DRAFT OF THE SOUTH AFRICAN MEDICAL DEVICES MASTERPLAN – VALUE CHAIN

2024

Liako Mofo
Gillian Chigumira
Wendy Nyakabawo

TIPS supports policy development through research and dialogue. Its two areas of focus are trade and inclusive industrial policy, and sustainable development.

info@tips.org.za
+27 12 433 9340
www.tips.org.za

Authors

Liako Mofo
TIPS Senior Economist

Gillian Cigumira
TIPS Senior Economist

Wendy Nyakabawo
TIPS Economist

CONTENTS

Disclaimer

ABBREVIATIONS

CNAS	China National Accreditation Service for Conformity Assessment
CT	Computerised Tomography
DSI	Department of Science and Innovation
DST	Department of Science and Technology
dtic (the)	Department of Trade, Industry and Competition
EMIA	Export Marketing and Investment Assistance
FDI	Foreign Direct Investment
GGDA	Gauteng Growth Development Agency
GIPD	Grants, Innovation and Product Development (unit)
GIDZ	Gauteng Industrial Development Zone Company
GMP	Good Manufacturing Practices
IDC	Industrial Development Cooperation
IT	Information Technology
IMF	International Monetary Fund
GFCF	Gross Fixed Capital Formation
GGDA	Gauteng Growth and Development Agency
MDMSA	Medical Device Manufacturers of South Africa
MeDDIC	Medical Device and Diagnostic Innovation Cluster
MRI	Magnetic Resonance Imaging
NEF	National Empowerment Fund
NHI	National Health Insurance
NT	National Treasury
PPE	Personal Protective Equipment
R&D	Research and Development
SADC	Southern African Development Community
SAMRC	South African Medical Research Council
SAHPRA	South African Health Products Regulatory Agency
SAVCA	Southern African Venture Capital and Private Equity Association
SIC	Standard Industrial Classification
SPII	Support Programme for Industrial Innovation
TIA	Technology Innovation Agency
TBT	Technical Barriers to Trade
WHO	World Health Organization
WIPO	World Intellectual Property Organization

GLOSSARY

Authorised Representative	Authorised representative means a natural person, resident in the Republic of South Africa, who a) has the written mandate to represent a manufacturer, distributor or wholesaler in the Republic; b) c) acts on behalf of a manufacturer, distributor or wholesaler, for specified tasks with regard to the latter's obligations and in whose name the manufacturer license, distributor license, wholesaler license or certificate of registration is issued; and is responsible for all aspects of the medical device, including performance, quality, safety and compliance with conditions of registration or clinical trials, where relevant.
Classification rules	The classification rules for medical devices other than IVDs depend on the features of the device, such as whether it: • is life supporting or sustaining; • is invasive and if so, to what extent and for how long; • incorporates medicinal products; • incorporates human or animal tissues or cells; • is an active medical device; • delivers medicinal products, energy or radiation; • could modify blood or other body fluids; • is used in combination with another medical device
Risk classification of medical devices	• Class A – low risk • Class B – low to moderate risk • Class C- moderate to high risk • Class D – high risk, where risk relates to patient or public health
In Vitro Diagnostic IVD	IVD means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
Manufacture	Manufacture means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, labelling, and refurbishing of a medical device or IVD, and includes putting a collection of IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls.
Manufacturer	Manufacturer means (i) a natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his or her behalf by a third party; (ii) or any other person who assembles, packages, reprocesses, refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD, with a view to their being placed on the market under the natural or legal person's own name, except a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients.

Medical device	Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: • diagnosis, prevention, monitoring, treatment or alleviation of disease; • diagnosis, monitoring, treatment, alleviation of or compensation for an injury; • investigation, replacement, modification or support of the anatomy or of a physiological process; • supporting or sustaining life; • control of conception; • disinfection of medical devices; • providing information by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
South African Health Products Regulatory Agency SAHPRA	SAHPRA is a schedule 3A public entity in terms of the Public Finance Management Act No. 1 of 1999 and is accountable to and reports to the Minister of Health.
Reprocess	Reprocess means the activity carried out on a used medical device to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used medical device.
Wholesaler	Wholesaler means a dealer that purchases medical devices from a manufacturer or distributor and sells them in terms of South Africa's Section 22H of the Medicines and Related Substances Act 1965.

OVERVIEW

The medical devices sector in South Africa is characterised by its complexity and diversity, involving numerous products, companies, and rapid innovation cycles. This sector, despite not being a major employment generator, plays a crucial role in healthcare delivery and offers growth potential through both local manufacturing and international investments. Currently, the sector contributes substantially to South Africa's trade deficit, due to high import levels driven by disease.

The development of a comprehensive Masterplan for this sector aims to address the trade deficit, encourage localisation, and boost export revenues. South Africa's medical devices industry, with more than 600 registered companies, remains heavily reliant on imports, with more than 90% of medical devices being imported. The COVID-19 pandemic underscored the urgent need for a robust local manufacturing base, particularly for essential items such as personal protective equipment (PPE) and ventilators.

This Masterplan is informed by a detailed value chain analysis based on the 2022 Medical Devices Landscape study by the South African Medical Research Council (SAMRC) and trade data from Trade & Industrial Policy Strategies (TIPS). The analysis identifies key challenges and opportunities within the sector, highlighting the need for strategic interventions to foster growth.

The plan also involves extensive collaboration between the private sector and government to pinpoint major obstacles and devise effective solutions. By creating an enabling environment that supports innovation and investment, South Africa can enhance its competitiveness in the global medical devices market, ultimately contributing to improved healthcare outcomes and economic growth.

This research comprises the main report and six annexures:
Annexure 1: Trade in medical devices
Annexure 2: Methodology of HS Codes for medical devices
Annexure 3: Quick Wins Working Group Workshop Report
Annexure 4a: Case Study – Turkey
Annexure 4b: Case Study – Notes on Costa Rica
Annexure 5: Manufacturing financial data

1. INTRODUCTION

The objective of the Medical Devices Sector Masterplan for South Africa is to make recommendations to increase economic activity in the sector by reducing the trade deficit, enabling localisation and increasing revenue from exports. South Africa has a vibrant medical devices industry currently with more than 600 companies registered (SAMRC, 2022). However, South Africa remains import dependent with over 90% of medical devices being imported.

A diagnostic value chain analysis was conducted on South Africa's medical devices industry, using insights from the SAMRC's 2022 Medical Devices Landscape study. This analysis is supported by trade data from Trade & Industrial Policy Strategies, providing a foundation for understanding the industry's key issues.

The mounting demand for medical services and equipment as a result of the COVID-19 pandemic necessitated the development of the Medical Devices Masterplan for South Africa. The medical devices industry had to respond to rapid growth in demand to manage the spread of the COVID-19 virus during the pandemic which included the need for items such as PPE, ventilators and syringes.

The development of the Masterplan included diverse perspectives from the private sector and government through strategic collaboration, with the aim of uncovering where the most significant obstacles to growing the medical devices industry lie, and what type of interventions are more likely to remove them.

Medical devices are divided into six categories: consumable, diagnostics, dental, orthopaedics and prostheses, patient aids, and other medical devices, as shown in Table 1.

Table 1: Medical devices and parameters

CONSUMABLES	DIAGNOSTIC IMAGING	DENTAL PRODUCTS
Medical Dressings (Adhesive)	Electrocardiographs	Dental Drills
Medical Dressings (Non-adhesive)	Ultrasound	Dental Chairs
Suturing Materials	Magnetic Resonance Imaging (MRI)	Dental X-Ray
Syringes (With/Without Needles)	Scintigraphic Apparatus	Dental Cements
Tubular Metal Needles/Needles for Sutures	Other Electrodiagnostic Apparatus	Dental Instruments
Other Needles, Catheters, Cannulae	X-Ray and Other Radiation Equipment	Teeth and Other Fittings
Blood-Grouping Reagents	Contrast Media	
First-Aid Boxes and Kits	Medical X-Ray Film (Flat)	
Ostomy Products	Medical X-Ray Film (Rolled)	
Surgical Gloves		
ORTHOPAEDICS AND PROSTHETICS	**PATIENT AIDS**	**OTHER MEDICAL DEVICES**
Fixation Devices	Hearing Aids	(Wheelchairs) Carriages and Accessories for Disabled Persons
Artificial joints, for orthopaedic purposes	Pacemakers	Ophthalmic Instruments
Artificial parts of the body (excluding artificial teeth)	Other Portable Aids	Hospital Furniture
Artificial Joints	Mechano-Therapy Apparatus	Medical, Surgical Sterilisers
Other Artificial Body Parts	Therapeutic Respiration Apparatus	Ultra-Violet or Infra-Red Ray Apparatus
Other orthopaedic		Other Instruments and Appliances

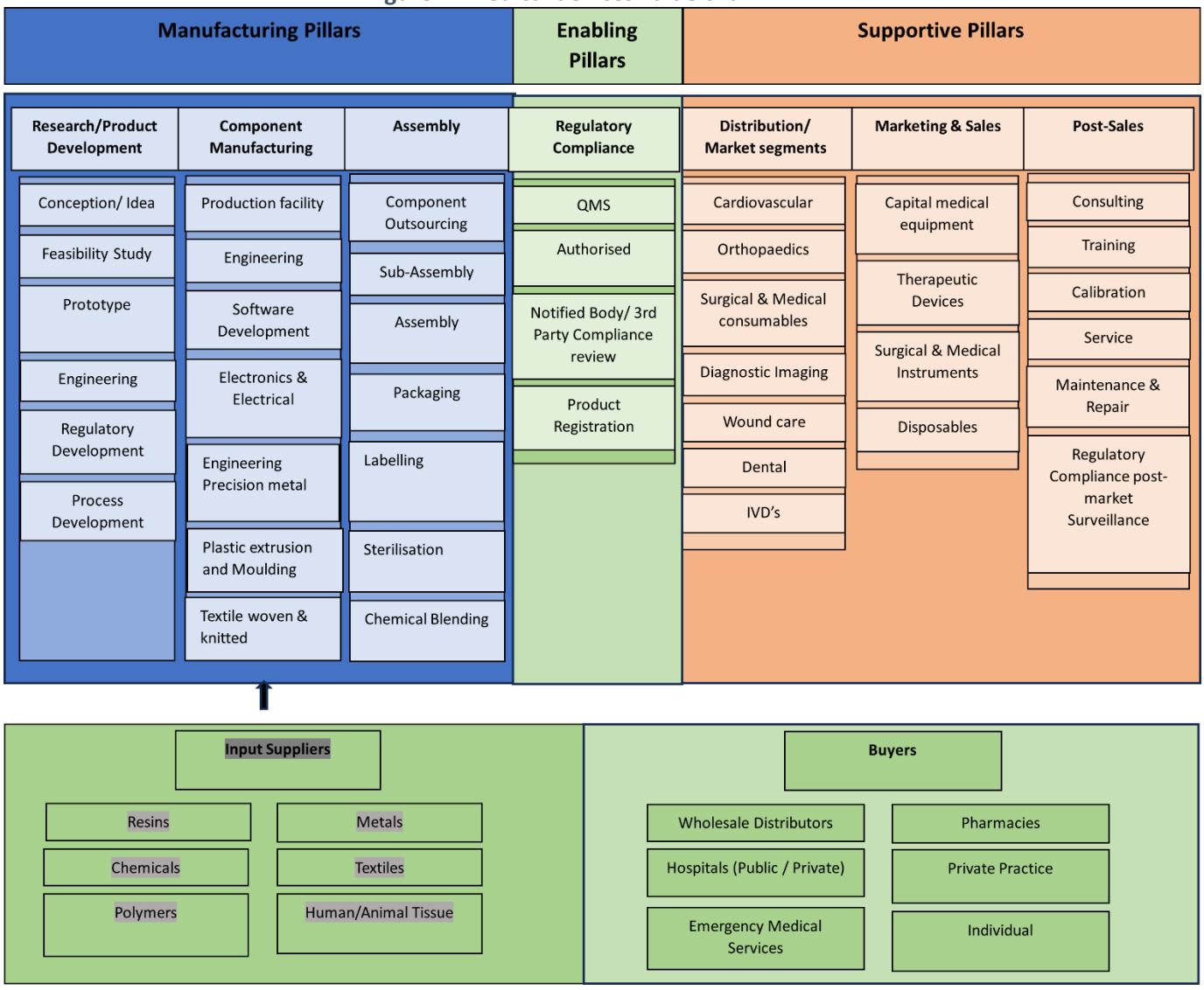
Source: SAMRC, 2022.

Section 2 of this report lays out the medical devices value chain. Section 3 discusses South Africa's medical devices performance for regulation; production; contribution of manufacturing to growth (GDP) and employment; cost drivers; investment and finance; and trade. Section 4 provides a short analysis of the demand for medical devices. Section 5 explores the case studies of countries with well-developed medical devices value chain and regulatory frameworks. Section 6 analyses the strengths, weaknesses, opportunities and threats (SWOT) of medical devices in South Africa. In section 7, conclusions are made.

2. MEDICAL DEVICES VALUE CHAIN

This section maps the broad scope of the value chain, adapted from Bamber and Gereffi (2013). The South African performance follows from Section 5. It discusses the manufacturing aspects of the value chain covered by research and development, component manufacturing, and assembly. The enabling environment follows in the form of regulatory compliance. Then, the supportive aspects of the value chain are explored looking at distribution, marketing and sales, and post-sales segments.

Figure 1: Medical devices value chain



Source: Adapted from Bamber and Gereffi, 2013.

Research and development

The medical devices value chain, depicted in Figure 1, starts with research and development (R&D). This stage involves conceptualising new products, producing and testing prototypes, and assessing potential market and manufacturing capabilities. Once initial concept tests are completed, the product undergoes regulatory approval in the desired markets, which can take up to six years depending on the risk category of the device and required clinical trials. The total time for a new device to come to market can take up to eight years. Process development occurs simultaneously with input from manufacturing plant engineers to determine the most efficient means of production. Validation

of inputs and production processes is required to obtain regulatory approval. At this stage, a firm's internal production capacity and the availability of potential vendors can impact production decisions. The initial product price is determined, and potential for reimbursement is evaluated. After production begins, engineers work to improve the production process in close collaboration with product development teams. Large companies are increasingly acquiring new products through mergers and acquisitions instead of developing them in-house, providing smaller firms with the opportunity to enter the market.

The segments related to production, which include components manufacturing and assembly, are reported to be usually the lowest in value-added parts of the value-chain (Bamber and Gereffi, 2013). They consist of various functions that are dependent on the final product.

Component manufacturing

Knitting, weaving, and cutting are used in the production of compression socks and mastectomy bras, while extrusion and molding are necessary for the production of plastic components for products such as intravenous drug delivery catheters. Precision metal works are required for stents and pumps, whereas electronic components and software development are necessary for various products, including small therapeutic devices like pacemakers and neuromodulators, as well as large equipment such as X-ray and ultrasound machines. To protect these components from chemical, electrical, and environmental corrosion, they may need to be coated, electroplated, or polished before assembly. The value added for each of these components is determined by the inputs used, such as resins or precious metals, as well as the complexity of the production process.

Assembly

Depending on the final product, manual labour or automation may be used for assembly. For instance, products like infusion pumps that have numerous components, up to 500 in some cases, and require up to 200 different assembly processes may have some parts automated while others are assembled by hand. In contrast, products like bovine tissue heart valves must be assembled carefully by hand. After final assembly, the product needs to be labelled, packaged, and sterilised before distribution. Labelling and inserts play a crucial role in the production process, as incorrect information regarding the use of a medical device can result in fatal consequences.

Sterilisation

After packaging, most products undergo sterilisation using one of three methods: e-beam sterilisation, where electrons are accelerated through the product; ethylene-oxide (E-O) sterilisation, where the product is sterilised using gas; and gamma ray sterilisation, which is required for dense products containing liquids. While e-beam or E-O sterilisation can be used for most other products, usually only one sterilisation method is chosen for regulatory approval per product due to the high costs of validation.

Distribution, marketing and sales

Medical device manufacturers have various options for distribution, including wholesale distributors or internal distribution centres for direct sales to end users. These end users may include hospital or clinic administrators, healthcare professionals like doctors and nurses, and even patients themselves for certain products. Distribution channels depend on the type and value of the products, with lower-value products typically going through wholesale distributors and high-value products sold directly to hospital administrators. To improve their negotiating positions and reduce costs, buyers implement

strategies such as establishing purchasing groups, moving doctors' practices under hospital administrations, and reducing their number of suppliers. This increased competition among suppliers has led to significant spending on marketing and sales, with up to 56% of the cost base for a product in Europe devoted to these activities (Frost and Sullivan, 2010, cited in Bamber and Gereffi, 2013).

Finished products are divided into four categories:

1. Disposables or high-volume commodities

Items that fall under the category of disposables or high-volume commodities comprise of products like bandages, surgical gloves, plastic syringes, catheters, and needles. These products are considered low tech and are typically designed for single-use and cost-effective purposes. The manufacturing of these products requires less medical expertise in comparison to other product categories; however, manufacturers must adhere to specific quality standards for medical devices.

2. Surgical and medical instruments

Surgical and medical instruments are a range of products that include forceps, medical scissors, dental drills, and specialised surgical instruments for cosmetic and endoscopic procedures. Although these products are typically designed for multiple uses and are sterilised between each use with different patients, the issue of sterility and patient use is highly contended. Some instruments may also be electrically powered. The production of many surgical and medical instruments is increasingly focused on cost-efficiency.

3. Therapeutic devices

Therapeutic devices are a range of products that are designed to help individuals manage physical illnesses or disabilities. These devices can both be implantable or non-implantable and include products such as hearing aids, pacemakers, and prosthetics. These products are typically directed towards specialists. The production of implantable devices requires significant expertise, particularly with regards to biocompatibility as they are used for prolonged periods inside the body. Obtaining regulatory approval for implantable devices is also a costly process, which significantly increases the value of each device, as well as marketing and sales sophistication.

4. Capital equipment

Capital equipment is a category of products that includes single-purchase equipment that can be used repeatedly over several years. These products require ongoing account management for accessories, services, and parts. This product category encompasses equipment used in patient monitoring, diagnostics, and imaging, ranging from infusion pumps and blood pressure monitors to significantly large investments such as MRI equipment or computed tomography. Equipment that requires these large, long-term investments typically involves multiple decision-makers.

Furthermore, it is reported that two new sets of products are emerging: integrated solutions and convergence products. Integrated solutions combine medical devices with training, consulting, and other post-purchase services. Convergence products are devices that combine important contributions from the medical devices, information technology (IT), and/or pharmaceutical sectors, such as drug-eluting stents. Medical IT systems, for example, include information systems used in the administration of laboratories and hospitals, as well as software interfaces used with different therapeutic devices, monitoring, and diagnostic equipment.

End market segments

End market segments are typically categorised according to the body system they are designed to treat. These segments include cardiovascular health, orthopaedics, respiratory issues, anaesthesia, neurology and spinal health, renal health, urology and reproductive health, haematology, dentistry, ophthalmology, biomaterials and tissue generation, as well as specific treatment types such as oncology, diabetes management, and advanced wound treatment. Cardiovascular and orthopaedics are the two largest market segments (Markets and Markets, 2011 cited in Bamber and Gereffi, 2013).

Due to the level of expertise and innovation required in the production of each device, manufacturers usually specialise in one or more specific end markets. Each end market may require all or a subset of the product categories described above.

In the treatment of cardiovascular conditions, for example, Bamber and Gereffi (2013) explain that disposable products such as gloves and catheters may be used for a transfusion, therapeutic products like a pacemaker may be used for cardiac rhythm management, surgical instruments such as clamps and forceps may be used during heart surgery, and capital equipment such as a patient monitor may be used during recovery. In additional, IT systems may be used to remotely monitor a patient's progress and adjust their pacemaker.

Lastly, post-sales services are critical in the competitive medical devices sector and include training on equipment and consulting, as well as account management for the supply of accessories, maintenance, and repairs.

3. SOUTH AFRICA'S MEDICAL DEVICES PERFORMANCE

This section highlights the South African performance in the medical devices value chain based on available information obtained from the SAMRC 2022 study.

3.1. Regulation

The medical devices industry is regulated by the South African Health Products Regulatory Authority (SAHPRA). Its regulatory functions have been implemented in phases following its establishment in 2017. It is the entity that provides licences and registration of the companies that manufacture, sell, import, export and distribute medical devices that are based in South Africa. Without a valid licence, the companies are not allowed to perform these activities. However, exemption is offered for manufacturers, distributors and wholesalers of non-sterile, non-measuring Class A medical devices (SAMRC, 2022).

In addition, in the pipeline for regulating the medical devices, is the registration of each medical device in South Africa by SAHPRA. While this is still in development, "licensing of specific devices is based on an attestation and checklist model, which requires applicants to provide required documentation and declarations to the regulator on application. For devices and In vitro diagnostic (IVD) devices in Classes B, C and D, reliance pathways are used, with regulatory approval from another jurisdiction, including Australia, United States, European Union, Brazil, Canada, Japan and/or pre-qualification of IVDs by the World Health Organisation, being required for the device to be marketed in South Africa" (SAMRC, 2022).

In terms of **regulatory approval**, South Africa, like many other countries in Africa, is at the early stages of regulating medical devices and continues to strive towards developing capacity within SAHPRA for regulating medical devices in line with international best practices. There are several initiatives

underway to fast track the appropriate regulation of medical devices. These initiatives include the African Medical Devices Forum, which is focused on capacity building and training with the involvement of the World Health Organization (WHO), United States Pharmacopeia and United States Pharmacopeia, African Union Development Agency (AUDA-NEPAD), and the Medical Devices Regulatory Convergence committee which is focused on supporting SAHPRA in implementing good regulatory practice for medical devices as per WHO guidelines and the Global Medical Technology Alliance(GMTA/Mecomed[1] Africa working group initiative. As the medical devices market has been historically unregulated in South Africa, international accreditations are preferred to instil confidence in the quality, safety and efficiency of products, especially in the private sector. This is further driven by requirements from hospital groups and medical schemes. The publication of new medical device guidelines as well as revised regulations is imminent.

3.2. Production

Medical device production capacity in South Africa is limited, leading to a heavy reliance on imports. Only a small percentage of local industry players produce devices, with the majority being imported – – 90% of the market value is supplied by imports (SAMRC, 2022). South Africa's medical device manufacturing output is estimated to be around US$200-US$300 million, with more than half of that being exported. Local manufacturers tend to focus on the export market, which has grown steadily, particularly in the Southern African Development Community (SADC) and Europe. The industry is highly fragmented, with between 350 and 600 suppliers ranging from small privately-owned enterprises to large multinational subsidiaries. Local manufacturing primarily focuses on low-tech and low-value devices, but there are some examples of locally developed high-tech devices. The country's domestic production is expected to continue growing in sophistication with the development of innovative medical devices.

On research and development, South Africa spends almost seven times below the global average of its turnover. However, there is innovation stemming from academic institutions such as Wits University and the University of Cape Town Biomedical Engineering Faculty that are internationally recognised. In addition, the country provides various incentives to encourage medical device innovation and manufacturing, which cover different stages of the value chain, from early development to growth and industrialisation. These incentives are provided by publicly funded agencies and departments as captured in Section 5.5 of this report.

The medical devices value chain has a direct linkage with other sectors such as plastics, steel, wood, glass, and textiles. The products that are mostly produced in South Africa are the consumables, orthopaedics, other and hospital furniture. The consumables constitute Classes A and/or B consumables.

3.3. Contribution of medical devices manufacturing to growth and employment

The medical devices sector in South Africa is identified among the industries that can contribute substantially to economic growth and employment, while improving health provision and quality of life (SAMRC, 2022). The industry is described as diverse, including local manufacturers that focus on producing a limited selection of products and also multinational distributors which offer a wider selection of products and healthcare categories (SAMED, 2020). In the literature, the sector is

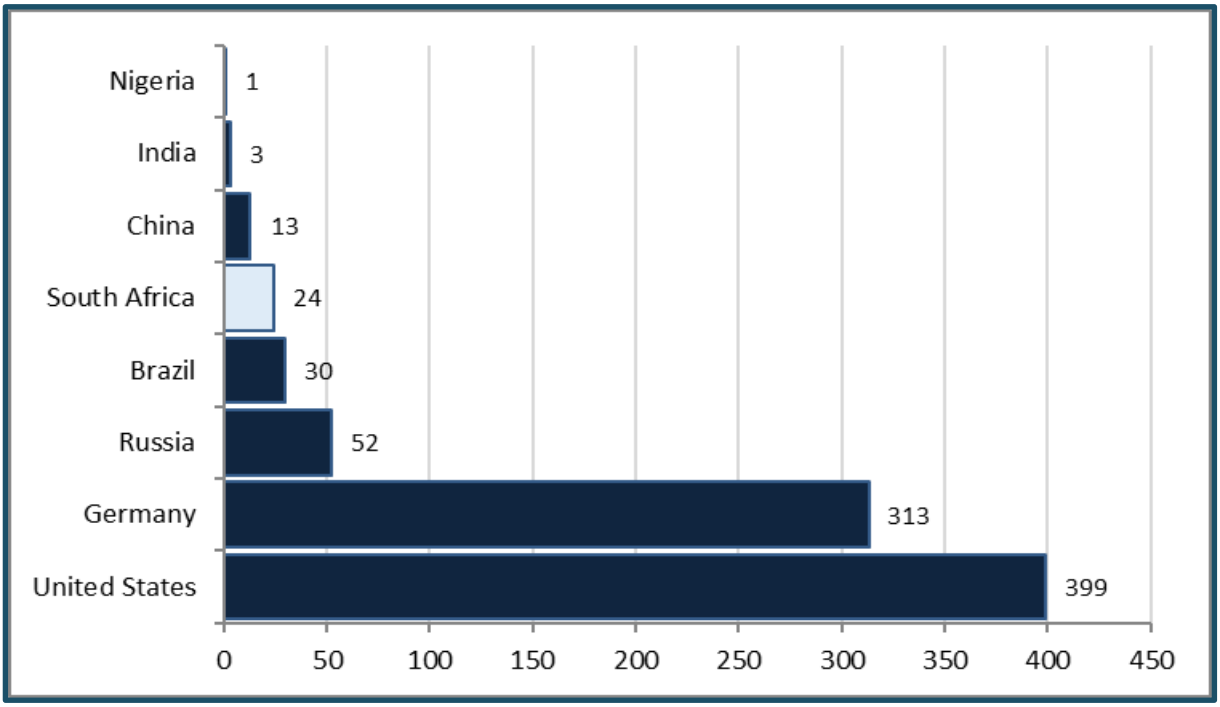
[1] Mecomed is the medical devices, imaging, and diagnostics trade association of international medical technology manufacturers and their partners across the Middle East and Africa.

sometimes referred to as medical technology or medtech, which ranges from simple technology such as syringes to more advanced high-tech devices such as MRI machines.

Widely cited data from secondary sources suggest that South Africa's medical devices market, which is estimated at a value of R21 billion (2021), is among the largest in the Middle East and Africa region. It is projected to grow by 41% to R29.6 billion by 2025 (SAMRC, 2022). Within the global market however, South Africa's medical devices market constitutes a marginal 0.3% of the world market.

Graph 1 presents per capita spending on medical devices across various countries. South Africa's per capita spending on medical devices in 2014 amounted to US$24, which was within a similar range to its comparator countries such as Brazil and Russia, which spend US$30 and US$52, respectively (SAMRC, 2022). Developed countries, however, have a considerably higher per capita spend on medical devices, with the United States and Germany recording per capita spend of US$399 and US$313, respectively. It is estimated that South Africa's per capita spend on medical devices will rise by 14% by 2025 to US$27.4, with the sector showing potential for growth in demand for medical devices.

Graph 1: Per capita spending (US$) on medical devices across countries



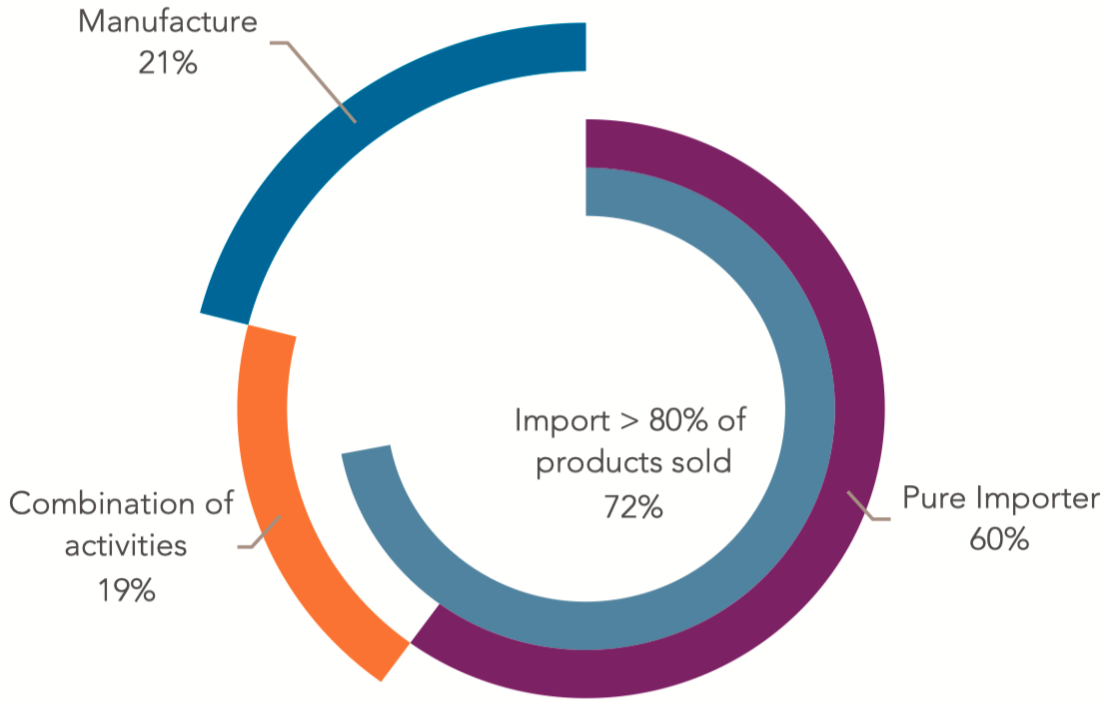
Source: Deilotte, 2014, cited in SAMRC, 2022.

In terms of manufacturing production capacity, South Africa's medical devices sector is relatively limited, with less than 5% local players involved in the manufacturing production of medical devices. This means that the larger proportion of domestic demand is supplied by imports, which are estimated to be 76% (Who Owns Whom, 2019). However, by market value it is estimated that 90% of South Africa's medical devices market is supplied by imports (SAMRC, 2022).

Results from a survey study by the South African Medical Devices Industry Association and KPMG in 2014 showed that out of 158 member companies, only 21% manufactured medical devices, with 60% of the companies involved in importing and distribution of packaged products and the rest involved in a combination of activities including repacking of imported products (see Figure 2).

Of the 158 companies surveyed, 113 (72%) companies imported over 80% of the medical devices products they sold (SAMRC, 2022), showing that the sector is heavily dependent on imports.

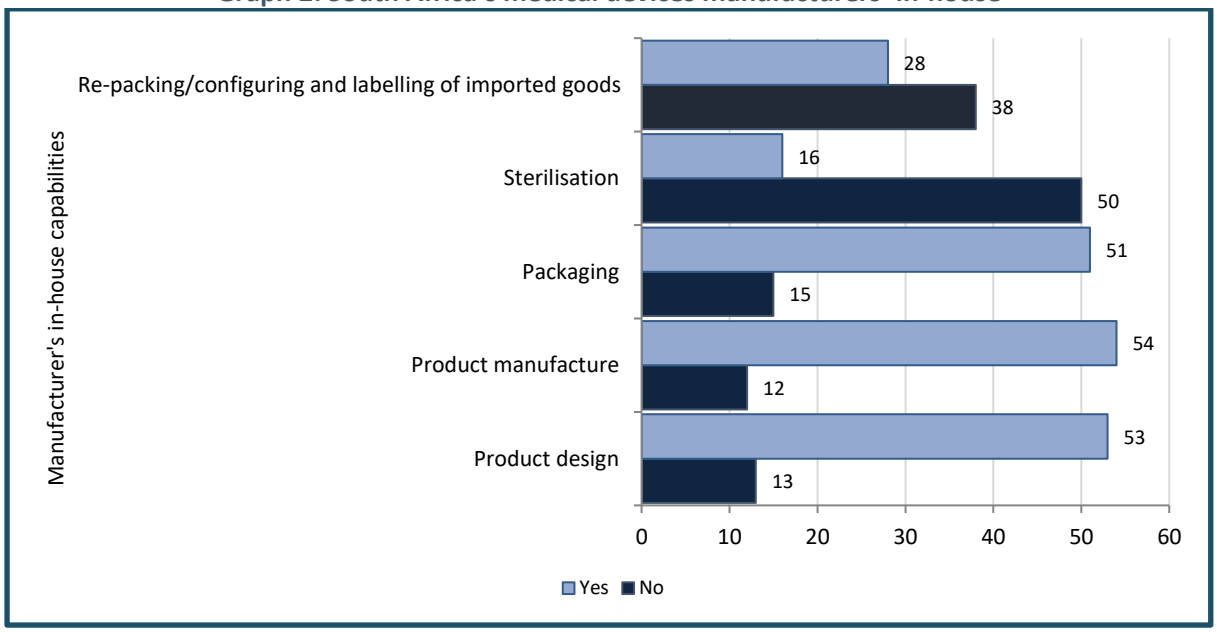
Figure 2: Proportion of local manufacturing vs imports in South Africa's medical devices sector



Source: SAMRC, 2022. *Note:* Results from 2014 SAMED/KPMG survey.

In terms of local manufacturing capabilities, South Africa's medical device manufacturers were surveyed[2] to evaluate their capacity in various processes such as product design, product manufacturing, packaging, sterilisation and repackaging of imported products (SAMRC, 2022). Evidence from the survey suggests that most companies have in-house capabilities in design (80%), manufacturing (82%), and packaging (77%) as presented in Graph 2. Outsourced capabilities are shown in Graph 3, with 38% of companies outsourcing sterilisation activities.

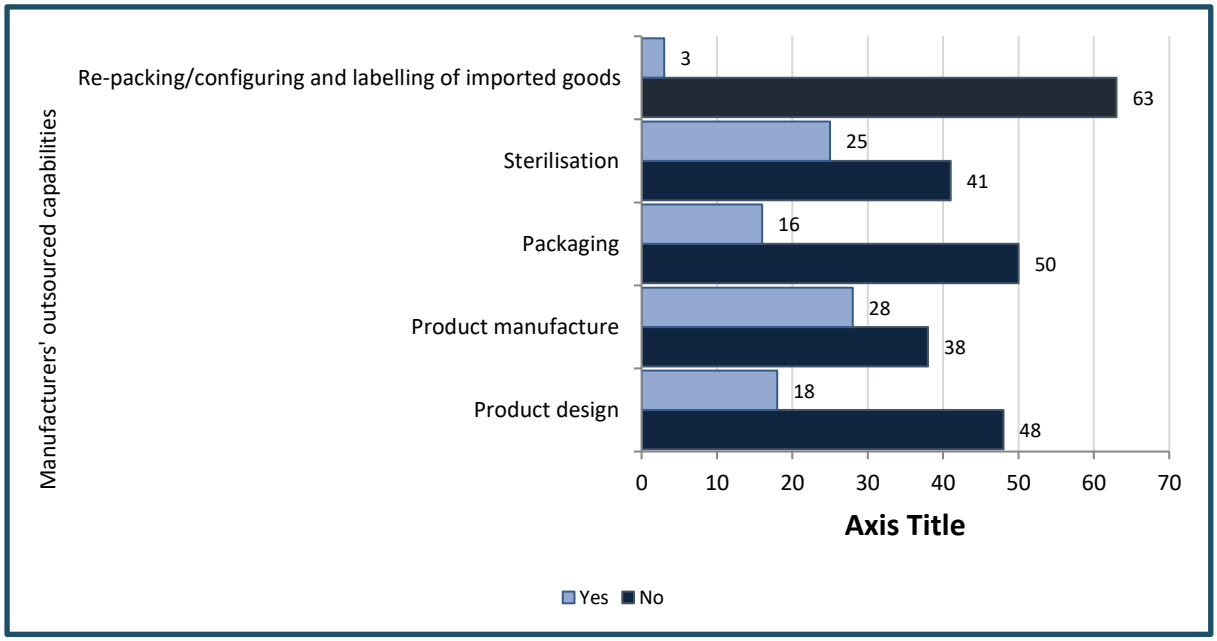
Graph 2: South Africa's medical devices manufacturers' in-house



Source: SAMRC, 2022.

[2] SAMRC survey included a total of 136 medical device manufacturing companies.

Graph 3: South Africa's medical devices manufacturers' outsourced capabilities



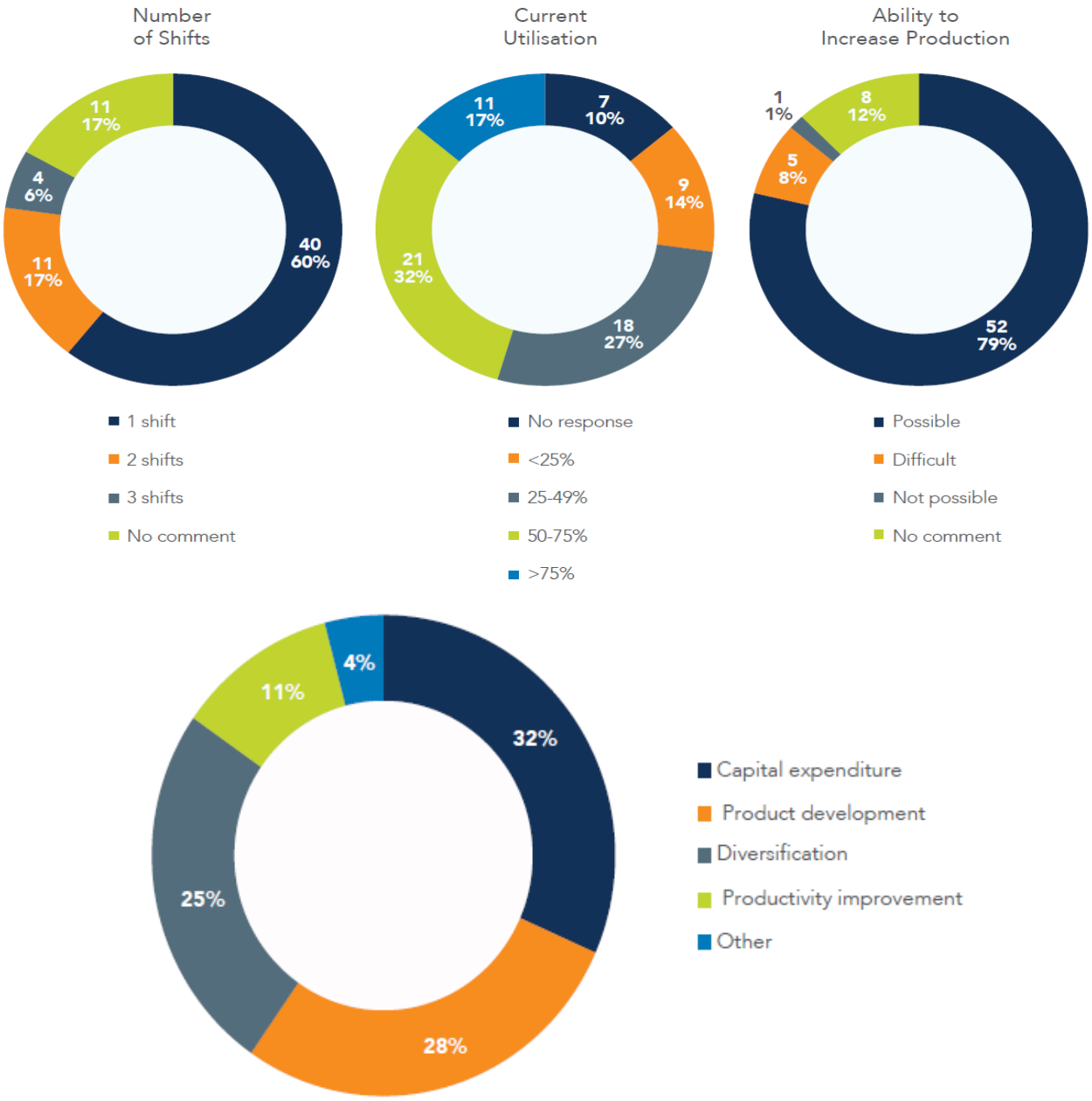
Source: SAMRC, 2022.

Moreover, an evaluation of manufacturing capacity and expansion plans was conducted through the survey in an attempt to assess the companies' manufacturing capacity utilisation. Four measures were used for the evaluation: number of shifts used, current capacity utilisation, the company's ability to increase production, and expansion strategies (SAMRC, 2022).

Results from the assessment of the number of shifts used show that most (60%) medical device manufacturers in South Africa use only one shift, while 17% and 6% used two and three shifts, respectively. Overall, South Africa's medical devices manufacturers use between 25% and 75% of their manufacturing capacity, with only 17% using more than 75% capacity and 14% using less than 25%. Therefore, evidence from the survey indicates that manufacturing capacity in South Africa's medical device sector is currently underutilised, although 79% of companies have the ability to increase production by 40%.

The manufacturers' ability to increase production is dependent on a number of strategic factors, which include capital expenditure, product development, diversification, productivity improvement and many others. Most medical manufacturers cited capital expenditure (32%) as their main strategy to increase production, followed by product development (28%), diversification (25%) and productivity improvement (11%) (see Figure 3).

Figure 3: Number of shifts, current utilisation, ability to increase production and production expansion strategies for South Africa's medical device manufacturers

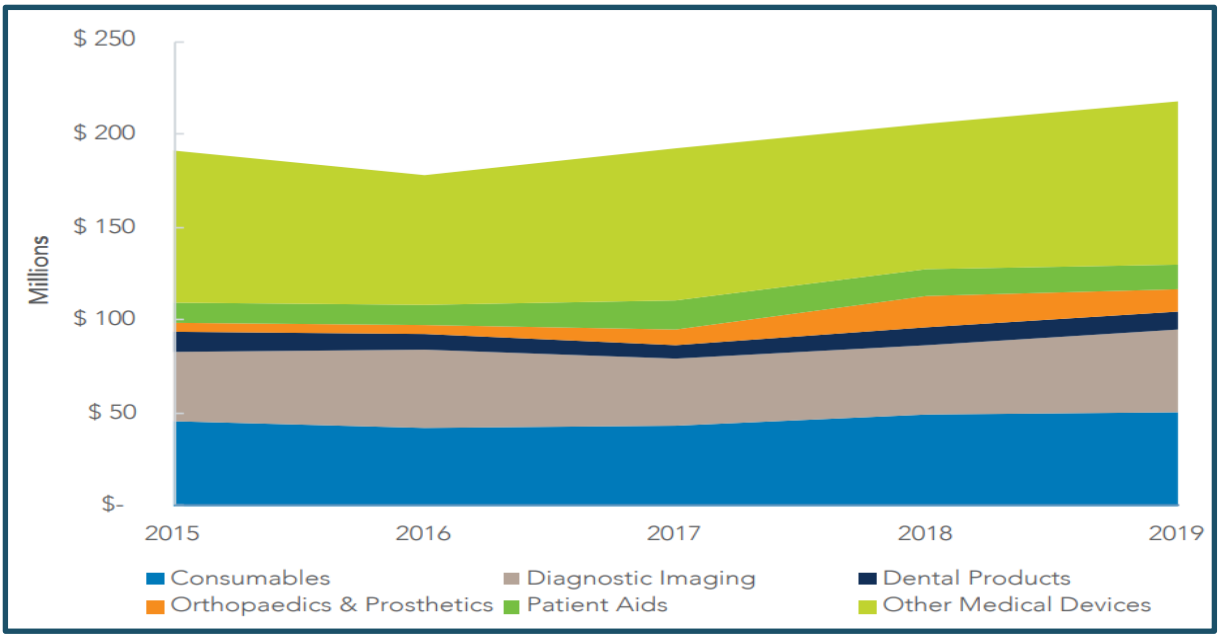


Source: SAMRC, 2022.

South Africa's medical devices manufacturing output is estimated to range between US$200 million to US$300 (SAMRC, 2022 citing Fitch Solutions, 2021). More than half of this is exported. Between 2017 and 2018, the sectors manufacturing output grew by 9%, amounting to US$211 million, and it was projected to grow by 8% to US$227.8 million in 2019 (Who Owns Whom, 2019).

South Africa's domestic manufacturing of medical devices by product category is shown in Graph 4, which illustrates value trends between 2015 and 2019. Consumables and diagnostic imaging are by far the largest medical devices product categories manufactured in South Africa, not taking into account the "other medical devices" category. Consumables product group includes bandages and dressings, syringes, suturing materials, needles and catheters, and many others. According to Fitch Solutions (2021), South Africa's consumables sector was estimated to be approximately US$240 million and projected to grow by 1.7% in 2020. Within the consumable sector, local manufacturing is approximately 10%, with 90% accounting for imports from markets such as China, India, US and Mexico.

Graph 4: South Africa's manufacturing of medical devices by product category



Source: SAMRC, 2022.

For diagnostic imaging, the sector is valued at US $192 million (Fitch Solutions, 2021), with the US and Germany as the main suppliers accounting for a market share of 20% each. South Africa's diagnostic imaging sector is described as underdeveloped, with urgent need for products such as radiotherapy equipment, MRI and PET scanners within the public sector. In terms of growth projections, the diagnostic imaging sector is expected to remain subdued because of unfavourable currency fluctuations and market conditions (International Trade Administration, 2024).

The dental products sector is estimated at $37 million and is projected to grow at approximately 3% by 2024 (Fitch Solutions, 2019). There are very few local manufacturers supplying dental instruments, implants and supplies, with almost 90% of products in the sector imported from the US, which accounts for 30% and Germany also taking an equal share.

Patient aids sector includes products categories such as portable aids (hearing aids and pacemakers) and therapeutic appliances like respiratory apparatus for example. South Africa's patient aids sector is valued at approximately $163 million (Fitch Solutions, 2019). Over 95% of South Africa's patient aids are supplied by imports from the USA, China, Germany and Switzerland.

South Africa's orthopaedics and prosthetics sector has an estimated value of US$164 million (Fitch Solutions, 2019), with most if not all products in this category supplied by imports from two main markets which are the United States and Switzerland.

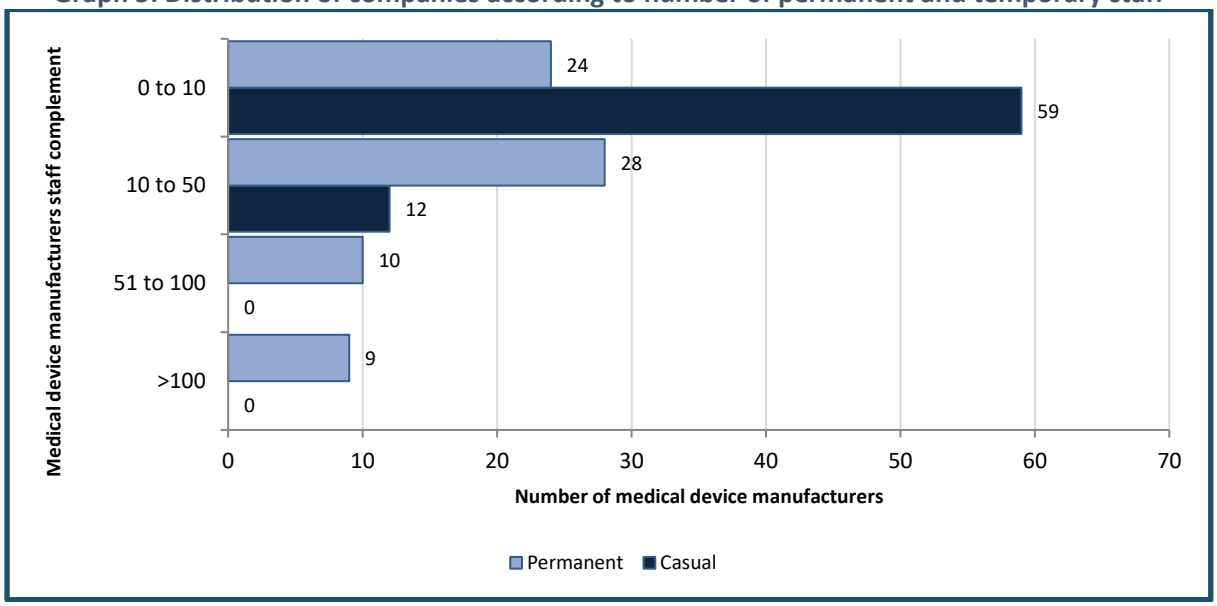
Overall, it is evident that South Africa's medical devices sector does very limited local manufacturing, with most product categories mainly supplied by imports. Furthermore, local manufacturing is mostly limited to assembly and lower end products, although there are exceptions.

3.3.1 Lack of medical devices sector employment data

There is nearly no comprehensive data of the extent and type of employment in South Africa's medical devices sector. According to estimates by the Medical Device Manufacturers of South Africa (MDMSA), there are more than 2 500 medical device stakeholders in South Africa, with 200 which are local manufacturers employing less than 250 staff (Bizcommunity, 2022). Based on these estimates, South Africa's medical device sector employs less than 50 000[3] people.

There is some limited data on employment within South Africa's medical device sector which is based on a survey of medical device manufacturing companies conducted of the SAMRC. The survey included a total of 136 medical device manufacturers. Based on the survey results, most medical device manufacturing companies are classified as small, employing 50 or less permanent staff (see Graph 5).

Graph 5: Distribution of companies according to number of permanent and temporary staff



Source: SAMRC, 2021.

3.4 Cost drivers

The cost drivers in the sector include operational costs as a result of inconsistency of electricity supply in the country. In addition, the medical schemes contribute significantly to the price increases for the medical devices in the private component of the country's healthcare sector.

Regulatory compliance is one of the key cost drivers for medical devices for both the South African market as well as export markets. This is due to the fact that medical device companies have to apply for international accreditation through international regulatory agencies for recognition of quality, safety and effectiveness. This is a baseline criterion for procurement decisions in South Africa and export markets. The regulatory compliance processes are complex, costly and time-consuming, and

[3] Authors' calculation based on MDMSA cited figures.

can become prohibitive for small to medium-sized companies operating in South Africa. Regulation is important for safety of people. However, the cost implications associated with it may not only affect the producers, but there is a risk that they are also passed on to the end users. Consequently, it is highly likely that the government will also bear the cost brunt as it subsidises the health sector – looking after the health and safety of communities.

Moreover, marketing and sales constitutes a significant proportion of operating costs for a medical device business due to the complex commercial and selling models that need to be applied in the market. This requires companies to recruit highly trained professionals who can, for example, engage with surgeons in theatre on products used during surgery and at the same time engage with procurement officers on payment of products and health economic evaluations with medical schemes. Local manufacturers will not necessarily have these skills in-house nor be able to afford to recruit such professionals on a permanent basis, especially in the early years of operation. Taking the high levels of competition in the market into consideration, it is not surprising that multinational companies would dominate certain parts of the market due to their reach, resources and internal technical expertise.

Some more complex medical devices require post sales services to be delivered to customers, including training, consulting, maintenance and repair. In the public sector, warranties and maintenance agreements are required as part of the tender application process.

Skills shortages in the broader ecosystem that medical device companies operate in can also hinder the cost competitiveness of local manufacturing.

In addition, currency volatility for both imported products as well as imported production inputs can impact the costs of production significantly. Also, the geographic location of South Africa has an impact on the time and cost of logistics and transport costs.

3.5 Medical devices sector investment level and industry finance

Sufficient investment and industry finance in any sector of the economy, is fundamental for sustainable economic growth and industrial development. Investment or industry finance has several benefits such as sustainability of a firm or industry to remain competitive with new processes or products and expand its market share and profitability; the ability to provide medical devices that cater to the various disease burdens more efficiently, safely and with new or improved products; A sustainable business offers trickle down impacts of job retention, creation, and generation; a sustainable business can export goods and contribute to balance of payments, demand for essential medical goods to help health sectors abroad and contribute to GDP. Indirectly, investment in R&D activities also add to the existing stock of knowledge.

Similar to most industries, it was reported by SAMRC (2022) that the medical device sector was facing challenges in funding and investment. R&D expenditure in medical devices in South Africa is low as a percentage of turnover for the industry, it is reported at less than 1%, compared to a global average of 6.8%. Despite facing constraints, it was noted most companies indicated in their strategies increasing capital expenditure, followed by product development and diversification.

Both the private and public sectors have been playing a major role in providing investment and industry finance to the medical devices sector. This section tracks investments, private equity and capital, seed funding, financial and non-financial incentives provided by government and financial institutions, grants, funds, foreign direct investment, spend on R&D, and outputs such as patents. Overall, there has been a drive for both the private and public sectors to continue investing and in addition to a push for centralised industrial finance initiatives (public and private) specific to the industry.

It has been noted by industry that there needs differentiation between pharmaceuticals and medical devices finance systems to understand flows to medical devices as opposed to the whole healthcare.

The above can be measured qualitatively or quantitatively by looking at a series of indicators listed in Table 2. This analysis makes use of some of these metrics, in as far as the data is available. Red indicates data is aggregate and does not provide further information, orange and green illustrates there is sufficient data to have a better understanding of investment in the medical devices sector.

Measuring investment level in South Africa

Table 2: Measuring the investment level in South Africa

INDICATOR	TYPE OF INDICATOR	SECTOR LEVEL AVAILABILITY	SOURCE	LEVEL
Investment	Gross Fixed Capital Formation (GFCF)	• South Africa Standard Industrial Classification (SIC) 374- 376) • Medical Devices (SIC)	**Quantec EasyData**	
Investment	Capital expenditure on new plant, machinery, and equipment	Retail Trade on Pharmaceutical and medical goods, cosmetic and toilet articles	**Retail Trade Statistics South Africa**	
Investment	Business Investments	Private Equity Value of Investments	**Southern African Venture Capital and Private Equity Association (SAVCA)**	
		Private Equity Investments in Healthcare	**SAVCA**	
		Venture Capital Investments in Medical Devises and Equipment	**SAVCA**	
		Venture Capital Deals Made in Medical Devices and Equipment	**SAVCA**	
Investment and industry finance	Government Departments	Seed funding, Technology Development, Commercialisation Support for Bio-Economy – Health Sector	**Technology Innovation Agency (TIA)**	
		R & D Investment Expenditure for Bio-Innovation for New Health Products and Services	**Department of Science and Technology (DST)**	
		Research and Development Tax Incentive on Manufacturing	**National Treasury (NT)**	
		The Cape Health Technology Park and Finance Portal – Fin Finder	**Wesgro**	

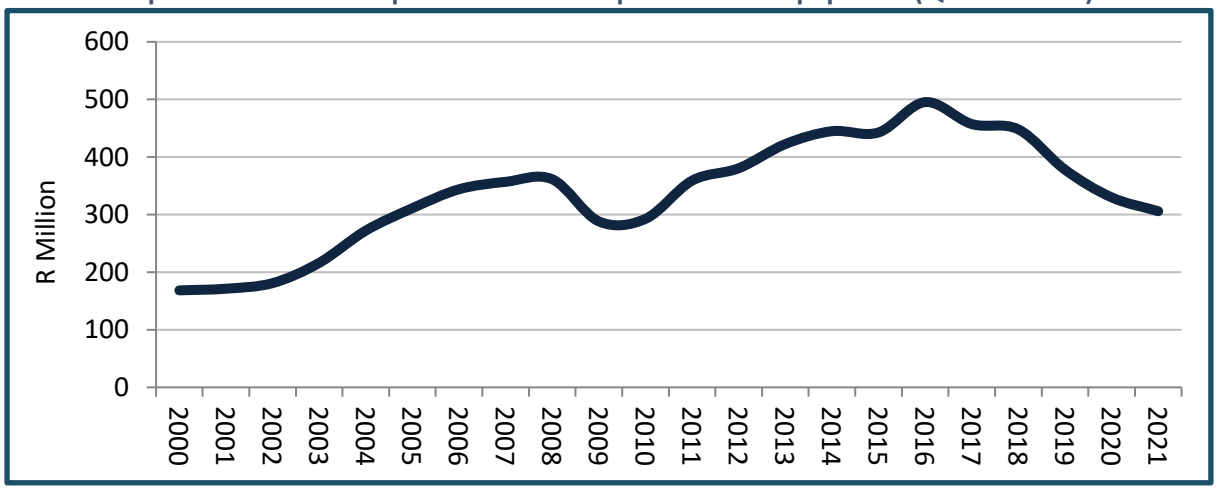
		Financial and non-financial incentives Medical manufacturing cluster.	**Gauteng Growth Development Agency (GGDA)**	
		Financial and Non-Financial Incentives, Support Programme for Industrial Innovation (SPII); Black Industrialists, Export Marketing and Investment Assistance (EMIA), Health Industry	**Department of Trade, Industry Competition (the dtic) Industrial Development Corporation (IDC)**	
Investment	Associations	SAMRC - Grants, Innovation and Product Development	**SAMRC**	
Foreign Direct Investment (FDI)	FDI	Companies with production plants in South Africa by name, year, location, parent company	**Trade Map (International Trade Centre)**	
Outputs	Patents and Designs	Patents Grants in Medical Technology by place of filing and origin of applicant	**World Intellectual Property Organization (WIPO)**	
Outputs	Research and Development	R&D as a % of GDP Researchers in R&D	**World Bank**	

Source: Institutions' websites.

Overall Gross Fixed Capital Formation for industry

One of the first indicators to determine investment levels for a particular industry or sector is GFCF. Using industry SIC codes, medical devices fall under code 3471. Available data only provide an aggregate of "374 – 376" for professional equipment. Graph 6 illustrates that GFCF from the year 2000 lay under R200 million and grew steadily to about R361 in 2008 million before facing a decline during the downturn. Between 2011 and 2016 GFCF continued to rise with the highest investment occurring in 2016 at R595 million. Since 2016 there has been a sharp decline without any recovery with investments dropping to R300 million and worsened by economic impacts of the COVID-19 pandemic (see Graph 6).

Graph 6: Gross Fixed Capital Formation in professional equipment (QSIC 374-376)

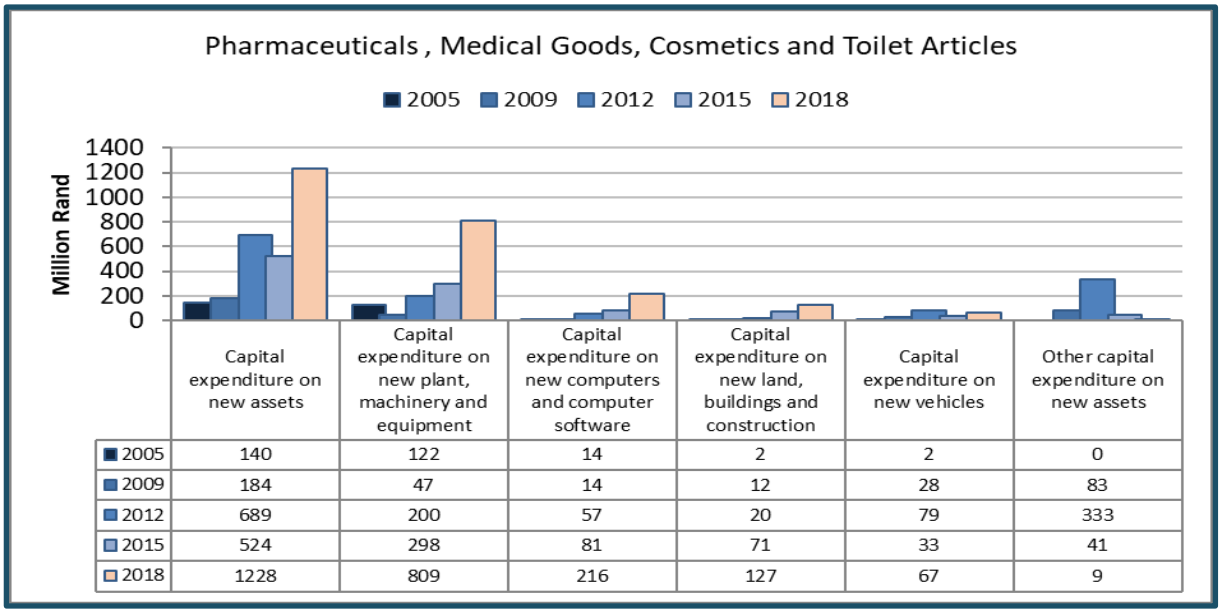


Source: Quantec Data Set: ICAP – SA Standardized Industry Gross Fixed Capital Formation, Fixed Capital Stock and Consumption of Fixed Capital.

Capital expenditure on new plant, machinery and equipment in pharmaceutical and medical goods, cosmetic and toilet articles

Statistics South Africa produces data on retail trade sales that cover capital expenditure on pharmaceutical, medical goods, cosmetics, and toiletries. Although it does not focus on medical devices, it does illustrate investment in that portfolio of goods. Over the years, expenditure on new plant machinery and equipment has risen but this is most probably driven by other industries (see Graph 7).

Graph 7: Capital expenditure in pharmaceuticals, medical goods and toilet articles



	Capital expenditure on new assets	Capital expenditure on new plant, machinery and equipment	Capital expenditure on new computers and computer software	Capital expenditure on new land, buildings and construction	Capital expenditure on new vehicles	Other capital expenditure on new assets
2005	140	122	14	2	2	0
2009	184	47	14	12	28	83
2012	689	200	57	20	79	333
2015	524	298	81	71	33	41
2018	1228	809	216	127	67	9

Source: Quantec Data Set: ICAP — SA Standardized Industry Gross Fixed Capital Formation, Fixed Capital Stock and Consumption of Fixed Capital.

Business private equity and venture capital

Private equity[4] and venture capital play an extremely vital role in stimulating the economy through investment. SAVCA reports business investments in various industries and sectors. SAVCA represents 180 members in Southern Africa, which collectively manage in excess of R205 billion in assets (SAVCA, 2022).

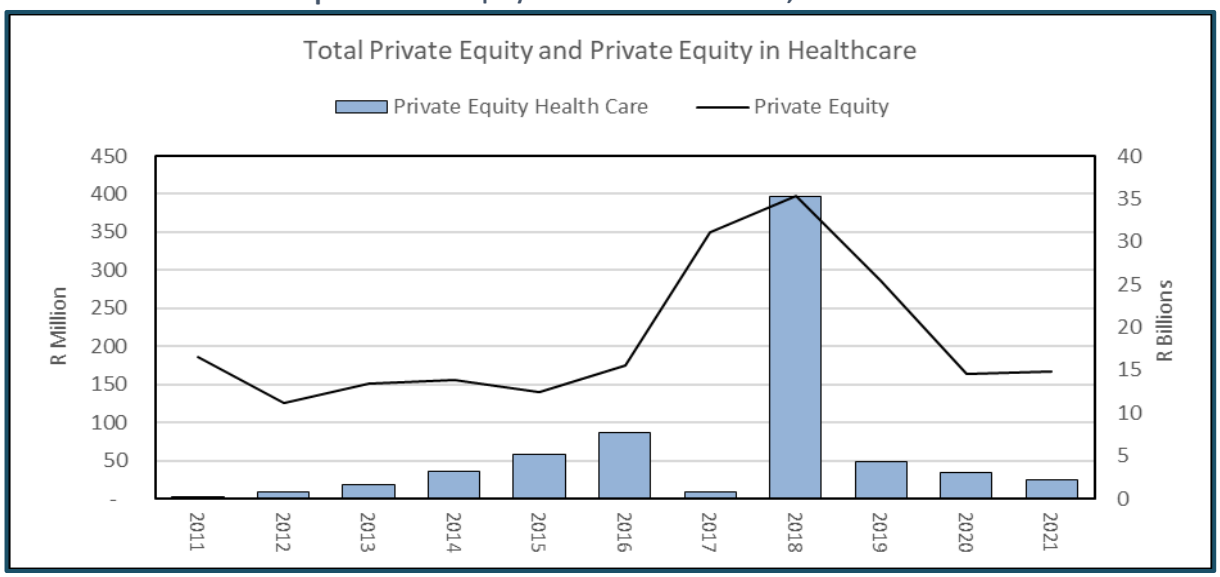
Investment in healthcare boosts consumption of medical goods. SAVCA tracks private equity investments across various sectors of the economy such as energy, infrastructure, financial services, manufacturing, healthcare, information technology, agro-processing, mining, education and other/unknown.

The 2021 SAVCA survey report highlights that private investment between 2011 and 2016 ranged on average R13.8 billion. Investments doubled in 2017 to R31 billion driven by investments in retail and services. In 2018, investments stood at R35 billion, the highest in the decade. Since then, investment share continued to drop with an average of R15 billion between 2020 and 2021. Although the category healthcare is not disaggregated, private equity investments in the sector rose sharply by 426%, from

[4] Private equity typically invests in established businesses at various stages and funding provided in exchange for a majority stake or to back a complete takeover, and venture capital financing that investors provide to businesses in the start-up and early growth phases that they believe have long-term, high growth potential. These are deals predominantly funded by equity.

R165 million in 2011 to R868 million in 2016. There was a huge decline in 2017 and a surge in 2018 of R3.9 billion. Since 2018 investments have seen a drop year-on-year with 2021 recording R253 million (see Graph 8).

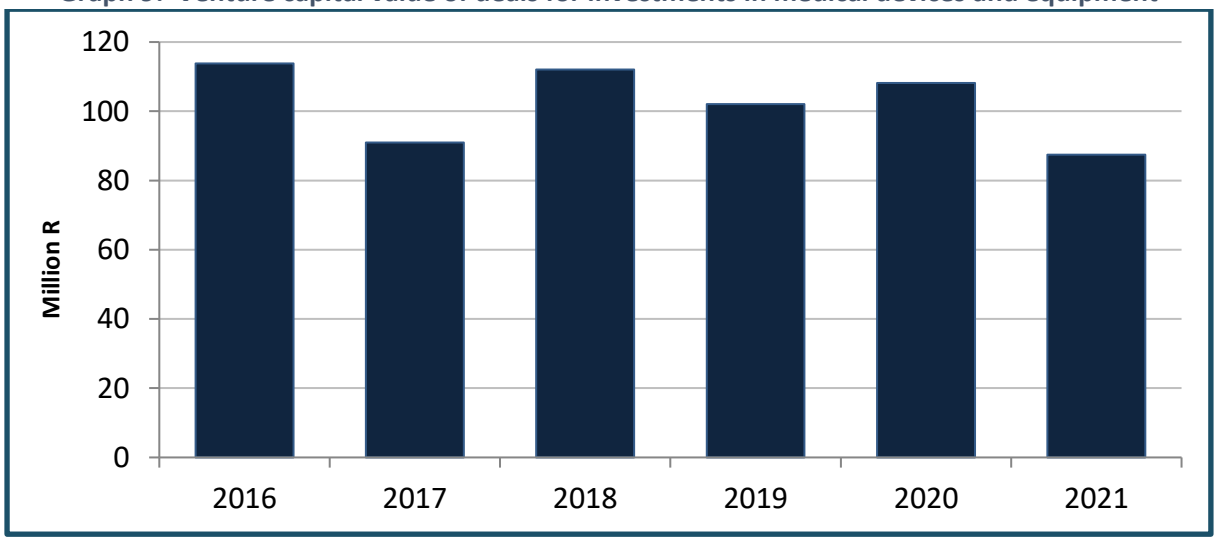
Graph 8: Private equity value of investments, 2011 to 2021



Source: SAVCA. 2022.Private Equity Industry Survey and Venture Capital Survey. https://savca.co.za.

SAVCA tracks venture capital in various industries. SAVCA highlights that in 2016 investments totalled R113 million into medical devices and equipment. In 2017, there was a decrease of approximately 20% from 2016 of R22,8 million. Investments picked up by 24% in 2018 at R112 million and have since declined by 22% to R87 million in 2021 (see Graph 9).

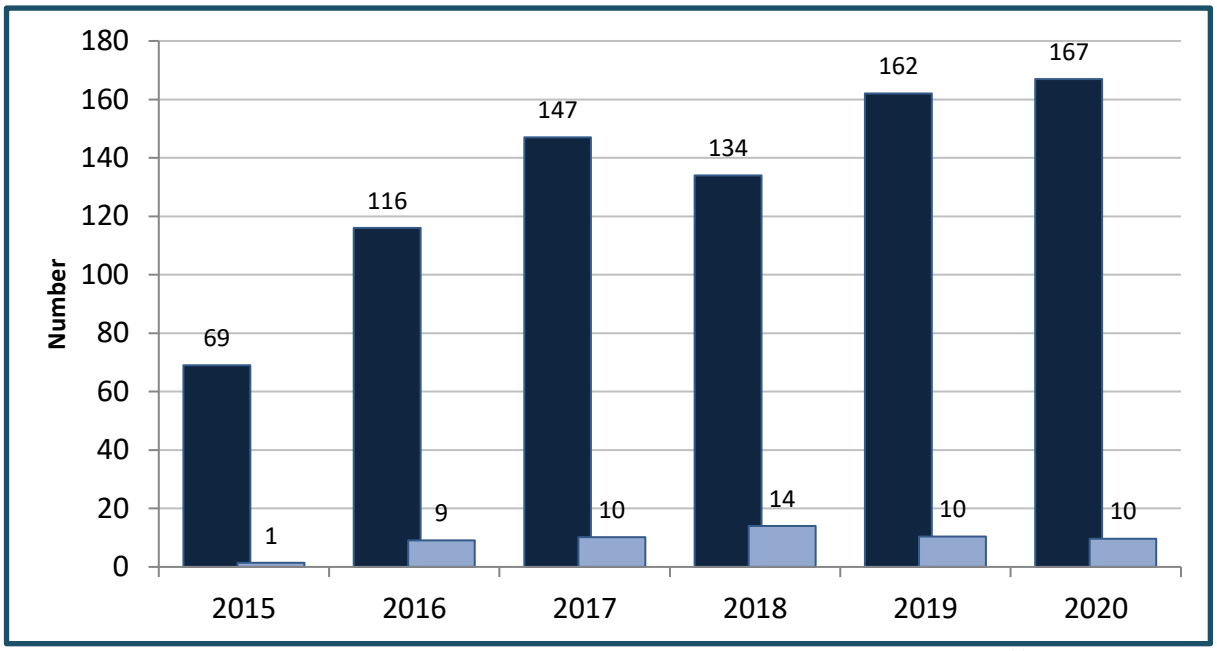
Graph 9: Venture capital value of deals for investments in medical devices and equipment



Source: SAVCA. 2022. Private Equity Industry Survey and Venture Capital Survey. https://savca.co.za.

In terms of deals made over the years in medical devices and equipment, in 2015, there was one deal and this grew to 14 in 2018. Thereafter, deals have remained constant to 10 deals per year in 2019 and 2020 (see Graph 10).

Graph 10: Number of deals 2015 to 2020



Source: SAVCA. 2022. Private Equity Industry Survey and Venture Capital Survey. https://savca.co.za.

Government departments investment and financial support

Several government departments at national level provide funding/investments/incentives to the medical devices industry. Although some funding models are specific to a department, there are collaborations in some cases. These departments encompass:

- Technology Innovation Agency
- Department of Science and Technology
- Department of Science and Innovation (DSI) and National Treasury
- Department of Trade, Industry and Competition

During the pandemic, there were some collaborations. In 2020, TIA, DSI, and SAMRC had an R18 million portfolio that went to local companies, organisations, and researchers in order to ramp up the country's ability to produce locally developed reagents and test kits for COVID-19 (SAMRC, 2022). The funds targeted the development of reagents that can be locally manufactured for existing gold standard COVID-19 tests and alternative, point-of-care diagnostic kits that can rapidly detect the presence of SARS-Cov-2 viral proteins and/or particles.

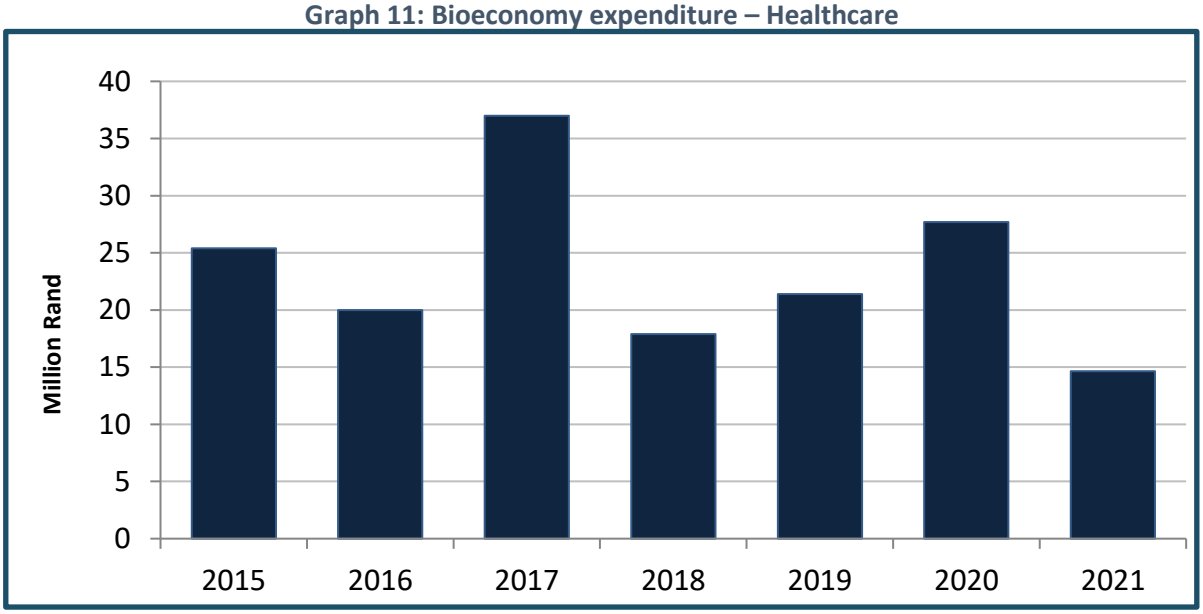
The Technology Innovation Agency

TIA is a national public entity that serves as the key institutional intervention to bridge the innovation chasm between research and development from higher education institutions, science councils, public entities, and the private sector with commercialisation of tech and innovation. TIA, among other sources, invests and provides funding for technology innovative opportunities. TIA provides **seed funding** to enable innovators to evaluate, demonstrate and advance the value proposition and commercial potential of their research outputs. The fund therefore contributes towards de-risking research outputs in order to increase the pipeline for TIA and other funders. These funds fall under the Technology Development Fund and Pre-Commercialization Support Fund, (TIA, 2021).

One of the areas of support under **bioeconomy** is healthcare. The health business sector aims to enhance South Africa's global competitiveness in the health arena and to deliver socio-economic value

through technological innovation in healthcare products and services that address the diagnosis, prevention and/or treatment of priority disease areas within South Africa. Within TIA, the main portfolio of investment expenditure for medical devices under the bioeconomy illustrates that spending lay at R25 million in 2015. Spending picked up by 48% in 2017 to R37 million. It dropped by 54% to R17 million in 2018, but gradually rose again to R27 million in 2020. In 2021 investment expenditure dropped by 48% to R14 million (see Graph 11).

Graph 11: Bioeconomy expenditure – Healthcare



Source: Technology Innovation Agency. Annual Reports (2015-2022 various).

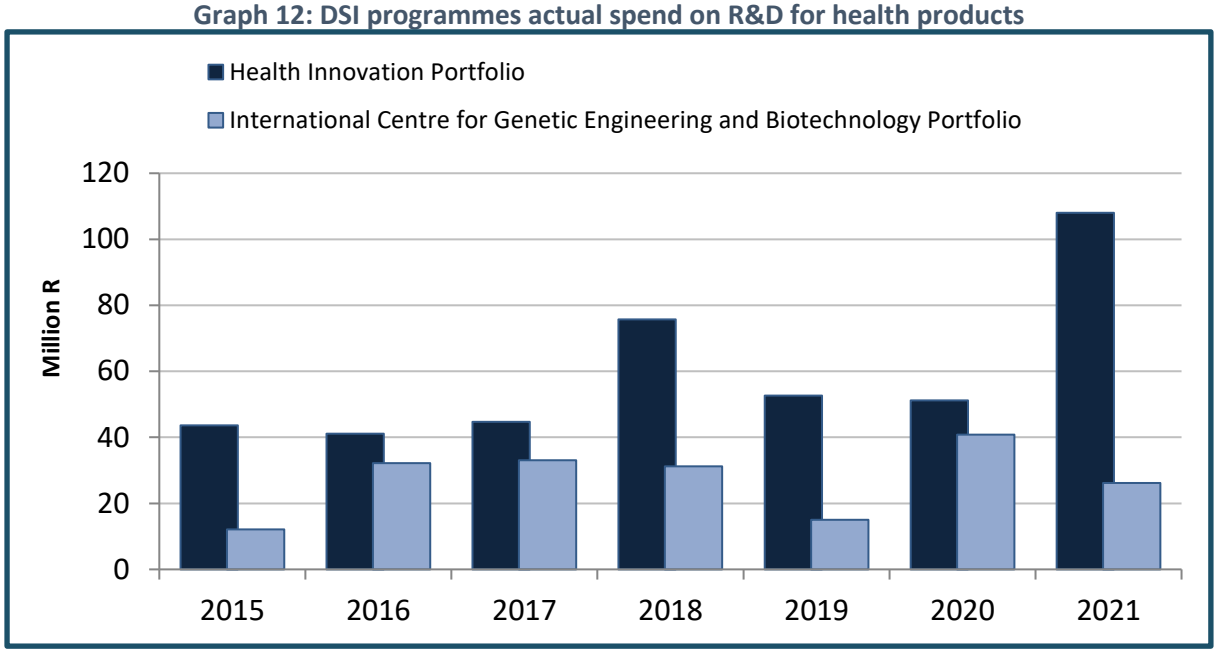
Department of Science and Innovation

The DSI provides support to programmes that can enhance the medical devices industry in the following programmes – Programme 2: Technology Innovation in relation to Programme 3: International Cooperation and Resources; Programme 4: Research Development and Support and Programme 5: Socio-economic Innovation Partnerships.

Programme 2 Technology Innovation aims to enable R&D in strategic and emerging focus areas. Under this programme is support for **bio-innovation,** which covers medical devices and the greater health sector. The sub-programme focuses on supporting and strengthening bio-economy-related research, development, and technology innovation in the country. It drives and coordinates innovation to support activities across the value chain, for example the creation of new and improved therapeutics, vaccines, and diagnostics (including animal drugs and vaccines), higher yielding crops, new crop development, bio-control agents, agro-processing, new and more efficient industry applications, and indigenous knowledge-based applications (DSI, 2023).

For the health innovation portfolio, investment expenditure remained almost constant between 2015 and 2017 at R43 million. In 2018, it rose by 75% to R75 million. The next two preceding year's expenditure remained constant at R51 million. The COVID-19-related needs for medical devices such as test kits raised spend in health and innovation in 2021 with an all-time record of R108 million. In terms of investment expenditure by the International Centre for Genetic Engineering and Biotechnology, it remained constant from 2016 to 2018 at R32 million. Spend declined in 2019 to R14 million and more than doubled in 2020 (R40 million), then dropped to R26 million in 2021, as depicted in Graph 12.

Graph 12: DSI programmes actual spend on R&D for health products



Source: DSI Annual Reports (various).

National Treasury and Department of Science and Innovation – R&D Tax Incentive

The South African government, overseen by NT and DSI, implemented a tax incentive to encourage private-sector companies to invest in scientific or technological research and development R&D in the country. According to NT, any company, irrespective of size or sector, that undertakes R&D within South Africa can apply for the incentive. Once an R&D project has been approved by the Minister of Higher Education, Science and Innovation, a company can deduct 150% of its qualifying R&D expenditure from its income (administered by the South African Revenue Service). This means a saving of 14c of every rand spent on R&D, at a corporate tax rate of 28% (National Treasury, 2021). There is no disaggregated data on tax incentives utilised specifically by the medical devices industry. The manufacturing sector reported on various companies from a diversity of sub-sectors such as software-related R&D, green-economy related R&D, and health-related R&D activities. The last recorded estimated R&D expenditure on approved applications in manufacturing was in 2018 at R11.7 billion.

Wesgro Cape Health Technology Park

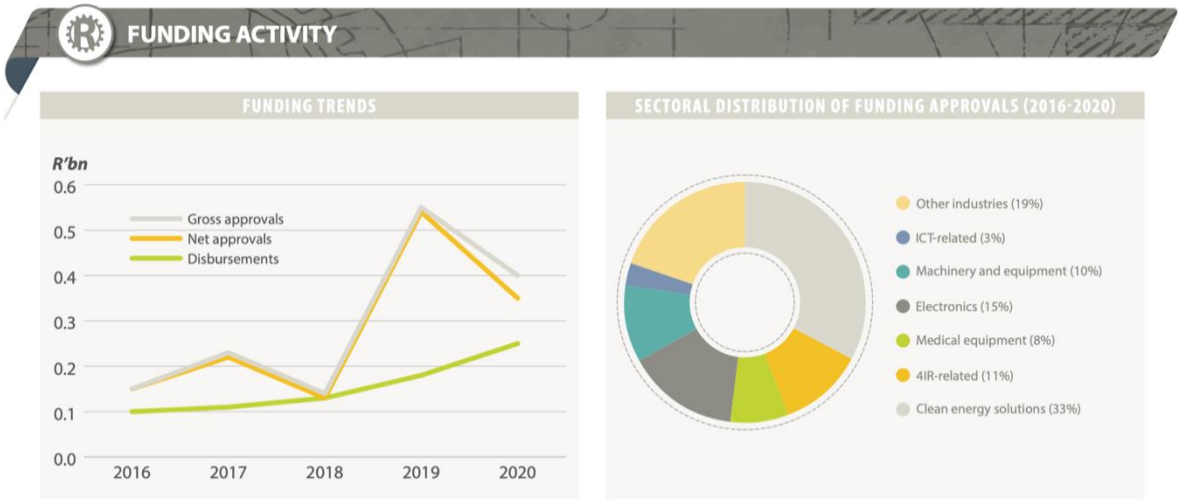
Wesgro is the official tourism, trade and investment promotion agency for Cape Town and the Western Cape. Wesgro assists investors and businesses looking to branch out into the province. Under its support programmes for different industries, is **healthcare infrastructure**. The Western Cape health technology sector spends R20 billion every year on research and development at South African universities, of which R3 billion is spent in the Western Cape, which boasts four world-class universities, two academic hospitals, the South African Medical Research Council, and the state-of-the-art Centre for Proteomic and Genomic Research. The largest portion of that spend is on health technology research and development (Wesgro, 2023).

The Cape Health Technology Park project is a partnership between Department of Economic Development and Tourism and DSI aimed at establishing a world-class innovation facility, which will culminate in the co-location of innovative firms, government and academia health innovation programmes, and business and innovation support organisations, with the main purpose of building a stronger pharmaceutical and human health technology industry in South Africa.

Industrial Development Cooperation and Gauteng Growth and Development Agency

The IDC provides funding for medical devices under the Chemicals, Medical & Industrial Mineral Products Strategic Business Unit, which supports entrepreneurship, promotes industrial development and strategic partnerships by building competitive industries and enterprises in South Africa and the rest of Africa. Medical devices are included in this portfolio. Some of the IDC funding is in combination with the dtic. The IDC also provides support within the machinery, equipment, and electronics sector. The IDC has approved investments in medical devices over the years as shown in Figure 4.

Figure 4: IDC spend on sectors



Source: IDC, 2020.

The GGDA is committed to creating an inclusive and transformed Gauteng economy that is focused on creating jobs, developing skills, developing innovative and sustainable enterprises, developing strategic economic infrastructure, increasing exports to the continent, and increasing foreign and domestic direct investment. It has the Gauteng Industrial Development Zone Company (GIDZ). The GIDZ has identified 29ha of land in the OR Tambo International Airport Precinct (ORTIA Precinct 2) to set up a medical manufacturing cluster. This is an approximately R4.2 billion (US$289.6 million) development located adjacent to the OR Tambo International Airport. This precinct has been earmarked for high-value, low-mass production like pharmaceutical and medical devices production as well as advanced component manufacturing. The GIDZ is looking to partner with developers to develop this land together. The GIDZ is also looking for investors wanting to set up medical manufacturing facilities in the ORTIA Precinct 2 (GGDA, n.d). Other funds available generally for industry include FinFind, Small Enterprise Development Agency (Seda) and the National Empowerment Fund (NEF).

Department of Trade, Industry and Competition

The dtic has several incentives for different sectors and industry. Incentives that can be utilised by the medical devices industry are listed in Table 3. The dtic also publishes an Annual Incentive Report.

Some of the incentives that can be utilised by the medical devices industry include in Table 3: Technology and Human Resources for Industry Programme (THRIP); Support Programme for Industrial Innovation (SPII); Manufacturing Investment Incentives; Investment Scheme; The Black Industrialists Scheme (BIS); Manufacturing Competitiveness Enhancement Programme (MCEP) Loan Facility; Export

Promotion Incentives; Export Marketing and Investment Assistance (EMIA); Sector-Specific Assistance Scheme (SSAS); Services Investment Incentives.

This section draws from existing public reports. In terms of classification of projects that may encompass medical devices, the range is wide, as medical devices can be reported under electronics, the health economy, or under pharmaceuticals, chemicals, and plastics. As such, reporting is an estimate of what could constitute – medical devices unless specified.

Between 2020 and 2021 a COVID-19 fund was created and implemented in partnership with NEF and the IDC to support manufacturers of essential products to contribute towards combating the COVID-19 pandemic. This funding attracted a total of 47 companies, which were approved for various medical supplies and equipment (the dtic, 2021) summarised in Table 3.

Table 3: Funding by the dtic, NEF and IDC between 2017/2018 and 2020/2021

YEAR	DESCRIPTION
2017/2018	Capital Projects Feasibility Programme - Medical park - R 2 200 000
2017/2018	Support Programme for Industrial Innovation (SPII) – e.g. Hearing devices - R1 162 000
2019/2020	Black Industrialists e.g. Plastics consumables for health industry and Test kits Beds - R31 703 971
2019/2020	Technology and Human Resources for Industry Programme (THRIP) e.g. Health technology - R74 548 777
2019/2020	Support Programme for Industrial Innovation (SPII) Health economy - R1 821 598
2019/2020	Export Marketing and Investment Assistance Scheme (EMIA) - R452 802
2020/2021	Export Marketing (EMIA) – e.g. showcase global medical equipment used for x-rays, ultrasounds, mammograms - R100 000
2020/2021	Health Economy e.g. Video Laryngoscope device Software laboratory information management, Video Laryngoscope device, Software application that focuses laboratory information management among others - R283 042 307

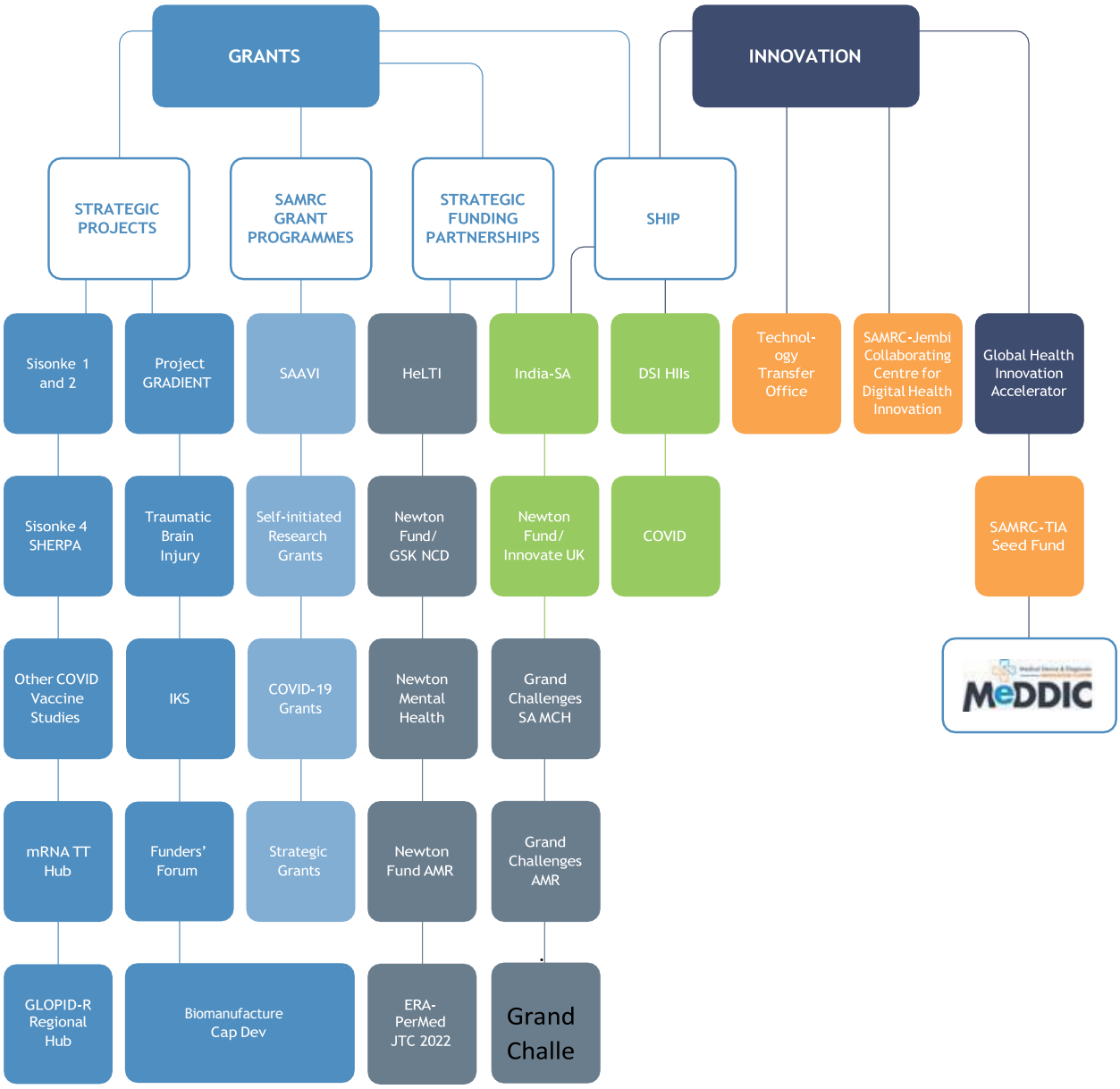
Source: the dtic, 2021. Annual Incentive Report.

Investment Associations and Banks

SAMRC

SAMRC has the **Grants, Innovation and Product Development (GIPD)** Unit, which is the custodian of grant funding and innovation. This unit was created to consolidate grants in 2016. The GIPD manages all external grant processes for strategic partnerships and innovative research projects. Figure 5 highlights various grants offered.

Figure 5: Type of programmes and grants administered by SAMRC



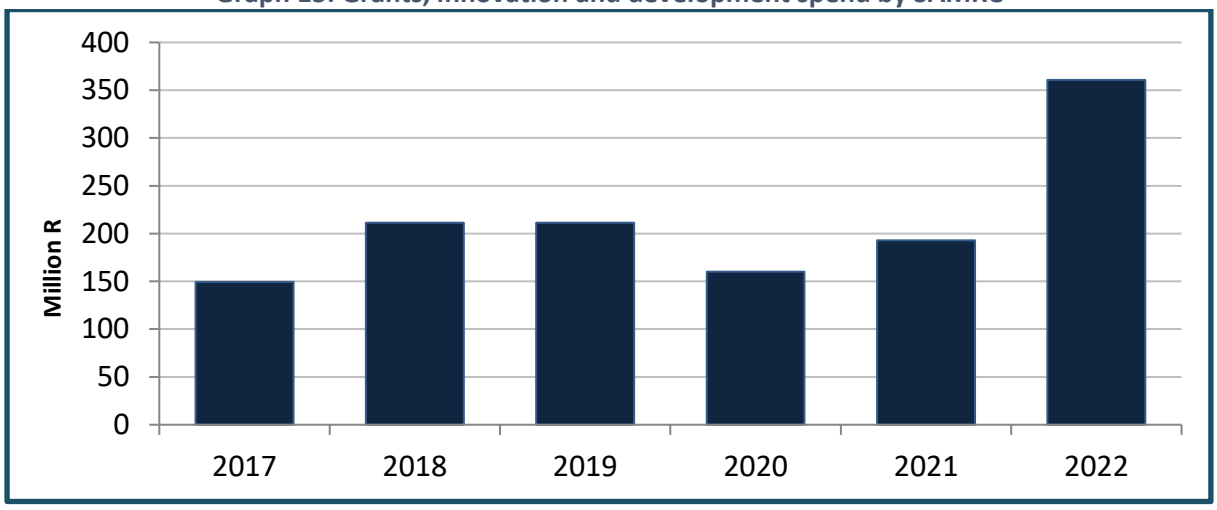
Source: SAMRC 2023. Website - Grants, Innovation and Product Development Unit.

External grants towards the various programmes include innovation and product development in medical devices, among others, were at R150 million in 2017. These grants increased in 2018 by 40% to R210 million. Although there was a decline in external grants in 2020 and 2021, these have recovered with R360 million in 2022, (SAMRC Annual Reports 2017-2022 various).

Under the Global Health Innovation Accelerator, and funded by TIA, SAMRC hosts the **Medical Device and Diagnostic Innovation Cluster (MeDDIC).** MeDDIC was launched in March 2021. According to SAMRC (2022:205), MeDDIC "is a national initiative created to exploit a high concentration of skills, expertise, infrastructure, and companies across South Africa within the medical devices field. The initiative, supported by TIA and DSI is aimed at stimulating and intensifying technology innovation within the sector as well as encouraging an integrated ecosystem in support of increasing the competitiveness of the industry." The cluster, among other initiatives, aims to leverage funding for the medical device industry. Since its inception funds have been granted to four industry projects for

the localisation of medical devices to replace imports and seed funding to nine projects to develop novel medical devices.

Graph 13: Grants, innovation and development spend by SAMRC



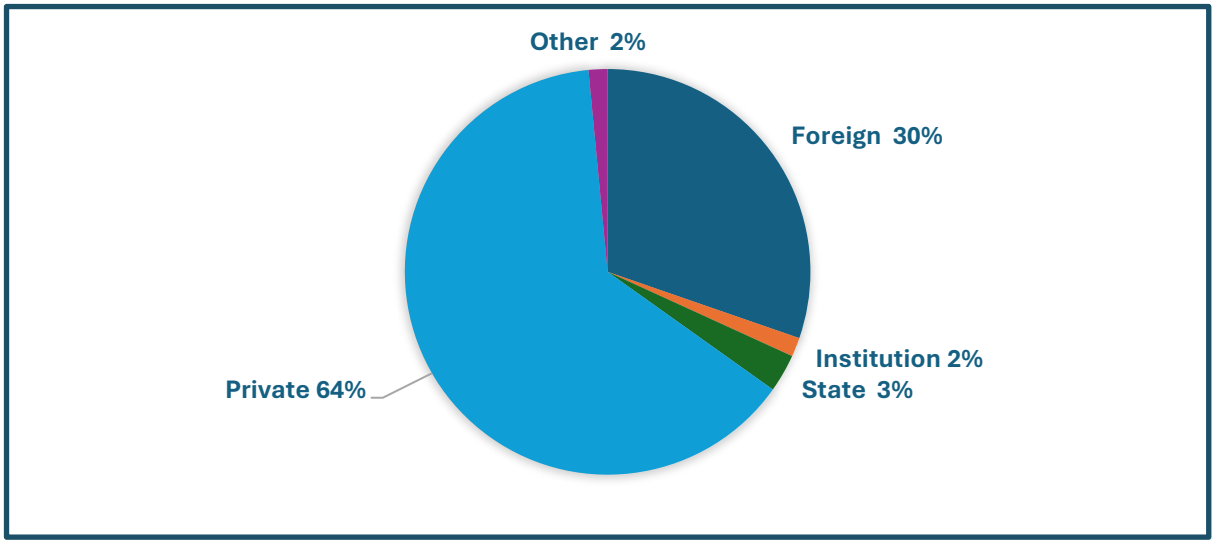
Source: SAMRC Annual Reports (2017-2022 various).

Banks

Although banks do invest in the medical devices industry, public data and information on spend is unavailable. Spend or investment would most probably be in the form of private negotiations with individual firms or groups.

Investments from abroad and ownership: Data on foreign direct investment into the local medical devices sector is fragmented. Trade Map offers some qualitative data capturing transactions by sector, year, parent company and domicile. About 30% of companies are foreign affiliated. The private sector comprises 64% and these companies can also have shareholder and investments from abroad (see Figure 6).

Figure 6: Ownership of companies



Source: Who Owns Whom, 2020.

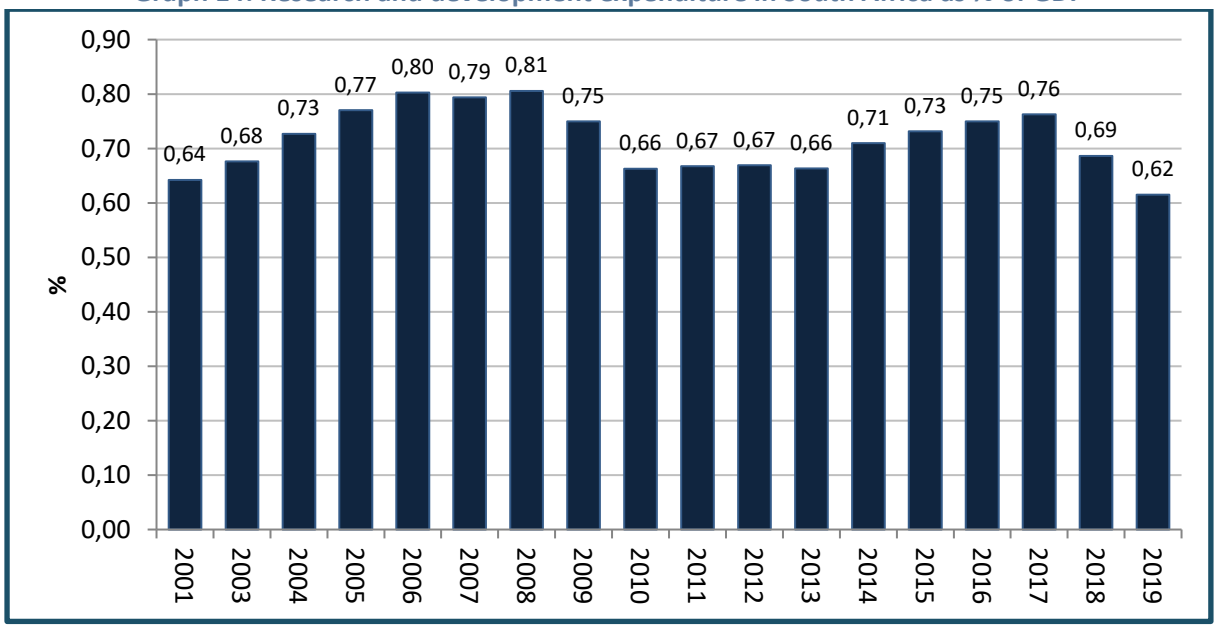
Research and development

As indicated, according to SAMRC (2022), research and development expenditure in medical devices in South Africa is low as a percentage of turnover for the industry. It is reported at less than 1%,

compared to a global average of 6.8%. Despite constraints, it was noted most companies indicated in their strategies to increase capital expenditure, followed by product development and diversification. R&D in medical devices in South Africa is low compared to other international industries. In terms of firm level investment in R&D, SAMRC (2022) notes that of the 66 firms interviewed 30 noted that they spend less than 5% of their turnover on R&D, while 21 firms spend 0% of their revenue on R&D.

R&D as a percentage of GDP in South Africa is below 1%, which need to improve as the world average is slightly above 6% (see Graph 14).

Graph 14: Research and development expenditure in South Africa as % of GDP



Source: World Bank, 2020. Research and Development Spend.

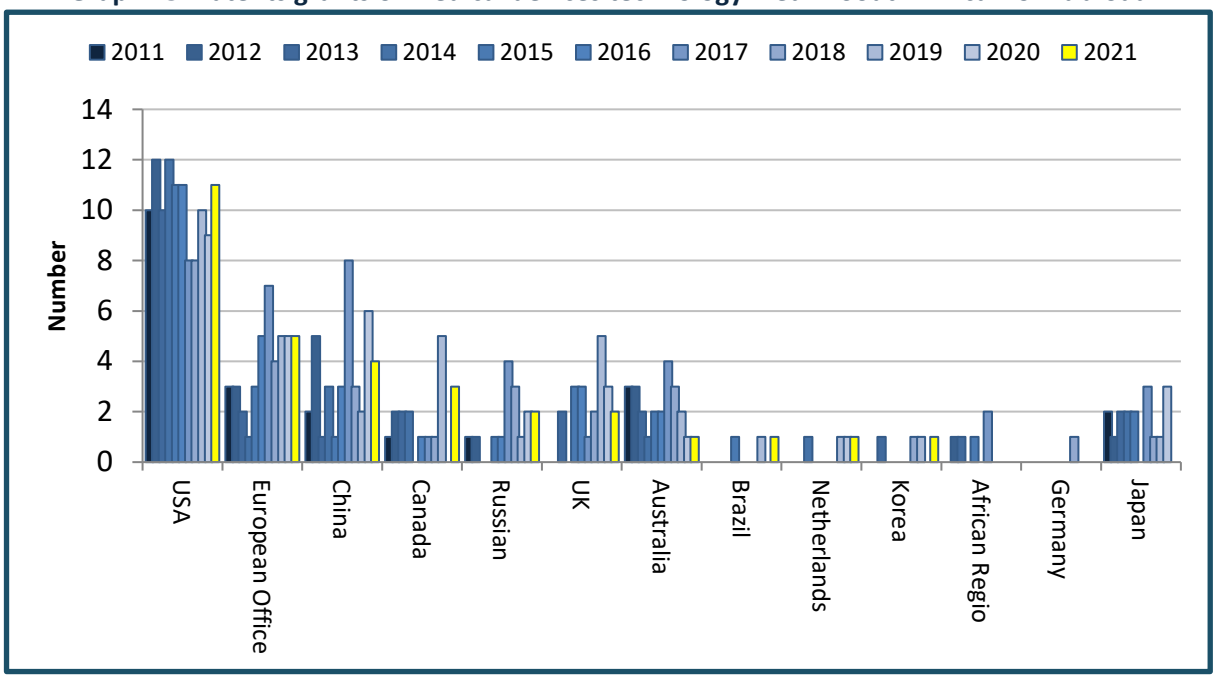
Patents

A patent is an exclusive right granted for an invention and is considered a territorial right. The exclusive rights are only applicable in the region or country in which a patent has been filed and granted, in accordance with the law of that country or region.

Patents protect investment backed expectations in the sense that inventors usually invest in developing and commercialising their inventions after the patent is granted. Holding granted patents or have pending patent applications are more likely to draw larger venture capital investments. Generally, patents contribute to firm growth because they confer monopolistic market rights, protection from any competitors, increase the negotiating position of patent holders and other benefits, (Hoenen, 2012). Graph 15 shows that patents filed from abroad in South Africa mainly originate the United States (US), European Union (EU) Patent Office, China, Canada, Russia, United Kingdom (UK), and Australia.

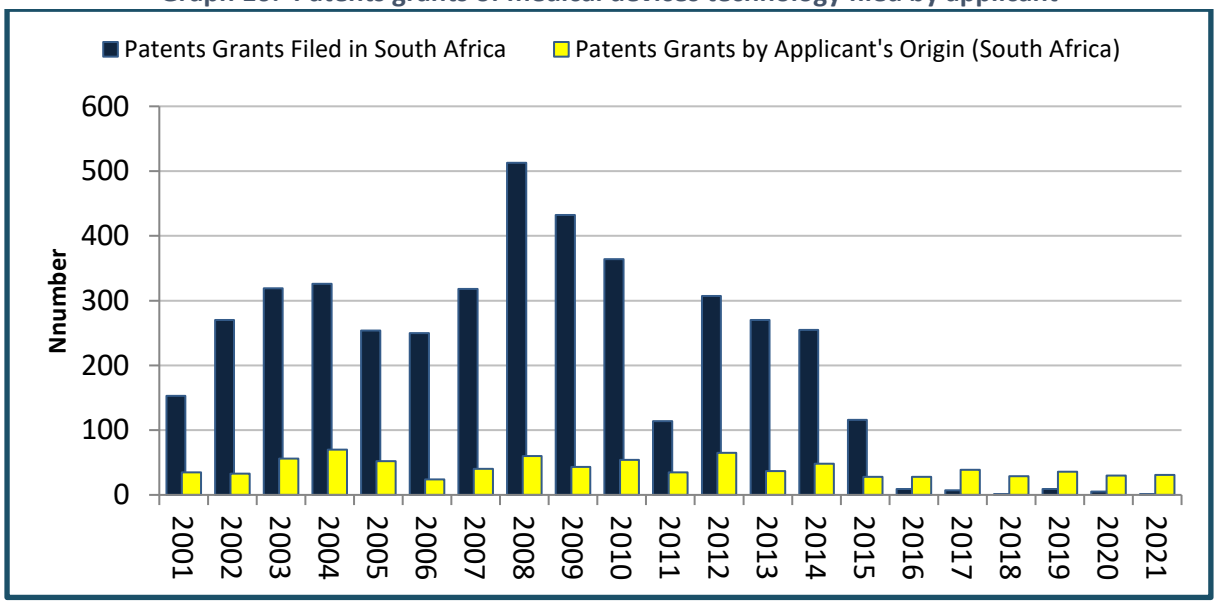
In terms of patents filed by origin, that is applicants originating from South Africa, the average was 33 over a period of five years (2017-2021). Patents filed in South Africa have been decreasing over the years, from a high of 513 in 2008 to just below 10 after 2016 (see Graph 15).

Graph 15: Patents grants of medical devices technology filed in South Africa from abroad



Source: WIPO, n.d. Statistics Center.

Graph 16: Patents grants of medical devices technology filed by applicant



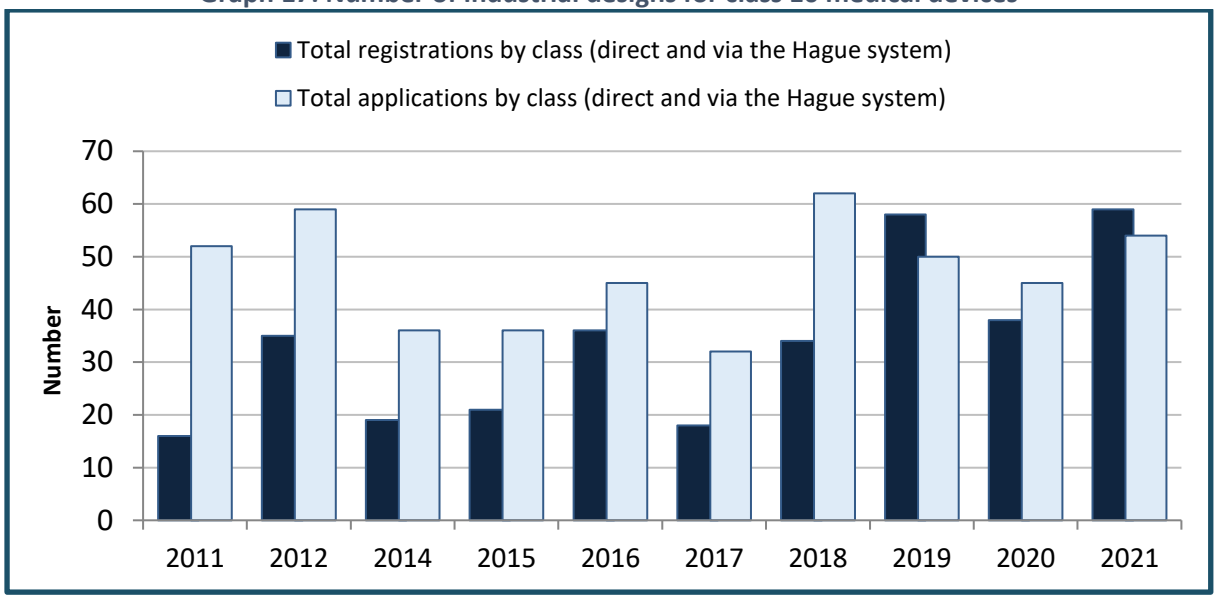
Source: WIPO, n.d. Statistics Center.

Designs

Essentially a "design" is about shape and features that appeal to the eye. Some designs are necessitated by function and others are aesthetic (WIPO, n.d.). Class 10 Medical Devices encompasses surgical, medical, dental, and veterinary apparatus and instruments. Designs also give manufacturing firms a competitive edge against other goods.

Drawing from the above definitions, data for South Africa provided by WIPO starts from 2011. It highlights that South Africa registered 16 designs in 2011, these later rose to 58 in 2019 and 59 in 2021. In terms of applications, the largest number were made in 2018, and after that they declined to 54 in 2021 (see Graph 16).

Graph 17: Number of industrial designs for class 10 medical devices



Source: WIPO, n.d. Statistics Center.

3.6 Trade in medical devices

Trade in medical devices is shaped by fundamental debates, particularly between trade, industrial policy, and health policy. A rise in imports, which is prevalent across Africa, highlights growing spend on healthcare for fighting disease burdens in the private and public domain, by individuals, government, or local and international organisation. It highlights expanding healthcare systems and a need to meet the Sustainable Development Goals. In terms of industrial policy, it helps to identify possible avenues for localisation and procurement, and the competitiveness of the industry. In terms of trade policy linked to industrial policy, it helps identity if there is a need for tariff protection, or export promotion or other issues that may impact the industry.

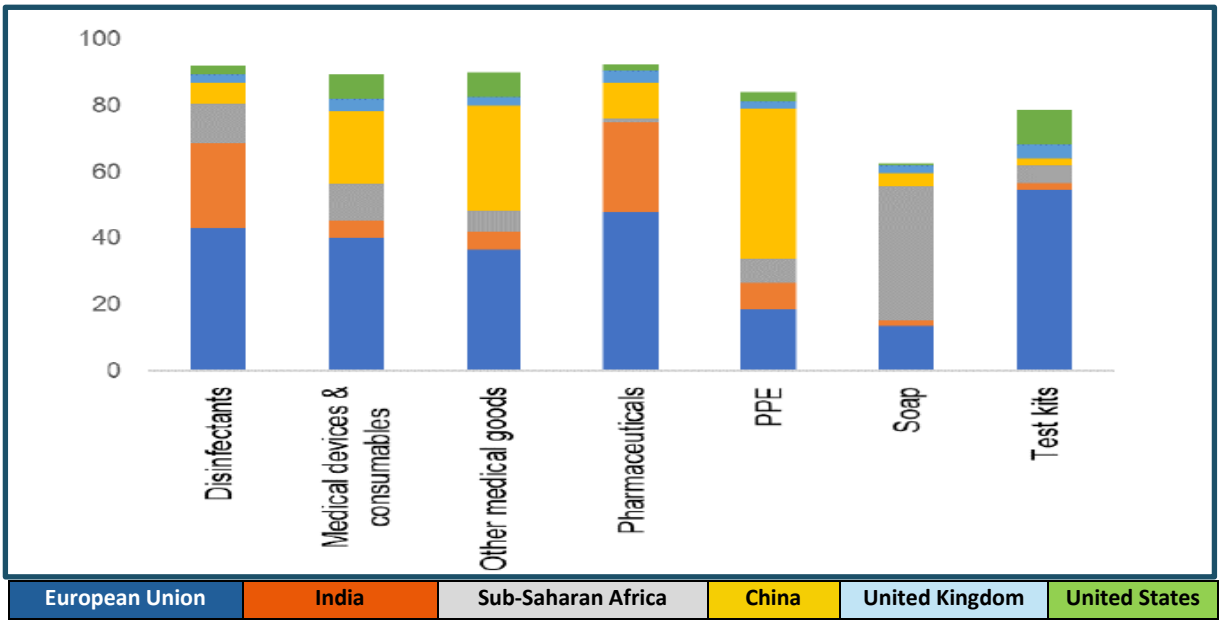
The International Monetary Fund (IMF) Africa department produced a special series in 2021 on the trade of medical goods in Sub-Saharan Africa. African countries import a significant amount of medical goods. The high level of imports is driven by factors such as spend and growth of public and private healthcare systems or spend by international and regional organisations providing healthcare services. At times very high imports of medical devices and consumables correlate with unforeseen pandemics such as COVID-19.

Imports by Sub-Saharan Africa are for: 1. Disinfectants 2. Medical Devices and Consumables 3. Other Medical Goods 4. Pharmaceuticals 5. Test Kits 6. Soap.

Graph 18 highlights the source of imports by percentage of Sub-Saharan Sources of Medical Goods by Category. It is clear there is very little intra-regional trade for medical goods save for soap. The supplier for most goods originates from Europe, China, and India. This also presents opportunity for South Africa to supply the region in medical device and test kits.

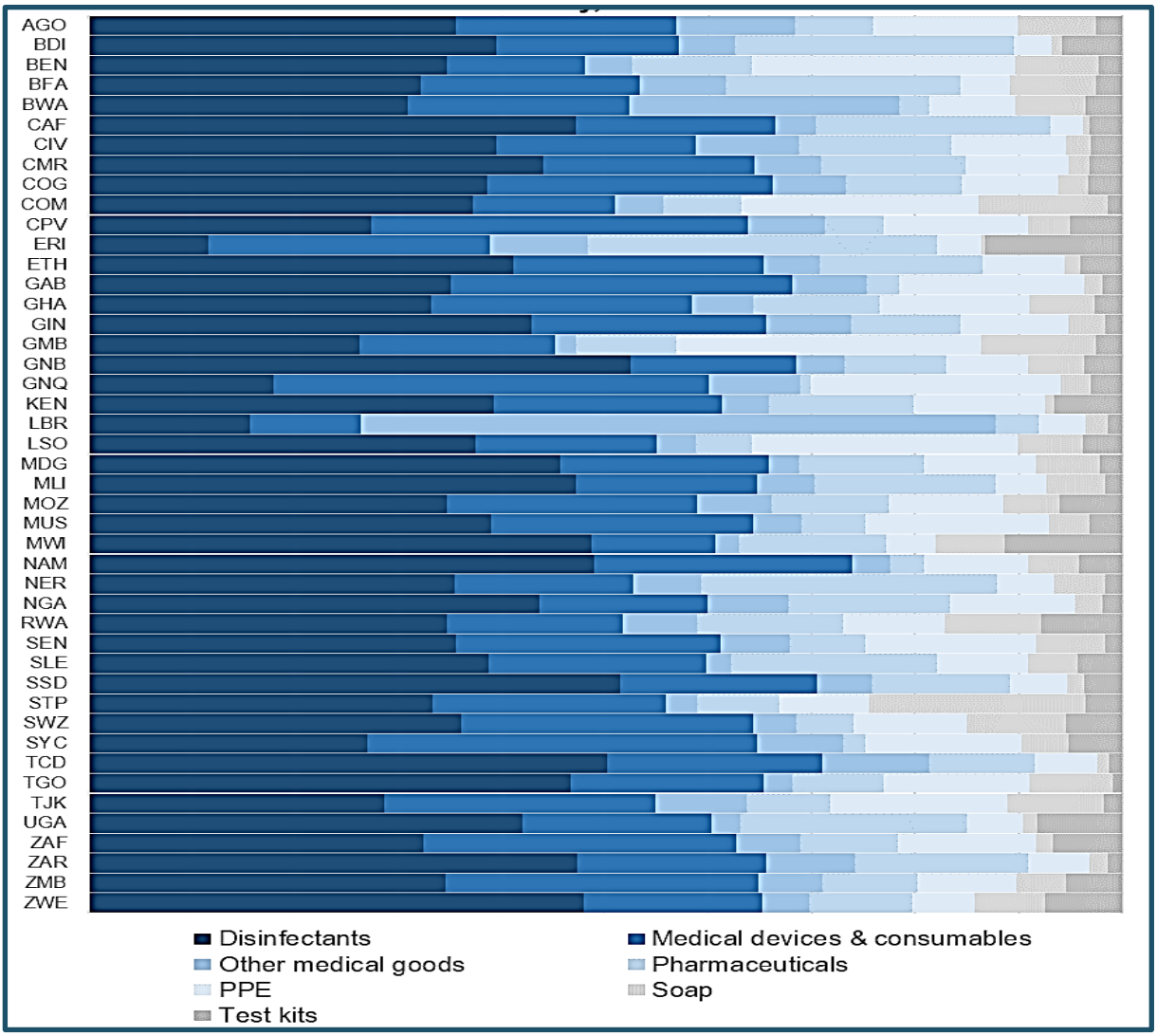
Graph 19 isolates imports by country and type of medical goods. Particularly for medical devices and consumables the following countries show a high level of imports: Cape Verde, Gabon, Equatorial Guinea, Seychelles, Swaziland, South Africa, Zambia, Namibia, Mauritius, Ghana, Guinea, and Gambia. The vast nature of imports in Africa, could represent an opportunity for the South African market of medical devices industry to export and provide crucial goods for health care systems. It should be highlighted that countries such as Namibia, Botswana, Eswatini and Lesotho import 60% to 70% from Southern Africa and in particular South Africa.

Graph 18: Sub-Saharan sources of medical goods imports by category, 2019 (percent)



Source: Shushanik and Cherif, 2021. Africa Department.

Graph 19: Share of imports of key medical categories in Southern Africa



Source: Hakobyan and Cherif, 2021.

Overall trade of medical goods in South Africa

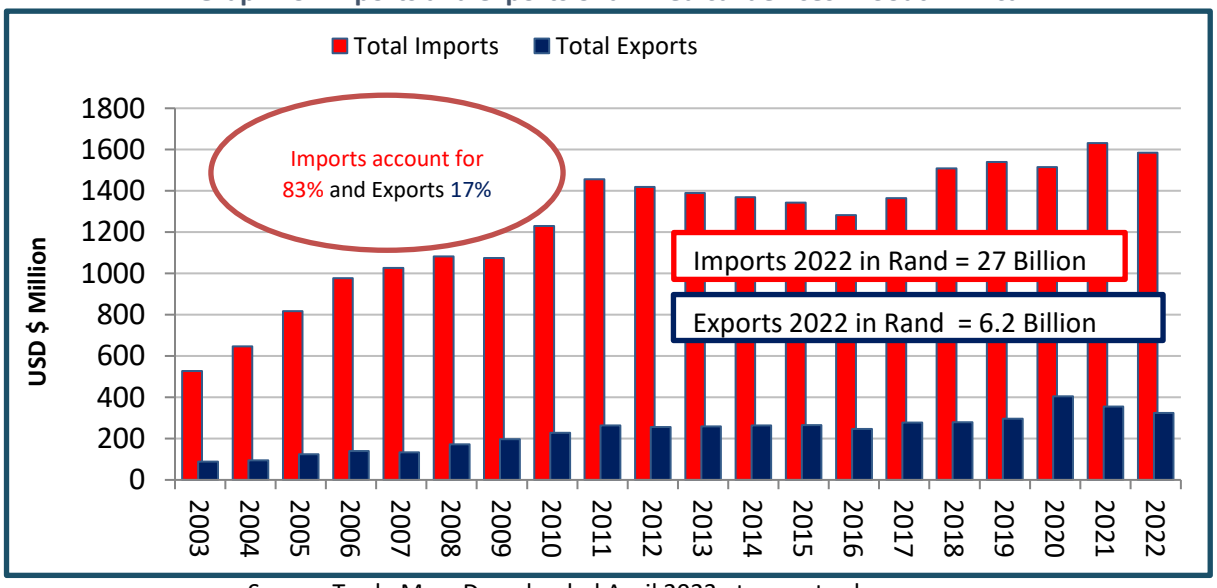
Trade of medical goods cuts across the textiles, steel, plastics, glass, wood products industry and many more. It is a large industry covering more than 55 HS codes.

The contribution of all medical devices imports to South Africa's total imports is substantial. About 83% of medical goods are imported compared to 17% which are exported. As stated, imports illustrate positive outcomes such as fighting the disease burden and as well increased spend on health by the public and private sectors, and some international organisations initiatives. The large number of imports signals demand and potential for growing the manufacturing sector. Due to the pandemic years between 2019 to 2022 imports will show a spike particularly for goods used to treat COVID-19. Imported products are often cheaper or accredited as per international quality and regulatory requirements compared to some local products.

In 2003, imports of medical devices stood at US$527 million. Imports continued to soar and doubled during the 2008 financial crisis to US$1 billion. Thereafter, imports continued to rise to US$1.4 billion in 2011. Imports decreased over the next five years to US$1.2 billion in 2016. Unfortunately, in the next three years, there was spike of US$300 million to bring imports to US$1.5 billion in 2018. Due to the COVID-19 pandemic, between 2020 and 2021 imports rose slightly to US$1.6 billion. Thereafter, there was some recovery in 2022 to US$1.5 billion, approximately R27 billion, demonstrated by Graph 19.

Exports of medical devices highlight capabilities the industry has in manufacturing as there are very negligible re-exports. Exports averaged US$91 million between 2003 and 2004. There was significant growth in the next three years (2005 to 2007) of an average US$132 million. Exports grew by a further US$61 million during the financial crisis to US$227 million. For the next four years (2011-2015) the medical device industry continued to show a positive growth trend with average imports at US$261 million. Exports grew by a further US$176 million to settle at an average of US$278 million by 2018. By the end of 2019 almost US$300 million worth of goods were exported. At the beginning of the pandemic, South Africa recorded its highest exports in 20 years of US$405 million or (R7.4 billion). Exports have since declined but remained above averages before 2019, at US$324 million in 2022 or R6.2 billion.

Graph 19: Imports and exports of all medical devices in South Africa



Source: Trade Map. Downloaded April 2023 at www.trademap.org.

Imports and exports of medical devices by categories

South Africa imports all six categories of medical devices. The largest share of imports are consumables and other medical devices followed by diagnostics images, orthopaedics, patient aids, and dental products, as shown in Graph 20. Each category mentioned above is further disaggregated in the annexure (see Annexure 1: Trade in Medical Devices and Annexure 2: Methodology of HS codes for Medical Devices).

Imports of **consumables** have significantly grown each year except for 2015 to 2017. Imports of consumables in 2003 stood at US$182 million. In 2013, imports of consumables rose to US$427 million. A decade later, imports of consumables in 2022 lay at US$630 million or R 11.5 billion, a 48% increase. Due to the COVID-19 pandemic, imports of consumables rose as they were mainly PPE which was a critical good required then.

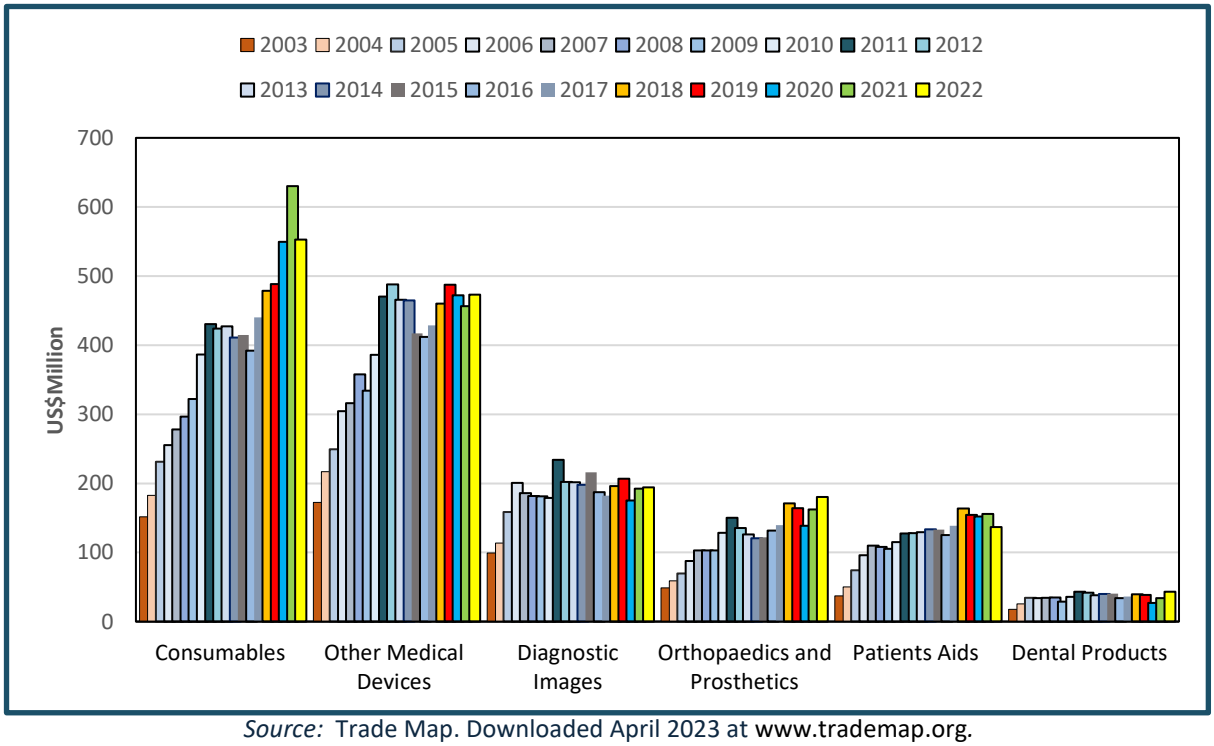
Other medical devices constitute a large share to imports of medical devices. Imports of this category soared from 2003 to 2012. Imports initially stood at US$172 million in 2003 to US$500 million in 2012. There was a decline until 2017 to US$459 million. Currently imports of other medical devices stand at US$453 million or R10 billion.

Imports of **diagnostic imaging** have remained fairly stable. Average imports in the last decade stand at US$194 million. In rand value 2022 imports stood at R3 billion.

Both **orthopaedic and prosthetics and patient aids** imports have shown an upward trend in the last two decades. Orthopaedic and prothesis imports lay at US$99 million in 2003, these rose to US$180 million in 2022 (R3.4 billion), an increase of 82%. Patient aids grew from US$49 million in 2003 to US$136 million in 2022 or R2.6 billion.

Dental products are the least type of medical devices imported. Imports have remained under US$44 million over the years. In 2022 imports stood at US$43 million or R830 million.

Graph 20: Imports of medical devices by six categories, 2003 – 2022



Source: Trade Map. Downloaded April 2023 at www.trademap.org.

In terms of exports, all medical devices except diagnostic imaging have shown growth over the years, as demonstrated by Graph 21, but are still outweighed by imports. In terms of **consumables**, South Africa exported a total of US$52 million in 2003. Exports of these products grew four-fold to US$200 million in 2020. With the coincidence of the COVID-19 pandemic, exports dropped by about 27% to US$147 million or R2 billion in 2022.

Exports of **other medical devices** remained constant between 2003 and 2005 at US$17 million. Thereafter, exports rose significantly to just over 50% to US$59 million in 2010. Exports continued to grow, averaging US$81 million between 2014 and 2019. In 2020, exports recorded a high of US108 million before declining by 16% to US$91 million or R 1.7 billion.

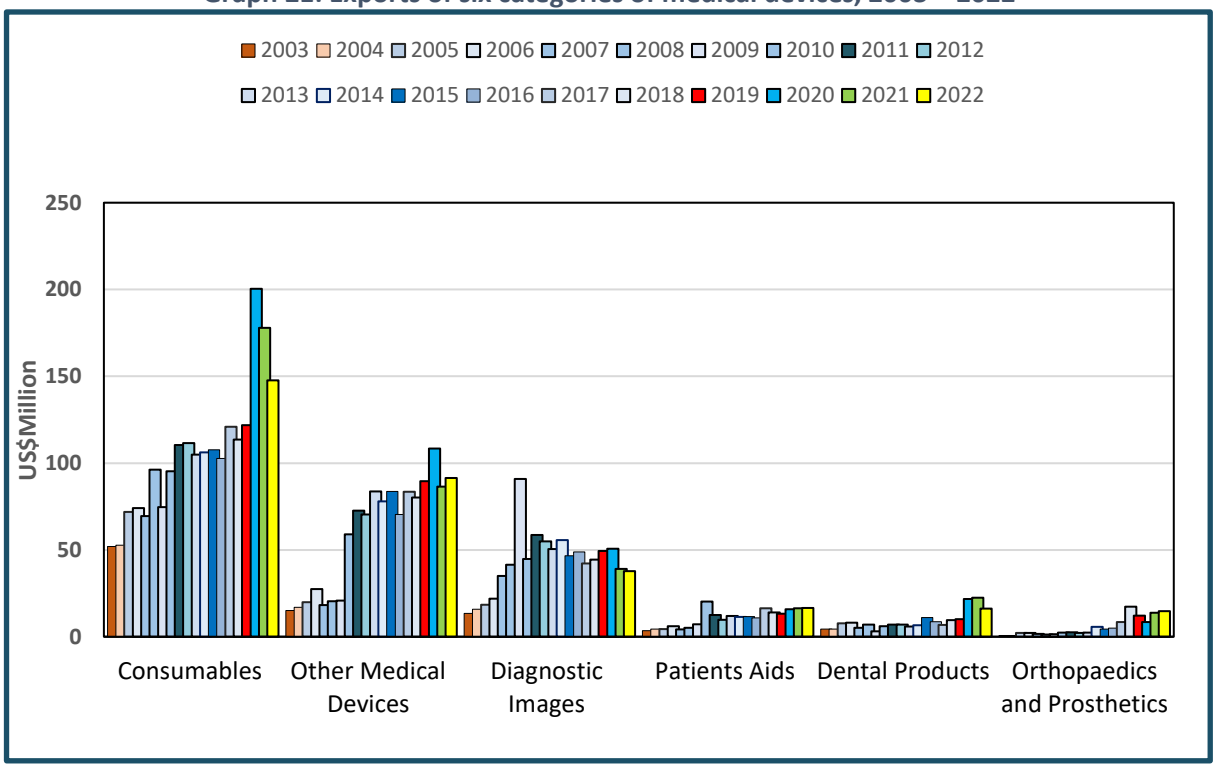
Diagnostic imaging exports showed an upward trend from 2003 to 2009, that is US$13 million to US$90 million (the highest yet recorded). Since 2009, exports of diagnostics have been declining with some slight pockets of growth. In 2014, exports stood at US$55 million before a further decline to US$50 million in 2022 or just under R1 billion.

Patient aids exports have never grown to more than US17 billion in the last 20 years. In 2003, exports stood at US$3 million and grew more than fivefold to US$16.5 million in 2022 or R 314 million.

Dental products exports averaged US$6 million from 2003 to 2014. In 2015 exports double to US$11 million before declining again in 2019 to US$10 million. There was significant growth in 2020 and 2021 of US$22 million. However, since then, exports have declined by 27% to US$16 million or R304 million.

Orthopaedics and prosthetics are the least exported medical devices. Exports averaged US$1.9 million, from 2004 to 2013. Exports rose significantly to US$8 million and soared to US$17 million in 2017. Since then, exports have declined to an average of US$14 million between 2021 and 2022. In Rand value this is R266 million.

Graph 21: Exports of six categories of medical devices, 2003 – 2022



Source: Trade Map. Downloaded April 2023 at www.trademap.org.

Top import origins of medical goods

Table 5 highlights the top exporters of medical equipment to South Africa. Most imports originate from the European Union, the US and Asia in particular China. Internationally, Ireland is one of the top leads in medical device manufacturing and exporter.

Table 4: Origin of imports

MEDICAL CATEGORY	TOP FIVE IMPORTED PRODUCTS	IMPORT DESTINATION
Consumables	1. Diagnostic or laboratory reagents 2. Needles, Catheters, Cannulae (medical, surgical, dental) 3. Surgical gloves, vulcanised rubber 4. Wadding, gauze, bandages, dressing, plasters 5. Adhesive dressings	US, EU (Ireland, Germany, Sweden, France), China
Diagnostic Imaging	1. Electro-diagnostics (physiological parameters) 2. Apparatus X-Rays, medical, surgical, veterinary 3. X-ray generators 4. Opacifying Prep X-ray exam; diagnostic reagents 5. Apparatus based on use of X-rays, medical, surgical, veterinary	USA, China, EU (Germany, Ireland UK, Netherlands), Malaysia Japan
Dental	1. Instruments and appliances dental sciences, 2. Dental cements /dental fillings; bone reconstruction cements 3. Dental fittings 4. Apparatus X-rays for dental uses Dentist chairs	EU – Germany, Switzerland, France, UK etc; Asia- China, Japan, Korea, Vietnam; US, Israel, Australia
Orthopaedics and Prosthesis	1. Orthopaedic or fracture appliances 2. Artificial joints for orthopaedic purposes 3. Artificial parts of the body (ex-dental) 4. Graduated compression hosiery. 5. Artificial joints, for orthopaedic purposes	US, Asia – China, Malaysia, EU – Germany, Switzerland France, UK, Ireland, Italy); Costa Rica, Mexico
Patient Aids	1. Articles/ worn/carried/implanted to compensate a defect or disability. 2. Ozone/oxygen/aerosol therapy/artificial - therapeutic respiration 3. Hearing aids (excluding parts) 4. Pacemakers for stimulating heart muscles (excluding parts) 5. Mechano-therapy; massages; psychological aptitude-testing apparatus	USA, EU (Ireland, Switzerland, Germany, Denmark, UK, Ireland, Sweden); Asia – China; Costa Rica
Other Medical Devices	1. Instruments/ appliances used in medical, surgical, or veterinary sciences. 2. Ophthalmic instruments/appliances, n.e.s. 3. Operating tables, examinations, other medical furniture 4. Thermometers and pyrometers 5. Medical, surgical or laboratory sterilisers	US and Costa Rica; Mexico; Asia - China, Japan, Singapore, Korea; EU (Germany, France, Ireland, UK Switzerland)

Source: Trade Map. Downloaded April 2023 at www.trademap.org.

Export destination of medical goods

Top destinations for trade are largely the SADC region, West Africa as well as the EU and US, as shown in Table 5. SADC is still growing its manufacturing base and imports medical goods largely from Europe. This presents an opportunity for increasing regional trade and security of supply over road and rail boarders compared to deep sea and possible disruptions.

Table 5: Export destination of medical goods

MEDICAL CATEGORY	TOP FIVE PRODUCTS	EXPORT DESTINATION
Consumables	1. Diagnostic or laboratory reagents 2. Adhesive dressings 3. Wadding, gauze, bandages, dressings, plasters etc 4. Needles, catheters, cannulae 5. Syringes, with or without needles (medical, surgical, dental)	SADC, US, EU (Netherlands, UK, Spain, Germany, Belgium)
Diagnostics	1. X-ray generators 2. Electro-diagnostics (physiological parameters) 3. Apparatus - X-rays, for medical, surgical, or veterinary 4. MRIs 5. Computerised tomography (CT) scans	SADC; West Africa; EU – Netherlands, Germany); US
Dental	1. Dental fittings (excl. artificial teeth) 2. Instruments/ appliances in dental sciences, n.e.s. 3. Dentists', barbers', or similar chairs 4. Dental cements/dental fillings; bone reconstruction cements 5. Dental drill engines/other dental equipment	USA, Australia, EU (Netherlands, Switzerland, Spain), SADC
Orthopaedics and Prosthesis	1. Artificial parts of the body (excluding artificial teeth and dental fittings and artificial ... 2. Artificial joints for orthopaedic purposes 3. Orthopaedic or fracture appliances 4. Graduated compression hosiery [e.g., stockings for varicose veins], of textile materials, knitted or crocheted (excluding hosiery for babies) 5. Artificial joints, for orthopaedic purposes	SADC, US, EU (UK, Germany, Netherlands)
Patient Aids	1. Ozone/oxygen/aerosol therapy/artificial -therapeutic respiration 2. Articles/Applian, worn/carried/implanted to compensate a defect or disability. 3. Hearing aids (ex-part) 4. Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus 5. Pacemakers for stimulating heart muscles (ex-parts)	SADC, US, EU – Germany, UK)
Other Medical Devices	1. Instruments and appliances used in medical, surgical, or veterinary sciences, n.e.s. 2. Ophthalmic instruments/appliances, n.e.s. 3. Operating tables, examinations, other medical furniture 4. Thermometers and pyrometers 5. Medical, surgical or laboratory sterilisers	SADC, Nigeria, US, Germany

Source: Trade Map. Downloaded April 2023 at www.trademap.org.

Impact of COVID-19 on Trade and General Tariffs and Non-Tariff Barriers

The global COVID-19 pandemic exposed weaknesses in the global medical device supply chain and distribution models, resulting in shortages of critical medical devices. However, the crisis also revealed the potential for emergent collaborative models capable of developing and manufacturing products quickly. Several medical device-related activities were developed in response to the COVID-19 pandemic, such as the National Ventilator Project and the South African Solidarity Fund.[5]

A survey conducted by SAMRC in 2020 with medical device stakeholders confirmed that the pandemic created significant challenges for the sector, including inadequate specification of requirements, limitations to the medical device life-cycle process, uncertainty on demand, and timeous availability of grant funding. Respondents supported several interventions to strengthen the medical device manufacturing sector, including coherence between public health procurement and industrial policy measures, regulatory challenges, skills development, transparent central coordination of product requirements, and increased collaboration, cohesion, and coordination among all role players.

Overall, the survey revealed that South Africa has latent potential to expand the medical device sector and become a global player in the field, and digitally enabled collaborative networks could help realise this potential. The stakeholders also suggested that increased visibility of South Africa's manufacturing capabilities and capacity in response to public health emergencies such as the COVID-19 pandemic and improved data and information sharing between the private and public sector are needed.

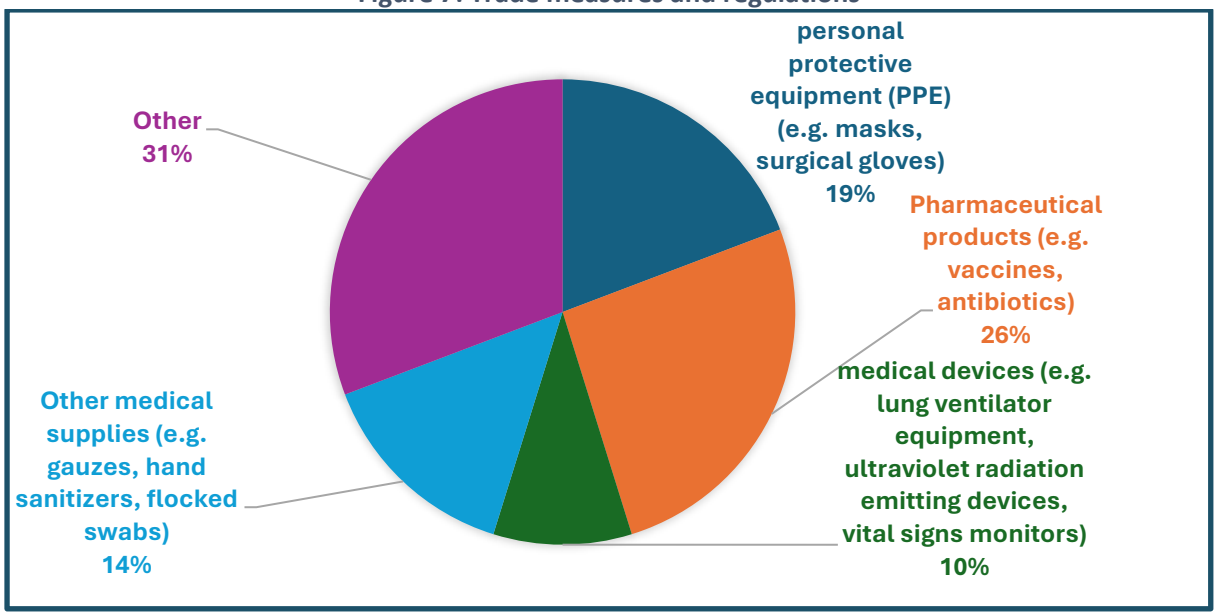
These suggestions were further stamped by the stakeholders in a workshop to identify the quick-win interventions that could be implemented in the short-term as laid out in Annexure 3: Quick Wins Workshop Report.

COVID-19 and trade in medical goods

The WTO notes the pandemic saw a rise in various trade-related measures amendments, notifications, and regulations. Some of these had a positive impact in facilitating trade during a pandemic and learning new ways that can alleviate cumbersome processes or barriers. Some, however, have added to the cumbersome process, appear undesirable but also emerged for the health and safety of the populace. According to the WTO's Technical Barriers to Trade (TBT) Committee, a significant number of the notified measures were reported as temporary (that is usually applying for a period of six months or one year, or for the duration of the public health emergency), however some are still running. Graph 8 illustrates by percentage notifications made.

[5] In fighting the Covid-19 pandemic, the National Ventilator Project was funded through the Solidarity Fund to engage local manufacturers to produce fit-for-purpose, non-invasive ventilators to improve access to ventilators of those who needed them. A total of R260.7 million was set aside for this project (Solidarity Fund, 2020).

Figure 7: Trade measures and regulations



Source: WTO, 2022.

Positively, some countries suspended or relaxed authorisation and certification procedures for PPE, other medical supplies (e.g., sanitisers, surgical gloves) and vaccines, allowing the use of IT tools to conduct remote conformity assessment procedures (e.g., remote inspections of pharmaceutical manufacturers situated abroad), and regulatory cooperation by, for instance, accepting test results from internationally accredited laboratories.

In addition, new developments, and suggestions to ease barriers were discussed in the latest TBT Committee convening, such as:

- Remote factory inspection through technology.
- Paper-based audits.
- Using e-labelling.
- Authorisation of qualified inspection bodies located in the exporting country to perform onsite factory visits.
- Acceptance of test results from third-party laboratories, third-party certification bodies of other members or recognised third-party certification experts instead of testing the products in a designated body in the importing country.
- Use of relevant international standards as a basis for technical regulations or standards on selected essential medical goods, as well as relevant international standards, guides, or recommendations as a basis for conformity assessment procedures associated with those measures.
- In Brazil, imports can happen without the agency registration as long as the products are regulated and marketed in the jurisdiction of one of the members of the International Medical Device Regulators Forum.
- EU member states to import Chinese masks manufactured and tested according to Chinese standards – as long as testing laboratories are accredited by the China National Accreditation Service for Conformity Assessment (CNAS). The CNAS has since cooperated with European Accreditation and published a list of accredited testing laboratories for PPE. This has helped EU authorities to gain confidence in CNAS accreditation.

Undesirably, there were also new regulatory requirements for medical goods that acted as barriers or challenges. Some of these included safety, quality, and efficacy criteria such as mandatory laboratory verification tailored for COVID-19 test kits; packaging and labelling technical specifications for hand-sanitizing solutions; and information and marketing requirements for masks.

A number of notifications for regulations, conformity, testing, and labelling have been submitted since 2020 by individual countries against any imports. Some did act as barriers, and some acted as opportunities for exports. To name a few, Brazil, in 2022, suspended the former need for compulsory certification for PPE; and in Kenya, minimum requirements were needed for testing methods during the COVID-19 pandemic or any other emergency.

Current tariff applications and bound rates for medical devices

The WTO released a series of information notes in 2022, 2021 and 2020 on **Trade in medical goods in the context of tackling COVID-19: developments.** Under the category, it should be noted that ***'medical supplies' fall under the broader category 'consumables' and 'medical equipment' fall under the broader category which form part of the greater goods for medical devices,*** the WTO tracked tariffs for the aforementioned.

Table 7 illustrates the average bound rates of members of the WTO. In the case of medical supplies, which are mainly consumables, all members of the WTO have an average duty rate of 30%. However, by actual numbers, 24 countries have a rate between 30% and 50%. For medical equipment the average duty is 23.7%, and by actual numbers 37 countries have a duty between 0% and 5%. This low duty is usually linked to the need for provision of healthcare and immediate response to facilitate access to key health products compared to protectionism. Looking at the maximum bounds of both the aforementioned categories, most countries have a bound rate between 95% and 100%.

Table 6: Average and bound rates at the WTO for all members

	All medical products	Medicines	Medical supplies	Medical Equipment	PPP		All medical products	Medicines	Medical supplies	Medical equipment	PPP
	Average bound duty [b] (%)						Maximum Binding coverage (%)				
All members	26.0	21.3	30.1	23.7	28.9		78.7	78.7	77.4	81.4	75.1
Range (%)	**Number of WTO members**						**Number of WTO members**				
Unbound		23		14	16			23		14	16
0 -5	21	42	14	37	11		11	24		15	16
5 <=10	16	4	16	11	15		7		17	1	2
10 <=15	11	14	9	10	9		1	1	2	4	4
15 <=20	11	5	13	11	20		2		7		2
20 <= 30	21	13	17	14	19		3	1			7
30 <= 50	23	27	24	29	31		3	1	7	4	4
50 <= 70	19	5	23	5	9		9	4	3	5	5

70 <=95	7		10		3		9	6	10	7	5
95 <= 100	4	2	6	3	2		90	98	89	99	90
GT 100	2		3	1							

Source: WTO, calculations from the Consolidated Tariff Schedules database and World Tariff Profiles 2020 dataset.
Note: PPP – Personal Protective Products

Tariffs applied by South Africa, other Upper Middle-Income Countries and SADC

Industrial policy often looks at tariffs applied by other countries to protect their industry and to weigh the implications for the local industry. For categorisation, the following methodology is used by the World Bank: low income, US$1085 or less; lower middle-income: US$1 086 to US$4 255; upper middle-income, US$4 256 to US$13 205; and high income, US$13 206 or more.

Tariffs, particularly for medical-related goods, can also be dependent on the disease burden of a country and therefore benchmarking depends on the capabilities a country has in manufacturing.

In terms of medical equipment, South Africa applies a much lower rate of 3.4% against other middle-income countries, i.e. Brazil 32.7%, China 4.9%, Russia 4.3%, Costa Rica 42.1%, Argentina 30.8%, Mexico 32.9%, Namibia 3.4%, Mauritius 0% and Malaysia 3%.

The nature of medical devices and impact on safety and health has led to some complaints being raised by many members of the WTO. Whether or not these disguise themselves as NTB can be difficult to gauge at times. Complaints seem to arise mostly among high-income countries such as the EU and US, and these are towards China, Brazil, India and Thailand. These complaints are issues around:

1. Meeting conformity assessment
2. Meeting regulations
3. Correct documentation
4. Quality system regulation, Good Manufacturing Practices (GMP)
5. Technical regulations
6. Devices GMP certification
7. Resolution on used, refurbished, rented, and lent medical devices.

Overall, trade in medical devices should be understood through the lens of health policy and industrial policy. High imports signal growing spending on healthcare, a human right, and demand which signals markets and potential for growing manufacturing base. There are issues that inhibit trade or become trade barriers such as meeting conformity assessments, yet at the same time are essential for safe use by end-user.

4. DEMAND

Public sector market

Government is the key consumer of the medical devices through procurement of healthcare equipment and supplies. Reportedly, it is made up of 86 516 registered beds in 4 283 facilities that are inclusive of 3 140 clinics (Who Owns Whom, 2020). However, public sector procurement is characterised by sluggish to non-payment of suppliers, with a knock-on impact on the producers' revenue. Slow payments further have a negative impact on small, medium and micro enterprises and black industry producers.

Private sector market

According to Who Owns Whom (2020), there are around 524 private health sector facilities with 40 514 registered beds. The demand for medical devices in the private sector is concentrated in the three hospital groups namely, Life Healthcare, Mediclinic and Netcare. Together, they account for around 67% of the private sector beds. The remaining 33% of the private sector facilities are the smaller independent facilities under the National Hospital Network (SAMRC, 2022). The private sector is also the largest employer of medical practitioners in South Africa, in excess of two thirds of the medical practitioners.

Both the public and the private sector healthcare markets in South Africa face high operational costs. Medical schemes have been cited as the cost drivers for medical devices, particularly in the private healthcare sector. Manufacturers of medical devices are price takers. The medical aids influence the prices. The manufacturers do not participate in price negotiations between the medical schemes and the hospital groups.

Out of the R173 billion total benefits paid by Medical Schemes for benefits where medical devices were used in 2018, medical specialists contributed the highest with 7.1% followed by surgical specialists at 5.6% and pathology at 5.5% (Who Owns Whom, 2020). In terms of utilisation of medical technology beneficiaries, the highest was CT scans at 44.28 patients per 1 000 beneficiaries, followed by MRI scans at 25.60 patients per 1 000 beneficiaries in 2018 (Who Owns Whom, 2020). Moreover, most of the revenue for the medical schemes arise from the private sector, constituting an excess of two thirds of total revenues. Furthermore, the private sector seemingly holds the best prospects of sales of advance technology, especially in the short run.

5. CASE STUDIES

The case studies were explored to provide an understanding of the medical devices industry by highlighting successful comparative and competitive advantages that enable them to be competitive. This will show where South Africa needs to improve to catch up, especially as it embarks on the localisation policy that seeks to strengthen local manufacturing capacity and capabilities. Two case studies were looked at, namely Costa Rica and Turkey. Costa Rica was selected as a case study for its developed medical devices value chain. Turkey was attractive due to its capability in building the regulatory environment that is aligned to the EU, the introduction to universal health care and its support to local industries (see Annexure 4: Case studies).

Box 1: Development of the medical devices value chain in Costa Rica

In the 1990s, Costa Rica strategically targeted the global medical devices industry to attract foreign direct investments (FDIs) and develop local manufacturing capabilities. This export-oriented FDI-driven strategy was supported by Costa Rica's investment promotion agency, CINDE, which provided services to attract investors and troubleshoot issues for foreign companies.

As a result of investment promotion policies and the establishment of Free Trade Zones, there was a significant influx of investments in the medical devices sector, leading to steady growth in exports and the creation of thousands of jobs. Costa Rica now hosts over 70 medical device companies, including major multinational players like Baxter, Medtronic, Allergan, Boston Scientific, and Hologic. The country offers attractive fiscal incentives such as tax exemptions to new medical technology firms operating within its free trade zones.

Costa Rica successfully diversified its economy, shifting from primarily agricultural exports to high-tech and service-based sectors, with medical devices becoming its top export in 2017. The country's strategy for economic diversification began in the late 1990s, focusing on medical devices as a key sector for growth.

Several factors attract investment in Costa Rica's medical devices industry, including fiscal incentives, a skilled workforce, investment in education and training, geographic location, English proficiency, industry growth and diversification, government stability and support, research and development, and adaptation to technology trends.

Despite challenges like the COVID-19 pandemic, the medical device industry in Costa Rica remained operational, demonstrating resilience and stability, with continued export growth. The country has become a hub for medical device production, attracting companies looking to nearshore their operations.

Looking to the future, Costa Rica anticipates further growth in health startups, particularly in areas like dental and cardiology, as well as in diagnostics, positioning itself to play a leading role in the global MedTech industry.

Box 2: Medical devices in Turkey

The Government of Turkey managed to attract investment in medical devices through its localisation policy programme in an effort to reduce the level of import dependence. This has been implemented through increased investment in healthcare infrastructure and services; promotion of medical tourism; as well as alignment of regulatory policies with international standards, especially with the EU standards.

Regulatory framework

While not an EU Member State, Turkey has aligned its regulatory framework for medical device manufacturers with that of the European Union.

- General: Customs Union
    - While Turkey is a de facto third country for the EU, the Customs Union between Turkey and the EU greatly facilitates the movement of commercial goods. As part of this agreement, Turkey has aligned its commercial law with EU law.
- Specifically: Medical devices
    - This is also true for medical device law. Turkey had already harmonised the EU medical device directives (Medical Device Directive (MDD), In Vitro Diagnostic Medical Device Directive (IVDD), Active Implantable Medical Device Directive (AIMDD)). In the meantime, the Turkish Medicines and Medical Device Agency has reconciled Turkish medical device and IVD regulations with the EU framework (Medical Device Regulation (MDR), In Vitro Diagnostic Medical Device Regulation (IVDR)).
- Harmonised requirements and CE marking
    - Since Turkey has aligned its legal framework with that of the European Union, devices which have successfully passed conformity assessment in Europe and bear a Conformité Européene (CE) mark, also meet the Turkish requirements. That is, medical devices with a CE mark may also be sold in Turkey – within the restrictions outlined below. No other conformity assessment is required.
    - No additional authorised representatives
        - In a notice to stakeholders, the EU Commission has made it clear that EU manufacturers are not required to have an authorised representative in Turkey and, by extension, Turkish manufacturers do not require an authorised representative in the EU either.
        - Moreover, manufacturers from third countries intending to supply both markets only need to appoint one authorised representative, either in Turkey or in the EU.
- Other
    - The Customs Union eliminates customs restrictions. After the transition periods, device registration and vigilance notifications in EUDAMED (European Database on Medical Devices) will also suffice. Manufacturers are no longer required to use the Turkish database for these aspects.

6. SWOT ANALYSIS

Table 8 highlights the strengths, weaknesses, opportunities and threats in South Africa as collated by SAMRC, 2022. The medical devices industry has several strengths and opportunities that are and can drive positive roll-over effects for growth, in addition to meeting and alleviating basic human rights of health care. There are also threats and weakness that must be comprehended.

The table below assesses SWOT by factors such as the:

- Macroeconomic environment and policy
- Global and local demand and developments
- Industry finance (financial and non-financial support)
- Industry regulatory systems, compliance, and dynamics
- Industry Growth and Development

Table 7: SWOT analysis of South Africa's medical devices sector

Strengths	Weaknesses
Global and Local Demand and Health Spend ○ Steady demand for medical devices, even during an economic downturn. ○ Large population. ○ Increased government spending on equipment as part of the National Health Insurance (NHI) scheme. ○ Access to Sub-Saharan African markets. ○ Private sector market affordability for high tech medical devices. **Macroeconomic Environment and Policy** ○ Political stability in South Africa, strong and independent institutions, judiciary and security services. ○ Limited threat of terrorism. ○ Industrialised economy and rich mineral resources. ○ Quality transport infrastructure. ○ Low staff turnover in medical device industry. ○ Strong private healthcare sector. ○ Weak Rand is a possible driver for local development and manufacture. ○ Established exports of hi-tech, high value medical device products. **Industry Finance and Investment (Financial and Non-Financial Support)** ○ Financial hub and stable banking sector. ○ Much of SA public debt is denominated in local currency.	**Macroeconomic Environment and Policy** ○ High structural unemployment, poverty and political disenfranchisement. ○ Corruption ○ Economy over-dependent on primary commodities ○ Currency volatility ○ Labour market rigidities ○ Very high crime rate ○ Private healthcare sector out of reach for most of the Black population. ○ Many rural facilities under-used or idle due to poor organisation ○ HIV/AIDS overburdening the system. ○ Chronic shortage of medical personnel ○ Poor healthcare infrastructure, particularly in the rural areas. ○ Small size of domestic market and only about 5% of devices used are manufactured locally. ○ Currency fluctuations create volatility for both imports as well as cost of production for locally manufactured medical devices. **Industry Regulatory Systems, Compliance and Dynamics** ○ Lengthy business registration, closing and opening turnarounds. ○ Purchasing procedures complex and fragmented ○ Inconsistent quality of local manufacture.

○ Public funding (the dtic and IDC) of the sector ○ Recent private equity investment in the sector. ○ Government support for exports and innovation in the Western Cape. **Industry Regulatory Systems, Compliance and Dynamics** ○ Observance of contracts and intellectual property rights. ○ Steady demand for medical devices ○ Licensing requirements promoting compliance and product safety. ○ Pockets of innovation excellence with market potential in resource-constrained environments	○ Lack of device level licensing/registration. ○ Lack of stakeholder/roleplayer alignment. ○ Medical aid schemes power over pricing of medical devices. ○ High compliance costs for international accreditation which is a procurement requirement. ○ Delayed payments from the public sector for medical devices which create financial constraints for companies, e.g., walking implants. **Industry Finance and Investment** ○ Low levels of R&D. ○ Medical device research underfunded. ○ Reimbursement for medical devices increasingly challenging and constrained.
Opportunities	**Threats**
Macroeconomic Environment and Policy ○ Emerging party-political diversity. ○ Microeconomic reforms, including improved skills training, to alleviate poverty. ○ Emergence of affluent, Black middle class. ○ Private security firms filling gaps left by the police. ○ Government health funding to increase in real terms. ○ Expansion of HIV treatment reducing pressure on public healthcare system. ○ NHI scheme prompting investment in the public healthcare system. ○ A large poor and under-served population that has difficulty accessing specialists, presents opportunities for innovation. **International Regional Developments** ○ Inter-regional trade agreements facilitate trade flows and reduce costs. ○ Greater interregional freight connections envisaged. **Industry Growth and Development** ○ Public-private partnership growth.	**Macroeconomic Environment and Policy** ○ High levels of HIV/AIDS impact on economic growth. ○ Political/policy uncertainty undermining investor confidence. ○ Land reform uncertainty. ○ Health policy affected by politics, alleged cronyism and corruption. ○ NHI implementation dependent on private practitioners contracting with the public sector uptake of which has been slow. ○ Inefficient public procurement and payment. ○ Exchange rate volatility. ○ Brain drain. Lack of skilled artisans who are required in the broader ecosystem of the sector. **Trade and Compliance** ○ Increased imports, especially cheap imports of inferior quality. **Industry Regulatory Systems, Compliance and Dynamics** ○ Cost of certification for local manufacturing and exporting.

○ Establishment of the new medical device regulator (SAHPRA). ○ New regulations will establish internationally aligned regulatory framework. ○ Aesthetic medical device market growth. ○ Alternative clinical therapies are presenting untapped sources of innovation. ○ Serving low income, under-served populations who have difficulties accessing specialists. ○ The use of wearable tech and other digital solutions presents an opportunity for local innovators.	○ Increasingly burdensome regulatory landscape increasing costs for local players. ○ Responsiveness of regulator to new technologies in the sector as well as shorter innovation cycle which is applicable to medical devices.

Source: SAMRC, 2022.

Constraints

Several constraints hinder investment in the medical devices industry. For instance:

- One of the reasons that private companies are reluctant to invest in R&D is also the perception that R&D is generally expensive and its outcomes uncertain. There is also a general lack of understanding of the medical devices sector vs pharma. The medical devices sector is much more varied in terms of the diversity of products as well as the shorter innovation cycle, which makes it much more competitive. Nevertheless, the sector remains highly profitable.
- Demand for medical devices has an effect on capital spend on research and development, firm expansion or upgrading machinery. Despite Sub-Saharan Africa having a population of over 300 million people, the region has the smallest market in relation to the rest of the globe for medical devices. Globally, this is driven by low per capita spending, a small elderly population, and low urbanisation and continued poverty (SAMRC, 2022).
- Although R&D activity may lead to a positive result (hoped for or unforeseen), it may not.
- Returns may not be attained as initially intended and the payback period for investment can be quite long.
- Limited access to information and consolidated platforms for finance.
- High product diversity and shorter innovation cycles increase the risks of investment in new technologies.

7. CONCLUSION

The paper examined the medical devices value chain in South Africa, looking at the issues of production, manufacturing, cost drivers, trade and demand as well as the sector's strengths, weaknesses, opportunities and threats. Furthermore, it looked at the cases of Costa Rica in terms of its well-established medical devices sector, and Turkey in terms of its robust regulatory environment.

The analysis of South Africa's medical devices value chain highlights the sector's complexity, encompassing a wide range of products, companies, and rapid innovation cycles. Despite these challenges, the sector remains an integral part of healthcare delivery and holds substantial potential for growth. To harness this potential, it is essential to establish a business and regulatory environment that is agile and responsive to technological advancements while ensuring public health and patient trust.

The medical devices sector presents numerous opportunities for local manufacturing and international investment. However, realising this potential will require addressing constraints such as limited R&D funding, regulatory compliance costs, and the need for skilled professionals. By fostering an enabling environment that supports innovation and investment, South Africa can enhance its position in the global medical devices market and contribute significantly to healthcare outcomes.

In summary, while the medical devices sector in South Africa faces several hurdles, its profitability and growth prospects are promising. Strategic investments and supportive policies can transform these challenges into opportunities, driving the sector towards sustainable development and greater contribution to the national economy.

REFERENCES

Bamber, P. and Gereffi, G. 2013. Costa Rica in the Medical Devices Global Value Chain: Opportunities for Upgrading. (August), p. 63. Available at: file:///C:/Users/regru/Downloads/2013-08-20_Ch2_MedicalDevices.pdf

Bizcommunity. 2022. The role of the MDMSA and recent MDMSA developments. Available at: https://www.bizcommunity.com/Article/196/148/231121.html#:~:text=The%20role%20of%20the%20MDMSA,less%20than%20250%20staff%20each

Department of Science and Innovation. 2023. DSI Annual Reports 2015 – 2022. Accessed Available at: https://www.dst.gov.za/index.php/resource-center/reports/annual-reports Accessed August 2023).

dtic (the). Annual Incentive Report. Department of Trade, Industry and Competition Accessed May 2023 at http://www.thedtic.gov.za/wp-content/uploads/PC-Trade-the-dtic-Annual-Incentive-Report.01-March-2022.pdf

dtic (the). 2021. Annual Incentive Report. Department of Trade, Industry and Competition. Available at: http://www.thedtic.gov.za/wp-content/uploads/PC-Trade-the-dtic-Annual-Incentive-Report.01-March-2022.pdf (Accessed May 2023).

Fitch Solutions. 2021. South Africa Medical Devices Report Q3 2021. Fitch Solutions Group Limited (London).

Frost and Sullivan. 2010. An Overview of the Medical Device Supply Chain and Trends in Europe.

GGDA, n.d. Five Development Corridors. Gauteng Growth and Development Agency. Available at: https://ggda.co.za/5-development-corridors/ (Accessed February 2024).

Hoenen, S. 2012. Do Patents Increase Venture Capital https://edepot.wur.nl/216191 Investments between Rounds of Financing? .Wageningen University and Research Center. Available at: (Accessed March 2024).

IDC. 2020. Integrated Annual Report 2020. Industrial Development Corporation of South Africa. Available at: https://www.idc.co.za/annual-results/

International Trade Administration. 2024. South Africa – Country Ciommercial Guide. Healthcare: Medical Devices and Pharmaceuticals. Available at: https://www.trade.gov/country-commercial-guides/south-africa-healthcare-medical-devices-and-pharmaceuticals

Markets and Markets. 2011. Global Top 10 Medical Devices Market (2010-2015). Dallas.

National Treasury. 2021. Research and Development Tax Incentive. National Treasury. Available at: https://www.treasury.gov.za/comm_media/press/2021/TaxPolicyDiscussion/2021121501%20Discussion%20Document%20-%20Research%20and%20Development%20Tax%20Incentive.pdf (Accessed March 2024).

Quantec EasyData. 2023. South Africa Standardized Industry Gross Fixed Capital Formation, Fixed Capital Stock and Consumption of Fixed Capital. Available at: https://www.quantec.co.za/easydata/ (Accessed June 2023)

SAVCA. 2022.Private Equity Industry Survey and Venture Capital Survey. Southern African Venture Capital and Private Equity Association. Available at: https://savca.co.za/

Hakobyan, S. and Reda Cherif, R. 2021. Trade in Medical Goods: Challenges and a Way Forward for Sub-Saharan Africa. IMF-Africa Department. Accessed October 2023 at https://www.imf.org/-/media/Files/Publications/covid19-special-notes/en-special-series-on-covid-19-trade-in-medical-goods-challenges-and-a-way-forward-for-ssa.ashx (Accessed October 2023).

SAMED. 2022. SAMED & the SA medtech industry. South African Medical Technology Industry Association

SAMRC Annual Reports. 2017, 2018, 2019, 2020, 2021, 2022. South African Medical Research Council. Available at https://www.samrc.ac.za/corporate-articles/annual-report (Accessed June 2023).

SAMRC. 2023. Funding at the SAMRC Grants, Innovation and Product Development (GIPD) Unit. South African Medical Research Council. Available at: https://www.samrc.ac.za/funding/funding Accessed May 2023).

SAMRC. 2022. The Medical Devices Landscape in South Africa. (January), Pp. 1–112. South African Medical Research Council.

Solidarity Fund. 2020. Support of National Ventilator Production Summary Report: Locally Manufactured Ventilators. Available at: https://solidarityfund.co.za/media/2020/10/SF_Health_Report_on_Ventilators_%E2%80%93_Final.pdf

Technology Innovation Agency. Annual Reports 2015 – 2022. Available at: https://www.tia.org.za/press-and-media/#1574795985752-8ff3e361-df4b (Accessed June 2023).

TIA. 2021. Annual Report 2021. Technology Innovation Agency. Available at https://www.tia.org.za/annual-reports/ (Accessed March 2024).

Trade Map. Trade in Medical Goods. Downloaded April 2023 at www.trademap.org

Wesgro. 2023. Healthcare Sector. Tourism, Trade and Investment Promotion Agency for Cape Town and the Western Cape. Available at: https://www.wesgro.co.za/invest/sector/health-tech (Accessed August 2023).

Who Owns Whom. 2019. The Supply and Manufacture of Medical and Surgical Equipment and Orthopaedic Appliances. Available at: https://www.whoownswhom.co.za/

Who Owns Whom, 2020. The Supply And Manufacture Of Medical And Surgical Equipment And Orthopaedic Appliances In South Africa. Available at: https://www.whoownswhom.co.za/ (Accessed June 2023).

World Bank. 2020. Research and development expenditure data (% of GDP) – South Africa. Available at: https://data.worldbank.org/indicator/GB.XPD.RSDV.GD.ZS?locations=ZA (Accessed November 2023).

WIPO. 2023. WIPO IP Statistics Data Center. World Intellectual Property Organization. Available at: https://www3.wipo.int/ipstats/IpsStatsResultvalue

WTO. 2022. Overview of discussions in the committee on technical barriers to trade relating to Covid-19. Available at: https://www.wto.org/english/tratop_e/covid19_e/tbt_report_e.pdf