Research to guide the development of strategy for the Medical Devices Sector of South Africa
prepared in partnership with the dti
# Table of Contents

1. **Background**................................................................................................................................................. 4  
   1.1. Project Background ................................................................................................................................. 4  
   1.2. Deloitte Consulting Approach ............................................................................................................... 5  
2. **Foundations for growth**.............................................................................................................................. 7  
3. **Introduction**.................................................................................................................................................. 8  
4. **Medical Device Market Overview**............................................................................................................... 12  
   4.1. Market Size ............................................................................................................................................. 12  
   4.2. Customs Codes and International Trade Analysis ................................................................................. 13  
   4.3. South African Medical Device Market Trade Stats ............................................................................. 15  
   4.4. International Trade Flows and Trade Partners ..................................................................................... 16  
   4.5. Medical Devices Classification and International Trade Analysis ................................................... 17  
5. **Medical Device Regulation and Policy**...................................................................................................... 29  
   5.1. Regulation and Regulatory Bodies ........................................................................................................ 29  
   5.2. Intellectual Property ............................................................................................................................... 33  
   5.3. Designation for Preferential Procurement ............................................................................................ 36  
   5.4. Incentives and Access to Finance ........................................................................................................... 38  
   5.5. Summary ................................................................................................................................................ 39  
6. **Complementary Services to Medical Devices**......................................................................................... 40  
   5.7. Sterilisation ............................................................................................................................................... 41  
   5.8. Software Design ..................................................................................................................................... 42  
   5.9. Packaging and labelling ........................................................................................................................... 43  
   5.10. Post-market Surveillance and Privacy and Security ............................................................................. 44  
   5.11. Summary ............................................................................................................................................... 45  
7. **Future Trends in Medical Devices**............................................................................................................ 47  
8. **Stakeholder Engagement Findings**............................................................................................................. 49  
   8.1. Development and Approach ................................................................................................................... 49  
   8.2. Industry Analysis ................................................................................................................................... 51  
   8.3. Manufacturer Analysis ........................................................................................................................... 56  
   8.4. Quality Systems Analysis ....................................................................................................................... 58  
   8.5. Research and Development .................................................................................................................... 59  
   8.6. Complementary Services ......................................................................................................................... 60  
   8.7. Procurement ........................................................................................................................................... 61  
9. **Strategy Recommendations** ..................................................................................................................... 64
Key
- AHWP – Asian Harmonisation Working Party
- BRICS – Brazil, Russia, India, China and South Africa
- BBBEE – Broad Based Black Economic Empowerment
- CAGR – Compound Annual Growth Rate
- GMP – Good Manufacturing Practice
- CE – Conformity Europeenne
- CSIR – Council for Scientific and Industrial Development
- CDRH – Centre for Devices and Radiological Health
- DST – Department of Science and Technology
- dti – Department of Trade and Industry
- EU – European Union
- FDA – Federal Drug Agency
- FDI – Foreign Direct Investment
- GHTF – Global Harmonisation Task Force
- HS – Harmonised System
- IMDRF – International Medical Device Regulators Forum
- IP – Intellectual Property
- IVD – In-vitro Diagnostics
- MCC – Medicines Control Council
- MDD – Medical Devices Directive
- NAICS – North American Industry Classification System
- NHI – National Health Insurance
- NDoH – National Department of Health
- NRCS – National Regulator for Compulsory Standards
- PAWHP – Pan African Harmonisation Working Party
- PPPFA – Preferential Procurement Policy Act
- R&D – Research and Development
- SEDA – Small Enterprise Development Agency
- SEZ – Special Economic Zone
- SANAS – South African National Accreditation System
- SABS – South African Bureau of Standards
- SMME – Small Medium Enterprise
- TGA – Therapeutic Goods Agency
- TIA – Technology Innovation Agency
- TRIPS – The Agreement on Trade Related Aspects of Intellectual Property Rights
- WCO – World Customs Organisation
- WIPO – World Intellectual Property Organisation
1. Background

1.1. Project Background

The Department of Trade and Industry (“dti”) requested Deloitte Consulting (Pty) Ltd (“Deloitte”) to conduct a scoping and research study into the South African healthcare medical products sub-sector, with a specific focus on medical devices.

The purpose of the study was to provide advisory services to aid the dti in the development of a strategy and appropriate policy interventions, to support the long term growth of the medical devices industry. The core objective of this research is to contribute to efforts aimed at making the medical device industry, and thus the overall manufacturing industry in South Africa more competitive on a global scale.
1.2. Deloitte Consulting Approach

The development of the report and recommendations was approached as follows:

- Analysing the macroeconomic status and outlook of the South African and wider global economies. The importance of such analysis lies in that these wider trends influence the medical devices market therefore in order to ensure a comprehensive scoping exercise, it is necessary for macroeconomic factors to be taken into account.

- An overview of the current medical device market in South Africa - covering historical trends and possible future trajectories. Analysis of the market in terms of total market composition and international trade composition was the primary focus in the overview.

- Analysis of international trade of medical devices was completed using data from the Harmonised System (HS) of trade. For the purposes of this study the systems data was analysed at a 2, 4 and 6-digits level; and where data was available, 8-digits HS classification were analysed (8-digit level information was found to be generally less well recorded than the subsequent stages in South Africa). Each successive level represents more specific capture of the type of product being trade. The strength of using such a system is that it is globally harmonised and an estimated 98% of world trade is captured using it.

- Using detailed product listings as per the North American Industry Classification System (NAICS) figures from the HS were aligned to the appropriate NAICS category in order to formulate a breakdown of trade by product type.

- Documentation and synthesis of the current policy challenges and barriers facing the South African Medical devices sector in South Africa (with key focus on local manufacturing) was carried out.

- Case study comparison of the South African medical devices industry in relation to other countries. With specific focus on regulation, research and development and manufacturing incentives.

- Extensive stakeholder interaction via industry wide surveys, interviews (for industry and government leaders) and facilitation of a stakeholder workshop formed a core part of the research.

- Execution of an intensive skills transfer programme to equip dti employees on how to keep up to date with research and to ensure the strategy remains relevant and is implemented.
Research to guide the development of strategy for the medical devices sector of South Africa
2. Foundations for growth

Research findings indicate that the medical devices sector in South Africa offers significant opportunity for not only reducing the trade deficit but also increasing employment and improving healthcare. However, this can only be achieved if the necessary processes and structures are put in place to encourage growth of the sector. These include:

- **Stakeholders Collaboration** in the sector: industry, government departments and academia need to formalise structures for regular collaborative engagements to align their efforts. Such alignment is at the foundation of igniting industrial growth and if managed effectively such interactions could significantly contribute to growing the domestic industry and making it more attractive for both local and foreign investment.

- **Introduction and enforcement of effective regulatory policy and processes** (including quality standards); lies at the heart of competitive industries. South Africa currently has no established regulatory framework or mandatory quality standard for medical devices other than those of a radiation emitting nature. Currently all such regulation is left to the discretion of individual procurers. In order to rectify this, introduction of an internationally graded and compulsory Quality Management Standards (QMS) needs to be introduced. This in turn will prevent substandard products from entering the healthcare market and equalise opportunities for local manufacturers whilst ensuring patient safety.

- **Comprehensive economic analysis** of the effects of various designation (specific requirements for local procurement in the public sector) methodologies and how they could effectively be implemented to best benefit not only industry, but also the various government departments is required. Using designation in an effective manner would increase demand for local production and if appropriately taken advantage of, local manufacturers may then be in a better position to invest more in making their business functions, such as scale of production of investment and research & development (R&D) more competitive.

It is highly recommend that the four issues highlighted above be resolved as soon as possible.

Implementation of the insights and advices further mentioned in this research are not likely to be as effective unless these four underpinning requirements are addressed.
3. Introduction

In line with global trends, economic growth has increased in South Africa over the last few years albeit at a lesser rate compared to peer countries in other emerging markets. Growth is expected to continue on an upward trajectory over the next few years; however, it is likely that global factors such as the phasing out of Quantitative Easing in the United States will continue to put pressure on economies elsewhere in the world, particularly in emerging markets – including South Africa.\(^\text{1,2}\)

South Africa’s current population is estimated to be 52.8 million and projected to grow to 53.5 million in 2015. 65% of the population is aged 15-64 and current life expectancy is 61.3 years. Pressures from a quadruple disease burden (communicable disease, non-communicable disease, traumatic injuries and HIV/AIDS) amongst this population are of considerable socioeconomic concern. Whilst significant progress has been made in reducing the communicable disease, disease burden from HIV/AIDS and non-communicable disease is increasing.\(^\text{3}\)

There are currently 622 registered hospitals in South Africa providing 2.2 beds per 1,000 population; comparable to other developing nations such as Brazil (2.3 beds per 1,000) and China (2.5 per 1,000) but considerably lower than Russia (9.1 per 1,000) and South Korea (8.8 per 1,000). In terms of skills; the country has been found to have 0.7 physicians; 4.9 nurses and 0.1 dentists per 1,000 population. The public sector is considered understaffed with only 0.2 doctors per 1,000 population indicating the disparity between the public and private healthcare systems.

South Africa’s healthcare expenditure is high by developing country standards and was recorded as being proportional to 9% of GDP in 2013. Expenditure between the public and private sectors is at approximately 50/50 parity although substantially more people use the public healthcare system as opposed the private sector. This is expected to be skewed to the public sector over the coming years with the phasing in of the National Health Insurance (NHI).\(^\text{4}\)

The South African Medical Devices market (consumption, production and trade) is valued at US$1.2 billion and is expected to grow at a Compound Annual Growth Rate (CAGR) of 7.74% from 2013 to 2018. Current per capita expenditure on medical devices stands at US$24 and is at a similar level to other developing countries such as Brazil (US$30 per capita), but considerably lower than in developed countries such as Germany and the United States at US$313 and US$399 per capita respectively. 90% of this market is estimated to be composed of imports contributing significantly to the country’s total trade deficit.\(^\text{4}\)

Analysis using the HS and NAICS systems found that the Surgical and Medical Instrument Supplies category of devices was largest component of the total medical devices trade deficit and imports had grown at a CAGR of 12.65% from 2004-2013. The fastest growing category was found to be Medical Furniture which had grown at a CAGR of 24.58% from 2004 to 2013.\(^\text{4}\)

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1 IMF WEO Update Oct 2013
2 Economist Intelligence Unit: South Africa Report March 2014
3 Statistics South Africa
4 BMI South Africa Medical Devices Report Q1 2014
Eight key factors have the potential to be significant growth drivers for the South African medical devices industry. These can broadly be split into two groupings: (1) Demographic and epidemiological changes that are driving demand; (2) Healthcare provider response to the increased demand. Population growth, longer life expectancy, recognition that disease burden must be reduced and the demand for private sector healthcare can be considered to be part of grouping 1; whilst increasing per capita spend on healthcare, introduction of the NHI and growing numbers of per capita healthcare professionals reflect government and private sector responses in group 2.

**Figure 1. Drivers of growth in the medical devices industry**
With the exception of radiation emitting devices there are no enforced regulations for medical devices entering the South African market. This has a negative effect of allowing products of a sub-standard quality to enter the market impacting patient safety and undercutting the local manufacturing industry - thus inhibiting upgrading and development of local industry.

The institutions necessary to effectively regulate the medical industry are already in existence. The key agencies being:

- The Medicines Control Council (MCC),
- South African National Accreditation System (SANAS),
- South African Bureau of Standards (SABS)
- The National Regulator for Compulsory Standards (NRCS).

South Africa is also a member of a number of transnational forums such as the Asian Harmonisation Working Party and the Pan-African Harmonisation Working Party which are dedicated to the global convergence of medical device regulation.

Incentives are considered a critical government tool for industrialisation, a number of which are available in South Africa for medical devices companies to utilise. Although these incentives are existent, they’re not always as competitive as those offered in other emerging markets.

Designation for medical devices via the Preferential Procurement Policy Act (PPPFA) is also an option available for use to help create demand for local manufacturers but is not enforced for the medical devices Sector.

In order for the medical devices industry in South Africa to really thrive it is necessary for services complementary to it to be developed in the market. The complementary services detailed in this report are as follows: sterilisation; software design; packaging and labelling; post-market surveillance; and privacy and security. All of these services are integral to improving the overall effectiveness of medical devices used in the healthcare system, particular high-risk and high-value devices.

Future industry trends were taken into account in the research. This was done in realisation that policy that is informed by such trends and appropriately made flexible enough to accommodate them will be best placed to ensure that new technologies are quickly and effectively regulated once they enter the market. Analysis of these has the additional benefit highlighting which emerging technologies are currently at the forefront of medical device industry growth and are therefore best targeted in terms of provision of incentives, designation and research and development.

12 recommendations towards the formulation of a medical device strategy have been made to address the following topics:

1. Regulations and Quality Management Standards
2. R&D and Manufacturing Incentives
3. Human Capital Development
4. Future Industry Trajectory
5. Recommendations for Further Research
4. Medical Device Market Overview

4.1. Market Size

The South African medical devices market (consumption, production and trade) is estimated at US$1.2 billion and is forecast to grow at a US$ billion Compound Annual Growth Rate (CAGR) of 7.74% between 2013 and 2018\(^5\). The reasons underlying such growth include population growth, increased life expectancy, growing quadruple disease burden and increased domestic healthcare spend due to the introduction of the NHI.

![Graph showing growth of the South African Medical Device Market from 2008 to 2012 and projected growth from 2013 to 2018.](image)

South Africa’s spend on medical devices per capita is US$24, which is comparable to fellow BRICS countries. However, when comparing to more mature markets such as the United States and Germany, where per capita spends stands at US$399 and US$313 per capita respectively, it suggests that there is ample room for growth\(^2\).

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\(^5\) *BMI Medical Devices Report South Africa, Q1 2014*
4.2. Customs Codes and International Trade Analysis

Trade data supplied by the dti was used to investigate the configuration of South African international trade flows in the medical devices sector. The Harmonised Commodity Description and Coding Systems generally referred to as “Harmonised System” (HS) was used. HS is a multipurpose international product nomenclature developed by the World Customs Organisation (WCO) and over 98% of the merchandise in international trade is classified in terms of the HS.

Analysis of trade data in accordance to the HS system was important because medical device imports make up 90% of the total medical device market, and exerts significant pressure on the trade deficit. It was essential to identify which specific groups of items within the wider medical devices market are significantly contributing to the deficit. Once this information is outlined evidence based policy making will then be possible and strategic policy recommendations can be made on how to address trade imbalances.

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One limitation in using the HS system in the South African context is that trade figures are usually only recorded to a 6-digit level. This means that the products captured are not always clearly defined – which in turn limits the depth of investigation possible. A second limitation is that figures may not always be accurately and completely recorded at all trade ports/points of entry. That said, the system still presents the most accurate way of measuring trade and will therefore be utilised.

Figure 4. Outline of the HS system headings and sub-headings
4.3. South African Medical Device Market Trade Stats

At present medical device imports make up 90% of the total medical device market. Analysis of international trade flows of medical devices shows that the gap between imports and exports has widened between 2004 and 2013.

- The total value of imports was R11.07 billion in 2013 compared to R3.74 billion in 2004.
- Exports of medical devices are recorded as considerably smaller although also having increased from 420 million in 2004 to R1.08 billion in 2013.

As a result of the above, South Africa’s medical device sector trade deficit within the products investigated, has trebled from R3.33 billion in 2004 to R9.99 billion in 2013.

Figure 5. International trade flows of medical devices in South Africa

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7 Easydata Trade Statistics, 2014
4.4. International Trade Flows and Trade Partners\(^8\)

Country level analysis of international trade data provides insights into which countries are South Africa’s main trade partners and which products are being traded. This analysis was done over a 10 year period in which cumulative imports and exports and the HS codes were assessed.

The United States of America has been the largest exporter of medical devices into South Africa by a significant margin (total exports valued at R19.9 billion between 2004 and 2013). Germany is the second largest exporter in South Africa at R9.8 billion over the same period. These two largest medical device importers are also the two largest medical device markets in the world\(^9\).

The largest market South African exports to is Mozambique, with trade valued at R1 billion; followed closely by the United States of America at 900 million. A large proportion of exports are also to other African countries.

It is however unclear whether these exports are manufactured in South Africa and then exported, or if South Africa is being used as a re-export gateway. It is recommended that this is investigation further.

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\(^8\) *Easydata Trade Statistics*

\(^9\) *BMI Special Report: Worldwide Medical Market Forecasts to 2018*
4.5. Medical Devices Classification and International Trade Analysis

4.1.1 NAICS Classification

The North American Industry Classification System (NAICS) was used as a basis for categorising the market. The clearly defined and comprehensive product listing proved most suitable and effective for alignment with the format of the data from the trade customs statistics. Whilst other classifications were considered, they were not as well defined and often included a category labelled “other” which reduced specificity.

Figure 7. Categories of the NAICS used in this research

10 NAICS.com: http://www.naics.com/
4.1.2 NAICS and Total International Trade of Medical Devices

**Figure 8. Total imports and exports of medical devices per analysed NAICS category**

Imports between 2004 and 2013 totalled R71 billion across the eight NAICS categories.

Surgical and Medical Instrument Supplies is South Africa's largest import category making up 49% of imports between 2004 and 2013 (R34.72 billion). Imports in this category in 2013 amounted to R 5.45 billion of total imports of R11 billion.

The total medical device exports between 2004 and 2013 were R7.34 billion. Surgical and Medical instrument Supplies was the largest export category for the same period, making up 32% of total medical device exports (R2.38 billion\(^\text{11}\)).

For detailed outlines of products in each of the categories please see Annexure A.

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\(^{11}\) Easydata Trade Statistics
4.1.3 International Trade of Surgical and Medical Instrument Supplies

HS Code import statistics reveal Surgical and Medical Instrument Supplies was the largest category contributor to the South African trade deficit between 2004 and 2013 (R32.34 billion). The trade deficit in this category in 2013 alone was recorded at R5.02 billion.

Sub-categories within this category include:
- HS901890: Instruments, appliances for medical
- HS901839: Needles, catheters, cannulae
- HS901850: Ophthalmic instruments and appliances
- HS901920: Therapeutic respiration apparatus
- HS902000: Breathing appliances and gas masks
- HS901831: Syringes, with or without needles
- HS901832: Tubular metal needles and needles for sutures

Figure 9. International Trade of Surgical and Medical Instrument Supplies
Of these sub-categories, Instruments and appliances for Medical is the biggest category contributor within this classification over the past 10 years making up 67% (R23 billion) of imports. As data is captured past the 6-digit HS level further investigation and more detailed capturing of trade flows is required to gain a better understanding.

Sub categories within this classification showing the potential for increased local manufacturing syringes, with or without needles (R130 million imports and R5.7 million exports) and Tubular metal needles and needles for sutures (imports of R98 million and R6.1 million of exports).

Please see Annexure A.
4.1.4 International Trade of Surgical Appliances and Supplies

Surgical Appliances and Supplies Manufacturing is the second largest category contributor to the medical devices trade deficit (R11.04 billion between 2004 and 2013). The trade deficit in this category in 2013 alone was recorded at R2.13 billion\textsuperscript{12}. The high CAGR suggests the medical devices in this category are indicative of a growth trend showing the increasing importance of these products to the healthcare system.

\textsuperscript{12} Easydata Trade Statistics
Sub-categories within this category include:

- H902190: Orthopaedic appliances
- H902139: Orthopaedic appliances
- H902131: Orthopaedic appliances
- H300590: Medical dressings etc except those with adhesive layer
- H300510: Medical dressings etc. having an adhesive layer
- H401511: Rubber surgical gloves
- H902110: Orthopaedic appliances
- H871390: Wheelchairs, mechanically propelled
- H871420: Wheelchair parts

Of the R13.02 billion worth of products imported in this category between 2004 and 2013, 65% (R8.5 billion) is comprised of products within the sub-categories HS902190, HS902139 and HS 902131 all titled Orthopaedic appliances. With these sub-categories not being well defined and no additional data being available, further investigation and more detailed capturing of trade flows is required.

Two of the better defined sub-cATEGORIES within this category, and with encouraging potential for manufacturing in the short term; are medical dressings manufacturing, which accounted for R240 million worth of imports and R70 million worth of exports in 2013 and rubber gloves, which accounted for R192 million worth of imports and R4.7 million worth of exports in 2013.

Please see Annexure A.
4.1.5 International Trade of Dental Equipment and Supplies

Although not one of the largest categories in terms of value (relatively small 2013 trade deficit of R200 million), the composition of the global market and current manufacturing capabilities in South Africa suggest there is potential for growing manufacturing in this category.

Figure 11. International Trade of Dental Equipment and Supplies

Sub-categories within this category include;

- **H901849: Instruments and appliances, used in dentistry**
- **H902129: Dental fittings**
- **H902121: Artificial teeth**
- **H901841: Dental drill engines**
63% of the R1.7 billion worth of products imported within this category is comprised of products within the sub-category instruments and appliances, used in dentistry. In 2013 R172 million worth of products within the sub-category instruments and appliances, used in dentistry were imported. Of the R244 million worth of products exported within this category, 43% (R105 million) are comprised within the sub-category dental fittings. In 2013 R16 million worth of products within the sub-category dental fittings were exported.

Please see Annexure A.

4.1.6 International Trade of Ophthalmic Goods

Ophthalmic Goods imports between 2004 and 2013 totalled R7.65 billion and exports R310 million. The trade deficit in 2013 was recorded at R1.14 billion.

Sub-categories within this category include;
- H900410: Sunglasses
- H900150: Spectacle lenses of other materials
- H900319: Frames & mountings for spectacles etc, except plastic
- H900490: Spectacles, goggles except sunglasses
- H900130: Contact lenses
- H900311: Frames & mountings for spectacles etc, plastic
- H900140: Spectacle lenses of glass
- H900390: Parts of frames and mountings for spectacles etc

Figure 12 International trade of Ophthalmic Goods

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13 Easydata Trade Statistics
Sunglasses made up the largest import product within this category (27% or R2.08 billion from 2004 to 2013); however with sunglasses being largely brand centric products, the potential for local manufacturing may be diminished.

Of the R310 million worth of products exported within this category from 2004 to 2013, 38% or R116 million are comprised of products within the sub-category spectacles, goggles except sunglasses. In 2013 R19 million worth of products within the sub-category spectacles, goggles except sunglasses were exported.

Please see Annexure A.

4.1.7 International Trade of Electomedical and Electrotherapeutic Apparatus

Trade imports in this classification between 2004 and 2013 totalled R6.60 billion and trade exports R1.60 billion, with a trade deficit of R740 million in 2013.

Sub categories within this category include:

- H901819: Electro-diagnostic apparatus
- H902140: Hearing aids, except parts and accessories
- H901812: Ultrasonic scanning apparatus
- H902150: Pacemakers for stimulating heart muscles
- H901813: Magnetic resonance imaging
- H901811: Electro-cardiographs
- H901820: Ultra-violet or infra-red ray apparatus

Electro-diagnostic apparatus make up the largest import (42% or R2.8 billion) and need to be considered for further investigation in the interests of long term planning and policy intervention.

In 2013 R342 million worth of electro-diagnostic apparatus were imported into South Africa. In the same year R142 million worth of products were exported.

Please see Annexure A.
4.1.8 International Trade of Irradiation Apparatus

Trade imports in this category between 2004 and 2013 totalled R5.94 billion and trade exports R560 million. The trade deficit in this category in 2013 was R500 million\(^{14}\). The low CAGR of products in this category suggests that the products within may be reaching a state of technological and demand maturity and thus on the decline.

Sub-categories within this categories include:

- H902214: X-rays apparatus
- H902290: Parts and accessories for radiation apparatus
- H902212: Computed tomography apparatus
- H902221: Medical apparatus using alpha, beta or gamma radiation
- H902230: X-ray tubes
- H902213: X-rays apparatus, dental
- H901814: Scintigraphic apparatus

\(^{14}\) Easydata Trade Statistics
Of the R5.94 billion worth of products imported within this classification, 37% (R2.17 billion) were in the sub-classification X-ray apparatus. 36% (R2.14 billion) were parts and accessories for radiation apparatus.

Of the R559 million products exported, 55% (R305 million) were the sub-classification parts and accessories for radiation apparatus. In 2012, R38.80 million in the sub-category parts and accessories for radiation apparatus were exported.

Please see Annexure A1.

### 4.1.9 International Trade of Medical Furniture

Trade imports in this category between 2004 and 2013 totalled R1.44 billion and trade exports R270 million. This is the fastest growing category analysed with a CAGR of imports of 24.58% between 2004 to 2013 and a trade deficit of R250 million in 2013. The high CAGR for this product category is likely attributable to the growing trend of infrastructure development in the form of new hospitals and hospital expansion programmes.

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**Figure 15. International Trade of Medical Furniture**

Sub categories within this category include:

- **H940290**: Medical, dental, surgical & veterinary furniture, nes
- **H940210**: Dentists, barbers or similar chairs and parts

**Total Imports vs. Exports (2004 – 2013)**

- Imports (ZAR billion): 0.27
- Exports (ZAR billion): 0.14
- 1.44

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15 *Easydata Trade Statistics*
Of the R1.44 billion worth of products imported 90% (R1.30 billion) are in the sub-category medical, dental, surgical and veterinary furniture. In 2013, R255 million in the sub-category mental, dental, surgical and veterinary furniture were imported. Due to the size and growth (CAGR 24.58%) of the medical furniture sector, it renders an attractive area for local manufacturing.

Of the R267 million worth of products exported between 2004 and 2013, 91% (R242 million) were in the sub-sector medical, dental, surgical and veterinary furniture. In 2013, R23 million worth of products in sub-category medical, dental, surgical and veterinary furniture were exported.

Please see Annexure A.
5. Medical Device Regulation and Policy

Effective regulation ensures that the medical devices manufactured and used in the market are of good quality and are not a danger to public health. Such regulation also forms the foundation for a local manufacturing industry to be deemed competitive to an international standard.

Supporting regulation and appropriate industrial policy is also essential to encourage and reward innovation, and local investment. It is also vital in encouraging private sector innovation and growth; which could greatly increase the likelihood of successful and internationally competitive companies developing within the South African medical devices industry.

5.1. Regulation and Regulatory Bodies

The institutions necessary to effectively regulate the medical industry are already existent. Namely:

- The Medicines Control Council (MCC)
- South African National Accreditation System (SANAS)
- South African Bureau of Standards (SABS) and;
- National Regulator for Compulsory Standards (NRCS).

5.1.1 Medicines Control Council (MCC)

The MCC is South Africa’s medical authority responsible for regulating the manufacture, distribution, sale and marketing of medicine within the country. The personnel in charge of product approval within the authority are not full-time employees; which has been noted a key reason for their often being delays with the approval of products.

In order to rectify some of the inefficiencies of the MCC, a Medicines and Related Substances Bill currently being considered by parliament is to transform MCC into a new entity called the South African Health Products Regulatory Agency (SAHPRA) and extend the mandate to include medical devices, including in-vitro diagnostics. Some of the proposed medical device legislations for SAHPRA include regulation for licensing, device classification and labelling regulations.

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16 Medicines Control Council: http://www.mcc.za.com/about/default.asp

17 Government Gazette No 37579 of 22 April 2014 – Notice R 315 "Medicines and Related Substances Act (101/1965)."
5.1.2 South African National Accreditation System (SANAS)

SANAS is the single government body that accredits a range of other bodies and institutions across various industries and gives formal recognition that they are competent to carry out specific tasks related to their industries.¹⁸

SANAS cannot directly accredit medical devices, manufacturing or servicing facilities, but it is able to accredit certification bodies that provide such services within or across industries. From a medical devices perspective one role SANAS could potentially play is to accredit the likes of the South African Bureau of Standards (SABS) and other privately run certification bodies to accredit ISO 13485 to an international standard for companies operating in the South African medical devices industry.

5.1.3 South African Bureau of Standards (SABS)

The SABS is a government affiliated certification body for product testing, product certification and standardisation and management system certification. It has its own local SABS standards, but can also, to a limited degree, certify to ISO and IEC standards.¹⁹

The medical device sector falls under one of the seven industry sectors that SABS looks after as per its mandate - namely Medical and Health related issues (which includes the medical devices sector). SABS currently accredits ISO 13485 to a national standard with some factors falling slightly short of the international standard. However, should SANAS provide the necessary accreditation it would be possible for this to be accredited to an international standard.

5.1.4 National Regulator for Compulsory Standards (NRCS)

The NRCS’ mandate covers five industries with the objective of protecting human health, safety and environment – as well as ensuring fair trade of goods. It’s core purpose is to develop, maintain and administer technical regulations including compulsory specifications (upon declaration from Minister of Trade and Industry) on behalf of other government entities. It also ensures that enforced regulatory policy meets South Africa’s obligations as per the World Trade Organisations (WTO) agreement on technical trade barriers. The relevance this has for medical devices are that the NRSC as an institution already has the necessary framework and processes that would, if mandated to do so, allow it to enforce medical device regulations decided upon by the likes of SAHPRA.²⁰ ²¹

5.1.5 Pending Medical Device Regulation

Potential new regulations for medical devices were outlined by the South African Department of Health Department on 22 April 2014.²² The proposed regulations are aimed at replacing the current system, whereby only a limited number of devices (for example radiation emitting devices and/or combination devices) require prior European CE Marking. The draft regulations are currently open to comment by the public, interested and affected parties.

Below are salient features of the draft regulations:

a) Classification

The South African regulatory system would include a four-tier, risk-based device classification system—Class A (lowest risk), Class B (low to moderate risk), Class C (moderate to high risk) and Class D (highest risk). The MCC would determine proper classification of devices based on their designs and individual uses.

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¹⁸ SANAS: http://home.sanas.co.za/
¹⁹ SABS: https://www.sabs.co.za/
²⁰ NRCS: http://www.nrsc.org.za/
²¹ SABS NRCS Overview: https://www.sabs.co.za/Sectors-and-Services/Services/NRCS/index.asp
b) Required registration components

Local manufacturers will have to register and certify their products with the MCC prior to marketing and distribution in South Africa. Medical device manufacturing and quality systems compliance with ISO 13485, FDA Quality Systems Requirements of Good Manufacturing Practices (GMP), European Medical Devices Directives (MDD) including CE Marking will help greatly in securing registration and certification by the Medicines Control Council.

Foreign manufacturers would need to appoint in-country (South African) representatives to manage their medical device and In Vitro Diagnostic (IVD) registrations in South Africa. Through their authorised representatives, registrants would have to provide relevant information and documentation to MCC reviewers. Examples of such information and documentation being:

- Proposed device labelling
- Proof of current quality management system certification
- Safety and performance data
- Country of origin and registration status data
- Clinical data, if applicable

The Medicines Control Council would then review registration applications and issue registration certificates, accordingly.

A common challenge to accessing numerous international markets is differing regulation for market entry across countries. In order to address this challenge it has been recognised that a degree of global regulatory convergence is required. On the basis of this realisation a number of voluntary transnational forums have been initiated, with the core objective being regulatory convergence across geographic areas.

Key areas of convergence:

1. **Device evaluation**: Standardisation of criteria for pre-market approval of devices
2. **Post-market surveillance/vigilance**: Uniformity of reporting of adverse incidences, standardisation of post-market surveillance processes and harmonisation of data collection criteria.
3. **Quality Systems**: Harmonisation of selection and enforcement of quality systems
4. **Quality Audit**: Harmonisation of audit of quality systems
5. **Clinical Safety**: Convergence of clinical practice in using medical devices. Including the harmonisation of clinical terms, reports and evaluations.

### 5.1.6 Transnational Forums

In an increasingly globalised world it has become apparent that in order for any nation to develop globally competitive industries it must ensure that domestic firms become better integrated and integral to global supply chains. In the medical devices industry such integration increasingly requires products that meet the standards of international best practice. As such it is critical for companies in the South African medical devices industry to try and become as well integrated into global supply chains as much as possible, so as to gain greater access to a wide range of international markets.
The four such transnational forums relevant to the South African case are the: Global Harmonisation Task Force (GHTF)\(^{23}\); International Medical Device Regulators Forum (IMDRF)\(^{24}\); Asian Harmonisation Working Party (AWP)\(^{25}\) and the Pan-African Harmonisation Working Party (PAHWP)\(^{26}\). Deeper engagement in these forums and implementation of their recommendations in the South African market may assist in bringing the South African medical device industry in line with international standards and best practice; thus increasing the chances of domestic companies being able to become integrated into global supply chains.

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\(^{24}\) International Medical Devices Regulators Forum: http://www.imdrf.org/

\(^{25}\) Asian Harmonisation Working Party: http://www.ahwp.info/

\(^{26}\) Pan African Harmonisation Working Party: http://www.pahwp.org/
5.1.7 Summary
SANAS has substantial potential to improve its accreditation abilities; SABS and other similar regulators could potentially certify to an international standard and NRCS could be an effective regulator post certification and post market. It can thus be said that SANAS, SABS and NRCS have a potentially key role to play in the enforcement of regulation going forward, particularly in terms of how they relate to establishment of SAHPRA.

If the pending regulations are implemented it will be necessary to ensure that product approval through the MCC is done with minimal delay. Delays will have a negative effect on the local medical device industry, due to these products having short life cycles when compared to other products regulated by the MCC.

5.2. Intellectual Property

Intellectual Property (IP) is a critical issue to consider with regards to protecting innovation and therefore also profits. Factors influencing IP generation in South Africa will therefore be outlined with view of making recommendations of how more locally derived IP can be generated.

5.2.1. Intellectual Policy in South Africa

South Africa currently has no unified and nor well-coordinated IP policy and a fragmented approach to IP related issues is currently being pursued.

In order to rectify this Government has released a draft IP bill with a range of proposals on how to address the critical issues surrounding the lack of co-ordination27.

IP primarily consists of Trademarks, Copyright, Patents and Designs and is cross-cutting in nature i.e. it covers a range of topics such as trade, science, agriculture and health. This means the effects of policy in this sphere have far reaching effects across various sectors and can directly and indirectly affect the livelihoods of all citizens. For this reason Government states that the aim of the policy proposal is to balance the interests of producers, consumers and users of IP for the benefit of all stakeholders. Further to this, uniformity in policy at national and international (WTO and WIPO) level is deemed important for investment stability and policy predictability when considering the prospects of a nation in the long term.

5.2.2. Patent Generation

South African companies are currently logging very low levels of IP generation. One way of measuring this is through analysing the number of patents registered within the country from both resident (local) and non-resident (foreign) companies.

When taking into account a range of sectors that feed into medical devices non-resident companies are logging considerably more IP in South Africa than resident companies28. This suggests that the levels of innovation in terms of design and function is presently low and more public and private investment or incentives for R&D are needed to increase local patent generation in the country. Actions that need to be taken to rectify this include increasing the R&D to GDP ratio of the country and working to have an increased output of researchers and technicians per million of the population29.

28 WIPO Patent Database
29 World Bank Databank
Figure 17. Local patents filed compared foreign patents filed in South Africa. A diagrammatic representation across technology clusters.

30 WIPO Patent Database

Research to guide the development of strategy for the medical devices sector of South Africa
5.2.3. Incubation Centres

Incubators are organisations that support the growth of new (typically technology-based) enterprises by providing business support services, and bringing together human and financial capital.

In 2001, the South African government established several publicly funded incubators to spur the development of life science ventures to tackle local health problems. Acorn and Godisa trust were two such incubators. Acorn was officially started in 2002 by a consortium (University of Cape Town, University of Stellenbosch, Catalyst Innovations and the biomedical device pioneer DISA vascular), under the auspices of a joint programme between the dti, Department of Science and Technology (DST), and the European Union (EU). In 2003, the DST withdrew from the programme to create its own set of biotech regional innovation centres including Cape Biotech Trust. This left the dti as the primary funder focussed only on operational funding.

Due to funding constraints, Acorn merged with Cape Biotech and the other biotechnology regional innovation centres, in turn merged into a national initiative - the Technology Innovation Agency (TIA).

EgoliBio is currently the only national life sciences and biotechnology incubator operating in South Africa, who assist clients from first generation support through to commercialisation of their product/s. EgoliBio partner with Small Enterprise Development Agency (SEDA), the Council for Scientific and Industrial Research (CSIR), Chemcity, the Innovation Hub, and agricultural research Council\textsuperscript{31}.

\textsuperscript{31} Can Incubators work in Africa: egolibio.co.za
5.3. Designation for Preferential Procurement

Public procurement has been cited by number of studies as a part of wider industrial policy aimed at encouraging innovation. By designating a proportion of government funds to be spent on local manufacturers, designation can assist to increase demand for local products\textsuperscript{32, 33}. In cases where R&D intensive companies are beneficiaries of designation the intended subsequent effect would be that it would contribute to driving their innovation processes.

The Preferential Procurement Policy Framework Act (PPPFA)\textsuperscript{34} includes clauses for designation that can be implemented to foster job creation and retention as well as the advancement of key growth sectors identified by government. The Act is typically applied for public sector procurement but some private sector firms also choose to subject themselves to the Act in their procurement process.

Designating a proportion of procurement for local manufacturers can be used as a means of achieving the following:

- Sustaining local industry by encouraging value to products to be added domestically
- Creating demand to increase the chances of technological upgrading occurring amongst Small Medium Enterprises
- Making use of existing domestic capacity to fulfil procurement demand

\textsuperscript{32} Public Procurement for Innovation as mission-oriented innovation policy, Research Policy (41), 2012.
\textsuperscript{33} Innovation Policy: A guide for Developing Countries, World Bank 2010
\textsuperscript{34} Preferential Procurement Regulations 2001
Present guidelines for how to designate takes a number of issues into account. One of these is the significance of public procurement for the industry – if the industry is deemed to be a one of high potential or importance to local manufacturing then designation is likely to have amplified effects (compared to an industry of lesser importance). The structure of the industry e.g. number of manufacturers, output levels, employment levels and competition should also be considered if the objectives of designation include job creation and/or retention.

Pricing of supply from local industry is also key in deciding whether or not designation based on company origin is a viable selection criteria. In the medical device sector price is an important factor for the National Department of Health (NDoH) so that they can ensure that their healthcare facilities are adequately stocked. Lastly, an assessment of the current level of local content and the ability of the industry to up-skill (technology and production capacity) over time needs to be taken into account.

At present there is no designation process for medical devices. Dependent on the criteria bidders are scored on a 90 or 80 point scale for price and 10 or 20 point scale for the Broad Based Black Economic Empowerment (BBBEE) level. Local content is not currently taken into account in the procurement process; however provision for this does exist if the procurer wishes to include this as a factor.
5.4. Incentives and Access to Finance

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D Tax Incentive</td>
<td>NRF</td>
<td>THRIP</td>
<td>SP2</td>
<td>Technology Venture Capital (TVC)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Centres of excellence / Competence**

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<tr>
<th>Strategic Health Innovation Partnership (SHIP)</th>
<th>Seda Technology Programme</th>
<th>Technology Innovation Agency (TIA)</th>
<th>Green Fund - DBSA</th>
<th>Innovation Hub</th>
<th>Venture Capital - IDC</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>South African National Energy Development Institute (SANEDOI)</th>
<th>Partnership Scheme - DST</th>
<th>MCEP</th>
<th>Incubation Support Programme (ISP)</th>
</tr>
</thead>
</table>

**Figure 19. Government driven incentives and their area of function**

Detailed descriptions of each incentive are illustrated in Annexure A

As with designation, incentives are often used as part of wider industrial policy to encourage innovation and support local business. Such incentives can be target a number of different business functions ranging from research and development to different stages of the product commercialisation process.
5.5. Summary

As illustrated throughout this section there are a number of methods in which government policy can be utilised to increase demand of local manufactured medical devices. The basic framework and institutions for how this can be done are already well established, and by aligning institutions and government policy South Africa can strengthen the domestic medical device landscape.

**Figure 20. Policy and regulatory factors affecting the medical devices industry**

- Effective policy and incentives which encourage local manufacturing and R&D
- Recognition of need to improve regulatory environment
- Engagement in transnational regulatory forums for medical devices shaping domestic discourse
- Incentives that encourage Foreign Direct Investment (FDI)
- Introduction of National Health Insurance
- Recognition of need for better support of local manufacturers and innovators
- A rational preferential procurement policy, to boost local industry
- IP Bill in its present form will have significant implications for the medical devices industry
6. Complementary Services to Medical Devices

In order for the medical devices industry in South Africa to really thrive it is necessary for services allied to the sector also flourish. The ones of particular interest to the device sector are sterilisation, software design, packaging and labelling, post-market surveillance and privacy and security. All of these services are integral to improving the overall effectiveness of medical devices used in the healthcare system, particular high-risk and high-value devices.
6.1. Sterilisation

The ability to sterilise medical devices appropriately (both pre- and post-market) is considered an essential complementary service for the industry and is important in maintaining public health. A number of sterilisation methods are available for use by the South African medical devices industry.

<table>
<thead>
<tr>
<th>Sterilisation type</th>
<th>Sterilisation method</th>
<th>South African companies performing sterilisation</th>
<th>Assigned international sterilisation standard</th>
</tr>
</thead>
</table>
| Ethylene oxide     | • An alkaline agent that infiltrates packaged medical devices to kill microorganisms  
|                    | • Popular method of sterilization of medical devices | • Litha health through Medical Innovative technology  
|                    |                                                    | • GMS | • ISO 11135 – 1  
|                    |                                                    | | - Sterilisation of Healthcare Products – ethylene oxide |
| Gamma              | • Radiation-based  
|                    | • Performed by exposing the product to continuous Gamma Rays | • Synergy Health (formerly Isotron) – Outsourced sterilisation services  
|                    |                                                    | • Gammawave (as Gammalink) | • ISO 11137-1:2  
|                    |                                                    | | - Sterilisation of Healthcare Products – radiation |
| E-beam             | • Radiation-based  
|                    | • Performed by exposing the product to electron beams | • Not currently performed in South Africa  
|                    |                                                    | • Believed, however to be a quicker, more environmentally friendly | • ISO 11137-1:2  
|                    |                                                    | | - Sterilisation of Healthcare Products – radiation |
| Steam              | • Simple but very effective decontamination method  
|                    | • Products are exposed to saturated steam at high temperatures (121 to 134 degrees) | • Hospitals and Clinics perform their own steam sterilisation | • ISO 17665-1:2006  
|                    |                                                    | | - Moist Heat / steam Sterilisation method |
|                    | • ISO 14937:2009  
|                    | • ISO 20857:2010 | • Other International Standards  
|                    |                                                    | • ISO 25424-2009 Low temperature Steam and formaldehyde method |

Figure 21. Types of sterilisation and the international standards governing them

35 Rainbow Nation; Emergo Group.com; Iso-Inc; and SABS
6.2. Software Design

Electronic products have become more technologically advanced and more dependent on embedded software. Technical failure in such devices has the potential to cause serious injury and even result in death. It is therefore necessary for appropriately designed software to be used to prevent such failures or minimise the damage of adverse effects should they occur. In a South African context an appropriate course of action to ensure software works as intended would be the enforcement of International standards for developing medical device software of all classes.\footnote{ISO, org: \url{http://www.iso.org/iso/home.html}} \footnote{CM-DM.com: \url{http://blog.cm-dm.com/post/2011/11/01/ISO-and-IEC-standards-explained-to-software-engineers-and-quality-managers}}

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 13485</td>
<td>Generic and apply to every medical device, from the simplest plaster to the most complex surgeon robot</td>
</tr>
<tr>
<td>ISO 14971</td>
<td>Generic and apply to every medical device, from the simplest plaster to the most complex surgeon robot</td>
</tr>
</tbody>
</table>
| IEC 60601-1 | Apply to software, but not limited to it
Add requirements mainly about network, software interfaces and hardware |
| IEC 62366 | Apply to software, but not limited to it
Add requirements about usability |
| IEC 62304 | Harmonised standard for software development
With the standard being “harmonised”, medical device manufacturers adopting it will satisfy the essential requirements contained in the medical devices sector
Is identical to the EN / ISO variant in all essential details
Also expects the manufacturer to assign a safety class to the software system as a whole
Class A – No injury or damage to health possible
Class B – non-serious injury is possible
Class C - Death or serious injury is possible |

The majority of software development for medical devices appear to be done internally and through research completed it does not appear that the ISO 62304 standard is required nor enforced locally.

Figure 22 International Standards for Software Design
6.3. Packaging and labelling

Packaging and labelling can range in simplicity from separating products into individual or multiple units and as complex as providing specialised environments for highly perishable items. Medical devices are a highly heterogeneous grouping of products and as such following strict rules about how to best package and label them is advisable to ensure standardisation.38 39

Following international best practices for packaging and labelling and compliance with such will reduce barriers to entry into key export markets for South African industry.

ISO 11607
- Specifies the basic attributes that materials must have for use in packaging for terminally sterile medical devices
- Provides the producer or manufacturer the guidance to conduct a formal qualification and validation of the packaging operations
- There must be a documented validation programme that demonstrates the efficacy and reproducibility of all sterilisation and packaging processes, to ensure the package integrity at the point of end-use
- Also provides a series of recommended tests and criteria to evaluate the performance of the complete package under all of the stresses and hazards inherent in the packaging and distribution process and these tests are based on the ASTM international medical packaging standards.
  - The ASTM tests sets out the course of action to develop and standardise all test methods and practices applicable for conformance to ISO requirements. Test include, testing for;
    - Package integrity
    - Package Strength
    - Distribution, storage and aging (shelf life)

ISO 15223
- States that symbols are to be used with medical device labels.
- Symbols to be used with medical device labels, labelling and information to be supplied

ISO 15223-2
- Aims to improve the quality of symbols developed for use in labelling by providing guidance on symbol development and a robust test methodology that assures a symbol's suitability.

Figure 23. International Standards for Packaging and labelling

38 ISO.org: http://www.iso.org/iso/home.html
6.4. Post-market Surveillance and Privacy and Security

Post market surveillance, privacy and security of medical devices are key in ensuring medical devices best serve the needs of public health and patient interests. Medical devices can be complex assemblies of multiple components and the failure of any single component can lead to unexpected and serious safety problems. In order to lower risk it would be beneficial to have effective systems for monitoring safety after a device reaches the market in order to protect public health. The wider technological trend called the “internet of things” is also of importance because of the security risks involved in the integration and interaction of medical devices with the internet\(^40\)\(^41\)\(^42\).

### Post-Market Surveillance

**The Federal Drug Agency**

Has relied on physicians, healthcare institutions, patients and manufacturers to provide feedback about medical device failures through the Medical Devices Reporting System

Although the Centre for Devices and Radiological Health (CDRH) receives more than 10,000 reports per annum the proportion of failures is only reported to be 0.5% - limiting the information available regarding balance of risk associated with a said medical device

In 2007 the FDA was given regulatory authority to mandate follow-up safety studies after initial market approval

In 2009 the FDA also launched the Sentinel initiative – a programme to integrate the electronic health records of large representative US populations for post-market safety analysis. However, this has largely been focused on medications rather than medical devices

Very few other countries have taken such steps towards post-market surveillance as such the US model may prove a useful frame of reference when developing processes towards realising this

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40 Postmarketing Surveillance of Medical Devices – Filling in the Gaps: New England Journal of Medicine
41 Security and Privacy Qualities of Medical Devices - An Analysis of FDA Postmarket Surveillance: Harvard University DASH
42 Improving the Security and Privacy of Implantable Medical Devices: New England Journal of Medicine

Privacy and Security

Many medical devices are connected to the web, perform complex analyses, have sophisticated decision making capabilities, store detailed personal medical information and communicate automatically, remotely and wirelessly

This makes them susceptible to security breaches that could impair their functioning and endanger the health and safety of patients whilst also compromising their confidentiality and data protection

Implantable devices such as implantable defibrillators were also shown to be susceptible to unauthorised communication, potentially harmful device reprogramming and unauthorised data extraction

Many device manufacturers use safeguards such as data validation and user authentication to provide limited security from viruses, worms, and other threats. Some modern devices can also receive firmware upgrades for additional protection and to improve device functionality

Other types of potential security breach could involve flooding devices with waves of communication that disrupt their functionality or prematurely depleting energy in the battery

These types of breaches present serious threats to the functionality of medical devices going forward and as such it going to be necessary for the industry to develop a robust secondary services sector focusing on this issue

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*Figure 24. Issues surrounding Post Market Surveillance and Privacy and Security*
6.5. **Summary**

The underlying importance of a strong complementary services sector to the medical devices industry is essential to the sector's overall success. If the government strategy does not factor in the importance of these services to long term growth in the medical devices industry, the industry is not likely to be as effective.

**Figure 25. Complementary services that drive growth in the South African Medical Devices industry**

- **Up-scaling of local regulatory bodies to international standards**
- **Effective sterilisation of devices required to ensure local devices meet international standards**
- **The internet of things and smart medical devices increases demand for appropriate privacy measures for data integrity**
- **IEC 62304 and 60601-1 critical for local software used in medical devices to be of international standards**
- **Service and Maintenance of devices to international standards**
- **Packaging and labelling of devices to ISO 11607 and ISO 11523 necessary to ensure products are internationally accepted upon export**
- **Post-market surveillance of device to protect public Health**
- **Devices such as pacemakers have been shown to be susceptible to external interference. This increases demand for security measures**
7. Future Trends in Medical Devices

In order for policy to best support the long term trajectory of the industry, it needs to be informed by future trends. Policy that is informed by these trends, whilst being appropriately flexible to accommodate them will be best placed to ensure that new technologies are quickly and effectively regulated. It also has the added benefit of government being aware which emerging technologies currently at the forefront of medical device industry growth, allowing them to best targeted incentives, R&D and designation to ensure South Africa is a key FDI market.

Increasing use of mobile health devices, pressure to lower healthcare costs, digitisation of health, the blurring of lines between medical technology and pharmaceuticals and demographic changes are examples of changes that need to be taken into account when formulating policy and strategy.

Figure 26. Future Medical Device industry trends
Research to guide the development of strategy for the medical devices sector of South Africa
8. Stakeholder Engagement Findings

11.1. Development and Approach

Development of the questionnaires was integral in obtaining the necessary information from respondents to inform the strategy for the medical devices sector. The questionnaires were designed to ensure maximum input from the various industry stakeholders in accordance to their business function.

Two questionnaires were developed, a detailed questionnaire for firms engaging in the activities outlined in Figure 27 which was intended to deal with the supply side of the value chain; and a questionnaire for procurers (public and private) of medical devices to deal with the demand side of the supply chain.

The questionnaire was sent to 279 companies, which included manufacturers, importers / distributors and research and development firms. 88 responses were received fully completed.

A stakeholder workshop was held at the Deloitte Offices in Woodmead, Sandton, South Africa. Attendees included government depart (including the NDoH and dti); industry stakeholders and representatives from the academic field. Findings from the workshop have been incorporated into the themes highlighted below. The core purposes of the workshop were to validate and prioritise findings and recommendations that had been arrived at throughout the research.

Figure 27. Percentage of responding firms engaging in the surveyed business functions

- Manufacturers
- Importer / distributor
- Assembly
- Consulting
- Research & Development
- Training
- Servicing & Repair
- Software Development

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Figure 27. Percentage of responding firms engaging in the surveyed business functions

- Manufacturers
- Importer / distributor
- Assembly
- Consulting
- Research & Development
- Training
- Servicing & Repair
- Software Development
28 procurement questionnaires were circulated to private hospital groups, the National Department of Health (NDOH) and healthcare associations to distribute to their member base.

The number of questionnaires distributed by the associations to their members is unknown as their member base is confidential. 26 procurement questionnaires were returned completed.

Based on feedback from both questionnaires, a select number of individuals / companies were identified for further questioning, which were performed via face to face or telephonic interviews in order to collect additional supporting information.

In order to protect sensitive information but still allow for comprehensive analysis, all data was aggregated and anonymised prior to analysis and reporting.

Figure 28. Diagrammatic representation of the questionnaire formulation process
11.2. Industry Analysis

11.2.1. Challenges facing the South African Medical devices sector

Although there are certainly challenges facing the medical devices sector in South Africa, confidence in the sector remains high and respondents believe there are opportunities for these challenges to be transformed into a competitive advantage if the correct approach is taken.

Lack of government support for local companies was highlighted as the primary challenge facing the sector. The high cost of having to comply with international regulations and the lack of local regulations in South Africa were also raised as a major concern. Specific mention was made that the lack of local regulatory standards allow for low quality products to enter the market, which undermines the efforts of local manufacturers.

From a human capital perspective there is a shortage of skilled and semi-skilled labour within certain areas of medical device manufacturing. In the face to face interviews further mention was made that until the lack of skilled and semi-skilled labour is resolved, manufacturing of even the simplest of low technology products would not be viable.

Of less concern was labour unrest in this sector. However it was highlighted by large organisations, those recent events in the motor industry, decreases confidence for international manufactures to enter the South African medical device manufacturing market.

Labour and production costs in South Africa are also considered to be relatively high compared to other emerging countries. This has an influencing factor as to whether local medical device manufacturing companies can compete in local and/or international markets producing either low or high technology items.

Access to project funding was further raised as a concern. It was noted manufacturers were unaware of all incentives available to them and felt minimal support and responsiveness was provided during the government incentive process. It was also noted that the institutions offering incentives often lacked funds.

Of less concern at this point are access to scientific and communication technology and the IP policy.

Workshop Insights:

- South African operational costs are considered high in terms of factors such as labour and freight. Especially compared to markets such as India and China
- Market size of South African industry is small and thus inhibits local companies from investing in the likes of Research & Development and clinical trials.
- Some participants noted that in order to implement immediate changes to the industry it may be necessary for the private sector to take serious steps towards self-regulation.
Factors questionnaire respondents believe can be transformed into a competitive advantage include: access to the local market, geographical location, better collaboration with government, and development of local technology.

Although lack of government support is rated by respondents as one of the biggest challenges facing the industry, respondents encouragingly believe through better collaboration with government this can be negated.

Another area respondents felt could be turned into a competitive advantage, is the private sector, government and higher learning institutions collaboratively working together to help establish a strong national scientific and research culture. The objective of which is assisting in creating a competitive advantage in development of local technology. Development of a research culture may also help in resolution of human capital related concerns in terms of access and availability of skilled labour.

Interview and questionnaire respondents also indicated that local companies could be more competitive at a domestic and international level through more generous government incentives. This includes, but is not limited to: tax incentives, depreciation incentives and investment incentives – all of which were highly favoured by respondents.
11.2.2. Factors, which would assist in promoting growth of the medical devices sector in South Africa

The intention to diversify production, increase employment, form joint ventures and expand into foreign markets is indicative of companies being confident about future growth. All of these were noted as strategies to be pursued in the future by a large number of respondents to the detailed questionnaire.

Workshop Insights:
- Looking at models for industrial support in the country such as those implemented in the auto industry may provide replicable ways to invigorate the medical devices industry
- The medical devices sector needs to ensure it keeps strongly pursuing better relations with government at all times

Strategies over the past 5 years, and Intention for the next 5 years

Figure 30. Historically used future intended business strategies
11.2.3. Government Incentives and Growth

Effective government incentive offerings and awareness of them will go a long way in growing the medical devices manufacturing sector.

Less than half of respondents who approached or utilised government incentive schemes provided positive feedback. Negative feedback regarding incentives included that they were of “no benefit to the industry”, the specific incentive approached “lacked funds”, “unresponsive” and “little support offered through the process”.

Those who did not apply for government incentives, stated they were not aware of them, that there was too much “red tape”, “what was required was not on offer” and lastly “financing was acquired from international head office”.

Workshop Insights:

- Increased awareness of incentives highlighted as crucial by a number of participants.
- In cases where companies are aware of incentives the process of applying and obtaining them was often viewed as laborious. It was therefore noted that the bureaucratic processes around utilising incentives need to be made more streamlined.
- Regulation of funding bodies such as the TIA also noted as needing to be more robust and transparent.

Institutions providing incentives approached or utilised in last five years

Figure 31. Government incentives and the percent of respondents reporting having used them
11.2.4. The Regulatory Environment

The regulatory environment or lack thereof, is a key issue for manufacturers in South Africa. It should be considered an issue of paramount importance to be addressed for the development of the medical devices sector.

The overarching response was that local regulations are required, but that they need to be aligned with international best practices. It was also noted that once local regulations are implemented, they need to be strictly enforced and quality measures need to be implemented to prevent dumping of inferior goods into the market.

Respondents believe that international regulatory accreditation such as CE (Conformite Europeenne) marking and FDA approval should be recognised locally and should mitigate the need for additional local accreditation.

Additionally respondents believe there should be a government subsidy put in place to assist local manufacturers to achieve international accreditation, for items such as ISO13485.

The majority of respondents believe that the ISO13485 standard should be a compulsory local standard. The concern however is that the cost of obtaining the ISO13485 standard is high and that a possible solution may be to obtain local representatives for testing in the manner of CE and FDA approval. Additional concern from respondents is that they do not believe that government institutions such as the NDoH, SANAS and SABS have the capacity to enforce implementation of regulatory systems.

**Figure 32. Respondents estimated annual spend on regulatory fees**

<table>
<thead>
<tr>
<th>Regulatory Body</th>
<th>Estimated Spend (Rand)</th>
</tr>
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<tbody>
<tr>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td>ISO 13485</td>
<td>100000</td>
</tr>
<tr>
<td>ISO 9001</td>
<td>200000</td>
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</tr>
<tr>
<td>SABS</td>
<td>200000</td>
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<tr>
<td>TGA</td>
<td>0</td>
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<tr>
<td>FDA</td>
<td>200000</td>
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<tr>
<td>CE Marking</td>
<td>200000</td>
</tr>
</tbody>
</table>

**Workshop Insights:**

- ISO 14971 (Risk Management Standard) and IEC device safety and performance standards were highlighted as additional industry standards to consider.
- SABS partnering with other regulatory/notified bodies in order to help scale up domestic QMS capability may help resolve issues around local certification.
- DTI subsidising SABS testing should be considered as an incentive for local manufacturing.
11.2.5. Employment within the medical devices sector

Medical device companies in South Africa are predominantly made up of small medium sized enterprises (SMME’s) employing between 1 and 50 individuals.

Results from the detailed questionnaire revealed that the average number of individuals employed by medical device companies in South Africa was 52. However, this figure was skewed by a few organisations with a large employee base. Results from the survey revealed the median of individuals employed by medical device companies in South Africa is 14 – highlighting the importance of measures to support small business.

11.3. Manufacturer Analysis

11.3.1. Barriers to entry

A number of barriers exist in entering the medical devices manufacturing market, and government’s assistance in addressing these must be prioritised. According to respondent the current regulatory environment (or lack thereof) as well as government policies, are some of the biggest barriers to entry into the market.

Cost and quality of raw materials are another significant factor for manufacturers to consider when setting up manufacturing facilities locally. Local raw materials do not always meet the necessary specifications / international quality standards, in order to be utilised in medical products. For this reason a large portion of raw materials are imported, despite a number of these being mined in South Africa.

Skilled personal was rated highly as a barrier to entry and to a lesser extent cost of labour. Further confirming previously noted views that human capital supply is a key issue that needs to be tackled.

Figure 33. Scoring for barriers to medical device manufacturing in South Africa

Concerns surrounding corruption within the industry as well as public sector reliability of payment were also mentioned as areas of concern. Resolution of these concerns will be critical in driving the domestic industry going forward.

Workshop Insights:

- It was noted that clearer description of what is considered manufactured is needed. I.e. Does manufacturing refer to the whole process from core value addition to raw material to assembly? Or can it refer to assembly alone?
- Business models in which products can be locally manufactured under licence need to further investigated.
- Collaboration between private sector players could have a positive effect in lowering costs. An example of such could be shared investment into the establishment of mutual testing facilities
5.1.2 Geographic location of local manufacturers

Provinces where manufacturing facilities are currently located

Figure 34. Geographic distribution of questionnaire respondents

The majority of responding manufacturers presently in the market are located in Western Cape and Gauteng. A sizeable number of firms are also located in the Kwa-Zulu Natal area.

The concentrated geographic clustering of responding firms may present opportunity for leveraging on spatial proximity to share services and find synergies between firms.
11.3.2. Barriers to Exporting South African Manufactured Medical Devices

80% of respondents rated regulatory compliance as the most significant barrier to exporting medical devices from South Africa. High export costs and fluctuations in the exchange rate were also mentioned as contributing factors.

In terms of countries where medical devices are being exported to, although Sub-Saharan Africa is the most significant destination for export, from a financial perspective, income generated from export to North America and Europe is higher than to other areas of the world.

11.4. Quality Systems Analysis

11.4.1. Effects of enforcement of local regulatory and quality management standards

Questionnaire results show that most importers/distributors were not worried about the enforcement of standards in the South Africa medical devices market, since the responding companies are largely already compliant with some form of international regulatory standard (e.g. CE mark, FDA or TGA).

When questioned about what would have the maximum effect on their business if it were implemented as a local requirement, ISO13485 was highlighted as having the most significant potential effect (Score of 5 signifies maximum effect, whilst 0 is no effect).

SABS approval was rated to have the second highest potential impact. Concern was raised that if an SABS standard became compulsory, and international standards were not recognised, this would increase market entry costs due to duplication.

Respondents felt that if local standards were to become compulsory, international accreditation should be acceptable and should mitigate the need to comply with a local standard and that they should be fast tracked through any local medical device regulatory process.

Figure 35. Effects of enforcement of quality standards
11.5. Research and Development

11.5.1. Critical factors for growth of the research and development sector

Government Incentives were once again highlighted by questionnaire respondents as a primary concern and as a priority requirement for growth of the R&D sector in South Africa.

Human capital was also of critical concern in terms of access of the appropriate skills to perform R&D to an internationally required standard. One company mentioned collaboration with universities as being a potentially effective way of increasing R&D output, but another company stated that they are currently spending a lot of their R&D budget with overseas universities because local ones do not know how to conduct trials to an international standard.

Costs related to both material and labour was highlighted as factors limiting growth of the R&D sector and relate back to their biggest concern in terms of lack of government incentives to support R&D.

A number of interviewed stakeholders also advised that countries and companies who are looking to increase their competitive advantage and produce more hi-technology products should strategically invest in R&D.

Workshop Insights:

- Government should look to create incentives aimed at increasing the number of partnerships and deep linkages between academia and the private sector
- Academia and the private sector tend to have very different objectives (research publications vs commercialisation) and this can prevent them from leveraging their strengths for mutual benefit
- Government should look to encourage the creation of R&D incubators, possibly in Special Economic Zones (SEZ), by providing financial or tax incentives at both a corporate and individual level

5.1.2 Intellectual property and the effect on the R&D sector

The majority of responding companies engaging in medical device R&D in South Africa also noted that they feel that IP rights in South Africa are in line international norms and standards.

Respondents feel current IP protection in South Africa is in line with international norms and standards

![Figure 36. Respondent views on IP protection in South Africa](image-url)
11.6. Complementary Services

11.6.1. Availability and use of local complementary Services

A strong local complementary services industry including the likes of assembly, packaging, sterilization, service and maintenance to name but a few, are critical for the growth of the medical devices industry to its full potential.

Sterilisation, packaging, service and maintenance and assembly proved to be the most popular operations that respondents noted they would be willing to use shared services for.

Respondents who currently use or would use a range of shared services

![Graph showing use and potential use of shared services]

Workshop Insights:

- Importance of locally manufacturing and procuring medical grade plastics, titanium and other metals/compounds used in medical devices was noted.

Figure 37. Respondent views on Shared Services
11.7. Procurement

11.7.1. Medical device purchasing considerations

It is self-evident that consumers are required for the growth of any industry or product. It was thus of vital importance to obtain a view of what medical device purchasers considered important when purchasing these products, and how they felt about locally manufactured medical devices fared against these considerations.

Overall, the responses to the procurement questionnaire indicate that medical device procurers are willing to support local medical device manufacturers. Nonetheless, certain concerns which hinder higher confidence in South African manufacturers remain.

*Importance of general considerations for medical device purchasing decisions (Scale 1-5)*

- Quality standards
- Access to spare parts
- Regulatory environments
- End user product preference
- Brand perception
- Deliver/lead time
- Cost
- Training
- Servicing and maintenance
- Availability of supply

These concerns include the:

- Quality of products is deemed by procurers as the most important consideration when purchasing medical devices, followed by servicing and maintenance, training and cost of medical devices respectively.
- Availability of supply and access to spare parts followed, receiving equivalent average ratings.
- The availability of supply, staff training requirements and servicing and maintenance are amongst the six most important purchasing considerations; however local manufacturers were found to perform poorly against these factors, receiving the lowest ratings.
- Ratings for performance of local manufacturers against purchasing considerations are generally poor, with procurers who purchase no products from local manufacturers giving the lowest scores across all considerations.
- Of concern to procurers who do not currently purchase equipment from local manufacturers, is the availability of specific equipment they require, branding and the staff training required to operate equipment, together with the availability of servicing and maintenance of that medical equipment.

Workshop Insight:

- Some participants felt that there are a large number of procurers who are willing to buy from companies that do not observe appropriate compliance standards.
- An information repository is required to note who the local manufacturers are and what they are locally producing.
- There is a perception that local products are of inferior quality and a marketing drive and adherence to international standards is thus required to change such perceptions.
8.7.2. Views on medical device procurement as expressed by public entities

Barriers to procurement of local goods

Corruption (including fly-by-night business activities) is viewed as a major factor in the medical devices industry and a threat to the supply of vital medical equipment. Certain public entities have suggested that risks of fly-by-night companies could be mitigated by a structure similar to the MCC but specifically for medical devices.

Furthermore, locally manufactured medical equipment is perceived to be of lower quality than some other destinations. Public procurers are also concerned about the lack of adequate post-sale support and secondary services from local manufacturers.

Preferential procurement policies

Public entities comment that an evidence based policy making decision should be made with regard to preferential procurement. It was suggested that only devices which have been shown to have a likely positive economic effect, whilst not adding significant cost pressure to procurers, should be considered for preferential procurement using policies such as designation. A further suggestion put forward states that as opposed to designation, tax credits may be offered to make manufacturers more competitive on price.

Quality and safety regulations

FDA and CE markings are accepted, but customised post-marketing surveillance is often required to ensure tailoring and usability of equipment under unique South African conditions. Such conditions include weather, strains of microbes, load shedding incidents and physical features of the indigenous African Population. Public entities are of the opinion that products and manufacturing sites should be required to be evaluated by procurers prior to purchase.

Clinical Evidence

Bidders are required to exhibit all academic publications as clinical evidence on their medical devices for consideration by procurers. This helps to give credibility to the products in question, and enables procurers to ignore unsuitable untested and subsequently unreliable products, to focus further evaluation efforts solely on products that meet basic requirements and standard.

Workshop Insight:

- Perverse incentives in the public sector are seen as playing a key role in local manufacturers being from lucrative public sector purchases. Examples of such incentives include large international manufacturers inviting purchase managers to conferences or providing user training.
- Some form of incentive to encourage public procurers to purchase from local manufacturers is required. Possibly a tax incentive of some sort in order to allow local products to compete with international ones on price.
- Security of supply deemed to be of paramount importance and more critical than willingness to purchase from local producers.
Research to guide the development of strategy for the medical devices sector of South Africa.
## 12. Strategy Recommendations

### 9.1. State Business Relations

Effective state business relations are required to foster collaboration, which in turn can be used to ignite growth of the industry. If this is not pursued and key stakeholders continue to work as separate entities, the industry will continue to underperform.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Establish a quarterly forum between key government and private sector stakeholders within the medical devices industry. Such a forum would work best if it had clear agenda setting and accountability mechanisms in place to ensure that timely action is taken on agreed upon resolutions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present State</td>
<td>There is currently no formal structures for regular collaborative engagement between government and the private sector. As a result interactions between government and the industry are often disjointed and opportunities for effective collaboration for the benefit of stakeholders on both sides are limited.</td>
</tr>
</tbody>
</table>
| Solution | a. Establish a formal structure for better State-Business relations between key medical device industry stakeholders  
  b. Appoint an inter-ministerial champion to ensure leaders of medical device related collaboration across government departments are kept account and judged on performance based measures. |
| Intended Outcomes | The intended outcome of such a forum would be the fostering of improved collaborative and target based interactions between government and private sector. If managed effectively such interactions could potentially contribute a great deal in growing the domestic industry and making it more attractive for both local and foreign investment. |
### 9.2. Regulations and Quality Management Standards

Effective regulatory policy and processes lies at the heart of competitive industries. As previously mentioned, South Africa currently has no established regulatory framework or mandatory quality standard for all medical devices enforced by government. All such regulation is left at the discretion of individual procurers.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Present State</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Introduction of an internationally graded ISO 13485 as a compulsory Quality Management Standard for all local manufacturers (South African owned companies).</td>
<td>South Africa does not currently have any regulatory or Quality Management Standards (QMS) for the medical devices sector and the ISO 13485 currently accredited by SABS does not conform to international standards nor is it enforced in South Africa.</td>
<td>Introduction of ISO 13485 to an international standard as a compulsory requirement for all South African based medical device manufacturers. This will be best applied to all medical devices with the exception of low risk (Class A) devices as defined by the latest International Medical Device Regulator Forum (IMDRF) risk classification nomenclature; class A devices being those that are not required to be sterile and are without measuring function. Upon accreditation, companies following this will be awarded with a certificate for South African market entry. The certification for market entry of medical devices within South Africa should be awarded at a low cost nominal fee (administration fee) by the government consigned medical devices regulatory authority upon gaining ISO 13485. The additional benefits is that it would lower costs of gaining other internationally recognised accreditation (e.g. CE mark and FDA approval) because ISO 13485 will ensure that the majority of FDA and CE requirements are met.</td>
</tr>
<tr>
<td>3. Mutual recognition of medical devices approved by well-established foreign regulatory bodies</td>
<td>At present there is no official government policy for mutual recognition of devices approved by internationally recognised bodies such as the FDA or CE. Recognition of such accreditation is completely down to procurer discretion</td>
<td>Formulation of a process that will allow local recognition of medical devices that have achieved ISO 13458 standards or alternatively accreditation by a well-established international regulatory body such as the FDA, EC or TGA. Fulfilment of these requirements will allow the appropriately accredited medical devices to be fast-tracked for certification of South African market entry for a low cost nominal fee (administration fee).</td>
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<tr>
<td>4. Engagement in Transnational Medical Device Forums</td>
<td>South Africa is currently a member of the Asian Harmonisation Working Party and the Pan-African Harmonisation Working Party. However, there are no clear moves of government policy being harmonised with the resolutions and recommendations of these forums.</td>
<td>Deeper engagement in Transnational Forums to ensure South Africa can remain abreast with international best practice and discourse. This will also provide the opportunity for South Africa to contribute to, and potentially shape international discourse and decision making with regard to the medical devices industry to its own benefit.</td>
</tr>
</tbody>
</table>
9.2. Regulations and Quality Management Standards

<table>
<thead>
<tr>
<th>Intended Outcomes</th>
<th>Enforcement of the solution above would ensure South African manufacturers become aligned with international standards and manufacturing best practice and ensure that local production is less likely to be of poor quality.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reducing duplication of market entry cost for medical devices that have already undergone a similar accreditation process and have already been proven as safe to use by reputable standards. This would have the additional use of ensuring the South African market remains business friendly despite implementation of regulations. Introduction of such standards would also limit poor quality products entering the country whilst simultaneously ensuring that good quality medical devices are not inhibited from entering the market.</td>
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<tr>
<td></td>
<td>Greater engagement in such forums will ensure South African regulators have better understanding of global regulatory issues; it also allows government to table proposals that suit South Africa’s interests.</td>
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</table>

9.3. Customs logging

A common problem at trade ports is that not all trade is logged to an 8-digit level. This limits the depth of analysis that can be done.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Record all customs data to an 8-digit HS level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present State</td>
<td>Availability of customs data to a product specific 8-digit HS level is only available for a limited number of products. As a result it is not always possible to fully define the exact types of products making up the bulk of trade. This is a significant limitation when looking at issues such as import composition with view of identifying what products are the main contributors to the trade deficit.</td>
</tr>
<tr>
<td>Solution</td>
<td>Accurate recording of trade customs data to an 8-digit HS level at all trade ports.</td>
</tr>
<tr>
<td>Intended Outcomes</td>
<td>Better quality data to ensure more comprehensive and representative data can be extracted for further analysis.</td>
</tr>
</tbody>
</table>
### 9.4. R&D and Manufacturing Incentives

In order to create a more favourable investment climate it is necessary to have appropriate and efficient incentives for local manufactures to flourish and also attract manufacturing FDI.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>More attractive incentives for local manufactures</th>
<th>Comprehensive economic analysis on the effects of various designation methodologies and how they could be effectively implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present State</td>
<td>There are currently various available incentives for local manufactures. However, insights from the research manufacturers’ questionnaire reveal that it is commonly felt that the processes surrounding access to these incentives could be made more efficient. A number of other questionnaire respondents also signified that they were not aware that the incentives were available. Other challenges highlighted in terms of how incentives are currently structured and administered include: lack of support or start-up companies, no notable incentives to encourage FDI and current support for activities such as R&amp;D is not as effective as it could possibly be.</td>
<td>As previously outlined in section the PPPFA contains provision for designation in the procurement process. There is however no policy for the procurement of medical devices in which designation is implemented.</td>
</tr>
</tbody>
</table>
| Solution | 1. Benchmarking the effectiveness of South Africa’s incentive programmes against other countries.  
2. In order to improve efficiency of existing incentives an audit of the current processes should be carried out, with view of identifying bottlenecks in the system.  
3. The proposed quarterly forum between government and the private sector could also be used as platform for finding more effective channels for increasing awareness of the available incentives.  
4. Lower corporate tax for local start-up companies to help reduce the chances of failure.  
5. Implementation of a medical device specific customs rebate incentive similar to the Motor Industry Development Plan (MIDP) incentive in order to lower inbound supply and production costs for local | A viable strategic objective could be to use the designation clause in the PPPFA to encourage procurement of local produce. Using designation in this manner would increase demand for local production. If appropriately taken advantage of local manufacturers may then be in a better position to invest more into increasing production and into R&D.  
However, before such a policy is implemented it is necessary for an evidence based decision to be made on how the designation process would be best implemented. This would require a comprehensive economic analysis for overall viability of designation and, if pursed, what types of locally manufactured medical devices can be most effectively designated from a cost and health quality perspective. |
9.4. R&D and Manufacturing Incentives

<table>
<thead>
<tr>
<th>Intended Outcomes</th>
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<tbody>
<tr>
<td>A more efficient and competitive incentive system would support growth.</td>
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<td>The comprehensive economic study would ensure that all designation decisions are made on the basis of solid empirical evidence and thus justifiable; further to this, projections of how the decisions could impact the government fiscus and costs to the department of health (and thus potentially affect healthcare service deliver) could also be taken into account.</td>
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<tr>
<td>manufacturers.</td>
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<tr>
<td>6. Use of Special Economic Zones to incentivise production at a lower corporate tax rate for foreign and local manufacturers.</td>
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<tr>
<td>7. A more effective R&amp;D incentive to encourage new product development and new technology in the long term.</td>
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<tr>
<td></td>
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<tr>
<td>8. Tax rebate for public and private procurers purchased devices from local medical device manufacturers in order to lower costs and help local companies become more cost competitive.</td>
</tr>
</tbody>
</table>
9.5. Human Capital Development

Human capital development is fundamental if South Africa is to develop its basic manufacturing base with view of further industrialisation into hi-technology manufacturing. Without the issue of skills development being addressed the other recommended policies are not likely to have as far reaching effect. The dti would do well to position itself as a champion of investment into upgrading the skills of the population to meet current and future demands for medical device innovation and production.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>More effective Skills and Research Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present State</td>
<td>South Africa currently has a shortage of semi-skilled and skilled labour compared to international standards (including other emerging markets). Spending on R&amp;D as a percentage of GDP is relatively low.</td>
</tr>
</tbody>
</table>
| Solution | Increase spending on R&D in both public and private sectors through the following interventions:  
1. Direct investment into medical device incubators for subsectors in the medium and high technology ranges.  
2. More investment and effective delivery of maths and science teaching at all levels of the education system.  
3. Encouraging Interdisciplinary capabilities across industries, which help realise synergies with view of future technological trends in the medical devices industry.  
4. Knowledge transfer and the continuous flow of research between public and private research institutions. |
| Intended Outcomes | As previously highlighted, having a better skilled labour pool will ensure that costs of high value addition during manufacturing are lowered. Investment into maths and science is likely to increase the chances of success in the funding of R&D - both within firms and in those using shared services such as R&D incubators. If properly managed such outcomes would significantly contribute to ensuring the South African medical devices industry more globally competitive. |
9.6. Additional Research Required

In order for the recommendations made this far to be effective, it is necessary for them to be implemented with future trends in mind, further supplemented by a short and long term vision. It is important to note that issues raised in sections 9.1 to 9.4 be addressed, otherwise the underlying conditions for working towards a future vision will not be appropriate.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Short term targets/Low hanging fruit</th>
<th>Long term targets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low hanging fruit can be defined as products that do not require significant capital investment or rare technical expertise to manufacture. As a result manufacture of such items is often high volume and subject to considerable cost pressure. These types of items are the most appropriate targets for short term intervention in order to address issues surrounding the trade deficit.</td>
<td>Due to the extent of South Africa’s reliance on medical device imports the task of reducing the need by stimulating local production is likely to require well targeted long-term intervention based on long term trends. It is also necessary for such intervention to focus on market sectors that are in a growing global market and to be of high added value. South Africa currently has minimal amounts of high value added manufacturing, with the exception of companies such as Lodox. Lack of fixed capital investment and scarcity of skills is often cited as a reason for South Africa having a minimal presence in this space.</td>
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</tbody>
</table>

| Present State | Based on the scoring criteria developed various forms of medical dressings, rubber surgical glove, and syringes and needles form the most viable products for manufacturing in the short term. Please refer to Annexure B for details on the scoring system. | Based on the scoring system developed Electromedical and Electrotherapeutic apparatus are deemed the most viable targets for long term intervention. Please refer to Annexure B for details on the scoring system. |

| Solution | Government should identify South African manufacturers in these product categories and give them preferential support using the basket of incentives currently available. In addition to this government should look to attract foreign investment in these products where possible. Attracting foreign investment using the additional incentives to be provided by SEZ’s may be an effective approach to take, in trying to attract investment from foreign multinationals and could potentially have the additional benefits of knowledge transfer within South Africa and open up business opportunities for local suppliers of primary and secondary inputs. | In order for targeting growth in local manufacturing in this sector, government first needs to ensure that the regulatory framework in South Africa is brought in line with international best practice and made effective; and also that skills development and education is made a priority. Once these factors have been achieved combinations of private and public research into how products in the Electromedical and Electrotherapeutic Apparatus markets can be developed and commercialised must be focused on. Where possible FDI by firms operating in this industry should also be welcome as a means of encouraging the necessary knowledge transfer into the local labour pool and potentially be tapped into in the long term. |
9.6. Additional Research Required

The intended outcomes of this would be a degree of short term relief on the reliance of imports within these categories, due to local producers taking up some of the market. If the appropriate regulation is put into place as detailed in recommendation 2, then the companies that grow or are formed as a result of such a policy may also then be manufacturing medical devices that are suitable for the global market and can pursue an export growth led strategy to tap into the wider market and thus not only lower reliance on imports but also increase exports – having a dual effect on the trade deficit. The size of the global market gives legitimacy to such a strategy being pursued.

The intended outcome of implementation of the solutions above is that the private sector would be given adequate support to ensure that attempted to enter the Electromedical and Electrotherapeutic Apparatus markets are more likely to succeed. However, it must be re-emphasised that addressing issues around human capital development and regulation and quality management standards need to be resolved in order for this to succeed.

<table>
<thead>
<tr>
<th>Surgical Appliances and Supplies</th>
<th>Defined product</th>
<th>Size of imports</th>
<th>Local market size</th>
<th>Global market size</th>
<th>Ease of production</th>
</tr>
</thead>
<tbody>
<tr>
<td>H300510: Medical dressings etc having an adhesive layer</td>
<td></td>
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<tr>
<td>H300590: Medical dressings etc except those having an adhesive layer</td>
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<td></td>
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<tr>
<td>H401511: Rubber surgical gloves</td>
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</table>

<table>
<thead>
<tr>
<th>Surgical &amp; Medical Instrument Supplies</th>
<th>Defined product</th>
<th>Size of imports</th>
<th>Local market size</th>
<th>Global market size</th>
<th>Ease of production</th>
</tr>
</thead>
<tbody>
<tr>
<td>H901831: Syringes, with or without needles</td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td>H901832: Tubular metal needles and needles for sutures</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>H901839: Needles, catheters, cannulae etc (medical)</td>
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</tbody>
</table>

Figure 39. Low Hanging Fruit
In order for South Africa to rebalance its medical device trade as much as possible it is necessary for South African manufactured products to enter global supply chains and key growth markets. Please see Annexure B for target markets.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Target High Growth Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present State</td>
<td>Medical device exports are minimal and it is not clear whether a significant proportion of exports are products manufactured in South Africa or if these are re-exports (imports that are subsequently exported). Case Study evidence highlighted China, the United States, India, Japan and Germany as key growth markets for the future.</td>
</tr>
<tr>
<td>Solution</td>
<td>The dti should promote and increase the amount of funds provided in its Export Marketing and Investment Assistance scheme (EMIA) to help South African firms that are looking to enter key growth markets. The dti should also look to provide financial assistance to help cover regular costs for market entry into these countries where applicable.</td>
</tr>
<tr>
<td>Intended Outcomes</td>
<td>Market entry of South African firms into high growth markets will contribute to efforts to rebalance trade in medical devices. If accompanied with effective regulation within South Africa to ensure local manufacturers are in line with international standards and best practice, entry into these markets may also have the additional benefit of growing the South African brand and positioning it as a reputable high quality one.</td>
</tr>
</tbody>
</table>
9.8. Additional Research Required

Due to the limited scope of this research exercise a number of other ways in which the medical devices industry could be better understood became apparent. The key issues gaps highlighted in the research here are as follows:

1. Lab Equipment such as microscopes and petri-dishes that are used in medical diagnostics were not included in the study, however this could also be a considerable contributor to the trade deficit.
2. Medical device industry statistics of the key growth markets do not breakdown which medical devices classifications are the main drivers for growth in these markets. It is necessary to know this to ensure that South African manufacturers that target these countries are entering high growth sectors within.
3. Whether or not a significant proportion of exports are actually re-exports is not clear. This has the potential to skew the value of the findings and inhibit accurate insight to be obtained.
4. A strong complementary services industry is required for the wider medical devices industry to be grow and thrive. However, scope for extensively researching this was limited in this study.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Future studies to better understand the medical devices market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present State</td>
<td>Medical device exports are minimal and it is not clear whether a significant proportion or not of exports are products manufactured in South Africa or if these are re-exports (imports that are subsequently exported). Case Study evidence highlighted China, the United States, India, Japan and Germany as key growth markets for the future.</td>
</tr>
</tbody>
</table>
| Solution | Research exercises looking at the following should be considered:  
1. Study for lab equipment  
2. Study into global trends to see which markets and sectors are really growing  
3. Study to clarify the issue of re-exports  
4. Study into the state and potential future role of complementary services |
| Intended Outcomes | The key outcomes of such studies is that they would provide greater understanding of the wider medical devices industry and where intervention by government can be made to assist growth. |
13.9. What does South Africa need to create a thriving Medical Devices Industry?

In sum it can be said that in order for the dti to help support the medical devices industry in South Africa it is necessary for the factors listed below to be given the utmost focus.

![Figure 18. Factors required for a competitive and thriving medical devices industry](image)

Should the appropriate action be taken Deloitte is confident that South Africa could develop a globally integrated and competitive medical device industry.