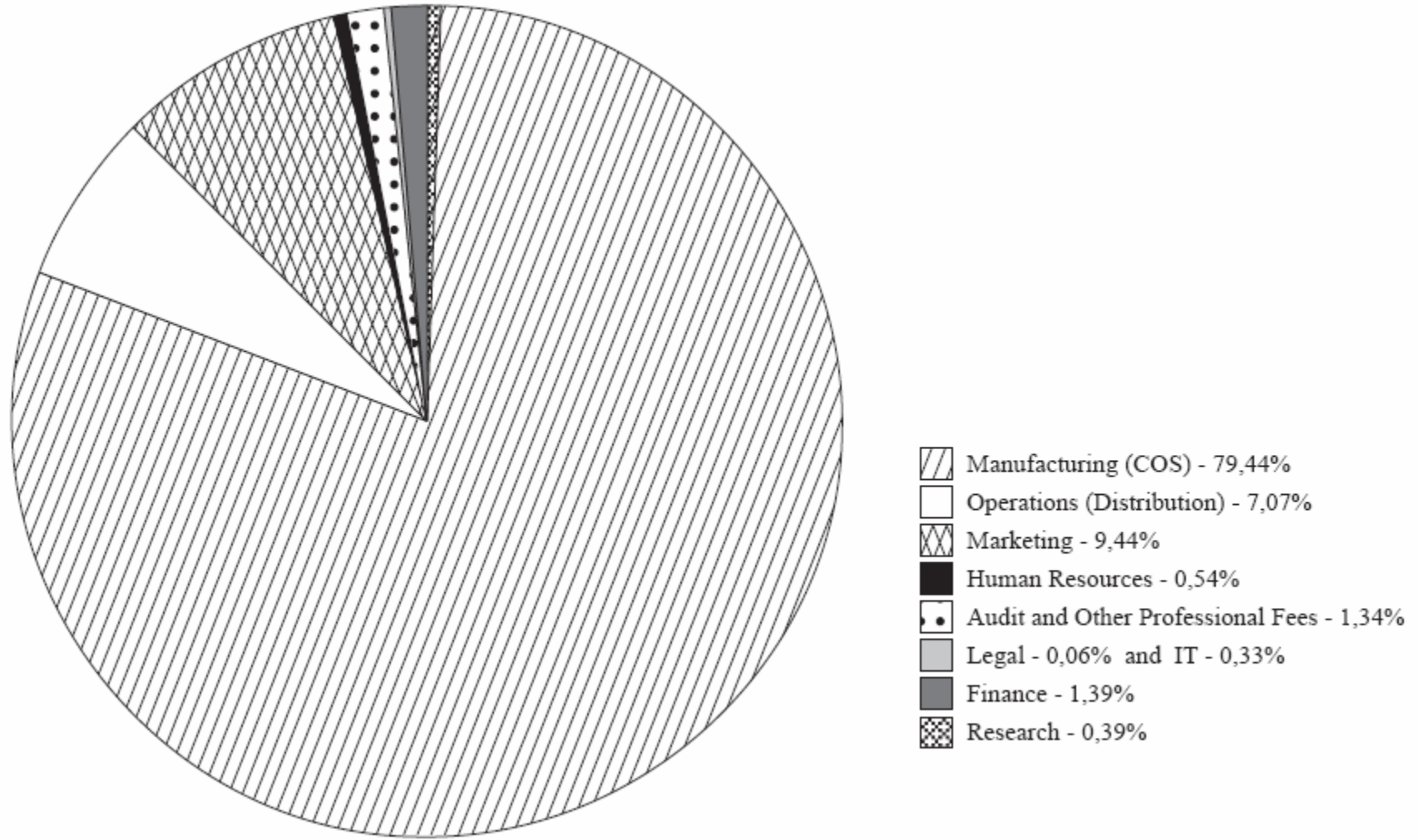
## Procurement is planned to increase until 2010

---



## ...with the majority of expenditure in the manufacturing part of the value chain

Breakdown of cluster spending



## In reviewing the environmental context care was taken to use the appropriate comparisons and draw the relevant conclusions

### Context for regulations

- Regulations exist to support/enable/strengthen a predefined sector/industry policy
- Therefore policies and regulation are implemented to encourage or discourage certain types of behaviour
- The enabling elements must be critiqued in the context of a to be determined sector policy
  - Pricing, reimbursement and access
  - Regulatory approval process
  - Intellectual property rights
  - R&D investment incentives
  - Skills availability
- Therefore the industrial policy for this sector must be agreed before the response to the five major policy areas can be agreed
- **The discussion which follows does not aim to recommend any one response. Rather it is a outline that the gap does exist and a decision needs to be made**

### Sector Policy

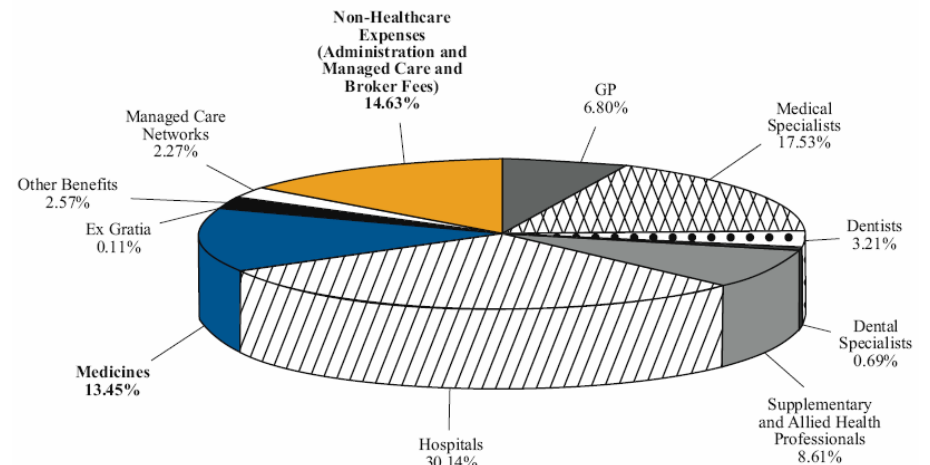
- The R&D-based MN pharmaceutical sector could grow in one of three ways:
  - **1 - All companies stay in South Africa yet there is limited or no R&D and manufacturing.** The companies maintain a significant sales force and drive the market growth by gaining new markets, maintaining existing markets and growing access in general
  - **2- South Africa becomes a favoured investment destination for R&D and manufacturing.** The domestic market continues to grow, yet the country is seen a key location for R&D, manufacturing and centres of excellence (COE)
  - **3 – This is the hybrid model** where the country focuses on driving sales and access while positioning itself as a R&D, manufacturing and CEO in niche diseases such as malaria, TB and HIV & AIDS
- **Only once option 1,2 or 3 is decided upon can the proper response to each of the policy areas be agreed**

# Medicines prices are no longer the key driver of healthcare costs in the private sector and should not be the only focus area to increase access

## Context for regulations

- Medicine prices are generally a key element in the healthcare system and any decrease in the costs has a large impact on the overall costs of provision and downstream healthcare costs, such as hospitalisation.
- Where medicine prices are very high, any decrease in prices will have a significant impact of the total costs of the healthcare system.
- However, as the cost of medicines decreases, a point is reached where medicines are no longer one of the largest costs and any further decrease in medicine costs will not have a significant impact on the total healthcare costs.**
- In other words, the cost of the total healthcare system is now only slightly sensitive to medicine prices. When this happens, in order to maximise benefits to patients, government must focus on the cost components to which the healthcare system is most sensitive. When this point is actually reached is debatable, yet based on the data, it is fair to say that South Africa may have reached this point.

## Breakdown of total medical system costs



- Medicines make up only 13.45% of the overall healthcare costs in the private sector
- Due to the limited reduction in volume, the decrease in costs have been driven by a unit price reduction

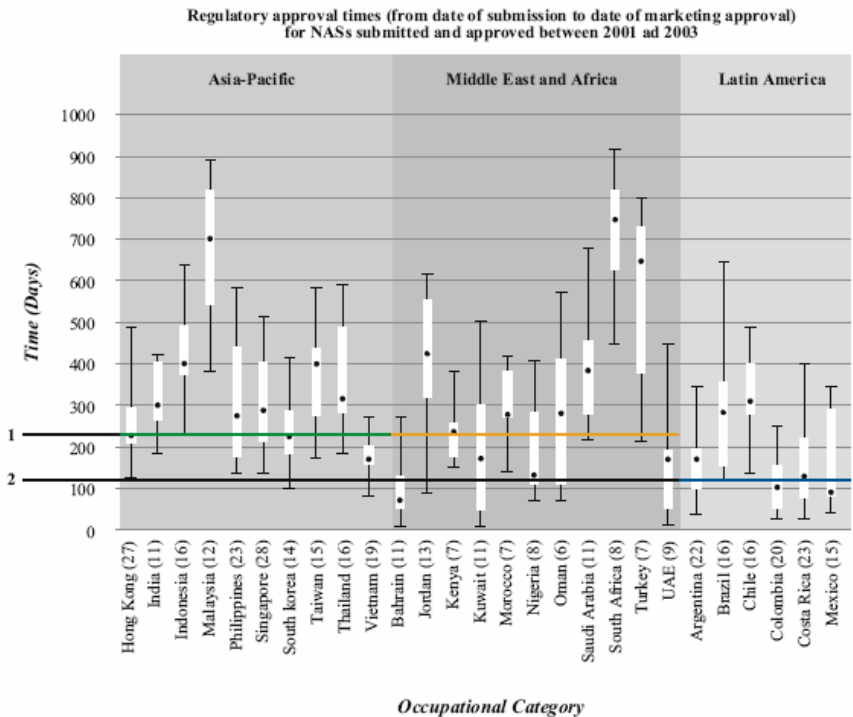
Source: Adapted data sourced from Council for Medical Schemes Annual Report 2005-2006

# Although acknowledged and acted upon by government, the approval time for new medicines still takes longer when compared to international benchmarks

## Recommendations to the Ministerial Task Team

- Risk-based system for assessment of dossiers based on decisions from benchmarked authorities
- Shift focus from assessment to compliance
- A single authority with transparent processes
- Adoption of International Conference on Harmonisation (ICH) standards
- Code of marketing practice should govern and ensure an ethical approach to the marketing of all medicines in South Africa.
- Effective communication between the industry and authority
- Provision should be made in the Medicines Act for data protection that will allow for the protection of submitted data
- Improve the clinical research approval processes as they are slow and is a deterrent to companies planning to do research in the country.
- Pharmaco-economic evaluation should remain independent of the medicines approval process.

## Comparison of regulatory approval times



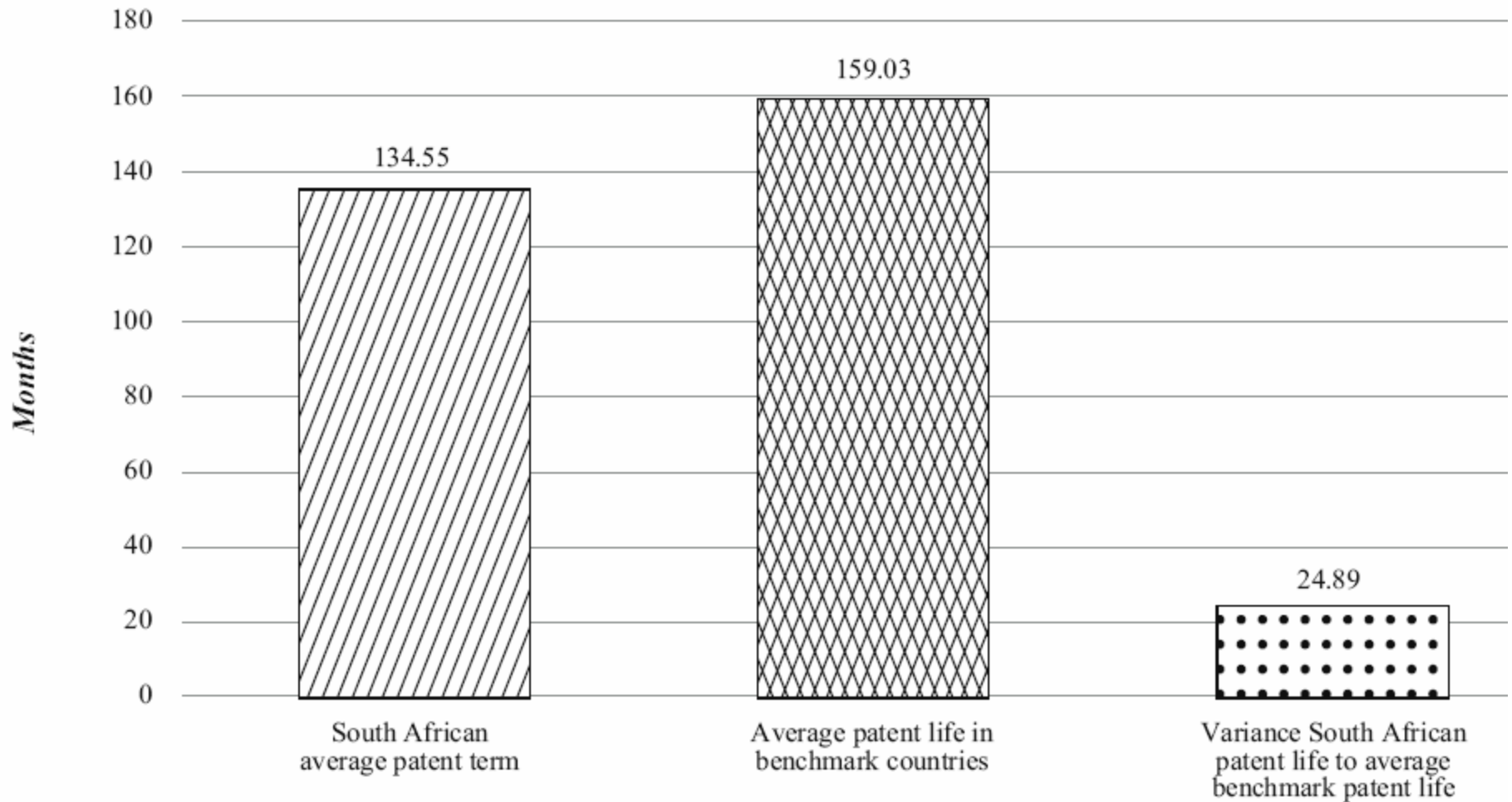
1. Regional median approval times for Asia-Pacific: 282 days, and ME Africa: 283 days  
 2. Regional median approval times for Latin America: 175 days

Source: CMR International Institute for Regulatory Science, 2006. A cross-regional comparison of the regulatory environment in emerging markets



# Investors in South Africa have over 2 years less to recoup investment costs as compared to other countries in the benchmark group

Variations in South African Patent Life  
Sample of 25 Products



Grant Thornton April 2007 Pharmaceutical Product Patent Life Benchmarking Report

## South Africa has a comprehensive set of grants for R&D and manufacturing

### Ireland & Puerto Rico

- Ireland
  - **A highly competitive corporate tax rate of 12.5%** is a major incentive as is the fact that no tax is paid on earnings from intellectual property where the underlying R&D work was carried out in Ireland.
  - Ireland also recently introduced a new R&D Tax Credit, designed to encourage companies to undertake new and/or additional R&D activity in Ireland.
- Puerto Rico
  - income and property tax reductions for a period of up to 25 years.
  - Additional deductions available to corporations located in areas of high unemployment and to companies committed to growth and employee development.
  - Companies relocating to or expanding their operations in Puerto Rico benefit from a **7% maximum income tax rate, with some companies paying as little as 2%**. There is no tax on dividend distributions and a super-deduction of up to 200% for R&D expenses and job training costs.

### South Africa

- R&D benefits include (this excludes the generous export assistance and other general programmes):
  - The Technology for Human Resources Industry Programme (THRIP) will contribute between 30% and 50% of the funds invested by a company in research projects. University students conduct research projects funded partly by THRIP and funded by the company.
  - The Innovation Fund provides funding through the Technology advancement programme, the Missions in Technology Programme, the Seed Fund, and Patent incentive fund. It provides a maximum grant R15 million over a three year period. It is applicable to collaborative projects which undertake R&D in all economic sectors.
  - The Technology Transfer Fund (TTF) funds defined components of the process of transferring available technology to entrepreneurs, communities and existing businesses. The benefit is a grant for the 2nd economy with no payback, and matching funding for the transitional and 1st economies with payback based on a percentage of turnover. The maximum funding is R500 000 per project.

# The economic model aimed to understand changes to key variables within South Africa's existing regulatory environment

## Key considerations

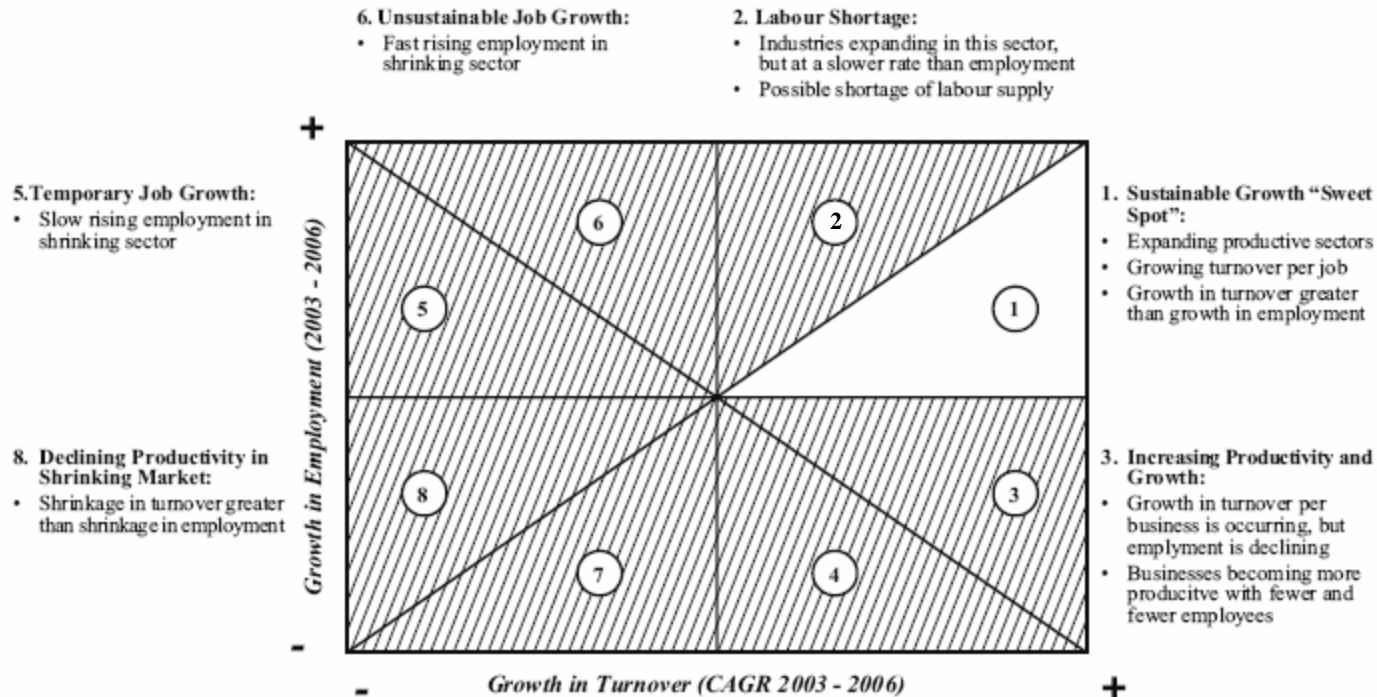
- **It is impossible to model and compare the regulatory environment of another country**
- The model used is robust in that it simply compare changes in the key variables within South Africa's regulatory environment
- **Within South Africa, the model cannot simulate drastic changes in regulatory policy. Why? This is because the model simulates changes by using past data relationships. Drastic changes to the regulatory policy may render these relationships irrelevant**
- The model has been tested by setting the variables to the conditions in 2006 and comparing the model output with actual data

## Questions tested

- How does the R&D-based MNC pharmaceutical sector compare with other industries and sectors?
- What is the expected position of the sector if it were to continue "as is"?
- What would happen to the sector if key variables changed?
  - Scenario 1: Increasing inflation by 1%, 3%, 5%, 6% and 7% without a corresponding increase in the price of medicines.
  - Scenario 2: Decreasing the price of medicines by 1%, 3%, 7% and 9%.
  - Scenario 3: Extending the patent life by 1,2,3,4 and 5 years.
  - Scenario 4: Increasing the sales volume by 1%, 3%, 5%, 7% and 9%

# Sector performance relative to peers was compared along the dimensions of growth in employment and growth in turnover

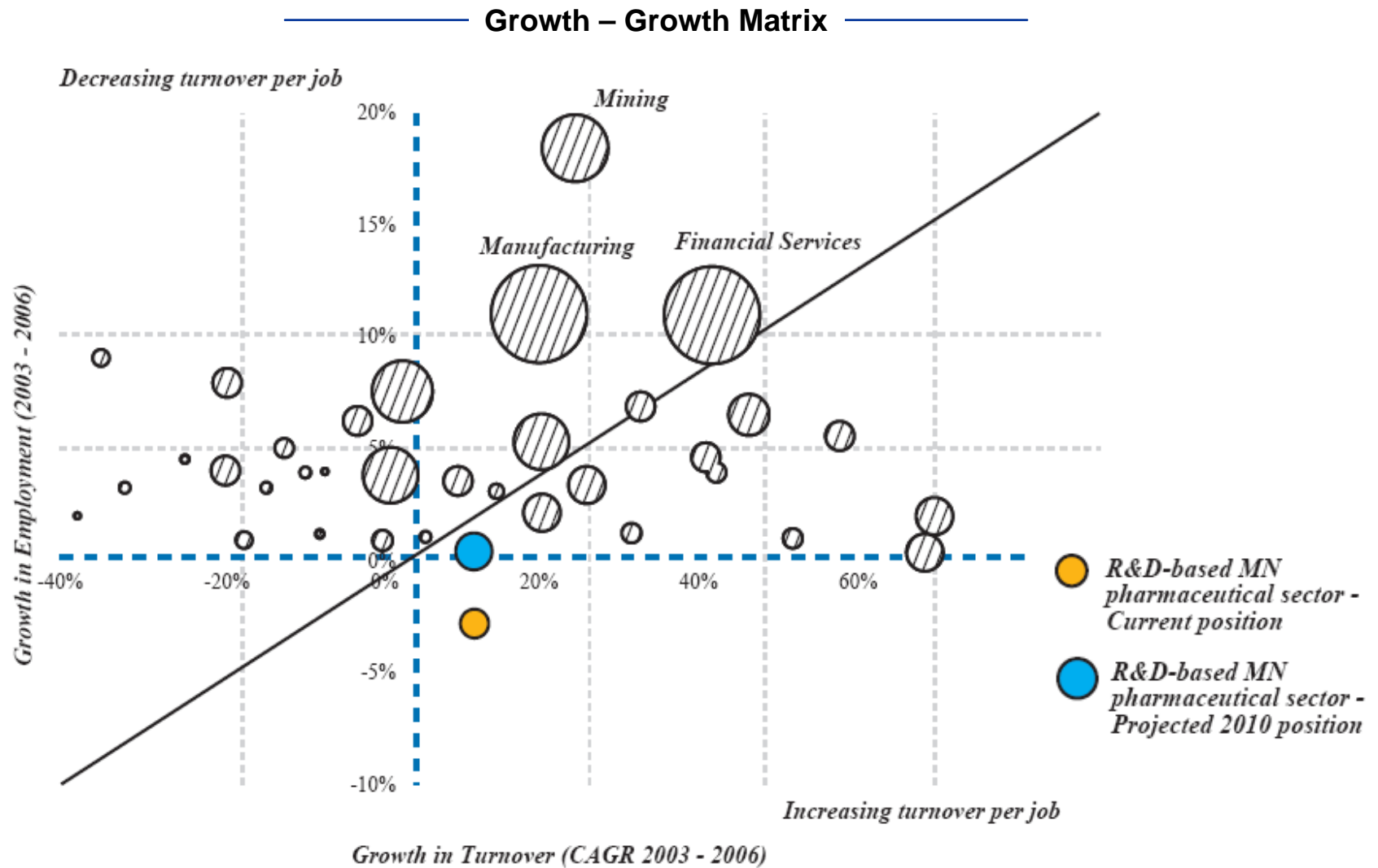
## Growth – Growth Matrix



- ① Most attractive
- ⑧ Least attractive

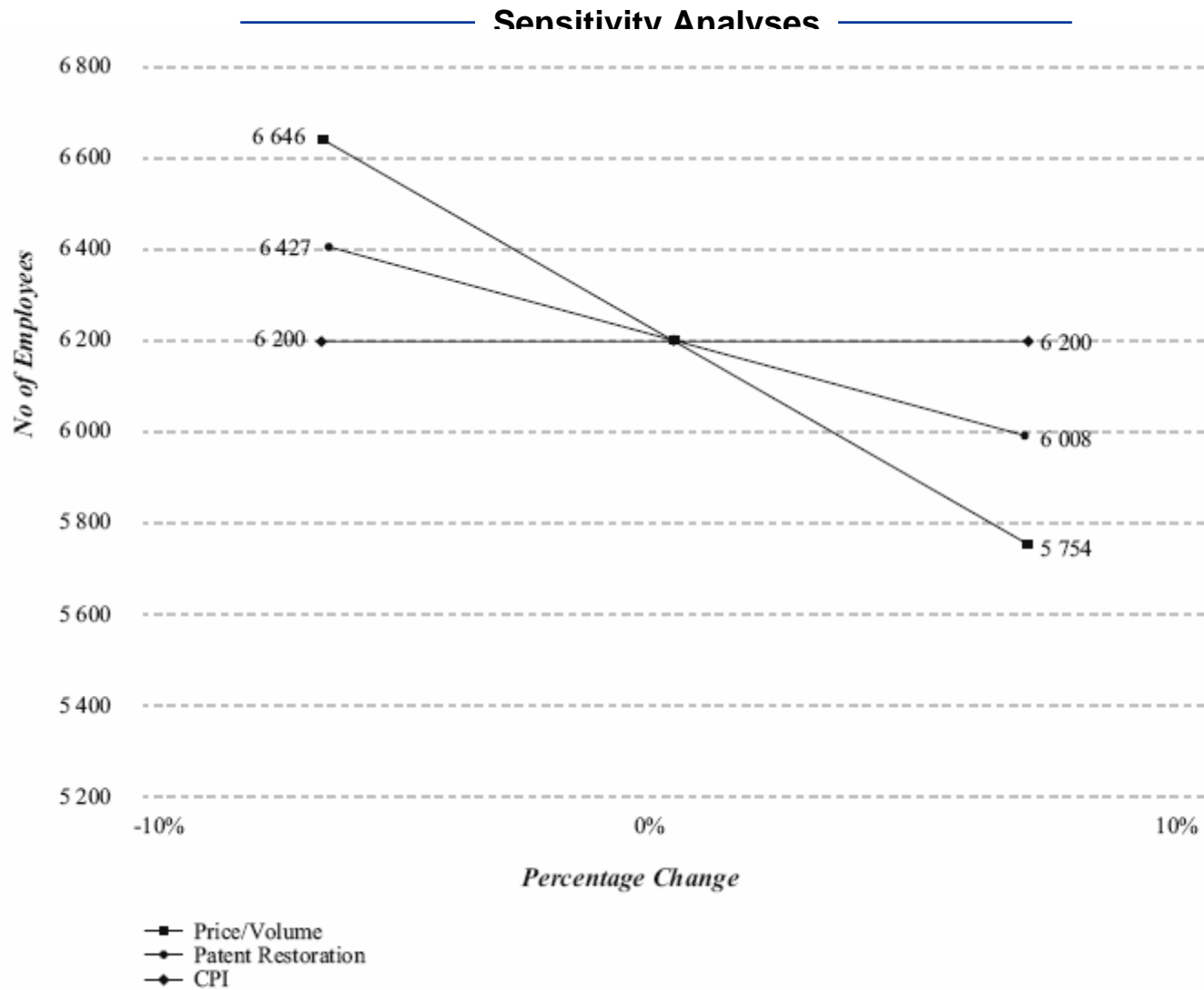
*Note 1: Assumes that for sustainability, growth in turnover is more important than growth in employment*

**Although the sector is currently (orange) with declining employment, this could change to growth in both in both employment and turnover by 2010 (blue)**



*Note: The Mining, Manufacturing and Financial Services sectors exclude medium-sized and small enterprises*

# The performance of the sector is the most sensitive to changes in pricing & volume while it is the least sensitive to changes in inflation



*Note: Since employment is linked to turnover and not profit, it is assumed that there will be no change in employment.*

## The optimal future for the sector does not lie in any one scenario but rather a combination which is dependent on the type of growth favoured

### Low Road

- Direct and indirect employment drops 1% for every percentage drop in price since fewer employees are required to handle decreased sales volume.
- Tax revenues decline by a significant 7% for every percentage point drop in the price.
- With a 9% drop in pricing the industry starts destroying economic profit since the profits do not cover the cost of capital.
- **In other words, the industry cannot earn enough to cover the cost of doing business in South Africa.**
- The economic modelling cannot capture the changes in perception which are likely due to these changes on the sector participants. **Such changes in perception may also affect investment decisions.**

### Middle Road

- Increasing the input costs by inflation without a balancing increase in the medicines price tends to have the largest impact on economic profit which declines by 15%.
- Since employment is linked to turnover, and not profit, it is assumed that there will be no change in employment.
- A sales volume increase has a large impact on employment, taxes and economic profit but not as large as extending the life of the patent.
- The middle road is therefore freezing prices as they are while finding a mechanism to increase sales.

### High Road

- The high road, which also leads to the most significant growth for the industry and the country as a whole, is brought about by increasing patent protection by two years or accelerating the review process
- This leads to an increase in employment of 6%, with an increase in indirect employment and an increase in taxes of 16%.
- The sector moves into the “sweet spot” segment and economic profit increases by approximately 20%.
- This, in turn, leads to increased possibilities in terms of spend within the cluster, and greater investment in corporate social responsibility programmes.

# The most important decision is a collective agreement on the future position of this sector

## What needs to be done

- **Decide and agree a future for the sector**
- **Agree and develop a sector roadmap** outlining the growth path for the way forward with milestones for a 3-year, 5-year and 10-year horizon with clear targets in place.
- **Share information and collectively** make decisions which are in the best interests of all stakeholders.
  - **Develop the manufacturing base for niche diseases** and pursue a programme to drive the exports of these products.
  - **Ensure a changed regulatory and investment environment** (e.g. by nurturing and monitoring the latest tax incentives) to bolster investment in clinical trials to strengthen South Africa's leading position which is fast being eroded by China and India.
  - **Work collaboratively to drive the growth of the sector and access of medicines while increasing patient health.** The challenge is in understanding the root cause of access problems.
  - Make a concerted effort to bolster the lack of interest and rapidly reduce depletion of skills in the sector

## What can industry do

- **The sector and its positive impact should be made known:** Although it creates significant indirect employment and a positive economic profit, it is rarely mentioned as a potential positive contributor to the economy. **As a group the sector must fully embrace and support the new growth plan if it is to work.**
- **There needs to be one clear industry body** and leadership group which represents the sector.
- There must be **greater collaboration** between the industry, research institutions and the healthcare sector.
- There must be one platform to discuss and solve common problems: **the research has clearly indicated that all stakeholders share similar frustrations.** There are also numerous forums available to tackle sector issues.



## The most important decision is a collective agreement on the future position of this sector...(cont.)

### What can government do

- **Government must become a clear champion and driver for the new sector growth plan:** a well-developed and structured sector programme must be developed to guide the sector towards its new targets.
- **Ensure a sector body to drive the new growth agenda obtains results:** policy, research and recommendations for the sector are currently of a fragmented nature. The single most important next step is in ensuring the operation of one forum which works together to make decisions. **This could simply mean strengthening the National Consultative Health Forum or creating a sub-team under its auspices.**
- **The appropriate business climate must be adopted:** the most important thing government could do is to bring certainty to the sector by outlining a set of policy actions it plans to implement over the next 5 to 10 years for the sector.
- Stem the loss of talent
- **Communication:** once the growth plan is adopted, the government must actively and deliberately communicate the goals of the sector at all levels.

### What can industry do

- **The sector and its positive impact should be made known:** Although it creates significant indirect employment and a positive economic profit, it is rarely mentioned as a potential positive contributor to the economy. **As a group the sector must fully embrace and support the new growth plan if it is to work.**
- **There needs to be one clear industry body** and leadership group which represents the sector.
- There must be **greater collaboration** between the industry, research institutions and the healthcare sector.
- There must be one platform to discuss and solve common problems: **the research has clearly indicated that all stakeholders share similar frustrations.** There are also numerous forums available to tackle sector issues.

# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

# Three areas were examined when calculating the direct benefits to the South African economy

---

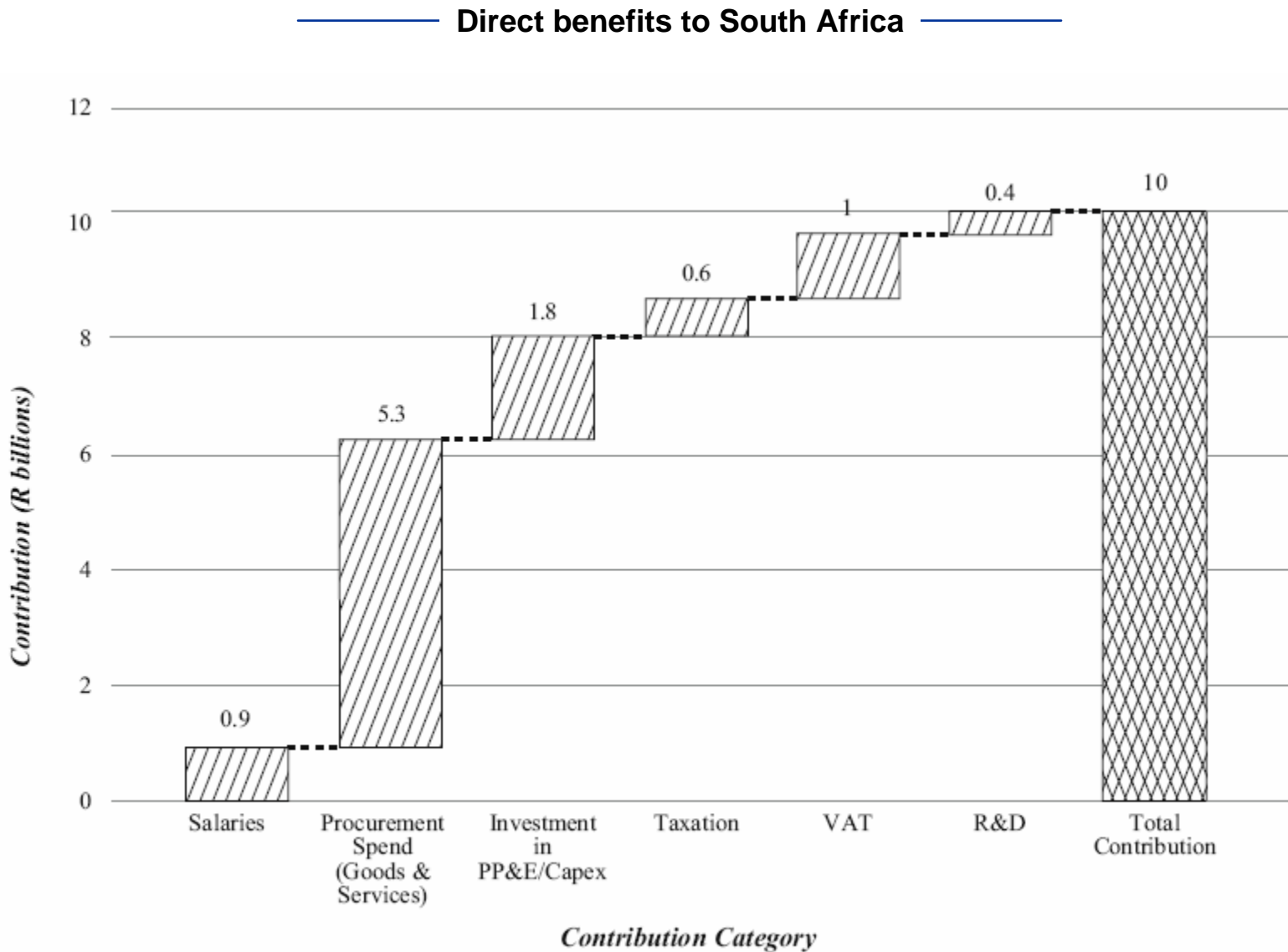
## Components of direct benefits

- Direct financial benefits
  - Capital investments
  - Salaries
  - Tax revenues
  - VAT
  - Procurement spend
  - R&D spend
- Employment equity and skills development
  - Employment equity
  - Internal skills development
  - External skills development
- Economic profit
- Manufacturing and export
- The product pipeline

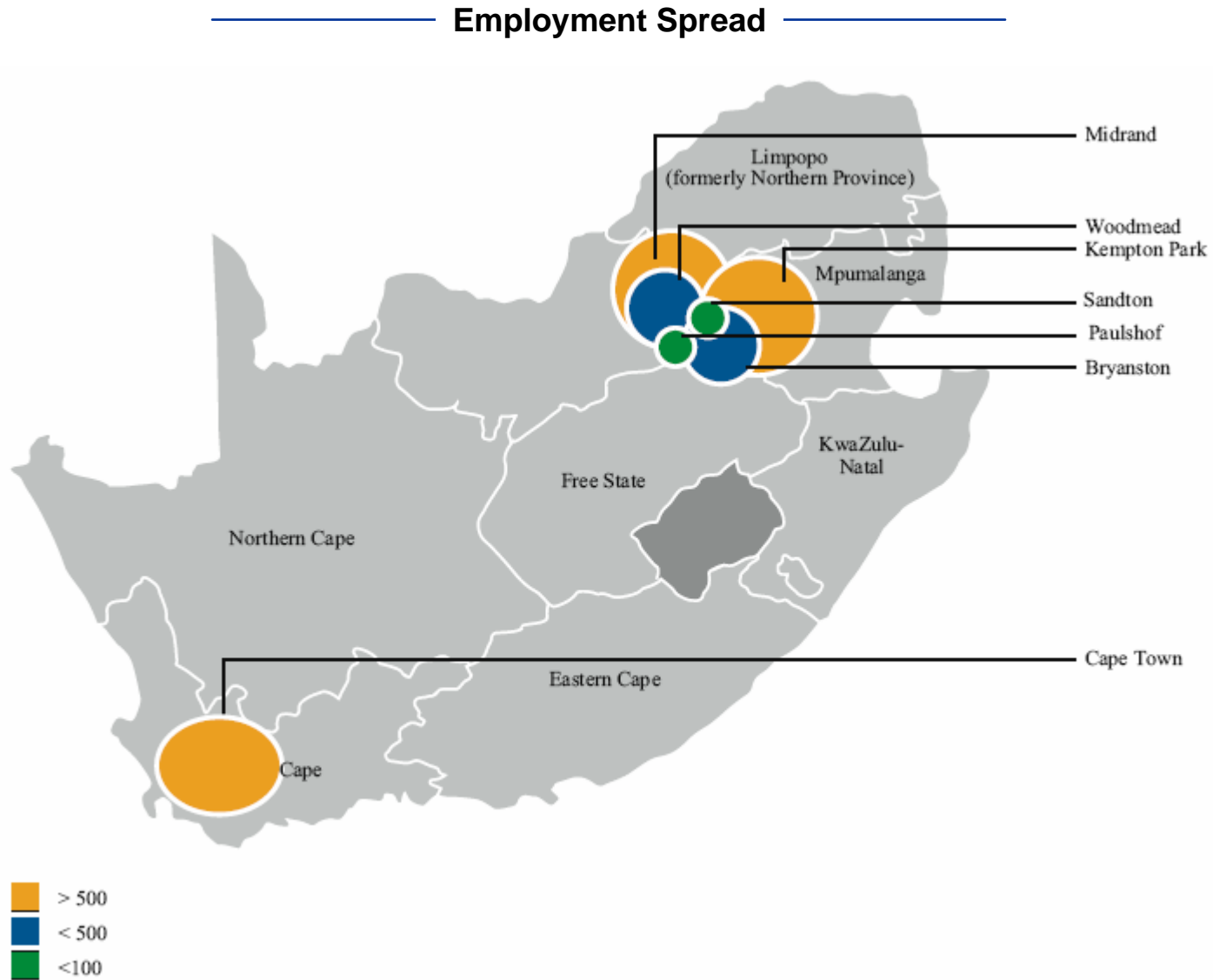
## Implications

- In calculating direct benefits, it is important to calculate both the absolute and relative benefit
- Therefore, the direct financial benefit is the absolute measure. However, it does not indicate what this number means relative to the cost of doing business in South Africa
- Economic profit has been used as the relative measure. This measure determines if the sector has earned a return which exceeds the cost of doing business in South Africa
- Furthermore, the quality of skills transfer and local skills development is important when earning this return. The employment equity and skills development area covers this measure

## In 2006, direct benefits to the South African economy equalled R10.0bn



# Employment, and therefore the spread of benefits, is primarily located in the Western Cape and Gauteng



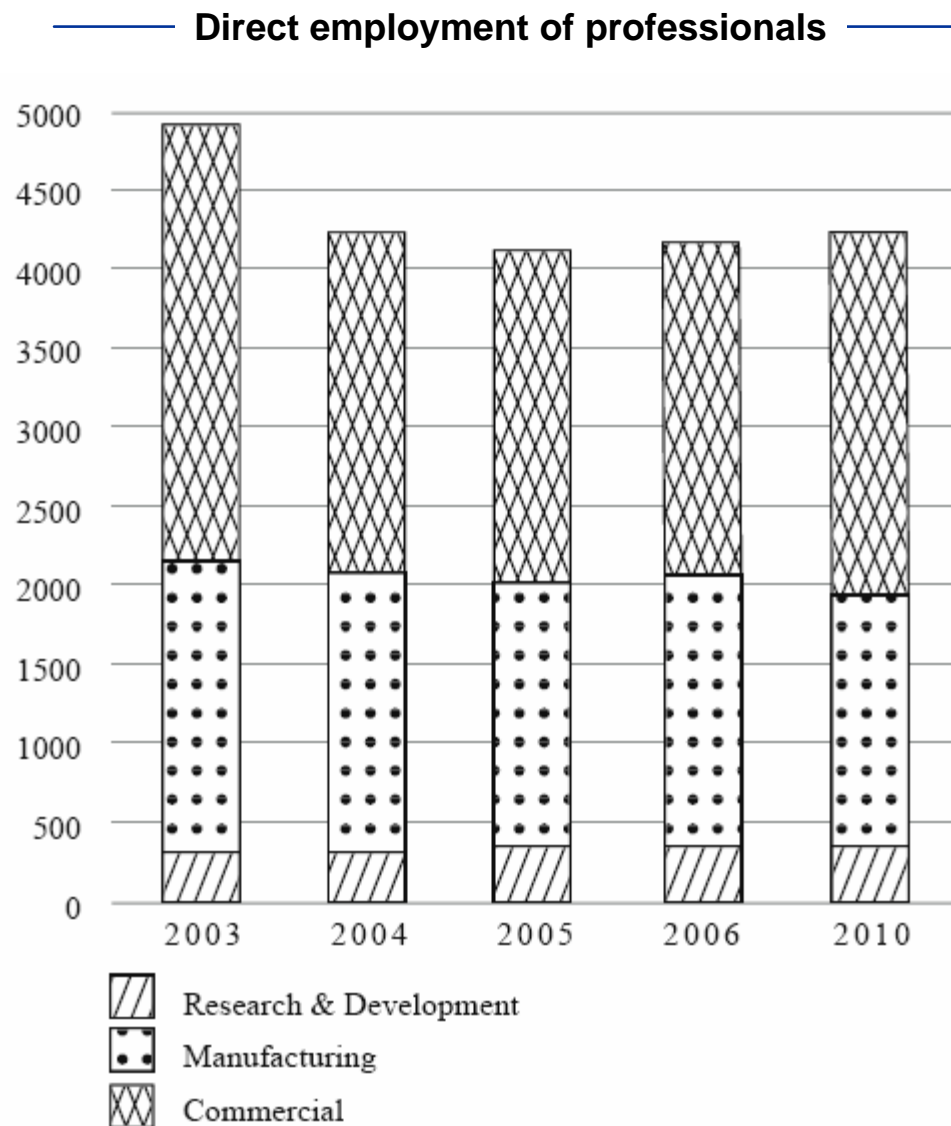
# Total capital infra-structure spending equalled R1.8bn in 2006 and was primarily made on buildings and equipment

---

## Capital Investments

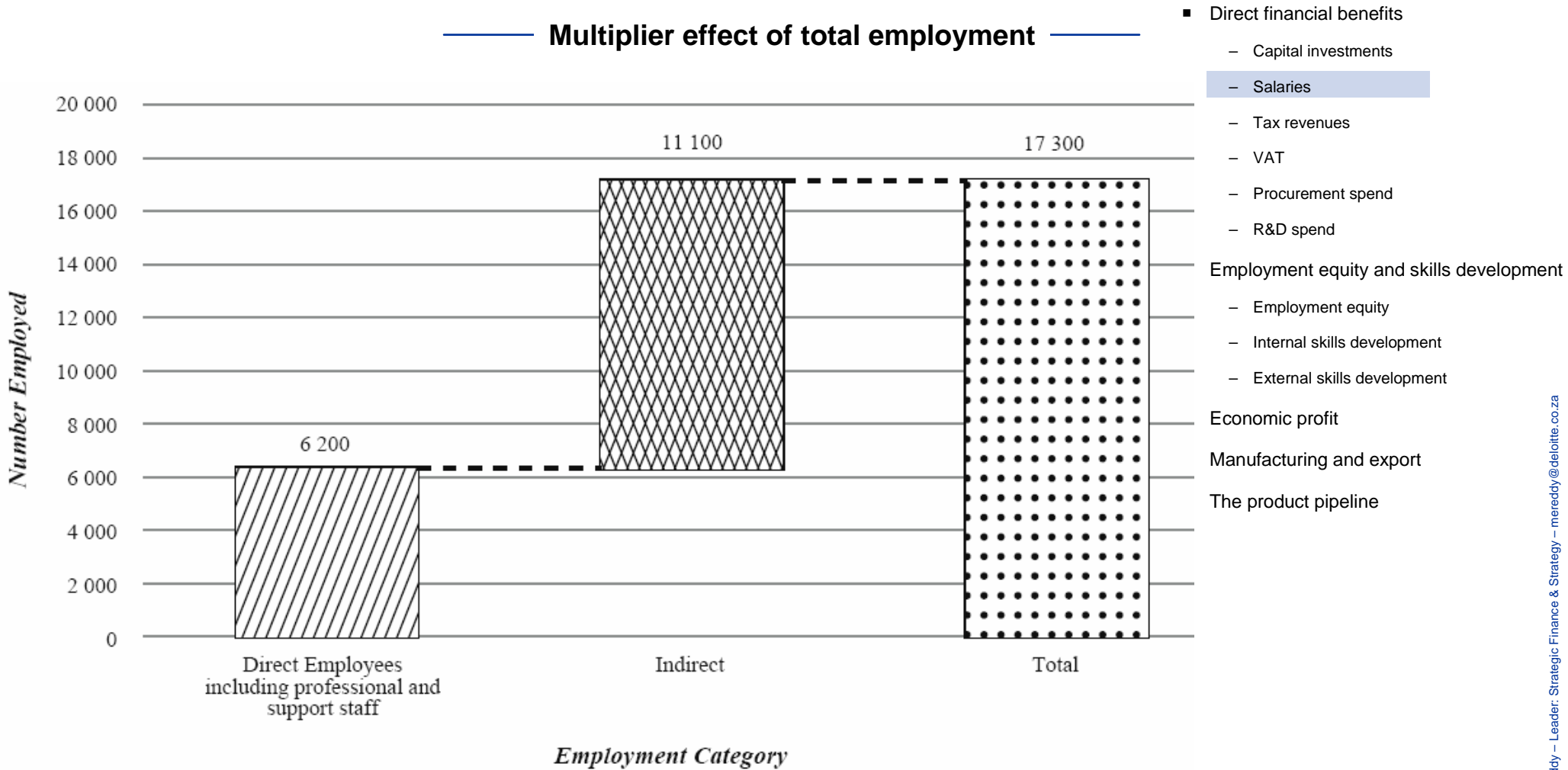
- Capital infra-structure spending equalled R1.8bn in 2006
  - 70% of the R1.8bn was allocated to buildings and equipment
  - Spending has increased at a CAGR of 17% over the last 3 years
  - These increases will continue yet at a lower rate of 5%
  - These investments broadly align with ASGISA objectives
- Direct financial benefits
    - Capital investments
    - Salaries
    - Tax revenues
    - VAT
    - Procurement spend
    - R&D spend
  - Employment equity and skills development
    - Employment equity
    - Internal skills development
    - External skills development
  - Economic profit
  - Manufacturing and export
  - The product pipeline

# The sector employed 6200 individuals in 2006 and has over the last 12 months reversed the trend of decreasing employment



- Direct financial benefits
  - Capital investments
  - Salaries
  - Tax revenues
  - VAT
  - Procurement spend
  - R&D spend
- Employment equity and skills development
  - Employment equity
  - Internal skills development
  - External skills development
- Economic profit
- Manufacturing and export
- The product pipeline

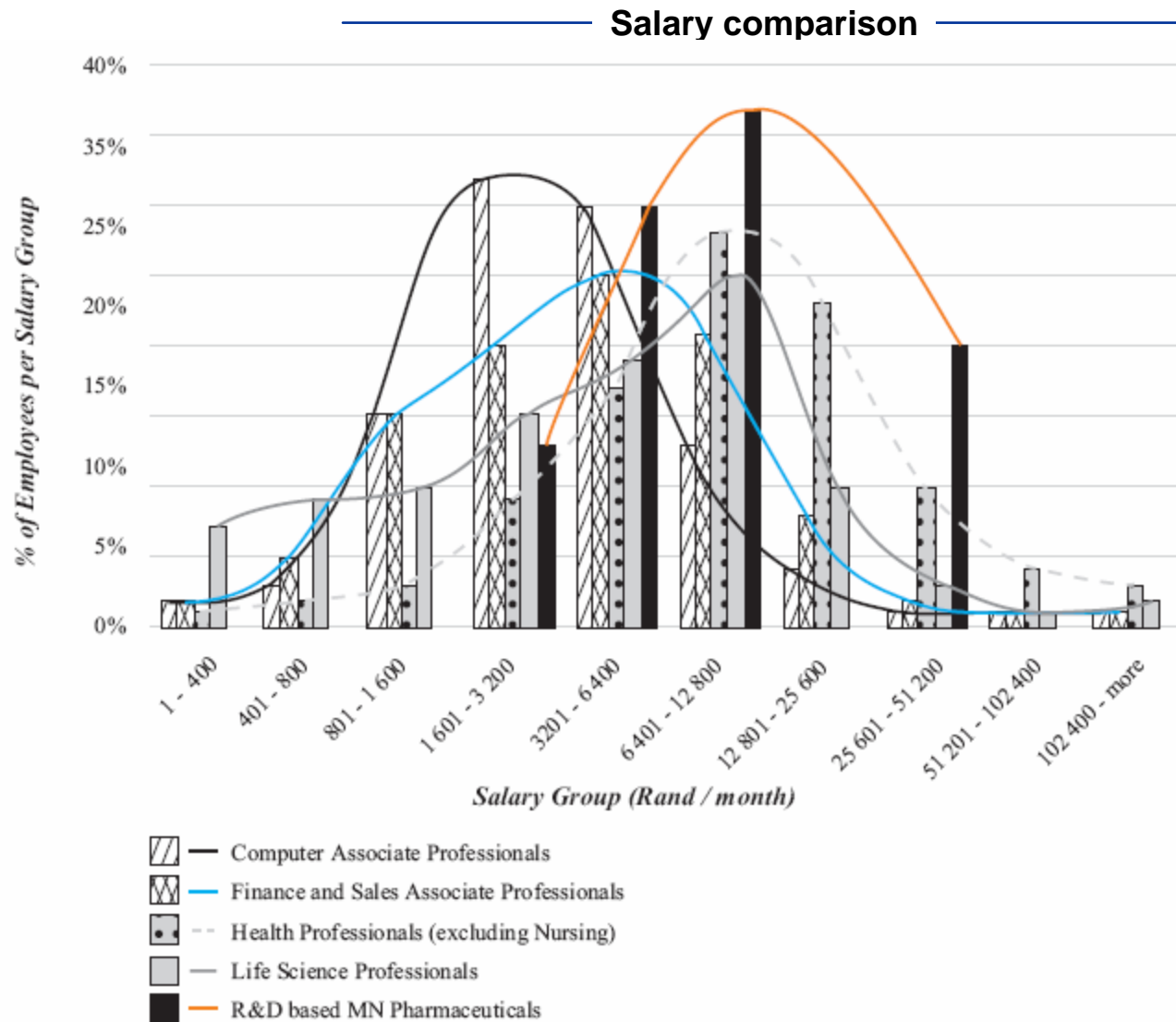
# The calculated sector multiplier of 1.79 indicated that 11 100 indirect jobs was created in 2006



***This exceeds the multiplier of sectors like information technology.***



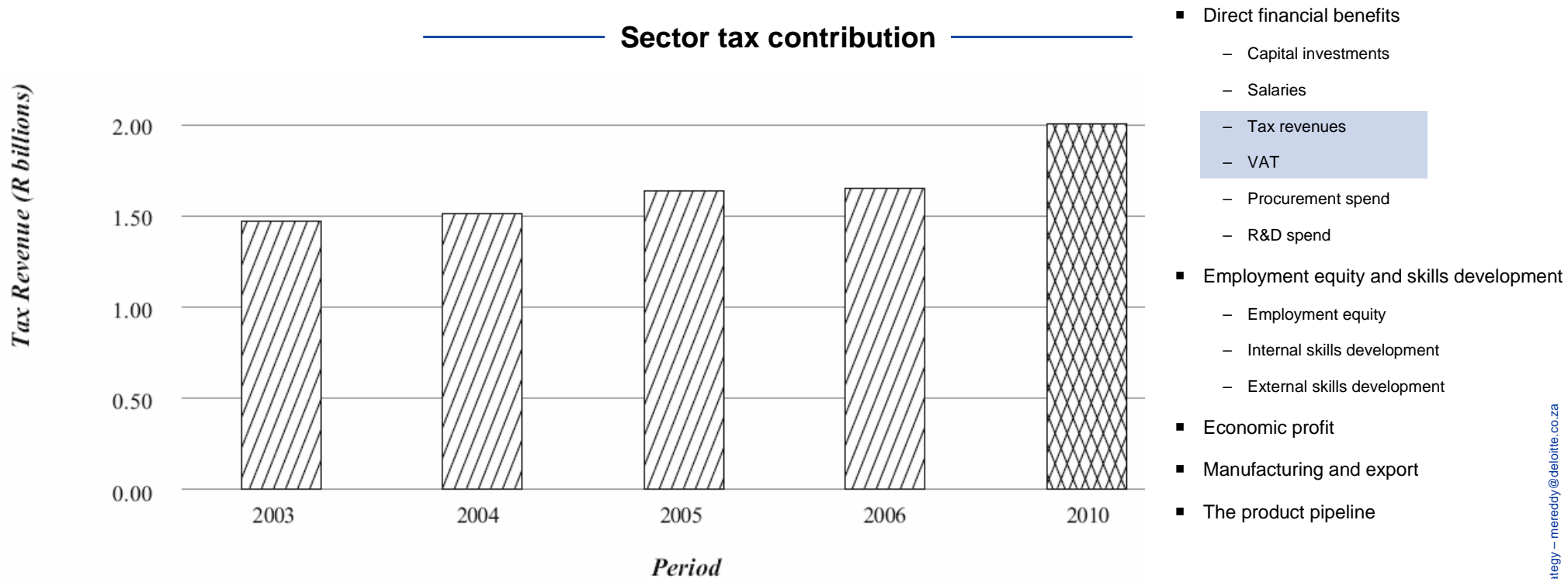
# The sector tends to employ skilled individuals and hence the average salary band exceeds that of the automobile and IT industries



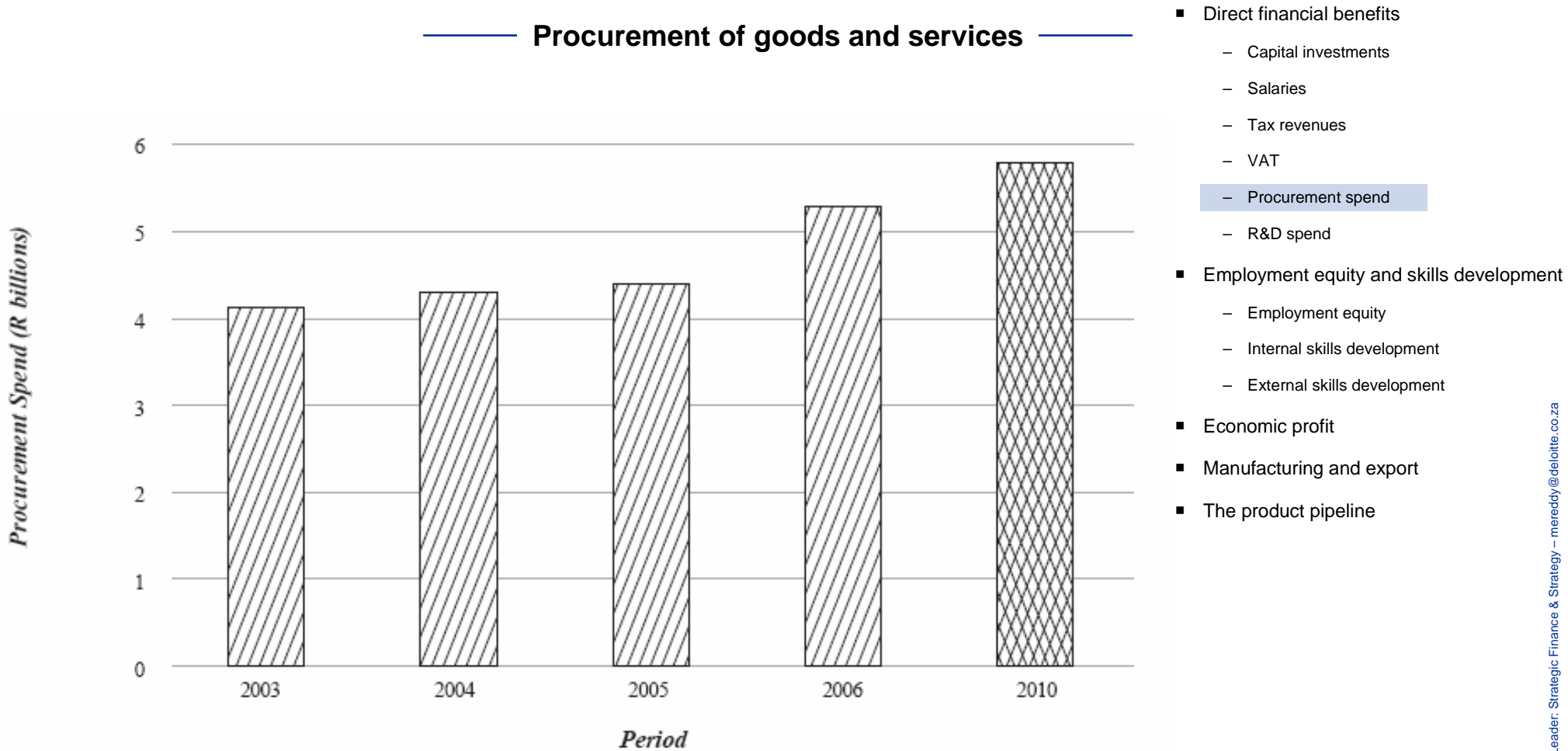
- Direct financial benefits
  - Capital investments
  - Salaries
  - Tax revenues
  - VAT
  - Procurement spend
  - R&D spend
- Employment equity and skills development
  - Employment equity
  - Internal skills development
  - External skills development
- Economic profit
- Manufacturing and export
- The product pipeline

Source: <http://www.eighty20.co.za>

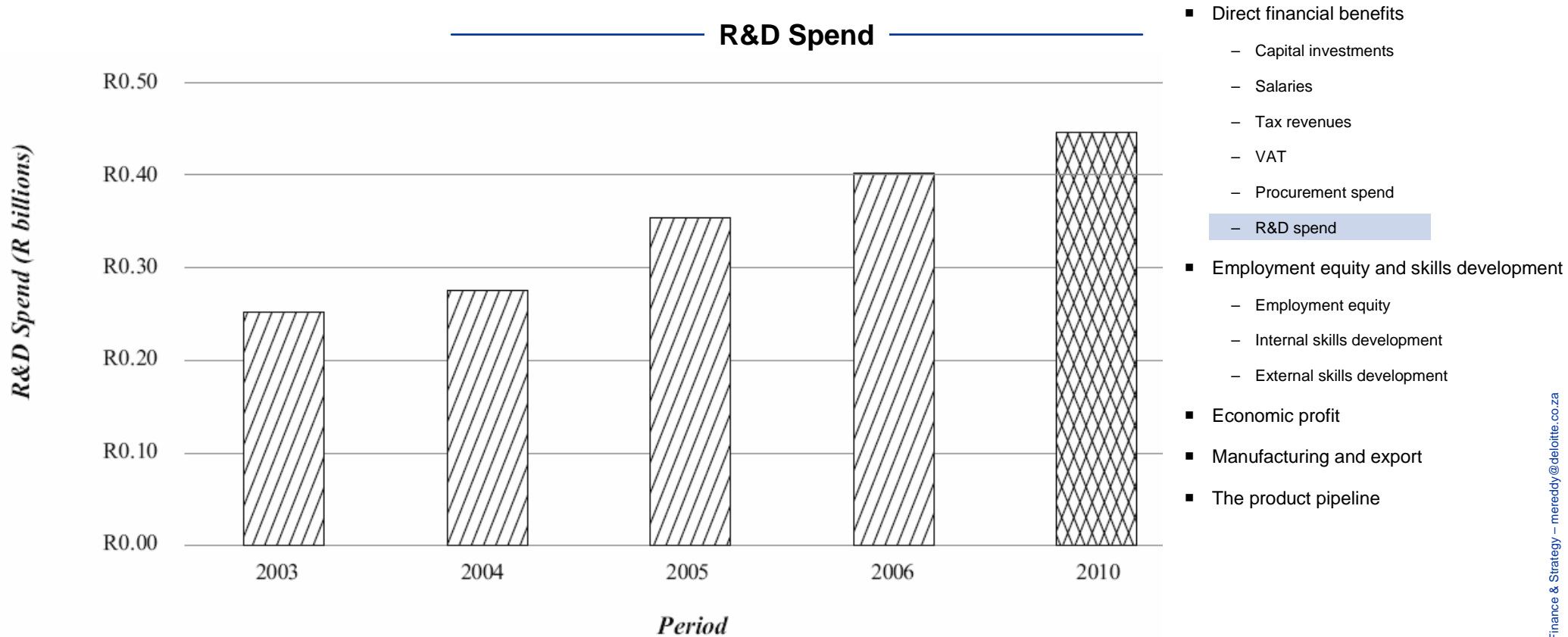
## Taxes, including VAT, were R1.6bn in 2006 and are expected to grow at a compound annual growth rate (CAGR) of 4% during the next three years



## Procurement spend was R5.3bn in 2006 and is expected to grow at a CAGR of 2.5% from 2006 to reach R5.83bn in 2010



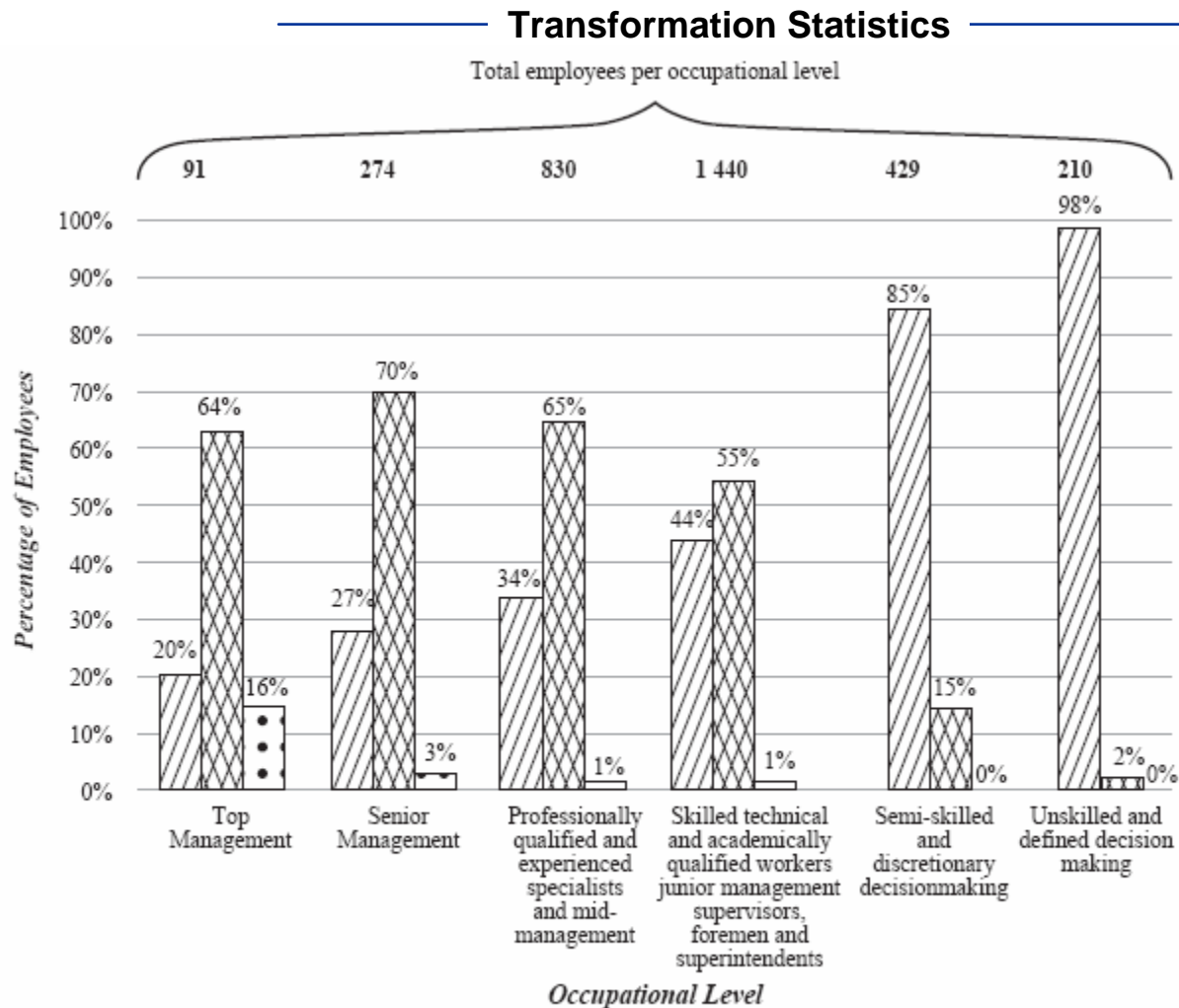
# R&D (clinical trials) spend grew 13% CAGR from 2004 to 2006 and is currently R400m



## Key Points

- R&D spend in South Africa significantly exceeds African spend
- For one participating company, the R&D spend in South Africa was second only to the whole of the South American continent

# Black professionals constitute 20% of top and 27% of senior management in the sector...

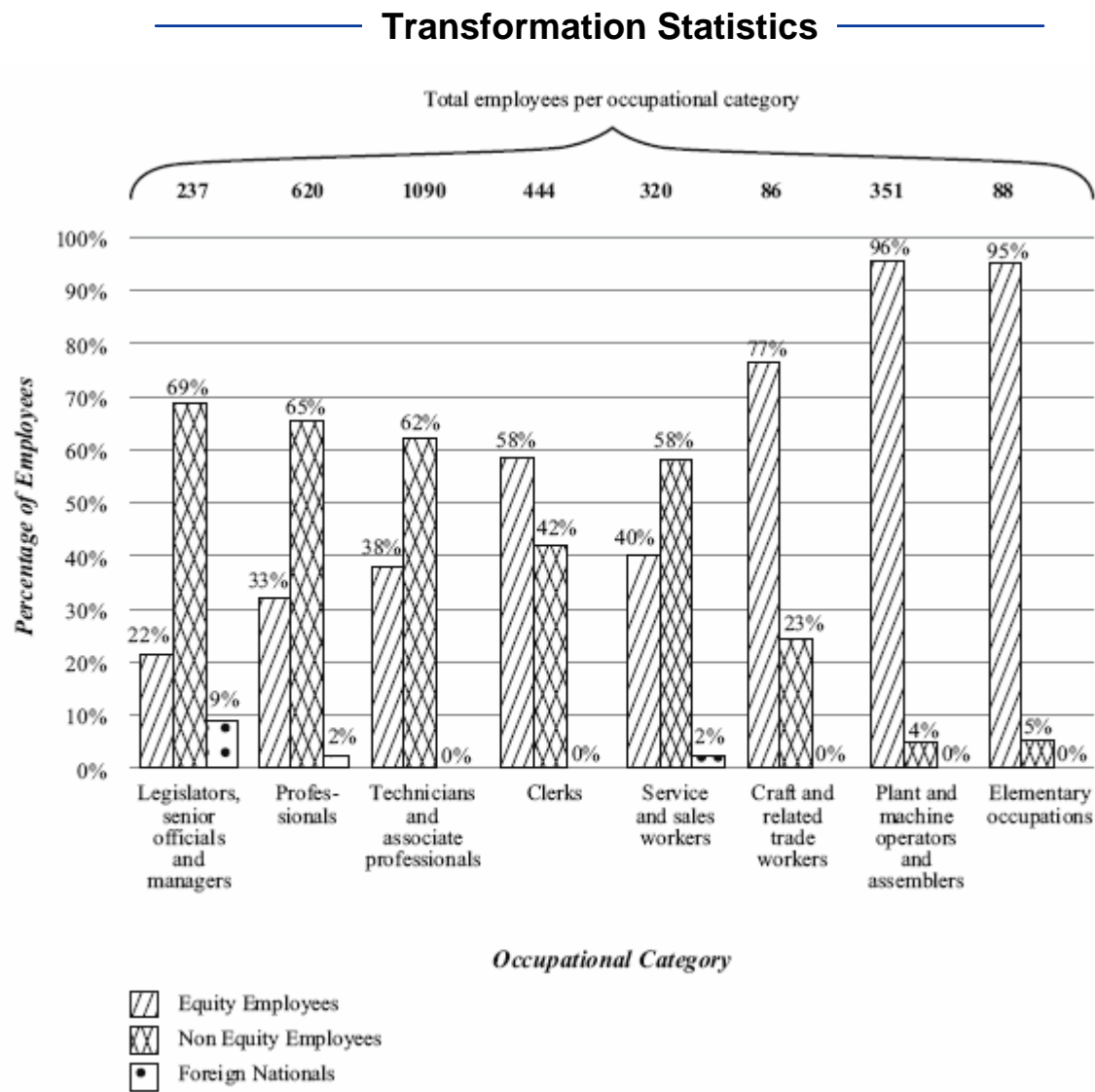


- Equity Employees
- Non Equity Employees
- Foreign Nationals

- Direct financial benefits
  - Capital investments
  - Salaries
  - Tax revenues
  - VAT
  - Procurement spend
  - R&D spend
- Employment equity and skills development
  - Employment equity
  - Internal skills development
  - External skills development
- Economic profit
- Manufacturing and export
- The product pipeline

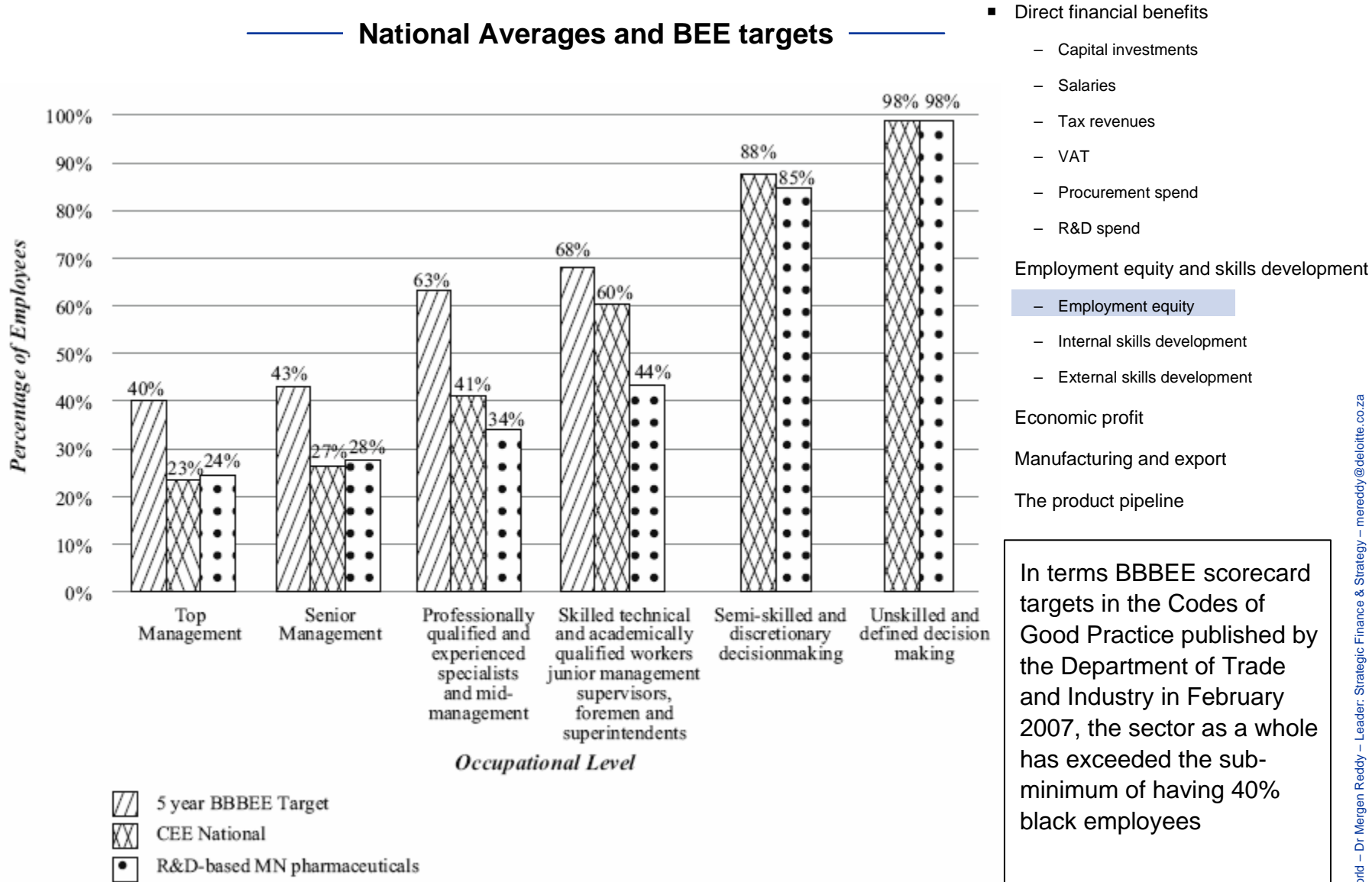
## ...as well as 22% of managers and 33% of professionals in the sector

In terms of the targets set by the BBBEE scorecard in the Codes of Good Practice published by the Department of Trade and Industry in February 2007, the sector as a whole has exceeded the sub-minimum of having 40% black employees



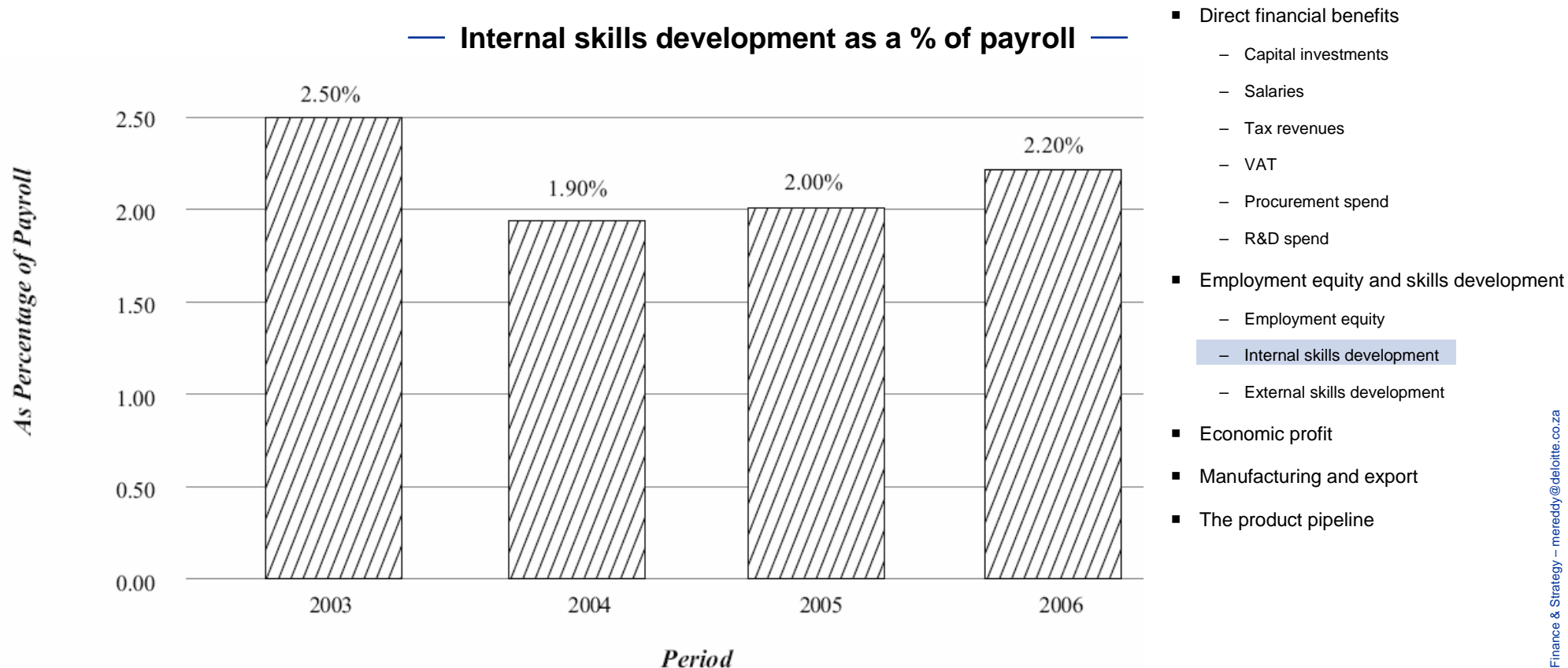
- Direct financial benefits
  - Capital investments
  - Salaries
  - Tax revenues
  - VAT
  - Procurement spend
  - R&D spend
- Employment equity and skills development
  - Employment equity
  - Internal skills development
  - External skills development
- Economic profit
- Manufacturing and export
- The product pipeline

# The sector exceeds the National equity average for the Top and Senior Management levels



In terms BBBEE scorecard targets in the Codes of Good Practice published by the Department of Trade and Industry in February 2007, the sector as a whole has exceeded the sub-minimum of having 40% black employees

## The sector spends double the statutory requirement of 1% of payroll costs on skills development and sent 2701 employees on training in 2005/06



### Key Points

- Approximately 50% (1326) of the 2701 employees were black
- Skills spend for the 2701 employees was R11.51m to the skills year ended March 2007.
- Approximately 5741 employees were scheduled for training programmes with the priority areas in the year beginning March 2007



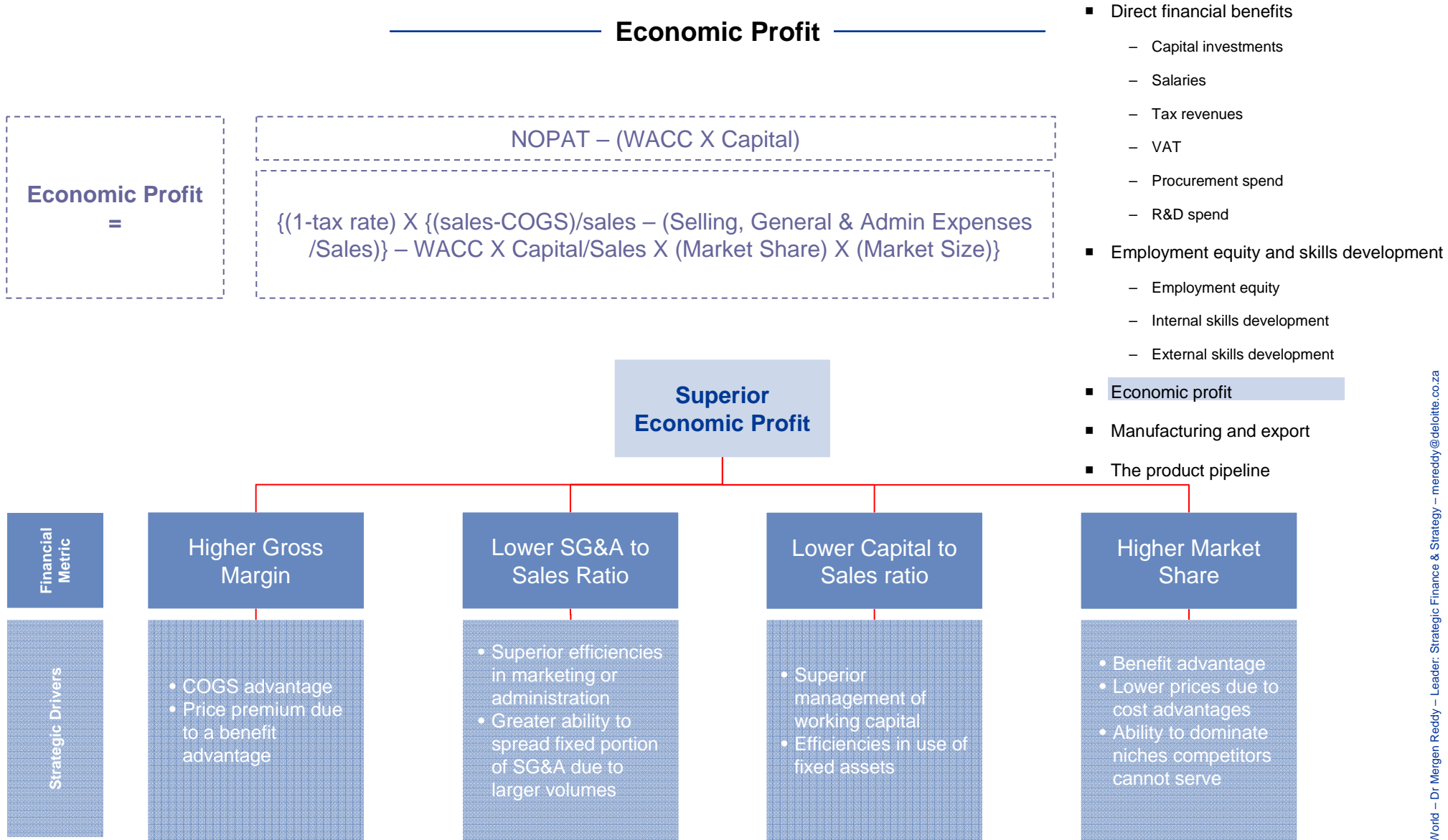
# External skills development was focused primarily on training medical professionals

---

## Key Points

- The sector spent R221m on external skills development in 2006
  - This is up from R178m, R163m and R190m in the three previous years respectively
- Direct financial benefits
    - Capital investments
    - Salaries
    - Tax revenues
    - VAT
    - Procurement spend
    - R&D spend
  - Employment equity and skills development
    - Employment equity
    - Internal skills development
    - External skills development
  - Economic profit
  - Manufacturing and export
  - The product pipeline

# Since true profit must account for the cost of capital, economic profit was used as a measure of performance rather than accounting profit



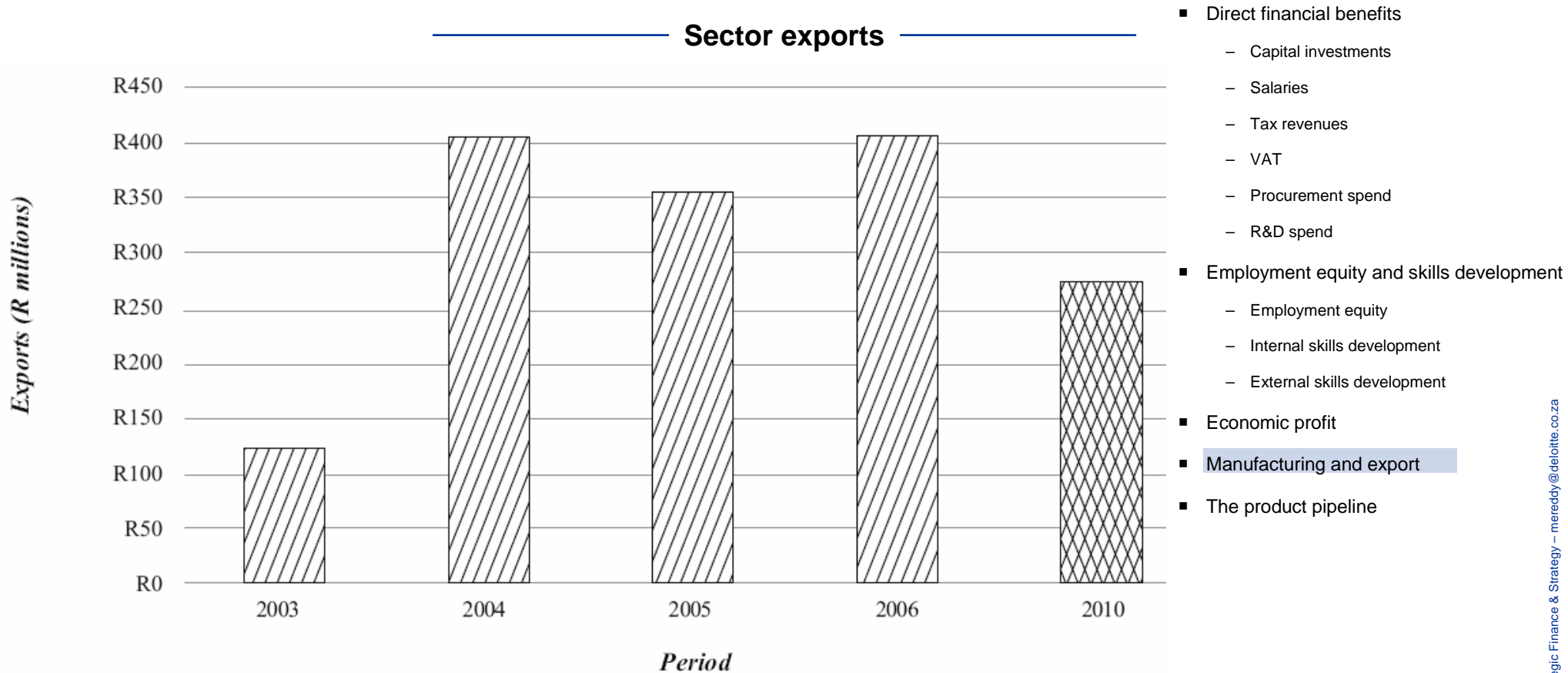
# The sector has consistently earned a positive economic profit since 2003 and is expected to continue doing so until 2010

## Key Points

- The economic profit has consistently been positive and is expected to be positive until at least 2010.
  - Declines in revenue and in one case, a doubling of overhead, led to a decline in the economic profit
  - Due to the positive economic profit, the sector has earned a profit above the cost of doing business in South Africa
  - Sectors with a positive economic profit are attractive to investors since they yield an above average market return
  - Should the sector not earn an economic profit, the participants *could* seek and/or require government support to continue operating in South Africa
- Direct financial benefits
    - Capital investments
    - Salaries
    - Tax revenues
    - VAT
    - Procurement spend
    - R&D spend
  - Employment equity and skills development
    - Employment equity
    - Internal skills development
    - External skills development
  - Economic profit
  - Manufacturing and export
  - The product pipeline

***Despite the challenges it has faced, the sector remains a positive contributor to the economy. With more assistance, it is logical to assume that this contribution could increase.***

# Despite the global consolidation of supply chains, the sectors exports have grown by 240% from 2003 to 2006



*This could continue to grow with the correct sector plan and business climate.*

## Despite the global consolidation of supply chains, the sectors exports have grown by 240% from 2003 to 2006...(cont.)

### Key Points

- Exports grew from R112m in 2003 to R414m in 2006
  - There will be a decline in exports until 2010 as more production facilities are closed
  - Six companies conducted manufacturing in 2006: Sanofi-Aventis, GSK, Roche, MSD, Jansen-Cilag and Pfizer
  - Sanofi-Aventis conducts Active Pharmaceutical Product (API) manufacturing
  - Manufacturing accounted for 1670 jobs in 2006
  - Manufacturing is refocusing on niche areas such as HIV & AIDS, malaria and TB
  - South Africa already offers generous tax breaks, R&D credits and manufacturing incentives which need to be effectively utilised. The challenge is in navigating the process to use them.
- Direct financial benefits
    - Capital investments
    - Salaries
    - Tax revenues
    - VAT
    - Procurement spend
    - R&D spend
  - Employment equity and skills development
    - Employment equity
    - Internal skills development
    - External skills development
  - Economic profit
  - Manufacturing and export
  - The product pipeline

***The industry needs to refocus on niche manufacturing to build a sustainable base which can utilise the grants available.***

# The product pipeline for innovative medicines is indicative of future generics which could enter the market

## Key Points

- In 2007, there were 153 originator medicines awaiting approval from the Medicines Control Council (MCC)
  - It is estimated that 95% of the products at the MCC approval stage will go to market
  - Research has shown that the number of generic formulations for each innovative medicine increases year on year
  - On average, two generics are introduced, in the first year of patent expiry for an innovative medicine.
  - Up to a maximum of ten generics are launched from the same patent five years after patent expiry
  - This does not include innovative drugs which are currently in the market and will soon expire
- Direct financial benefits
    - Capital investments
    - Salaries
    - Tax revenues
    - VAT
    - Procurement spend
    - R&D spend
  - Employment equity and skills development
    - Employment equity
    - Internal skills development
    - External skills development
  - Economic profit
  - Manufacturing and export
  - The product pipeline

***New drug launches are a proxy for future generics in the market.***

# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

# Technology transfer in the sector is focused on generic manufacturers and empowerment transactions

---

## Key Points

---

- Although technology transfer is a direct benefit, it is difficult to quantify the total value nor attribute it to one specific year
- Technology and skills transfer include, but are not limited to: out-licensing of rights to manufacture, rights to market and sell, as well as property sales such as manufacturing plants.
- We have distinguished between price and value when analysing these transactions



## Over 11 technology and BEE transactions took place across a broad range of areas

### Selected Activities

Company	Description of Transaction
GSK	Voluntary licensing of ARVs to the following companies: <ul style="list-style-type: none"> <li>• Aspen</li> <li>• Biotech</li> <li>• Cipla Medpro (Pty) Ltd</li> <li>• Feza Pharmaceuticals</li> <li>• Ranbaxy</li> <li>• Adcock Ingram</li> </ul>
MSD	Granted a voluntary licence to Aspen for ARVs
Janssen-Cilag	Manufacturing facility sold to Specpharm Holdings (Pty) Ltd, a BEE company
Eli Lilly	Marketing agreement with Batswadi Pharmaceuticals to the value of R67m, a BEE company who will distribute, market and promote their diabetes medicines Sale of antibiotic products to Ikhambi, a local BEE company Transfer of technology of TB medicines to Aspen to the value of R21m
Roche	Free of charge technology transfer to Aspen to enable local production of HIV medicine for Africa Technology transfer to Aspen for the production of a generic version of Oseltamivir for African countries Empowerment of Holisizwe Medical through enterprise development in the areas of health outcome research
Sanofi-Aventis	Joint venture with Litha Healthcare to form Sisonke Pharmaceuticals, a BEE company who will distribute the TB medicines
Other	Development of operational and financial capacity of small enterprises such as security services, catering services, courier services and car wash services

# A four step method was used to distinguish between the price of a transaction and its value

---

## Four step method

---

- Step 1: Determine the cost of the technology transfer transaction to the donor
- Step 2: Determine the cost of the next best alternative to the recipient
- Step 3: Determine the cost to the recipient / South Africa of developing the technology should no alternative be available
- Step 4: The future-cash-flows generated by the technology for the recipient
- Example
  - Step 1: A technology transfer for the plant to manufacture a drug costs R20m (current consumption for the drug is R8.5m and demand is at R74m)
  - Step 2: The next best alternative receiving the plant and manufacturing technology is to import the drugs from outside the country (current consumption costs R10m and total demand is at R90m)
  - Step 3: Should South Africa choose to develop the technology itself, the total cost is approximately R702m
  - Step 4: Future cash-flows from the plant is approximately R740m generated over a 10 year period.
  - Therefore, while the transfer may cost the donor R20m, the value to the recipient and country in terms of security of supply, and savings on technology development far exceed the R20m donation

## The sector has engaged in some meaningful technology and empowerment deals

### BEE Joint Venture

- In 2006, Sanofi-Aventis announced its joint venture with Litha Healthcare Investments (Pty) Ltd, a 100% Black-owned Company. The new company, Sisonke Pharmaceuticals (Pty) Ltd, is dedicated solely to the supply and distribution of TB medicines to the public sector.
- The company only engages in sales and marketing, but also has a robust support operation in place to assist the Department of Health's TB Control and Management programmes in all provinces.
- The medicines promoted are used in the fight against tuberculosis, a major disease burden in South Africa, and were largely researched and developed in South Africa. They are manufactured at the Sanofi-Aventis production facility in Waltloo, Pretoria, and nearly all of the directors and staff – including production staff - are South African.
- Sisonke Pharmaceuticals is based at the Sanofi-Aventis head office in Midrand. It is expected to be a major player in the TB arena, not only in South Africa but also in Lesotho and Swaziland.

### Sale of manufacturing facilities

- Janssen-Cilag sold its Midrand manufacturing facility Specpharm Holdings (Pty) Ltd, to a BEE Company. In addition to the change of ownership, the transaction includes the signing of a five-year manufacturing contract with the new owners to ensure product continuation.
- Janssen-Cilag invested substantially in upgrading the Midrand facility in 2006. The company's factory, which employs 85 staff, produces mainly Janssen-Cilag products including over-the-counter medication, liquids, creams and animal health solutions. The balance of production is for other pharmaceutical companies.
- For Specpharm the opportunity exists to leverage off the current activities and through a combination of its own pipeline and additional third party work grow the business and secure the future of the operation.

## The sector has engaged in some meaningful technology and empowerment deals...(cont.)

---

### Diabetes care partnership

- Batswadi Pharmaceuticals, a black empowered pharmaceutical group and Eli Lilly and Company (Lilly) concluded a diabetes related business sale.
- This sale of business agreement will facilitate the supply of insulin products to Batswadi who will distribute, market and promote the products into both the public and private health sectors of South Africa.
- This is a ten year renewable partnership, which will include the transfer of 18 Lilly employees to Batswadi Pharmaceuticals, transferring skills and a total of 114 years experience in diabetes care and pharmaceutical sales and distribution.

# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

## Seven broad groups of CSI activities were analysed in this study...

### CSI Activities

- **Provision of medicines:** Medicines supplied to government and organisations at no or minimal costs, supply of medicines during crises or outbreaks and all programs that make medicines and healthcare accessible.
- **Primary healthcare:** Bringing basic healthcare to the most vulnerable individuals living in rural areas, improvements in the delivery of care to patients and the provision of back-up support to healthcare workers and institutions.
- **Social development:** The development of communities through basic education, supporting people affected by disease and their families. Partnerships with government to bring development into communities and basic infrastructure provision like sanitation and water.

### CSI Activities

- **Enterprise development:** The development of local businesses, including assistance with starting and sustaining the business.
- **Educational support:** Medical and related health bursaries, bursaries for equity students. Supporting educational institutions with donations, equipment, upgrading infrastructure and sponsoring awards in the healthcare faculties.
- **Burden of disease:** Training and financial support of programs that address communicable diseases (HIV and AIDS, TB, and Malaria) and lifestyle and non-communicable diseases (diabetes, depression and cancer).
- **Training:** Training and development of healthcare workers and communities. The training is rendered in conjunction with government departments, local and international organisations.

## ...and most participating companies engaged in activities across all seven CSI groups

Selection of CSI Activities	# Participating companies
<ul style="list-style-type: none"><li>■ Provision of medicines<ul style="list-style-type: none"><li>– Public private partnerships to provide access to innovative medicines</li><li>– Partnerships with NGO's to provide access to medicines and treatment</li></ul></li></ul>	10
<ul style="list-style-type: none"><li>■ Primary healthcare<ul style="list-style-type: none"><li>– Contributions to facilitate improvements in the delivery of care to patients in community hospitals, providing back-up and support for primary healthcare initiatives</li></ul></li></ul>	10
<ul style="list-style-type: none"><li>■ Social development<ul style="list-style-type: none"><li>– Supporting SOS children's homes</li><li>– Immunisation projects</li><li>– Building of clinics and healthcare infrastructure</li></ul></li></ul>	8
<ul style="list-style-type: none"><li>■ Enterprise development<ul style="list-style-type: none"><li>– Assisted in the creation of a black-owned security- and a courier firm</li><li>– Assisting development of operational &amp; financial capacity of small enterprises, for example cafeteria &amp; carwash facilities</li></ul></li></ul>	2

## ...and most participating companies engaged in activities across all seven CSI groups...(cont.)

### Selection of CSI Activities

# Participating companies

#### ■ Education & educational infrastructure

10

- Vehicle provided to Rhodes University to transport students to previously disadvantaged communities for training in the use of pharmaceutical products and compliance
- Opportunity for 20 final year SA Chemistry students to spend a week at a research site in the UK
- 4 Equity individuals received a scholarship to study an international MBA
- Dinner and award to Pharmacy Student of the year
- Medical bursaries for medicine and allied medical professions for equity students (MESAB & Manto Tshabalala Msimang Bursary Fund)
- Computer and book donations
- Book donations of international standard manuals

#### ■ Burden of disease

8

- TB FREE supports Department of Health's National TB Control Programme (NTCP) by Training Health TB Patient supporters and Implementing TB Mobilization and awareness initiatives
- HIV projects in partnership with NGO's and different clinics
- Contribution to facilitate studies into depression related to pregnancy
- Annual grant given to Diabetes Association
- Trained nurses on Diabetes care and management



## ...and most participating companies engaged in activities across all seven CSI groups...(cont.)

### Selection of CSI Activities

# Participating companies

8

#### ■ Training

- Providing on the job training for equity candidates busy with health related studies
- HIV home based care training
- Training to healthcare workers with regards to diabetes, cancer, etc.

## Many of the CSI benefits cannot be quantified and are best described to outline their indirect qualitative effects

### Burden of Disease

- The programmes offer medicines free or at a very low cost for the reduction, and ultimately the total eradication, of prevalent diseases in South Africa
- The disease targeted; malaria, HIV & AIDS and TB, are all focus areas of the Department of Health
- The savings on the donated medicines for these diseases are estimated at R1.4bn

### Educating learners

- Several companies offer equity candidates bursaries and scholarships
- One such example is the Novo Nordisk MBA Scholarship
- The impact of these are significant since students in the medical and pharmaceutical fields have limited alternative funding sources

### Innovative Healthcare Access

- The Phelophepa healthcare train makes proper health facilities available to rural communities at no cost
- The train travel around rural communities and offers basic healthcare
- The facilities offered by the train help overcome healthcare infra-structure gaps due to limited electricity, roads and water supply

### Enterprise Development

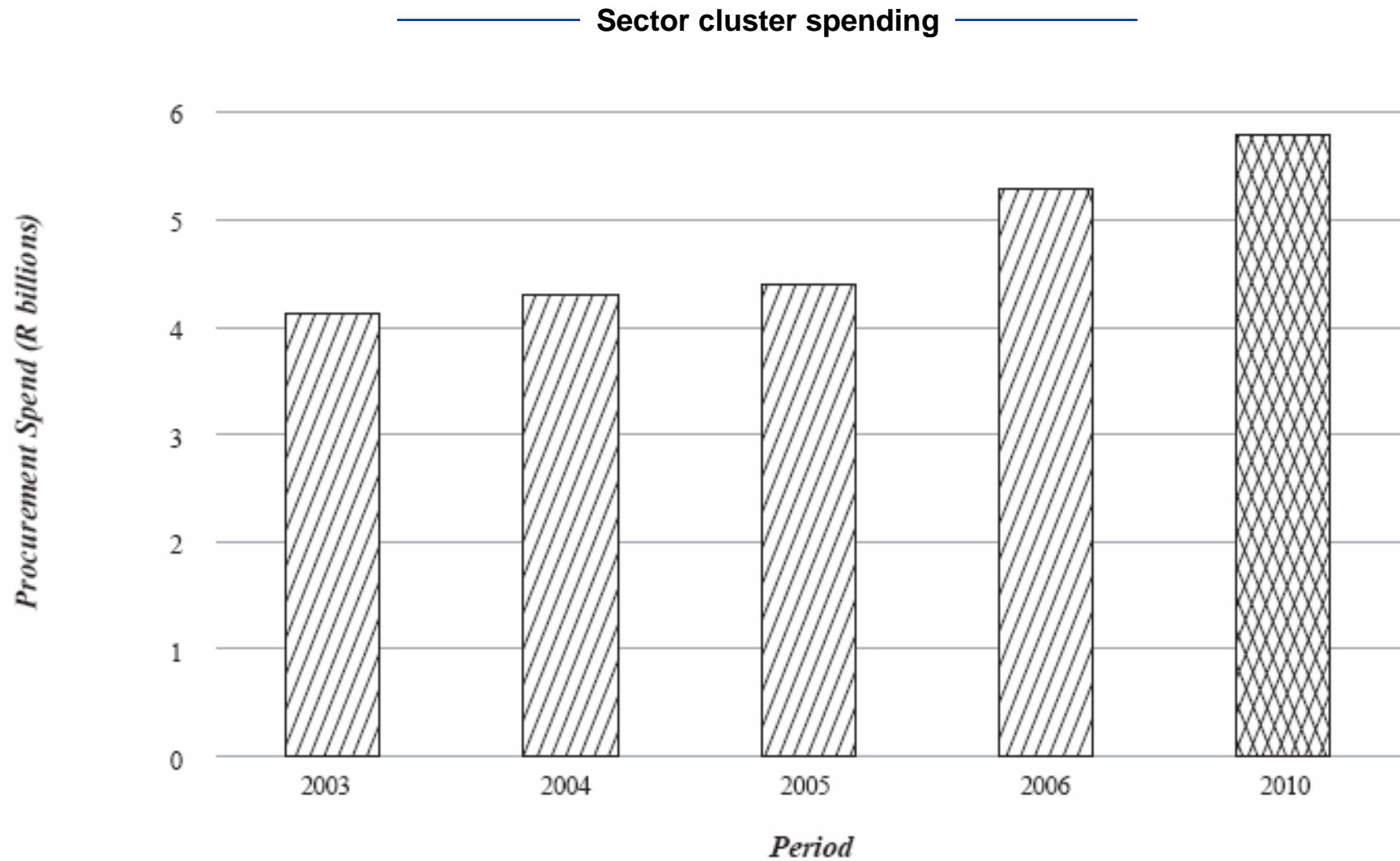
- Novartis spun off its cafeteria business by creating a new company, Thokozela Food Enterprises CC, which was staffed by employees in the cafeteria
- The company survived due to a contract with Novartis and now serves six other companies while growing its staff complement from seven to eleven
- MSD used the same approach to create a security and courier business

# Contents

---

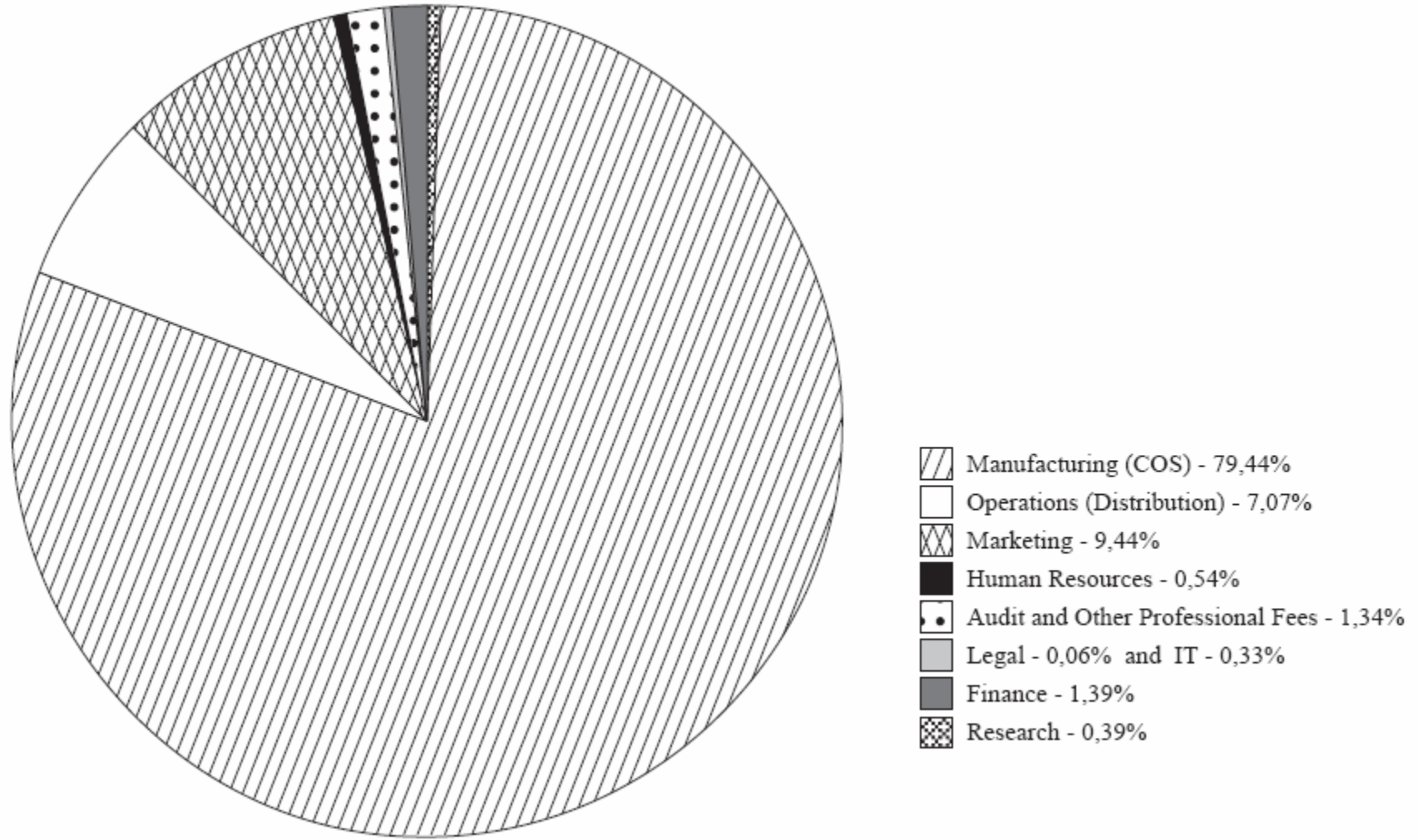
	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

## Spending in the cluster equalled R5,3bn in 2006...



## ...with the majority of expenditure in the manufacturing part of the value chain

Breakdown of cluster spending

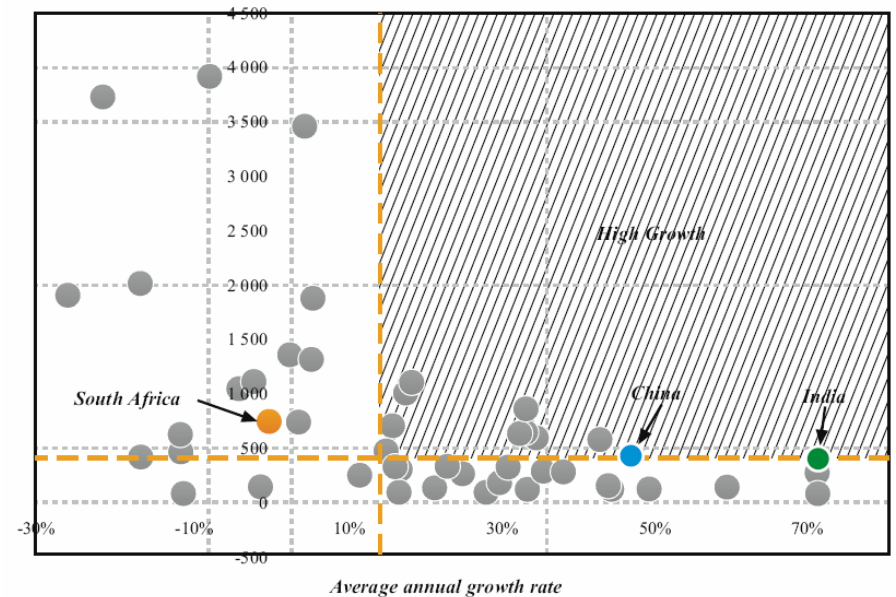


# Clinical research organisations have played a strong role in developing the cluster around the R&D part of the value chain

## R&D of a molecule

- In response to the need for specialised skills and competency to drive clinical trials in South Africa, a number of CRO's (clinical research organisations) have established a presence in South Africa.
- CRO's are one part of the cluster which services the needs of R&D-based MN pharmaceutical companies.
- One such CRO alone was managing approximately 300 medical sites, involving 7100 randomized subjects and an estimated 1000 site staff in 2006.
- In 2006, data from just five of the participating companies showed that;
  - 553 sites were managed in South Africa,
  - 5777 patients went through these sites,
  - Approximately 630 investigators were engaged in managing these trials
  - At a cost of R297m
  - One company alone outsourced R50m worth of work

## Changes in Clinical Trials



- The figure above indicates that while South Africa is a key location for clinical trials it is declining relative to China or India as a favoured location.
- While CRO's have also embraced the business requirements of the country. Quintiles Transnational Corporation, to provide one example, engaged in a direct equity BEE deal and transferred 30% of its share to Thebe Healthcare.

Source: Fabio A. Thiers, M.D., 'The Globalisation of Clinical Drug Development'. MIT Center for Biomedical Innovation, 2006.

# Specialist packaging companies have benefited by providing niche production capabilities

## Research to patient ready medicine

- The manufacturing standards in South Africa are on par with best global practices and apply equally to manufacturers and suppliers. This implies that only suppliers with high GCP ratings that are able to demonstrate compliance with these standards can be used.
- As a result, specialised companies have grown up around the pharmaceutical industry. The largest spend locally in the manufacturing process goes to the purchase of both locally supplied materials and imports. These are mainly packing materials, active ingredients and ingredients obtained from local vendors.
- An important aspect of manufacturing is that of quality assurance. Local manufacturing plants tend to have their own laboratories for quality control that are supplied with chemicals and equipment on an ongoing basis. Pharmaceutical companies that do not have their own manufacturing facilities, similarly have to monitor the quality of their products, as a regulatory requirement set by the MCC and this is generally done through contract laboratories, thereby adding to the cluster effect.

## Consul Example

- Consul Plastics (Pty) Ltd is an example of a company able to make selected capital investments due to supply agreements with MSD.
- In 2006 Consul invested about R4m in equipment for injection blow moulded bottles to produce approximately four million container bottles.
- The company made this investment to upgrade their quality of bottles due to an exclusive supplier agreement with MSD and a view to future growth. MSD had previously imported the bottles.
- By buying locally, MSD was capturing a saving of 60 cents per bottle. The bottle is used to store the ARV, Stocrin, which is sold at a not-for-profit price.
- Given the success of the programme, Bayer and Roche are also involved in similar agreements with Consul, and company has developed a dedicated manufacturing site in Durban.

## One company was profiled in Kwa-Zulu Natal to outline the cluster of companies involved in the delivery of medicines at the point of consumption

---

### Kwa Zulu Natal Case Example

- NFM is a Durban based sales and field marketing agency. It manages the sales activity for companies like Roche Pharmaceuticals
- The company's entire field force is black and 1/3 of the management is black
- The company shares its offices with representatives from the participating group of companies, for whom NFM sells and manages the in-store supply of products
- Through the link with the sector, the employees of NFM receive training and skills transfer in marketing, sales, presentation skills and leadership training. This is a significant advantage for the sales representatives and marketers who in some cases may not have university degrees or high school certificates



# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

## In reviewing the environmental context care was taken to use the appropriate comparisons and draw the relevant conclusions

### Context for regulations

- Regulations exist to support/enable/strengthen a predefined sector/industry policy
- Therefore policies and regulation are implemented to encourage or discourage certain types of behaviour
- The enabling elements must be critiqued in the context of a to be determined sector policy
  - Pricing, reimbursement and access
  - Regulatory approval process
  - Intellectual property rights
  - R&D investment incentives
  - Skills availability
- Therefore the industrial policy for this sector must be agreed before the response to the five major policy areas can be agreed
- **The discussion which follows does not aim to recommend any one response. Rather it is a outline that the gap does exist and a decision needs to be made**

### Sector Policy

- The R&D-based MN pharmaceutical sector could grow in one of three ways:
  - **1 - All companies stay in South Africa yet there is limited or no R&D and manufacturing.** The companies maintain a significant sales force and drive the market growth by gaining new markets, maintaining existing markets and growing access in general
  - **2- South Africa becomes a favoured investment destination for R&D and manufacturing.** The domestic market continues to grow, yet the country is seen a key location for R&D, manufacturing and centres of excellence (COE)
  - **3 – This is the hybrid model** where the country focuses on driving sales and access while positioning itself as a R&D, manufacturing and CEO in niche diseases such as malaria, TB and HIV & AIDS
- **Only once option 1,2 or 3 is decided upon can the proper response to each of the policy areas be agreed**

## Depending on the growth plan selected for the sector, different emphasis needs to be placed on each of the policy areas

---

### Context for regulations

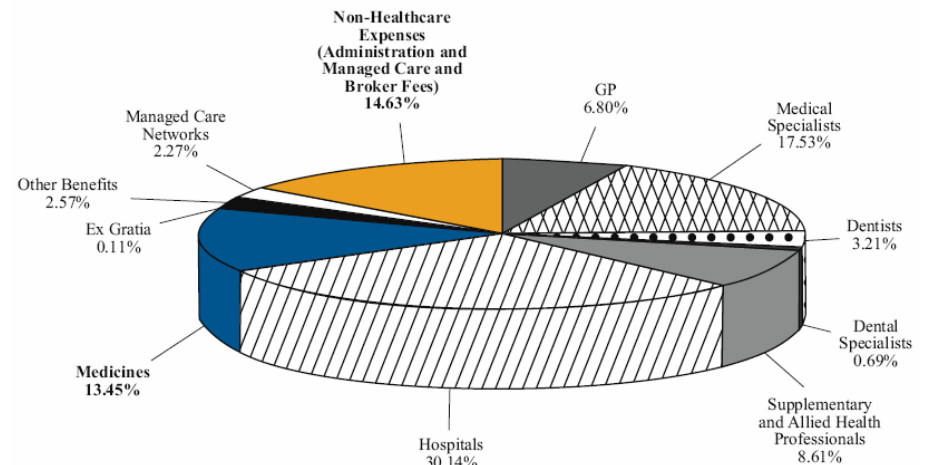
- 1 - All companies stay in South Africa yet there is **limited or no R&D and manufacturing**. The companies maintain a significant sales force and drive the market growth by gaining new markets, maintaining existing markets and growing access in general
  - Pricing, reimbursement and access (PRA)
  - Regulatory approval process (RAP)
- 2 – South Africa becomes a **favoured investment destination for R&D and manufacturing**. The domestic market continues to grow, yet the country is seen as a key location for R&D, manufacturing and centres of excellence (COE)
  - Intellectual Property Rights (IPR)
  - R&D Investment Incentives
  - Skills Availability
- 3 – This is the hybrid model where the country focuses on driving sales and access while positioning itself as a R&D, manufacturing and CEO in niche diseases such as malaria, TB and HIV & AIDS

# Medicines prices are no longer the key driver of healthcare costs in the private sector and should not be the only focus area to increase access

## Context for regulations

- Medicine prices are generally a key element in the healthcare system and any decrease in the costs has a large impact on the overall costs of provision and downstream healthcare costs, such as hospitalisation.
- Where medicine prices are very high, any decrease in prices will have a significant impact of the total costs of the healthcare system.
- **However, as the cost of medicines decreases, a point is reached where medicines are no longer one of the largest costs and any further decrease in medicine costs will not have a significant impact on the total healthcare costs.**
- In other words, the cost of the total healthcare system is now only slightly sensitive to medicine prices. When this happens, in order to maximise benefits to patients, government must focus on the cost components to which the healthcare system is most sensitive. When this point is actually reached is debatable, yet based on the data, it is fair to say that South Africa may have reached this point.

## Breakdown of total medical system costs



- Medicines make up only 13.45% of the overall healthcare costs in the private sector
- Due to the limited reduction in volume, the decrease in costs have been driven by a unit price reduction

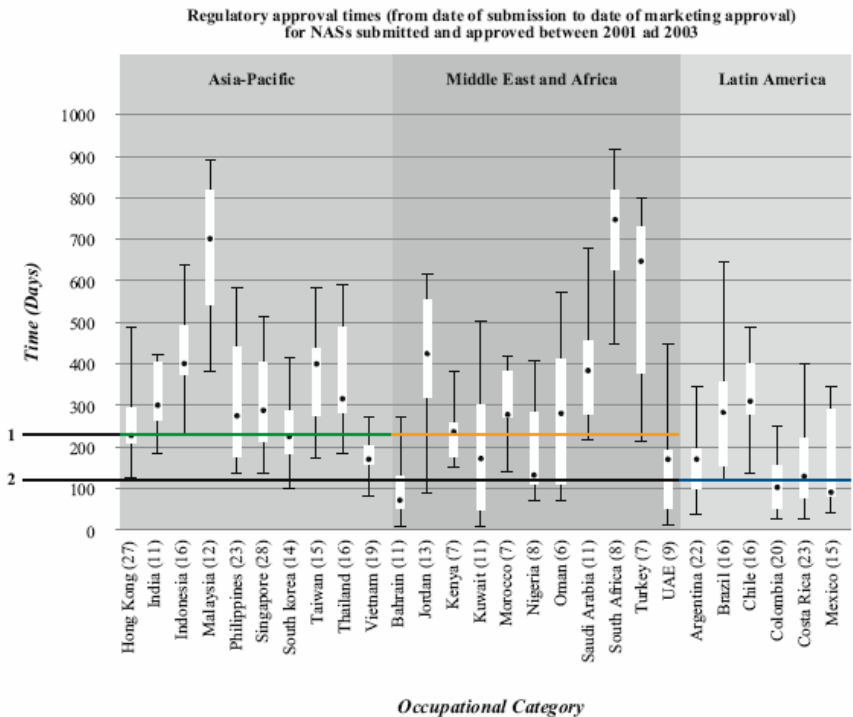
Source: Adapted data sourced from Council for Medical Schemes Annual Report 2005-2006

# Although acknowledged and acted upon by government, the approval time for new medicines still takes longer when compared to international benchmarks

## Recommendations to the Ministerial Task Team

- Risk-based system for assessment of dossiers based on decisions from benchmarked authorities
- Shift focus from assessment to compliance
- A single authority with transparent processes
- Adoption of International Conference on Harmonisation (ICH) standards
- Code of marketing practice should govern and ensure an ethical approach to the marketing of all medicines in South Africa.
- Effective communication between the industry and authority
- Provision should be made in the Medicines Act for data protection that will allow for the protection of submitted data
- Improve the clinical research approval processes as they are slow and is a deterrent to companies planning to do research in the country.
- Pharmaco-economic evaluation should remain independent of the medicines approval process.

## Comparison of regulatory approval times



1. Regional median approval times for Asia-Pacific: 282 days, and ME Africa: 283 days  
 2. Regional median approval times for Latin America: 175 days

Source: CMR International Institute for Regulatory Science, 2006. A cross-regional comparison of the regulatory environment in emerging markets

# Irrespective of the sector growth plan, IPR must be a key focus area to grow the sector and make the country competitive

## Reward for Innovation

- IPR is one primary mechanism to reward the significant investment in the sector
- IPR protection for medicines is 20 years yet is reduced due to registration processes and the need to register the patent prior to clinical trials, in order to ensure effective legal protection.
- The public benefits from this process since the MN pharmaceuticals produce new medicines and the generics which enter the market lower the price

## Bolar Provision

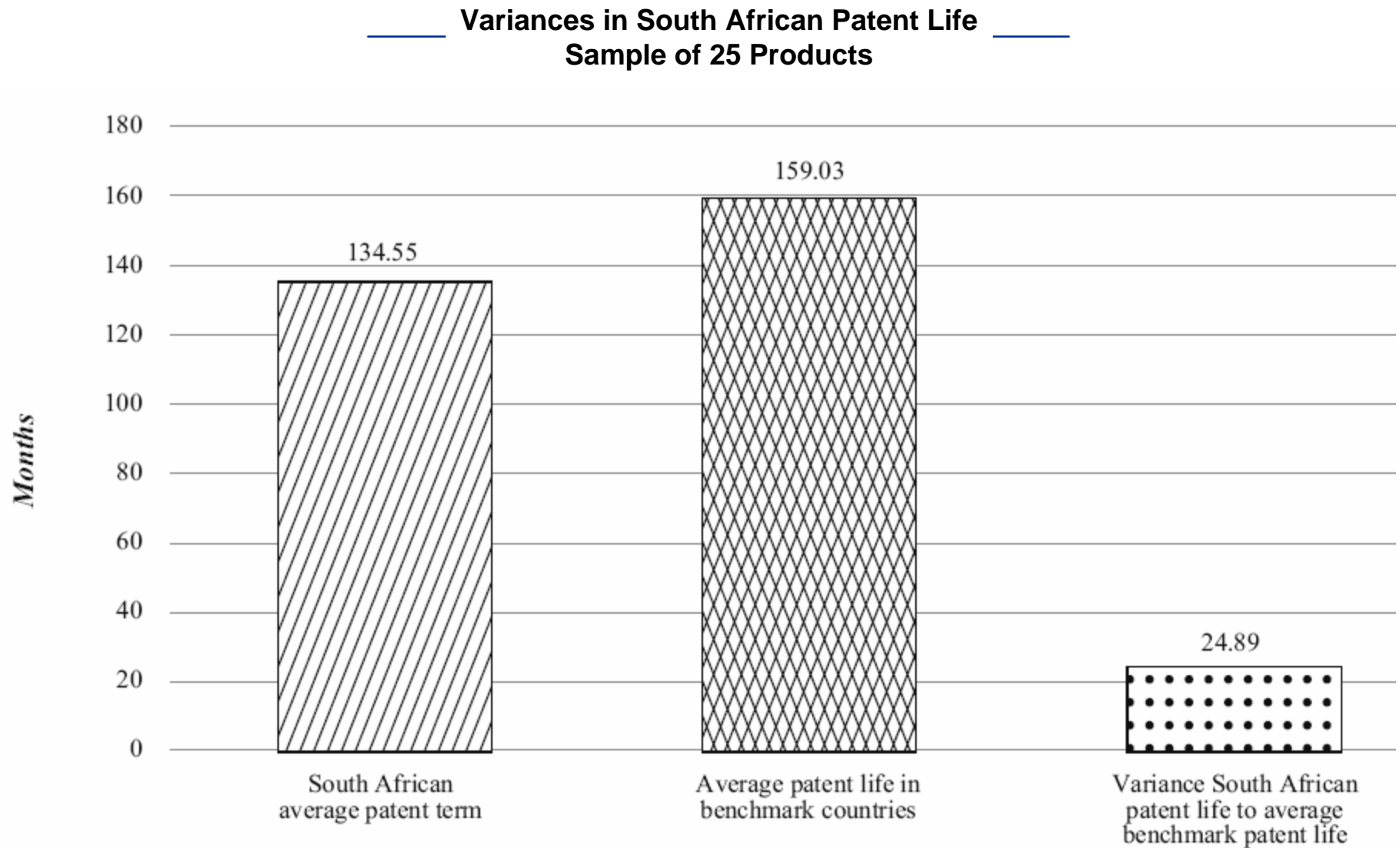
- The 'Bolar' provision in some countries and in South Africa in particular allows early working on a patented substance. It also allows generic companies to perfect their manufacturing processes and to prepare and submit registration dossiers during the product's patent life. However, in most countries this commercial advantage to generic companies is counterbalanced by the existence of effective data protection for a period of at least five years, as the minimum period of protection.

Source: [http://www.ifpma.org/documents/NR2799/DataExclusivity\\_2005.pdf](http://www.ifpma.org/documents/NR2799/DataExclusivity_2005.pdf). Based on information collected by IFPMA and updated in January 2005

## Patent Life and Patent Term Restoration

- South Africa has a 20-year patent law but two important issues hinder investment.
- The first is that effective patent life for products is shorter in South Africa because of the registration processes. A study of some 25 top products in South Africa has shown that investors in South Africa have over 2 years less to recoup investment costs, when, for example compared to countries proposed in the pricing benchmarking model
- South Africa, unlike most other countries, does not have a mechanism to add back patent life to a pharmaceutical product due to delays in the registration process.

## Investors in South Africa have over 2 years less to recoup investment costs as compared to other countries in the benchmark group



Grant Thornton April 2007 Pharmaceutical Product Patent Life Benchmarking Report

## South Africa has a comprehensive set of grants for R&D and manufacturing

### Ireland & Puerto Rico

- Ireland
  - **A highly competitive corporate tax rate of 12.5%** is a major incentive as is the fact that no tax is paid on earnings from intellectual property where the underlying R&D work was carried out in Ireland.
  - Ireland also recently introduced a new R&D Tax Credit, designed to encourage companies to undertake new and/or additional R&D activity in Ireland.
- Puerto Rico
  - income and property tax reductions for a period of up to 25 years.
  - Additional deductions available to corporations located in areas of high unemployment and to companies committed to growth and employee development.
  - Companies relocating to or expanding their operations in Puerto Rico benefit from a **7% maximum income tax rate, with some companies paying as little as 2%**. There is no tax on dividend distributions and a super-deduction of up to 200% for R&D expenses and job training costs.

### South Africa

- R&D benefits include (this excludes the generous export assistance and other general programmes):
  - The Technology for Human Resources Industry Programme (THRIP) will contribute between 30% and 50% of the funds invested by a company in research projects. University students conduct research projects funded partly by THRIP and funded by the company.
  - The Innovation Fund provides funding through the Technology advancement programme, the Missions in Technology Programme, the Seed Fund, and Patent incentive fund. It provides a maximum grant R15 million over a three year period. It is applicable to collaborative projects which undertake R&D in all economic sectors.
  - The Technology Transfer Fund (TTF) funds defined components of the process of transferring available technology to entrepreneurs, communities and existing businesses. The benefit is a grant for the 2nd economy with no payback, and matching funding for the transitional and 1st economies with payback based on a percentage of turnover. The maximum funding is R500 000 per project.



## Although recognized by the South African government, skills availability is still a growing problem

### Skills Availability

- South Africa has a fast growing economy with a demand for specialised non-medical skills in the financial services, construction and other sectors
- The challenge is to retain healthcare skills when individuals want to either emigrate or work outside the sector
- The availability of skills is a strong reason for both pharmaceutical companies as well as for the clinical research organisations (CROs) to establish themselves in a country, as was seen in India, where over a dozen well-known CROs such as Quintiles, ClinTec, Pharmanet, PPD etc. established themselves in the country.
- This establishment was due not only to the local knowledge and experience but also to the availability of the abundant talent within the pharmaceutical and IT industries to allow rapid start-up and sustain high quality of clinical and data operations. The confirmation of this talent was also evidenced by the EIU ranking of India as being only second to the US (8.4) with a score of 7.78 for labour skills and availability.
- South Africa has already identified the urgency of addressing the skills shortage in the country. The programmes such as ACCELERATED AND SHARED GROWTH-SOUTH AFRICA (ASGISA) and Joint Initiative for Priority Skills Acquisition (JIPSA) which government have initiated are steps in the right direction to ensure that this gap is filled, however as suggested this needs to be a national initiative with strong sector participation rather than a government programme.
- Skills availability is therefore a growing problem, although recognized by the South African government

# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

# The economic model aimed to understand changes to key variables within South Africa's existing regulatory environment

## Key considerations

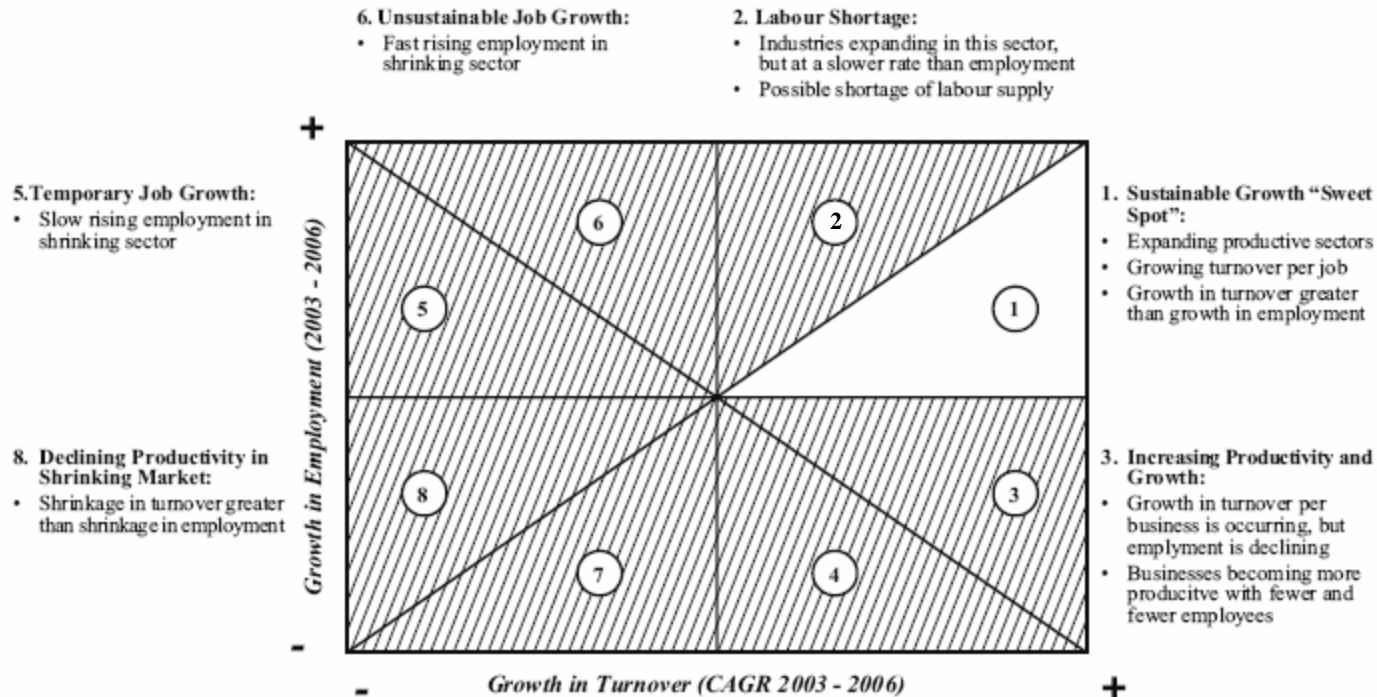
- **It is impossible to model and compare the regulatory environment of another country**
- The model used is robust in that it simply compare changes in the key variables within South Africa's regulatory environment
- **Within South Africa, the model cannot simulate drastic changes in regulatory policy. Why? This is because the model simulates changes by using past data relationships. Drastic changes to the regulatory policy may render these relationships irrelevant**
- The model has been tested by setting the variables to the conditions in 2006 and comparing the model output with actual data

## Questions tested

- How does the R&D-based MNC pharmaceutical sector compare with other industries and sectors?
- What is the expected position of the sector if it were to continue "as is"?
- What would happen to the sector if key variables changed?
  - Scenario 1: Increasing inflation by 1%, 3%, 5%, 6% and 7% without a corresponding increase in the price of medicines.
  - Scenario 2: Decreasing the price of medicines by 1%, 3%, 7% and 9%.
  - Scenario 3: Extending the patent life by 1,2,3,4 and 5 years.
  - Scenario 4: Increasing the sales volume by 1%, 3%, 5%, 7% and 9%

# Sector performance relative to peers was compared along the dimensions of growth in employment and growth in turnover

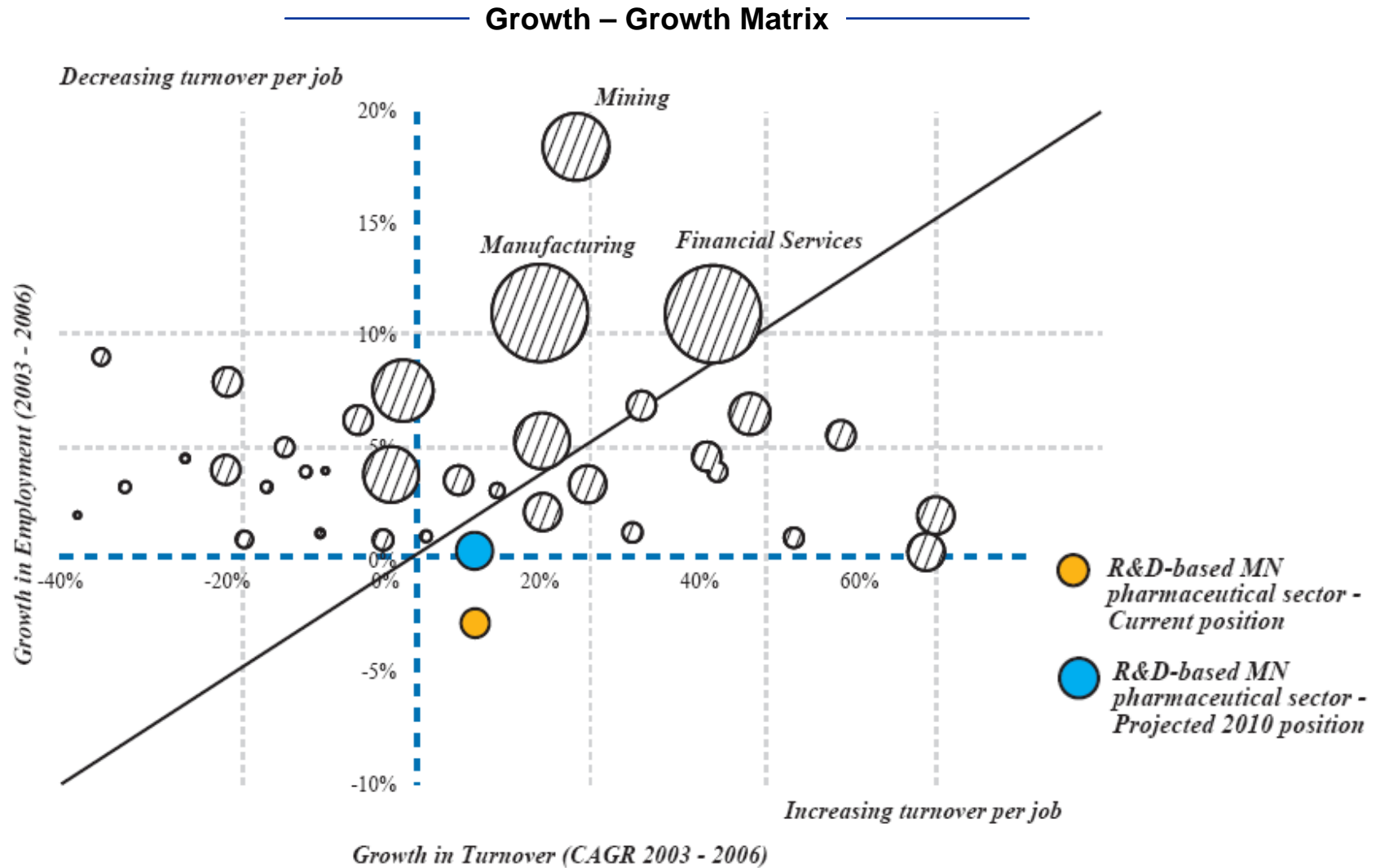
## Growth – Growth Matrix



- ① Most attractive
- ⑧ Least attractive

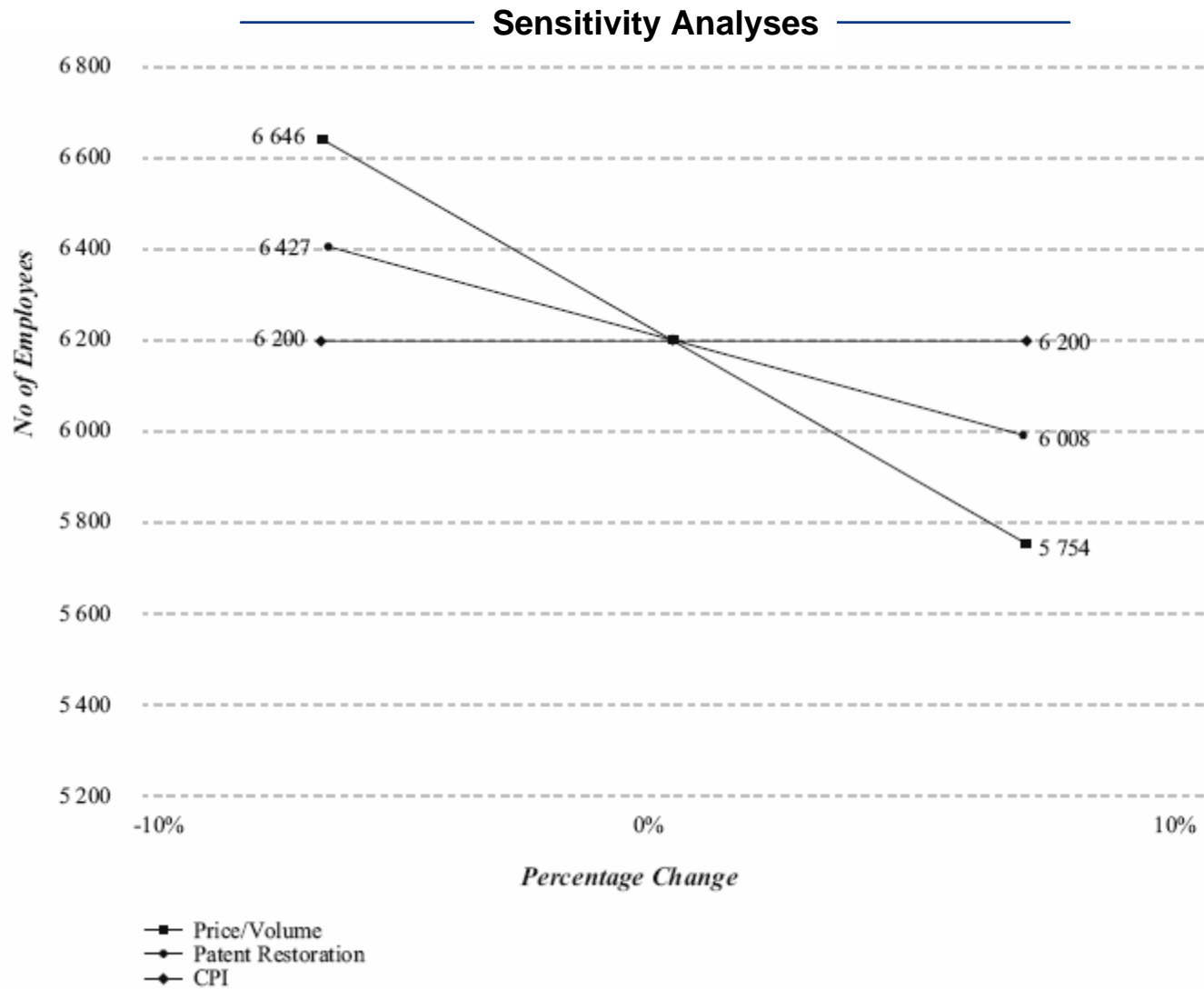
*Note 1: Assumes that for sustainability, growth in turnover is more important than growth in employment*

**Although the sector is currently (orange) with declining employment, this could change to growth in both in both employment and turnover by 2010 (blue)**



Note: The Mining, Manufacturing and Financial Services sectors exclude medium-sized and small enterprises

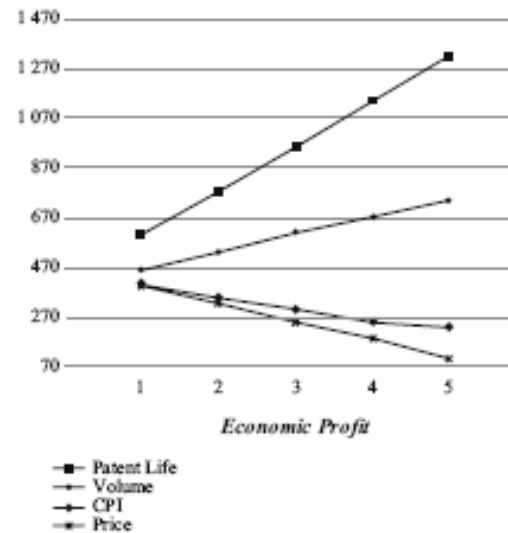
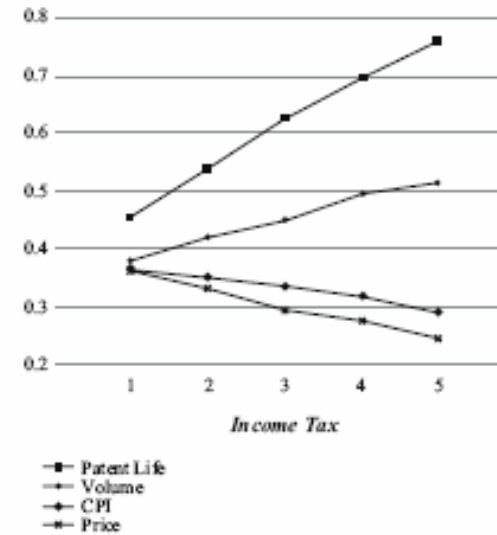
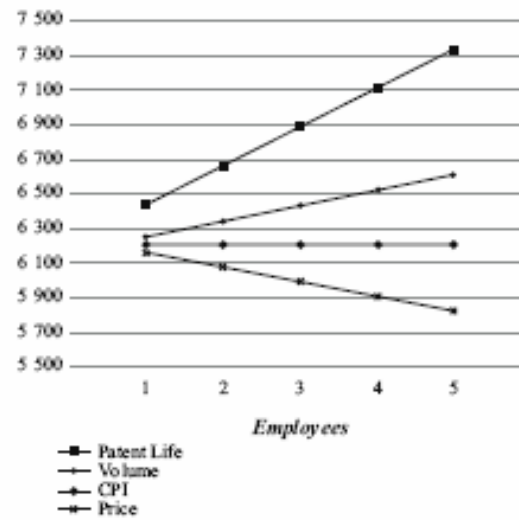
# The performance of the sector is the most sensitive to changes in pricing & volume while it is the least sensitive to changes in inflation



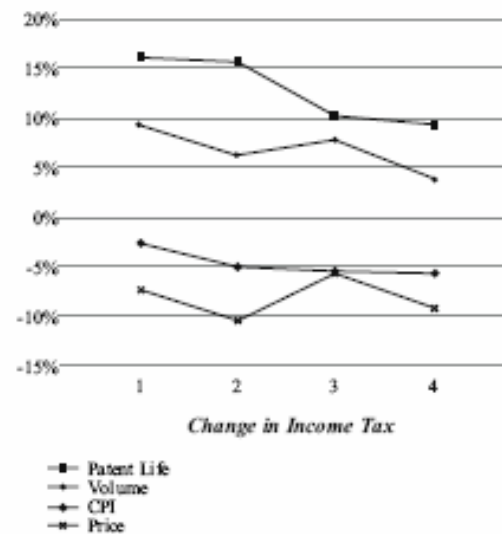
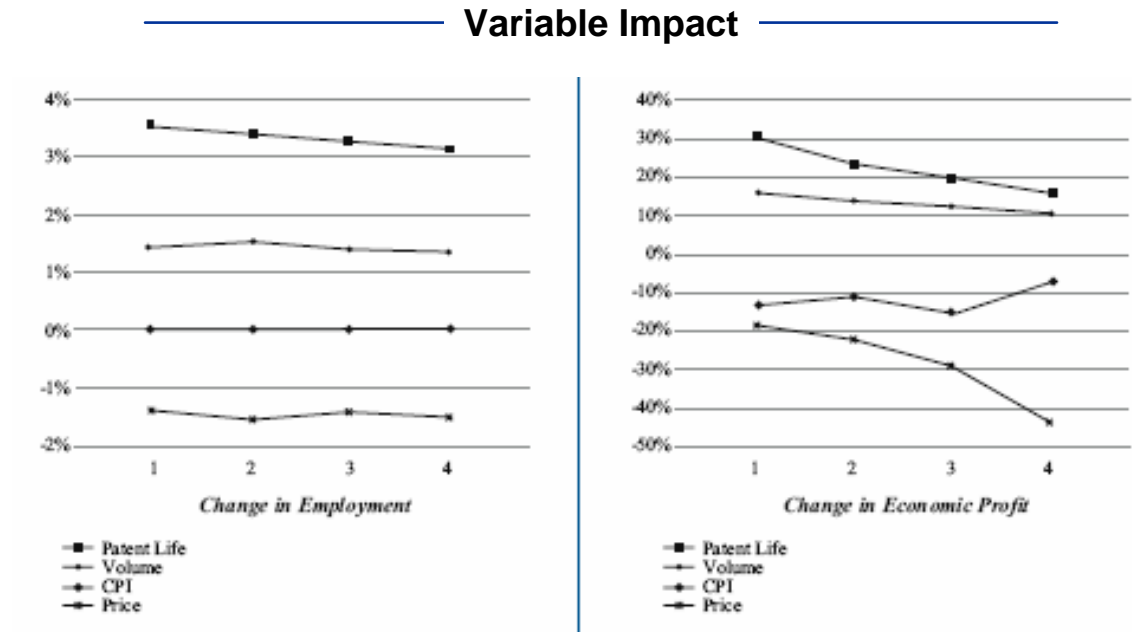
*Note: Since employment is linked to turnover and not profit, it is assumed that there will be no change in employment.*

# Decreasing the price of medicines and inflation has the largest negative impact...

## Variable Impact



# ...and the negative impact of a price reduction increases dramatically with each increment until economic profit is destroyed





## The optimal future for the sector does not lie in any one scenario but rather a combination which is dependent on the type of growth favoured

### Low Road

- Direct and indirect employment drops 1% for every percentage drop in price since fewer employees are required to handle decreased sales volume.
- Tax revenues decline by a significant 7% for every percentage point drop in the price.
- With a 9% drop in pricing the industry starts destroying economic profit since the profits do not cover the cost of capital.
- **In other words, the industry cannot earn enough to cover the cost of doing business in South Africa.**
- The economic modelling cannot capture the changes in perception which are likely due to these changes on the sector participants. **Such changes in perception may also affect investment decisions.**

### Middle Road

- Increasing the input costs by inflation without a balancing increase in the medicines price tends to have the largest impact on economic profit which declines by 15%.
- Since employment is linked to turnover, and not profit, it is assumed that there will be no change in employment.
- A sales volume increase has a large impact on employment, taxes and economic profit but not as large as extending the life of the patent.
- The middle road is therefore freezing prices as they are while finding a mechanism to increase sales.

### High Road

- The high road, which also leads to the most significant growth for the industry and the country as a whole, is brought about by increasing patent protection by two years or accelerating the review process
- This leads to an increase in employment of 6%, with an increase in indirect employment and an increase in taxes of 16%.
- The sector moves into the “sweet spot” segment and economic profit increases by approximately 20%.
- This, in turn, leads to increased possibilities in terms of spend within the cluster, and greater investment in corporate social responsibility programmes.

# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

# The most important decision is a collective agreement on the future position of this sector

## What needs to be done

- **Decide and agree a future for the sector**
- **Agree and develop a sector roadmap** outlining the growth path for the way forward with milestones for a 3-year, 5-year and 10-year horizon with clear targets in place.
- **Share information and collectively** make decisions which are in the best interests of all stakeholders.
  - **Develop the manufacturing base for niche diseases** and pursue a programme to drive the exports of these products.
  - **Ensure a changed regulatory and investment environment** (e.g. by nurturing and monitoring the latest tax incentives) to bolster investment in clinical trials to strengthen South Africa's leading position which is fast being eroded by China and India.
  - **Work collaboratively to drive the growth of the sector and access of medicines while increasing patient health.** The challenge is in understanding the root cause of access problems.
  - Make a concerted effort to bolster the lack of interest and rapidly reduce depletion of skills in the sector

## What can industry do

- **The sector and its positive impact should be made known:** Although it creates significant indirect employment and a positive economic profit, it is rarely mentioned as a potential positive contributor to the economy. **As a group the sector must fully embrace and support the new growth plan if it is to work.**
- **There needs to be one clear industry body** and leadership group which represents the sector.
- There must be **greater collaboration** between the industry, research institutions and the healthcare sector.
- There must be one platform to discuss and solve common problems: **the research has clearly indicated that all stakeholders share similar frustrations.** There are also numerous forums available to tackle sector issues.

## The most important decision is a collective agreement on the future position of this sector...(cont.)

### What can government do

- **Government must become a clear champion and driver for the new sector growth plan:** a well-developed and structured sector programme must be developed to guide the sector towards its new targets.
- **Ensure a sector body to drive the new growth agenda obtains results:** policy, research and recommendations for the sector are currently of a fragmented nature. The single most important next step is in ensuring the operation of one forum which works together to make decisions. **This could simply mean strengthening the National Consultative Health Forum or creating a sub-team under its auspices.**
- **The appropriate business climate must be adopted:** the most important thing government could do is to bring certainty to the sector by outlining a set of policy actions it plans to implement over the next 5 to 10 years for the sector.
- Stem the loss of talent
- **Communication:** once the growth plan is adopted, the government must actively and deliberately communicate the goals of the sector at all levels.

### What can industry do

- **The sector and its positive impact should be made known:** Although it creates significant indirect employment and a positive economic profit, it is rarely mentioned as a potential positive contributor to the economy. **As a group the sector must fully embrace and support the new growth plan if it is to work.**
- **There needs to be one clear industry body** and leadership group which represents the sector.
- There must be **greater collaboration** between the industry, research institutions and the healthcare sector.
- There must be one platform to discuss and solve common problems: **the research has clearly indicated that all stakeholders share similar frustrations.** There are also numerous forums available to tackle sector issues.

# Contents

---

	<b>Page</b>
Background	3
Executive Summary	7
The direct benefit of R&D-based MN pharmaceutical companies in the South African economy	34
Value of technology and skills transfer, voluntary licensing and empowerment	55
Corporate Social Investment	61
The R&D-based MN Pharmaceutical Cluster	67
Environmental factors and Policy Changes	73
Scenario Analyses and Sector Comparisons	83
Recommendations and Conclusions	91
Appendices	94

## Contacts

---

### **Dr Mergen Reddy**

Leader: Strategy & Strategic Finance

Johannesburg

+27 82 558 3086

[mereddy@deloitte.co.za](mailto:mereddy@deloitte.co.za)

### **Thiru Pillay**

Leader: FWpbD

Johannesburg

+27 83 6547033

[thpillay@deloitte.co.za](mailto:thpillay@deloitte.co.za)

---

## About Deloitte

Deloitte refers to one or more of Deloitte Touche Tohmatsu, a Swiss Verein, its member firms and their respective subsidiaries and affiliates. Deloitte Touche Tohmatsu is an organization of member firms around the world devoted to excellence in providing professional services and advice, focused on client service through a global strategy executed locally in nearly 140 countries. With access to the deep intellectual capital of approximately 135,000 people worldwide, Deloitte delivers services in four professional areas, audit, tax, consulting and financial advisory services, and serves more than 80 percent of the world's largest companies, as well as large national enterprises, public institutions, locally important clients, and successful, fast-growing global growth companies. Services are not provided by the Deloitte Touche Tohmatsu Verein and, for regulatory and other reasons, certain member firms do not provide services in all four professional areas.

As a Swiss Verein (association), neither Deloitte Touche Tohmatsu nor any of its member firms has any liability for each other's acts or omissions. Each of the member firms is a separate and independent legal entity operating under the names "Deloitte", "Deloitte & Touche", "Deloitte Touche Tohmatsu" or other related names.

In South Africa, Deloitte is the member firm of Deloitte Touche Tohmatsu, and services are provided by Deloitte and its subsidiaries. Deloitte is among the Netherlands' leading professional services firms, providing audit, tax, consulting, and financial advisory services through over 6000 people. Known as an employer of choice for innovative human resources programs, it is dedicated to helping its clients and its people excel. For more information, please visit the South African member firm's website at [www.deloitte.co.za](http://www.deloitte.co.za)