The Medical Devices Landscape in South Africa

Report of a survey conducted by the
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Finally, Laurens Cloete (independent consultant) collated the available information and data, conducted data analysis and compiled the current report with review, input and editing from Michelle Mulder, Grace Baloyi and Tony Bunn. Marlon Cerf and Michelle Galloway also contributed to the initial data analysis and editing, respectively.

List of Acronyms

4IR	4th Industrial Revolution
AI	Artificial Intelligence
BMGF	Bill and Melinda Gates Foundation
BRICS	Brazil, Russia, India, China and South Africa
CE mark	Certification indicating conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
CSIR	Council for Scientific and Industrial Research
CT	Computed Tomography scan (formerly, computed axial tomography or CAT scan)
DTIC	Department of Trade, Industry and Competition
DSI	Department of Science and Innovation
DST	Department of Science and Technology
DUT	Durban University of Technology
EU	European Union
FDA	United States Food and Drug Administration
FDI	Foreign Direct Investment
GHIA	Global Health Innovation Accelerator
HDI	Historically Disadvantaged Institution
HEI	Higher Education Institution
IDC	Industrial Development Corporation of South Africa
IoT	Internet of Things
IVD	*In Vitro* Diagnostics
KZN	KwaZulu-Natal Province
MCC	Medicines Control Council
MD	Medical Device
MDC	Medical Device Company
MDM	Medical Device Manufacturer
MDMSA	Medical Device Manufacturers South Africa
MNC	Multinational Corporations
MRD	Minimal Residual Disease
MRI	Magnetic Resonance Imager
MUT	Mangosuthu University of Technology
NGS	Next Generation Sequencing
NHI	National Health Insurance
NIPT	Non-Invasive Prenatal Testing
PLM	Product Life-Cycle Management
POC	Point of Care
SA	South Africa
SAHPRA	South African Health Products Regulatory Authority
SAMED	South African Medical Technology Industry Association[1]
SAMRC	South African Medical Research Council
SAMTI	South Africa Medical Technology Industry
SC	Science Council
STI	Science Technology and Innovation
TIA	Technology Innovation Agency
TIS	Technology Innovation System
TT	Technology Transfer
TTO	Technology Transfer Office
UKZN	University of KwaZulu-Natal
UoT	Universities of Technology
UZ	University of Zululand
WC	Western Cape
WHO	World Health Organisation

1 Previously known as the South African Medical Device Industry Association

Executive Summary

It is widely recognised that the medical device (MD) industry in South Africa can contribute more significantly to economic growth, job creation, enhanced health outcomes and improved quality of life. The COVID-19 pandemic further emphasised the importance of a robust innovation and production capability in key medical device areas so as to ensure greater health systems resilience and self-sustainability, and to enable a more agile response to public health emergencies.

This study was undertaken to better understand the size, characteristics and dynamics of the MD industry, to acquire more information on local capabilities, expertise and stakeholders within the value chain, such as for product development, testing, manufacture, market introduction and commercialisation, and to identify any gaps and barriers.

Methodology

The study consisted of a review of secondary literature and a survey of medical device manufacturers (MDMs), universities and science councils (science, technology and innovation (STI) institutions) active in MD research and innovation, and the supporting institutions/entities. In total 136 MDMs were identified through databases from various sources, supplemented with desktop research, of which 66 completed the full survey (49% response rate). A total of 25 HEIs and 5 science councils active in research were contacted. Seventeen HEIs (68%) responded; however, 2 of these indicated no activity. All 5 science councils contacted completed the survey, including two different units at the CSIR, while 10 support companies (46% response rate) completed the survey. As the study coincided with the COVID-19 pandemic, an additional survey was undertaken to document the experiences of various role-players in the MD field during the pandemic. The approach of technological innovation systems (TIS) was used as an analytical framework and, particularly, as a means of identifying the key interventions which may be required in order to further develop the MD industry.

Available Information and Gaps

The main findings from 9 existing reports on the medical devices sector in South Africa, released between 2008 and 2021, are summarised below and in more detail in the report. Some of the information, figures and conclusions are now out of date and are largely focused on the private sector. These reports revealed a number of barriers, threats and weaknesses in the industry as well as strengths and opportunities, and a list of recommendations for improving the sector. These are incorporated in the overall landscape summary and recommendations in the report.

Medical device industry overview

The secondary literature review revealed that South Africa is one of the largest medical device markets in the Middle East and Africa region and was estimated at R21 billion in 2021 and projected to grow to R29.6 billion by 2025 (FitchSolutions, 2021). However, it makes up only 0.3% of the global market for medical devices[1]. Government is the major purchaser of healthcare equipment and supplies in South Africa, associated with a public healthcare sector comprising 7 901 facilities with 85 362 registered beds (Who Owns Whom, 2019).

South Africa has relatively limited production capacity for medical devices. The market is therefore largely dependent on imports (FitchSolutions, 2021). Fewer than 5% of local industry players manufacture devices, with more than 76% of devices being imported (Who Owns Whom, 2019). Deloitte (2014) estimates that in terms of market value, 90% of the market is supplied by imports.

South Africa's manufacturing output of medical devices is estimated to be about US$200 million to US$300 million, of which more than half is exported (FitchSolutions, 2021). Manufacture grew by 9.1% to US$211 million from 2017 to 2018, to account for about 13.5% of the total market value (Who Owns Whom, 2019). Local manufacture was expected to grow by 8% to US$227.8 million in 2019 (ibid.). Domestic manufacture and exports of medical devices are dominated by products in the other medical devices, consumables and diagnostic imaging product areas. Local manufacturers tend to focus on the export market, which grew at a CAGR of 8.3% between 2014 and 2019 to reach R3.1 billion by 2019 (FitchSolutions, 2021) and includes substantial re-exports of foreign produced medical devices. Most of the leading export markets are in Africa, in the Southern African Development Community (SADC) in particular, followed by Europe.

South Africa has a large number of industry players with between 350 and 600 suppliers, ranging from companies listed on the JSE to opportunistic agency traders (Who Owns Whom, 2019). The substantial number of suppliers is associated with a high degree of fragmentation, competition and instability (ibid.). Suppliers range from large multinational subsidiaries, distributors and agents for disposable medical devices to major equipment manufacturers (ibid.). More than 80% of the industry consists of privately-owned small and medium-sized enterprises (SMMEs) with less than 50 employees who often combine distribution activities with manufacturing (ibid.). Local manufacturing is focused on the production of low-tech and low-value devices such as surgical goods and disposable needles. There are, however, several examples of locally developed hi-tech devices, including the design and manufacture of advanced breast imaging technology and low radiation full body Xray machines that are used internationally (Who Owns Whom, 2019). Domestic production is anticipated to continue to grow in sophistication as indicated by the number of innovative medical devices at different development stages (FitchSolutions, 2021; BMIResearch, 2016).

Medical device R&D expenditure in South Africa is low as a percentage of turnover for the industry, at less than 1%, compared to a global average of 6.8%[2]. South Africa has a range of incentives available to medical device innovators

1 Author's calculation based on FitchSolutions (2021) estimate of South African Market size in 2020 and Frost & Sullivan (2016) estimate of Global market size of US$377 billion in 2020

2 Author's calculations for 2011 to 2020 based on https://www.statista.com/statistics/309305/worldwide-medtech-research-and-development-spending-as-percent-of-revenue/

and manufacturers that span the value chain from early development to industrialisation and growth. All of these are offered by publicly funded departments and agencies.

As mentioned, the local industry is dominated by imports, with medical technology imports to South Africa valued at R11 billion in 2013, growing to R18.1 billion by 2019 (FitchSolutions, 2021). Seventy-five percent of all medical device imports are sourced from ten countries and around half from the top three[3] - USA, Germany and China (BMIResearch, 2017). More than 76% of medical devices used in South Africa are imported by multinational companies (Who Owns Whom, 2019).

Regulation of medical devices

The Medicines and Related Substances Amendment Act 14 of 2015 brought about significant changes in the regulation of medical devices. Specifically, the act included the establishment of the South African Health Products Regulatory Authority (SAHPRA) in June 2017 to replace the Medicines Control Council and provides for implementation of a dedicated regulatory framework for medical devices. The Amendment Act introduced a four-tier, risk-based licensing and registration system, which applies to South Africa-based companies that manufacture, sell, import, export, distribute and wholesale medical devices in the country. SAHPRA is implementing the regulation of medical devices in a phased approach, starting with a call up notice, published in February 2017, requesting all manufacturers and distributors of medical devices to apply for a SAHPRA license within 6 months of publication and wholesalers within 12 months. Currently, no medical device may be manufactured, distributed, imported, exported or sold without a valid SAHPRA medical device establishment license. An exemption has been introduced for manufacturers, distributors and wholesalers of non-sterile, non-measuring Class A medical devices (SAHPRA, 2021b).

The next step in applying the regulation of medical devices in South Africa will be registration of each medical device. This process is still in development but will involve a Registration Call-Up Plan. Until such time as devices are called up to be registered, 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 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. On 21 May 2021 the proposed "Regulations Relating to Medical Devices" were published in the Government Gazette for comments by interested persons (SAHPRA, 2021c). The proposed regulations include provisions for the supply of medical devices, the registration of medical devices, licensing of establishments to manufacture, distribute or wholesale medical devices, management of medical devices and investigations, offences and penalties related to the regulations.

Medical Devices Landscape Survey Results

Medical device manufacturers

The medical devices landscape survey indicated that South Africa has at least 136 medical device manufacturing companies with substantial diversity in terms of size, turnover, products produced and levels of R&D expenditure. The sector is concentrated in three provinces, with most medical device manufacturers being located in Gauteng (60), followed by the Western Cape (WC) (47) and KwaZulu Natal (KZN) (26). The average age of companies that responded to the survey was 20 years, with more than half of the companies older than 20 years. There has been a declining trend in company formation since 2004, and only 7 new companies were founded in the period 2015-2019.

Most companies that responded to part A of the survey (73%) are classified as small, employing 50 or less permanent staff, with around one third employing 10 permanent staff or less. Most medical device companies fall within the micro (<R10 million) and small (R10-R50 million) enterprise categories in terms of turnover. Only a small percentage (24%) qualify as medium to large enterprises (>R50 million turnover). Around 62% of respondents reported having a BBBEE level of 1-4, while 28% are deemed non-compliant or exempt due to having a turnover of less than R10 million.

The South African medical device manufacturing industry is active across a range of fields and device classes. Over half (53%) of MDM respondents operate in the consumables field, followed by orthopaedics (27%), other (21%) and hospital furniture (14%).

The industry produces and sells a variety of consumable medical device products ranging from medical devices for wound care to diagnostic test kits. More than two thirds (43) of companies that operate in the consumables field sell mostly Class A and/or Class B consumables.

The domestic private sector is the most important market for the companies surveyed, with a quarter of the companies (16) indicating that 75-100% of their revenue is earned from this sector. This is followed by the domestic public sector for which eight (12%) companies indicated that 75-100% of their revenue is attributable to this sector. Slightly more than two thirds (69%) of the respondent companies derive less than 25% of their revenue from exports and fifteen companies focused exclusively on the South African market. Africa, Europe, the Middle East and North America are the most important export markets amongst the respondents. China and India were consistently rated the lowest priority amongst manufacturers. These countries are likely seen as competition rather than markets for South African products. They are also countries where local manufacture of medical devices is prioritised.

More than two thirds (68%) of the surveyed companies indicated that they were export ready. Only 10% indicated that they required assistance to become export ready.

Most companies have in-house design (80%), manufacture (82%) and packaging (77%) capabilities. Sterilisation is the most frequently outsourced activity, with 25 (38%) companies outsourcing this function. Component assembly

3 Author's calculations based on data in FitchSolutions (2021)

was the most frequently cited facility capability, with 58% of the companies indicating this capability. This was followed by mechanical turning (45%), OEM manufacture (41%) and material or component testing (41). Overall, the highest number of capabilities related to machining and the lowest to chemicals. In terms of manufacturing materials used, metals and plastics were the materials most frequently used, followed by chemicals and liquids. Forty-four percent of MDM respondents had access to cleanroom facilities, 47% did not and 9% did not comment on this aspect.

The survey indicates that manufacturing capacity is presently underutilised. Most respondents (60%) only used one shift, 17% used two shifts and 6% three shifts. Most respondents (59%, n = 39) were using between 25% and 75% of their manufacturing capacity, 17% (11) were using more than 75% of their manufacturing capacity and 14% (9) less than 25%. Most companies (79%) indicated that they could increase production by 40% through capital expenditure (32% of companies), product development (28%) and diversification (25%). A small number of companies (11%) intended to improve productivity, and a few (4%) planned other expansion strategies.

Most of the medical device company respondents (73%) indicated that they were SAHPRA registered and, as of July 2021, this had increased to 79%[4]. Eighty-nine percent of the companies surveyed either had a quality management system (predominantly ISO 13485) in place or were in the process of implementing a quality management system. Fifty one percent (36) of the companies reported having ISO 13485 in place, with a further 24% (17) in the process of implementation. The most widely used quality management standard was ISO-9001 which was reported to be in place by 32% of the companies (23) with a further 8% (6) in the process of implementing this standard. Eighteen respondents have FDA approvals/certification and 42 a CE mark for their products. Three quarters (74%) of the 66 respondents indicated a requirement for regulatory and compliance assistance. A range of challenges relating to regulation were cited, predominantly related to a lack of human and financial resources and long turnaround times.

Over three quarters (77%) of MDM respondents indicated that they were active in R&D; however, R&D expenditure as a proportion of turnover in South Africa is low when compared with international examples. Most (51%) medical device manufacturers in South Africa spend less than 5% of their turnover on R&D, of which 33% spend 0% (R&D is externally funded). Most of the highly R&D intensive companies (R&D expenditure >20% of revenue) are small and young enterprises (less than ten years old), although two have revenues of over R50 million. Some respondents indicated that the expertise required for R&D is insourced to supplement the in-house teams. The more R&D intensive medical device companies are concentrated in the WC and Gauteng.

Only 4 of respondents (9%) who indicated some internal expenditure on R&D have applied for an R&D tax rebate, all of whom were successful. However, they reported issues with applying such as administrative hurdles and delays in approval. The major reasons for not applying for an R&D tax rebate were a lack of awareness and perceptions that the process for applying was overly bureaucratic. Twenty-three (35%) of the respondents have applied for government R&D funding, of which 74% (17 MDMs) indicated that they were successful. The main reasons for not applying for R&D funding were, as in the case of the R&D rebate, lack of awareness and perceived bureaucracy.

Just under half of the respondents (48%, 32 MDMs) have collaborated with STI institutions locally and abroad in 54 separate collaborations over the past five years. Only fifteen international collaborations were reported in which the United States was the most frequently cited country for collaboration. The University of Cape Town and University of Stellenbosch participated in the most domestic collaborations with MDMs, followed by the CSIR. Collaborations with industry showed a similar trend, with 27 (41%) respondents indicating that they collaborate with industry and 24 (36%) with no industry collaborations. Of the 27 companies that have collaborated with other companies on R&D, fifteen collaborated with companies from South Africa, five with international companies, and seven with both South African and international companies. Critical success factors cited for working with universities and research institutions included shared goals and expectations, ability of STI institutions to meet commercial timelines, and ownership and commitment by students through long term collaboration.

Only 11 (17%) respondents indicated that they had co-developed products with or licensed products from research institutions – mostly (73%) with local institutions. Forty-nine (74%) of the MDM respondents were interested or conditionally interested in performing R&D with external parties or already had ongoing collaboration with STI institutions and 77% (51) were interested or conditionally interested in manufacturing innovations by South African research institutions. A large majority of respondents (58 - 88%) were either already collaborating with South African research institutions to develop their own innovations or interested or conditionally interested in doing so. The most common interest in working with research institutions was in co-development (33%), followed by research contracts (28%) and supervision of postgraduate students (25%).

Just over half of the MDMs surveyed are members of an industry association or industry cluster, with the two most important industry associations for the sector being SAMED and MDMSA and 23% of the sample indicating membership of each of these two associations. There is significant overlap in membership of the two associations with 14% of the sampled companies reporting membership of both SAMED and MDMSA. The Western Cape Medical Devices Cluster, with seven founding members, is the only institutionalised medical device cluster in South Africa. Fifty-eight percent of respondents that are not currently members of a medical device cluster expressed an interested in becoming members of a cluster. There is thus significant potential for expansion of the WC cluster and for new clusters in Gauteng and KZN.

The companies surveyed make use of consultants (27) followed by public agencies (13) and industry associations or clusters for various types of support. Public agencies cited included TIA, The Innovation Hub, DTIC, IDC, the SAMRC, eGoliBio and SAHPRA. The overwhelming majority (95%) were interested in having an online portal connecting them to innovators and vice versa. Some stated that this would foster collaboration, marketing, communication and

4 Licenses issued to survey respondents were verified on the SAHPRA website: https://www.sahpra.org.za/medical-devices-licences-issued/ on 18 July 2021.

information sharing. It was also seen as a tool to increase their client base. Another important support mechanism required was assistance with regulatory compliance.

The issues affecting the medical devices sector that were most frequently cited by respondents related to regulation and certification, following by funding, access to capital financing, support for product development and growth (especially for small companies) and cash flow issues. The third most cited issue related to protection of local MDMs from imports and the dominance of multinational corporations. Other frequently cited issues related to the lack of coordination and championship of the industry by government or preferential procurement for local suppliers, insufficient focus on job creation, difficulties in accessing the local public sector market through procurement and Government budget constraints (prioritising price over quality), BBBEE implementation, which has excluded a number of manufacturers with a small number of employees from the public sector market and public incentives, the administrative burden on small enterprises, and inefficiencies in importation of components and raw materials. General business conditions that affect MDMs include corruption, kickbacks and incentives, crime, civil unrest, labour issues, power cuts and the generally poor investment climate. Some respondents indicated a lack of technical capabilities such as for product testing and regulatory compliance and difficulty retaining skilled human resources.

Respondents made a wide range of suggestions for improving conditions for domestic manufacture of medical devices, aimed at increasing local MDMs' share of the local market, enhancing exports, and enabling product development. These are incorporated in the list of recommendations emanating from this study. For the MDM sector to capture a greater share of the R21 billion domestic market and to penetrate the large and growing international market, several challenges and gaps have to be overcome. These include those listed above as well as the declining rate of company formation over the past several years and the distribution of companies in terms of turnover, which is heavily skewed towards small firms. Domestic manufacture is also focussed on low value consumables where competition with Asian commodity producers will be difficult to sustain. In addition, R&D investment and international cooperation is low.

STI institutions

The survey revealed that several STI institutions (publicly funded universities, universities of technology and science councils) are active in medical device related R&D and innovation activities although to widely varied extents. Public institutions involved in medical device innovation are concentrated in Gauteng (7), the WC (5) and Eastern Cape (4). There are two institutions in the Free State, two in the Northwest Province and one in KZN that are also involved in medical device innovation. Notably, all four universities in the Eastern Cape have some involvement in medical device innovation, including two historically black institutions, although the medical device outputs from most of these have been limited to date. The high concentration of STI institutions involved in medical device innovation in Gauteng and the WC is consistent with the presence of most of the research-intensive universities and the higher degree of R&D spend by medical device companies in these provinces.

The STI institutions listed a range of platforms, capabilities and infrastructure that supports or can be applied to medical device innovation and manufacturing. Most STI institutions had capabilities in basic and applied research (60%), innovation, product development, business and manufacturing (70%); followed by preclinical (30%) and clinical research (25%).

Most of the institutions surveyed (75%) are working on 5 or less medical device R&D and innovation projects, 10% 6-10 technologies and 15% ≥10 technologies which have been reported to their TTO. This suggests a limited focus on medical device innovations in most STI institutions in the public sector with a few exceptions. Most institutions have filed less than five patents on medical devices, spun out two or fewer successful medical device companies, and have two or fewer products in the market. Encouragingly, some institutions achieved much higher outputs: between 20 and 30 patents, 4 to 6 products in the market and 6 to 8 spin-out companies, indicating some pockets of excellence in this sector. A total of 82 patent families (granted and/or pending) on MD technologies were reported by respondents. This is a substantial number that warrants further investigation and it is possible that not all of these relate directly to a novel medical device.

A total of 35 IP assignment or license transactions for medical device innovations over the last 10 years were reported by the respondents. More than half of these (18 assignments or licenses, 2 of which were in the process of being licensed) were to spin-out companies of the institution, followed by existing local companies (12 assignments or licenses, 5 of which were in the process of being licensed) and a small number to international companies (5 assignments or licenses, 2 of which were in the process of being licensed). STI institutions reported 20 successful medical device spin-out companies in 8 different institutions. The WC stands out in all four areas of patenting, licensing and IP assignment, products in the market and successful spin-outs. This is primarily due to the two research-intensive institutions in the province with substantial health faculties and biomedical engineering departments, namely the University of Cape Town and University of Stellenbosch.

Most (60%) STI institutions engage in collaborative partnerships with medical device companies on their medical device projects, with half of them having local partners, 30% international partners, and 20% both local and international partners. All twenty respondents indicated an interest in increasing collaboration with the medical device industry, predominantly for joint R&D and technology transfer, followed by experiential training for students, contract research, advisory and mentoring roles for industry and collaboration on manufacturing. The most listed funder for medical devices development amongst the respondents was the TIA, followed by the SAMRC, the DTIC and the South African Breweries (SAB) Foundation. In terms of other external support, 55% of STI institutions involved in medical device development reported not making use of external support. The rest made use of commercial firms and consultants, public institutions and universities. In particular, a number of respondents reported making use of facilities at universities of technology.

The main gaps, barriers and challenges to the development and commercialisation of medical devices in South Africa identified by STI institutions were the lack of clear market guidance and pathways to commercialisation, including

insight into market requirements and regulation and certification, insufficient funding along the full value chain, industry limitations, and a lack of critical mass of R&D capacity. Other challenges cited included the early stage of inventions from STI institutions and their lack of alignment with market needs, inadequate Government support and appropriate policies for the medical device sector, gaps in the available human capital in the field, including seasoned entrepreneurs, the need for greater industry/R&D community collaboration and cohesion along the value chain, and the need for incubation support as well as access to high-tech fabrication facilities.

Support service organisations

Seven companies and three public institutions that provide support services to medical devices companies and STI institutions were surveyed. The main services and support provided to clients was technical consulting. Other services included regulatory advice, product design and development, manufacturing support, R&D and technical services, collaboration and mentoring and support for clinical and field trials. The three public institutions provided largely funding support. This support component of the survey was not a key focus and therefore has limitations. A more comprehensive analysis of this component of the industry may be valuable in future.

The main barriers and challenges cited by these respondents with respect to the medical device sector were funding and investment, followed by business and technical challenges. Other challenges were regulatory and the cost of certification, small markets, product and market understanding, lack of support for innovators, few entrepreneurs and lack of expertise and skills. Key interventions suggested to benefit the sector included securing sustainable funding, the provision of relevant courses, training and workshops, championing of enterprise development, fostering of consultation and collaboration, and the provision of regulation, compliance and product design support.

Impact of COVID-19

The global coronavirus pandemic exposed deficiencies in existing global medical device manufacturing supply chains and distribution models, leading initially to shortages of testing reagents, diagnostic test kits, personal protective equipment, and respiratory devices such as non-invasive and invasive ventilators. On the other hand, the crisis revealed the potential of an emergent, collaborative model capable of developing and manufacturing products at short notice. It also saw a flood of new and reallocated funding directed towards expanding health services, product development and roll-out and emergency relief. Some medical device related activities that were a direct response to the COVID-19 pandemic and are highlighted in the report include the National Ventilator Project, which saw the design, development, manufacture and deployment of 20 000 CPAP ventilators to 69 public hospitals in all nine provinces of South Africa; the South African Solidarity Fund, which supported the National Ventilator Project, COVID-19 testing, vaccine purchase and roll-out and PPE procurement and distribution; the South African Pandemic Intervention and Relief Effort Fund, which supported the purchase of additional essential medical equipment and protective wear and the development of the Intubox to protect hospital workers and critical care patients; and the SAMRC-DSI-TIA investments in local diagnostics for COVID-19 which have to date resulted in 2 locally produced diagnostic tests/kits being approved by SAHPRA.

During September and October 2020, MDMSA, under joint auspices with the SAMRC, carried out a short online survey to capture the experiences of medical devices stakeholders with respect to COVID-19 as an adjunct to the present survey. Sixty-four responses were received, of which the major proportion (47%) were from medical device manufacturers. In response to specific prompts, the survey confirmed the challenges experienced by the medical device sector during the pandemic, which ranged from inadequate specification of requirements to limitations to the current medical device life-cycle process, finding suitable partners, uncertainty on demand and the timeous availability of grant funding.

More than half the respondents had to work with more than 50% new parties during the pandemic. Eighty-three percent of the respondents agreed or strongly agreed that South Africa's COVID-19 response revealed latent potential to expand the sector and for South Africa to become a global player in the field and most (67%) agreed or strongly agreed that digitally enabled collaborative networks will be helpful in realising this potential. The respondents supported all the proposed interventions to strengthen the medical device manufacturing sector. Some of the issues and suggestions emerging from this survey included the following:

- The need for coherence between public health procurement and industrial policy measures, Government support for SA MDMs to have preferential status for public sector procurement, protection from imports and a well-funded and coordinated strategy for creating foreign markets for SA medical device products and boosting exports;
- Improved alignment of grant and commercial funds and more agile funding that is available in a streamlined way from one stage to the next;
- Regulatory challenges, including the regulators' efficiency, lack of adequate capacity and communication issues, with the need for transparent, dexterous, and efficient regulatory processes, and resourcing of regulatory and related testing and assessment capability;
- Skills development in product development, quality management and regulatory;
- The need for transparent and regularly updated central coordination of product requirements to make clear the demand for medical devices in a pandemic;
- Measures to increase conversion of public research into products with earlier movement of projects from academia or science councils to the commercial domain;
- Increased collaboration, cohesion and coordination amongst role-players on all aspects, including research, development, production, regulation, funding, and procurement;
- 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; and
- A need for greater agility amongst all role players.

Survey Summary and Analysis

This medical device landscaping survey, although it has limitations, has added to the existing understanding of the medical device innovation and manufacturing ecosystem in South Africa. It has revealed important aspects regarding the size and shape of the manufacturing sector, the country's knowledge generating capacity manifested in its STI institutions and the support infrastructure available to manufacturing companies and STI institutions. Importantly, it has reaffirmed and added to the previous knowledge base around the key gaps and barriers that have been hampering the growth of the sector.

The survey has revealed that South Africa has at least 136 medical device manufacturing companies with substantial diversity in terms of size, turnover, products produced and levels of R&D expenditure. The following clusters of broadly similar companies can be identified:

- **Young, high-tech companies** developing and producing sophisticated medical devices for the domestic and export market in fields such as molecular diagnostics, orthopaedic implants, diagnostic imaging and audiometers and spending a significant portion of their revenue on R&D.
- **Medium to large high-tech companies** producing sophisticated medical device capital equipment and implants for the domestic and export market, with some investment in R&D.
- **Large commodity producers** producing large volumes of commodity products such as class A and B consumables for the domestic market with some exports to neighbouring countries with little to no investment in R&D.
- **Small commodity producers** producing smaller volumes of specific lower technology products mainly for the local market with little to no investment in R&D.

These clusters are further reflected in the manufacturers' facilities and use of quality management systems as well as in their propensity to collaborate with STI institutions. A clear geographic pattern can be distinguished with the WC, Gauteng and KZN being the three provinces containing the bulk of the industry. Gauteng and the WC are home to the small and medium to large high-tech manufacturers whereas KZN's industry is largely focussed on the production of commodities.

Several STI institutions are active in medical device related R&D and innovation activities, although to widely varied extents. The University of Cape Town and University of Stellenbosch, both in the WC, stand out in terms of the number of patents, technology disclosures, spin-off companies and products in the market. Of the science councils, the CSIR is the most active in the field. Although many universities, including universities of technology have relevant capabilities, except for the two aforementioned universities, knowledge generation and associated entrepreneurial activity in the medical device field by STI institutions is low.

A range of companies provide support services to the industry, including technical services, quality improvement and regulatory compliance. The list of support organisations surveyed was not comprehensive and did not include the regulatory consultants. The three public institutions included focus on funding of innovation and commercialisation activities.

Overall, the study has revealed that the medical devices innovation and manufacturing sector has:

- activities in each of the major product life-cycle stages from basic and applied research through to experimental and product development, manufacture and scale-up, although these are currently not well aligned;
- the necessary role-players (e.g. idea creators, innovators, pre-clinical and clinical scientists, research engineers, established MDMs, STI institutions, support companies and distributors) required to enable end-to-end MD solutions through the product life-cycle but these are not suitably networked for collaboration and optimal outcomes;
- sophisticated processes, tooling, expertise and competent role-players whose needs for optimal value addition are seldom met;
- access to digital collaboration technologies such as Product Life-Cycle Management (PLM) software although these are not optimally used with no common "lingua franca"; and
- access to funding, especially early-stage funding, for the product life cycle, although only a small fraction of these investments is converted into sustainable products at huge loss to the country.

Given the level of imports and the associated trade imbalance, it is fair to say that, as a country, South Africa has not realised its potential as a medical device manufacturer. The sector continues to be hampered by the same broad issues identified in previous surveys dating as far back as 2008, including regulatory, funding, market access, skills shortages and lack of cohesion. The country's medical device value chain is disjointed and not optimal for maximum value creation. While the COVID-19 pandemic highlighted key gaps in the innovation value chain and local product offerings, it also demonstrated that funds could be rapidly raised and deployed, expertise could be pivoted to new priorities and all participants in the innovation and manufacturing ecosystem could collaborate towards a common goal.

The literature review and survey confirmed that South Africa has capability in all the elements of a functioning TIS. However, deficiencies in the TIS prevent the country from realising the opportunity to reduce the considerable trade imbalance, enable localisation and increase revenue from exports. In addition, more vibrant local innovation and increased manufacture will address the need for sovereign and strategic capabilities during times of crisis when global supply chains can break down, impacting negatively on health outcomes.

Conclusions and Recommendations

This landscaping report has contributed to an enhanced understanding of the South African medical device landscape, focussing on technological innovation, product development and manufacturing. Table A lists the key recommendations that have emerged from this survey, based on prior reports, responses from stakeholders, the TIS evaluation and author inputs.

Table A: Recommendations for enhancement and growth of the Medical Devices Sector and Ecosystem in South Africa across the value chain

Academia – Public Sector Innovators
Basic Research – Applied Research, Design & Engineering – Technology Development
• Build on and strengthen pockets of excellence and existing technology and innovation platforms to transform them into world class centres of excellence • Promote and facilitate broader utilisation of these capabilities by innovators in the public and private sectors in South Africa • Establish mechanisms to transfer this knowledge and skills to other STI institutions, especially historically disadvantaged institutions • Promote these capabilities internationally to attract foreign collaborators and private sector partners
• Identify new/emerging technology areas and capabilities requiring special attention and support
• Increase overall investments in public sector medical devices R&D, including incentives to collaborate with the private sector and historically disadvantaged institutions, to enhance knowledge generation and expand the participation of other STI institutions
• Invest in relevant skills development, especially regulatory skills, product design and development, product life cycle management and entrepreneurship
• Incentivise and support international collaboration and partnerships by STI institutions and industry, with a focus on inward technology transfers and local commercialisation
Product/Process Development – Small Scale Manufacturing – Market Entry/Launch
• Establish mechanisms to promote and facilitate STI institution–industry linkages to facilitate cross-learning and the conversion of expertise into new products, for example through joint funding instruments, exchange programs, a medical devices portal and a coordinated cluster hub – linkages may include co-development, research contracts, testing, commercialisation, supervising postgraduate students, internships, and business mentoring of academia

• Design and implement mechanisms to enhance the appropriateness and readiness of technologies from academia for uptake by industry, including, for example:
  • greater exposure of STI institutions to market requirements and involvement of end users in product design and development
  • skills development in academia with respect to product development and health technology/ medical devices life-cycle management under the relevant ISO standards
  • increased funding for late stage product development and testing

• Increase awareness of and access to technology development and testing capabilities and high-tech fabrication facilities
• Invest in local facilities and skills for auditing, laboratory and mechanical testing
• Design mechanisms to identify and pair up experienced entrepreneurs with strong networks with new technologies/products
• Invest in entrepreneurial skills development
• Increase incubation support to the STI institutions and new start-ups
• Consider establishing a "white label" manufacturer for single devices that emerge from STI institutions that would not sustain an independent company
Industry – Medical Device Manufacturers
Basic Research – Applied Research, Design & Engineering – Technology Development
• Increase public funding of industry R&D to improve absorptive capacity for new technologies, enable differentiation through higher value add and stimulate market led innovation and import replacement
• Incentivise industry to grow their own R&D investments in medical devices
• Invest in relevant skills development in industry for product design and development, regulatory, product life cycle management and entrepreneurship
• Promote and facilitate access to resources for R&D

Product/Process Development – Small Scale Manufacturing – Market Entry and Development – Growth

• Establish mechanisms to increase the local development and production of medical devices to replace imports, focusing on higher value products, including:
  • engage with National Treasury and the National and Provincial Departments of Health to identify those medical devices currently imported into SA which can profitably be redeveloped and manufactured in SA
  • work with National and Provincial Departments of Health to set up processes to enable clear articulation of health technology needs that can be addressed by the innovation networks and local manufacturers
  • increase awareness of and access to technology development and testing capabilities
  • increase funding for medical device innovation across the value chain
  • invest in local facilities and skills for auditing, laboratory and mechanical testing
  • harness under-utilised manufacturing capacity to increase local medical device output
  • facilitate capital expenditure for infrastructure expansion, product diversification and productivity improvement

• Nurture and support local high-tech MDM start-ups
• Increase awareness and visibility of local and international business development opportunities, including the potential for import replacement, exports and opportunities arising from public procurement in the medical devices space
• Increase awareness of support instruments for new business development and job creation

• Address regulatory barriers, for example through the following interventions:
  • capacitate SAHPRA to allow for rapid and efficient device registration and certification
  • Government investment in the accreditation of a local certification body to reduce costs and increase efficiencies and implement measures to enable international recognition of SA certification
  • facilitate international certification, including increasing the capacity to provide internationally certified product testing locally
  • establish a forum or think tank of experience to provide regulatory support
  • increase regulatory and compliance training, assistance and access to information for both the public and private sectors

• Promote increased membership of and participation in SAMED, MDMSA, and the Western Cape Medical Devices Cluster • Support strengthening of the existing cluster in the Western Cape and institutionalise clusters in Gauteng and KZN - link institutions/ companies in the Free State and North West with the Gauteng cluster and those in the Eastern Cape with the KZN cluster
Government & Support Agencies
• Enhance and align the legislative and regulatory framework, policies, standards, guidelines, processes and capacity in support of local medical device manufacture and export
• Collectively design new incentives and support mechanisms for the sector within Government (between the DTIC, DSI, National Treasury and NDOH) and amongst support organisations, such as TIA, IDC, SAMRC, incubators, etc.
• Raise awareness of available incentives and support mechanisms amongst industry and academia and improve access to information thereon • Reduce bureaucracy and turnaround times for the R&D tax rebate and other government R&D funding and incentives while maintaining rigour and responsible investments
• Increase funding for R&D, regulation and certification in the public and private sectors • Increase funding for infrastructure, equipment and expansion in the private sector • Create a more favourable investment climate for foreign direct investment in the sector
• Broker bilateral R&D cooperation with targeted countries

Market/End User
• Make requirements (demand) and capabilities (supply) for medical devices more visible - promote Government-private sector collaboration and sharing of national supply and demand data and information
• Identify customer unmet needs across the care continuum at all levels of delivery and increase visibility of health care system requirements
• Increase participation of the public health sector and end users in priority setting, articulation of demand, and product design, development and testing to ensure uptake
• Provide platforms for enhancing interaction between the developers, manufacturers and end users, particularly in the public sector
• Ensure sustainable and efficient public procurement to stimulate innovation and manufacturing, including improving turnaround and payment
• Introduce designation for public procurement and earmark strategic medical devices for local manufacture
• Design and implement incentives for the private sector, including private health care groups and medical schemes, to buy locally manufactured medical devices
• Introduce/increase import tariffs for medical devices that can be sourced locally
• Increase the focus on preparing markets for the adoption of new products, including health technology assessments, implementation studies, policy and practise changes and change management
• Develop export markets for SA medical device products aligned with SA strengths (Africa and global where SA has competitive products) through an integrated, well-funded and coordinated strategy • Provide assistance with export readiness • Promote regional cooperation to increase market opportunities for SA medical device products • Facilitate improvements in international payments by having a dedicated team for this on the Financial Services Board with an understanding of the nature of the businesses • Develop and implement deliberate strategy to position SA science, technology and niche manufacturing capabilities into global value chains • Increase access to information on foreign markets, such as market intelligence, barriers and routes to market and how to establish international distribution
• Facilitate adoption and promotion of local products by Government and other sectors
Sector-wide/All Stakeholders
• Collaborative development of a vision and roadmap for the medical devices sector, facilitated by the DTIC and DSI, ideally through the Healthcare Products Master Plan process, with substantial participation by industry and academia - identify and support niche areas where South Africa can build competitive advantage
• Establish a national medical device sector brand and awareness and increase its international profile through closer cooperation between industry and government and show casing capabilities and success stories
• Utilise SAMED, MDMSA, the Western Cape Medical Devices Cluster and MeDDIC to drive sector-wide interventions in a coordinated approach

• Promote and enable stakeholder alignment, cooperation and collaboration within the sector to enhance linkages, information sharing and collaboration between STI institutions (knowledge producers) and industry (knowledge users) and within the medical devices industry through mechanisms such as:
  • increasing the visibility of expertise and technology capability within STI institutions and manufacturing capabilities and capacity of industry
  • develop an online portal to connect MDMs and innovators, foster collaboration, marketing, communication and information sharing
  • provide opportunities and platforms for regular, direct interactions and information sharing between stakeholders, for example through SAMED, MDMSA and MeDDIC
  • Utilise new digital technologies to facilitate linkages and cooperation
  • Publicise success stories of local innovations

• Increase the role of Government in directing efforts to specific disease focus areas, enabling technologies, inputs and components
• Establish an emergency protocol for pandemic and other national emergencies to enable resilient responses in future • Learn from the COVID-19 experience and entrench new mechanisms for agility, cooperation and rapid response

The conclusion of this study is that most, if not all, of the building blocks are in place for a strong and vibrant medical devices industry in South Africa, driven by a combination of local innovations emerging from STI institutions, both high and low technology capabilities within existing companies to produce a diverse range of high quality products suitable for the local and export markets, and ongoing efforts to replace specific imports with locally produced devices. A bold strategy is required in which Government, the STI sector and the medical device manufacturing industry collaborate in a dynamic way to transition from an import-based incumbent regime to a new regime in which domestic innovation and production captures a far greater portion of the domestic demand. This strategy will require the use of instruments to destabilise the incumbents (through the promotion of competition), incentives to attract manufacturing investments and direct financial support for small, high growth companies. Existing funding instruments need to be better tailored and directed, and academia and industry will need to become more efficient, effective and economical at converting ideas into products and solutions that are commercially viable and satisfy customers. This needs to be underpinned by improved and more cohesive legislative and policy frameworks to support local innovation and manufacturing, skills development, regulatory and compliance support and enhanced cooperation and collaboration between ecosystem players. A dedicated task team and specialised working groups with representatives from academia, industry and Government are needed to drive the design and implementation of interventions to address the blocking mechanisms underlying TIS weakness and blockages and work towards a highly innovative, cohesive and globally competitive medical devices sector.

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Introduction and Purpose

1. Introduction and Purpose

There has been an increased focus on the medical device (MD) industry in South Africa over the past few years, intensified in 2020 by the COVID-19 pandemic that has seen an unprecedented urgency to localise the manufacture of devices, from personal protective equipment to ventilators. This industry sector is of particular importance to a range of local stakeholders who see it as an opportunity for economic growth, job creation, localisation, reduction of trade imbalances, and reduced reliance on imports. These stakeholders, which include the Department of Trade, Industry and Competition (the DTIC), the Department of Science and Innovation (DSI), the Technology Innovation Agency (TIA), the Council for Scientific and Industrial Research (CSIR), the South African Medical Research Council (SAMRC), and the medical device industry associations, the South African Medical Technology Industry Association (SAMED) and Medical Device Manufacturers South Africa (MDMSA), have a shared vision to grow a vibrant local medical devices innovation and manufacturing ecosystem in South Africa. To achieve this, there needs to be a complete and functioning local innovation value chain for the development, commercialisation, manufacture and uptake of new devices and a well-supported, competitive industry sector unhampered by unnecessary bureaucratic, procedural or regulatory hurdles.

The first step towards developing and improving the sector is to gain a better understanding of its size, characteristics and dynamics, to have ready access to information on local capabilities, expertise and stakeholders with which to partner along the value chain, i.e., for product development, testing, manufacture, market introduction and commercialisation, and to identify any gaps therein.

Several landscaping reports on the medical devices industry in South Africa have been compiled over the last decade, from which much information has been drawn for the current medical device landscape analysis (described in detail in the next section). However, many of these reports are now outdated and none provide a comprehensive, innovation ecosystem view of the sector. Specifically, the reports lack details on:

- The primary MD innovators within higher education institutions (HEIs) and science councils (SCs);
- Technology or product pipelines;
- The extent of linkages and collaborations between the value chain participants; and
- The platform technologies, capabilities and expertise existing within individual MD companies, HEIs and SCs.

This survey was not intended to duplicate previous research and findings, but rather to fill the gaps in information, such as those listed above, and to produce an up-to-date resource that could make a positive impact on the growth and development of the local MD innovation ecosystem.

The aims of this medical device landscape analysis were to:

The project was funded by a grant from the Bill and Melinda Gates Foundation (BMGF) to the Global Health Innovation Accelerator (GHIA), a program of the SAMRC. GHIA has taken the lead, working with MDMSA, the DTIC, DSI, and TIA. Committee members of the MDMSA were able to provide valuable recommendations and support throughout the landscaping process.

1.1. Scope of the Survey

The survey included medical devices as defined in the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, read in conjunction with the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No. 1515 of 09 December 2016, i.e.

"A 'medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) – intended by the manufacturer to be used alone or in combination for humans or animals for one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes 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 or animal body, but which may be assisted in its intended function by such means."

The survey included *in vitro* diagnostics, which are defined as "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 diagnostics, monitoring or compatibility purposes", but excluded borderline medical products (e.g. fitness products). The survey further excludes the substantial number of health-related digital applications available to consumers.

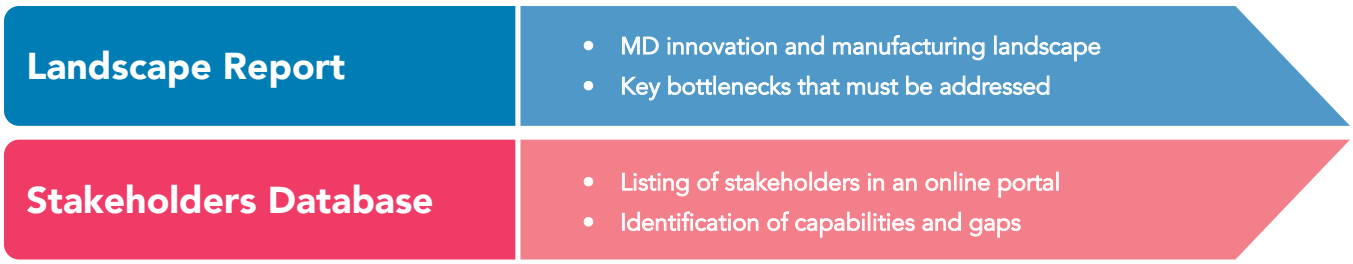
The geographic scope of the survey was limited to South Africa. The key stakeholder type or role players targeted for the survey and the type of information sought from each are summarised in Table 1.

Table 1: Stakeholders included in the survey

Stakeholder Type	Description	Key Information Solicited
Medical device manufacturers (MDMs)	Companies that undertake some element of manufacture of medical devices in South Africa (SA), including companies that develop new products and/or processes. Companies only involved in import and/or distribution were excluded.	Types of products, client markets, manufacturing capacity/ production output, capabilities/competencies/areas of expertise, certification, R&D, training requirements, challenges, gaps and opportunities.
Higher education institutions (HEIs) and science councils (SCs)	Publicly funded HEIs and SCs that undertake medical device research and development.	Technology capabilities, existing products, licenses and spin-outs, pipeline technologies and products, key academic departments and innovators involved in MDs, and challenges and gaps.
Service providers	Designers and other sub-contractors for medical device development and manufacture.	Capabilities and services offered, companies worked with, challenges and gaps.
Support agencies	Consultants, funders, associations, incubators and innovation support providers.	Capabilities and services/funding offered, companies worked with, technologies funded/ supported, challenges and gaps.

1.2. Survey Outputs

The outputs of the survey will serve as a platform to catalyse and design sector-development interventions and to promote and facilitate increased collaboration amongst local stakeholders to increase the development and manufacture of transformative medical devices for local and export markets, with concomitant growth of the medical device ecosystem. The expected outputs of the survey are as follows:



Methodology and Analytical Framework

2. Methodology and Analytical Framework

2.1. Methodology

The methodology for the survey, which was planned in four phases, is depicted in Figure 1. The survey commenced with a desktop review of existing documents and stakeholder consultations. This allowed the team to identify what information was already available on the MD sector in South Africa and the information gaps that remained. This was followed by the survey development and data collection and analysis. This report represents the end of Phase 3. Phase 4 will build on the outputs to date, as described below.

The remainder of the current chapter describes the four phases in more detail and presents the analytical framework that was used to analyse existing information and the information gathered in this study.

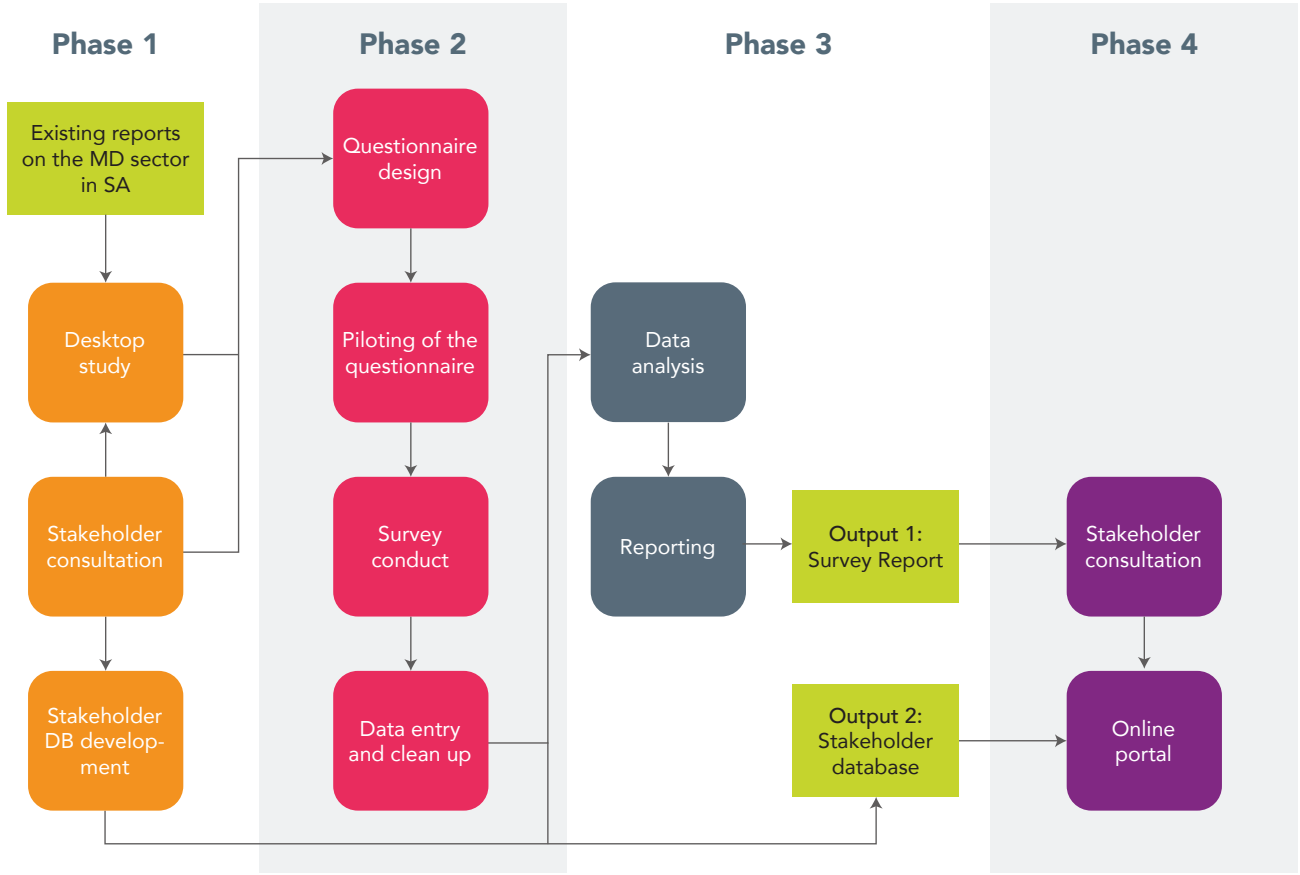


Figure 1: Survey methodology

2.2. Phase 1: Inception Phase

2.2.1. Consultation with key stakeholders

The concept and proposal for the conduct of the landscape analysis was presented and discussed at various meetings of the Medical Devices Stakeholder Forum and a small working group was established, led by the SAMRC, to discuss this in more detail. Various consultations were held with the key stakeholders who collectively have an interest in driving the medical devices sector to identify their information needs, including DTIC, IDC, SAMED, MDMSA, GHIA, TIA, DSI, and the CSIR.

2.2.2. Secondary data analysis

Existing reports on the medical devices industry in South Africa were reviewed and information on the below-mentioned categories was collated:

- Stakeholders targeted;
- Data/information collected;
- Methodology used;
- Data/information reported;
- Data sources;
- Highlighted findings; and
- Information gaps.

The major findings from the existing reports were synthesised, and the analytical framework was used to identify gaps in the existing information. The results of this report synthesis are summarised in Chapter 3.

2.2.3. Compilation of stakeholder database

The survey collected information from South African-based MDMs, HEIs and SCs involved in the research, development and manufacture of medical devices. The survey also covered MD support organisations who provide services in the form of consultancy, funding and product incubation.

The MDMs database was compiled from various sources, including:

- A database received from the Medical Device Manufacturers Association
- Information from the DTIC
- Internet searches and referrals from stakeholders
- Information on hand at the SAMRC
- Referrals from survey participants

A list of service providers that support medical device stakeholders in the form of design, components, engineering consulting, sterilisation, etc. was compiled from referrals, existing databases and internet searches. Similarly, a list of funders and incubators that provide support for medical device innovations/companies was compiled. It is recognised that the lists of support agencies and service providers may not be exhaustive as there may be several in South Africa that are unrelated to the medical devices sector but that do provide services to medical device stakeholders. This survey focused on services specific to the MD sector and/or those widely used by medical device stakeholders.

The HEI and Science Council databases include all HEIs and all relevant SCs; however, not all of these have capabilities in, or are presently involved in medical device development.

2.3. Phase 2: Primary Data Collection

2.3.1. Questionnaire design and piloting

The survey was designed by the SAMRC in consultation with members of MDMSA. The draft questionnaire for the MDMs was workshopped with a selection of MDMSA members and refined. The draft questionnaires for all target sectors were sent to a number of stakeholders for comment; however, no additional inputs were received.

2.3.2. Survey conduct and response rate

The survey team included four SAMRC staff members, one SAMRC-GHIA consultant and one medical device consultant based in KwaZulu-Natal (KZN), hired specifically to assist with the survey in that province. The survey was administered through an online survey platform developed by Jembi Health Systems NPC, based on the open source Open Data Kit (ODK) (Hartung *et al.*, 2010). Jembi specialises in digital health-information systems for low-resource settings, with a focus on enterprise software and facility hardware, and hosts the SAMRC-Jembi Collaborating Centre for Digital Health Innovation. The survey team received training from Jembi on how to capture and retrieve data from the online survey platform prior to the roll out of the survey.

The target population for the survey included all medical device manufacturers in South Africa and the unit of analysis was the MDM companies. A total of 136 MDMs were identified through databases from various sources supplemented with desktop research. Initial contacts were made telephonically with companies, followed by an email including introductory documents explaining the purpose and aims. The MDMs survey was composed of two parts. Part A captured information relating to the company's profile and a brief overview of the company's business focus and market segmentation (see Appendix II). Participation was voluntary and companies were requested to indicate their interest in participating by completing Part A via an online survey link. Thereafter, an appointment was scheduled for the completion of Part B. Interviews were conducted either in person or telephonically. Part B captured information relating to manufacturing capability and capacity, product registration and certification, research and development and use of support services, and to understand the risks and barriers affecting the local MDMs.

The response rate for Part A was 52% and for Part B 49%. Repeated follow-ups were conducted with non-responders over several months; however, the team was not able to increase the response rate.

Due to the small population size, the HEI, SC and support service surveys were completed via email. For the HEIs, initial contacts were made telephonically, followed by an email detailing the purpose of the survey. A total of 25 HEIs and 5 science councils active in research were contacted, and the survey was sent to the director or manager of the university or science council's technology transfer office for completion. Seventeen HEIs (68%) responded; however, 2 of these indicated no activity. All 5 science councils contacted completed the survey, including two different units at the CSIR. Finally, the survey of the support companies followed the same methodology to that of the HEIs and science councils and a survey response rate of 46% was achieved.

2.3.3. Data entry and clean up

Once data entry was completed for the online MDM survey (in most cases following an interview) the data sets from both questionnaires were exported from the ODK system to a comma-separated values (CSV) file, which was then imported into an Excel document for analysis. An additional manual data quality check was conducted to ensure the integrity of the data. The survey responses were divided into qualitative and quantitative data for each category and analysed accordingly. The survey questionnaires for HEIs, SCs and support companies were completed by participants in an MS Word document and submitted to the SAMRC via email. The data were then transferred to an Excel document for analysis.

2.4. Phase 3: Data Analysis and Reporting

2.4.1. Survey results and descriptive analysis

All data was analysed in Excel spreadsheets. Data analysis started with a descriptive analysis which included summarisation, combining and ordering of quantitative and qualitative data reported in graphs and tables in Chapter 4. The survey included a number of open-ended questions where respondents could answer in open text format. The responses to these questions were analysed for patterns and themes and where appropriate were coded to provide additional quantitative data which was then descriptively analysed as quantitative data. In addition, qualitative answers were summarised in tables and in narrative descriptions.

The main survey was supplemented with an adjunct survey aimed at capturing the experiences of medical devices stakeholders during the COVID-19 pandemic. The results of this survey are described in section 5.5.

2.4.2. Analytical framework and diagnostic analysis

A diagnostic analysis was performed using the Technological Innovation Systems (TIS) framework and is reported in section 6.2.

The approach of Technological Innovation Systems (TIS) has become a widely applied analytical framework for mapping the elements of innovation systems which together shape the evolution of emerging technologies. Although there are several definitions, this work has used the definition of Markard and Truffer (2008), who define TIS as a "set of networks of actors and institutions that jointly interact in a specific technological field and contribute to the generation, diffusion and utilisation of variants of a new technology and/or a new product".

The framework defines seven important dimensions, as shown in Table 2 below. The TIS framework was primarily applied during the analysis and reporting phase of the project with section 6.2 providing an analysis of the South African medical device sector as a TIS and proposing interventions for strengthening it.

Table 2: TIS Functions[2]

Function	Definition
Knowledge development	The breadth and depth of the knowledge base and how that knowledge is developed. Various types of knowledge serve as inputs for innovation, including that generated from R&D and different learning processes (i.e., learning-by-doing, learning-by-using).
Knowledge diffusion	The exchange of information through networks of diverse actors in a heterogeneous context where R&D meets Government, competitors, and the market. Here policy decisions (standards, long term targets) should be consistent with the latest technological insights, and, at the same time, R&D agendas should be affected by changing norms and values. Network activity can be regarded as a precondition to learning by interacting.
Experimentation and upscaling by entrepreneurs	The testing of new technologies, applications, and markets whereby new opportunities are created, and a learning process unfolds. This includes the development and investments in artefacts such as products, production plants, and physical infrastructure.
Guidance of the search	The incentives for organisations and actors to enter the technological field. These incentives may stem from visions, expectations of a growth potential, policy instruments, technical bottlenecks, etc. In an early phase, it also includes how prime movers manage to define technological opportunities and make it attractive for other actors to enter the field.
Market formation	The factors that stimulate the emergence of markets for new products. These include articulation of demand from customers, institutional change, and changes in price and performance of the products. Market formation normally goes through different stages, i.e. demonstration projects, niche market, and mass markets.
Resource mobilisation	The extent to which actors within the TIS are able to mobilise human and financial capital, as well as complementary assets such as products, services, network infrastructure, etc.
Legitimation	The social acceptance of the technology and the actors and compliance with relevant institutions. Legitimacy is formed through conscious actions by organisations and individuals, and this process may often be complicated by competition (and lobbying) from adversaries defending existing technologies and regimes.

2 Adapted from Hellsmark, H., Mossberg, J., Söderholm, P. & Frishammar, J. 2016. Innovation system strengths and weaknesses in progressing sustainable technology: the case of Swedish biorefinery development. Journal of Cleaner Production, 131, pp 702-715.
Hekkert, M. P., Suurs, R. A., Negro, S. O., Kuhlmann, S. & Smits, R. E. 2007. Functions of innovation systems: A new approach for analysing technological change. Technological forecasting and social change, 74(4), pp 413-432.

Available Information and Gaps

3. Available Information and Gaps

Baseline information and data on the medical devices landscape in South Africa were drawn from the following reports:

1. The Supply and Manufacture of Medical and Surgical Equipment and Orthopaedic Appliances (Who Owns Whom, 2019)
2. South Africa Medical Device Report, January 2017 (BMIResearch)
3. 2016 Global Outlook for the Healthcare Industry: Value-Based Healthcare Transformation Drives Opportunity (Frost & Sullivan, 2016)
4. Industry Overview and Economic Impact Assessment for the South African Medical Technology Industry (KPMG, 2014)
5. Research to Guide the Development of Strategy for the Medical Devices Sector of South Africa (Deloitte, 2014)
6. Situational Analysis of the RSA Medical Device Innovations Landscape (MDI-SIG, 2008)
7. Wesgro Cape Town & Western Cape Research report on the Medical Devices Sector (Wesgro)

These reports were supplemented with data and information from the following reports when the final report was compiled:

8. South Africa Medical Devices Report Q3 2021 (FitchSolutions, 2021)
9. 2021 Global Health Care Outlook – Accelerating Industry Change (Deloitte, 2021)

The main findings from the reports are summarised below.

3.1. Demand

3.1.1. Domestic market size and growth trends

South Africa is one of the largest medical device markets in the Middle East and Africa region and was estimated at R21 billion in 2021 and projected to grow to R29.6 billion by 2025 (FitchSolutions, 2021). The domestic market size is supported by a large population and Africa's most industrialised economy (ibid.). Despite this relatively large size of the market in regional terms, it makes up only 0.3 percent of the global market for medical devices[3]. Local manufacturers therefore tend to focus on exports markets (Who Owns Whom, 2019).

The healthcare need in South Africa is growing in part due to the HIV epidemic, tuberculosis, maternal and child mortality, and violence and injuries, as well as the growing burden of health problems such as obesity and non-communicable diseases (NCDs) (Frost & Sullivan, 2016). Growth over the next five years will be supported by global economic recovery in 2021 driven by net-exports and private consumption, and a slight improvement in domestic consumer and business confidence (FitchSolutions, 2021). The South African market will also benefit from increased Government health spending and increasing private sector investment (ibid.). The establishment of the National Health Insurance (NHI) is prompting further investment in the public healthcare system. Continued delays in its implementation are however negatively impacting on the attractiveness of the domestic market (ibid.).

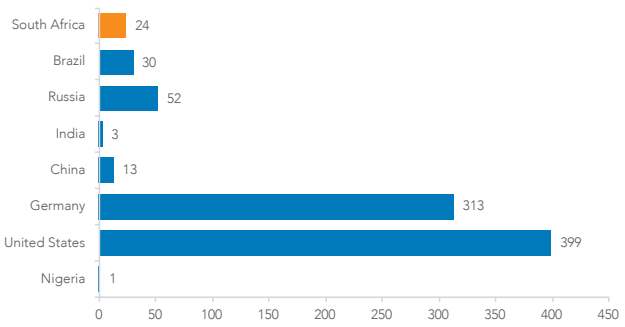


Figure 2: Per capita spending (US$) on medical devices across countries (Deloitte, 2014)

3 Author's calculation based on FitchSolutions (2021) estimate of South African Market size in 2020 and Frost & Sullivan (2016) estimate of Global market size of US$377 billion in 2020

As indicated in Figure 2, South Africa, like other BRICS countries, has considerable potential for demand growth for medical devices, with 2014 per capita spend of US$24 compared to over US$300 for developed countries (Deloitte, 2014). FitchSolutions (2021) provides an even lower estimate of US$19.2 for South Africa in 2020 but forecast that this will rise to US$27.4 by 2025.

Global demand for healthcare is expected to grow at an annual rate of 7.3% to reach US$636 billion by 2022 from US$304 billion in 2011 (Wesgro). Between 2020 and 2024, global health spending is expected to rise at 3.9% compound annual growth rate (CAGR) with the fastest growth occurring in Asia and Australasia (5.3%) and the transition economies of Central and Eastern Europe (5.2%), and the slowest in Latin America (0.7%) (Deloitte, 2021).

The growth in healthcare markets is driven by gradual economic recovery, aging populations, changing disease burdens, diagnostic and therapeutic advances, new and significant emerging markets and rising global income levels in developing countries (Deloitte, 2021; Deloitte, 2014).

South Africa is seen as one of the most attractive markets in sub-Saharan Africa, partly due to the improving regulatory environment in the country (FitchSolutions, 2021).

3.1.2. Public sector market

Government is the major purchaser of healthcare equipment and supplies in South Africa, associated with a public healthcare sector comprising 7 901 facilities with 85 362 registered beds (Who Owns Whom, 2019). The public sector market is characterised by a tender-based system that is price sensitive. Whilst a national tendering system exists, each province also has independent tendering systems (FitchSolutions, 2021). Public sector procurement is plagued by slow or non-payment which impacts supplier capital and cash flow (Who Owns Whom, 2019). Public tertiary hospitals have also had severe budget constraints in recent years and are struggling to maintain or replace existing equipment (FitchSolutions, 2021).

Government tenders are intended to support the Government's broader objectives such as support for small, medium and micro enterprises, local suppliers and broad-based black economic empowerment (FitchSolutions, 2021).

3.1.3. Private sector market

A growing private sector is a key feature of the SA market, employing close to 70% of the medical practitioners in the country (Wesgro). The private healthcare sector comprises 524 facilities with 40 514 beds (Who Owns Whom, 2019). The main private hospital operators are the JSE-listed Life Healthcare, Mediclinic and Netcare, which together operate two-thirds of all private sector beds. The remaining private sector facilities form part of the National Hospital Network, which represents smaller independent facilities (ibid.).

As is the case for the public healthcare sector market, the private sector market operates under significant cost pressures (DST, 2008). Medical schemes are major players in the private component of the SA healthcare sector, with a significant influence on prices and price increases for medical devices (Who Owns Whom, 2019). Reportedly medical aid schemes frequently reject higher than inflation price increases and threaten to delist suppliers who do not accept the prices that are proposed by the schemes (ibid.). Notably, medical device manufacturers are not currently involved in price negotiations between medical schemes and hospitals groups. Total benefits paid by medical schemes in 2017 was R160.56 billion, of which the largest contributors for services were medical devices used by medical specialists (6.9%), followed by pathology (6.8%) (ibid.). As of 2017, medical devices were not yet included in the treatment for prescribed minimum benefits (PMB), or in the chronic diseases list (ibid.).

Local medical device companies derive most of their revenues from clients in the private sector (70%) (KPMG, 2014). According to the reports reviewed, in the short term, the best prospects for sales of advanced technology and equipment remain in the private sector (FitchSolutions, 2021).

3.1.4. Nature of the market

Figure 3 provides an overview of the South African medical device market in 2019 in terms of product areas. The medical devices market is diverse, ranging from consumables to major capital items. Other medical devices (38%) and consumables (19%) constitute almost 60% of the market followed by diagnostic imaging (15%), orthopaedics (12%), patient aids (12%) and dental products (3%) (FitchSolutions, 2021). Cost-effective products will be in greater demand, especially those that promote primary health care and are re-usable (ibid.). There is focus on reliable, low-maintenance products and a growing interest in high-tech, non-invasive equipment (ibid.). Purchasers are increasingly buying cheaper products from Asian markets to save costs (Who Owns Whom, 2019).

Disruptive forces affecting the industry globally are heightened regulatory scrutiny, new healthcare delivery models and a shift in buying power from doctors to end-users as a result of evidence-based healthcare (Who Owns Whom, 2019). Clinical pathology laboratories are repositioning themselves to compete in a consumer-driven marketplace by being more transparent with test prices (Frost & Sullivan, 2016).

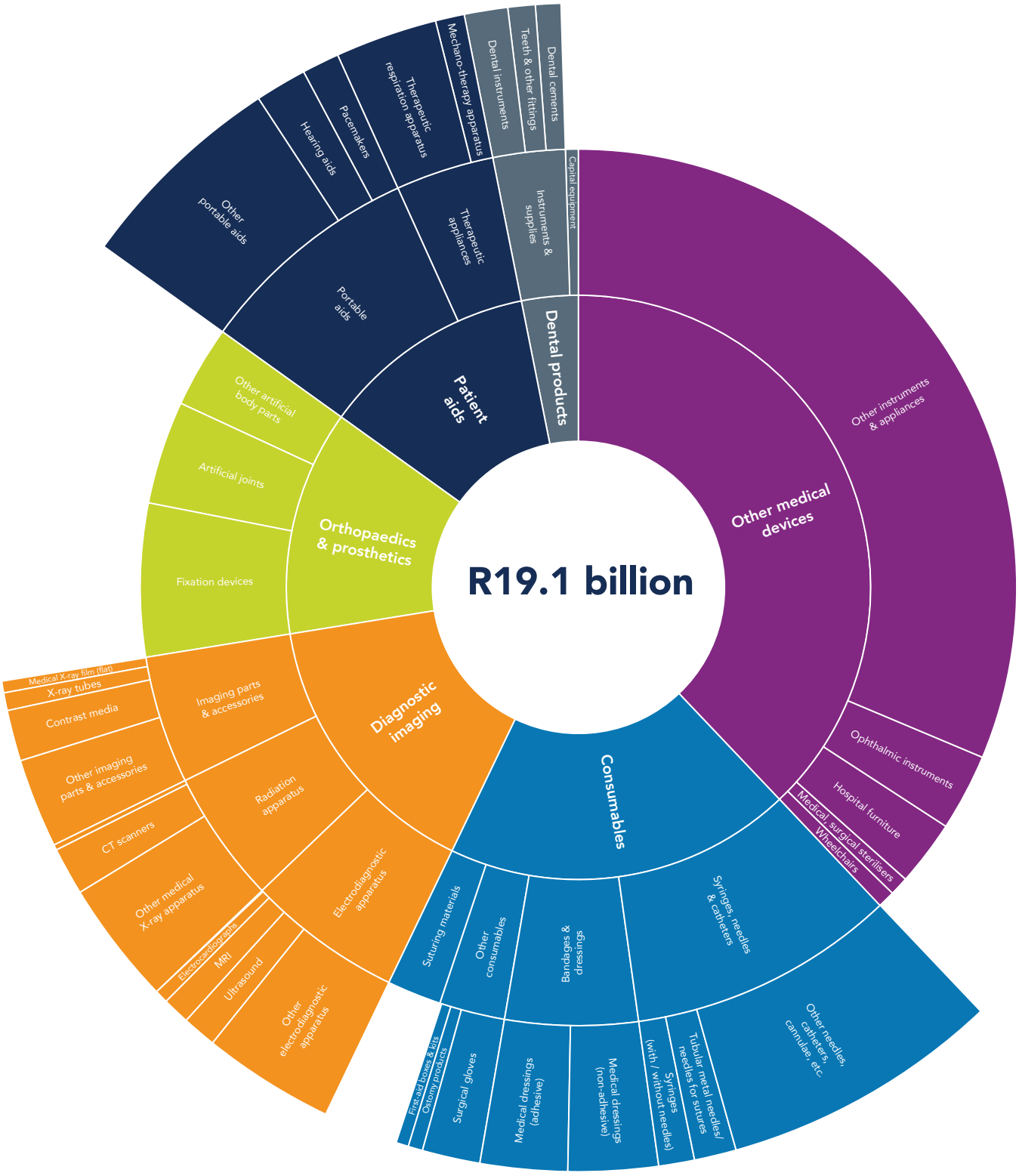


Figure 3: Overview of the South African medical device market in 2019 in terms of product areas[4]

4 Author's diagram based on data in FitchSolutions (2021).

3.2. Supply

3.2.1. Manufacturing

South Africa has limited production capacity for medical devices. The market is therefore largely dependent on imports (FitchSolutions, 2021). Fewer than 5% of local industry players manufacture devices, with more than 76% of devices being imported (Who Owns Whom, 2019). Deloitte (2014) estimates that in terms of market value, 90% is supplied by imports.

South Africa's manufacturing output of medical devices is estimated to be about US$200 million to US$300 million, of which more than half is exported (FitchSolutions, 2021). Manufacture grew by 9.1% to US$211 million from 2017 to 2018, to account for about 13.5% of the total value (Who Owns Whom, 2019). Local manufacture was expected to grow by 8% to US$227.8 million in 2019 (ibid.). Figure 4 illustrates trends in domestic manufacture of medical devices which is dominated by products in the other medical devices, consumables and diagnostic imaging product areas.

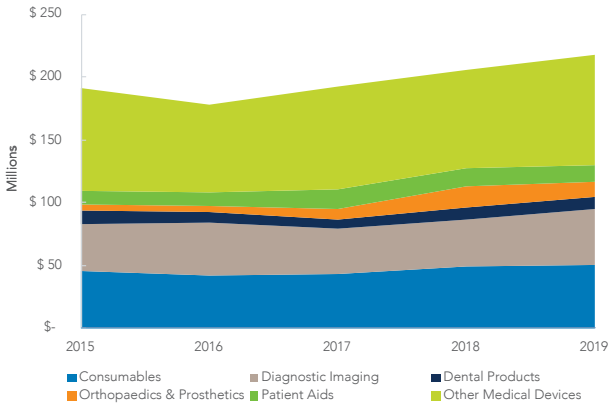


Figure 4: Trends in domestic manufacture of medical devices[5]

South Africa has a large number of industry players with between 350 and 600 suppliers, ranging from companies listed on the JSE to opportunistic agency traders (Who Owns Whom, 2019). The substantial number of suppliers is associated with a high degree of fragmentation, competition and instability (ibid.). Suppliers range from large multinational subsidiaries, distributors and agents for disposable medical devices to major equipment manufacturers (ibid.). More than 80% of the industry consists of privately-owned small and medium-sised enterprises (SMMEs) with less than 50 employees who often combine distribution activities with manufacturing (ibid.). Multinational companies frequently operate in joint ventures with local firms (ibid.). Most SA manufacturers focus on producing basic medical equipment and supplies (FitchSolutions, 2021).

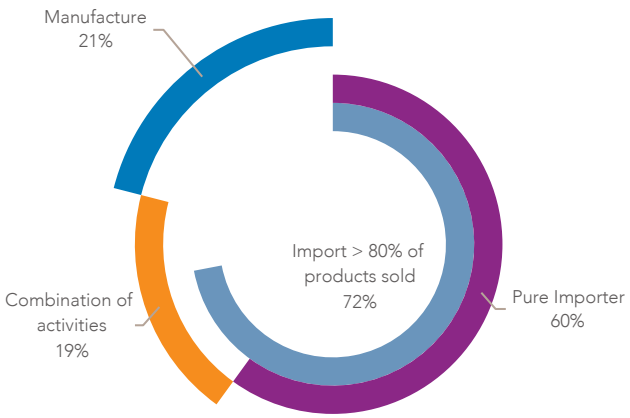


Figure 5: Proportion of medical device companies engaged in importing vs manufacture in the 2014 SAMED/KPMG survey

In 2014 the South African Medical Device Industry Association[6] (SAMED) commissioned a study by KPMG (2014) in which 158 members of SAMED and the Southern African Laboratory Diagnostics Association were surveyed. A summary of the proportion of companies engaged in domestic manufacture vs importation is provided in Figure 5. According to this survey, only 21%[7] of respondents manufactured medical device products in South Africa, 60% import and distribute packaged products, with the remainder engaging in a combination of activities including importing and repackaging medical device products. Notably, 72% of the medical device companies surveyed imported more than 80% of the products sold. According to the KPMG survey, multinational MD companies earn significantly higher revenues than their local counterparts.

Local manufacturing is focused on the production of low-tech and low-value devices such as surgical goods and disposable needles (Who Owns Whom, 2019). There are however several examples of locally developed hi-tech devices including the design and manufacture of advanced breast imaging technology and the development and manufacturer of low radiation full body X-ray machines that are used internationally (ibid.). Detail on the domestic manufacturing output compared to the domestic market is provided in Figure 6. According to Who Owns Whom (2019), local manufacturers tend to focus on the export market where SA manufactured devices are well accepted based on high quality and competitive prices (ibid.).

The possibility of increased local medical device manufacturing is welcomed by domestic purchasers, with the quality of the product, availability of supply and post-sales support being remaining concerns (Deloitte, 2014). Despite the challenges cited regarding public procurement, some local manufacturers are taking advantage of the public sector tendering process (DST, 2008).

5 Author calculations based on domestic market, import and export data in FitchSolutions (2021)
6 Later known as The South African Medical Technology Industry Association
7 Note that Who Owns Whom (2019) cites an even lower proportion of fewer than 5%

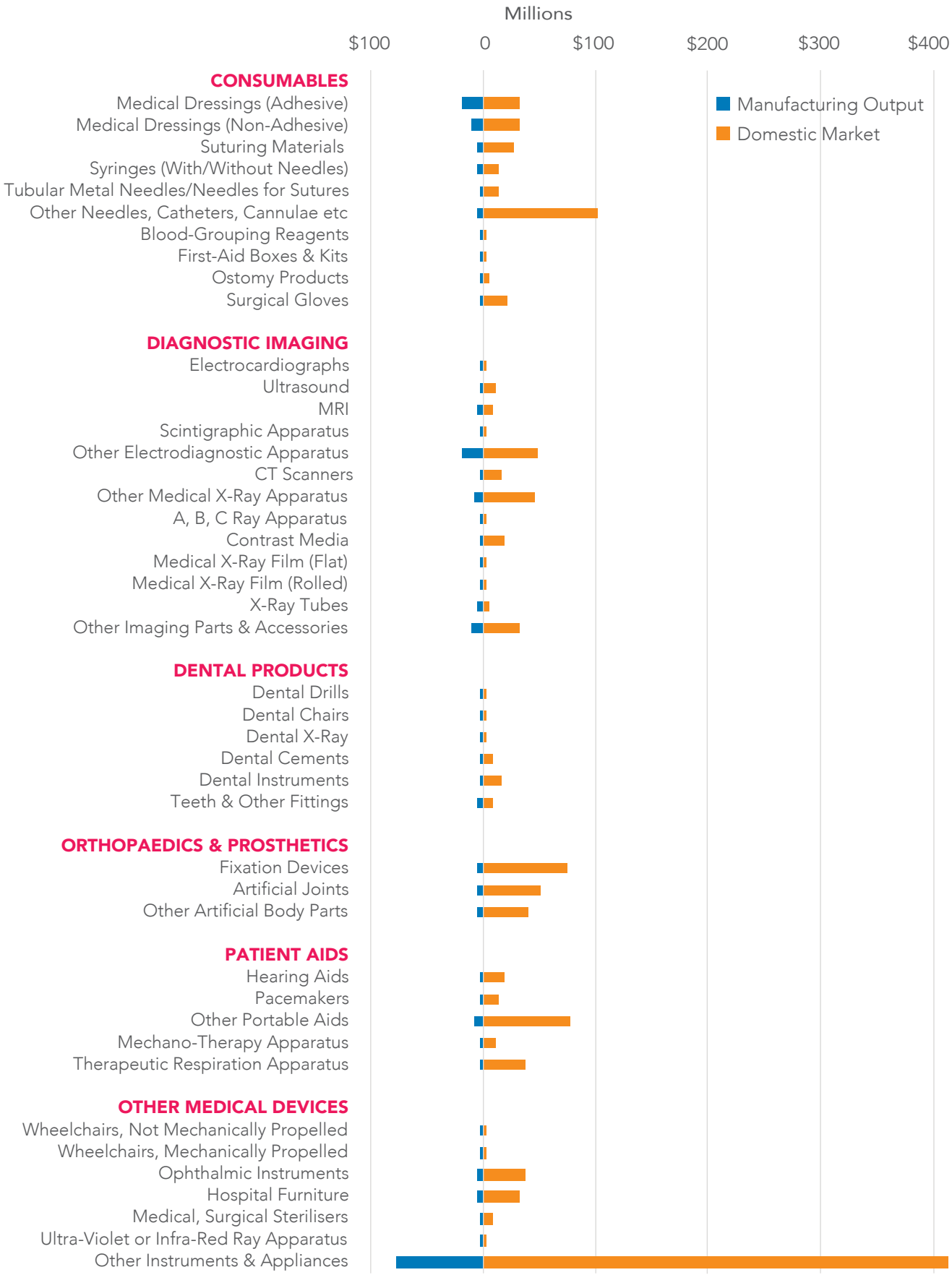


Figure 6: South African medical device manufacturing output vs domestic market

Local manufacturers are likely to grow market share as they move into higher value add, high-tech areas (Wesgro). Globally, there is a trend for healthcare companies to endeavour to move up the value chain with new initiatives to capture services and other elements of support related to disease prevention education, diagnosis, and tracking (Frost & Sullivan, 2016). Domestic production is anticipated to continue to grow in sophistication as indicated by the number of innovative medical devices at different development stages (FitchSolutions, 2021; BMIResearch, 2016).

In terms of age and location, multinationals and the local MD companies have been running operations in SA for an average of 26.5 years (KPMG, 2014). The MD sector is concentrated in Gauteng, Western Cape (WC), KwaZulu Natal (KZN) and Eastern Cape (Who Owns Whom, 2019).

The reports reviewed provided limited information on the South African medical device manufacturing landscape at a detailed level.

3.2.1.1 Western Cape medical devices sector

The reports reviewed included a report by Wesgro[8] and Who Owns Whom (2019) with a section devoted to the WC medical devices sector. Similar reports are not currently available for the other three provinces active in the medical device industry.

WC is a major market in the healthcare and medical devices sector and hosts the highest concentration of medical device and healthcare companies, research institutes and research groups in South Africa (Wesgro). Medical instruments and appliances were the leading export product from the WC in 2013, valued at R66 million. WC exports increased by 67% in 2013, while imports increased by 7%. The African region represented about 40% of the top 10 WC export markets in 2013. Kenya was the leading export market for medical devices from the WC in 2013, with a value of R37 million. The leading product was instruments and appliances for medical use, valued at R13 million. The WC Government has partnered with the City of Cape Town to create a strategic clustering of pharmaceutical companies, research institutes and groups, clinical trial facilities and R&D facilities. A technology park along with national incentives for R&D are considered to be highly attractive for foreign direct investment (ibid.).

The WC received the largest foreign investment in the sector during the recent past, valued at R67 million, from Emergo, a medical device regulatory consulting firm from the United States (ibid.).

3.3. Exports

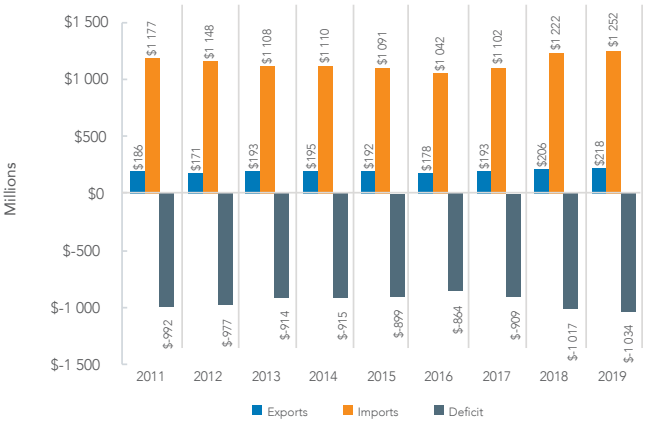


Figure 7: International trade flows of medical devices in South Africa[9]

Even though more than half of South Africa's medical device manufacturing output is exported, and exports have tripled (in Rand terms) in the past decade, overall, South Africa is still not a major exporter of medical devices, with the volume and expenditure on imported products far exceeding exported products as indicated in Figure 7. Between 2014 and 2019, exports grew at a CAGR of 8.3% to reach R3.1 billion by 2019 (FitchSolutions, 2021).

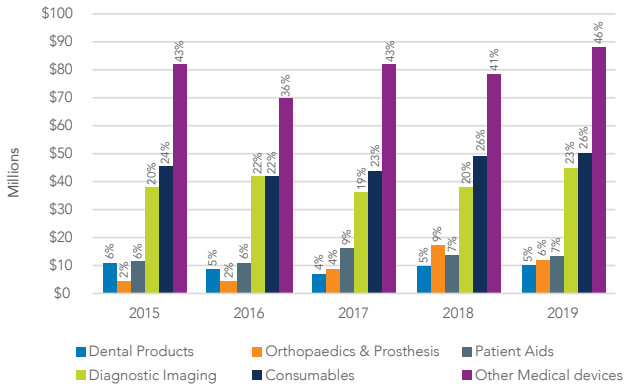


Figure 8: Exports by product area (2015-2019)[10]

Figure 8 illustrates medical devices exports from 2015 to 2019. South African medical device exports are dominated by products in the "other" category (46% in 2019) followed by consumables (26% in 2019) and diagnostic imaging (23% in 2019). The "other" product area is further broken down in Figure 9.

8 The official tourism, trade and investment promotion agency for Cape Town and the Western Cape (https://www.wesgro.co.za/corporate/about)
9 Author's graph based on data in FitchSolutions (2021) and BMIResearch (2016)
10 Author's graph based on data in FitchSolutions (2021)

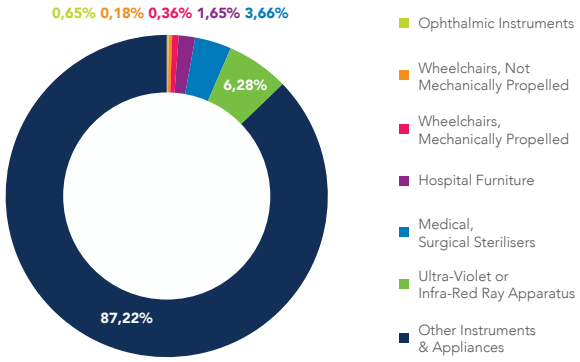


Figure 9: Detailed breakdown of exports in Other Medical Devices product area in 2019[11]

Local manufacturers tend to focus on the export market, with South African manufactured devices valued for their high quality and competitive prices (Who Owns Whom, 2019). Figure 10 shows South Africa's top medical device export destinations for 2019. Most of the leading export markets are in Africa, in the Southern African Development Community (SADC) in particular, followed by Europe. It must be borne in mind that the available data does not provide information on value added to exports as it does not distinguish between products imported and re-exported and products manufactured in South Africa. At least some exports are re-exports of medical devices for which South Africa is used as a springboard into Africa (Who Owns Whom, 2019).

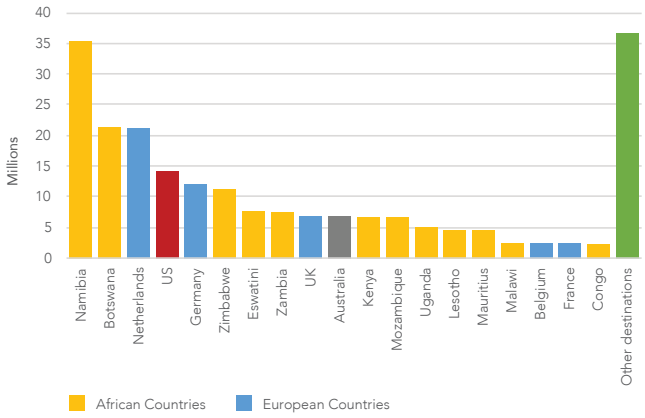


Figure 10: South Africa's top medical device export destinations in 2019

Exports should continue to benefit from a weak Rand (FitchSolutions, 2021). However, breaking into the international markets can be very costly (Deloitte, 2014).

3.4. Imports

As mentioned, the local industry is dominated by imports, with medical technology imports to South Africa valued at R11 billion in 2013, growing to R18.1 billion by 2019 (FitchSolutions, 2021), while South Africa exported R1 billion in 2013 and R3.1 billion in 2019. Seventy-five % of all medical device imports are sourced from ten countries and around half from the top three[12] (BMIResearch, 2017). More than 76% of medical devices used in South Africa are imported by multinational companies (Who Owns Whom, 2019). The leading suppliers of imported medical equipment to South Africa in 2019 were the United States (US$311 million), Germany (US$159.6 million) and China (US$146 million). The European Union supplied 35% of all medical device imports to South Africa in 2019. Additional detail on leading sources for imports is provided in Figure 11 and additional detail on imports from the United States in Table 3.

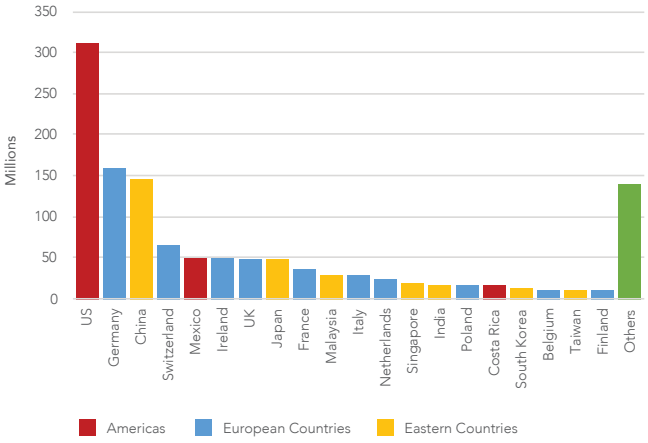


Figure 11: Leading sources of medical device imports to South Africa

11 Author's calculations based on domestic market, import and export data in FitchSolutions (2021)
12 Author's calculations based on data in FitchSolutions (2021)

Table 3 : South Africa – Medical Devices Trade in US$ millions[13]

	2018	2019	2020[14]
Total Market Size	1 278.40	1 323.40	1 468.30
Total Local Production	115.05	119.10	132.14
Total Imports	1 163.34	1 204.29	1 336.19
Imports from the U.S.	232.26	240.85	267.23

The breakdown of imports across product areas from 2015 to 2019 is illustrated in Figure 12 with details on the "other" category in Figure 13.

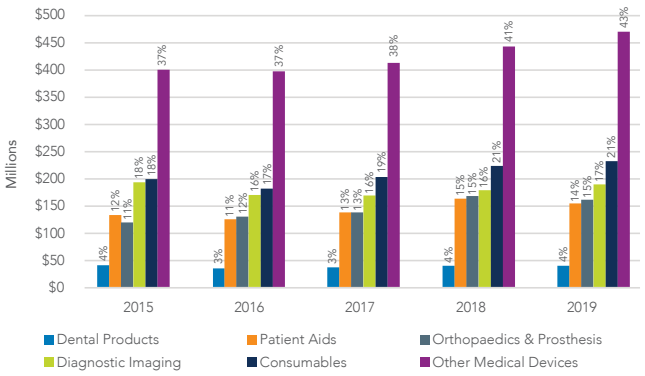


Figure 12: Imports by product area (2015-2019)[15]

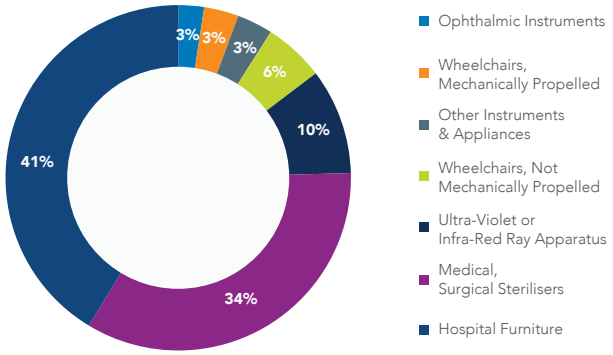


Figure 13: Detailed breakdown of imports in Other Medical Devices product area in 2019[16]

3.5. Regulation of Medical Devices

3.5.1. Historical situation

Globally, including in South Africa, medical devices have historically been under-regulated, with the sale and use of sub-standard and poorly tested medical devices impacting patients' health, quality of life or even mortality (Tomlinson, 2020). Most of the reports reviewed were published before the establishment of the South African Health Products Regulatory Authority (SAHPRA) in 2017. Deloitte (2014) reported that the "lack of regulations allow low-quality products to enter the SA market" (Deloitte, 2014) and KPMG (2014) "the SA medical technology industry is mainly unregulated, except for a few regulated medical technology product categories".

The KPMG (2014) survey found that industry respondents strongly supported the implementation of quality regulation, although most opposed price regulation. Regulations that require role players to be licensed were expected to promote fair competition and contribute towards ensuring safe, high quality products for consumers (Who Owns Whom, 2019). New (at the time) Medicines Control Council (MCC) licensing requirements relating to the manufacture, import and distribution of medical devices were expected to "increase compliance for manufacturers of moderate to high-risk devices in line with the move to establish an internationally aligned regulatory system" (Who Owns Whom, 2019).

Although regulation is mostly viewed in a positive light, lengthy registration processes could adversely affect the saleability of medical devices with short life cycles (Who Owns Whom, 2019). Respondents to the Deloitte (2014) survey expressed support for the use of United States Food and Drug Administration (FDA) and CE markings but indicated that post-marketing surveillance is required to cater for unique SA conditions and, in some cases, products and manufacturing sites should be evaluated post distribution.

Regarding exports, the South African National Accreditation System (SANAS) and the South African Bureau of Standards (SABS) are not accredited by the FDA, and the requirement by European clients that compels local manufacturers to use international accreditors increases the cost and time to export products (Who Owns Whom, 2019).

Although there have until recently been no legislative requirements for the regulation of medical devices in South Africa, electronic products (electromagnetic medical devices or radiation-emitting devices) were required to be registered before being sold, leased, used, operated or applied in South Africa (Saidi and Douglas, 2018). Other medical devices were unregulated, leaving advertisers and marketers few legislative formalities with which to comply (ibid.). However, public procurement of devices generally included a requirement for a CE mark to ensure the requisite levels of safety and quality, again resulting in cost barriers for local companies.

13 Source: https://www.export.gov/apex/article2?id=South-Africa-medical-devices
14 Figures for 2019 were estimates based on preliminary data and 2020 are forecasts
15 Author's graph based on data in FitchSolutions (2021)
16 Author's graph based on data in FitchSolutions (2021)

3.5.2. Recent regulatory developments

The Medicines and Related Substances Amendment Act 14 of 2015 brought about significant changes in the regulation of medical devices (Saidi and Douglas, 2018). Specifically, the act included the establishment of the South African Health Products Regulatory Authority (SAHPRA) in June 2017 to replace the MCC and provides for implementation of a dedicated regulatory framework for medical devices. SAHPRA was legally established in February 2017 as a Schedule 3A Public Entity in terms of the Public Finance Management Act (PFMA), 1999 (Act 1 of 1999) (Keyter *et al.*, 2018). As a Schedule 3A Public Entity, SAHPRA is a separate juristic person outside of the National Department of Health, mandated to regulate (monitor, evaluate, investigate, inspect and register) all health products. This includes clinical trials, complementary medicines, medical devices and *in vitro* diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973) (SAHPRA, 2021a).

The Medicines and Related Substances Amendment Act 14 (2015) introduced a four-tier, risk-based licensing and registration system, which applies to South Africa-based companies that manufacture, sell, import, export, distribute and wholesale medical devices in the country. The Act also regulates procedures for device registration and requirements relating to advertising and labelling, and the restriction of sampling for the sale of medical devices.

SAHPRA is implementing the regulation of medical devices in a phased approach, starting with a call up notice, published in February 2017, requesting all manufacturers and distributors of medical devices to apply for a SAHPRA license within 6 months of publication and wholesalers within 12 months. Companies that manufacture, pack, label, service, import and export medical devices were required to apply for a medical device establishment license as a manufacturer, those that import, export and distribute as a distributor, and those that are involved in storage, transportation and delivery as a wholesaler. Currently, no medical device may be manufactured, distributed, imported, exported or sold without a valid SAHPRA medical device establishment license. This is especially important for eligibility to bid for National and Provincial tenders. An exemption has been introduced for manufacturers, distributors and wholesalers of non-sterile, non-measuring Class A medical devices (SAHPRA, 2021b).

As part of the application for a SAHPRA medical device establishment license, a company must appoint an Authorised Representative based in South Africa who is responsible for adherence to the law, regulations and guidelines, and must list all the medical devices that it manufactures, distributes or wholesales. The application must also include a declaration on the quality management system in place in the company, which, upon renewal of the SAHPRA license, must include ISO 13485 certification (SAHPRA, 2021b).

ISO 13485:2016 is the latest standard from the International Organisation for Standardisation that sets out quality management system requirements, rules and guidelines for any company that designs, manufactures, installs, distributes or services medical devices (ISO, 2016). This includes companies that provide related services or components at any stage during a medical device product lifecycle, such as technical support, suppliers and external third parties, and relates to any instrument, apparatus, equipment, implant, in-vitro reagent or similar, which is used to diagnose, prevent or treat a medical condition. ISO 13485 allows a company to demonstrate that it consistently meets customer needs and medical device regulatory requirements and complies with local legislation. It is closely related to ISO 9001, which covers requirements for quality management systems, but emphasises areas such as risk management, the work environment and medical device documentation and reporting.

The next step in applying the regulation of medical devices in South Africa will be registration of each medical device. This process is still in development but will involve a Registration Call-Up Plan, still to be published, to inform stakeholders of the phased approach in which medical devices will be called up for registration. Until such time as devices are called up to be registered, 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. The requirements differ depending on the license applied for, the activities applied for, and the category of medical devices listed. For devices and 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. Although the call up and registration of devices has not yet been initiated, the COVID-19 pandemic has necessitated fast-tracking of the registration of certain *in vitro* diagnostics, including those developed in South Africa that do not as yet have registration in other recognised jurisdictions (SAHPRA, 2021b).

On 21 May 2021 the proposed "Regulations Relating to Medical Devices" were published in the Government Gazette for comments by interested persons (SAHPRA, 2021c). The proposed regulations include provisions for the supply of medical devices, the registration of medical devices, licensing of establishments to manufacture, distribute or wholesale medical devices, management of medical devices and investigations, offences and penalties related to the regulations. In terms of registration of medical devices, the proposed regulations specify the classification of medical devices (according to risk), the labelling of medical devices, instructions for use of medical devices which are not *in*

vitro diagnostic devices, instructions for IVDs, application for registration of a medical device, information that must appear in the register for medical devices, application for amendments to the register for medical devices and certificates of registration.

Implementing the call up and registration of medical devices in South Africa will be a mammoth task, with in excess of 2 000 products included on the product lists of companies with SAHPRA establishment licenses. This will require full digitisation of the process with an integrated online registration system to replace the current email-based system.

Aside from statutory regulation of medical devices, in 2011, SAMED became a member of the Marketing Code Authority (MCA), making it a signatory to a single Code of Marketing Practice, adopted by various health product associations in South Africa (Who Owns Whom, 2019). The Medical Device Code of Ethical Marketing and Business Practice was published in 2018. The intention is to facilitate ethical behaviour in the industry. Healthcare practitioners, customers and patients may lodge a complaint with the MCA regarding marketing and advertising of healthcare products (ibid.).

3.6. Research and Development (R&D)

Medical device R&D expenditure in South Africa is low (less than 1%, possibly as low as 0.5% (KPMG, 2014), compared to a global average of 6.8%[17]) as a percentage of turnover for the industry and minuscule in volume by global standards. In the KPMG (2014) survey of 47 SA MD companies, the total spend on R&D was a mere R21 million. In the same study the majority of the respondents indicated that the contribution of the medical technology industry to R&D was not significant. These low figures for R&D were related to the limited local manufacturing capacity (ibid.). Figure 14 reports the R&D spend of the twenty largest medical device companies globally, indicating what it requires to be globally competitive in the industry.

In Deloitte (2014), respondents commented that R&D spend was inevitably higher than budgeted for and that collaboration with universities was highlighted as a potentially effective way of increasing R&D output. In De Jager *et al.* (2017), four sectors – academia, healthcare, industry, and science and support – were identified. The study found seven local institutions, from three of the four sectors, to be the most dominant. The three highest-ranking dominant institutions were University of Cape Town (UCT), Groote Schuur Hospital and Stellenbosch University (SU). These institutions collaborated far more with each other (72%) than with international institutions (28%), indicating potential for greater international collaboration on MD related R&D. The study also found that there is scope for increased translational collaboration within SA.

The outflow of skilled people from the country and its impact on domestic R&D was identified as hampering innovation in MD as early as 2008 (DST, 2008).

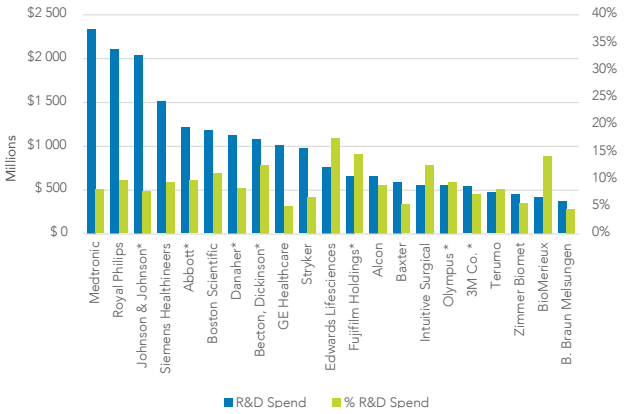


Figure 14: R&D spend for 20 of the largest medical device companies globally (Medical Design & Outsourcing, 2020)

*R&D figures are for the medical devices component only of these companies

3.7. Commercialisation, Investment and Incentives

FitchSolutions (2021) reports that Sub-Saharan Africa (SSA) remains the least attractive region in the world in which to commercialise a medical device based on their Medical Devices Risk/Reward (RRI) Index. Despite having a population of over 300 million, the region has the smallest market in a global context, with low per capita spend, a small elderly population and low urbanisation, with the majority of the population living in poverty.

However, within the SSA region, South Africa is the most attractive country, with a large market, the lowest risks in SSA, a relatively strong domestic economy that is business friendly, good healthcare access, higher levels of urbanisation which facilitate access to healthcare and an improving regulatory framework (ibid.).

Globally 1 735 foreign direct investment (FDI) projects in the medical devices sector were recorded between 2003 and 2014, with the United States being the largest investor with 818 investments. In this period 6 FDI projects with an average investment of R29.76 million per project were recorded in South Africa, creating 196 jobs (Wesgro).

17 Author's calculations for 2011 to 2020 based on https://www.statista.com/statistics/309305/worldwide-medtech-research-and-development-spending- as-percent-of-revenue/

South Africa, as of 2021, has a range of incentives available to medical device innovators and manufacturers as summarised in Figure 15 (DTIC, 2021b).

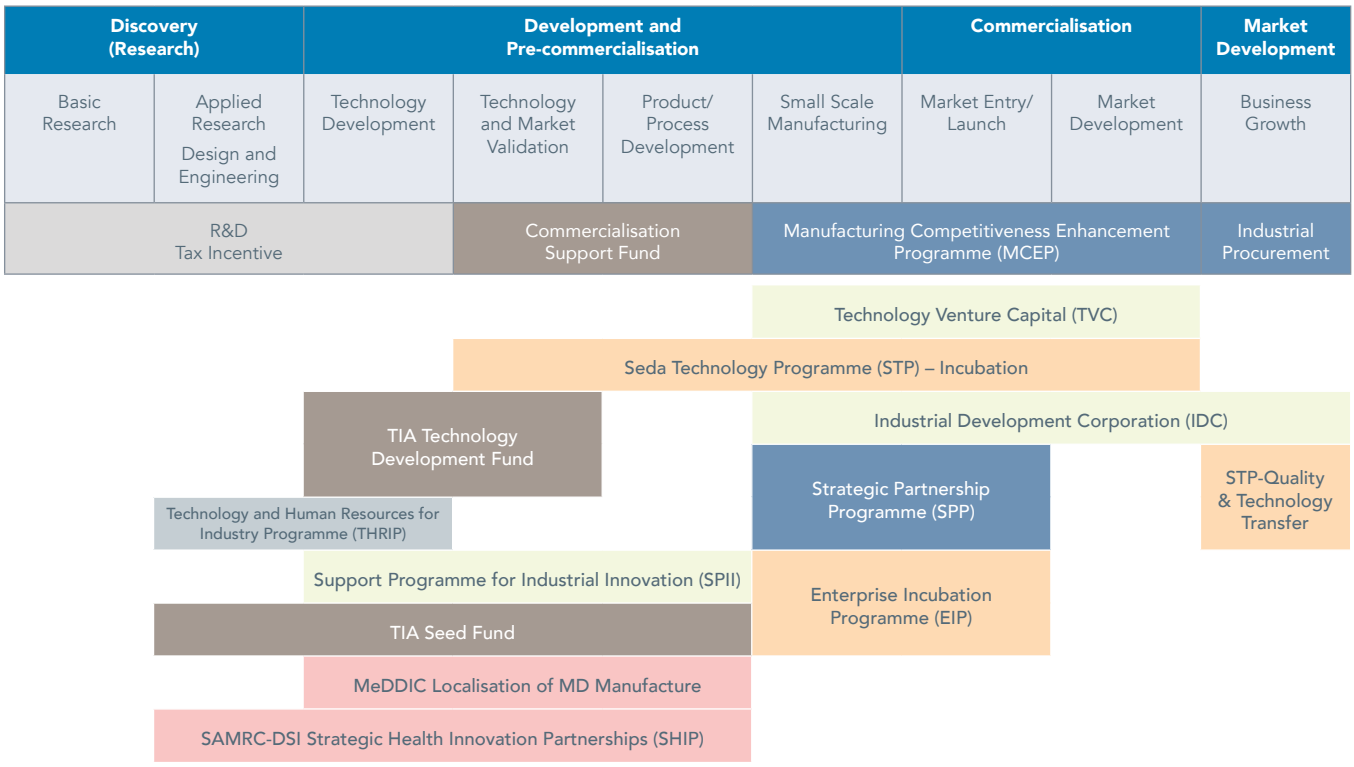


Figure 15: Innovation and technology funding instruments[18]

The high-level details of the various instruments are as follows:

- **The R&D Tax Incentive** is an incentive implemented by the DSI designed to encourage private-sector investment in scientific and technological research and development activities. In terms of the instrument, private-sector investors conducting R&D can claim up to 150% of qualifying expenditure incurred as a tax deduction.
- **The Commercialisation Support Fund** is an instrument that provides limited support for market testing and validation implemented by the TIA.
- **The Manufacturing Competitiveness Enhancement Programme (MCEP)** is a support scheme which offers manufacturing companies incentives to raise their competitiveness and retain jobs. It has a budget of R5.8-billion over a three-year period. The MCEP comprises two sub-programmes: the Production Incentive (PI) and the Industrial Financing Loan Facilities which will be managed by the DTIC and the Industrial Development Corporation respectively.
- **Technology Venture Capital (TVC)** is a fund established by the DTIC and managed by IDC which provides business support and seed capital for the commercialisation of innovative products, processes and technologies. TVC aims to increase the number of economically-productive companies in SA, and thus contribute to economic growth and international competitiveness through innovation and technological advancement.
- **TIA Technology Development Fund** supports the development of technologies from proof of concept, leading to product prototype and ultimately demonstration thereof in an operating environment. Eligible beneficiaries for the fund include science councils, higher education institutions, small, medium and micro-sised enterprises and start-up companies.
- **Seda Technology Programme (STP)** supports technology and market validation, process/ product development, small scale manufacturing, market entry and market development through incubation support.
- **The Industrial Development Corporation's (IDC)** Chemicals, Medical & Industrial Mineral Products Strategic Business Unit (SBU) supports entrepreneurship and promotes industrial development and strategic partnerships in a range of sectors and sub-sectors including medical devices (IDC, 2021). This is done through:
  - Loan- and equity-based financial assistance to new and existing businesses
  - The attraction of foreign direct investment
  - The search for strategic, technical, and marketing alliances, both locally and internationally.
- **The Technology and Human Resources for Industry Programme (THRIP)** aims to boost South African industry

18 Adapted from DTIC. 2021b. Innovation and Technology Funding instruments [Online]. Department of Trade, Industry and Competition. Available at http://www.theDTIC.gov.za/financial-and-non-financial- support/incentives/innovation-and-technology-funding-instruments/ [Accessed 08 July].

by supporting research and technology development and increasing the number of appropriately skilled people. All companies undertaking science, engineering and technology (SET) research, in collaboration with educational institutions, and with the aim of addressing the participating firms' technology needs are eligible for funding. The instrument operates as a 50:50 cost-sharing grant, to a maximum of R8m per annum, across any number of projects.

- **The Support Programme for Industrial Innovation (SPII)** provides financial assistance to South African private-sector enterprises for the development of commercially viable, innovative products and/or processes and to facilitate commercialisation of such technologies.
- **TIA Seed Fund** funds applied research, technology development and pre-commercialisation to assist small, medium and micro-sised enterprises, higher education institutions and science councils in bridging financing requirements to translate research outputs into fundable ideas for commercialisation.
- **The Strategic Partnership Programme (SPP)** funds private sector enterprises to undertake small scale manufacturing and market entry to develop and support programmes/interventions aimed at enhancing the manufacturing and services supply capacity of suppliers with linkages to strategic partner's supply chains, industries or sectors.
- **The Enterprise Incubation Programme (EIP)** funds small scale manufacturing and market entry to prepare early-stage entities to supply to local markets.
- **The Seda Technology Programme (STP)** Quality Standards and Technology Transfer Fund funds business start-up and business growth to promote and facilitate the transfer of technology. The Quality & Standards fund's main objective is to enhance the competitiveness and sustainability of small enterprise in South Africa by promoting Quality and Excellence as competitive tools for SMME's, cooperatives and incubators in realising their short, medium and long term strategic objectives.
- **Industrial Procurement** – The revised Preferential Procurement Policy Framework Act (PPPFA) regulations, which came into effect on the 7 December 2011, empower the Department of Trade and Industry to designate industries, sectors and sub-sectors for local production at a specified level of local content (DTIC, 2021a).
- **Strategic Health Innovation Partnerships (SHIP)** is a joint initiative between the DSI and the SAMRC aimed at investing in early-late stage product development in key health priority areas. It is hosted as a program at the SAMRC and is supporting a range of research and innovation projects.
- **The Medical Device and Diagnostic Innovation Cluster (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 through a partnership between the SAMRC, the TIA and the DSI. MeDDIC is rolling out various interventions to build and support the medical devices innovation and manufacturing ecosystem. These include a pilot funding programme that is supporting the localisation of medical device manufacture, specifically aimed at medical devices already in the market in South Africa that are either fully or substantially imported.

3.8. Impact

The medical technology industry's contribution to the SA GDP was estimated at R3.88 billion in 2014 with an associated economic multiplier of 1.25. The industry supported 20 901 jobs and contributed R1.86 billion in tax revenue (KPMG, 2014).

In addition to the impact on economic indicators, the medical technology industry has positive impacts on patients' quality of life, health professionals and the health system (ibid).

3.9. Barriers

Barriers to local manufacturing are discussed in the reports from the perspectives of healthcare buyers, suppliers and exporters.

Domestic medical device buyers' views on barriers to the use of local manufacturers include corruption, fly-by-night companies, poor quality of locally available equipment and lack of adequate post-sales support (Who Owns Whom, 2019; Deloitte, 2014). Ratings for the performance of local manufacturers against purchasing considerations are generally poor (Deloitte, 2014). Buyers who do not purchase any products from local manufacturers gave the lowest scores to local manufacturers (ibid.).

Suppliers indicated that there were benefits to manufacturing outside South Africa, including their perception that FDA regulations are easier to comply with, foreign manufacturers are located closer to large markets thereby reducing transport and logistics costs, the historical location of manufacturing plants with associated existing capital investment and specific skills as well as local legislation protecting existing sites (Deloitte, 2014).

Barriers to exporting SA manufactured devices include foreign customs tariffs, high production costs, high export costs, regulatory compliance, fluctuations in the exchange rate, transport costs of raw material and inconsistent customs timelines (Deloitte, 2014).

3.10. Strengths, Weaknesses, Opportunities and Threats According to the Literature

Three of the reports reviewed include a SWOT (strengths, weaknesses, opportunities and threats) analysis (FitchSolutions, 2021; Who Owns Whom, 2019; BMIResearch, 2017). These have been synthesised into a combined SWOT analysis incorporating items from other reports in Table 4.

Table 4: SWOT for the South African medical devices industry according to prior reports

Strengths	Weaknesses
1. Political stability in SA, strong and independent institutions, judiciary and security services 2. Limited threat of terrorism 3. Industrialised economy & rich mineral resources 4. Financial hub & stable banking sector 5. Much of SA public debt is denominated in local currency 6. Observance of contracts and intellectual property rights 7. Quality transport infrastructure 8. Large population 9. Low staff turnover in MD industry 10. Strong private healthcare sector 11. Steady demand for medical devices 12. Licensing requirements promoting compliance and product safety 13. Public funding (DTI and IDC) of the sector 14. Weak Rand a driver for local development and manufacture 15. Increased Government spending on equipment as part of the NHI 16. Recent private equity investment in the sector 17. Government support for exports and innovation in the WC 18. Access to sub-Saharan African markets 19. Established exports of hi-tech, high value MD products	1. High structural unemployment, poverty and political disenfranchisement 2. Corruption 3. Economy over-dependent on primary commodities 4. Currency volatility 5. Labour market rigidities 6. Very high crime rate 7. Lengthy business registration, closing and opening turnarounds 8. Poor healthcare infrastructure, particularly in the rural areas 9. Private healthcare sector out of reach for most of the Black population 10. Many rural facilities under-used or idle due to poor organisation 11. HIV/AIDS overburdening the system 12. Chronic shortage of medical personnel 13. Purchasing procedures complex and fragmented 14. Small size of domestic market and only ~5% of devices used are manufactured locally 15. Low levels of R&D 16. Inconsistent quality of local manufacture 17. Lack of device level licensing/registration 18. Medical device research underfunded 19. Registration of products in overseas markets expensive 20. Medical aid schemes power over pricing of MDs 21. Lack of stakeholder/role-player alignment
Opportunities	**Threats**
1. Emerging party-political diversity 2. Microeconomic reforms, including improved skills training, to alleviate poverty 3. Emergence of affluent, Black middle class 4. Private security firms filling gaps left by the police 5. Inter-regional trade agreements facilitate trade flows and reduce costs 6. Greater interregional freight connections envisaged 7. Government health funding to increase in real terms 8. Expansion of HIV treatment reducing pressure on public healthcare system 9. National health insurance (NHI) scheme prompting investment in the public healthcare system 10. Public-private partnership growth 11. Establishment of the new medical device regulator (SAHPRA) 12. New regulations will establish internationally aligned regulatory framework 13. Aesthetic medical device market growth 14. Alternative clinical therapies are presenting untapped sources of innovation 15. Serving low income, under-served populations who have difficulties accessing specialists	1. High levels of HIV/AIDS impact on economic growth 2. Political/policy uncertainty undermining investor confidence 3. Cost of compliance to Black Economic Empowerment requirements 4. Land reform uncertainty 5. Health policy affected by politics, alleged cronyism and corruption 6. NHI implementation dependent on private practitioners contracting with the public sector uptake of which has been slow 7. Increased imports, especially cheap imports of inferior quality 8. Inefficient public procurement and payment 9. Exchange rate volatility 10. Skills loss due to emigration 11. Cost of certification for local manufacturing and exporting 12. Increasingly burdensome regulatory landscape increasing costs for local players

3.11. Recommendations in the Literature

The reports reviewed provide a variety of recommendations for the promotion of medical device manufacturing in South Africa. Although the recommendations from the reports are not in all cases fully justified, the reports are broadly aligned in terms of their recommendations. The prescriptions from the literature are also not adequate to address all aspects of a fully functional TIS for medical devices in South Africa as there are some functions with major weaknesses that are not addressed by the recommendations in these reports. The recommendations from the reports are summarised below in terms of the technological innovation system (TIS) functions.

Entrepreneurial experimentation

- Leverage existing innovation platforms and incentivise industry to grow R&D investments in MDs.
- Establishment of a 'Centre of Competence' for medical devices.
- Recognition and continued support of current areas of expertise and 'niche' leadership, as well as identification of new/emerging areas requiring special attention.

Knowledge development

- Invest in relevant skills development.
- Capacity building for health technology /medical devices innovation.
- Capacity building for health technology/medical devices life-cycle management.

Knowledge diffusion

- Promote and enable stakeholder alignment and collaboration in the sector.
- Engender active collaboration amongst national and regional stakeholders and international innovation partners.
- Unite, collaborate, and share insights with key stakeholders and the population.
- Promote translational collaboration within SA.
- Align Government/national regulations, standards and guidelines relating to medical devices.

Guidance of the direction of research

- Identifying 'customer' unmet needs across the care continuum at all levels of delivery.
- Policies structured to help engender more cross-sector interaction could create opportunities for more collaboration.

Market formation

- Improve turnaround for public procurement and payment by major payers.
- Incentivise the market.
- Demand creation and support of R&D through designation for public procurement.

Resource mobilisation

- Consider the establishment of free trade zones that create incentives for exports.
- Creation of a more favourable investment climate for FDI in the sector.

Legitimation

- Industry and Government should work more closely and raise awareness of the local medical technology industry and promote local manufacturing.
- Enhance the legislative and regulatory framework and capacity in support of local MD manufacture and export.
- Ensure effective regulatory policy and processes (including quality standards).
- Implement quality improvement interventions.

3.12. Summary and Conclusions

This chapter has summarised the main findings from 9 existing reports on the medical devices sector in South Africa, released between 2008 and 2021. Some of the information, figures and conclusions are now out of date and are largely focused on the private sector. They do, however, reveal the following high-level features of the industry:

- The medical devices market in South Africa is one of the largest in the Middle East and Africa region but makes up only 0.3% of the global market.
- The local industry is dominated by imports, comprising around 90% by value.
- South Africa's manufacturing output of medical devices is small (US$200 million to US$300 million), of which more than half is exported. This output is dominated by low-tech and low-value devices in the other medical devices and consumables product areas, with some hi-tech products for diagnostic imaging.
- Medical device R&D expenditure in South Africa is low as a percentage of turnover for the industry in relation to global standards; however, a range of incentives exist to address this and overall industry competitiveness.
- The regulation of medical devices in South Africa is still in the process of introduction and significant regulatory hurdles in foreign jurisdictions affect the cost and complexity of compliance.

These reports also revealed a number of barriers, threats and weaknesses in the industry as well as strengths and opportunities, with a list of recommendations for improving the sector. These are incorporated in the overall landscape summary and recommendations in Chapters 6 and 7. The remaining chapters discuss the findings of the SAMRC-led survey which focused across the innovation value chain in both the public and private sectors and aimed to capture data up to the 2018 financial year.

Survey Results

4. Survey Results

4.1. Introduction

Although the review of nine reports provided an initial sketch of the medical device manufacturing sector in South Africa, significant gaps remained in our understanding of the size and nature of the sector and particularly its innovation capacity and potential. To address this knowledge gap, it was decided to undertake a survey of the sector, focussing specifically on medical device manufacturers, innovators in the public research sector and relevant support organisations. This chapter reports the results of this survey, which was conducted during 2019 and 2020.

The survey consisted of three components: a survey of medical device manufacturing companies (reported in 4.2), a survey of science, technology and innovation institutions (reported in 4.3) and a survey of public and private organisations providing support to medical device manufacturing companies (reported in 4.4).

4.2. Medical Device Manufacturers

4.2.1. Sector characteristics

A total of 136 medical device manufacturers in South Africa were identified in the survey, of which seventy-one (71) completed Part A of the survey and sixty-six (66) Parts A and B. Salient features of the sector are highlighted below, including the geographic spread, company age, size, turnover and black economic empowerment (BEE) status.

Geographic distribution

As indicated in Figure 16, the sector is concentrated in three provinces, Gauteng, WC and KZN. Most medical device manufacturers are located in Gauteng (60), followed by WC (47) and KZN (26). Outside these three provinces, three companies have their registered addresses in the Eastern Cape. This geographic distribution is broadly consistent with the distribution of manufacturing and economic activity in South Africa, although the WC share of the medical device manufacturers is proportionately larger given the size of its manufacturing base relative to the other provinces, suggesting a degree of specialisation in medical devices in the province.

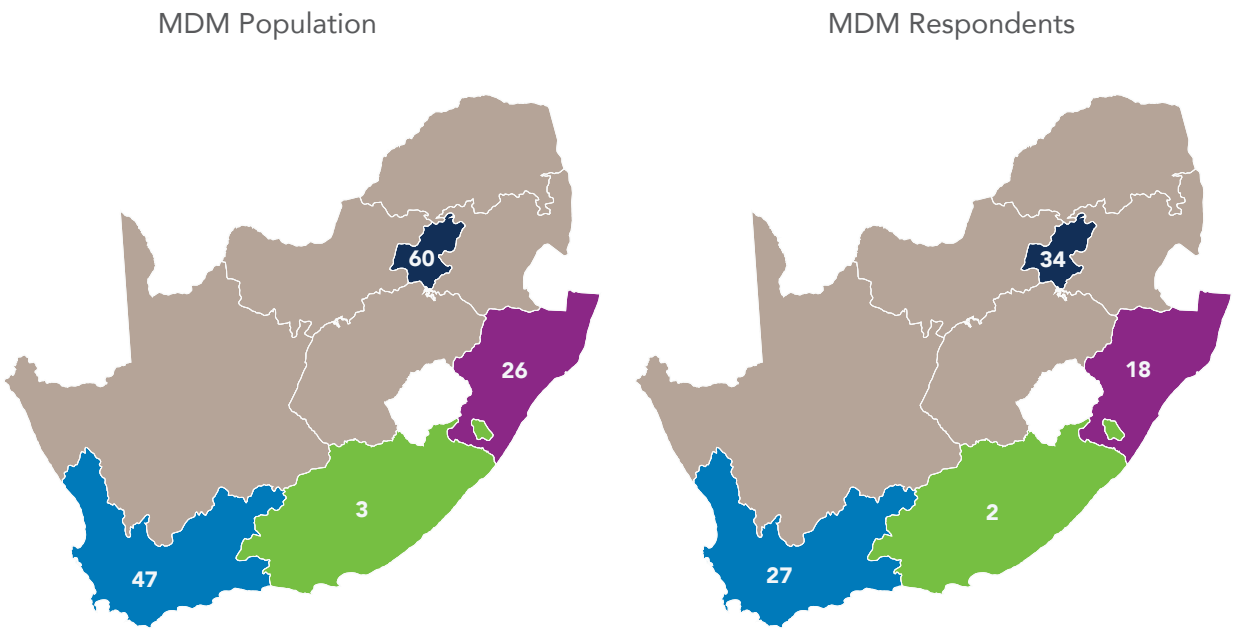


Figure 16: Geographical distribution of the identified medical device manufacturers in South Africa (136) and the sample that responded to Part A of the survey (71)

Company age

The average age of companies that responded to the survey was 20 years, with more than half of the companies older than 20 years. The company age distribution is provided in Figure 17, based on year of establishment.

The survival and transition of start-up companies to more mature companies are critical to growth and renewal of the sector. The existence of a considerable number of older companies indicates that they can build sustainable business in the sector. However, the small number (7) of new companies founded in the period 2015-2019 indicates a weakness in the system, especially when taken together with the declining trend in company formation since 2004. It suggests at least that university innovations in the medical devices sector are not being commercialised through the start-up route.

Young firms are especially effective in translating R&D into product innovation and are therefore a key element of the "entrepreneurial activity" function in a TIS. However, there is a high failure rate for companies during their first five years of operation. One would therefore expect a funnel-shaped

profile in the graph with a large number of companies in the 0 to 5-year age bracket and progressively fewer in the higher age brackets, as some companies fail or due to industry consolidation. These comments should be considered against the background of five years of low growth in the country. On the positive side, mature companies are effective in translating technological acquisitions (TAs) into process innovation where repeatability and cost effectiveness are important. Newly established medical device companies can also learn from the established companies that have been in existence for more than 10 years, to chart their pathways to sustainability and success.

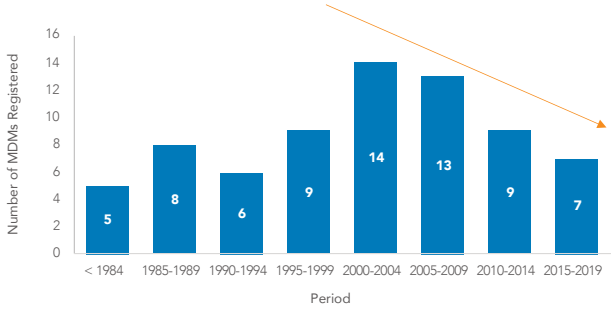


Figure 17: Historical distribution of medical device manufacturer establishment

Company size

The size of the MDMs in terms of numbers of permanent and temporary employees reveals that most companies that responded to Part A of the survey (73%) are classified as small, employing 50 or less permanent staff, with around one third employing 10 permanent staff or less. In addition, 17% of the respondents employ between 11 and 50 temporary staff. The lowest size range provided in the survey was 0-10, as such, it is possible that most of the 59 companies selecting this size range employ no temporary staff. See Figure 18 for more detail.

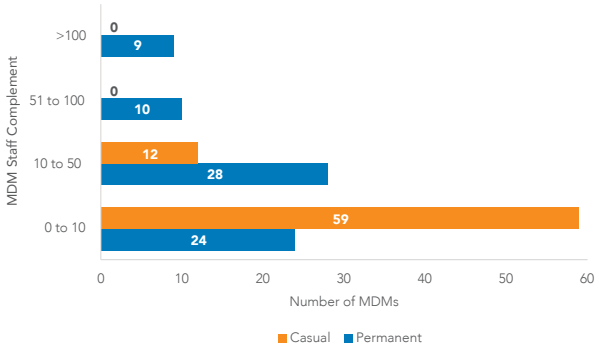


Figure 18: Distribution of companies according to number of permanent and temporary staff

Turnover

As indicated in Figure 19, most medical device companies fall within the micro (<R10 million) and small (R10-R50 million) enterprise categories. Only a small percentage (24%) qualify as medium to large enterprises (>R50 million turnover).

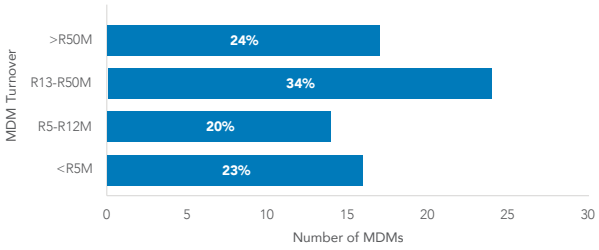


Figure 19 : Company distribution according to annual turnover

Eighty percent of the respondents indicated that all or the majority (90%) of their income is related to medical devices. As would be expected, turnover and staff numbers are highly correlated as indicated by the heatmap in Table 5.

Table 5: Medical device manufacturers size vs turnover

Turnover	Number of Permanent Staff: 0 to 10	10 to 50	51 to 100	>100
R <5M	15	1		
R 5-12M	6	7	1	
R 13-50M	3	15	4	2
R >50M		5	5	7

Black Economic Empowerment

Black Economic Empowerment (BEE) is a key Government policy to achieve broad-based and effective participation of black people in the economy and promote a higher growth rate, increased employment and more equitable income distribution (Broad-Based Black Economic Empowerment Act 53 of 2003). As such, BEE is a crucial element in any business in South Africa. Amongst other provisions, the BBBEE Act provides for businesses to be classified according to their BBBEE level, which is awarded based on a weighted basket of elements. In practical terms a company's BBBEE level substantially influences its ability to do business and to benefit from public procurement in particular.

The distribution of medical device companies surveyed according to BBBEE levels is depicted in Figure 20. Around 62% of respondents reported having a BBBEE level of 1-4, while 28% are deemed non-compliant or exempt due to having a turnover of less than R10 million. This is encouraging as it means that a substantial proportion of the MDMs would be eligible for more local business opportunities with the public and private sectors.

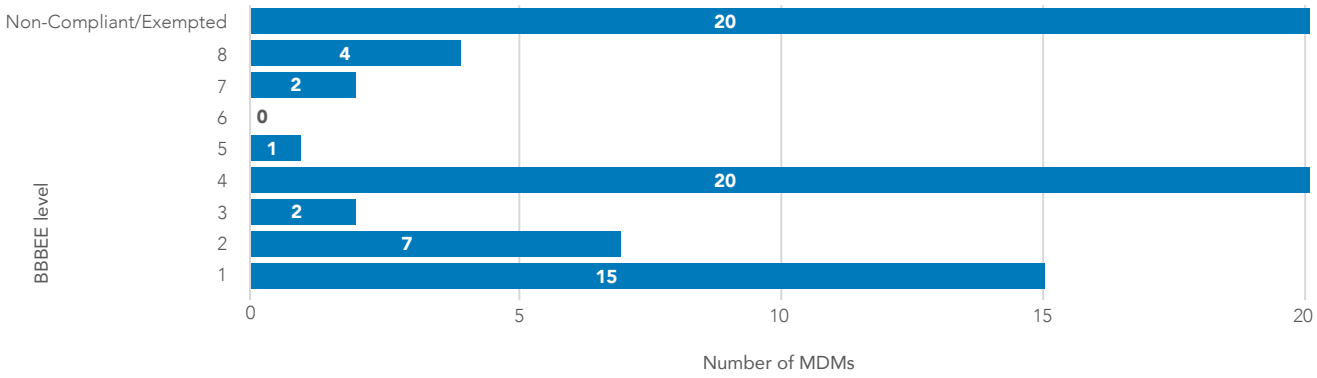


Figure 20: Distribution of MD companies according to BBBEE level

Table 6 provides information on the size of the surveyed companies vs BBBEE level. Just over half of the larger companies (>50 staff) and 63% of the smaller companies are rated at level 4 or above.

Table 6: Permanent staff vs BBBEE level

BBBEE Level	Number of Permanent Staff: 0 to 10	11 to 50	51 to 100	100+	Total	%
1	6	5	3	1	**15**	**21%**
2		2	2	3	**7**	**10%**
3		1		1	**2**	**3%**
4	11	8	1		**20**	**28%**
5		1			**1**	**1%**
6					**0**	**0%**
7		1	1		**2**	**3%**
8		2		2	**4**	**6%**
NC/Exempt	7	8	4	1	**20**	**28%**
Total	**24**	**28**	**11**	**8**	**71**	

4.2.2. Products and markets

Medical device fields

The South African medical device manufacturing industry is active across a range of fields and device classes, as depicted in Figure 21. Over half (53%) of MDM respondents operate in the consumables field, followed by orthopaedics (27%), other (21%) and hospital furniture (14%).

A ranking of manufacturers according to medical device fields is provided in Figure 22 and detail on field and class in Table 7.

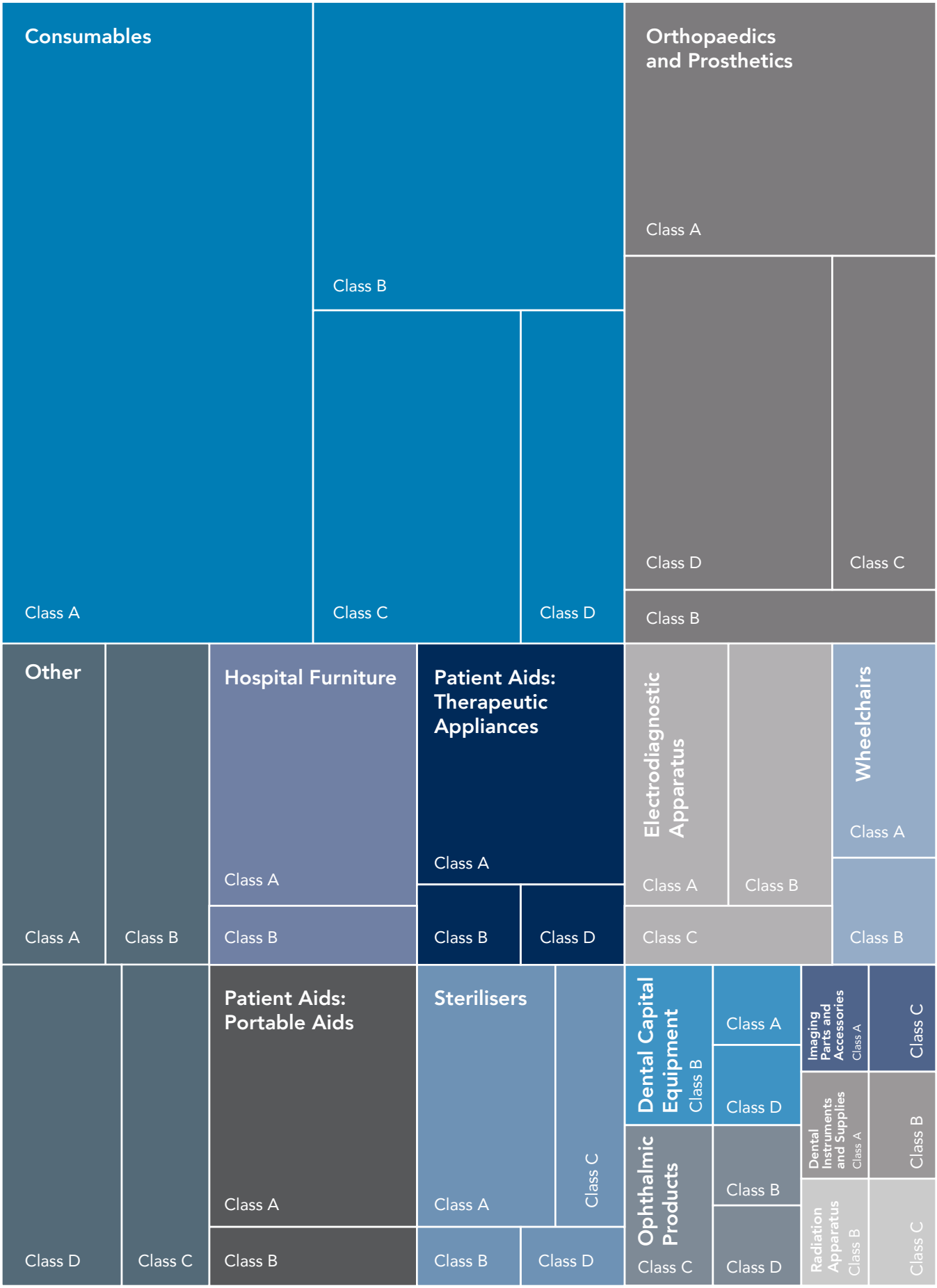


Figure 21: Distribution of medical device manufacturing according to field and device class

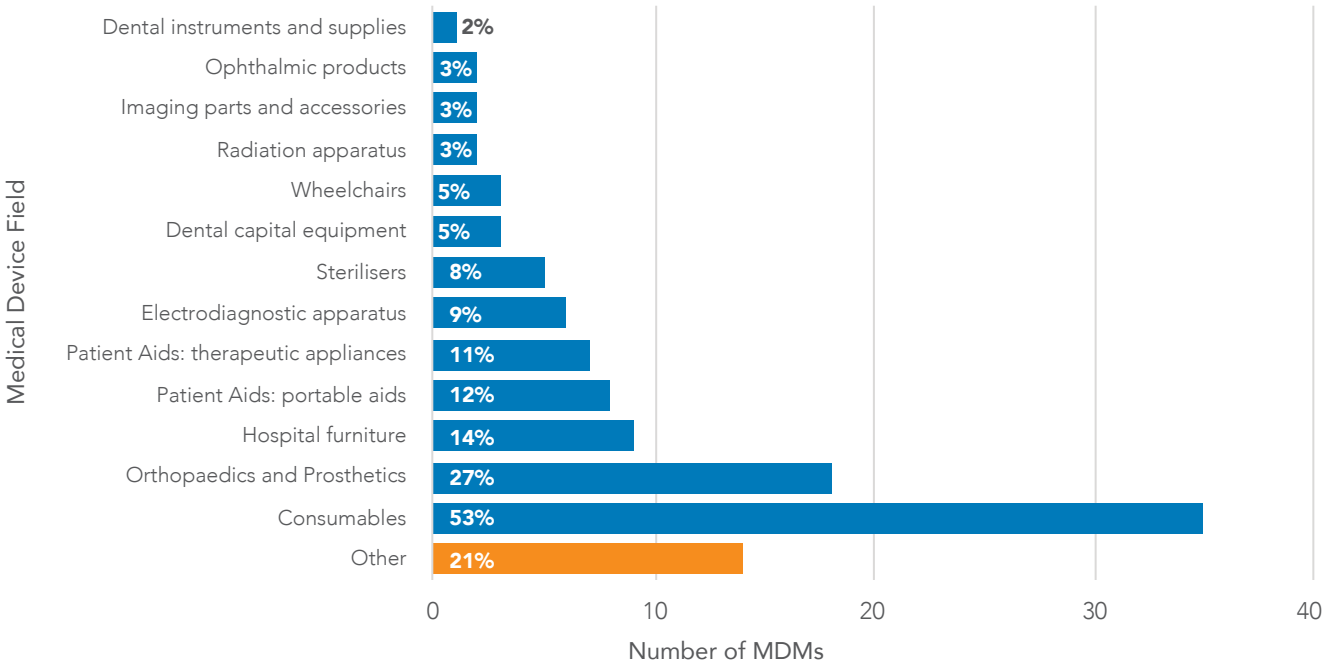


Figure 22: Distribution of companies active in different medical device fields

Table 7: Manufacturing according to field and device class

	Total	Class A	Class B	Class C	Class D
Consumables	35	27	16	11	6
Electrodiagnostic apparatus	6	3	3	1	
Radiation apparatus	2		1	1	
Imaging parts and accessories	2	1		1	
Orthopaedics and Prosthetics	18	11	3	5	9
Patient Aids: portable aids	8	7	2		
Patient Aids: therapeutic appliances	7	6	1		1
Dental capital equipment	3	1	2		1
Dental instruments and supplies	1	1	1		
Wheelchairs	3	3	1		
Hospital furniture	9	8	1		
Ophthalmic products	2		1	2	1
Sterilisers	5	4	1	2	1
Other	14	5	5	4	5

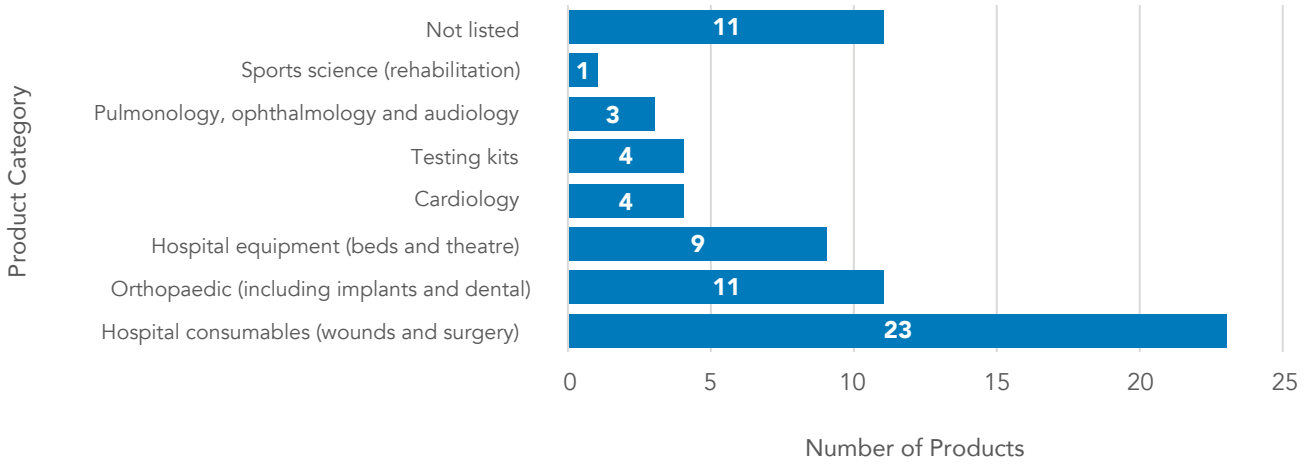


Figure 23: Medical device products in the market

Figure 23 depicts the number of medical device products in the market as reported by respondents in the survey. The numbers reported in the survey are low and dominated by hospital consumables (23 products). These figures should be interpreted with some caution as higher numbers are included in SAHPRA data. A number of respondents did not list their products individually but rather referred to their brochures.

Consumables field

Since the consumables field represents the largest number of medical device manufacturers in South Africa, it has been analysed in more detail. Overall, 35 of the 66 medical device manufacturers in the sample indicated that they manufacture consumables (in some cases along with other medical devices). Twenty-seven of these respondents indicated that they manufacture Class A consumables, of which fourteen manufacture only Class A consumables. Sixteen respondents manufacture Class B, eleven Class C and six Class D. As indicated in the Venn diagram in Figure 24, many of the respondents manufacture consumables in more than one class. Notably four respondents manufacture consumables in all four classes. More than two thirds (43) of these companies sell mostly Class A and/or Class B consumables.

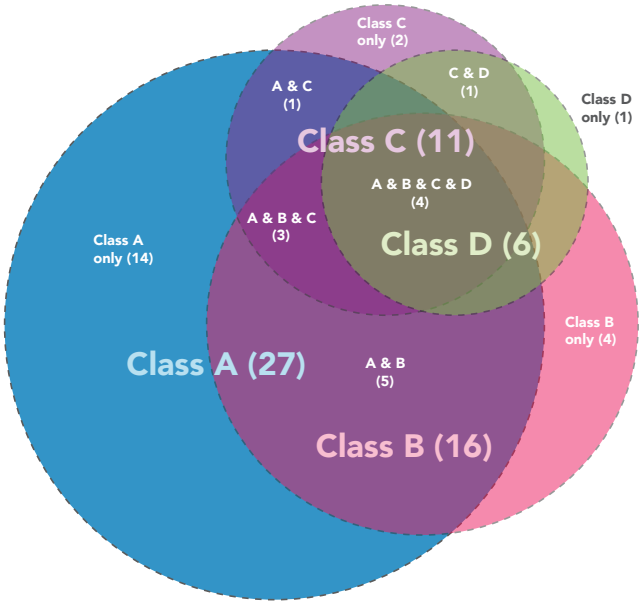


Figure 24: Distribution of consumables manufacturers according to class of consumable produced

The industry produces and sells a variety of consumable medical device products ranging from medical devices for wound care to diagnostic test kits. Products reported by respondents are listed in Text Box 1.

Bandages and dressings

Advanced wound dressing
Bandages
Dressings
Elastic adhesive bandages
Rigid strapping tapes
Skin traction kits
Surgical dressings
Sterile packs
Impregnated sterile dressings
Gauze
Nonsterile bandages
First aid dressings
PU wound dressings
IV dressings
Wound care dressings
Wound dressing pack
Wound dressing sachets
Wound pads

Syringes, needles & catheters

IV cannulas
Syringes

Surgical support

Safety scalpels
Blade management systems
Surgical packs for gynaecology
Surgical sponges
Surgical sutures
Swabbing

Transducers, extension lines, electrosurgical accessories and electrodes

ECG electrodes
Transducers & extension lines

Sterilants, sterilisers, disinfectants, hygiene products and decontaminants

Blue Crepe paper
CSSD supplies
Instrument reprocessing products
Instrument sterilants
Medical device disinfectants
Hygiene products (skin and hand)

Protective gear

Hospital staff apparel
Bedpan covers/urinal covers
Disposable aprons
Protective wear
Surgical gloves

First-aid boxes & kits, emergency kits

Emergency procedure packs
First aid safety kits

Test kits

HIV test kits
Pregnancy test kits
Drugs test kits
Malaria test kits
Ovulation test kits

Other consumables

Chest drains
Chord clamps
CPR mouthpieces
Disposable thermometers
Gel pads
Hot/cold packs
Instrument lubricant
Lubricating gels
Maternity towels
Plaster of Paris
Respiratory devices
Surgical drapes

Text Box 1: South African medical device consumable products reported

Markets

The medical devices offered by the respondents are sold in South Africa and internationally to the public and private sectors and aid agencies (see Figure 25 and Figure 26). The domestic private sector is the most important market for the companies surveyed, with a quarter of the companies (16) indicating that 75-100% of their revenue is earned from this sector. This is followed by the domestic public sector for which eight (12%) companies indicated that 75-100% of their revenue is attributable to this sector. Slightly more than two thirds (69%) of the respondent companies derive less than 25% of their revenue from exports and fifteen companies focused exclusively on the South African market.

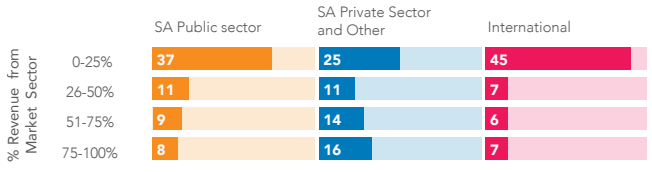


Figure 25: Distribution of medical device manufacturers according to % revenue generated from SA public sector, SA private sector and international sales

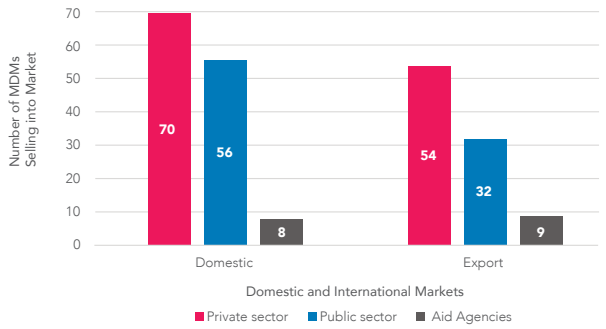


Figure 26: Number of companies selling into each of the three domestic and international medical device market sectors[19]

As indicated in Figure 27 and Table 8, Africa, Europe, the Middle East and North America are the most important markets amongst the respondents. China and India were consistently rated the lowest priority amongst manufacturers. These countries are likely seen as competition rather than markets for South African products. They are also countries where local manufacture of medical devices is prioritised.

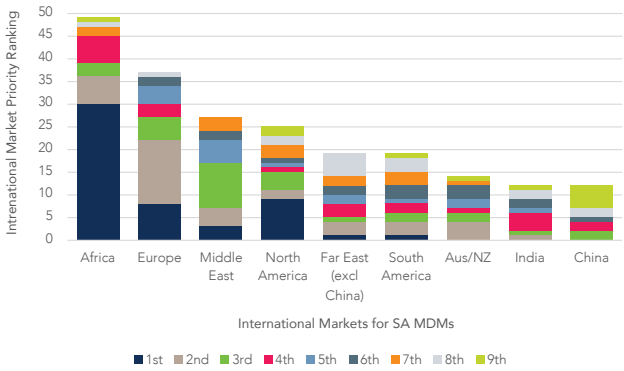


Figure 27: Market importance per region for medical device manufacturers

Table 8: Market importance per region (number of MDMs)

	1st	2nd	3rd	4th	5th	6th	7th	8th	9th
Africa	30	6	3	6			2	1	1
Europe	8	14	5	3	4	2		1	
Middle East	3	4	10		5	2	3		
North America	9	2	4	1	1	1	3	2	2
Far East (ex Cn)	1	3	1	3	2	2	2	5	
South America	1	3	2	2	1	3	3	3	1
Aus/NZ		4	2	1	2	3	1		1
India		1	1	4	1	2		2	1
China			2	2		1		2	5

More than two thirds (68%) of the surveyed companies indicated that they were export ready. Only 10% indicated that they required assistance to become export ready.

19 The chart includes all companies that reported selling into the respective markets irrespective of the sales volume. Many companies sell into more than one market sector.

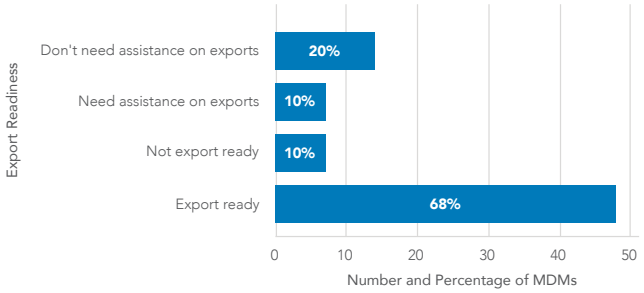


Figure 28: Export readiness of South African MDMs

4.2.3. Manufacturing capabilities

In-house and outsourced capabilities

Companies were surveyed on their capabilities for product design, product manufacturing, packaging, sterilisation and repackaging/configuring and labelling of imported products. Most companies have in-house design (80%), manufacture (82%) and packaging (77%) capabilities (see Figure 29).

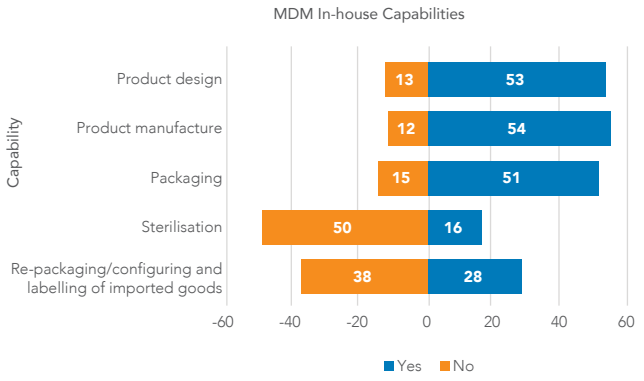


Figure 29: In-house capabilities of South African MDMs

Sterilisation is the most frequently outsourced activity, with 25 (38%) companies outsourcing this function, whilst 16 (24%) do this in-house. Twenty-eight companies (42%) do in-house repackaging/configuring and labelling of imported products with a further 3 companies (5%) outsourcing these activities. See Figure 30 for more detail on outsourced capabilities.

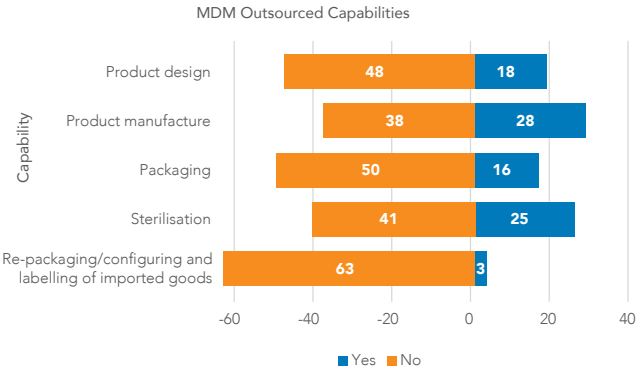


Figure 30: Outsourced capabilities of South African MDMs

Manufacturing facilities

Companies were surveyed on their manufacturing facilities and specialities, including machining, plastics, chemicals, paper, textiles & films and other, the input materials used and whether they had access to clean room facilities.

The distribution of manufacturing facilities across the sample is summarised in Figure 31.

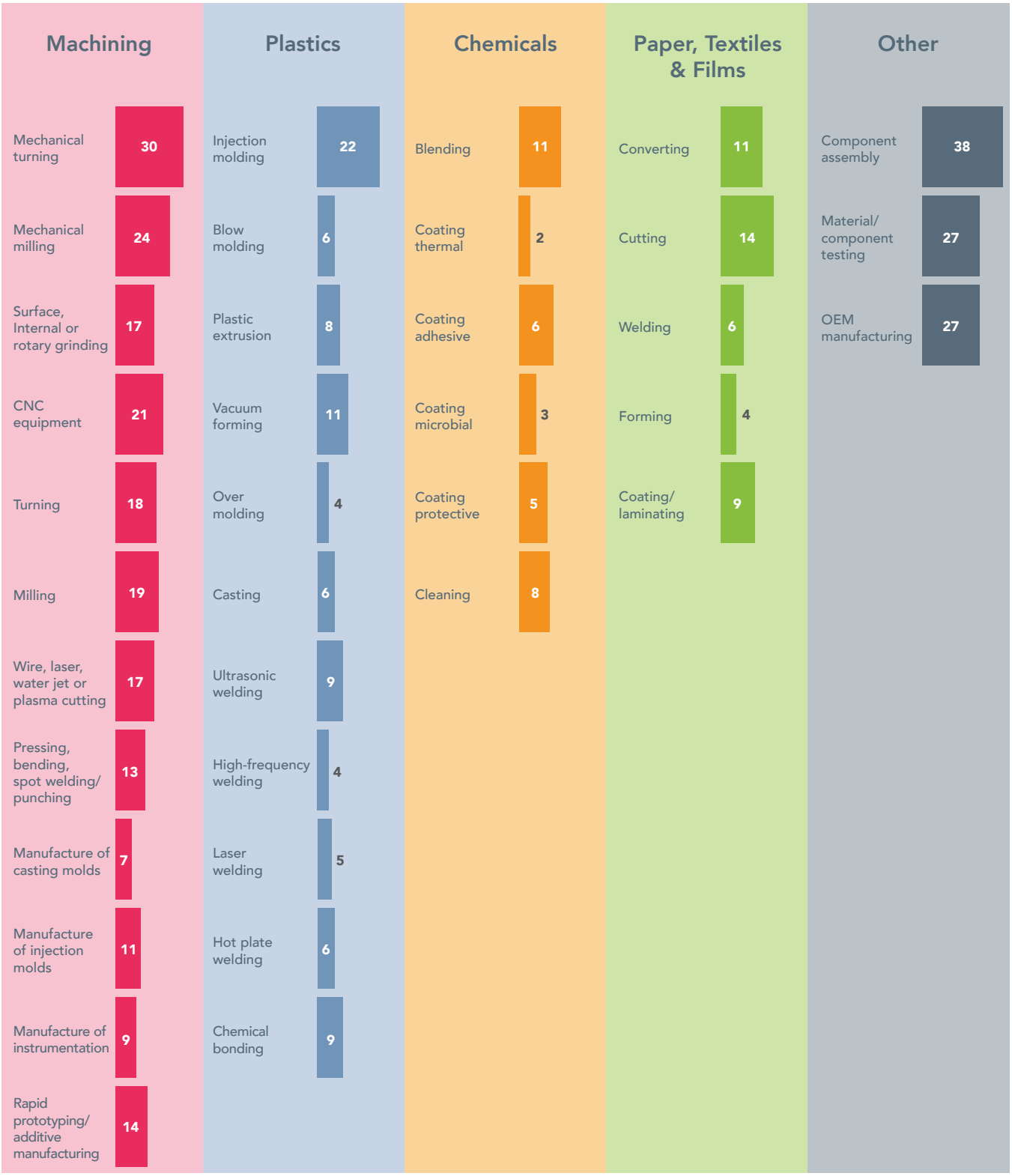


Figure 31: Manufacturing capabilities of South African medical device companies

Component assembly was the most frequently cited facility capability, with 58% of the companies indicating this capability. This was followed by mechanical turning (45%), OEM manufacture (41%) and material or component testing (41). Overall, the highest number of capabilities related to machining and the lowest to chemicals.

Input materials

In terms of manufacturing materials used, metals and plastics were the materials most frequently used. This was followed by chemicals and liquids. Animal products and gasses were used by the smallest number of companies. Over two thirds of respondents used a unique combination of manufacturing materials, with 3-5% using specific combinations of metals, chemicals, liquids, paper and animal products. Further detail on input materials is provided in Figure 32.

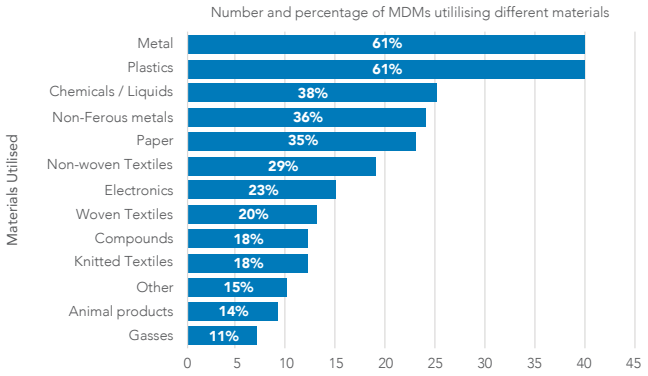


Figure 32: Input materials used for manufacturing by South African MDMs

Forty-four percent of MDM respondents had access to cleanroom facilities, 47% did not and 9% did not comment on this aspect.

Other in-house skills or innovation areas

Over half (58%) of the MDMs indicated that they had other medical innovation skills that would be of benefit to the sector or to those seeking to collaborate or contract with the company. Other in-house skills not listed above included technical and business skills, regulatory and compliance, and antibody production.

Manufacturing capacity and expansion plans

Companies were surveyed on the number of shifts used, current capacity utilisation, ability to increase production and their expansion strategies.

Most respondents (60%) only used one shift, 17% used two shifts and 6% three shifts. Most respondents (59%, n = 39) were using between 25% and 75% of their manufacturing capacity. Seventeen percent (11) were using more than 75% of their manufacturing capacity and 14% (9) less than 25%. Most companies (79%) indicated that they could increase production by 40%. The survey therefore indicates that manufacturing capacity is presently underutilised. More detail on shifts, current utilisation and ability to increase production is provided in Figure 33.

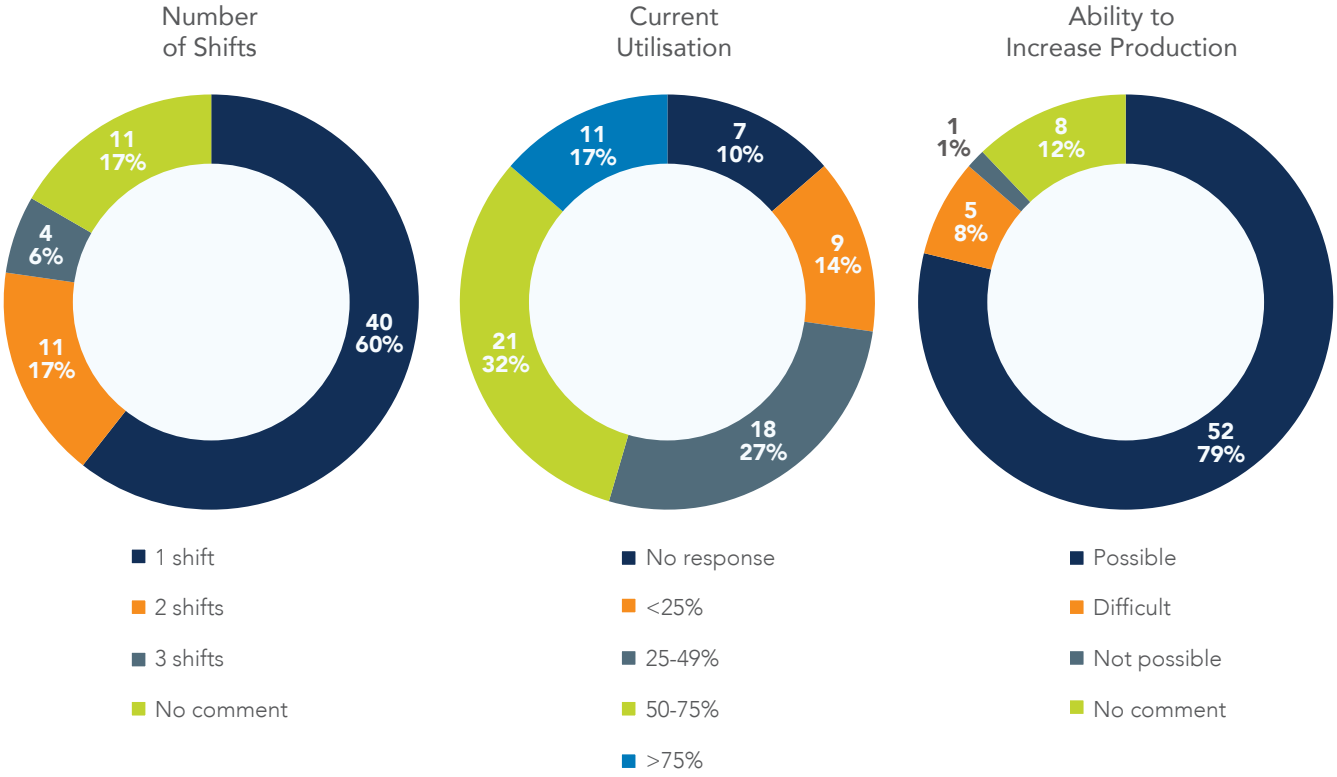


Figure 33: Detail on number of shifts, capacity utilised and ability to increase production

Most companies indicated that they intend to pursue a basket of strategies to increase production. Capital expenditure was most frequently included in the strategies to be pursued (32% of companies), followed by product development (28%) and diversification (25%). A small number of companies (11%) intended to improve productivity, and a few (4%) planned other expansion strategies (Figure 34).

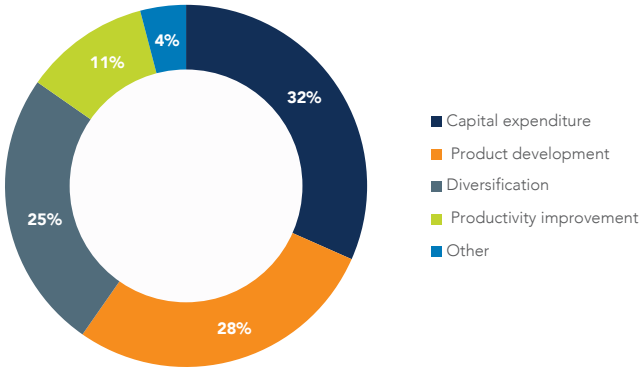


Figure 34: MDM expansion strategies

4.2.4. Regulation and quality

Regulatory registration and quality management

As mentioned in Chapter 3, it is now a requirement for all medical device manufacturers in South Africa to have SAHPRA establishment licenses. Most of the medical device company respondents (73%) indicated that they were SAHPRA registered. As of July 2021, this had increased to 79%[20].

Eighty-nine percent of the companies surveyed either had a quality management system in place or were in the process of implementing a quality management system. The leading quality management system was ISO 13485 which is an ISO standard specifying the requirements for a comprehensive quality management system for the design and manufacture of medical devices. Fifty one percent (36) of the companies reported having this system in place, with a further twenty four percent (17) in the process of implementation. This is encouraging, given that, on renewal of their SAHPRA establishment licenses, all companies will need to have ISO 13485 in place. See Figure 35 for detail on the quality management systems adopted by MDMs.

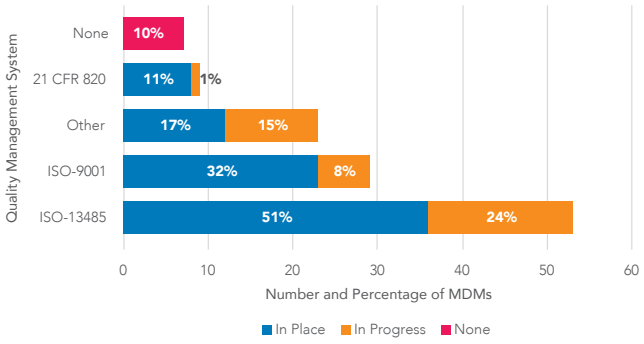


Figure 35: Quality Management Systems in place or in progress in South African MDMs

The second most widely used quality management standard was ISO 9001 which was reported to be in place by thirty-two percent of the companies (23) with a further eight percent (6) in the process of implementing this standard. ISO 9001 specifies the requirements for meeting customer and other stakeholder needs within statutory and regulatory requirements related to a product or service. Title 21 of the Code of Federal Regulations (21 CFR 820) governs food and drugs within the United States for the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy. Eleven percent (8) of the companies reported having this system in place with a further one percent (n=1) in the process of implementing it.

The other quality management systems reported by the respondents (see Figure 36) constituted a wide range of standards, including:

Facility level standards and registration requirements

- AS9100 – standardised quality management system for the aerospace industry;
- IATF 16949:2016 – a technical specification aimed at the development of a quality management system which provides for continual improvement;
- ISO 11135:2014 – specifies requirements for the development, validation and routine control of a sterilisation process for medical devices;
- ISO 14000 – a family of standards related to environmental management to help organisations minimise how their operations negatively affect the environment, comply with applicable laws, regulations, and other environmentally oriented requirements, and continually improve on these;
- ISO 22715 – guidelines for manufacturers in the best practices for cosmetic packaging and labelling of cosmetic products;
- ISO/IEC 17020:2012 – conformity assessment – specifies requirements for the operation of various types of bodies performing inspection;
- MDSAP – Medical Device Single Audit Program for medical device manufacturers in the following five jurisdictions: USA, Australia, Canada, Japan and Brazil;
- OHSAS 18001 – Occupational Health and Safety Assessment Series;
- United States Food and Drug Administration (FDA) Medical Device Establishment Registration (Title 21 CFR Part 807); and
- SA GMP – the South African Guide to Good Manufacturing Practice for Medicines.

Device level standards and registration requirements

- CE mark – an administrative marking with which the manufacturer or importer affirms its conformity with European health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)[21];
- MDD 93/42/EEC – Medical Device Directive for active medical devices that specifies the requirements for a manufacturer to legally place a medical device on the European market. Products conforming with the MD Directive must have a CE mark applied;
- FDA Medical Device Registration and Listing.

20 Licenses issued to survey respondents were verified on the SAHPRA website: https://www.sahpra.org.za/medical-devices-licences-issued/ on 18 July 2021
21 The EEA links the European Union member states and three European Free Trade Association (EFTA) states (Iceland, Liechtenstein, and Norway) in an internal market governed by the same basic rules

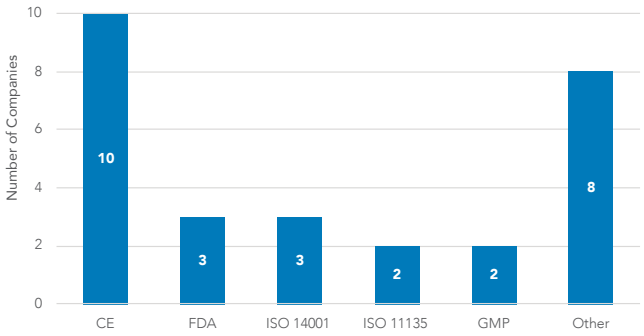


Figure 36: Other quality management systems, standards, registrations, and conformity marks reported by respondents

Manufacturing facility ISO class

Respondents were asked under what ISO level their facility fell from ISO 3 to ISO 8 in terms of ISO 14644-1, which specifies the degree of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones in a facility. ISO 1 is the level with the most stringent requirement and ISO 9 the least. Most MDM respondents (59%) listed no ISO class facility. ISO 7 (20%) and 8 (23%) were the most common ISO certifications in the rest. Only three companies reported facilities at ISO level 3 and 4. Several companies had more than one facility rated at distinct levels. More detail on the distribution of facilities by ISO level is provided in Figure 37.

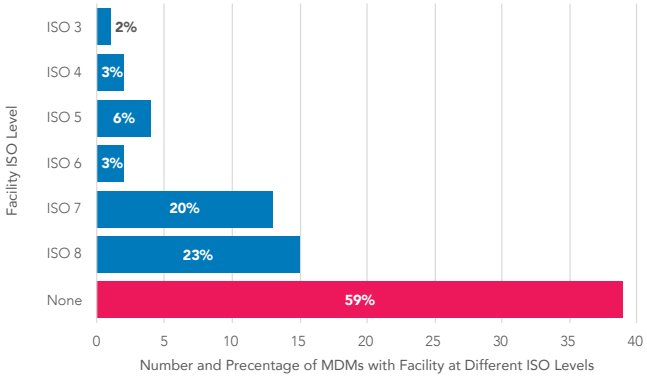


Figure 37: ISO facility classification of South African MDMs

Product registration and certification

Over half (53%) of the 66 MDM respondents indicated that they had obtained product registration, certification and/or approval, with a further third in progress (total of 88%). The most frequent form of registration, certification and/or approval indicated was the European CE mark (64%) followed by SAHPRA (48%), the FDA (29%) and SABS (12%), with a limited number of registrations in other international jurisdictions (Figure 38). CE marking is widely used for certifying medical devices internationally and is, in many cases, a minimum requirement for devices sold in South Africa until such time as full registration with SAHPRA is possible. As indicated in Chapter 3, SAHPRA has not yet called up medical devices for registration in South Africa. As such, those indicating product registration with SAHPRA have presumably been provided a SAHPRA license for these products, i.e. permission to include the product in their product listing under their establishment license, most likely through approval in another recognised jurisdiction.

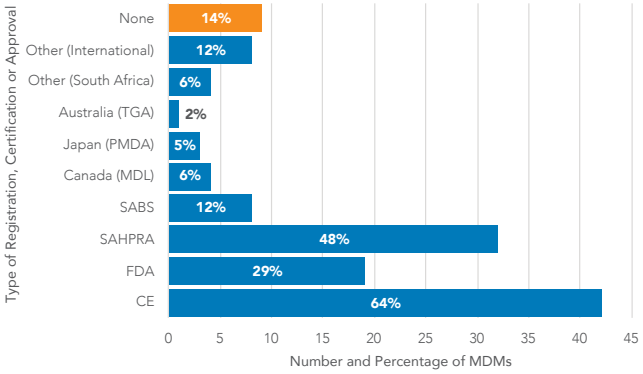


Figure 38: Product registration, certification and/or approval

Three quarters (74%) of the 66 respondents required regulatory and compliance assistance. Providing regulatory and compliance assistance to MDMs is therefore a lever to advance and develop the sector. This intervention can (i) lead to new entrants (MDMs to the sector and products to the market); (ii) facilitate product diversification in existing MDMs for market expansion and realise greater potential and sustainability; and, (iii) allow MDMs more time to focus on their products, markets and sales.

In their comments, respondents highlighted additional issues regarding regulatory compliance, including the expense and therefore a lack of financial resources to achieve compliance. This is aggravated by the small size of the South African market which means that registration needs to be done internationally, which is costly. Respondents also commented on long turnaround times from the regulatory authority (SAHPRA); a lack of certified auditors in South Africa; inadequate regulatory skills on the part of their own staff; the fact that many of the South African regulations are based on the European Union regulations and therefore not necessarily applicable locally; discrepancies between international and local regulatory requirements; having to compete with non-compliant manufacturers; lack of financial assistance or slow processes in obtaining Government assistance, especially when having to outsource the process internationally; lack of clear information; and the need for training.

4.2.5. Research and development

Research and development expenditure

Research and Experimental Development (R&D) is defined by the OECD Frascati manual to comprise creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge (OECD, 2015). R&D is a key process for generating novel technology and innovative products. R&D undertaken by firms also enhances their absorptive capacity, thereby improving their ability to adopt, assimilate and adapt knowledge generated elsewhere. Over three quarters (77%) of MDM respondents indicated that they were active in R&D, which is expected when developing products. The remaining quarter (23%) appear to focus entirely on manufacturing existing products and do not perform any R&D.

Many respondents found it difficult to quantify their R&D expenditure as, in many cases, this is not an ongoing priority and is instead conducted on an as-needed-basis. In addition, for some companies R&D is externally funded. For these

reasons 11% of the respondents reported their R&D spend as 0%, despite reporting that they are active in R&D. Some respondents indicated that the expertise required for R&D is insourced to supplement the in-house teams.

Most (51%) medical device manufacturers in South Africa spent less than 5% of their turnover on R&D, of which 33% spend 0% of their revenue on R&D. Reasons cited included: R&D (i) is funded externally; (ii) is conducted by collaborators and partners; and (iii) is not a key focus of MDMs as they use their turnover for manufacturing and general operations (e.g. sales, marketing, costs for licensing, etc.). In summary, R&D expenditure as a proportion of turnover in South Africa is low when compared with international examples (the average R&D expenditure as a proportion of revenue for the hundred biggest medical device companies is 8.3%). See Figure 39 for the distribution of MDMs according to R&D intensity.

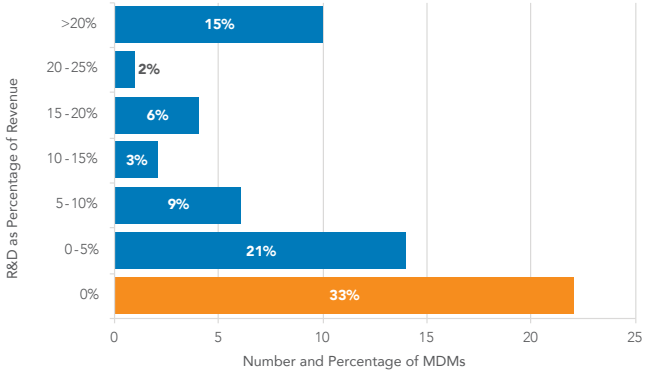


Figure 39: R&D expenditure of MDMs as a percentage of turnover

Table 9 provides detail on R&D expenditure versus turnover for the companies surveyed. Five of the companies spending more than 20% of their revenue on R&D are small companies with a turnover of less than R5 million. Four of these are younger than ten years old and appear to be high-tech start-ups. Notably, although most of the highly R&D intensive companies (R&D expenditure >20% of revenue) are small enterprises, two have revenues of over R50 million. Both are mature high-technology companies in the orthopaedic field that have been in existence for more than twenty years.

Firms reporting no or less than 1% of turnover expenditure on R&D include nine established companies with a revenue of more than R50 million. Other groups of companies include 11 companies with revenue of less than R12 million that do no R&D and 13 companies with a revenue of R13 to R50 million that spend between 1 and 10% of their turnover on R&D.

Table 9: R&D expenditure of MDMs relative to turnover

	0%	<1%	1-5%	5-10%	10-15%	15-20%	>20%
R <5M	6	2	1			1	5
R 5-12M	5	2	3	1		1	1
R 13-50M	3	2	8	5	2	2	1
R >50M	8	1	4				2
Total	**22**	**7**	**16**	**6**	**2**	**4**	**9**

As indicated in Figure 40, the more R&D intensive medical device companies are concentrated in the WC and Gauteng.

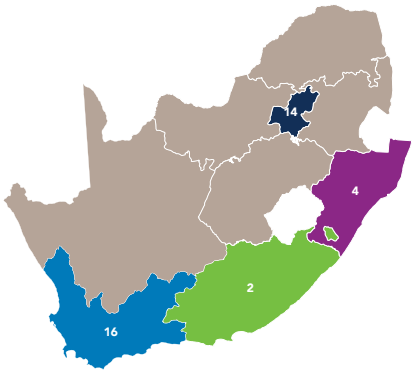


Figure 40: Number of MDMs reporting R&D expenditure greater than 1% of turnover per province

External research and development funding

Public funding of R&D in South Africa is enabled both through direct grants and through an R&D tax rebate in terms of which firms undertaking R&D in the country qualify for a 150% tax deduction of their operational R&D expenditure.

Only four (6%) of the respondents had applied for an R&D tax rebate, 23% did not comment and 71% have not applied. This translates to 9% of respondents who indicated some internal expenditure on R&D that have applied for an R&D tax rebate. Of those who applied, all four were successful in receiving R&D tax rebates. However, the successful companies reported issues with applying such as administrative hurdles and delays in approval.

The major reasons for not applying for an R&D tax rebate were a lack of awareness and perceptions that the process for applying was overly bureaucratic. A small number of companies believed that they did not comply, did not pay

tax or felt that it would not be worth the effort. Detail on past and intended applicants and reasons companies gave for not applying are illustrated in Figure 41.

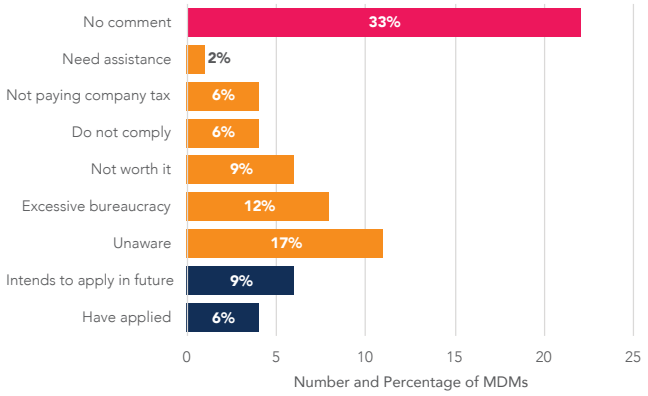


Figure 41: R&D rebate applications by MDMs and reasons for not applying

Twenty-three (35%) of the respondents have applied for Government R&D funding, of which 74% (17 MDMs) indicated that they were successful. The main reasons for not applying for R&D funding were, as in the case of the R&D rebate, lack of awareness and perceived bureaucracy. See Figure 42 for more detail.

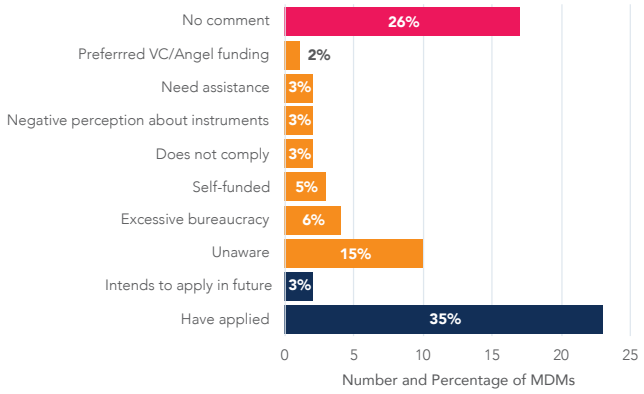


Figure 42: R&D funding applications and reasons for not applying

Those that indicated non-compliance cited non-BBBEE compliance[22].

R&D collaboration

Just under half of the respondents (48%, 32 MDMs) have collaborated with science, technology and innovation (STI) institutions locally and abroad in 54 separate collaborations over the past five years. Only fifteen international collaborations were reported in which the United States was the most frequently cited country for collaboration. The University of Cape Town and University of Stellenbosch participated in the most domestic collaborations with MDMs, followed by the CSIR. See Figure 43 for more detail.

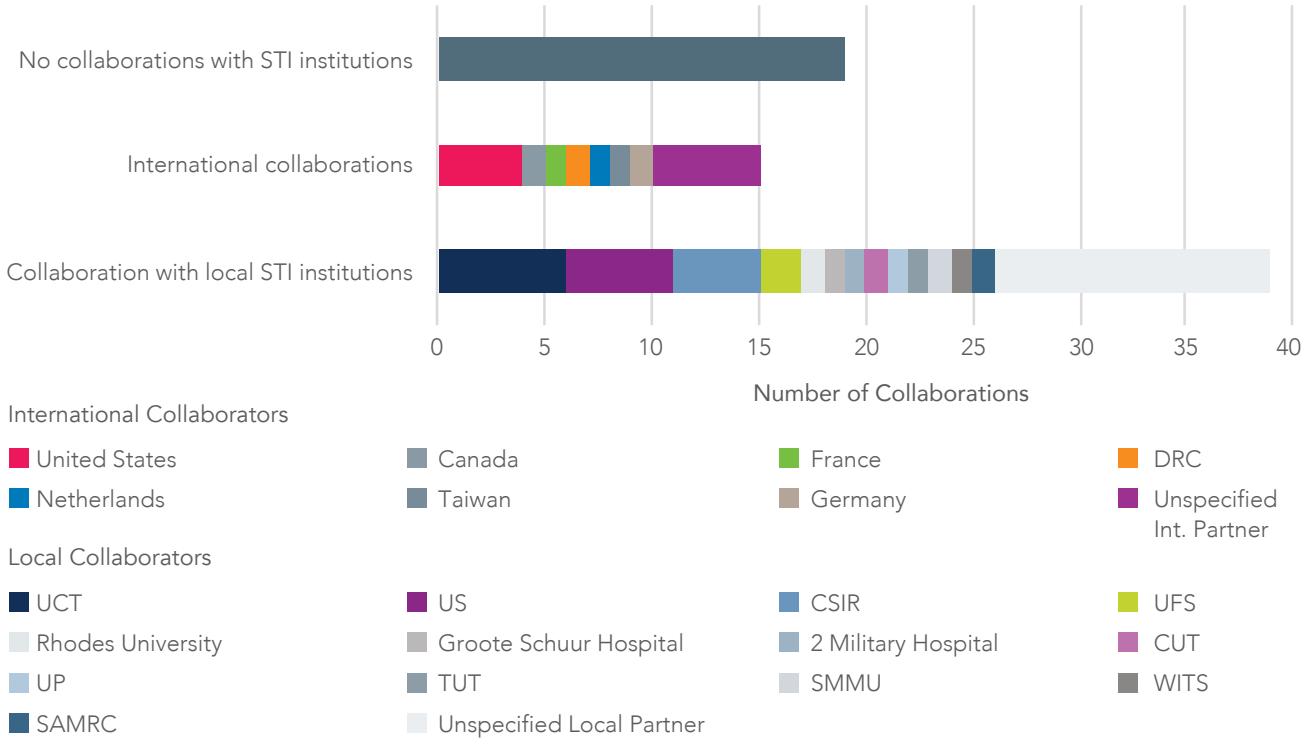


Figure 43: MDM R&D collaboration with STI institutions

22 For SPII, non-compliant firms are not excluded but funding levels are higher for firms with more than 50% Black ownership. In the case of THRIP, non-compliant firms are required to partner with a historically disadvantaged higher education institution. The TIA funding guidelines specify that assessment of applications will, amongst other things, consider "Prospect of promoting of BBBEE".

Collaborations with industry showed a similar trend, with 27 (41%) respondents indicating that they collaborate with industry and 24 (36%) with no industry collaborations. Twenty three percent did not comment on this aspect. Of the 27 companies that have collaborated with other companies on R&D, fifteen collaborated with companies from South Africa, five with international companies, and seven with both South African and international companies.

MDMs cited several benefits of working with universities and research institutions, including "getting a real product to market", access to complementary expertise, sharing of ideas and knowledge, access to advanced facilities and expertise, product testing and assistance with regulatory compliance. Critical success factors cited included shared goals and expectations, ability of STI institutions to meet commercial timelines, and ownership and commitment by students through long term collaboration.

Barriers to STI collaboration included long timelines and cumbersome processes with some organisations – in particular universities and science councils; the effort involved in clarifying expectations; a perception that local collaborations may be more expensive in the long run than international collaborations; the need for clear IP ownership and knowledge transfer agreements; and lack of continuity.

Only 11 (17%) respondents indicated that they had co-developed products with or licensed products from research institutions, 16 (24%) indicated they had not, and the rest (59%) did not comment. Of the 11 companies that answered in the positive, most (8 – 73%) had co-developed products with or licensed them from South African institutions, one was with an international institution, and two were with both national and international institutions. Given the high rate of respondents who did not comment on this, it is not possible to draw conclusions on the level of collaboration on the co-development of products and/or in-licensing from research institutions; however, the overall high level of collaboration with research institutions and even companies reported, particularly with South African entities, is encouraging.

Interest in R&D collaboration

Forty-nine (74%) of the MDM respondents were interested or conditionally interested in performing R&D with external parties or already had ongoing collaboration with STI institutions. Conditions for collaboration included alignment of focus, complementarity of capabilities, availability of funding and safeguards on IP and competition. A quarter of companies were not interested in collaboration, of which 2 respondents cited lack of trust or university bureaucracy as their reasons.

Most respondents (48 – 77%) were interested or conditionally interested in manufacturing innovations by South African research institutions. Conditions cited included having sufficient capacity, terms and conditions, alignment with company scope and financial arrangements. Slightly less than a quarter of respondents were not interested in manufacturing STI innovations from South African research institutions.

A large majority of respondents (50 – 74%) were already collaborating with South African research institutions to develop their own innovations or interested or conditionally interested in doing so. Conditions for this type of collaboration cited included return on investment, nature of the opportunity, alignment of scope and capability, mutual benefit and availability of funding. Twelve percent of the MDMs surveyed did not indicate an interest or indicated that they are unlikely to explore collaborations with institutions to develop their own innovations.

Respondents' interest in R&D collaboration, manufacture of STI institution innovations and collaboration with STI institutions to develop their own innovations is summarised in Figure 44.

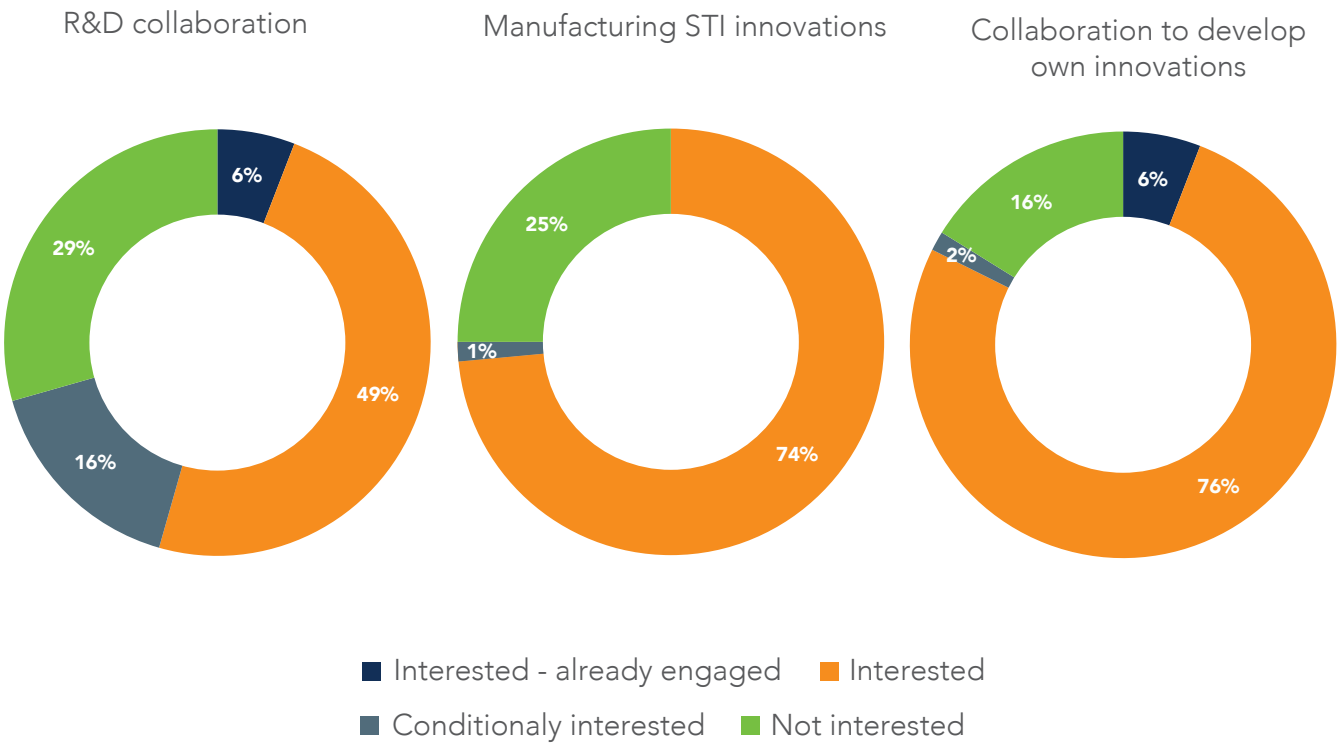


Figure 44: Interest of MDMs in R&D collaboration with external parties, manufacture of STI institution innovations and collaboration with STI institutions to develop own innovations

Preferred collaborative relationship

When asked about the type of working relationship they would be interested in having with research institutions, a third of the companies (33%) indicated they were interested in co-development, slightly less than a third (28%) in research contracts and a quarter (25%) in supervising postgraduate students. Other forms of collaboration mentioned included testing and commercialisation, internships, and business mentoring of academia. Several companies were interested in multiple types of working relationships. See Figure 45 for detail.

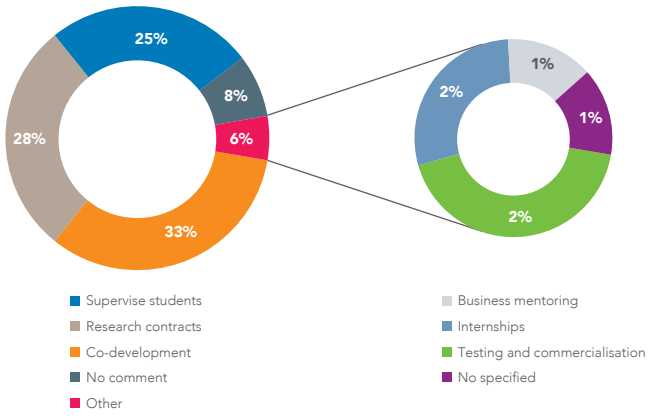


Figure 45: Preferred working relationship of MDMs with research institutions

4.2.6. Membership of industry associations and clusters

There are two main industry associations focussing specifically on medical devices in South Africa, namely the South African Medical Technology Industry Association (SAMED)[23] and the Medical Device Manufacturers Association of South Africa (MDMSA)[24]. In addition to the national associations, there is at least one regional cluster, the Western Cape Medical Devices Cluster[25].

SAMED was founded in 1985 as a not-for-profit industry association committed to advancing patient care through medical technology (MedTech). Its objective is to be the voice of the South African MedTech and *in vitro* diagnostics industry. SAMED assists its members to contribute to and participate in the health sector in South Africa by providing a platform for engagement between industry members and their stakeholders. It advances the interests, knowledge and expertise of its members through its committees and works to increase the visibility, credibility and standing of the MedTech industry, advocate to inform policy and improve market access. SAMED members include more than 160 companies operating in the medical device, medical equipment and *in vitro* diagnostics sector in South Africa as well as a number of associate members that include the South African Laboratory and Diagnostic Association (SALDA), the Medical Imaging Systems Association (MISA) and MDMSA.

MDMSA is a non-profit voluntary association of medical device manufacturing companies in South Africa. It provides commentary to the National Department of Health (NDoH) and SAHPRA on medical device legislation as well as securing local manufacturing incentives through the DTIC.

As part of the survey, MDMs were requested to provide information on membership of industry associations and clusters. Just over half of the MDMs surveyed are members of an industry association or industry cluster, with the two most important industry associations for the sector being SAMED and MDMSA and 23% of the sample indicating membership of each of these two associations. There is significant overlap in membership of the two associations with 14% of the sampled companies reporting membership of both SAMED and MDMSA.

Detail on association and cluster membership is provided in Figure 46. Other industry associations and related bodies cited included the International Federation of Hospital Engineering (SAFHE), the South African Electrotechnical Export Council (SAEEC), the Dental Technicians Council South Africa, the Dental Traders Association, the Jewellery Council of South Africa, the Health Professions Council of South Africa (HPCSA), the National Employers Association of South Africa (NEASA), the Southern African Protective Equipment Marketing Association (SAPEMA), the Southern Africa Compressed Gases Association (SACGA), the Metal & Engineering Industry Bargaining Council (MEIBC), the Steel and Engineering Industries Federation of Southern Africa (SEIFSA) and the Institute of Directors of SA (IoDSA).

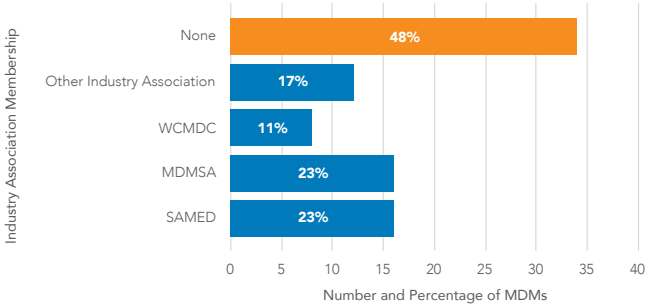


Figure 46: MDM Industry Association membership[26]

The Western Cape Medical Devices Cluster (WCMDC) was founded in 2016 through the initiative of Wesgro, the Western Cape Department of Economic Development and Tourism and the National Department of Science and Technology. It comprises seven founding members who aim to support the development of a competitive, growing medical devices sector in the WC region. It does so by providing services that benefit the industry, including raising awareness, certification support, providing information on skills development, job opportunities and the transformation of the medical devices sector in the WC and by lobbying for more local procurement from the healthcare sector.

23 https://samed.org.za/
24 https://www.sbs.co.za/safhe2017/exhibitor/mdmsa.html
25 https://wcmdc.org.za/
26 The percentages add up to more than 100% as several MDMs are members of two or more associations or clusters

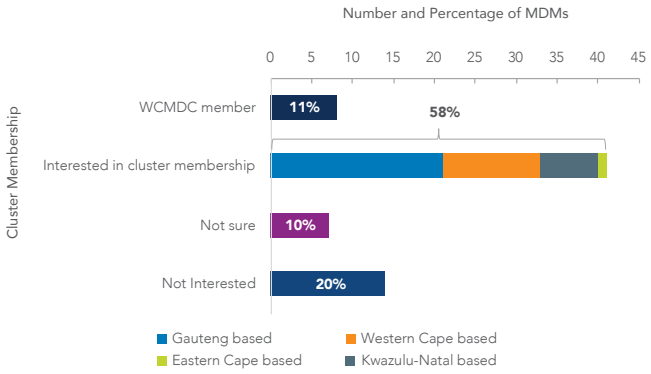


Figure 47: Interest in and current membership of industry clusters

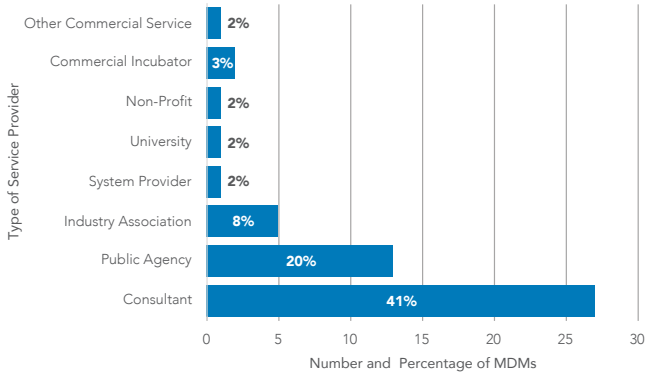


Figure 48: Sources of support utilised by MDMs

To date WCMDC is the only institutionalised medical device cluster in South Africa. Notably, as indicated in Figure 47, 58% of respondents that are not currently members of a medical device cluster expressed an interested in becoming members of a cluster. There is significant potential for expansion of the WC cluster and for new clusters in Gauteng and KZN.

4.2.7. Use and requirement for support services

The survey included a number of questions on support that industry members are receiving and their interest in such support (see Figure 48). The companies mostly make use of consultants (27) followed by public agencies (13) and industry associations or clusters for various types of support. Public agencies cited included TIA, The Innovation Hub, DTIC, IDC, the SAMRC, eGoliBIO and SAHPRA.

TIA, the DTIC and IDC provide funding for different product development phases (see section 3.7 for more detail on funding support and incentives for MDMs).

SAHPRA is responsible for the licensing of medical device manufacturers and will, in the near future, also be licensing medical devices. In this context it provides information and guidance to MDMs on the regulatory requirements and processes to register establishments and devices.

The eGoliBIO Life Science Incubator Trust supports the commercialisation of Life Science research, products, services and technology platforms through business incubation services.

The SAMRC supports medical device manufacturers in a variety of ways, including through the Technology Innovation Cluster Program (TICP) for Medical Devices and Diagnostics (MeDDIC). MeDDIC aims to strengthen the medical devices and diagnostics innovation ecosystem through a cluster-based approach. It has three focus areas namely: creating an integrated and cohesive ecosystem, facilitating localisation and rapid product development and human capital development. The SAMRC also has a number of product development grant programmes, some of which are open to MDMs.

Responses to questions on the companies' interest in various forms of assistance are summarised in Figure 49.

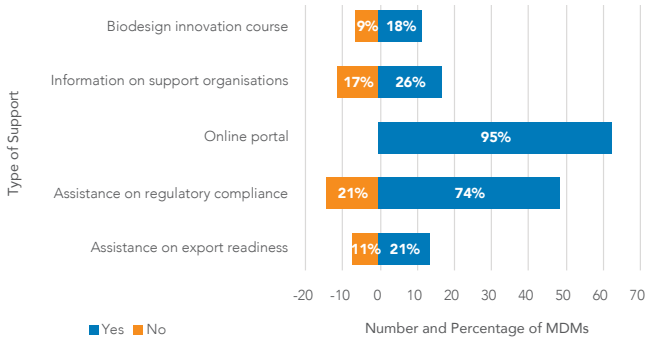


Figure 49: Company interest in utilising support services and facilities

The overwhelming majority (63/66 – 95%) were interested in having an online portal connecting them to innovators and vice versa. Some stated that this would foster collaboration, marketing, communication and information sharing. It was also seen as a tool to increase their client base. Another important support mechanism was assistance with regulatory compliance, which was not surprising, given the fact that this is one of the major barriers to success in the industry (see section 3.5 of this report). There was only a small response to the questions on other support mechanisms (interest in training of staff on bio-design in health innovation, access to information on support organisations and assistance with export readiness); however, for all of these the majority answered in the positive.

4.2.8. Factors affecting medical device manufacturers

MDMs were asked to indicate what the main barriers and challenges affecting them were and to make suggestions on how those barriers and challenges could be addressed. Their responses are summarised below under the respective subheadings.

Barriers and challenges in the medical device manufacturing sector

The issues that were most frequently cited by respondents related *to regulation and certification*. Respondents indicated that the cost of compliance with regulation was high and that there was inadequate support to achieve certification of devices and facilities, especially for exporters that needed to comply with the requirements of foreign jurisdictions. The small SA market necessitates foreign registration for most companies. Respondents cited the lack of local facilities and skills for auditing, laboratory and mechanical testing and the high costs and time taken for independent testing of, for example, electromedical devices, which has to be done overseas. Where there are local testing capabilities, these are expensive. One respondent also cited difficulties with SABS accreditation for local tenders and another the slow pace of introducing regulation in the local market. The slow turnaround times and lack of communication from SAHPRA were also noted.

The second most frequently cited challenge or barrier related *to finances*. This included access to capital financing, support for product development and growth (especially for small companies) and cash flow issues. Regarding cashflow issues, several respondents complained that Government was slow to pay. The distribution of Government grants and decision making thereon is also slow.

The third most cited issue related to protection of local MDMs from *imports* and the dominance of multinational corporations. Respondents felt that the lack of import duties exposed them to competition from cheap and low-quality imports. Local companies are often competing with non-compliant manufacturers, many of which are making unbranded, cheap replicas.

Other frequently cited issues related to the lack of preferential procurement for local suppliers (there is no culture of "buy local" in the public and private sectors), insufficient focus on job creation, difficulties in accessing the local public sector market and Government budget constraints (prioritising price over quality), the way BBBEE regulations were implemented (this has excluded a number of manufacturers with a small number of employees from the public sector market and public incentives), incapacity in Government to properly run and adjudicate tenders, the administrative burden on small enterprises, including value added tax requirements, inefficiencies in importation of components and raw materials (logistical costs for bringing in raw materials and shipping out of the country, especially with exchange rate fluctuations), insufficient championship of the industry by Government, and a lack of access to, coordination within (linkage between Government departments) and responsiveness of Government.

General business conditions that affect MDMs include corruption (doctors taking backhand payments into untraceable accounts was cited), kickbacks and incentives, crime, civil unrest, labour issues, power cuts and the generally poor investment climate.

Some respondents indicated a lack of technical capabilities such as for product testing and regulatory compliance and difficulty retaining skilled human resources.

Other issues raised were:

- Tenders needing updating to match the latest technologies
- Challenges with medical aid reimbursement and medical funding administration access for product and procedure approvals
- Lack of investment in hospital infrastructure by Government and the private sector
- Lack of access to information on foreign markets, such as market intelligence, barriers and routes to market and establishing international distribution
- Difficulties and delays in making international payments, including obtaining the necessary approvals
- Slow rebates from SARS for exports, which affect cashflow
- Getting new products into the market and the cashflow issues while waiting for revenues to come in
- Limited awareness and visibility of local and international business development opportunities
- Poor policing of compliance.

Suggestions on how these barriers and challenges could be addressed

Respondents made wide-ranging suggestions on improving conditions for domestic manufacture of medical devices. These suggestions are aimed at increasing local MDMs' share of the local market, enhancing exports, and enabling product development:

- Enable sustainability of the local industry by improving access to the local public and private sector medical devices market. Specific suggestions included preferential procurement (designation and minimum local content for Government tenders), tax incentives in the private sector to buy local, and greater transparency on public sector requirements (e.g. opportunities for discussing tender specifications between Government and industry). This must go hand-in-hand with sound tendering processes, including implementing tender quality control and timeous payment of suppliers. It was recommended that DTIC and Treasury drive discussions with DOH particularly around preference for local in the tender processes.
- Linked to the above, it was suggested that there needs to be increased awareness of the issues facing the sector within Government in order to encourage solutions.
- There needs to be much stronger support from Government in general for the sector, including more incentives, business, regulatory and financial assistance, with more flexibility within these. Government needs to speed up plans to grow the industry and focus on putting supportive policies in place.
- Mechanisms must be put in place to address regulatory hurdles. Some recommendations included: increased regulatory assistance and access to information, Government investment in SAHPRA to improve efficiencies in regulation, accreditation of a local certification body, e.g. SABS, increase capacity to provide internationally certified product testing locally, improve SABS competency and accreditation of test facilities to international standards, DTIC funding to assist local companies to become certified, regulatory training (include a module on QM in undergraduate courses, develop a course for auditors and consultants), and establishment of a forum or think tank of experience to field regulatory queries.

- There is a need for value chain support, e.g. access to components which are predominantly sourced internationally and are costly and take time to receive. The import process for components must be made easier (reduce customs delays) and more affordable. This includes making improvements in international payments by having a dedicated team for this on the Financial Services Board with an understanding of the nature of the businesses.
- At the same time, the local industry should be protected from unfair competition from overseas suppliers by imposing import tariffs for products already available locally.
- Exports should also be supported, including support for certification and facilitating access to overseas markets.
- There needs to be greater cooperation and collaboration within the sector. Multi-stakeholder collaboration should be enabled through virtual platforms and investments in physical infrastructures such as technology parks. As an example, companies should get more involved in providing regulatory assistance and training to each other. Regional clusters would also assist with enhanced collaboration between those in close proximity.
- More funding needs to be made available to the sector, including funding for new product development, regulation and certification, facilities, and expansion. There should also be more incentives and support to create jobs in the industry. Quicker turnaround times and less paperwork for funding should be encouraged.
- Availability of the necessary human capital, including business training, must be ensured.
- There is a need to revitalise existing health facilities, for example through an online platform for sourcing spares.
- General improvements in the economy are needed, including addressing investor confidence, security, corruption and tender irregularities.

4.2.9. Summary and conclusions

The survey results for MDMs have confirmed some of the trends reported in the reports reviewed in Chapter 3. In addition, the survey provided data on issues not covered in these reports. In particular, the survey revealed details on the sector size, its geographic spread, the products and markets serviced by local medical device manufacturers, R&D intensity, export market prioritisation, manufacturing capabilities and the quality systems employed. The survey also provided detail regarding R&D trends in the sector and collaboration with local and international STI institutions. Lastly the survey established the extent to which MDMs participate in industry associations and clusters, their interest in doing so and their requirements for various types of support.

The survey identified 136 medical device manufacturers. Based on the 49% in the surveyed sample, four clusters or groupings of MDMs can be identified based on R&D intensity and size. In Figure 50 these groupings are plotted on a two by two matrix. Different policy interventions are required for the different quadrants to move the industry towards higher domestic value-add. The rationale for the proposed policy interventions is discussed in more detail in sections 6 and 7.

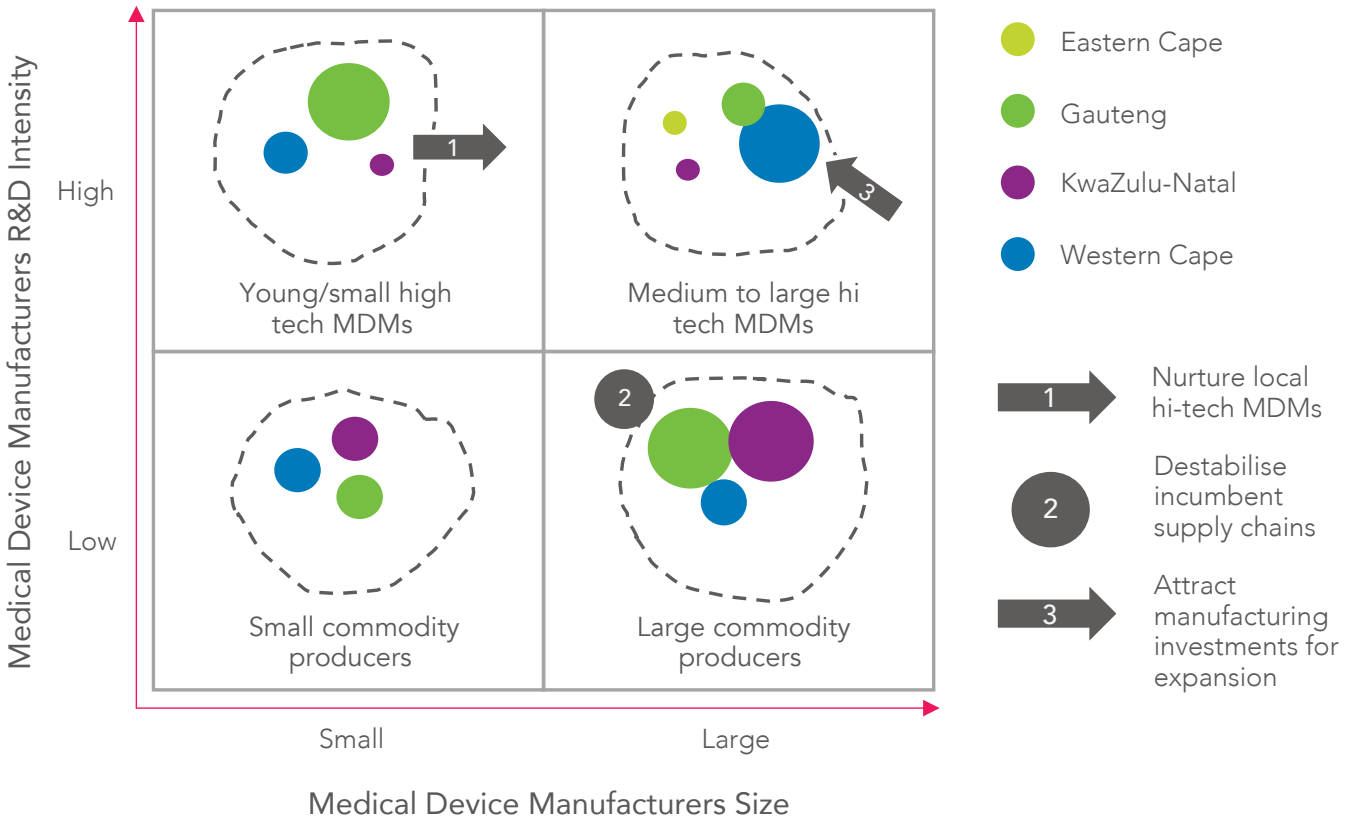


Figure 50: Distribution of MDMs according to province, R&D intensity, and size

The survey revealed the following high-level features of the MDM sector:

- The sector is concentrated in three provinces, Gauteng, WC and KZN.
- The average age of companies is 20 years, with more than half older than 20 years, and most are classified as small, employing 50 or less permanent staff, and falling within the micro (<R10 million) and small (R10-R50 million) enterprise categories.
- There has been a declining trend in company formation since 2004, with only 7 new companies founded in the period 2015-2019.
- The industry is active across a range of fields and device classes, predominantly in consumables (mostly Class A and/or Class B), orthopaedics, hospital furniture and other.
- The domestic private sector is the most important market, while Africa, Europe, the Middle East and North America are the most important export markets.
- Most companies have in-house design, manufacture and packaging capabilities, predominantly component assembly followed by mechanical turning, OEM manufacture and material or component testing.
- Manufacturing capacity is presently underutilised and most companies could increase production by 40% using various strategies.
- Around 79% of companies are SAHPRA registered, but only 51% have ISO 13485 in place.
- Over three quarters of MDM respondents are active in R&D; however, R&D expenditure as a proportion of turnover in South Africa is low when compared with international examples. Although <10% of companies with an R&D expenditure applied for an R&D tax incentive, all of them were successful.
- Around a third of MDMs active in R&D have applied for Government R&D funding, around 74% of whom were successful.
- Just under half of the MDMs have collaborated with STI institutions locally and abroad and 41% with industry. However, around three-quarters of companies are interested in collaborations, including manufacturing innovations by South African research institutions.
- Just over half of the MDMs are members of an industry association or industry cluster, predominantly SAMED and MDMSA.

The issues affecting the medical devices sector that were most frequently cited by respondents related to regulation and certification, following by funding, access to capital financing, support for product development and growth (especially for small companies) and cash flow issues. The third most cited issue related to protection of local MDMs from imports and the dominance of multinational corporations. Several other challenges and gaps have to be overcome for the MDM sector to capture a greater share of the R21 billion market and to penetrate the large and growing international market.

4.3. STI Institutions

The 'innovation sector' component of the medical devices landscaping comprised a survey of public science, technology and innovation institutions that perform R&D and related science and technology activities in the medical devices field. Included in the definition of STI institutions are publicly funded universities, universities of technology and science councils in South Africa.

The Universities of Venda and Limpopo indicated that they were not involved in medical device innovations and were therefore not surveyed. The CSIR was surveyed through two different units, the Licensing and Ventures office (TTO) and the Centre for Nanostructured Materials/Chemical Cluster but the data was merged for the analysis.

4.3.1. Institutional profile

Public institutions (universities and science councils) involved in medical device innovation are concentrated in Gauteng (7) the WC (5) and Eastern Cape (4). There are two institutions in the Free State, two in the Northwest Province and one in KZN that are also involved in medical device innovation. The low level of involvement of public STI institutions in KZN is surprising given the size of the province's economy, its high-level of industrialisation and the number of medical device companies active in the province; however, it is probably indicative of the fact that there is only one major, research-intensive university in the province. Notably, all four universities in the Eastern Cape have some involvement in medical device innovation, including two historically black institutions, although the medical device outputs from most of these have been limited to date. The high concentration of STI institutions involved in medical device innovation in Gauteng and the WC is consistent with the presence of most of the research-intensive universities and the higher degree of R&D spend by medical device companies in these provinces.

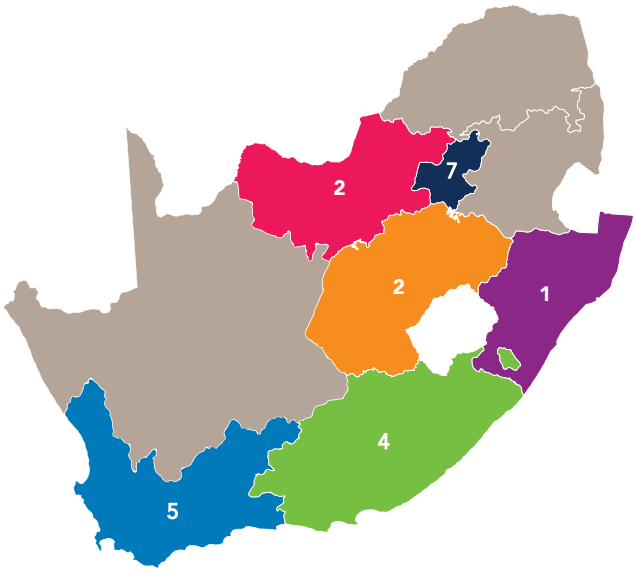


Figure 51: Geographic distribution of STI institutions involved in medical device innovation

Most of the institutions involved are universities, followed by science councils and universities of technology. Although only four universities of technology are involved, it should be borne in mind that there are only seven such institutions in the country (see Figure 52).

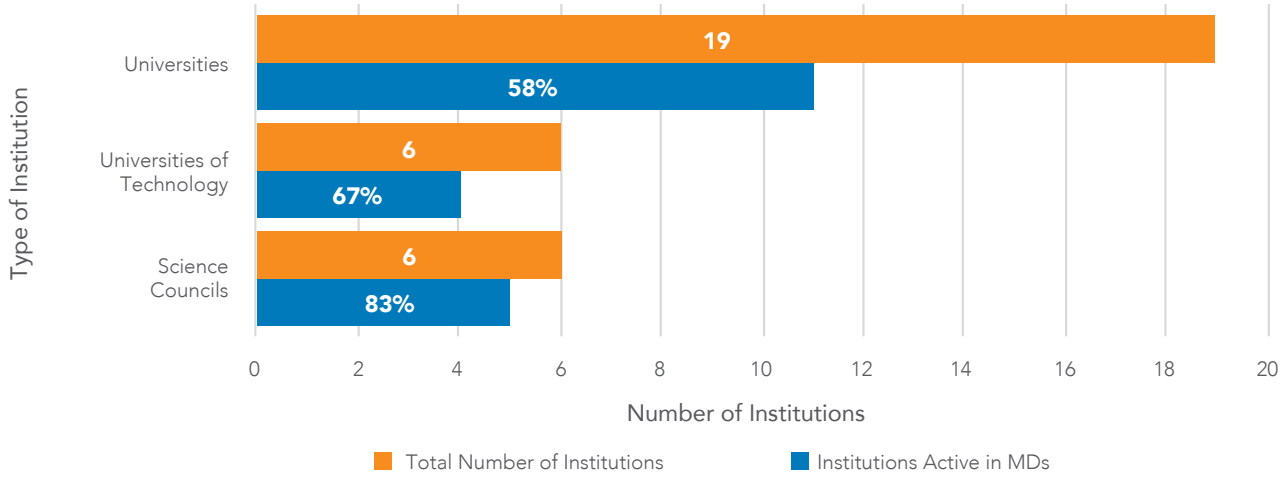


Figure 52: Number and percentage of public institutions involved in medical device innovation[27]

Innovation capacity

Table 10 summarises the platforms, capabilities and infrastructure that supports or can be applied to medical device innovation and manufacturing as reported in the survey. Most STI institutions had capabilities in basic and applied research (60%), innovation, product development, business and manufacturing (70%); followed by preclinical (30%) and clinical research (25%).

Table 10: Medical device related platforms, capabilities and infrastructure at STI institutions

Institution	Platforms and Infrastructure	Capabilities
Free State University		Clinical trials Nuclear medicine Cardiology and cardiac arrest Virology Medical physics
Nelson Mandela University		Sensor prototyping Digital health
Rhodes University		Electroanalytical methods X-ray photoelectron spectroscopy Protein-protein interaction
Stellenbosch University	Laboratory for Advanced Manufacture Institute for Biomedical Engineering (IBE)	Clinical research Biomedical engineering Genetics Biochemical science Engineering prototyping/production Nanotechnology Advanced manufacture
University of Cape Town	UCT Clinical Research Centre **Infrastructure:** Biomechanics laboratory Low-dose X-ray, Medical Electronics & Biomechatronics, High-resolution EEG Automated Microscopy MRI analysis Confocal and Light Microscopy Facility	Clinical trials Medical imaging 3-D printing Biomedical engineering Frugal innovation Health economics Sports medicine

27 Science Councils limited to research performing councils

Institution	Platforms and Infrastructure	Capabilities
University of KwaZulu-Natal		Prototyping
University of Pretoria		ENT-related technologies
University of the Western Cape	Biolabels Unit SensorLab Unit Nanotechnology Unit	
University of the Witwatersrand	Pharmaceutical Biomaterials and Polymer-Engineered Drug Delivery Technologies WITS Advanced Drug Delivery Platform (WADDP) Research Unit PharmApprentice Programme	
Walter Sisulu University		Prosthetics and orthotics Physiotherapy Audiology Speech and language science
Cape Peninsula University of Technology	Adaptronics AMTL (Advanced Manufacturing Technology Laboratory) ATS (Agrifood Technology Station) TSCT (Technology Station in Clothing and Textiles) Product Lifecycle Management Competency Center (PLMCC)	Health and wellness Biomedical sciences Emergency medical sciences
Central University of Technology	Centre for Rapid Prototyping and Manufacturing (CRPM) Product Development Technology Station	3D printing (metal laser sintering) Custom medical implants Surgical aid devices
Vaal University of Technology	Technology Station for Materials and Processing Technologies French South Africa Institute (F'Sati) Institute for NanoEngineering Research	
ARC		Sequencing LC MS/MS PCR capacity
CSIR	Photonics prototyping facility Nanotechnology Centre Sensor science and technology unit Mechatronics and Micro-Manufacturing unit **Infrastructure:** Sensor testing facilities	Nanotechnology Biotechnology Sensor science and technology ICT systems for handling patient data and diagnostic data Mechatronics and Micro-Manufacturing prototyping and manufacturing Product Life-cycle Management
MINTEK	**Infrastructure:** Infrastructure for Batch production of Lateral Flow assays Nanotechnology characterisation	Lateral flow assay prototyping Nanotechnology R&D
NECSA	**Infrastructure:** Animal imaging facilities	Nuclear imaging and treatment Producing medical devices (emerging capability) Applied chemistry

Institution	Platforms and Infrastructure	Capabilities
SAMRC	Biomedical Research and Innovation Platform (BRIP) Primate Unit (PUDAC) Biostatistics Unit Medical Device and Diagnostic Innovation Cluster	Biomarker identification for diagnostics Test & evaluation of devices in clinical trials *In vivo* diagnostics testing Digital innovation

The departments in STI institutions involved in medical devices R&D were mainly from health sciences, natural sciences, and engineering. The involvement of both health science and engineering is critical for a value chain approach. Detail reported by the institutions is summarised in Table 11.

Table 11: Departments involved in medical device R&D

Institution	Health Sciences	Natural Sciences	Engineering
		Universities	
Free State University	Cardiology Virology Nuclear medicine Medical physics		
Nelson Mandela University	Clinical Care Sciences Medicinal Sciences Community Technologies	Chemistry	eNtsa Engagement Institute
Rhodes University		Biochemistry Microbiology and Biotechnology Chemistry	
Stellenbosch University	Biomedical Sciences Virology AIMS SACEMA	Biochemistry Genetics Polymer Sciences	Mechanical/Mechatronic Engineering Electrical/Electronic Engineering Chemical/Process Engineering
University of Cape Town	Molecular & Cell Biology Human Biology Exercise Science and Sports Medicine Surgery Medicine Cape Universities Body Imaging Centre (CUBIC)		Electrical Engineering Mechanical Engineering Biomedical Engineering
University of Fort Hare	Faculty of Science and Agriculture		
University of Pretoria	Steve Biko Academic Hospital ENT Department		
University of the Western Cape		Biotechnology Chemistry	
University of the Witwatersrand	Advanced Drug Delivery Platform (WADDP) Pharmacy and Pharmacology		
Walter Sisulu University	Rehabilitation Medicine Laboratory Services Medical Orthotics and Prosthetics		

Institution	Health Sciences	Natural Sciences	Engineering
Universities of Technology			
Cape Peninsula University of Technology	Emergency Medical Sciences Medical Imaging and Therapeutic Sciences		Mechanical Engineering Oxidative Stress Research Centre Biomedical Sciences
Central University of Technology			Centre for Rapid Prototyping and Manufacturing (CRPM)
Tshwane University of Technology	Biomedical Sciences, Sports, Rehabilitation and Dental Science Pharmaceutical Sciences		Chemical, Metallurgical and Materials Engineering Electrical Engineering Industrial Engineering Mechanical Engineering Mechatronics and Industrial Design
Vaal University of Technology			Engineering and Applied Sciences Advanced Manufacturing Technology Station
Science Councils			
ARC	Vaccines and Diagnostics Development, Epidemiology Parasites and Vectors, Vaccine Production, Diagnostic Services and Public Health and Zoonoses		
CSIR		Biosciences Material Sciences and Manufacturing Laser Science	
MINTEK		Material Science (Nanotechnology) Biotechnology	
NECSA		Physics departments at various universities	
SAMRC	Biomedical Research and Innovation Platform (BRIP)		

4.3.2. Medical device R&D and innovation

Most of the institutions surveyed (75%) are working on five or less medical device R&D and innovation projects, 10% six to ten technologies and 15% ten or more technologies which have been reported to their TTO (see Figure 53). Moreover, over the past decade, 75% of the respondents indicated that their researchers had disclosed less than five technologies. This suggests a limited focus on medical device innovations in most STI institutions in the public sector with a few exceptions.

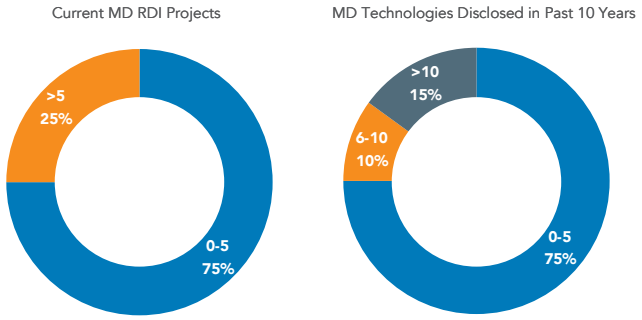


Figure 53: Current medical device projects and medical device technologies disclosed to the TTO over the past 10 years

Innovation Outputs

The respondents were surveyed on their medical device innovation output in terms of patents, licenses, spin-outs based on medical device technologies that have been successful (i.e. are currently trading) and products in the market over the past ten years (Figure 54 and Figure 55). In all cases, the distribution of institutions is heavily skewed to the left with most institutions having filed less than five patents on medical devices, spun out two or fewer successful medical device companies, and having two or fewer products in the market. Encouragingly, in each case, some institutions achieved much higher outputs: between 20 and 30 patents, 4 to 6 products in the market and 6 to 8 spin-out companies, indicating some pockets of excellence in this sector.

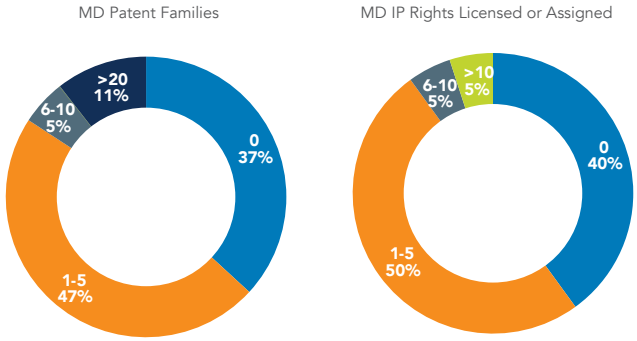


Figure 54: Medical device patent families and licenses and assignments

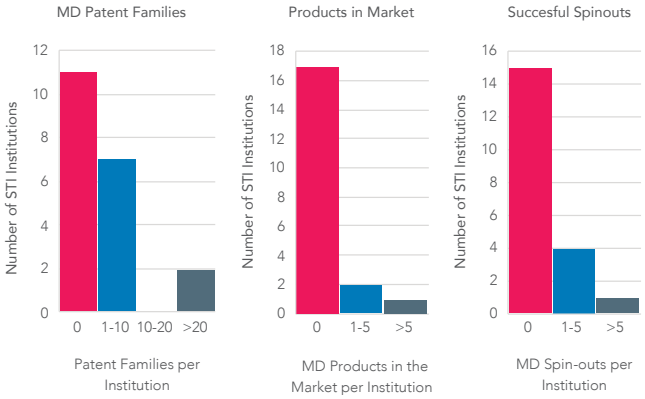


Figure 55: Total innovation outputs of STI institutions over the past 10 years

A total of 82 patent families (granted and/or pending) on MD technologies were reported by respondents. This is a substantial number that warrants further investigation. It is possible that not all of these relate to a novel medical device, for example, where patents were specifically listed, at least 7 of these were either methods of treatment or novel biomarkers.

A total of thirty-five IP assignment or license transactions for medical device innovations over the last 10 years were reported by the respondents. As indicated in Figure 56, more than half of these (18 assignments or licenses, 2 of which were in the process of being licensed) were to spin-out companies of the institution, followed by existing local companies (12 assignments or licenses, 5 of which were in the process of being licensed) and a small number to international companies (5 assignments or licenses, 2 of which were in the process of being licensed). If all of these assignments or licenses relate to a single patent family each, it suggests a maximum success rate of between 42 and 47% (depending on the number of true medical device patents) in the commercialisation of medical device patents, which is higher than the reported average success rate for commercialisation of university technologies. However, a number of these could relate to licensing of know-how or designs.

STI institutions reported twenty successful medical device spin-out companies in eight different institutions as indicated in Figure 57.

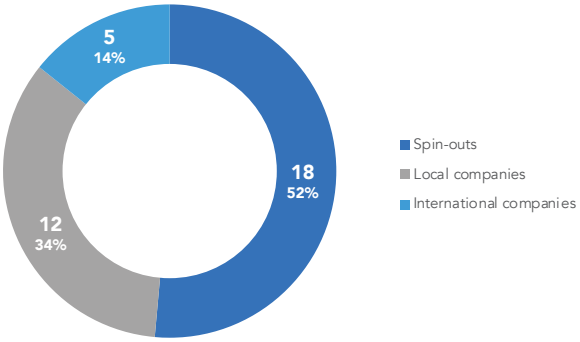


Figure 56: IP rights on medical device innovations assigned or licensed by STI institutions to spin-outs, local companies and international companies (n = 35)

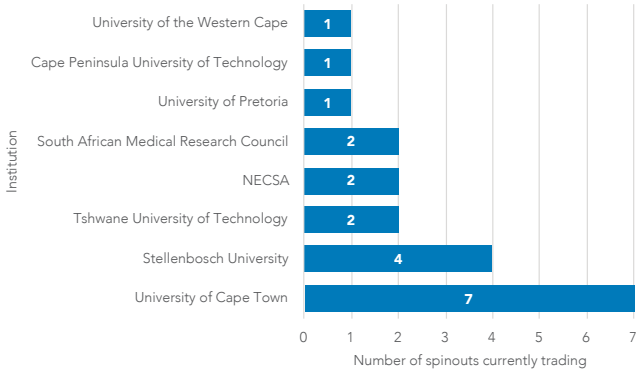


Figure 57: Successful medical device spinouts reported by STI institutions

The geographic distribution of medical device innovation outputs is depicted in Figure 58. The WC stands out in all four areas of patenting, licensing and IP assignment, products in the market and successful spin-outs. This is primarily due to the two research-intensive institutions in the province with substantial health faculties and biomedical engineering departments, namely the University of Cape Town and University of Stellenbosch.

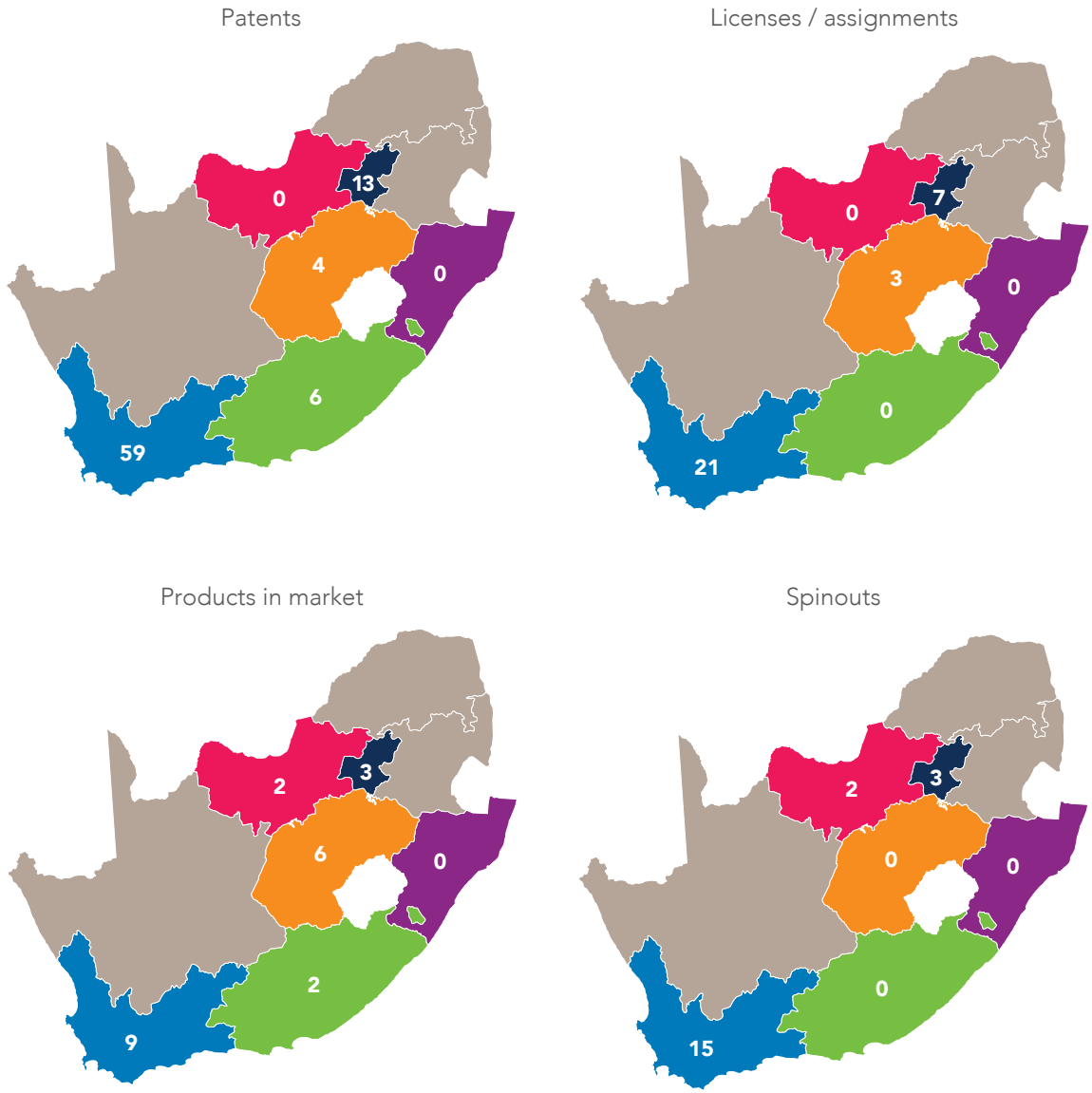


Figure 58: Geographic distribution of medical device innovation outputs

Medical device innovation partnerships

STI institutions were asked whether any of their medical device research projects were being conducted collaboratively with medical device companies. Most (60%) STI institutions engage in such partnerships on their medical device projects. Half of the respondents reported having local partners and 30% had international partners, while 20% had both local and international partners (See Figure 59). Partnerships are structured around specific objectives, including postgraduate student supervision, contract research and co-development (see Figure 60).

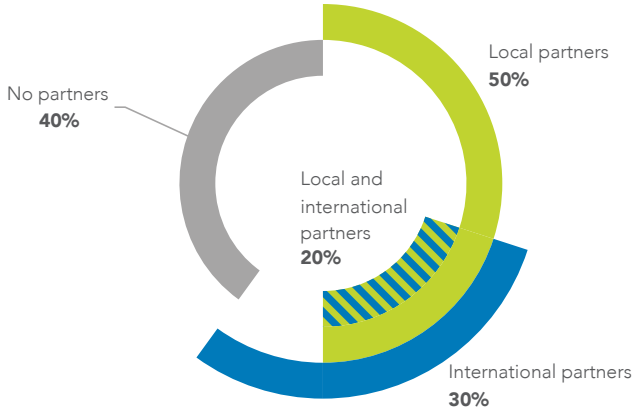


Figure 59: Partnerships of STI institutions for medical device innovation

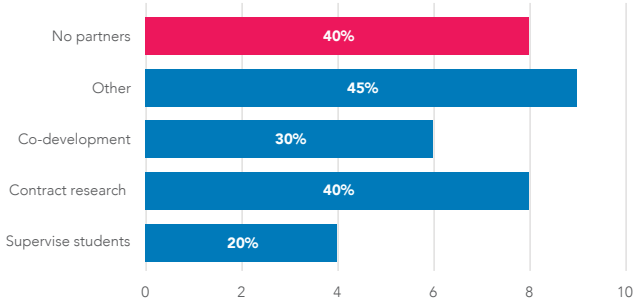


Figure 60: Existing partnership modalities between STI institutions and medical device companies

All twenty respondents indicated an interest in increasing collaboration with the medical device industry. Most (60%) confirmed an interest in joint R&D and in technology transfer, with a smaller number confirming an interest in experiential training for students. In addition, respondents suggested contract research, advisory and mentoring roles for industry and collaboration on manufacturing[28] (see Figure 61).

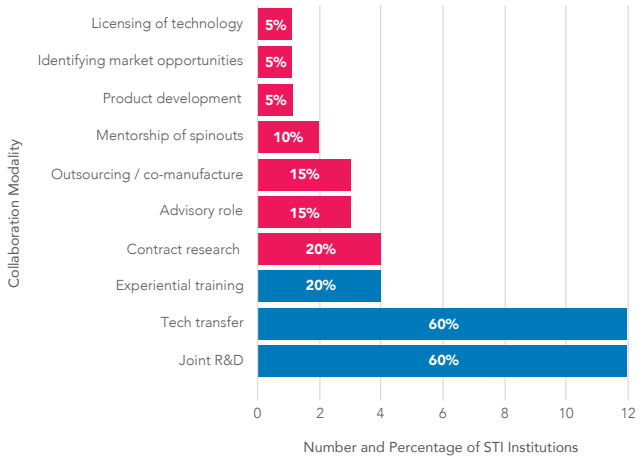


Figure 61: Modalities for increased collaboration with local medical device manufacturing companies

Funding, services and support

The role-players involved in obtaining regulatory approval for medical devices in STI institutions were mainly industry partners, followed by external consultants and the research institutions' own capacity, especially their technology transfer offices.

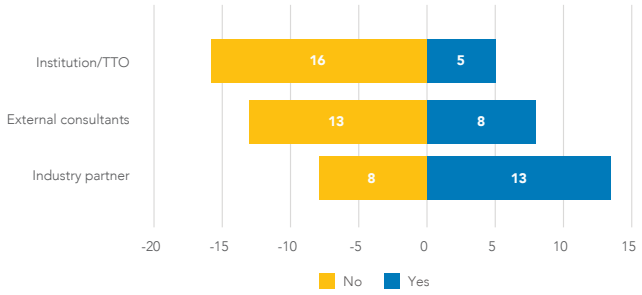


Figure 62: Actors involved in the regulatory process

The most listed funder for medical devices development amongst the respondents was the TIA, followed by the SAMRC, the DTIC and the South African Breweries (SAB) Foundation. Other funders listed included Bidvest, SPII (DTIC), THRIP (DTIC), IDC (Venture Capital Fund), Economic Development, Tourism and Environmental Affairs (EDTEA), GAP sciences award (Innovation Hub), Donald Wood Foundation, Grand Challenges Canada Transition to Scale Funding, and grants and donations from the USA, including the Bill & Melinda Gates Foundation and the NIH (See Figure 63).

28 Respondents were not specifically asked about these other forms of collaboration, hence interest in contract research, manufacture, licensing, etc. may be under-represented in the figure.

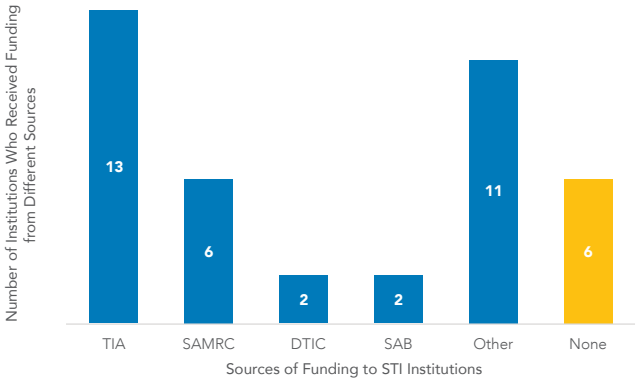


Figure 63: External innovation funding for medical device technologies

In terms of other external support, 55% of STI institutions involved in medical device development reported not making use of external support. The rest made use of commercial firms and consultants, public institutions and universities. In particular, a number of respondents reported making use of facilities at universities of technology (Figure 64).

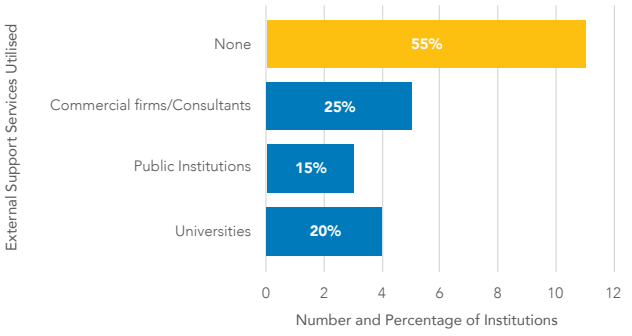


Figure 64: External support services used by STI institutions

All except one of the institutions indicated that they would support a web-portal linking the MD manufacturers with the innovators and MD R&D conducted in their institution.

Respondents reported a variety of mechanisms for finding commercialisation partners. Frequently the lead is generated by the inventor based on an existing relationship between the inventor and an industry partner. This also includes cases where R&D collaborators become the commercialisation partner. A second mechanism used is for technology transfer offices or similar functions to actively reach out to potential partners through their website, participation in tradeshows and conferences and the use of technology marketing platforms such as InPart or Innovation Bridge. STI institutions rely both on informal mechanisms, such as word of mouth or their existing networks, and more formal mechanisms, such as industry challenges or calls for expression of interest, to commercialise specific MD technologies.

4.3.3. Factors affecting medical device R&D and innovation

Innovation barriers

The STI institutions were asked to identify, based on their experience, the barriers to the development and commercialisation of medical devices in South Africa. Those identified included the need for clearer market guidance and pathways to commercialisation, more incentives, clearer guidance on regulation and certification, sufficient funding (also greater funding risk appetite and longer-term funding), industry limitations, a lack of critical mass of R&D capacity, and difficulties related to clinical trials, regulation and scale-up. These inputs were provided in response to an open-ended survey question and represent a combination of causes and consequences that interact with one another and impact on the health of the TIS. Ideally these issues should be further interrogated through interviews and analysed, supported by analytical tools. A potential approach to do so is presented in De Oliveira *et al.* (2020) in which systemic problems and blocking mechanisms are linked to TIS functions through blocking mechanisms as causal mechanisms. Figure 65 presents an example from Oliveira *et al.* in which the lack of a long term vision negatively impacts on the market creation function in a TIS.

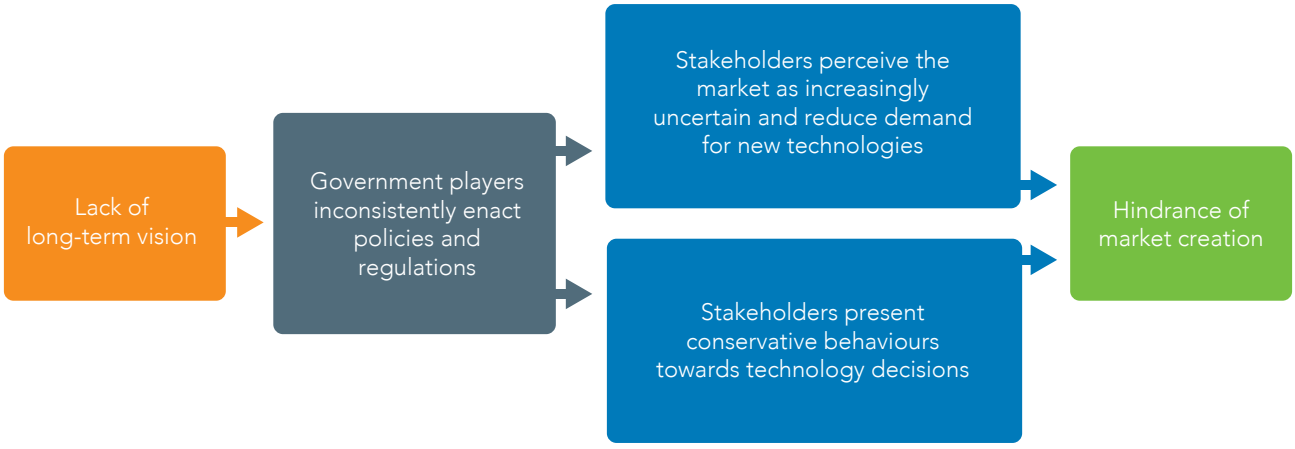


Figure 65: Example of ambiguous behaviour by Government as blocking mechanism

One of the themes that emerged from the responses relates to deficiencies in industry that impact on the potential to commercialise innovations from the STI sector. One respondent commented that the "absorptive capacity of the South African industry is a challenge. The SA MD industry concentrates on importing finished products and distribution. Little manufacturing capability exists. Very few ISO 13485 certified facilities exist". Another indicated that "ideally, a far greater synergy or synchronisation is required between academia and industry than currently exists. This approach is common in more developed countries. For example, in Germany more than 70% of funding for HEI Engineering projects come from partners in Industry. Academia and industry should really team up to tackle SA's healthcare issues".

Another theme relates to a lack of insight into market requirements by STI institutions. One respondent reported that "research often does not address the needs of the market and in instances where this is the case, the cost of introducing the technology far outweighs the return on investment. The knowledge and capacity to drive the industry-oriented commercial success of technological innovations is not usually available in academic institutions. This includes knowledge regarding Medical Device Regulation, which means that compliance is often sought at great expense after R&D giving rise to innovations, rather than early-on or intrinsic to the process". Inadequate links between STI institutions and industry may be contributing to R&D innovations from these institutions tending to adopt a technology-push rather than market-pull strategy as well as resulting in both inadequate documentation of early product development, as required for regulatory compliance, and the need for a degree of product redesign when industry partners do get involved and have to factor in manufacturing considerations and end user requirements. Several institutions also struggled to find industry partners for technology transfer, which is related to the low absorptive capacity of the industry.

There is clearly a disconnect and lack of information flows in the sector, as some of the above perceptions are not supported by the results of the MDM survey, which indicate a sizable number of MD manufacturers, at least half of which already have ISO 13485 certification, with a further 24% in process. Further, as reported in section 4.2.5, 77% of MDMs were interested or conditionally interested in manufacturing innovations by South African research institutions. The reasons for the low uptake to date therefore need to be interrogated further and remedied.

Lastly, a number of issues were raised regarding deficiencies in the funding regime. Respondents reported that the current approach to funding has focussed on a project-by-project approach provided by specialised agencies, such as the TIA, SPII and others. The short-term nature of these types of funding prevents STI institutions from building sustainable long-term pipelines for innovation. Several respondents commented that funding is project based which makes it difficult to build critical mass. To address this problem, investment is required in human and institutional capacity that is focussed on market-driven requirements and Government funding instruments should incentivise synchronisation with the private sector.

Figure 66 presents the results of a coding of different responses into different barrier categories. In addition to the themes highlighted above, difficulties with clinical trials and regulatory approval were cited by 43% and 33% of respondents, respectively. Under systemic failures, respondents commented that incentives for higher education did not favour technology outputs as the subsidy system counts publications and graduations only.

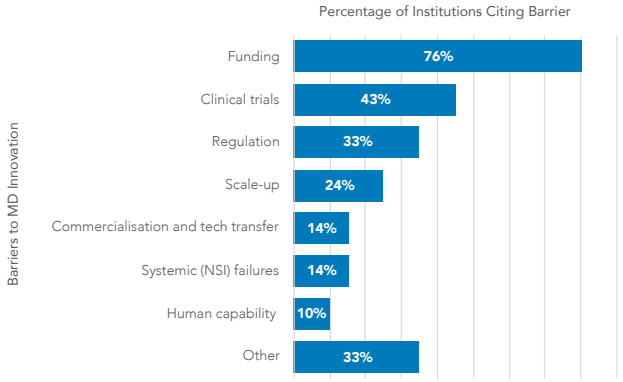


Figure 66: Barriers to medical device innovation cited by STI institutions

Gaps in the development and commercialisation of medical devices in South Africa

The gaps in the development and commercialisation of medical devices in South Africa cited by respondents overlapped with some of the innovation barriers discussed above and included issues that relate to Government efforts and interventions aimed at stimulating local innovation and technology development, industry related challenges, funding gaps, regulatory challenges, and several other gaps.

In terms of Government's role, gaps cited included inadequate support for the medical device sector, including policies or regulation on public procurement that promote local industry competitiveness, challenges with the public procurement process and uncertainty regarding the approval of new technologies for use in State health facilities as well as insufficient or poorly capacitated funding of medical device R&D and initiatives for medical device R&D and manufacture. Respondents reported that they lacked access to local markets and that there was no uptake by the Department of Health (specifically through preferred local procurement).

Respondents reported a gap in the available human capital in the field and the need for more seasoned entrepreneurs to take opportunities forward. Interventions are required for maintaining and building a skilled labour force; particularly in support of human capacity development of the educators at HEIs who must produce the future crop of innovators.

One respondent proposed that Government should play a stronger role in directing efforts to specific disease focus areas, enabling technologies, inputs and components.

Several institutions cited inadequate funding. Some cited specific aspects of the innovation process that are inadequately supported, such as funding for proof of concept and pre-commercialisation funding, investments in technology companies and gaps between first round funding and later stage funding. Respondents indicated a need for funding for the full value chain of R&D, product development, testing and registration. In addition, funding processes needed to be efficient with rapid decision-making as this critically impacts the momentum of medical device manufacturers. One respondent shared that one of their

inventors says, "funders don't have a risk appetite, they don't trust innovators".

Several institutions expressed a view that there was inadequate collaboration between STI institutions and industry. Institutions indicated that they struggled to find suitable industrial partners for the development and manufacturing of medical devices. Respondents indicated that there is a need for greater industry/R&D community cohesion along the value chain. Amongst the industry gaps cited was a lack of local manufacturers of raw materials for medical devices. One of the respondents suggested that there was a need for a "white label" manufacturer for single devices that would not sustain an independent company. Respondents' desire for greater risk appetite extended to the private sector with one stating, "big corporates are not willing to take risks on our technologies".

On regulation, respondents indicated uncertainty around the regulatory process and standards, a lack of regulatory experience, delays in the regulatory approval process, regulatory and quality management challenges and constraints as well as prohibitive regulatory costs associated with obtaining certifications such as CE marking.

Other challenges cited included difficulties in transitioning of research ideas into commercialisable products, technology readiness levels (TRLs) that are too low, inventions that do not address needs, limited health economic assessments performed and expensive equipment and raw materials for medical devices fabrication through 3D printing for example.

As in the case of innovation barriers, a more in-depth qualitative analysis using an approach such as the one suggested by De Oliveira *et al.* (2020) would be useful.

Innovation success factors

Respondents were asked to share any of their successes in commercialisation of medical devices and why they believed they were successful. As indicated in Figure 67, the main factors for commercialisation success were attributed to the founder and the team (reported by a third of STI institutions), the funding and funders (a fifth), and entering good markets (a fifth). This was supported by networks and collaboration, synergies and incubation.

In describing the attributes of successful founders and teams, respondents used descriptors like "dynamic entrepreneurial inventor", "passionate team that are experts in their field and who have strong networks", "strong founders that are serial inventors with international industry linkages", "strong COO/CEO", "passion/tenacity of scientists/entrepreneur", "tenacious, persistent, resilient founders who survived fundraising" and the "grit of a few people who refused to give up".

Several respondents indicated a need for incubation support or an incubating environment provided by the universities as well as access to high-tech fabrication facilities. Industry interest in university technology with practical application in mind and industry-university synergies borne of complementary capabilities and a holistic and open innovation approach were other factors cited.

In terms of funding, respondents cited enablers such as "patient funder with sufficiently deep pockets", "funding that allowed recruitment of senior staff and acquire key equipment" and "critical funding from SAMRC SHIP and relationship between DSI/TTO".

A focus on "critical developing world needs" was seen as key and which one respondent exampled as unexpectedly gaining developed world interest due to the savings that it enables.

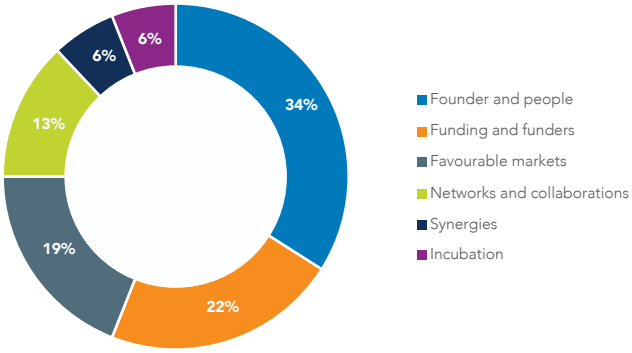


Figure 67: Commercialisation success factors

4.4. Support Service Organisations

Seven companies and three public institutions that provide support services to medical devices companies and STI institutions were surveyed. The companies surveyed were: BioTech Africa, Skeg Product Development, BMEC Technologies, Steri Solutions, Technimark, TNMC Medical Devices, and CJN Consulting. The public institutions surveyed were the TIA, the SAMRC and the IDC. Six of the organisations were based in the WC (all in Cape Town) and four were from Gauteng (three in Johannesburg and one in Pretoria). Regulatory consultants were not included but form an important component of the support services utilised by the industry. This support component of the survey was not a key focus and therefore has limitations. A more comprehensive analysis of this component of the industry may be valuable in future.

While three of the support companies were not able to list their main clients, either due to confidentiality or their client base being too large, most of the others appear to support mainly medical devices companies, with a small number also supporting STI institutions. The main services and support provided to clients was technical consulting. Other services included regulatory advice, product design and development, manufacturing support, R&D and technical services, collaboration and mentoring and support for clinical and field trials. The three public institutions provided largely funding support. See Figure 68 for a detailed breakdown.

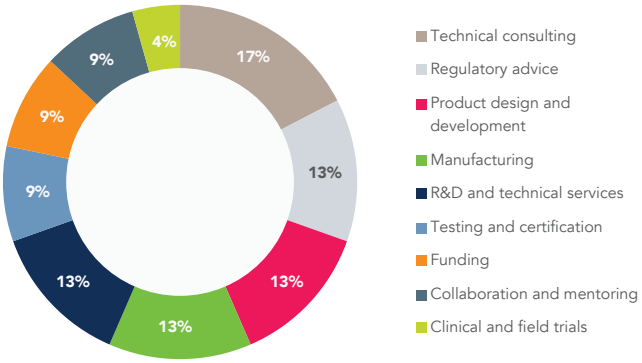


Figure 68: Services provided to medical device developers

Service and support challenges and barriers

The main challenges cited by these respondents with respect to the medical device sector were funding and investment, followed by business and technical challenges. Other challenges were the cost of certification, small markets, client management, and to a lesser extent, the regulatory environment and lack of support for innovators (see left most pie chart in Figure 69).

The main barriers to providing services and support, or those faced by clients, were regulations and certifications, and product and market understanding; followed by entrepreneurial barriers (few entrepreneurs and limited business skills, unwilling to consider equity). In addition, lack of expertise or skills, lack of quality management systems, and limited funding; followed by technology failure, high costs and poor feedback and communication were listed (see middle pie chart in Figure 69).

Enabling interventions

The companies supporting medical device development conveyed that the key intervention to benefit the sector was to provide relevant courses, training and workshops, and to champion enterprise development. This was followed by fostering consultation and collaboration, providing regulation and compliance support; then by providing product design support. Other suggested interventions were to provide safe and fit-for-purpose medical devices and to secure sustainable funding (see right most pie chart Figure 69).

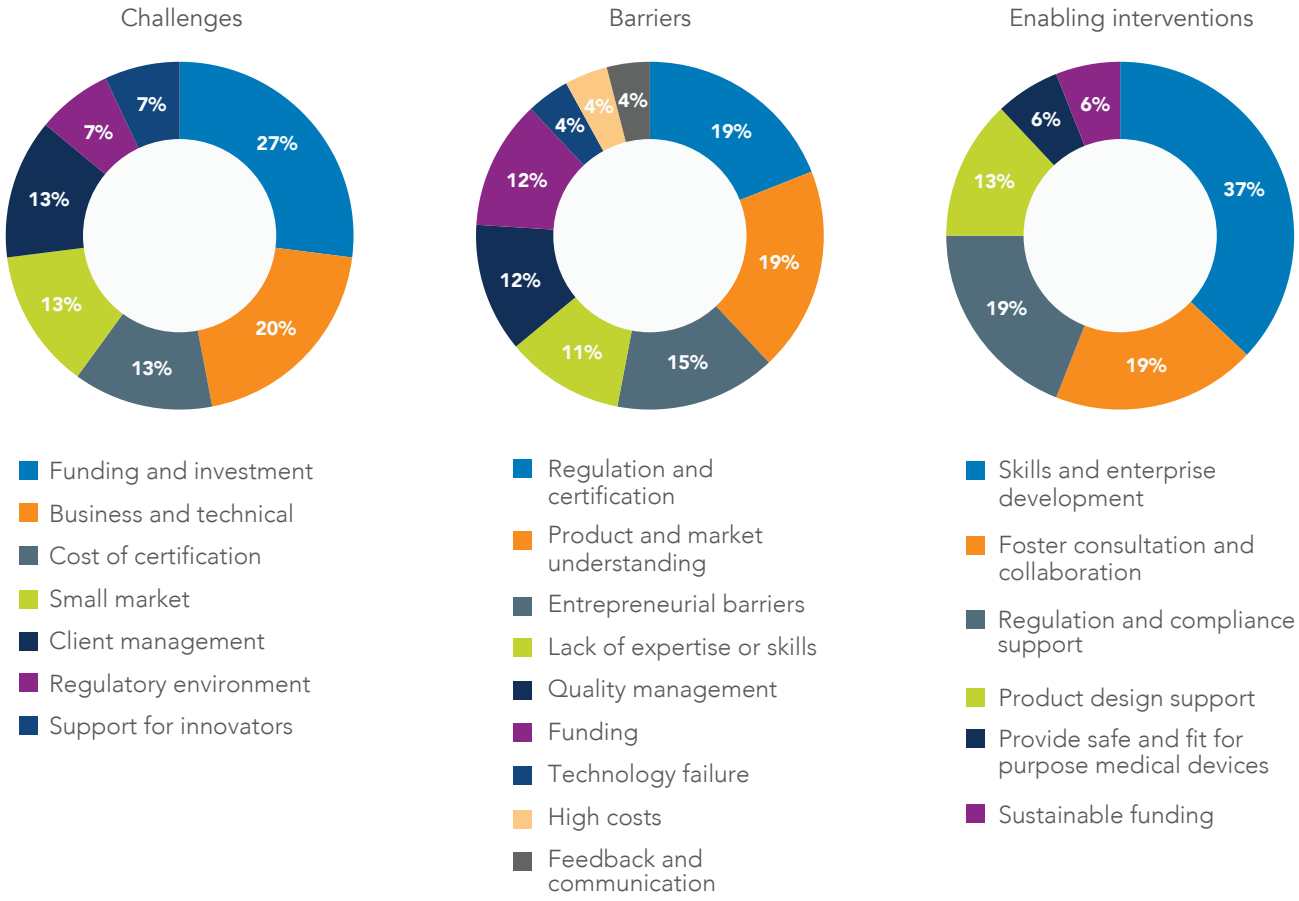


Figure 69: Challenges, barriers and enabling interventions for the medical devices sector as cited by support organisations

The Impact of the COVID-19 Pandemic

5. The Impact of the COVID-19 Pandemic

5.1. Introduction

As a result of the global coronavirus pandemic, the world has had to adapt in profound ways in every aspect of daily life. The medical device industry has been particularly challenged by the unprecedented scale of the pandemic. Shortages of testing reagents, diagnostic test kits, personal protective equipment, and respiratory devices such as non-invasive and invasive ventilators have exposed deficiencies in existing global medical device manufacturing supply chains and distribution models, with some of the developed countries depleting global supplies with bulk and pre-purchase commitments.

On the one hand, the pandemic exposed the risk posed by fragmented and skewed global value chains and 'medical nationalism' during time of crises. Countries without domestic R&D and production capabilities were left at the mercy of factors outside their control in securing medical devices ranging from simple consumables such as masks, gloves and sanitisers to sophisticated equipment such as ventilators. On the other hand, the crisis revealed the potential of an emergent, collaborative model capable of developing and manufacturing products at short notice.

A full investigation into the requirements for strategic and sovereign capabilities that South Africa needs to develop and maintain for its future security during similar events is beyond the scope of this report. Similarly, a collation of the numerous efforts to deliver relevant medical devices in direct response to the epidemic is a substantial exercise on its own. Instead, we highlight a few examples of medical device related activities that were a direct response to the COVID-19 pandemic, namely the National Ventilator Project, the South African Solidarity Fund, the South African Pandemic Intervention and Relief Effort Fund and the SAMRC-DSI-TIA investments in local diagnostics for COVID-19, and we report highlights from a supplementary survey that surveyed medical devices stakeholders on their experience and views on South Africa's response to the COVID-19 pandemic.

5.2. National Ventilator Project

The first COVID-19 case in South Africa was confirmed on 5 March 2020. While most patients experience only mild symptoms, in a sizeable number of cases it results in severe respiratory complications which requires intensive care admission with passive or active ventilation. The experience in Italy and other countries during the early phase of the outbreak highlighted the risk of medical facilities being overwhelmed by the influx of patients with severe disease. At the time, South Africa was estimated to have around 6 000 ventilators in public and private hospitals, whereas it was estimated that 35 000 intensive care unit (ICU) beds would be required between June and November 2020, in most cases with ventilation.

In anticipation of this eventuality, a project was initiated to ensure that South Africa had adequate medical ventilators. At the end of March 2020, the DTIC mandated the South African Radio Astronomy Observatory (SARAO) to lead a process that would enable the production of 20 000 ventilators by the end of September 2020. The SARAO was selected because of the experience its engineers gained in the development of complex systems for the MeerKAT radio telescope system in the Karoo, the precursor to the Square Kilometre Array (SKA) project.

The project was initiated through a call for proposals inviting companies and experts from across the country to participate in projects to develop and produce Continuous Positive Airway Pressure (CPAP) ventilators. CPAP machines provide a nearly continuous flow and mild overpressure of respiratory gas (air/oxygen mix) via a mask and are therefore non-invasive, meaning patients don't need to be intubated and heavily sedated. The objective of the call for proposals for the CPAP ventilators was to meet the anticipated demand for simple, low-cost ventilators that can be rapidly produced, certified, and deployed in large numbers, in order to treat the majority of hospitalised COVID-19 patients.

Four institutions, the CSIR and three companies, were shortlisted and eventually the CSIR and SA Ventilator Emergency Project (SAVE-P), a consortium of companies, were contracted to develop and manufacture 20 000 ventilators. The development, production, and procurement cost for the 20 000 units was funded through a R250 million donation from the Solidarity Fund.

The CSIR ventilator systems were assembled and packaged by Akacia Medical in the WC. Individual components for the CPAP-ventilator were manufactured by a consortium of industry partners in Gauteng, KZN and Eastern Cape, including the Central University of Technology and firms such as Black Capital Systems, Andani Futuretech Manufacturing, UV Tooling, Sola Medical, Gabler Medical and Pitchline Engineering. All manufacturing was done for the CSIR (Patel, 2020). In addition, Siemens South Africa provided Product Lifecycle Management (PLM) software support to the CSIR team. By using a digital product life cycle design methodology, the product could be manufactured in multiple factories in the industry and in large volumes. In the case of the CSIR CPAP ventilator, all components of the ventilator, which had a bill of materials of a "couple of hundred items", were manufactured in South Africa with the exception of the soft plastic mask with inflatable rim that was imported from China at less than R50 per unit (Sanne, 2021). The initial cost estimate for the ventilators was R20 000 per device but by the end of the production run this was brought down to less than R5 000. The CSIR manager responsible estimates that the per device cost could be brought down to as low as R800 (ibid.).

SAVE-P is a Durban-based non-profit organisation (NPO) started by local businessman Justin Corbett and Dr Greg Ash. The SAVE-P consortium incorporated manufacturers located in Cape Town, Pinetown, Durban, Midrand and Alberton, consisting of MCR Manufacturing, Reef Engineering, Bosch, Executive Engineering, Rhomberg Instruments, Dowclay Products, ISO Health SA, Pegasus Steel, NAACAM, AFRIT, Corruseal, New Age Medical Supplies, Aveti and Non-Ferrous Metal Works (Patel, 2020). The team was assembled with the assistance of the National Association of Automotive Component and Allied Manufacturers, which played an important role in the early stages of the SAVE-P effort.

Production of the South African ventilators began in late July 2020 and, on 24 August 2020, the Solidarity Fund handed over the first units to the Charlotte Maxeke Johannesburg

Academic Hospital (Patel, 2020). By November 2020, the CSIR had completed production of 18 000 Venturi-type CPAP devices and SAVE-P 2 000 blender-type CPAP devices at an average cost of R12 500 each (ibid.). The 20 000 CPAP ventilators were distributed to 69 public hospitals in all nine provinces of South Africa (Patel, 2020). Three hundred devices have also been produced by Sabertek on a commercial basis, of which some were exported to Malaysia and Namibia (Patel, 2020).

A number of key factors played a role in enabling the rapid development and production of the 20 000 ventilators. Firstly, SARAO played a decisive role through the development of the right specification and by not getting distracted or swayed by the many well-meaning opinions on what should be done. According to project participants, if changes were made to the specification, the timelines would not have been met. Secondly, both ventilator projects relied on expertise spread across a multitude of organisations including companies, research institutions and universities. In the CSIR case, this collaboration, which extended to manufacturing and sourcing of parts, was facilitated by the Product Lifecycle Management (PLM) software provided by Siemens. In some cases, the extensive collaboration was facilitated by existing collaborative relationships such as the DSI's Centres of Competence programme in which various institutions collaborate towards common innovation goals. The laboratory facilities and advanced equipment at various universities such as the University of Cape Town and the Central University of Technology were critical. Thirdly, the development process was enabled by close collaboration between the developers and SAHPRA which provided regulatory oversight, and which showed itself to be sufficiently agile to effectively function under emergency conditions. Fourthly, the availability of funding from the Solidarity Fund ensured that financial constraints did not hamper the development or production process. Lastly, clinicians played a key role in the development process and complemented the technological know-how of the technology partners during design, development, and testing phases.

5.3. South African Solidarity Fund

The South African Solidarity Fund was established in March 2020 as a public benefit fund to support the national health response, contribute to humanitarian relief efforts and mobilise South Africans in the fight against COVID-19. It is a platform for financial contributions from industry, Government, and the general public, with the funds administered by Old Mutual on a pro bono basis. The fund's health response has included the following investments/allocations:

- R884M for the procurement and distribution of PPE, R50M of which is earmarked for locally produced PPE
- R409M to support COVID-19 testing by the NHLS
- R23M for surge testing by academic laboratories
- R282M for ventilators, R250M of which was for the National Ventilator Project
- R402M for the procurement of essential equipment for hospitals and field hospitals
- R283M down payment to COVAX to secure access to vaccines and R50M co-funding for the Sisonke study on the J&J vaccine in healthcare workers

The fund, which totals in excess of R3 billion, has had a substantial impact to date on several dimensions, including health, humanitarian and behavioural (https://solidarityfund.co.za/).

5.4. South African Pandemic Intervention and Relief Effort Fund

The South African Pandemic Intervention and Relief Effort (SPIRE) Fund is a public benefit fund created by FirstRand through a R100 million donation by the FirstRand Foundations, FNB and RMB following the first COVID-19 lockdown in 2020. SPIRE was created to assist Government and other social partners in responding to the healthcare challenges of COVID-19 in South Africa and Africa.

The fund has three focus areas, namely: healthcare capacity, care homes and food. In terms of healthcare capacity, the fund focussed on adding capacity to the public healthcare system through the purchasing of additional essential medical equipment and protective wear as well as extending medical facilities in a long-term sustainable manner such as ICU extensions.

Some of the achievements of the SPIRE fund include:

- Expanding ICU capacity by more than 100 beds across several public sector hospitals.
- Supplied high-flow oxygen equipment to regional hospitals.
- Contributed to the acquisition of 200 ventilators.
- Manufactured more than 300 000 cloth masks through the Maskathon initiative.
- Distributed food parcels.
- Supported donor-dependent retirement homes (>150 vulnerable care homes).
- FirstRand procurement platform provision to Solidarity Fund (enabled the procurement of over R100 million PPE purchases).
- Developed and shared advanced epidemiological models focused on containing the spread of COVID-19 and ensured optimal allocation of resources.
- 94 000 N95 masks and 100 000 UltraGene COVID-19 kits distributed to various hospitals and facilities.

Specific projects enabled by SPIRE included Intubox, Ubuntu Beds and additional ICU capacity for Charlotte Maxeke Hospital.

Intubox is a Perspex box created to protect hospital workers and critical care patients from airborne virus-spreading particles during intubation, extubation or aerolising procedures during treatment of acutely ill COVID-19 patients. Intubox enables treatment that requires barrier enclosure protection for hospital workers. Beyond COVID-19 it has application in the treatment of patients with multidrug-resistant or extensively drug-resistant tuberculosis or viral haemorrhagic fever such as Ebola. The Intubox was developed by aeronautical engineers from Paramount Group, the African-based aerospace and technology company, and emergency doctors at the Charlotte Maxeke Academic Hospital in Johannesburg. SPIRE funded the development

of a prototype and the manufacture of the first 500 boxes, 375 of which were donated to Charlotte Maxeke hospital. "The creation of the Intubox demonstrates the world-class medical, biomedical, engineering and financing skills that exist in South Africa, and shows/proves that medical needs, employment and production capacity can all be activated simultaneously in new ways to solve new challenges, especially if funding is immediately available" (FirstRand, 2021).

In a separate development, Nissan and UP's Faculty of Health Sciences developed a similar solution called **INTUbox** which was deployed at the Steve Biko Academic Hospital (tent and isolation) and the Tshwane District Hospital (University of Pretoria, 2020).

5.5. SAMRC-DSI-TIA Investments in Local COVID-19 Diagnostics

It became evident early on in the pandemic that global supply of COVID-19 diagnostics would be an issue, especially for low- and middle-income countries. In response, the SAMRC brought together key local partners from Government, academia and industry to support the development and scale up of local reagents and point of care tests for SARS-CoV-2, with the intention of reducing reliance on international supplies and offering rapid and robust alternatives that can produce results before patients leave the site of testing. Based on guidance received from the National Health Laboratory Services (NHLS), the SAMRC, DSI and TIA jointly ran a request for applications (RFA) to identify suitable projects for funding, expediting the SAMRC's RFA, peer review, selection and approval processes to make the first awards within 6 weeks of release of the RFA. A total of 7 grants were awarded across a range of organisations, including science councils (the CSIR and Mintek), universities (UCT), and small enterprises (Medical Diagnostech (Pty) Ltd, Diagnostic Aptamer Technologies-Aminotek (Pty) Ltd, and GKnowmix (Pty) Ltd), 3 aimed at delivering fully localised production of reagents and controls for RNA extraction and RT-PCR and 4 aimed at developing rapid point of care tests for COVID-19.

The awards built on substantial developments and investments already made by the awardee institutions and companies in these products as they rapidly applied their existing capacity and expertise to developing solutions for COVID-19. They also harnessed the infrastructure, capacity and expertise resulting from previous public investments in technology platforms, projects and facilities in the country. This meant that the projects were not starting from scratch and that the SAMRC grants would essentially "help them to the finish line" to deliver products in as short a time as possible.

The investments, totalling R14 million, saw an unprecedented collaboration between the public, private and academic sectors, with awardees working closely with Business 4 South Africa, the IDC and the DTIC to plan for downstream scale up and manufacturing of the resulting products. The first product resulting from these investments, an RT-PCR test for SARS-CoV-2 developed by the CSIR and CapeBio, was approved by SAHPRA in August 2021 and a second product, the Medical Diagnostech rapid antigen test, was approved by SAHPRA in December 2021. A further 4 of the products have either been submitted or will shortly be submitted to SAHPRA for approval.

5.6. COVID-19 Add-On Survey

During September and October 2020, MDMSA, under joint auspices with the SAMRC, carried out a short online survey to capture the experiences of medical devices stakeholders with respect to COVID-19 as an adjunct to the present survey. Invitations to participate were sent to SAMRC stakeholders and MDMSA members and other parties who had been involved in COVID-19 response activities. Sixty-four responses were received, of which the major proportion (47%) were from medical device manufacturers. Further details on the composition of the sample for the COVID-19 add-on survey are provided in Figure 70.

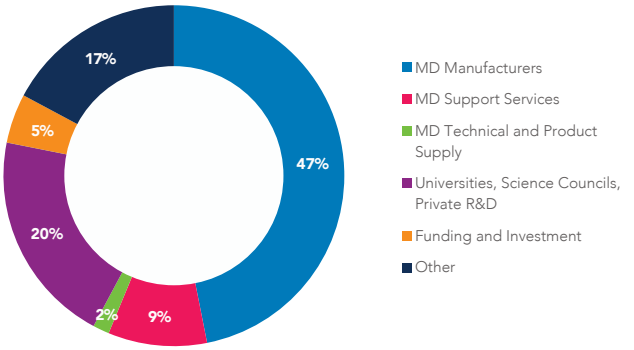


Figure 70: COVID-19 add-on survey participants

Figure 71 displays the results of several propositions that were put to the respondents. In all cases, the majority of respondents agreed with the proposition, confirming challenges experienced by the medical device sector during the pandemic, which ranged from inadequate specification of requirements, limitations to the current medical device life-cycle process, finding suitable partners, and uncertainty on demand to the timeous availability of grant funding.

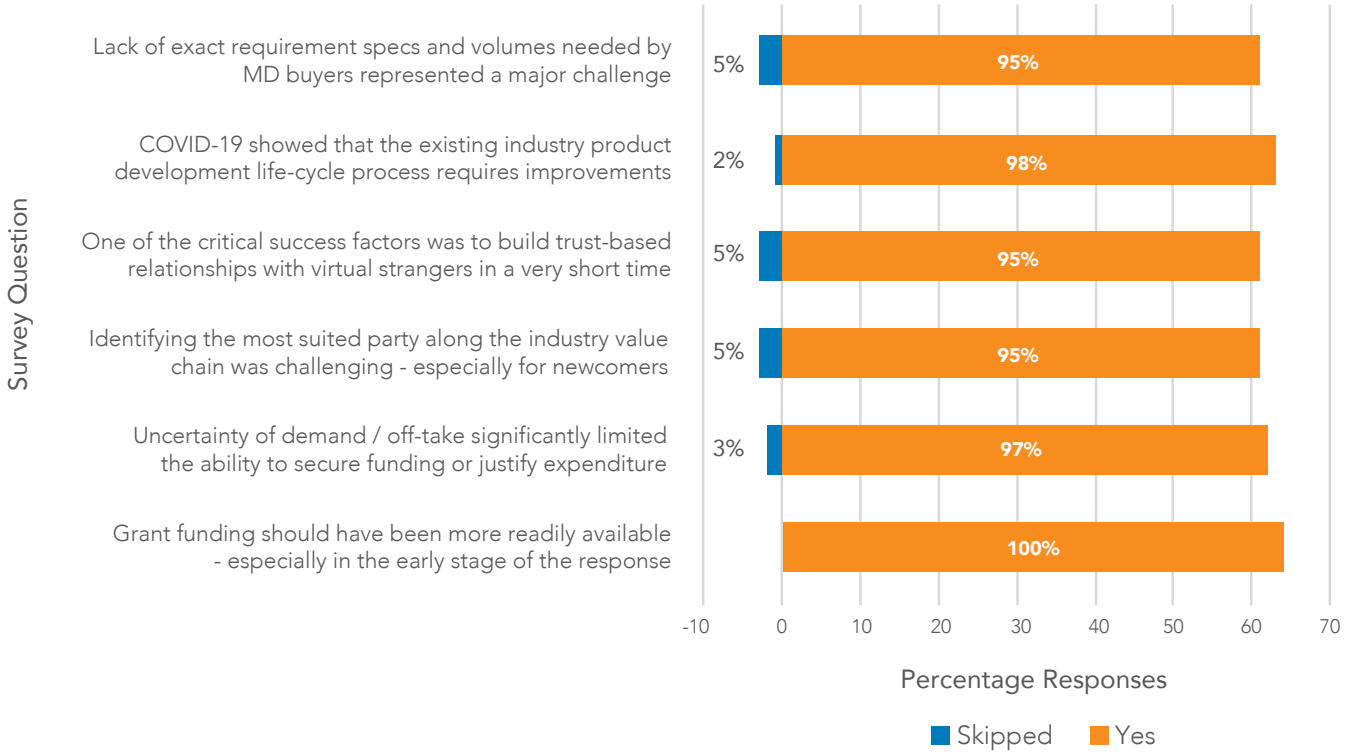


Figure 71: Insights from the COVID-19 experience survey

As indicated in Figure 72, more than half the respondents had to work with more than 50% new parties during the pandemic, which points to the need for agile mechanisms to identify new partners during a crisis.

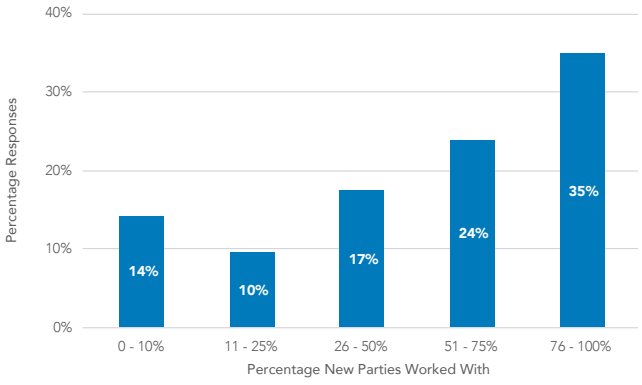


Figure 72: Percentage of respondents that had to work with new parties during the pandemic

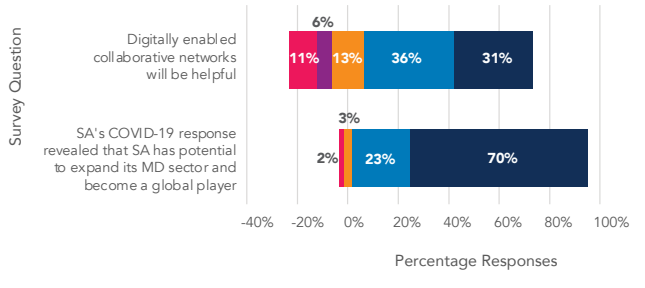


Figure 73: South Africa's potential as MD player revealed and the need for digitally enabled collaborative networks

Eighty-three percent of the respondents agreed or strongly agreed that South Africa's COVID-19 response revealed latent potential to expand the sector and for South Africa to become a global player in the field (see Figure 73). Most (67%) of the respondents agreed or strongly agreed that digitally enabled collaborative networks will be helpful in realising this potential.

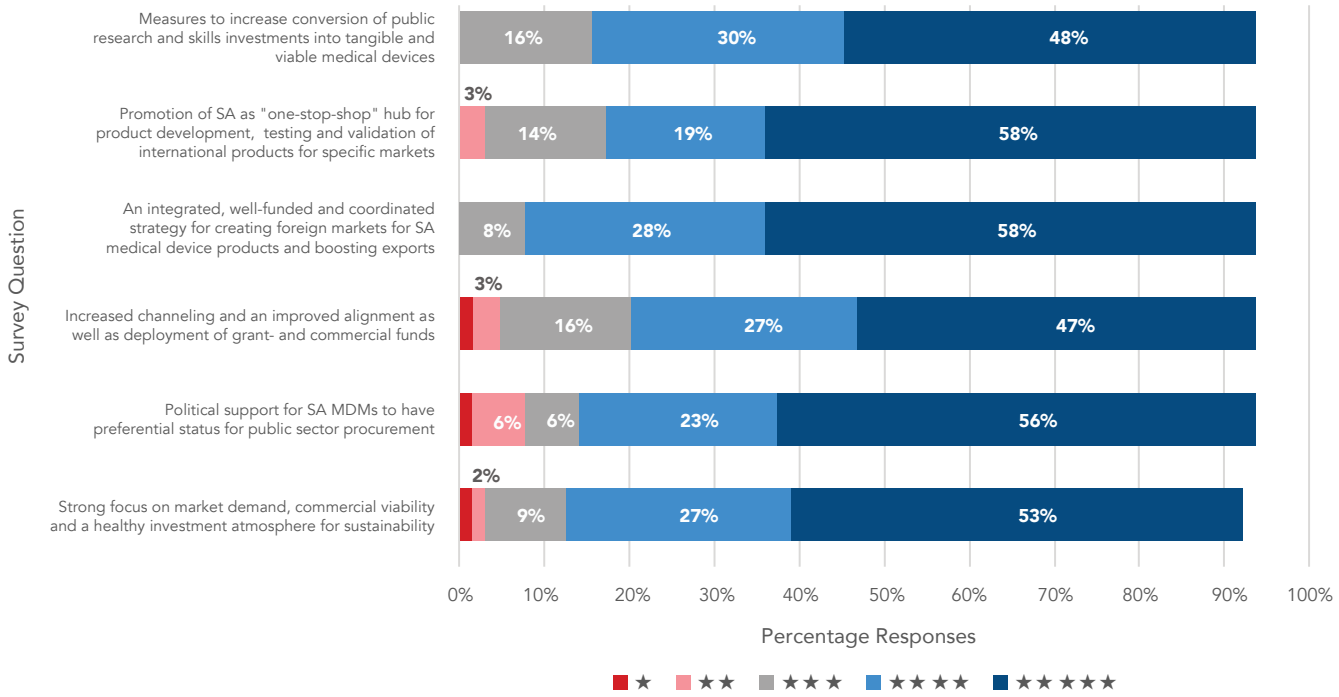


Figure 74: The importance of various measures to strengthen the MD sector

Respondents were asked to assess the importance of various possible interventions to strengthen the medical device manufacturing sector, the results of which are displayed in Figure 74. The respondents supported all the proposed measures which included a strong focus on market demand, commercial viability and a healthy investment atmosphere for sustainability, political support for SA MDMs to have preferential status for public sector procurement, increased channelling and an improved alignment as well as deployment of grant- and commercial funds, an integrated, well-funded and coordinated strategy for creating foreign markets for SA medical device products and boosting exports, promotion of SA as "one-stop-shop" hub for product development, testing and validation of international products for specific markets and measures to increase conversion of public research and skills investments into tangible and viable medical devices.

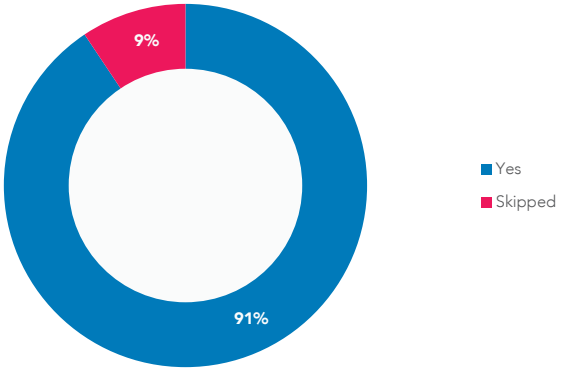


Figure 75: Respondents' familiarity with Internet-enabled digital platforms/portals

As indicated in Figure 75, most respondents are familiar with Internet-enabled digital platforms/portals and, as indicated in Figure 76, support the functionalities proposed in the survey. Overall interest and support for such a platform is summarised in Figure 77.

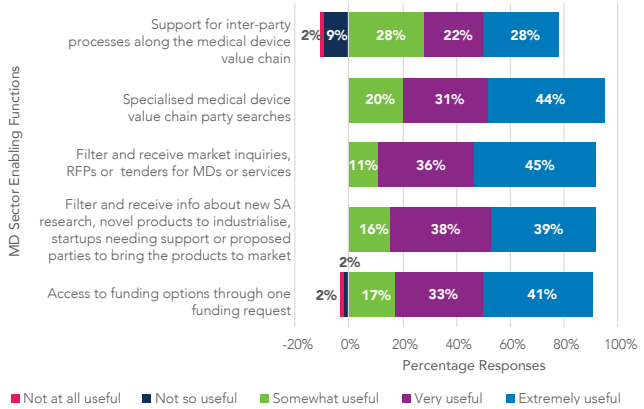


Figure 76: Respondents' views on digital platform functions

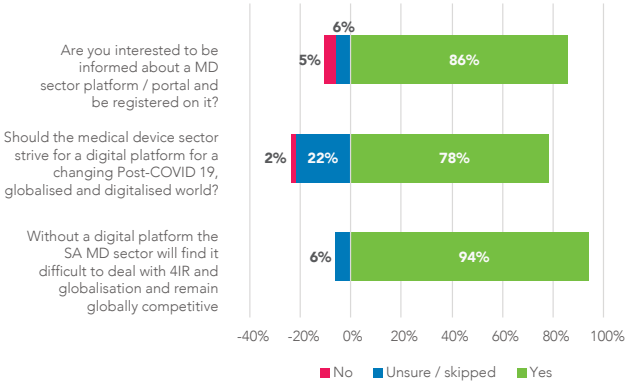


Figure 77: Respondents' views on a MD platform/portal

Views related to South Africa's COVID-19 pandemic response

Respondents were asked to share their insights and thoughts related to South Africa's COVID-19 pandemic response. Two thirds of the respondents provided responses which covered a range of topics including their view on the effects of COVID-19 on the medical device sector, the value and potential of the sector that the pandemic response revealed, weakness in the sector, regulatory challenges, funding issues, a need for greater agility amongst all role players, the threat of corruption, and requirements for fair and transparent processes even during times of emergency. Various suggestions were made on Government policy measures required to nurture and strengthen the industry. Respondents indicated a need for greater cohesion and coordination amongst role-players. Stronger direction setting for the industry and the publication of health care system requirements were seen as key enablers of local innovation and manufacture.

Regarding the effect of the COVID-19 pandemic, one respondent described it as "an accelerator of existing momentum". Another described it as "the perfect storm that should have shown that South Africa has the capability to manufacture the most basic of PPE items for our own market but alas, we had to import over 90% of all of our disposable PPE products". The same respondent stated that industry had been advocating measures to support the industry to no avail and that they doubted that much would change in terms of Government support of local manufacturers. Other respondents commented on missed opportunities such as setting up of a very high throughput RT-PCR testing platform with the ability to test 200 000 samples per day.

Some respondents commented positively regarding collaboration amongst stakeholders, indicating that they were "very impressed with collaboration of all across various sectors". Strong trust relationships were seen as essential to counter bureaucracy in the public and private sector. One respondent commented that "independent groups worked well (WhatsApp etc.) but there were big issues in Government response". Collaboration was seen as critical in the face of a global threat such as the COVID-19 pandemic, which had shown that the digital environment was more resilient than traditional ways of working. Digital collaboration is therefore seen as the most sustainable way forward. According to respondents, the medical device sector needs to be at the forefront in future and Government should defer to the MDMSA for support.

Some respondents saw the medical device value chain as disjointed and stated that it would be useful to make visible South Africa's manufacturing capabilities and capacity in response to public health emergencies such as the COVID-19 pandemic. South Africa currently lacks a central database of manufacturers and there is a lack of data and information sharing between the private and public sector.

Respondents were of the view that South Africa retains a capable and undervalued manufacturing sector and lamented the fact that the country did not have the ability to manufacture simple but essential medical devices. Respondents' rationales for domestic manufacture of basic medical devices included both the risk presented by the breakdown in global supply chains during pandemic lockdowns and rapid changes in demand which had led some countries to stop or delay the export of health products, including medical devices, and the potential for job creation that domestic manufacture presents. Respondents believed that South Africa had the "skills and capability to re-build what we have lost. We need co-operation across the supply and demand chain to re-build our capability and capacity. Not everything can be driven by cost-competitiveness". Regional alignment was seen as a potential enabler of adequate market demand to sustain the industry outside emergency situations.

Respondents indicated that, during a national emergency, "the speed of response is crucial – from all parties (but especially the regulatory boards), otherwise the moment has gone". A consistent theme in the responses was the need for transparent and regularly updated central coordination of requirements to make clear the demand for various personal protection items and medical devices throughout the pandemic. One respondent commented that "Ideally, a product requirement landscape should have been the first port of call – working out what was needed (product specs) and what resources were available (within hospitals for use, raw materials, and manufacturing capabilities). These requirements, if then made publicly accessible, would enable manufacturers to quote and be assessed for their fitness of purpose". Similarly, "a database of existing manufacturers and their capabilities (type, volume, qualifications, etc.) would have been useful" to enable agile communication of specifications and receiving of offers. The information held by various industry associations was not optimally leveraged in the country's pandemic response. The lack of adequate coordination measures and demand and supply information caused both unnecessary duplication and overlooking of critical capabilities in specifying requirements and sourcing solutions. In summary, the pandemic highlighted the need to have an emergency protocol in place for pandemic and other national emergencies to enable resilient responses in future. It also highlighted that the ability to secure certain medical devices and other health products was a strategic ability akin to strategic national defence capabilities.

Respondents commented that a national emergency presented particular funding requirements. Whilst manufacturers appreciate the need for due diligence based on a solid business case, it was felt that the "pandemic required agile funding sources prepared to take risks and that health/social outcomes can dominate the immediate business case evidence requirements in such a crisis situation". At the same time, it was difficult for companies to make the necessary investments with no clear returns, resulting in slow decision making. Respondents felt that "going forward, a mix of funding sources along the innovation chain are needed but, if these remain siloed, the paperwork side is a major obstacle to moving a product through to market in an agile way. Funding needs to be available in a streamlined way from one stage to the next".

Several respondents commented on regulation and the national regulator, SAHPRA. These comments need to be seen against the background of a fledgling institution that had to operate under lockdown conditions and that was in the process of implementing a new regulatory regime for medical devices when the pandemic hit. Whilst some respondents felt strongly about the need for strong regulation to ensure quality and safety, and to prevent unfair competition from possibly sub-standard imports, several expressed frustration with issues such as the regulators' efficiency, lack of adequate capacity and communication

issues. Nevertheless, one respondent commented that "for many manufacturers the daunting world of MD Regulation has always been a strong deterrent, but I think the experience has shown that the obstacle is possibly not insurmountable". Respondents felt that resourcing of regulatory and related testing and assessment capability was required of SAHPRA, but not limited to the regulator only.

Respondents made several comments that relate to the type of industrial policy measures that are required to support the medical device industry and the need for coherence between public health procurement and industrial policy measures. Protection from imports was motivated by national strategic considerations and it was felt that some products deserved commanding a premium over imports. On a related note, there were calls for greater regulatory scrutiny of companies importing PPE. One respondent commented that "It is essential that we stop the deindustrialisation of South Africa. We are very fortunate to have maintained a world class manufacturing base within the auto sector and much of this capability can be used within the bio-medical sector". Another felt that there was a "need to create a common goal and ability to create a trust-based relationship with an equitable value share arrangement". It was felt that South Africa has the necessary skills and expertise to improve and fast track its re-industrialisation process. This will require reforms at Governmental level as well as industry levels and will require industries to work together to achieve a cohesive objective of becoming an exporting nation. Amongst the policy measures that were suggested were labour market reforms to allow employers more flexibility. South Africa will also need to make strategic choices on areas where it can compete in the global medical devices landscape. One respondent urged that this should be based on the country's unique strengths and domestic and regional market requirements.

One respondent commented on corruption surrounding the supply of personal protective equipment which they found "staggering" but "par for the course at the moment". Another complained that awarding of grants was not transparent and, in their case, unfair.

Views on the most important issues to be addressed

Respondents were asked to provide their opinion on the most important issues to be addressed in dealing with the COVID-19 pandemic and the future of the industry. Responses from 45 out of 64 respondents addressed similar themes to that of the question above and touched on the need to align supply and demand by making requirements visible, regulation, industrial policy measures, funding requirements, coordination amongst role players, and strengthening domestic capability.

Respondents repeated the need for visibility of requirements and suggested that there needed to be a centralised information hub that could address this as well as provide information on regulatory and other processes. Respondents felt that it was critical that commercial viability is established early in the process and that compliance and certification must be embedded throughout the process, from idea to de-commissioning. Projects must be moved from academia or science councils to the commercial domain much earlier to enable productising and commercialising of innovations.

Closely aligned to the need for visible requirements, respondents emphasised the need for collaboration between all players in the value chain, including players who compete in the marketplace. It was suggested that this could include common manufacturing facilities to increase throughput and reduce capital outlays, while still allowing competition in the market. Japanese models of supply chain co-operation were cited as examples of such an approach. Coordination is required on all aspects: research, development, production, regulation, funding, and procurement. Government-private sector collaboration and sharing of national supply and demand data and information is seen as key. Respondents expected that both Government and the private sector needed to support locally manufactured medical devices. Better collaboration and more complementary work are required – South Africa cannot support "20 ventilator manufacturers for example". One respondent suggested "getting the industry coordinated with a portal to link all players and move us into a new 4IR enable medical device sector".

Respondents supported appropriate regulation, stating that the medical device industry should not be overregulated to allow South Africa to compete in the international market. Administrative procedures must "not strangle innovation, production, exploration of markets and regulation. The political will to do this, and to remove stumbling blocks, will be important for success". Respondents called for a transparent, dexterous, and efficient regulatory processes. One respondent claimed that it was "quicker and cheaper to have devices certified in other jurisdictions and use reliance for local approval". Enforcement was seen as critical to combating importation of medical devices by non-licensed operators. Investment in the regulator's capability was required including through cooperation with strong regulators such as those in the European Union. In addition, industry personnel need to be skilled in regulatory issues and local testing and approval support need to be strengthened

In terms of policy interventions, respondents called for a national strategy and alignment of stakeholders (including various Government departments). Increased labour market flexibility was required to enable risk taking related to new device production where success is not certain. Other interventions called for included upskilling of people with technical qualifications, investments in quality management and regulatory skills and easy to access and well managed financial support for eligible medical devices projects. Some respondents proposed that the local industry needs protection from Chinese imports through the BBBEE rating system and preferential public procurement. A respondent stated that "the number one issue that needs to be addressed is that Government agencies that drive import substitution and localisation need to give clear guidance by means of a policy document that they are committed to funding local manufacturers and then, critically important, to procuring these quality products from these local manufacturers. This will create jobs, retain income in the country and satisfy the creation of BEE entrepreneurs and innovators". Support for global partners with advanced expertise or market access may be required in some cases.

Respondents cited various issues around funding that needed to be addressed, including grant/seed funding for new developments (including very early stage funding), availability of venture capital funding, and funding of industry R&D. Funding agencies need to have sufficient market and technical competence to assess the merit of funding applications which, according to the respondents, is not currently the case for agencies like TIA.

Respondents indicated that Government support is crucial for enabling the local landscape, "maintenance of our remaining technology base", and building a testing and certification ecosystem.

Lastly, the intellectual property of local manufacturers needs to be protected from unscrupulous international players who copy locally patented medical devices without any sanction and sell these back to South Africa, and "corruption needs to be dealt with faster and more efficiently".

Summary and Analysis

6. Summary and Analysis

6.1. Summary of the South African Medical Device Landscape

This medical device landscaping survey, although it has limitations, has added to the existing understanding of the medical device innovation and manufacturing ecosystem in South Africa. It has revealed important aspects regarding the size and shape of the manufacturing sector, the country's knowledge generating capacity manifested in its STI institutions and the support infrastructure available to manufacturing companies and STI institutions. Importantly, it has reaffirmed and added to the previous knowledge base around the key gaps and barriers that have been hampering the growth of the sector. The implications of the survey results, seen together with the results of the literature study, are analysed in section 6.2. In this section a summary is provided of the main features of the medical device landscape revealed by the survey, which are depicted graphically in Figure 78 in terms of the innovation value chain.

Firstly, South Africa has at least 136 medical device manufacturing companies with substantial diversity in terms of size, turnover, products produced and levels of R&D expenditure. The following clusters of broadly similar companies can be identified:

- **Young, high-tech companies** developing and producing sophisticated medical devices for the domestic and export market in fields such as molecular diagnostics, orthopaedic implants, diagnostic imaging and audiometers. Companies in this cluster spend a significant portion of their revenue on R&D and in some cases are only now making their first sales. Some of these companies are spin-outs from STI institutions and many collaborate with local and international STI institutions.
- **Medium to large high-tech companies** producing sophisticated medical device capital equipment and implants for the domestic and export market. Companies in this cluster also tend to continue to invest in R&D.
- **Large commodity producers** producing large volumes of commodity products such as class A and B consumables for the domestic market with some exports to neighbouring countries. Companies in this cluster do not invest significantly in R&D.
- **Small commodity producers** producing smaller volumes of specific lower technology products mainly for the local market. Companies in this cluster do not invest significantly in R&D.

These clusters are further reflected in the manufacturers' facilities and use of quality management systems as well as in their propensity to collaborate with STI institutions.

A clear geographic pattern can be distinguished with the WC, Gauteng and KZN being the three provinces containing the bulk of the industry. Gauteng and the WC are home to the small and medium to large high-tech manufacturers whereas KZN's industry is largely focussed on the production of commodities.

Secondly, several STI institutions are active in medical device related R&D and innovation activities, although to widely varied extents. The University of Cape Town and University of Stellenbosch, both in the WC, stand out in terms of the number of patents, technology disclosures, spin-off companies and products in the market. Of the science councils, the CSIR is the most active in the field. Although many universities, including universities of technology have relevant capabilities, except for the two aforementioned universities, knowledge generation and associated entrepreneurial activity in the medical device field by STI institutions is low.

A range of companies provide support services to the industry, including technical services, quality improvement and regulatory compliance. The list of support organisations surveyed was not comprehensive and did not include the regulatory consultants. The three public institutions included focus on funding of innovation and commercialisation activities.

The study has revealed that the medical devices innovation and manufacturing sector has:

- activities in each of the major product life-cycle stages from basic and applied research through to experimental and product development, manufacture and scale-up, although these are currently not well aligned;
- the necessary role-players (e.g. idea creators, innovators, pre-clinical and clinical scientists, research engineers, established MDMs, STI institutions, support companies and distributors) required to enable end-to-end MD solutions through the product life-cycle but these are not suitably networked for collaboration and optimal outcomes;
- sophisticated processes, tooling, expertise and competent role-players whose needs for optimal value addition are seldom met;
- access to digital collaboration technologies such as Product Life-Cycle Management (PLM) software although these are not optimally used with no common "lingua franca"; and
- access to funding, especially early-stage funding, for the product life cycle, although only a small fraction of these investments is converted into sustainable products at huge loss to the country.

Given the level of imports and the associated trade imbalance, it is fair to say that, as a country, South Africa has not realised its full potential as a medical device manufacturer. The sector continues to be hampered by the same broad issues identified in previous surveys dating as far back as 2008, including regulatory, funding, market access, skills shortages and lack of cohesion. The country's medical device value chain is disjointed and not optimal for maximum value creation. Despite past investments and resources deployed, the country is unable to achieve a sufficient return on investment for optimal growth from a variety of perspectives such as commercial sustainability, viable products, creation of jobs and forex earnings. This stems from the ongoing barriers and the inability of parts of the sector to secure sufficient and sustainable demand-side income and profit to maintain the process and re-invest in new product offerings for optimal growth.

The COVID-19 pandemic has highlighted key gaps in the innovation value chain and local product offerings and the need to urgently address these to increase self-sustainability. On the other hand, the crisis revealed the potential of an emergent, collaborative model capable of developing and manufacturing products at short notice and demonstrated that funds could be rapidly raised and deployed, expertise could be pivoted to new priorities and all participants in the innovation and manufacturing ecosystem could collaborate towards a common goal.

The MDM sector is blessed with most of the necessary components for a vibrant and growing industry, but lacks cohesion, a vision, roadmap and ability to integrate these into a streamlined and well-oiled "system" with the maximum returns for the participating companies, the country and its people.

Figures 78 and 79 summarise the characteristics of the South African medical devices landscape, and the barriers, gaps and challenges hampering the sector, respectively.

Discovery (Research)		Development and Pre-commercialisation				Commercialisation		Market Development
Basic Research	Applied Research Design and Engineering	Technology Development	Technology and Market Validation	Product/Process Development	Small Scale Manufacturing	Market Entry/Launch	Market Development	Business Growth
Academia – Public Sector Innovators								
11 Universities, 4 Universities of Technology & 5 science councils active in MD innovation – Innovation capabilities across the value chain and technology and product areas Small MD innovation output per institution except for a few pockets of excellence (SU, UCT, CSIR)					60% of STIs partner with industry on MD projects (student supervision, contract research and co-development) – 50% of these with local partners, 30% international partners, 20% both			
82 patent families (granted and/or pending) on MD technologies		35 MD IP transactions in the last 10 years – 18 to spin-out companies of the institution, 12 to local companies and 5 to international companies			20 successful medical device spin-out companies from 8 different institutions			
	Industry – SA Medical Device Manufacturers							
		At least 136 MDM manufacturers – mostly Gauteng, W Cape and KN – 73-76% are small (<50 staff and/or <R50M T/0) 53% of MDs manufacture consumables – predominantly Class A; Strong manufacturing capability especially component assembly and testing, OEM manufacture, machining and injection molding and mostly in metals and plastics Decline in new MDM company formation since 2014						
	77% of MDMs are active in R&D but 51% of these spend <5% of T/O on R&D and 33% spend 0% Small, young, hi-tech start-ups are R&D intensive – concentrated in the WC and Gauteng			27 (41%) MDMs collaborate with industry, 15 with SA companies, 5 international and 7 both		US$200-US$300 million manufacturing output in 2021 Manufacturing capacity is presently underutilised- 79% could increase production by 40%		
	32 (48%) MDMs have collaborated with STIs locally and abroad in 54 separate collaborations over the past five years (15 international) 11 (17%) MDMs have co-developed products with or licensed products from STIs-73% of these in SA 74% of MDs are collaborating (or interested in collaborating) with SA STIs to develop their own innovations			79% of MDMs are SAHPRA registered 51% have ISO 13485; 24% in process 64% have CE mark for products and 29% FDA 23% Members of SAMED, 23% MSMSA; 14% both		Primary markets: 1. domestic private sector; 2. domestic public sector 3. International (Africa, Europe, the Middle East and North America) >50% of MDs manufactured in SA are exported (R3.1 billion in 2019) Largest exports to SADC 68% of MDMs are export ready		
Government & Support Agencies								
Support companies mostly support MD companies & a few support STIs- funding, regulatory advice, product design and development, manufacturing support, R&D and technical services, collaboration and mentoring, support for clinical/field trials Available incentives, funding and support mechanisms include the following:								
R&D Tax Incentive			TIA Commercialisation Support Fund		MCEP			Industrial Procurement
				Technology Venture Capital (TVC)				
	TIA Tech Development Fund			Seda Technology Programme (STP) – Incubation				
	THRIP				Industrial Development Corporation support instruments			
		Support Programme for Industrial Innovation (SPII)			Strategic Partnership Programme (SPP)			STP-Quality & Technology Transfer
	TIA Seed Fund				Enterprise Incubation Programme (EIP)			
		MeDDIC Seed Fund and Localisation of MD Manufacture						
	SAMRC-DSI Strategic Health Innovation Partnerships (SHIP)							
						Market		
						SA MD market in 2021 was estimated at R21 Billion – One of the largest MD markets in Africa & Middle East 0.3% of global MD market – 90% supplied by imports		

Figure 78: Characteristics of the South African Medical Devices Landscape

Discovery (Research)		Development and Pre-commercialisation				Commercialisation		Market Development
Basic Research	Applied Research Design and Engineering	Technology Development	Technology and Market Validation	Product/Process Development	Small Scale Manufacturing	Market Entry/Launch	Market Development	Business Growth
Activities across the value chain are not well-aligned and not suitably networked for collaboration and optimal outcomes – lack of synergy or synchronisation between academia and industry								
Academia – Public Sector Innovators								
					High development costs – cost of introducing the technology far outweighs the return on investment			
• Lack of critical mass of R&D capacity • Incentives for higher education (subsidy system) do not favour technology outputs • Lack of product development expertise and skills • Lack of understanding of regulatory requirements, products and markets				• Difficulties in transitioning research ideas into commercialisable products, including clinical trials, regulation and scale-up • Technologies do not address market needs – poor feedback and communication from end users • Technologies too early in development and many fail				
Lack of quality management systems & regulatory consideration – compliance is not intrinsic to the development process					• Struggle to find suitable industrial partners for development and manufacture • Few seasoned entrepreneurs and limited business skills to take opportunities forward			
MD research is underfunded in academia and industry	**Industry – SA Medical Device Manufacturers**							
	STI collaboration: long timelines; cumbersome processes and university bureaucracy; effort involved in clarifying expectations; perception that local collaborations may be more expensive than international; need for clear IP ownership and knowledge transfer agreements; lack of trust and lack of continuity						Competition with non-compliant manufacturers	
				• Low absorptive capacity of the industry for new innovations • Few manufacturers and few ISO 13485 certified facilities		Small SA market therefore costly international registration needed		
	Regulatory: long turnaround times from SAHPRA; inadequate in-house regulatory skills and experience; discrepancies between international and local regulatory requirements; high cost of certification in SA and especially foreign jurisdictions (e.g. CE marking); lack of certified auditors in South Africa; lack of financial assistance or slow processes in obtaining Government assistance; lack of information and uncertainty around the regulatory process and standards					• Export barriers: foreign customs tariffs, high production costs, high export costs, regulatory compliance, fluctuations in the exchange rate, transport costs of raw material and inconsistent customs timelines • High cost of compliance with BBBEE requirements		
					• Lack of local manufacturers of raw materials for medical devices • Expensive equipment and raw materials for MD fabrication/3D printing			
Government & Support Agencies								
• Shortage of funding throughout the MD development value chain, especially proof of concept and pre-commercialisation funding, investments in technology companies and gaps between first round funding and later stage funding • Current project-based and short-term approach to funding makes it difficult to build sustainable long-term pipelines for innovation and critical mass • Administrative hurdles and delays in approval with public funding instruments • Lack of awareness of R&D tax rebate and other incentives								
Inadequate Government support for the MD sector, including policies or regulations on public procurement that promote local industry competitiveness						**Market**		
						• Dominance of imports, especially cheap consumables • Inefficient public procurement and payment • Lack of access to local markets – limited uptake by the Department of Health (e.g. through preferred local procurement) • Uncertainty regarding the approval of new technologies for use in State health facilities • Corruption and fly-by-night companies, resulting in poor quality of locally available equipment and lack of adequate post-sales support		

Figure 79: Summary of barriers, gaps and challenges in the South African medical devices sector

6.2. The South African Medical Device Technological Innovation System

In this section, the results of the synthesis of existing literature and the survey of the medical device innovation and manufacturing sector are analysed based on the TIS framework. The literature review and survey confirmed that South Africa has capability in all the elements of a functioning TIS. However, deficiencies in the TIS prevent the country from realising the opportunity to reduce the considerable trade imbalance, enable localisation and increase revenue from exports. In addition, more vibrant local innovation and increased manufacture will address the need for sovereign and strategic capabilities during times of crisis when global supply chains can break down, impacting negatively on health outcomes.

In Table 12, a high-level assessment of the South African medical device technological innovation system functions is provided. The status of each function is summarised, and high-level recommendations to address gaps and challenges and exploit opportunities are proposed, based on responses from stakeholders and author inputs. Given the challenging economic times in the country and the competitiveness of this industry globally, the recommendations build on existing strengths and selection criteria should emphasise excellence and high performance.

Table 12: Assessment of the South African Medical Device Technological Innovation System functions and recommendations to address gaps and challenges and exploit opportunities

Status	Proposed Interventions
Knowledge development	The breadth and depth of the knowledge base and how that knowledge is developed. Various types of knowledge serve as inputs for innovation, including that generated from R&D and different learning processes (i.e. learning-by-doing, learning-by-using).
Significant technical expertise for medical device innovation exists in the public research sector, including pockets of excellence at selected universities and science councils; however, the contributions from other STI institutions are low	Build on and strengthen pockets of excellence and existing technology and innovation platforms to transform them into world class centres of excellence and promote and facilitate the broader utilisation thereof by innovators in the public and private sectors in South Africa Promote these capabilities internationally to attract foreign collaborators and private sector partners Promote and facilitate STI institution – industry linkages to facilitate the conversion of this expertise into new products Identify new/emerging technology areas and capabilities requiring special attention and support Increase overall investments in public sector medical devices R&D to enhance knowledge generation and expand the participation of other STI institutions Establish mechanisms to transfer knowledge and skills in medical devices R&D between existing centres of excellence and other STI institutions, especially the historically disadvantaged institutions
Insufficient investment in R&D by local companies by global standards	Incentivise industry to grow R&D investments in medical devices Invest in relevant skills development in industry for product design and development Promote and facilitate access to resources for R&D (see Resource Mobilisation)
Knowledge diffusion	The exchange of information through networks of diverse actors in a heterogeneous context where R&D meets Government, competitors, and the market. Here policy decisions (standards, long term targets) should be consistent with the latest technological insights, and, at the same time, R&D agendas should be affected by changing norms and values. Network activity can be regarded as a precondition to learning by interacting.
Insufficient linkages, information sharing and collaboration between STI institutions (knowledge producers) and industry (knowledge users) and within the medical devices industry	Promote and enable stakeholder alignment, cooperation and collaboration within the sector Establish mechanisms to strengthen links between industry and STI institutions and enable agile cooperation, such as joint funding instruments, exchange programs, a medical devices portal and a coordinated cluster hub
Weak absorptive capacity in industry for new medical device innovations	Increase public funding of industry R&D to improve absorptive capacity for new technologies and enable differentiation through higher value add Invest in relevant skills development in industry for product design and development Design and implement mechanisms for enhancing synergy and synchronisation between academia and industry Design and implement mechanisms to enhance the appropriateness and readiness of technologies from academia for uptake by industry Consider establishing a "white label" manufacturer for single devices that would not sustain an independent company

Status	Proposed Interventions
Weak international linkages	Incentivise and support international collaboration and partnerships by STI institutions and industry, with a focus on inward technology transfers and local commercialisation Brokering of bilateral R&D cooperation with targeted countries
Entrepreneurial experimentation and up-scaling	The testing of new technologies, applications, and markets whereby new opportunities are created, and a learning process unfolds. This includes the development and investments in artefacts such as products, production plants, and physical infrastructure.
Low levels of domestic innovation and production – domestic market mainly served by imports	Establish mechanisms to increase the local development and production of medical devices to replace imports, focusing on higher value products
Declining rate of new company formation and a shortage of seasoned entrepreneurs to take new product opportunities forward	Increase awareness and visibility of local and international business development opportunities, including the potential for import replacement, exports and opportunities arising from public procurement in the medical devices space Design mechanisms to identify and pair up experienced entrepreneurs with strong networks with new technologies/products Increase awareness of support instruments for new business development and job creation Invest in entrepreneurial skills development Increase incubation support to the STI institutions and new start-ups
Guidance of the search	The incentives for organisations and actors to enter the technological field. These incentives may stem from visions, expectations of a growth potential, policy instruments, technical bottlenecks, etc. In an early phase, it also includes how prime movers manage to define technological opportunities and make it attractive for other actors to enter the field
No national strategy for development of the medical devices sector	Collaborative development of a vision and roadmap for the medical devices sector, facilitated by the DTIC and DSI, ideally through the Healthcare Products Master Plan process, with substantial participation by industry and academia Identify and support niche areas where South Africa can build competitive advantage Increase the role of Government in directing efforts to specific disease focus areas, enabling technologies, inputs and components Promote and enable stakeholder alignment and collaboration in the sector towards a common goal
Lack of cohesion, coordination and awareness of incentives and support mechanisms	Align national policies, regulations, standards and guidelines relating to medical devices Collectively design new incentives and support mechanisms for the sector within Government and amongst support organisations Raise awareness of available incentives and support mechanisms amongst industry and academia
Lack of clarity on public health requirements in industry and STI institutions	Make requirements (demand) and capabilities (supply) for medical devices more visible Identify customer unmet needs across the care continuum at all levels of delivery Increase participation of the public health sector in priority setting and product design and development Provide platforms for enhancing interaction between the developers, manufacturers and end users, particularly in the public sector

Status	Proposed Interventions
Market formation	The factors that stimulate the emergence of markets for new products. These include articulation of demand from customers, institutional change, and changes in price and performance of the products. Market formation normally goes through different stages, i.e. demonstration projects, niche market, and mass markets.
Unexploited domestic market, especially in the public sector, dominated by imports – public procurement underutilised	Increase participation of the public and private health sectors in priority setting, articulation of demand, and product design, development and testing Increase visibility of health care system requirements and promote Government-private sector collaboration and sharing of national supply and demand data and information Ensure sustainable and efficient public procurement to stimulate innovation and manufacturing, including improving turnaround and payment Introduce designation for public procurement and earmark strategic medical devices for local manufacture Design and implement incentives for the private sector to buy locally manufactured medical devices Introduce/increase import tariffs for medical devices that can be sourced locally Increase the focus on preparing markets for the adoption of new products, including health technology assessments, implementation studies, policy and practise changes and change management
Domestic market is small by global standards but likely to grow due to NHI and rising middle class Many local medical device companies have a foothold in several export markets of which Africa, Europe, North America and the Middle East are currently the most important Poor integration into global supply chains	Develop export markets for SA medical device products aligned with SA strengths (Africa and global where SA has competitive products) through an integrated, well-funded and coordinated strategy Promote regional cooperation to increase market opportunities for SA medical device products Develop and implement deliberate strategy to position SA science, technology and niche manufacturing capabilities into global value chains Increase access to information on foreign markets, such as market intelligence, barriers and routes to market and how to establish international distribution
Resource mobilisation	The extent to which actors within the TIS are able to mobilise human and financial capital, as well as complementary assets such as products, services, network infrastructure, etc.
Funding for parts of the innovation value chain lacking and limited awareness of existing funding instruments, including the R&D tax rebate	Increase funding to academia for product development, including incentives to collaborate with the private sector and historically disadvantaged institutions Public funding of industry R&D to increase absorptive capacity and to stimulate market led innovation and import replacement Increase funding for regulation and certification in the public and private sectors Increase funding for infrastructure, equipment and expansion in the private sector Create a more favourable investment climate for foreign direct investment in the sector Improve marketing of existing funding instruments and access to information thereon
Public resources viewed as difficult to access by some medical device companies	Reduce bureaucratic hurdles and turnaround times for accessing public funds while maintaining rigour and responsible investments
Skills gaps in academia and industry, especially with respect to product development and regulation	Invest in relevant skills development, especially regulatory skills, product design and development, product life cycle management and entrepreneurship

Status	Proposed Interventions
Legitimation	The social acceptance of the technology and the actors and compliance with relevant institutions. Legitimacy is formed through conscious actions by organisations and individuals, and this process may often be complicated by competition (and lobbying) from adversaries defending existing technologies and regimes.
Limited cohesion in the sector, limited awareness of the sector strengths, capacity and opportunities and low international profile of the sector and players	Establish a national medical device sector brand and awareness and increase its international profile through closer cooperation between industry and Government and show casing capabilities and success stories Establish mechanisms to increase cohesion, cooperation and collaboration between all medical device stakeholders Develop a collective vision and roadmap for the medical devices sector through the Healthcare Products Master Plan
Two industry bodies, SAMED and MDMSA, a Western Cape Medical Devices Cluster and the MeDDIC cluster hub provide legitimisation, support and platforms for coordination and cooperation	Promote increased membership of and participation in SAMED, MDMSA, and the Western Cape Medical Devices Cluster Support strengthening of the existing cluster in the Western Cape and institutionalise clusters in Gauteng and KZN – link institutions/companies in the Free State and North West with the Gauteng cluster and those in the Eastern Cape with the KZN cluster Utilise SAMED, MDMSA, the Western Cape Medical Devices Cluster and MeDDIC to drive sector-wide interventions in a coordinated approach
Significant progress on the regulation of medical devices in South Africa; however, substantial regulatory barriers remain with respect to implementation, timelines, costs and knowledge	Enhance the legislative and regulatory framework, policies, processes and capacity in support of local medical device manufacture and export Capacitate SAHPRA to allow for rapid and efficient device registration and certification Government investment in the accreditation of a local certification body to reduce costs and increase efficiencies and implement measures to enable international recognition of SA certification Facilitate international certification, including increasing the capacity to provide internationally certified product testing locally Establish a forum or think tank of experience to provide regulatory support Increase regulatory training, assistance and access to information for both the public and private sectors
Lack of trust/confidence in local products	Promotion of local products by Government and other sectors Increase involvement of end users in the product design, development and testing to enhance uptake
Demonstrated ability to rapidly respond to emergency product needs when required	Establish an emergency protocol for pandemic and other national emergencies to enable resilient responses in future Learn from the COVID-19 experience and entrench new mechanisms for agility, cooperation and rapid response

Conclusions and Recommendations

7. Conclusions and Recommendations

This landscaping report has contributed to an enhanced understanding of the South African medical device landscape, focussing on technological innovation, product development and manufacturing. The report consists of a review and synthesis of a number of pre-existing industry reports, a survey of medical device manufacturers, STI institutions and support companies and organisations, a review of the impact on the medical device sector of South Africa's response to the COVID-19 pandemic and an analysis of the aforementioned data using the technological innovation systems framework.

The report confirms and elaborates findings of previous reports. South Africa has a relatively small but diverse medical device manufacturing sector concentrated in three provinces, the WC, Gauteng and KZN, with a small footprint extending to the Eastern Cape and Northwest Provinces. South Africa has a significant and growing medical devices market that is mainly served by imports. The growing domestic and regional African markets and a track record of exporting a number of high value niche products to developed world markets indicates significant potential for increasing manufacture of medical devices in the country. This is supported by an existing manufacturing base and a small number of strong universities and science councils working on medical device technologies and applications.

Whilst South Africa has produced several world class medical device innovations that are sold to international markets, the inescapable fact is that the domestic market is dominated by imports which supply up to 90% of the over R21 billion domestic demand. This is served by supply chains consisting of foreign suppliers in established relationships with local distributers, some of which have been operating in the country for many decades. The domestic manufacturing industry is caught between two major forces. Firstly, the high-end portion of the market is dominated by an incumbent regime of global companies headquartered in developed countries. Secondly, the lower end of the market is dominated by a similarly powerful incumbent regime that supplies cheap imports from China, India and other developing countries. The entire medical device ecosystem is also plagued by ongoing challenges that have slowed the growth of the sector and the development and uptake of local innovations.

Table 13 lists the key recommendations that have emerged from this survey, based on prior reports, responses from stakeholders, the TIS evaluation and author inputs. For some of these, specific interventions are proposed to address gaps and challenges and exploit opportunities; however, most require further discussion to flesh out more detailed interventions, as recommended below.

Table 13: Recommendations for enhancement and growth of the Medical Devices Sector and Ecosystem in South Africa across the value chain

Academia – Public Sector Innovators
Basic Research – Applied Research, Design & Engineering – Technology Development
• Build on and strengthen pockets of excellence and existing technology and innovation platforms to transform them into world class centres of excellence • Promote and facilitate broader utilisation of these capabilities by innovators in the public and private sectors in South Africa • Establish mechanisms to transfer this knowledge and skills to other STI institutions, especially historically disadvantaged institutions • Promote these capabilities internationally to attract foreign collaborators and private sector partners
Identify new/emerging technology areas and capabilities requiring special attention and support
Increase overall investments in public sector medical devices R&D, including incentives to collaborate with the private sector and historically disadvantaged institutions, to enhance knowledge generation and expand the participation of other STI institutions
Invest in relevant skills development, especially regulatory skills, product design and development, product life cycle management and entrepreneurship
Incentivise and support international collaboration and partnerships by STI institutions and industry, with a focus on inward technology transfers and local commercialisation
Product/Process Development – Small Scale Manufacturing – Market Entry/Launch
Establish mechanisms to promote and facilitate STI institution–industry linkages to facilitate cross-learning and the conversion of expertise into new products, for example through joint funding instruments, exchange programs, a medical devices portal and a coordinated cluster hub – linkages may include co-development, research contracts, testing, commercialisation, supervising postgraduate students, internships, and business mentoring of academia
Design and implement mechanisms to enhance the appropriateness and readiness of technologies from academia for uptake by industry, including, for example: • greater exposure of STI institutions to market requirements and involvement of end users in product design and development • skills development in academia with respect to product development and health technology/ medical devices life-cycle management under the relevant ISO standards • increased funding for late stage product development and testing

Increase awareness of and access to technology development and testing capabilities and high-tech fabrication facilities
Invest in local facilities and skills for auditing, laboratory and mechanical testing
Design mechanisms to identify and pair up experienced entrepreneurs with strong networks with new technologies/products
Invest in entrepreneurial skills development
Increase incubation support to the STI institutions and new start-ups
Consider establishing a "white label" manufacturer for single devices that emerge from STI institutions that would not sustain an independent company
Industry – Medical Device Manufacturers
Basic Research – Applied Research, Design & Engineering – Technology Development
Increase public funding of industry R&D to improve absorptive capacity for new technologies, enable differentiation through higher value add and stimulate market led innovation and import replacement
Incentivise industry to grow their own R&D investments in medical devices
Invest in relevant skills development in industry for product design and development, regulatory, product life cycle management and entrepreneurship
Promote and facilitate access to resources for R&D
Product/Process Development – Small Scale Manufacturing – Market Entry and Development – Growth
Establish mechanisms to increase the local development and production of medical devices to replace imports, focusing on higher value products, including: • engage with National Treasury and the National and Provincial Departments of Health to identify those medical devices currently imported into SA which can profitably be redeveloped and manufactured in SA • work with National and Provincial Departments of Health to set up processes to enable clear articulation of health technology needs that can be addressed by the innovation networks and local manufacturers • increase awareness of and access to technology development and testing capabilities • increase funding for medical device innovation across the value chain • invest in local facilities and skills for auditing, laboratory and mechanical testing • harness under-utilised manufacturing capacity to increase local medical device output • facilitate capital expenditure for infrastructure expansion, product diversification and productivity improvement
Nurture and support local high-tech MDM start-ups
Increase awareness and visibility of local and international business development opportunities, including the potential for import replacement, exports and opportunities arising from public procurement in the medical devices space
Increase awareness of support instruments for new business development and job creation
Address regulatory barriers, for example through the following interventions: • capacitate SAHPRA to allow for rapid and efficient device registration and certification • Government investment in the accreditation of a local certification body to reduce costs and increase efficiencies and implement measures to enable international recognition of SA certification • facilitate international certification, including increasing the capacity to provide internationally certified product testing locally • establish a forum or think tank of experience to provide regulatory support • increase regulatory and compliance training, assistance and access to information for both the public and private sectors
• Promote increased membership of and participation in SAMED, MDMSA, and the Western Cape Medical Devices Cluster • Support strengthening of the existing cluster in the Western Cape and institutionalise clusters in Gauteng and KZN – link institutions/companies in the Free State and North West with the Gauteng cluster and those in the Eastern Cape with the KZN cluster

Government & Support Agencies
Enhance and align the legislative and regulatory framework, policies, standards, guidelines, processes and capacity in support of local medical device manufacture and export
Collectively design new incentives and support mechanisms for the sector within Government (between the DTIC, DSI, National Treasury and NDOH) and amongst support organisations, such as TIA, IDC, SAMRC, incubators, etc.
• Raise awareness of available incentives and support mechanisms amongst industry and academia and improve access to information thereon • Reduce bureaucracy and turnaround times for the R&D tax rebate and other Government R&D funding and incentives while maintaining rigour and responsible investments
• Increase funding for R&D, regulation and certification in the public and private sectors • Increase funding for infrastructure, equipment and expansion in the private sector • Create a more favourable investment climate for foreign direct investment in the sector
Broker bilateral R&D cooperation with targeted countries
Market/End User
Make requirements (demand) and capabilities (supply) for medical devices more visible – promote Government-private sector collaboration and sharing of national supply and demand data and information
Identify customer unmet needs across the care continuum at all levels of delivery and increase visibility of health care system requirements
Increase participation of the public health sector and end users in priority setting, articulation of demand, and product design, development and testing to ensure uptake
Provide platforms for enhancing interaction between the developers, manufacturers and end users, particularly in the public sector
Ensure sustainable and efficient public procurement to stimulate innovation and manufacturing, including improving turnaround and payment
Introduce designation for public procurement and earmark strategic medical devices for local manufacture
Design and implement incentives for the private sector, including private health care groups and medical schemes, to buy locally manufactured medical devices
Introduce / increase import tariffs for medical devices that can be sourced locally
Increase the focus on preparing markets for the adoption of new products, including health technology assessments, implementation studies, policy and practise changes and change management
• Develop export markets for SA medical device products aligned with SA strengths (Africa and global where SA has competitive products) through an integrated, well-funded and coordinated strategy • Provide assistance with export readiness • Promote regional cooperation to increase market opportunities for SA medical device products • Facilitate improvements in international payments by having a dedicated team for this on the Financial Services Board with an understanding of the nature of the businesses • Develop and implement deliberate strategy to position SA science, technology and niche manufacturing capabilities into global value chains • Increase access to information on foreign markets, such as market intelligence, barriers and routes to market and how to establish international distribution
Facilitate adoption and promotion of local products by Government and other sectors

Sector-wide/All Stakeholders
Collaborative development of a vision and roadmap for the medical devices sector, facilitated by the DTIC and DSI, ideally through the Healthcare Products Master Plan process, with substantial participation by industry and academia – identify and support niche areas where South Africa can build competitive advantage
Establish a national medical device sector brand and awareness and increase its international profile through closer cooperation between industry and Government and show casing capabilities and success stories
Utilise SAMED, MDMSA, the Western Cape Medical Devices Cluster and MeDDIC to drive sector-wide interventions in a coordinated approach
Promote and enable stakeholder alignment, cooperation and collaboration within the sector to enhance linkages, information sharing and collaboration between STI institutions (knowledge producers) and industry (knowledge users) and within the medical devices industry through mechanisms such as: • increasing the visibility of expertise and technology capability within STI institutions and manufacturing capabilities and capacity of industry • develop an online portal to connect MDMs and innovators, foster collaboration, marketing, communication and information sharing • provide opportunities and platforms for regular, direct interactions and information sharing between stakeholders, for example through SAMED, MDMSA and MeDDIC • Utilise new digital technologies to facilitate linkages and cooperation • Publicise success stories of local innovations
Increase the role of Government in directing efforts to specific disease focus areas, enabling technologies, inputs and components
• Establish an emergency protocol for pandemic and other national emergencies to enable resilient responses in future • Learn from the COVID-19 experience and entrench new mechanisms for agility, cooperation and rapid response

The conclusion of this study is that most, if not all, of the building blocks are in place for a strong and vibrant medical devices industry in South Africa, driven by a combination of local innovations emerging from STI institutions, both high and low technology capabilities within existing companies to produce a diverse range of high quality products suitable for the local and export markets, and ongoing efforts to replace specific imports with locally produced devices. A bold strategy is required in which Government, the STI sector and the medical device manufacturing industry collaborate in a dynamic way to transition from an import-based incumbent regime to a new regime in which domestic innovation and production captures a far greater portion of the domestic demand. This strategy will require the use of instruments to destabilise the incumbents (through the promotion of competition), incentives to attract manufacturing investments and direct financial support for small, high growth companies.

Given the state of the country's economy, new public investment in the medical devices sector going forward will be hard to come by, requiring better tailoring and directing of existing funding instruments, creating better awareness of these instruments and making them more efficient. If the sector is to survive and prosper, it will need to shift from being largely supply-side ideation driven to demand-side commercially focused and maximise its current infrastructure to increase productivity. Academia and industry will need to become more efficient, effective and economical at converting ideas into products and solutions that are commercially viable and satisfy customers. Funding instruments that target both academic and industry R&D and innovation as well as manufacturing infrastructure expansion will be key in steering efforts in this direction.

Other levers for Government to enact the required changes include improving the overall legislative and policy frameworks to support local innovation and manufacturing, procurement for innovation and localisation, ensuring coherence between public health and industrial policy, regulation of competition, strengthened regulation, certification and quality management capability, specialised skills development, making health requirements visible to the R&D community and entrepreneurs and supporting regional cluster development. Key to this will be active facilitation of cooperation and collaboration between ecosystem players through digital platforms, opportunities for direct engagement and information sharing.

This effort should be managed as a transition that disturbs the existing regime, nurtures local niches and addresses the blocking mechanisms underlying TIS weakness and blockages. It is proposed that a dedicated task team and specialised working groups be established with representatives from academia, industry and Government. These groups must address the findings of this study and report on its progress using a clear monitoring and evaluation framework. The latter must have specific targets on economic value added, employment and import replacement with the target collective outcome being a highly innovative, cohesive and globally competitive medical devices sector.

References and Appendices

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APPENDIX I: Survey Participants

A. Medical Device Manufacturers (MDMs)

MDMs that Completed Both Parts A and B of the Survey	
ABC PLASTICS	K2Medical
Afrisky (Pty) Ltd	LifeAssay Diagnostics (Pty) Ltd
Akacia Medical (Pty) Ltd	Lodox
Akili Labs (Pty) Ltd	Logan Medical and Surgical
Altis Biologics	LRS Implants
Amana Medical (Pty) Ltd	Medical Diagnostec
Amtronix (Pty) Ltd	Medical Plant Africa (Pty) Ltd
ATTRI Orthopaedics	MEDIKA SA
Beier Drawtex Healthcare (Pty) Ltd	Medi-Safe Surgicals
BeSafe Paramedical	Metal Free Dental (Pty) Ltd
BSN Medical (Pty) Ltd	National Bioproducts Institute NPC
CapeRay Medical (Pty) Ltd	New Horizons Metals cc
Cerdak	Ophthalmica (pty) ltd
Champion Healthcare (Pty) Ltd	Orthopaedic Textiles (Pty) Ltd
Cranium (Pty) Ltd	Ortho-Sol Development
Diacoustic Medical Devices: StoneThree Pty Ltd	Praestet
Disa Vascular	PrimeSafe Pty Ltd
Dynamed Pharmaceuticals (Pty) Ltd	Radical Mobility Pty Ltd
ElectroSpyres	Respitek
Elite surgical Pty Ltd	Rob Dyer Surgical
eMoyo (Pty) Ltd	Royal Medical and Surgical Supplies
Endo Med	Safmed (Pty) Ltd
Ensemble Medical Manufacturers Pty Ltd	Shonaquip (Pty) Ltd
Evergreen Latex	Sinapi Manufacturing (Pty) Ltd
Executive Engineering (Pty) Ltd	Skin Rejuvenation Technologies
Gabler Medical (Pty) Ltd	Southern Implants (Pty) Ltd
Glycar SA (Pty) Ltd	Southern Medical
Grucox Medical (Pty) Ltd	Steriliser Technologies CC
Hospifurn	Suprahealthcare
Hourglass (Pty) Ltd 39 t/a Mobility Solutions	The BioLab
Hutz Medical	Ti-TaMED (Pty) Ltd
Illaymed (Pty) Ltd	Viva Medical
Infantrust	Xpella

MDMs that Completed Part B of the Survey Only

Draeger South Africa (Pty) Ltd

Harmony Dental Laboratory

IDT DIAGNOSTICS

Synthecon Sutures Manufacturing SA cc

UNITRADE 1032 CC

B. STI Institutions

Higher Education Institutions that Participated in the Survey

Cape Peninsula University of Technology

Central University of Technology

Free State University

Nelson Mandela University

Rhodes University

Stellenbosch University

Tshwane University of Technology

University of Cape Town

University of Fort Hare

University of KwaZulu-Natal

University of Pretoria

University of the Western Cape

University of the Witwatersrand

Vaal University of Technology

Walter Sisulu University

Science Councils that Participated in the Survey

Agriculture Research Council

Council for Scientific and Industrial Research

MINTEK

South African Nuclear Energy Corporation SOC Limited

South African Medical Research Council

C. Medical Device Support Organisations

Medical Device Support Organisations that Participated in the Survey

BioTech Africa

BMEC Technologies

CJN Consulting

Industrial Development Corporation

Skeg Product Development

South African Medical Research Council

Steri Solutions

Technimark

Technology Innovation Agency

TNMC Medical Devices

APPENDIX II: MDM On-line Survey Part A

Numerous stakeholders, including the Department of Trade & Industry (DTI), the Department of Science & Technology (DST), the National Department of Health (NDoH), the Medical Device Manufacturers Association (MDMSA), the South African Medical Research Council (SAMRC), through its Global Health Innovation Accelerator (GHIA), and the Technology Innovation Agency (TIA), have a shared mission to grow a vibrant local medical devices innovation and manufacturing ecosystem in South Africa by providing innovative, appropriate, affordable and sustainable health technology solutions to meet both local and global developing country needs. In order to achieve this, there is a need for a comprehensive landscaping analysis to be conducted to facilitate the seamless linkages between the medical device innovators (MDIs), mainly in universities and science councils, and the local medical device manufacturers (MDMs).

In order to achieve this, the SAMRC needs to collect information from the local medical device manufacturers to gauge their capacity and the support needed for collaboration with innovators leading to growth through the development, manufacture and market introduction of innovative medical device technologies. Similarly, the innovation sector (e.g. Universities and Science Councils) will be surveyed to determine what prototype medical device technologies already exist, the current capacity, platforms and R&D being undertaken and the ability to link these technologies and R&D endeavours with local manufacturers.

It is planned that the information gathered will enable the linkages between local medical device manufacturers, the medical device innovators and supporting entities, through an interactive, online portal available to all stakeholders and managed and facilitate by the SAMRC's GHIA. This portal is aimed at promoting and driving collaboration towards sector growth through market introduction of innovative and appropriate medical technologies.

What is the scope of the survey?

The survey has been compiled for the Medical Device Manufacturers (MDMs) to gauge their manufacturing capacity and opportunity to grow through development and manufacture of innovative technologies. This will inform the MDIs which technologies should be researched and developed and whether a need and market exist for these technologies.

It is hoped that the following voluntary survey will be completed by all MD manufacturing companies operating in South Africa for the benefit and growth of the sector as a whole through innovation and manufacture of needed and sustainable medical devices. Note that the intention is to collect data for the financial year ending in 2018. Please use this time period in responding particularly to the quantitative questions.

What about confidentiality of my company's information?

Information gathered by this survey will be held in confidence. Data, not in the public domain, will be anonymised and may be used for statistical purposes to compliment research. Permission will be obtained to publish, release, or disclose any information gathered on or identifiable with, individual firms or business units.

Who should complete this questionnaire?

The CEO or Managing Director of the company should complete this questionnaire. Where possible, we would prefer to have face-to-face meetings, but telephonic or on-line completion of the survey may be used.

How will the survey be completed?

MDMs that are willing to participate in this initiative should indicate by responding to the SAMRC email, indicating their preferred method for undertaking the survey and complete the link to Part 1 of the survey (http://ghia.jembi.org:8090/x/#fsEwM7v5).

Once we have received the completed Part 1 of the survey, we will schedule an appointment for the completion of Part 2 or will send you the link to Part 2 for completion of the survey online. We look forward to working with you in this exciting initiative.

Company Details		
Registered Name		
Trading As *(if applicable)*		
Business Type *(Pty) Ltd, CC, Partnership, Sole trader, other*		
Registration Number		
Physical Address		
Contact Person		
Tel No.		
Cell No.		
Email Address		
Website		
1. General Information about the Company		
1.1 In which year was your company established?		
1.2 What is your total number of permanent employees?	◯ 0-10	◯ 11-50
	◯ 51-100	◯ >100
1.3 What is your total number of casual employees?	◯ 0-10	◯ 11-50
	◯ 51-100	◯ >100
1.4 What is your current B-BBEE Level?	◯ 1	◯ 2
	◯ 3	◯ 4
	◯ 5	◯ 6
	◯ 7	◯ 8
	◯ Non-compliant	
1.5 Is your company a member of one or more Industry Associations?	◯ Yes	◯ No
Please provide the name of the Industry Association(s)		
1.6 Is your company part of a Membership Cluster such as the Western Cape Medical Devices Cluster, the Medical Devices Stakeholder forum, etc.?	◯ Yes	◯ No
Please provide the name of the Membership Cluster		
Would you be interested in being part of a Membership Cluster?		
1.7 What is your company's annual turnover?	◯ <R5m	◯ R5-12m
	◯ R13-50m	◯ >R50m
1.7.1 Is all or the majority (above 90%) of this income related to medical devices?	◯ Yes	◯ No

1.8 Does your company have any of the following Quality Management Systems in place?			
ISO 9001	◯ Yes	◯ No	◯ In-Progress
ISO 13485	◯ Yes	◯ No	◯ In-Progress
21 CFR 820	◯ Yes	◯ No	◯ In-Progress
Other	◯ Yes	◯ No	◯ In-Progress
Specify Other			

1.9 In which market do you currently sell your products?			
South Africa	◯ Private sector	◯ Public sector	◯ Aid agencies
International	◯ Private sector	◯ Public sector	◯ Aid agencies

1.9.1 Approximately what percentage of turnover accounts for:				
International Sales	◯ 0-25%	◯ 26-50%	◯ 51-75%	◯ 75-100%
South African Government Tender Sales	◯ 0-25%	◯ 26-50%	◯ 51-75%	◯ 75-100%
South African private sector and other sales	◯ 0-25%	◯ 26-50%	◯ 51-75%	◯ 75-100%

1.9.2 If your company sells products in international markets, which markets are you most active in? (Please select from the adjacent list and rank them in order of importance, i.e. number them from 1 upwards, with 1 being your most important or largest market)

Africa	Aus/NZ	China	Europe	Far East	India	Mid East	N. America	S. America
◯ 1	◯ 1	◯ 1	◯ 1	◯ 1	◯ 1	◯ 1	◯ 1	◯ 1
◯ 2	◯ 2	◯ 2	◯ 2	◯ 2	◯ 2	◯ 2	◯ 2	◯ 2
◯ 3	◯ 3	◯ 3	◯ 3	◯ 3	◯ 3	◯ 3	◯ 3	◯ 3
◯ 4	◯ 4	◯ 4	◯ 4	◯ 4	◯ 4	◯ 4	◯ 4	◯ 4
◯ 5	◯ 5	◯ 5	◯ 5	◯ 5	◯ 5	◯ 5	◯ 5	◯ 5
◯ 6	◯ 6	◯ 6	◯ 6	◯ 6	◯ 6	◯ 6	◯ 6	◯ 6
◯ 7	◯ 7	◯ 7	◯ 7	◯ 7	◯ 7	◯ 7	◯ 7	◯ 7
◯ 8	◯ 8	◯ 8	◯ 8	◯ 8	◯ 8	◯ 8	◯ 8	◯ 8
◯ 9	◯ 9	◯ 9	◯ 9	◯ 9	◯ 9	◯ 9	◯ 9	◯ 9

1.9.3 If your company does not sell products in international markets, are you export ready?	◯ Yes
	◯ No
1.9.4 Do you need assistance to become export ready?	◯ Yes
	◯ No
1.10 Have you registered your company with SAHPRA?	◯ Yes
	◯ No

APPENDIX III: MDM On-line Survey Part B

Registered Name or Trading Name					
2. Product Information					
2.1 Please select the medical device field(s) and the product class(es) which your medical devices fall under (you can select more than one):					
Consumables	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Electrodiagnostic apparatus	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Radiation apparatus	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Imaging parts and accessories	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Orthopaedics and Prosthetics	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Patient Aids: portable aids	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Patient Aids: therapeutic appliances	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Dental capital equipment	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Dental instruments and supplies	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Wheelchairs	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Hospital furniture	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Ophthalmic products	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Sterilisers	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Other					
Other as specified	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Other					
Other as specified	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
Other					
Other as specified	◯ Class A	◯ Class B	◯ Class C	◯ Class D	◯ NA
2.1.1 Please list all your medical device products in the market, if possible?					
2.1 Are your products certified/ registered/approved?	◯ Yes	◯ No	◯ In-Progress		
If 'Yes' and or 'In-process', indicate the type of certification/registration/approval					
◯ CE	◯ FDA	◯ SAHPRA			
◯ SABS	◯ Canada (MDL)	◯ Brazil (ANVISA)			
◯ Japan (PMDA)	◯ Australia (TGA)	◯ Other: Specify			
Other					
Other					
Other					

2.3 Would you be interested in assistance with regulatory compliance?	◯ Yes	◯ No
Comment		
3. Company Research & Development		
3.1 Does your company perform R&D?	◯ Yes	◯ No
What percentage of the company's turnover is used for R&D?		
Comment		
3.2 Have you ever applied for a tax-rebate for performing R&D?	◯ Yes	◯ No
3.2.1 Why Not?		
3.2.1 What issues have you encountered when applying?		
3.2.2 Was your tax-rebate application for performing R&D successful?	◯ Yes	◯ No
3.3 Have you applied for external funding for performing R&D (e.g. TIA, SPII, MRC, IDC, Grand Challenges, BMGF, etc)	◯ Yes	◯ No
3.3.1 Why Not?		
3.3.1 Were you successful in this application?	◯ Yes	◯ No
Comment		
3.4 Have you worked in the last 5 years on R&D with external parties in academia such as universities or science councils?	◯ Yes	◯ No
Please indicate whether these parties are in South Africa or abroad	◯ South Africa	◯ International
Comment		
3.5 Have you worked in the last 5 years on R&D with other companies?	◯ Yes	◯ No
Please indicate whether these parties are in South Africa or abroad	◯ South Africa	◯ International
Comment		
3.6 What aspects of the collaboration have been positive and/or worked well?		
3.6.1 Did you encounter any problems, such as IP ownership, lack of delivery, long timelines etc. (please elaborate)? Are there ways in which such collaborations could be improved?		
3.7 Have you ever licensed in or co-developed a technology or product from/with a research institution?	◯ Yes	◯ No

Was it a South African or international research institution?	◯ South Africa	◯ International
Comment		
3.8 Would you be interested in performing R&D with external parties?	◯ Yes	◯ No
Comment		
3.9 Would you be interested in manufacturing innovations developed by research institutions in South Africa?	◯ Yes	◯ No
Comment		
3.10 Would you be interested in collaborating with research institutions in South Africa to develop your OWN innovations?	◯ Yes	◯ No
Comment		
3.10.1 What type of working relationship would you be interested in having with research institutions?		
◯ Supervised postgraduate students	◯ Research Contracts	
◯ Co-development	◯ Other	
Specify other		
Please explain		
Would you be interested in having an online portal connecting you to innovators and vice versa?	◯ Yes	◯ No
Comment		
4. Company support		
4.1 Does your company use organisations that provide support in the form of funding and/or business advice and/or incubation services, and/or regulatory advice/assistance and/or technical advice/product development assistance etc':'?		
◯ Yes	◯ No	
Comment		
4.4.1 Which support organisations have you used?		
4.4.1 Would you be interested in using or getting information on them?	◯ Yes	◯ No
5. Manufacturing		
5.1 Please indicate which of the following activities your company is involved in and whether it is outsourced or done in-house		
Product Design	◯ Outsourced	◯ Done in-house
Indicate which company you outsourced to		
Product manufacture	◯ Outsourced	◯ Done in-house
Indicate which company you outsourced to		

Packaging	◯ Outsourced	◯ Done in-house
Indicate which company you outsourced to		
Sterilisation	◯ Outsourced	◯ Done in-house
Indicate which company you outsourced to		
Re-packaging/configuring of imported goods and labelling	◯ Outsourced	◯ Done in-house
Indicate which company you outsourced to		

6. Manufacturing Facility		
6.1 Does your manufacturing facility have a cleanroom?	◯ Yes	◯ No
6.2 Under which ISO Class does your manufacturing facility fall?		
◯ ISO 8	◯ ISO 7	◯ ISO 6
◯ ISO 5	◯ ISO 4	◯ ISO 3
6.3 Which of the following materials are used in your manufacturing facility?		
◯ Metals	◯ Non-ferrous metals	◯ Compounds
◯ Plastics	◯ Chemicals/ liquids	◯ Paper
◯ Non-woven textiles	◯ Knitted textiles	◯ Woven textiles
◯ Electronics	◯ Gasses	◯ Animal products
◯ Other		
Specify Other		

7. Manufacturing Capabilities				
7.1 Does your company have or make use of any of the manufacturing capabilities listed below?				
Machining	◯ Turning – mechanical	◯ Milling – mechanical	◯ Grinding – surface / internal / rotary	◯ Cnc equipment
	◯ Turning	◯ Milling	◯ Wire cutting / laser cutting / water jet / plasma cutting	◯ Pressing / bending / spot welding / punching
	◯ Manufacture of casting molds	◯ Manufacture of injection molds	◯ Manufacture of instrumentation	◯ Rapid processing / additive manufacturing / 3D printing
Plastics	◯ Injection molding	◯ Blow molding	◯ Plastic extrusion	◯ Vacuum forming
	◯ Over molding	◯ Casting	◯ Ultrasonic welding	◯ Chemical bonding
	◯ Laser welding	◯ Hot plate welding	◯ High frequency welding	
Chemical	◯ Blending	◯ Coating thermal	◯ Coating adhesive	◯ Coating microbial
	◯ Coating protective		◯ Cleaning	

Paper & Textiles, Films	◯ Converting	◯ Cutting	◯ Welding	◯ Forming
	◯ Coating / laminating			
Other	◯ Component assembly	◯ Material/ component testing	◯ OEM manufacturing	

7.2 Do you have any other in-house skills in the medical device innovation area not mentioned above that would be of benefit to the sector or to those seeking to collaborate with or contract your company?		
◯ Yes	◯ No	
Please elaborate		

8. Manufacturing Capacity			
8.1 How many work shifts do you have?			
8.2 What percentage of your manufacturing capacity is being utilised?	◯ <25%	◯ 25-49%	
	◯ 50-75%	◯ >75%	
8.3 If you were required to increase your production output by 40% would this be:	◯ Not possible	◯ Difficult	◯ Possible
Comment			

9. Company Expansion and Training		
9.1 Are you interested in expanding your operation through:	◯ Capital expenditure	◯ Financial assistance / investment
	◯ Productivity assessment	◯ Product development
	◯ Product diversification	◯ Other
Specify other		
Comment		

9.2 Would you be interested in training your production engineers/technicians if a course in Biodesign Health Innovation was offered here in South Africa?		
◯ Yes	◯ No	
Comment		

10. Barriers and Challenges
10.1 What are the main barriers and challenges that your company has encountered in its operation in the medical devices arena? Please include any barriers and challenges hampering your general operations, product development, product and/or facility certification, market entry, maintenance of market share etc.
10.2 Do you have any suggestions on how these barriers and challenges could be addressed and by whom (e.g. government, industry associations, academia, support agencies, etc.)?

APPENDIX IV: Questionnaire for Medical Device Innovators

The intention of this survey is to collect information from the South African research and innovation sector (e.g. HEIs and SETIs) involved in the research & development of medical devices (including diagnostics) so as to gauge their;

- research and development capacity and outcomes, and
- potential for linkages with local medical device (MD) manufacturing companies, other collaborators and support agencies towards sector growth.

For the purpose of this survey, Medical Devices (MD) include diagnostics, mobile applications, therapeutic devices, etc…, and are described as any apparatus, appliance, software, material, or other article to be used specifically for diagnostic and/or therapeutic purposes.

Institutional Information

Institution Name	
Institution Type (HEI, Science Council, Other)	
Department/Unit	
Physical Address	
Contact Person	
Tel No.	
Cell No.	
Email Address	
Website	

1. Medical Device R&D and Innovation Capacity

1.1	What capacity, expertise, platforms and infrastructure exist in your institution that could support or be applied to the MD innovation and manufacturing ecosystem (e.g. medical imaging, electronics, sensor technologies, digital health, nanotechnology, prototyping, product testing, etc.)?
1.2	Which academic departments are presently, or could be, involved in MD R&D?
1.3	Which researchers are presently, or could be, involved in MD R&D that you are aware of?

2. Medical Device R&D and Innovation Capacity

2.1	How many MD R&D and innovation projects are taking place at your institution that you are aware of?	0-5		>5
2.2	How many MD technologies have been disclosed to and/or worked on by the TTO in the last 10 years?	0-5	6-10	>10

2.3	How many patent families (granted and/or pending) do you have on MD technologies?		
2.4	How many MD IP rights have been assigned or licensed in the last 10 years for commercialisation to:		
	Spin-outs		
	Local companies		
	International companies		
2.5	How many MD products are or have been on the market in the last 10 years?		
2.6	How many spin-outs based on your MD technologies have been successful (i.e. are currently trading)?		
2.7	If possible, could you list your spin-outs based on MD technologies and indicate which of these are considered successful?		
2.8	How do you identify industry partners for your MD technologies?		
2.9	Are any of the MD research projects being conducted collaboratively with MD companies	Yes	No
	Local		
	International		
2.10	If 'Yes', what type of working relationship is in place with the companies?		
	Supervised postgraduate students		
	Contract research		
	Co-development		
	Other		
2.11	If 'Yes", could you list the companies that you are working with or have worked with?		
2.12	Who is normally involved in the regulatory process for the MD?		
	Your institution/TTO		
	External consultants		
	Industry partner		
	Other		
2.13	Have you received external innovation funding for any of your MD technologies? If yes, please can you provide details		

2.14	Have you made use of any other external support services for any of your MD technologies? If yes, please can you provide details

3. Medical Device R&D and Innovation Growth and Challenges

3.1	Would your institution be interested in closer collaboration with local medical device manufacturing companies and in what respect, e.g. joint research towards higher degrees, experiential training, tech transfer, etc.		
3.2	Would you support a web-portal linking the MD manufacturers with the innovators and MD R&D conducted in your institution?	Yes	No
3.3	What if any barriers to commercialisation of MDs has your institution encountered? (e.g. funding, regulatory, scale-up, trials, sales, other)		
3.4	Where, in your experience, are the gaps in the development and commercialisation of MD in South Africa?		
3.5	Would you share any of your successes in commercialisation of MD and why you believe they were successful?		

APPENDIX V: Questionnaire for Medical Device Support Organisations

The intention of this survey is to collect information from innovation and/or business support agencies, consultants and funders in South Africa who have previously, are currently and/or have the potential to provide support to those involved in the development, manufacture and/or implementation of medical devices (including diagnostics), including medical device companies, academic institutions or individual innovators, so as to gauge their;

- experiences to date in this regard,
- support capacity and offering, and
- opportunities for improving and/or expanding such support in the medical devices arena.

Organisational Information

Organisation Name	
Physical Address	
Contact Person	
Tel No.	
Cell No.	
Email Address	
Website	

Support Offering and Provision

1.	Have you previously or are you currently offering support or services of any kind to local companies, academic institutions or individual innovators involved in developing, manufacturing and/or implementing innovative medical device technologies?	Yes	No
	If 'Yes':		
1.1	Would you list the companies, academic institutions and/or innovators?		
1.2	What types of services or support have you provided to date?		
1.3	Please describe your experience with such engagements, i.e. have these been straightforward or challenging and why?		
2.	Are there any additional services or other support not listed above that you could/do offer to local companies, academic institutions or individual innovators involved in developing, manufacturing and/or implementing innovative medical device technologies?		
3.	What are the main challenges/barriers experienced by you when providing services or support to local companies, academic institutions or individual innovators or generally faced by such clients in developing, manufacturing and implementing innovative medical device technologies?		
4.	Can you suggest any key interventions that might address some of the challenges/barriers listed above or that you feel would benefit the medical devices innovation sector in general?		

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