MEDICAL TECHNOLOGY
MASTER PLAN

the dtic

Department:
Trade, Industry and Competition
REPUBLIC OF SOUTH AFRICA

2030 NDP

Towards full-scale **industrialisation** and inclusive **growth**
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MEDICAL TECHNOLOGY MASTER PLAN

SUPPORT FOR THE MEDTECH MASTER PLAN

The following government, labour and industry representatives commit as workstream leads to work with all social partners towards the Master Plan outcomes

Organisation	Signature
Department of Trade, Industry and Competition **(*the dtic*)**	
Congress of South African Trade Unions **(COSATU)**	
Medical Device Manufacturers of South Africa **(MDMSA)**	
South African Medical Technology Industry Association **(SAMED)**	
Southern African Laboratory Diagnostic Association **(SALDA)**	
Council of Scientific and Industrial Research **(CSIR)**	
National Hospital Network **(NHN)**	
Lenmed Group	
National Department of Health **(NDOH)**	

MEDICAL TECHNOLOGY MASTER PLAN

The Medical Technology (MEDTECH[1]) Master Plan aims to provide guidance for the public and private sectors to dedicate resources and time to strengthening the sector to put it on a growth trajectory. This process will involve developing agreements on areas for intervention, collaboration, and commitments for ongoing investment and development. Leadership and coordination for the implementation of the MEDTECH Master Plan will be provided through the establishment of an executive industry oversight committee comprised of representatives from government, industry, academia, and professional associations.

The plan outlines three key strategic objectives in line with a vision for the development of the South Africa MEDTECH industry over the period 2024–2035.

Vision 2035

A digitalised, integrated and cohesive ecosystem that enables, supports and encourages development, growth, and competitiveness of local medical technology value chains to produce reliable, safe, quality, and affordable MEDTECH for domestic and export markets.

Strategic Objectives

The key strategic objectives that will enable the achievement of the vision include:

- The growth of a proficient and competitive medical technology industry over the next three years, with special focus on the development of small and medium enterprises, that will supply domestic and international markets.
- The reduction of the industry specific trade deficit by 5% over the next five years.
- The generation of employment and development of technical skills with the aim of creating 1 000 new jobs over the next three years.
- To digitalise and use artificial intelligence to enable proficient regulatory processes.

[1] *The term MEDTECH includes medical devices and In Vitro Diagnostics as defined in the Medicines and Related Substances Act 101 of 1965 as amended.*

OVERVIEW OF MEDTECH IN SOUTH AFRICA

MEDTECH economic operators such as manufacturers, distributors and authorised representatives are governed by the Medicines and Related Substances Act 101 of 1965 and the related regulations and guidelines.

MEDTECH covers medical devices which includes in vitro diagnostic (IVD) devices. In South Africa MEDTECH provides for human and animal intervention, which does not follow international norms where animal interventions are legislated through the agriculture government structures.

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):

(a) 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

(b) which does not achieve its primary intended action [in or on the human body] 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;'

And

'IVD' (***in vitro*** diagnostic) means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

This broad definition includes a wide range of technologies used in the health practice system, from simple technologies such as syringes, disinfectants, bandages, and medical equipment and furniture to high-tech electromedical devices such as Magnetic Resonance Imaging machines (MRI), machine learning, computerised and software systems, and robotic surgery devices.

The definition of Manufacturer of Medical Devices and IVDs (as per Medical Device Regulations) is where an organisation places the product on the market in their name. Manufacture means: (a) A natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD at a physical address in South Africa before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his behalf by a third party; or (b) Any other person who assembles, packages, reprocesses, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD with a view to these being placed on the market under the natural or legal person's own name, apart from a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients.

The South African Health Products Regulatory Authority (SAHPRA) classifies MEDTECH into four categories based on the risk the products pose to patient or public health. Categories run from Class A devices, which present the lowest potential risk, to Class D devices, which present the greatest potential risk (see Table 1).

Table 1: Risk classification of MEDTECHs as stipulated by SAHPRA with an example for each category.

Classification	Level of Risk	Examples
Class A	Low Risk	Tongue depressor.
Class B	Low-moderate risk	Powered wheelchairs and electrotherapy devices.
Class C	Moderate-high risk	Diagnostic X-ray equipment and implantable hearing aids.
Class D	High risk	Implantable heart pacemakers and insulin pumps.

The classification levels of risk for IVDs are:

- Class A: no public health risk or low personal risk;
- Class B: low public health risk or moderate personal risk;
- Class C: moderate public health risk or high personal risk;
- Class D high public health risk.

The same classification rules apply to both commercial IVDs and in-house IVDs.

INDUSTRY OVERVIEW

The MEDTECH industry in South Africa has been identified as a potentially important contributor to economic growth and employment, whilst simultaneously enabling an improvement in health provision and quality of life for the South African population[2]. The industry is diverse across many materials, such as metals (implants), materials and chemicals (disinfectants), textiles (bandages), plastics (catheter), wood (prosthetics) and minerals or plants (wound products), plant, with products that range from simple (bandage) to complex (ultrasound machine). It includes local manufacturers that focus on producing a limited selection of products and local subsidiaries of large multinational corporations, and a range of small to medium-sized distributors offering a wide selection of MEDTECH products.

Market size

South Africa is one of the largest MEDTECH markets across Africa and the Middle East. The market size was estimated at R21 billion in 2021 and is projected to grow to R29.6 billion by 2025. The South African Government is the major purchaser of healthcare equipment and supplies, with the public healthcare sector comprising 7 901 facilities with 85 362 registered beds. The private sector has 524 facilities with 40 514 beds.

[2] *SAMRC MEDTECHs landscape report 2022*

The majority (76%) of companies in the South African MEDTECH sector are classified as small or micro enterprises, with turnover of between R10m – R50m per annum.

According to the Who Owns Who Report of 2020 South Africa comprises approximately 0.3% of the global market for MEDTECH. Local manufacturing is valued at between US$200m to US$300m p.a., of which more than half is exported. Local production is estimated to have grown by 3.5% from 2018 to 2019 and was expected (before the onset of the COVID-19 pandemic) to grow by 10.9% to US$132.1m in 2020. Growth in local manufacturing has been lower than expected, as a 2016 forecast projected that the total revenue for locally produced devices would grow by 8% to US$227.8m in 2019. Based on market value, 90% of the market is supplied by imports[3].

Company sizes

The majority (76%) of companies in the South African MEDTECH sector are classified as small or micro enterprises, with turnover of between R10m – R50m per annum. These companies supply approximately 80% of the locally manufactured MEDTECH products on the market. Medium and large companies with turnover greater than R50m per annum comprise 24% of the South African MEDTECH sector.

According to a survey conducted by the South African Medical Research Council (SAMRC), South Africa has at least 136 MEDTECH manufacturing companies. There is substantial diversity in the sector in terms of company size, turnover, products produced, and levels of research and development expenditure. The SAMRC report identifies the following clusters of broadly similar companies:

- Young, high-tech companies focusing on developing and producing sophisticated MEDTECH for the domestic and export market. These companies operate in fields such as molecular diagnostics, orthopaedic implants, diagnostic imaging, and audiometers and spend a significant portion of their revenue on R&D.
- Medium to large high-tech companies focused on producing sophisticated MEDTECH capital equipment and implants for both the domestic and export market, with some investment in R&D.
- Large commodity producers focused on producing large volumes of low-risk commodity products, primarily in class A and B, for the domestic market with some exports to neighbouring countries and 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.

In terms of the composition of the MEDTECH manufacturing sector in South Africa, companies producing predominantly "low risk" consumables comprise approximately 53%; companies producing orthopaedics and prosthetics comprise around 27%; producers of hospital furniture make up 14%; while companies producing electro-diagnostics comprise 9%, those producing sterilisers comprise 8%, and those producing dental equipment making up 5% of the sector[4].

Trade

In determining the trade patterns of MEDTECH the analysis below constructs a set of categories with four clusters and twenty-three specific product groups (Table 2).

[2] *SAMRC MEDTECHs landscape report 2022, SAMED annual report 2020*

[3] *SAMRC MEDTECHs landscape report 2022*

Table 2: MEDTECHs trade clusters and categories

Cluster 1: Diagnostic equipment	Cluster 2: Therapeutic equipment	Cluster 3: Surgical equipment	Cluster 4: Operational equipment
Cardiographs	Breathing devices	Dental equipment	Medical furniture
CT scan devices	Hearing aids	Gauze, bandages and related	Medical gel
Medical (and other specialist) cameras	Ophthalmic equipment	Gloves	Medical glassware and containers
MRI devices	Orthopaedic and prosthetic equipment		Other equipment
Other diagnostic devices	Other implanted devices	Syringes, needles and related	Sterilisation equipment
Ultrasound devices	Pacemakers	Disinfectants	IVD analysers, hardware
X-ray and radiography devices	IVDs	Catheters, IV lines	

Based on this classification, South Africa exported a total of R4,6 billion in MEDTECHs in 2022. South Africa also plays an important role as a distribution hub for MEDTECHs for the broader Southern African region, and these transition goods are included in the data. In 2022, about 19% of MEDTECH exports (equivalent to about R888 million) were purely transit trade. While this dampens the picture of South Africa's manufacturing for export, it does highlight the important role the country plays as a logistics and distribution hub. This could also be an opportunity for import/transit replacement with locally manufactured devices.

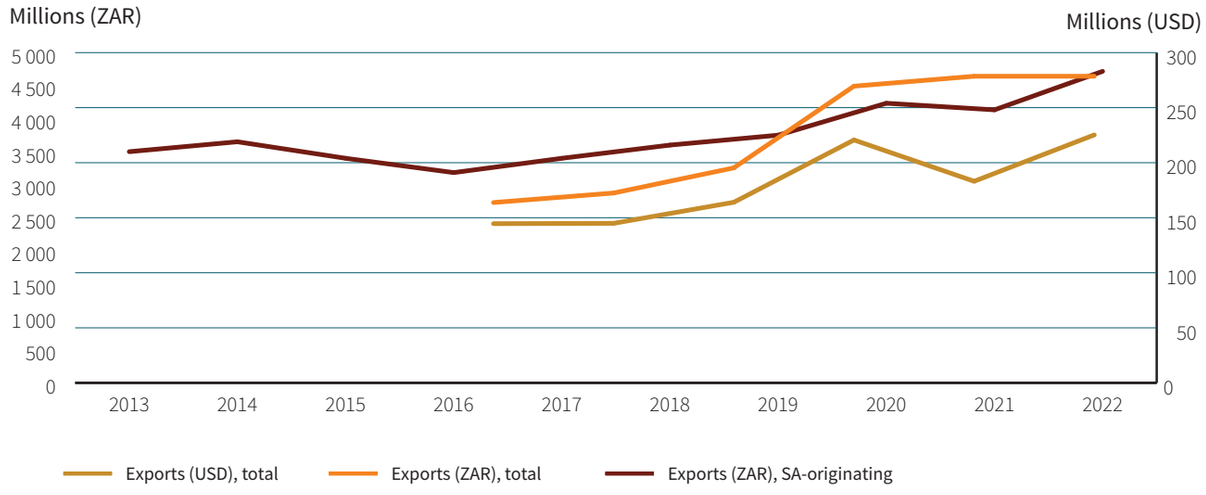


Figure 1: Exports of MEDTECHs from South Africa, 2013 - 2022 (Source: UN COMTRADE (USD data); SARS customs (ZAR data))

South Africa is also a notable exporter of basic MEDTECH (like gauze and syringes), alongside more advanced machinery like diagnostic equipment and prosthetics (Table 3). Based on South African Revenue Service (SARS) Customs data, South Africa's largest export category comprises "Other equipment" exports. This is a large generic category of the items being exported, and which introduces significant uncertainty in terms of the composition of the products included in the category (Table 3).

Table 3: Exports of MEDTECHs, by product and cluster, 2022 (Source: SARS customs)

Products	Exports 2022	Share of total exports 2022
Diagnostic equipment	**R1 241 653 129**	**33%**
Medical (and other specialist) cameras	R890 986 318	24%
X-ray and radiography devices	R204 788 070	5%
Other diagnostic devices	R78 691 495	2%
CT scan devices	R29 955 879	1%
MRI devices	R18 499 076	0%
Ultrasound devices	R11 714 466	0%
Cardiographs	R7 017 825	0%
Operational equipment	**R1 129 853 887**	**30%**
Other equipment	R943 296 616	25%
Medical glassware and containers	R112 311 266	3%
Medical furniture	R68 256 803	2%
Medical gel	R5 989 202	0%
Surgical equipment	**R777 588 858**	**21%**
Gauze, bandages and related	R464 967 458	12%
Syringes, needles and related	R160 179 268	4%
Dental equipment	R90 435 722	2%
Gloves	R34 801 481	1%
Sterilisation equipment	R27 204 929	1%
Therapeutic equipment	**R590 939 625**	**16%**
Prosthetics	R233 107 231	6%
Breathing devices	R124 590 771	3%
Ophthalmic equipment	R86 834 991	2%
Other implanted devices	R62 837 754	2%
Orthopaedic equipment	R48 582 500	1%
Hearing aids	R28 299 911	1%
Pacemakers	R6 686 467	0%
Grand Total	**R3 740 035 499**	**100%**

As shown in Figure 2 below, exports of MEDTECHs have grown by approximately 12% since 2018. Overall, most subsectors have grown, with prosthetics showing the most significant growth, followed by dental equipment and syringes & needles (Figure 2).

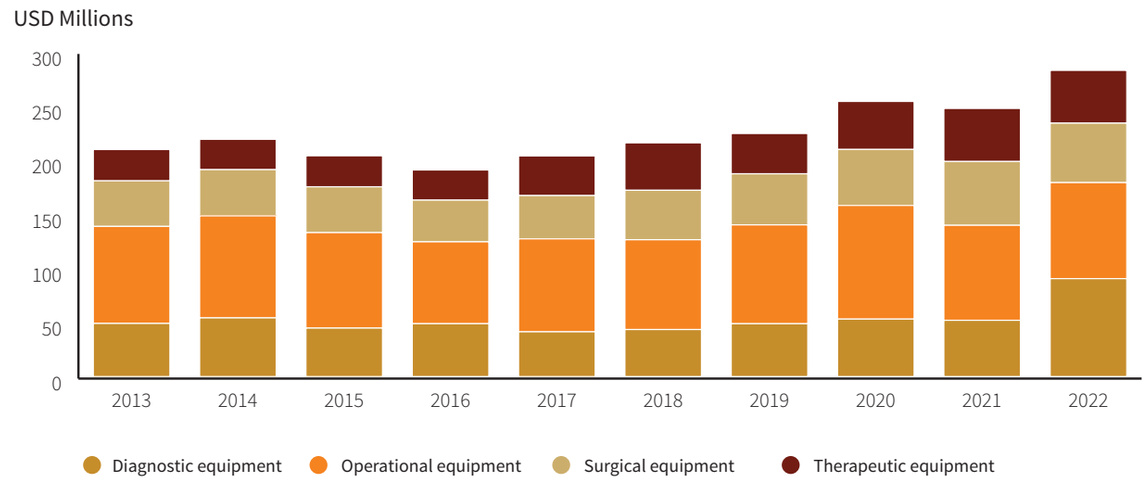


Figure 2: Medical device exports, by major cluster (Source: UN COMTRADE)

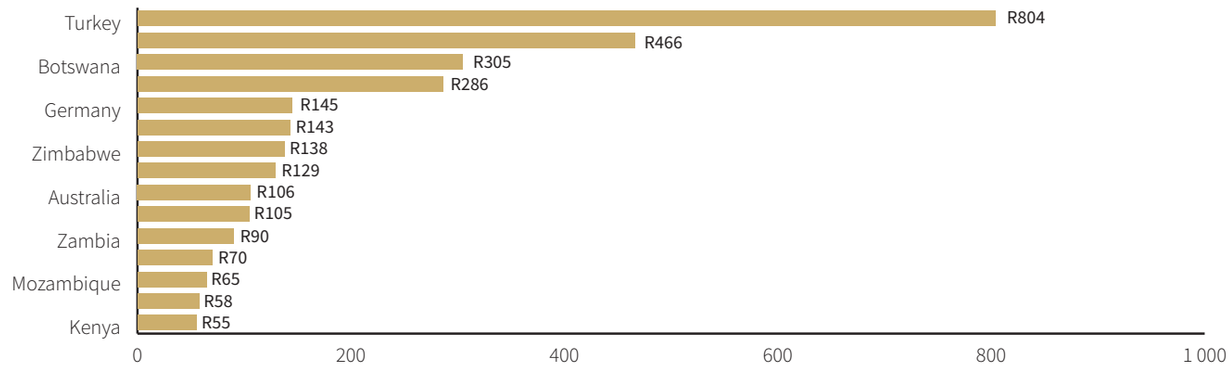


Figure 3: Top export destinations for medical products, 2022 (Source: SARS customs)

Turkey is nominally the largest destination for South African MEDTECHs, but this is primarily the result of the categorisation of medical cameras listed in Table 4 below. A more realistic assessment shows that Namibia, United States, and Botswana are South Africa's largest export markets, and then a mix of regional and European markets (Figure 3).

Table 4: Top product and market export combinations, 2022 (Source: SARS customs)

Market	Product	Value
Turkey	Medical (and other specialist cameras)	**R799 323 522**
Namibia	Other equipment	**R249 298 469**
United States	Gauze, bandages and related	**R131 295 348**
Botswana	Other equipment	**R120 122 639**
Netherlands	Gauze, bandages and related	**R66 555 424**
Australia	Gauze, bandages and related	**R59 721 136**
Germany	Medical (and other specialist) cameras	**R51 488 390**
United States	Prosthetics	**R51 153 939**
Eswatini	Other equipment	**R50 003 645**
Uganda	Other equipment	**R44 606 654**
Zimbabwe	Other equipment	**R43 203 111**
United States	Other equipment	**R42 507 023**
Zambia	Other equipment	**R38 192 603**
Malawi	Other equipment	**R35 276 193**
United Kingdom	Prosthetics	**R33 993 355**
Namibia	Gauze, bandages and related	**R32 499 982**
Germany	Other equipment	**R32 346 122**
Netherlands	Other equipment	**R31 257 421**
Namibia	X-ray and radiography devices	**R29 850 182**
United States	X-ray and radiography devices	**R29 375 832**
United Kingdom	Ophthalmic equipment	**R28 436 559**
Spain	Dental equipment	**R26 458 228**
United Kingdom	Gauze, bandages and related	**R25 499 024**
Namibia	Syringes, needles and related	**R24 552 883**
Australia	Prosthetics	**R24 089 982**

Employment

There is a relatively high degree of uncertainty in terms of the exact number of people employed in the MEDTECH sector. This is partly due to the sector's small size which limits the quality of available data. Overall, it appears that the sector employs between 10 000 and 30 000 people.

Statistics South Africa's (StatsSA) Quarterly Employment Survey, which surveys larger, formal enterprises, is likely to be the most reliable source of an estimate. This survey shows positive employment growth between 2015 and the end of 2019, but a steady decline since the onset of the COVID-19 pandemic, with employment in the sector falling to 9 624 people by the middle of 2023 (Figure 4).

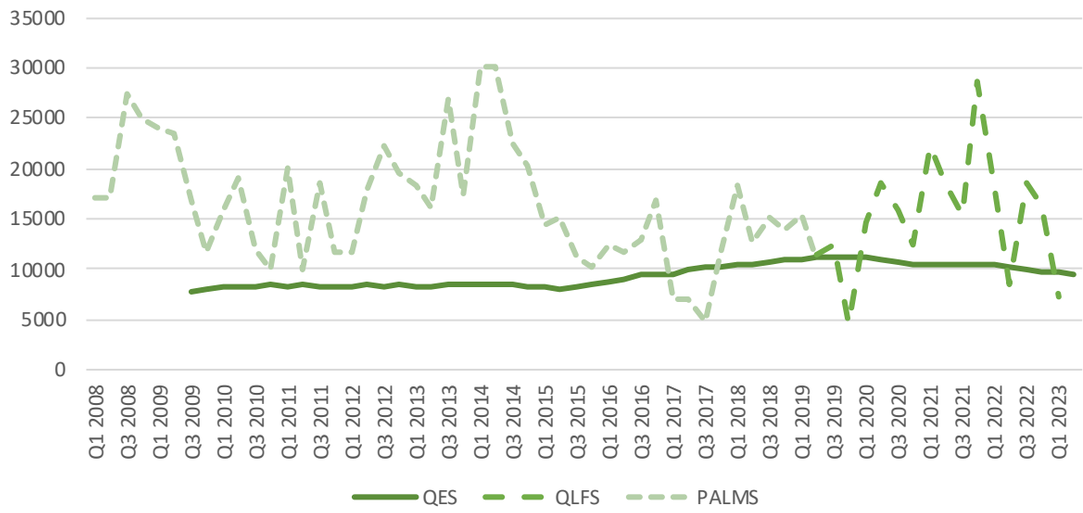


Figure 4: Employment in the Medical Devices Sector, 2008 – 2023 (Source: StatsSA Quarterly Employment Survey (QES); StatsSA Quarterly Labour Force Survey (QLFS); UCT, Post-Apartheid Labour Market Series (PALMS))

In geographic terms, employment in the MEDTECH sector is overwhelmingly concentrated in Gauteng and the Western Cape. The demographics of employment in the sector feature a notably prominent role for women, in contrast to trends seen in most other manufacturing sectors (Figure 5). Unsurprisingly, given the high-tech nature of the sector, there is a disproportionate share of employees in managerial or advanced technical occupations. While there are still a significant portion of total employees in more accessible roles, like machine operators, the capital- and skills-intensive nature of the sector means it is probably a poor candidate for mass employment creation (Figure 5).

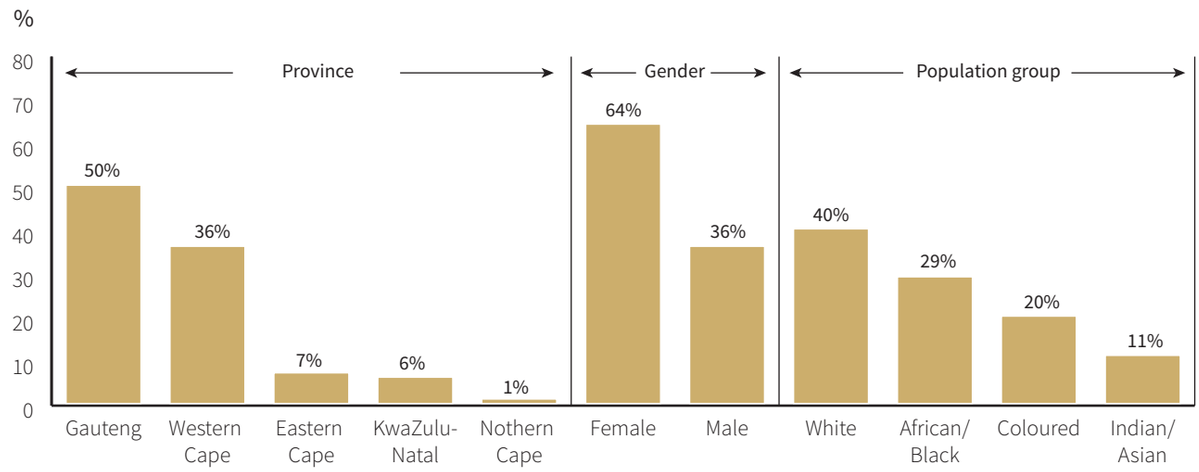


Figure 5: Demographics of employment in the Medical Devices sector, 2019 (Source: StatsSA Labour Market Dynamics, 2019)

MEDTECH MASTERPLAN FRAMEWORK

Realising the vision and objectives of the Master Plan requires institutional coordination, as well as a range of policy, regulatory and programmatic interventions and based on research, four pillars have been identified as key focus areas to be actioned through to 2030. These pillars will support the realisation of the vision but in doing so will need institutional structure support.

Vision 2035

An integrated and cohesive ecosystem that enables, supports, and encourages development, growth, and competitiveness of local medical technology value chains to produce reliable, safe, quality, and affordable MEDTECH for domestic and export markets.

Strategic Objectives

- Grow a proficient and competitive medical technology industry over the next three years, with special focus on small business development, that will supply domestic and international markets.
- Reduce the trade deficit by 5% over the next five years.
- Generate employment and build productive and technical skills with the aim of creating 1 000 new jobs over the next three years.
- To digitalise and use artificial intelligence to enable proficient regulatory processes.

Regulatory Framework | **Market Growth** | **Technology, Production and Skills Development** | **Research, Innovation and Data**

Supportive institutional environment (including monitoring and evaluation)

Key Deliverables

Creation of an enabling regulatory environment

Preferential procurement agreements in both public and private sectors

African Market Access Strategy

Identification of MEDTECH to be manufactured locally

Establish a path of Innovation and commercialisation to manufacturing

MEDTECH MASTERPLAN FRAMEWORK

Government

- Create enabling regulatory environment.
- Conduct regulatory and commercialisation impact assessments where appropriate.
- Review or introduce tariffs, subject to applicable legal processes and on good grounds.
- Facilitate timeous payment to MEDTECH providers.
- Develop a business case to evaluate support required, whether incentives, loans, preferential procurement and/or export promotion.
- Invest and participate in skills development and awareness programmes.
- Create exporters and stakeholder forums.
- Develop Africa Market Access Strategy.
- Identify potential new trade facilitation agreements.

Industry MEDTECH

- Identify MEDTECH for local manufacturing.
- Increase domestic innovations and manufacturing.
- Identify areas that may need support through incentives and/or other forms of assistance.
- Invest to grow capacity and capability.
- Invest in technology, innovation, R&D, CAPEX.
- Invest and participate in skills development and awareness programmes.
- Support Proudly SA and SAHPRA.
- Develop Africa Market Access Strategy.
- B-BBEE Initiatives.
- Facilitate timeous payment to small businesses providers of MEDTECH.

Public and Private Procurers

- Identify MEDTECH for local manufacture.
- Preferential procurement.
- Support Proudly SA and SAHPRA.

Labour

- Support Proudly SA and SAHPRA.
- Participate in training and awareness programmes.

Academia and Professional Associations

- Promote the co-ordination, alignment of training.
- Provide advice and information on technical, quality, and legislative skills development in MEDTECH.
- Identify future skills in line with market needs.
- Identify skills categories in niche areas.
- Support the integration of medical device legislative requirements and artificial intelligence into training curricula.
- Support the broadening of the educational programmes to more educational institutions.

PILLAR 1 Regulatory Framework

MEDTECH is different from some other consumer goods or products. They play an important role in, and are an integral part of, healthcare delivery. Therefore, it is important to understand that – from a government perspective – it is not only safety and effectiveness but also accessibility, affordability and security of supply of MEDTECH that counts. MEDTECH standards are important to help designers and manufacturers create products that are safe, effective, and in line with user needs.

Harmonising MEDTECH regulatory regimes across Africa will help to reduce the regulatory and commercialisation costs for African manufacturers selling into other markets on the continent thereby supporting the growth of Africa's local MEDTECH manufacturing sector. The Africa market is also important for the development and growth of the South African MEDTECH industry and regulatory alignment. This will play a key role in creating an enabling environment to promote regional trade and generating much needed volumes through exports. Currently the regulatory pathway in the region is fragmented. Regulation in MEDTECH has been limited in South Africa and confirmation to international certifications are often preferred to instil confidence in the quality, safety and performance of products. There is an opportunity for the regulator and industry to work together in making the South African regulator a key African standard bearer or African Competent Authority on MEDTECH.

Effective stakeholder collaboration will facilitate the creation of an enabling environment for the domestic MEDTECH industry to stimulate growth through capacity building and improved capability whilst at the same time ensuring patient safety.

Leading MEDTECH countries tend to have mature independent legislation that regulates the industry. The concept of independent legislation needs to be explored to ascertain the growth benefits for the South African MEDTECH industry. This could enable a focussed delivery on high levels of safety and preforming MEDTECH whilst supporting innovation and commercialisation, a smooth functioning of domestic markets, whilst at the same time considering the many small and medium enterprises active in MEDTECH.

PILLAR 1 Actions

- Establish a joint public and private MEDTECH stakeholder forum to co-ordinate, align and provide information and advice on the MEDTECH regulatory framework towards a safe and enabling environment. The forum will include DTIC, NDOH, Industry Bodies, SAHPRA, SANAS, SABS, National Treasury, SARS, Labour, ICASA, MEDDIC, Port Health, and the NRCS **(2024–2025)**.
- Consider the desirability, cost and time required of the proposal for submission of all pending and future MEDTECH regulations to a Regulatory Impact Assessment to ascertain the impact on the MEDTECH industry and all relevant stakeholders **(2024–2025)**.
- Identify joint initiatives to:
  - Enhance the capacity and capability of the regulator in implementing its mandate **(2025)**.
  - Review and develop meaningful consultation processes between the regulator and MEDTECH sector **(2024–2025)**.
  - Identify blockages and challenges and initiate appropriate actions and/or programmes **(2024–2025)**.
  - Develop appropriate skills development programmes for officials and industry players **(2024–2026)**.
  - Upgrade technology and artificial intelligence by the regulator and industry organisations **(2024–2026)**.
  - Harmonise African standards and registration processes and where possible simplify these, subject to health standards being maintained.
- Investigate the costs and benefits of the introduction of trade measures or alternatives to support the MEDTECH sector **(2024–2026)**.
- Aim to fast-track discussions/negotiations with appropriate African/SADC regional bodies (AMDF, AFCTA etc) to align regulation and registration of MEDTECH with a view to establish an African standard in order to facilitate African Continental Free Trade Area (AfCFTA) trade and reduce the cost on manufacturers **(2027)**.
- Undertake research/investigation to determine the benefits of government promulgating stand-alone legislation for MEDTECH that will benefit industry growth **(2030)**.

MEDTECH MASTERPLAN FRAMEWORK

DTIC

The Department of Trade, Industry and Competition is the department of the South African government with responsibility for commercial policy and industrial policy.

NDOH

The National Department of Health is the executive department of the national government that is assigned to oversee healthcare in South Africa.

EMPLOYERS

An employers' organisation or employers' association is a collective organisation of manufacturers, retailers and distributors and includes the South African Medical Technology Industry Association (SAMED), the Southern Africa Laboratory Diagnostics Association (SALDA), Medical Devices Manufacturer of South Africa (MDMSA) and the Hospital Association of South Africa (HASA).

LABOUR

A labour organisation is a collective organisation of trade unions and includes the Congress of South African Trade Unions (COSATU), the Federation of South African Trade Unions (FEDUSA) and National African Confederation of Trade Unions (NACTU).

SAHPRA

South African Health Products Regulatory Authority is an entity of NDOH that ensures that health and wellbeing of human and animal health are at its core.

SANAS

The South African National Accreditation System is responsible for carrying out accreditations in respect of conformity assessment.

SABS

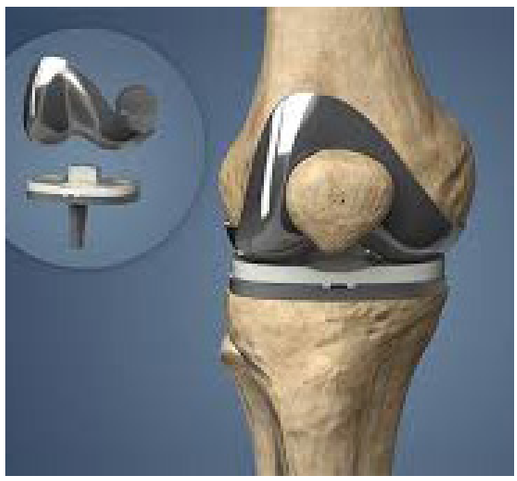
The South African Bureau of Standards develops, promotes, and maintains South African national standards.

NATIONAL TREASURY

The National Treasury manages national economic policy, prepares the annual budget, and manages the government’s finances.

NRCS

The National Regulator for Compulsory Specifications ensures businesses produce, import, and sell products or services that are not harmful to consumers and the environment or that fall short of the declared measured quantity.



PILLAR 2 Market Growth

Globally, competitive industries do not become successful overnight. The origins of success of many countries in exporting MEDTECH starts with a local manufacturing value chain that is supported by all stakeholders and government. Legislative and policy support will also assist to grow local manufacturing in the short to medium term. Cross cutting elements such as local procurement legislation and information systems will ensure full sight of the value chain. There is a need for a value chain pillar to be linked (from R&D – Manufacturing – Market Development – Buyers), effective coordination amongst the industry and government agents to prevent acting in silos, support for new entrants' participation in the value chain and to facilitate access to funding and markets, amongst others. Through a social compact, the need for such a role can be clearly defined.

"—most, if not all, of the building blocks are in place for a strong and vibrant MEDTECH industry in South Africa, driven by a combination of local innovations emerging from STI institutions and 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."

Local manufacturers are competing for demand against imported MEDTECH. Imported products are often cheaper or accredited as per international quality and regulatory requirements, whereas local testing and product assessment bodies and facilities are limited in capability, skills capability, minimal resources, and their costs are prohibitively high. The immediate opportunity for local manufacturing of MEDTECH appears to reside in the Class A and B products, but not limited thereto, which are easier to develop and could compete effectively with imported products.

PILLAR 2 Actions

Phase 1 (2024–2026)

- Hospital groups, healthcare practitioners, NHLS, private pathology labs, SAMRC, medical aids, industry bodies and MEDTECH manufacturers to identify products currently being imported that can feasibly be manufactured locally. The immediate opportunity for local manufacturing of MEDTECH appear to reside in the Class A and B, which are easier to develop and could compete effectively with imported products but conducting a feasibility study will facilitate more accurate identification of these products.
- Multinational companies and local manufacturers to identify products that can be manufactured locally including the manufacture of component parts and assembly.
- Identify funding sources to assist enterprises to increase manufacturing for local and export markets through lending institutions such as the IDC.
- Identify areas that may need support through other forms of assistance.
- Engage the Localisation Support Fund to identify initiatives contributing to industry growth that can be supported by the fund.
- Identify three areas where advantageous trade facilitation agreements can be pursued and concluded.
- Create a joint exporters forum that will target 10 markets over the next two years.
- Proudly SA to actively promote local MEDTECH, medtech manufacturers and products manufactured in the country.
- Work with government departments to facilitate processes toward expediting the payment to the private sector.
- Increase the level of women and black participation and particularly ownership across the value chain by identifying specifically women and black ownership targets through broad-based and inclusive models.
- Develop an Africa export strategy to identify and facilitate market access into the continent by leveraging the AfCFTA.

Procurement

- Collaboratively identify products manufactured locally that can be considered for preferential procurement by the private healthcare facilities (including hospitals, GPs, day clinics, surgeons, pathology labs etc.) and state procuring authorities (government departments, SOEs, NHLS, NHI etc.).
- Investigate the mechanisms for procurement and planning from a long-term perspective to ensure alignment between budgets presented, and what is being procured.
- Patient care consideration is necessary when planning procurement including the consideration of value-based procurement that will facilitate for a successful healthcare system.

- Explore the implementation of local content provision in procurement processes.
- Conduct training workshops with NDOH, provincial departments of health, NHLS, National and Provincial Treasury to understand national procurement for MEDTECH.
- Conduct education and awareness programmes for public and private healthcare professionals and healthcare industry employees on importance of local procurement.
- Engage retailers and medical professionals to increase support for local manufacturers.

Phase 2 (2026–2035)

A work programme/work stream to consider the viability of the following:

- Maximising the benefits for local manufacturers through international and regional trade agreements.
- Utilising generic substitution legislation as per the pharma industry and explore import substitution programmes.
- The development of a Circular Economy and Renewable Energy Plan for local MEDTECH manufacturers.
- Engage retailers and medical professionals to increase support for locally manufactured MEDTECH.

PILLAR 3 Skills Development

At present there is a global shortage for skills in the MEDTECH industry. However, South Africa is producing adequate skills to meet the current market demand. This is largely due to many enterprises training employees on site to meet their specific needs. It is important that attention be given to identifying future skills needs and gaps to cater for an increase in demand.

Skills development must be approached holistically starting with a local analysis and then forging international partnerships. There needs to be a clear identification of skills categories in niche areas such as clinical engineering and increasing graduate skills in manufacturing, biomedical engineers, scientists, researchers, innovators, and the education of regulatory scientists.

There is a need to work with technical schools in the integration of artificial intelligence as well as technology training for graduates. There can also be a cross-pollination of skills programmes between the various industries. There is an opportunity to broaden the scope of development by following a unified approach rather than only focusing on one or two educational institutions.

PILLAR 3 Actions

- Establish a joint stakeholder skills forum to co-ordinate, align and provide information and advice and identify and recommend specific actions and interventions on skills development for the MEDTECH industry. The forum will monitor the implementation and progress of these actions and interventions. This forum will include the DHET, DEL, DSI, the dtic, CHIETA, MEDTECH employers; SAMED, SALDA, MDMSA, HWSETA and labour organisations as well as the SAMRC (2024–2025).

The following immediate interventions have been identified:

- Identify future skills needs through an industry gap analysis by 2024.
- Conduct an audit on current training available at the educational institutions and institute initiatives to fill the gaps in the offering levels by 2025.
- Engage with educational institutions with the aim of achieving a more coordinated and aligned approach to skills development in the industry by 2025.
- Initiate a process to forge partnerships with international institutions to align skills development with global best practice by 2026.

PILLAR 4 Research & Development, Innovation and Data

Research and Innovation

In the MEDTECH industry R&D involves conceptualising new products, producing, and testing prototypes, and assessing potential manufacturing capabilities. Once initial concept tests are completed, the product undergoes regulatory approval in the desired markets, which can take up to six years depending on the risk category of the device and required clinical data. The total time for a new device from concept to market can take up to eight years.

According to MDMSA report of August 2016 top global MEDTECH players spend between 6% and 12% of revenues towards R&D investment. For smaller manufacturers, technology and innovation are differentiating factors. Thus, R&D expenses remain significant cost components that drive the long-term productivity of companies. Big players, however, make smaller investments in R&D and focus on improving margins and productivity through expanding scale and services. In South Africa, the MEDTECH industry spends less than 1% of its turnover on research and development, which is significantly lower than the global average of 6.8%. Even though there is a thriving research and development base in the country, it remains underfunded and fragmented. There is also a need to further invest in translational science to ensure that innovations are commercialised successfully. Venture capital funding for innovators is scarce in South Africa. However, there is ample opportunity for new product development and commercialisation as per the SAMRC landscape report, which revealed that 80% of local manufacturers surveyed have in-house product design capabilities.

There needs to be alignment of innovation hubs with the gaps identified for growth and development. Multiple sources of knowledge, both domestic and international, through formal and informal partnerships are important in complementing in-house R&D and product design capabilities. It is necessary to create a process to access R&D funding. The first step is to create an enabling environment for R&D investment and to foster collaboration with research units at universities.

Process is equally important as content and there needs to be a smooth transition from R&D to market. Failure to facilitate this will create gaps and little incentives for the MEDTECH market to heavily invest in R&D. There needs to be a solid base of local manufacturers to conduct R&D to the fullest. Currently the base of local manufacturers is small. R&D is relatively new to the South African market, and this is one reason why R&D investments have been low. It is also necessary to develop the requisite skills sets as there are limited available skills/know how to conduct R&D and/or clinical trials.

There are already some collaborative efforts between medical technology firms and some universities. This bridges the gap between the academia and industry and is necessary for innovation and R&D, in the long-term.

A path must be followed to establish and/or nurture existing links and collaboration with academic institutions, research, and other organisations as well as manufacturers in the African region.

To achieve goals and implement actions it is important to consider the ‘how’ by linking many of the threads together. This will ensure that there is no creation of silo-type behavior in execution. To this end a Programme in MEDTECH Innovation and Growth has been developed that will link all the various goals and role players together. **(See model below)**

The essence of the programme is:

- **An Innovation/Localisation Programme**

  This works to identify MEDTECHs to be localised in some way or developed from scratch. The next step is to understand the “case” for them and decide how best to manage through to market. Some may require full product development and clinical trials, others just localisation of manufacture with limited need for development and clinical data.

This phase will include conducting any development and clinical testing activities. An important aspect is a funding system that is not fragmented and can speak to the whole process through to market entry.

- **A Supplier Development Programme**

  This is particularly for SMMEs. The aim is to develop the business and position it for market entry and to facilitate linkages to/involve all supporting associations, resources, agencies to help them along their path.

- **A Skills Development Programme (Link to pillar 3)**

To develop skills throughout the whole innovation chain (technical, regulatory, business etc.).

- **A Shared Infrastructure Programme**

There is a lot of existing infrastructure that could be used to support a MEDTECH initiative such as the Nano Micro-Manufacturing-Facility that DSI funds, various product development & clinical testing setups at test houses, CSIR, SABS and similar entities, free-trade zones etc.

Data

There is an inadequate systematic collection of all forms of data in MEDTECH. Many research papers that are relied upon are outdated and in many instances, there is no available data at all. There are some limited data on enterprises within MEDTECH based on a survey by the SAMRC of 136 MEDTECH manufacturing companies. Based on the survey results, most MEDTECH manufacturing companies are classified as small, employing 50 or less permanent staff. It is necessary to establish (i) a centralised database on the various aspects of the MEDTECH industry and (ii) a knowledge base/portal on R&D and design capabilities including IVD innovation.

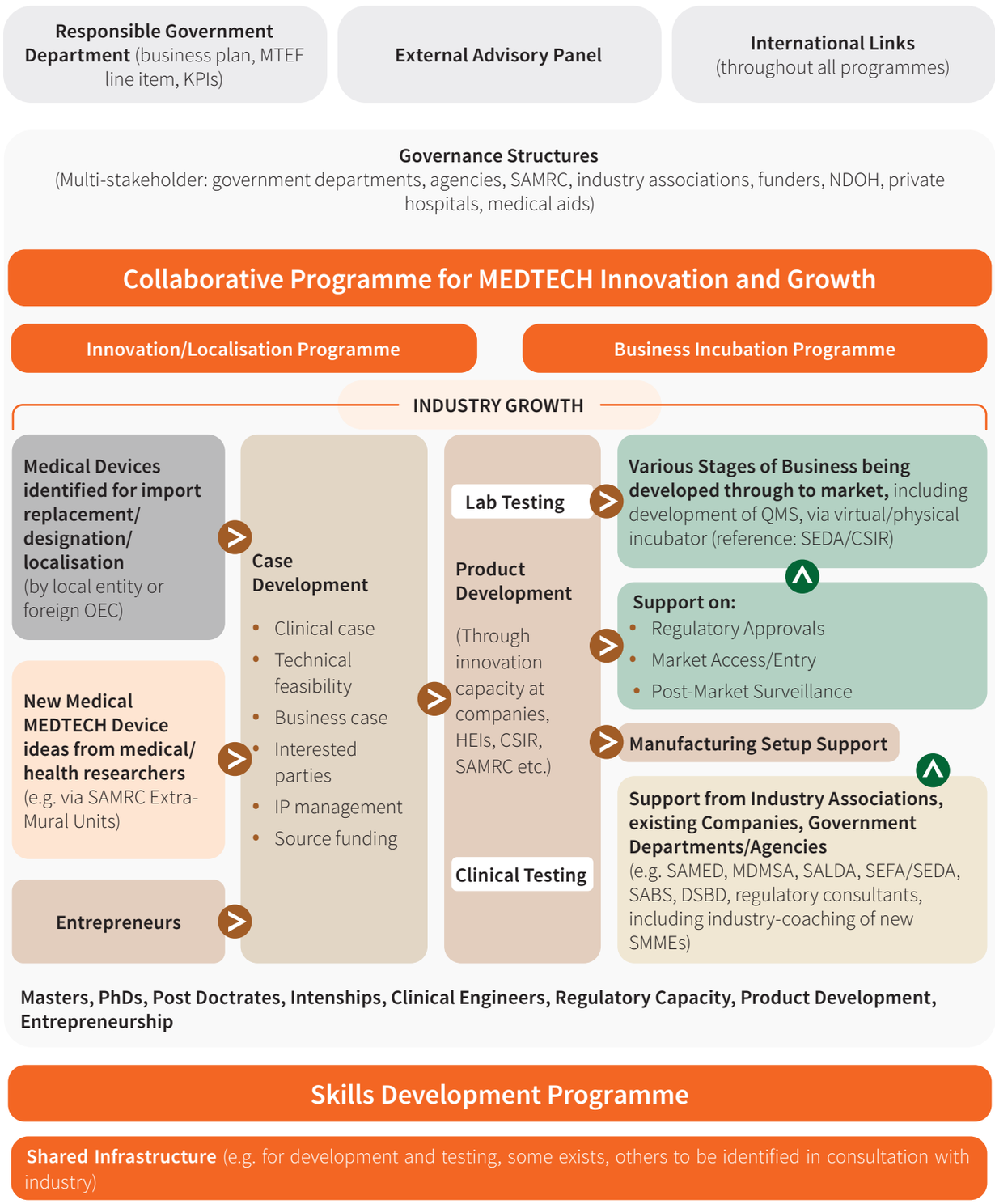
PILLAR 4 Actions

The MEDTECH Executive oversight committee to play a collaborative role in providing guidance and advice on specific actions and interventions on R&D, innovation, and data collection for MEDTECH and to monitor the implementation and progress on these actions and interventions. Specific actions and interventions to be considered are:

- Develop and build an innovation, science, and technology (STI) platform which will link the R&D, manufacturing, and buyers to create a globally competitive industry with an effective and efficient level of coordination and stakeholder alignment (2024–2025).
- Build on and strengthen pockets of excellence and existing technology and innovation platforms to transform them into world-class centres of excellence.
- Establish mechanisms to transfer knowledge and skills to other STI institutions, especially historically disadvantaged institutions.
- Promote 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 MEDTECH 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.
- Establish a centralised data capturing facility that will enable informed industry decisions in all facets of the MDS and be a valuable resource to the other task teams (2024–2026).

MEDTECH MASTERPLAN FRAMEWORK

A collaborative model for MEDTECH localisation and growth.



SUPPORTING INSTITUTIONAL ENVIRONMENT (INCLUDING MONITORING AND EVALUATION)

Establishment of a MEDTECH Executive Oversight Committee (EOC)

The objective is to provide high level leadership and coordination of the MDS master plan implementation and ensure and promote ownership and accountability for outcomes and commitments amongst the social partners.

Terms of Reference

- Champion the vision, objectives, and implementation of the MEDTECH master plan.
- Provide high level leadership, guidance, and co-ordination of implementation.
- Monitor and evaluate Master Plan implementation.
- Agree Master Plan baselines and targets and a baseline monitoring and evaluation framework.
- Establish a small representative MEDTECH implementation management team to drive day-to-day implementation.
- Receive reports from and provide guidance to task teams.
- Meetings at least once every six months chaired by the Director General of DTIC.
- Oversee the establishment and functioning of the pillar committees.

NOTES

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