



TRADE & INDUSTRIAL POLICY STRATEGIES

**DRAFT OF THE SOUTH AFRICAN
MEDICAL DEVICES MASTERPLAN – VALUE CHAIN 2024**

**ANNEXURE 3: WORKING GROUP WORKSHOP
ON QUICK WIN INTERVENTIONS**

WORKSHOP REPORT

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Contents

1	Introduction	3
2	Project context.....	3
3	Purpose of the workshop.....	4
4	General outcomes.....	5
4.1	Definition of the Quick Wins.....	5
4.2	The Quick Wins	5
5	Key outcomes by theme	6
5.1	Quick Win 1: Regulatory and Policy Advocacy.....	6
5.1.1	Discussions	6
5.1.2	Current initiatives and champions.....	7
5.1.3	Outcomes – to be implemented in the short-term	7
5.2	Quick Win 2: Creation on an enabling ecosystem	7
5.2.1	Discussions	7
5.2.2	Current initiatives and champions.....	9
5.2.3	Outcomes – to be implemented in the short-term	9
5.3	Quick Win 3 - Skills and capacity development	9
5.3.1	Discussions	9
5.3.2	Current initiatives and champions.....	11
5.3.3	Outcomes – to be implemented in the short-term	11
5.4	Quick Win 4 - Improving Market access and export enablers	11
5.4.1	Discussions	11
5.4.2	Current initiatives and champions.....	11
5.4.3	Outcomes – to be implemented in the short-term	11
5.5	Quick Win 5 - Achievement of global competitiveness	12
5.5.1	Discussions	12
5.5.2	Current initiatives and champions.....	12
5.5.3	Outcomes – to be implemented in the short-term	12
5.6	Quick Win 6 - Integration into global value chain.....	12
5.6.1	Discussions	12
5.6.2	Current initiatives and champions.....	13
5.6.3	Outcomes – to be implemented in the short-term	13
6	Conclusion and way forward	13
	Annexure A: Workshop Agenda	13
	Annexure B: Project Methodology.....	14
	Annexure C: Quick wins presented	15

1. Introduction

As part of the Industrial Policy Reimagined, a Medical Devices Industry Masterplan is being developed to put the industry on a growth trajectory. The Masterplan approach has been used in several other sectors to develop a vision for the industry between industry, labour and government, identify blockages and constraints, and come up with a set of key actions in the short and medium term.

The Department of Trade, Industry and Competition (the dtic) through Trade & Industrial Policy Strategies (TIPS), is developing the South African Medical Devices Industry Masterplan. The Medical Devices industry has the potential to create jobs, contribute to exports, and foster Small, Medium and Micro Enterprises. Additionally, it has strong linkages with other sectors. Desktop research is under way, informed by previous extensive research in the sector as well as the work undertaken by Thematic Working Groups of representatives of industry, government, labour and academia.

A Medical Devices Masterplan Quick Wins Working Groups Workshop was held on the 16th of February 2023 to validate quick interventions, previously identified by the Thematic Working groups, that can be made immediately to address industry constraints and improve performance. The workshop, hosted by TIPS via Zoom brought together 62 industry stakeholders including manufacturers, industry associations, government and labour.

The workshop was conducted in a highly interactive format to allow comprehensive discussions and in-depth exchange and exploration of the following areas:

- Regulatory and policy advocacy;
- Creation of an enabling ecosystem;
- Skills and capacity;
- Improving market access and export enablers; and
- Achievement of global competitiveness and integration into global value chains.

It was agreed to move forward with a quick survey/final evaluation of the approved top interventions with the working groups.

This report provides a summary of discussions of the key thematic areas, and is structured as follows:

- Background: Project context.
- Purpose of workshop.
- Key outcomes.

The Annexure provides a process map which broadly captures the overall workshop structure including the workshop agenda, project methodology and initial quick wins presented.

2. Project context

The masterplan approach results from the President's Re-imagined Industrial Policy. Masterplans are meant to develop economic value chains by promoting evidence-based co-ordination. They are developed through collaboration between government, labor and private business to unlock growth in the industry. Both public and private sector dedicate resources and time for developing and implementing the masterplan with agreements on areas for intervention, collaboration and commitments.

The objectives of the medical devices masterplan include encouraging sector growth, investment, job creation and competitiveness; reduction of the trade deficit through increased exports, especially with

South Africa as a gateway to Africa; provision of a legislative framework for producing competitive medical devices that meet internationally approved safety and performance requirements.

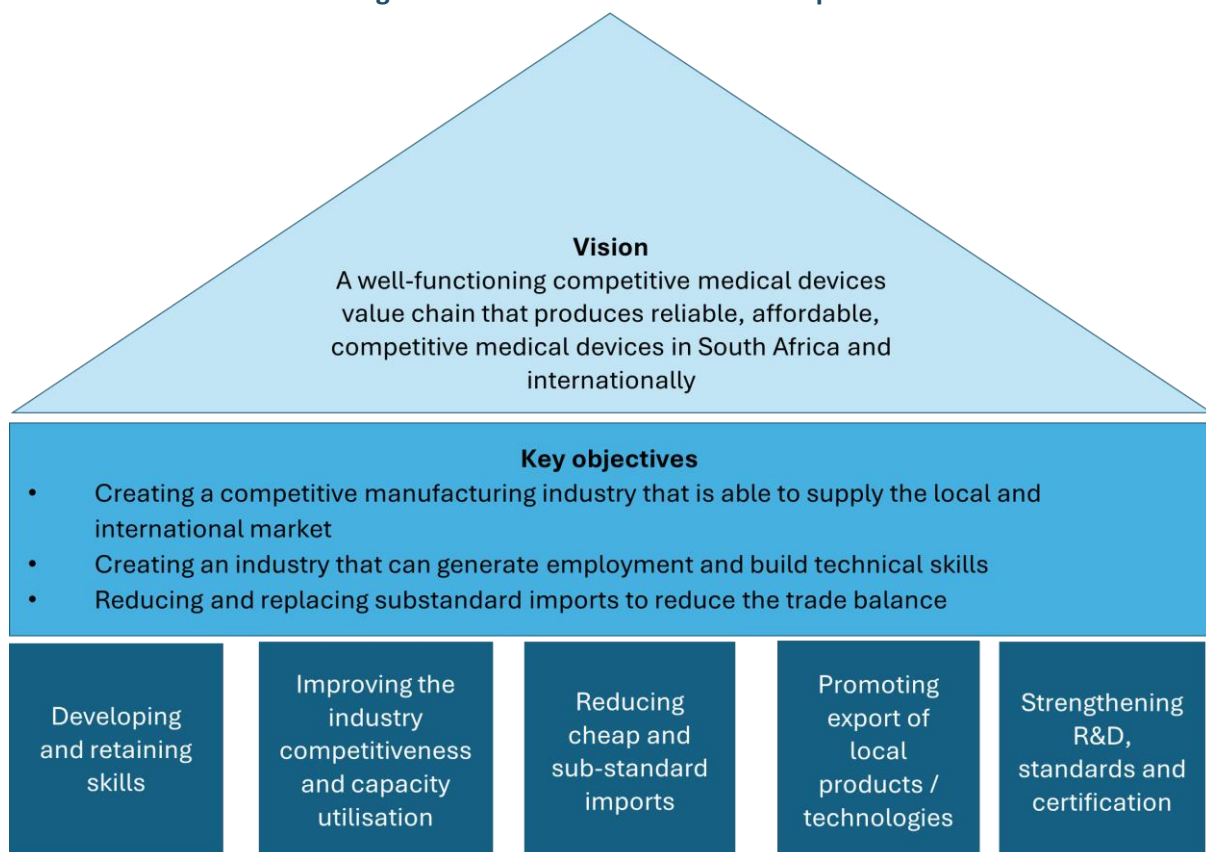
The DTIC started developing the Medical Devices Masterplan around 2021. The process led to the formation of Working Groups with representatives from industry, government and labour. The five Working Groups are as follows and they are operational:

1. Skills and capacity development (and regulation policy);
2. Create an enabling ecosystem;
3. Improve market access and export enablers;
4. Achieve global competitiveness; and
5. Integration into global value chains.

In 2022, the DTIC engaged TIPS to help further develop the masterplan. The development process entails research informed by the work that has been undertaken by the Working Groups and other stakeholders in the industry. The research process is expected to be completed in March 2023.

The core elements of the masterplan are shown in Figure 1. They require an ongoing engagement on unblocking growth, monitoring, enabling policies and regulation.

Figure 1: Core Elements of the Masterplan



Source: TIPS, 2022

3. Purpose of the workshop

The purpose of the workshop was to agree on the definition of a “Quick win”. The Quick Wins under each theme were presented, discussed and agreed upon. In some cases, representatives committed to championing the implementation of some Quick Wins, which is reflected in the report.

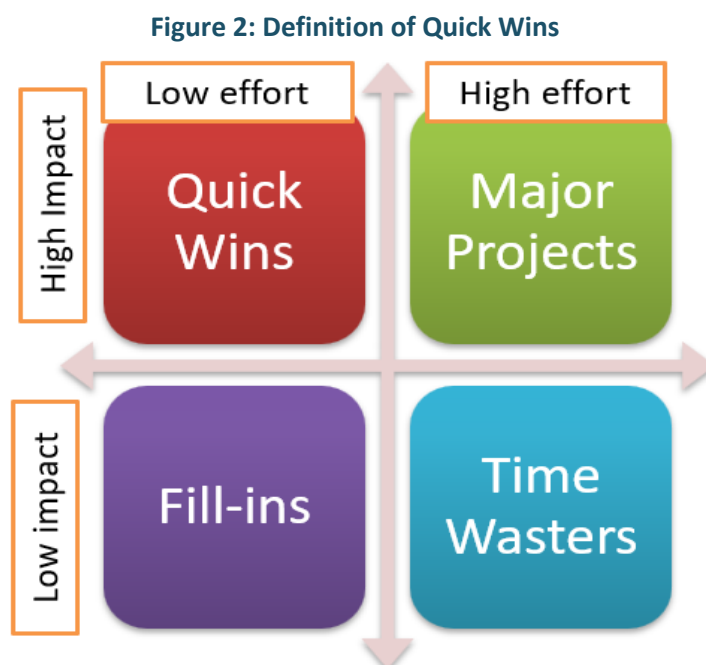
The objective of the workshop was therefore to:

1. Run parallel, actionable quick-win interventions while production of the masterplan is under way;
2. Agree on actions in the short run to support industry growth;
3. Drive preliminary commitments among industry, associations, labour, supporting organisations and government; and
4. Identify possible champions for the agreed quick win.

4. General outcomes

4.1 Definition of the Quick Wins

An important outcome of the workshop was to achieve a common understanding of the definition of Quick Wins by all. The Quick Win interventions are understood to be those that can be implemented immediately to enable the industry to perform. Consensus was reached that Quick Win interventions will have **high impact** but require **low effort** to execute, and are implementable within **6–12 months**. When identifying the Quick Wins, the cost implications or availability of funds must be considered as well as the resourcing needs, technical or other. Figure 2 demonstrates the definition of the Quick Wins.



Source: Compiled by Authors, 2023

4.2 The Quick Wins

Following the agreed definition of the Quick Wins, parameters illustrated in Table 1 were used to guide the discussions and formulate the quick-win delivery framework.

Table 1: Quick Win Delivery Framework

INITIATIVE	TIMEFRAME	RESOURCING NEEDS	DEPENDENCIES/ RISKS	DESIRED OUTCOMES	CHAMPION

Source: Compiled by Authors, 2023

5. Key outcomes by theme

5.1 Quick Win 1: Regulatory and Policy Advocacy

5.1.1 Discussions

- The industry is enquiring from the regulator if there can be more local conformity assessment bodies that industry can work with on acquiring product licenses and assessments for compliance for suitability and fitness for purpose.
- Discussions have centered on the need to increase skills within industry for compliance with ISO 13485 and to look at internships and courses/skills training and a panel of experts to assist and provide advice. Another issue was the lack of internationally recognised and certified notifying bodies and lack of testing facilities. Fixing this was classified as one of the quick wins and the newly established Medical Device and Diagnostic Innovation Cluster (MEDDIC) of the South African Medical Research Council (SAMRC) volunteered to champion this intervention.
- Funding support should be in place to assist SMMES with testing for ISO 13485 for a few years.
- Audits on good regulatory practices should not be limited to local manufacturers alone and they should be done on a voluntary basis. An aspect of good practice for regulators is that impact analysis should be conducted before implementing regulations and guidelines to ensure they are fit for purpose. The South African Health Products Regulatory Authority (SAHPRA) needs to do more impact analysis so that regulations do not hinder sustainability and trade. For example, an impact analysis would have to ensure that desired fees for licensing and product registration are appropriate.
- A national oversight body of health technology assessment (HTA) is needed so that it fits into the procurement process. This is important enough for groundwork to be regarded as a part of the quick win interventions, while the major project can be implemented in the longer term.
- Are we looking for access to international accreditation, or capacitation locally for accreditation and certification? The assumption is that the term “accreditation” refers to both, because they are two separate aspects. We need accreditation of test methods and bodies that ought to be performing the certification and competency of the conformity assessment bodies themselves.
- On funding, pharmaceuticals and medical devices must be clearly differentiated.
- The South African Medical Device Industry Association (SAMEDI) has produced research (a position paper) on an HTA agency for South Africa. In particular on how medical technology can fit in that. (The paper is to be shared with stakeholders). SAMEDI would need a mandate, but it is keen to get all the stakeholders onboard.
- The medical technology sector, particularly in the private sector, faces many challenges. Approval of a product by medical schemes is a long process. Even when a product is approved by a medical scheme, the hospital groups must do another HTA process to approve the product. Much duplication occurs and time is spent, and this has to be taken into account by an HTA agency. Many devices are on the market and which products will undergo the HTA process must be selected to avoid obstacles in the process.
- A communication/policy advocacy strategy in the form of policy briefs to a wider stakeholder audience would help visibility. This becomes important given the complexity of the medical devices compared to the pharmaceutical sector in technical and legislative areas. This is already part of the thinking on the ongoing MEDDIC endeavours. A health advocacy NGO, PATH, will be an active member of the group working on this.

- The policy advocacy strategy document would be sent for members to improve the wording to reflect the intervention correctly.

5.1.2 Current initiatives and champions

1. MEDDIC under SAMRC has been working on a platform embedded in the Innovation Bridge Portal where manufacturers and developers can list their product(s). They are also trying to set up a raw materials platform in the same portal so companies can see who is ordering which material and maybe club together to negotiate a discount. This still needs more input from manufacturers.
2. MEDDIC has volunteered to champion the skills and development of advocacy strategy (PATH is potential co-champion on advocacy strategy).

5.1.3 Outcomes – to be implemented in the short-term

1. Advocating with regulator (SAHPRA) for local conformity assessment body
2. Funding support for SMMEs for international accreditation
3. Conducting impact analysis of new legislation, regulations and guidelines, including registration fees before implementation to assess how companies may be affected.
4. Developing a position/approach which is appropriate to SA for health technology assessments.
5. Prioritising differentiation between pharma and medical devices.
6. Developing advocacy strategy through policy briefs and other communication tools to raise awareness of the sector among a much broader audience.

5.2 Quick Win 2: Creation on an enabling ecosystem

5.2.1 Discussions

- Raw materials are core to the industry. The sector reportedly lacks data on raw materials being used such as medical grade titanium, medical grade and stainless steel. It was noted there are too many entities gathering data, without consolidation. It was also suggested that a research desk is needed at DTIC that gathers data and collates it for industry. Also, it was reported by ITAC that its investigations into the need for tariff protections on raw materials could take at least 4 - 6 months. It can assist with exemptions for raw or intermediate materials but needs sufficient evidence that no local firms are producing the raw material or that they cannot provide enough. There has been communication with Arab Health to manufacture products for the industry, and this should be supported with DTIC assistance. On rebates, there needs to be a submission and SARS will be involved. It was suggested this work stream makes a submission for exemptions. However, it was noted there has been no movement on submissions already made.
- Again, on tariffs, caution was advised on many tariff protections as these can build complacency and deter competitiveness. However, the masterplan can identify what products can be protected. Medical Device Manufacturers of South Africa (MDMSA) noted it had started a process some time ago of identifying products that can be protected and this initiative can be resuscitated with collaboration from DTIC.
- Investments and industry finance are fundamental to any industry and its sustainability and competitiveness. A need for centralised industry finance and grant capital, bond capital, and tax incentives. was suggested. Some initiatives already exist. For example SAMED also noted its portal shows funding opportunities for SMMEs from various government

departments. The link is: <https://samed.org.za/library-accessed/library-market-access/smme-local-manufacture-support/>.

- Access to markets is essential for any manufacturer. Both local and export markets play a key role in the sustainability of firms and in ensuring provision of medical goods to end users and the health care system. It was recommended that end users in the local market should be made aware of the existence of local medical devices. SAMRC through MEDDIC launched a platform embedded in the Innovation Bridge Portal where manufacturers and developers can list their product(s). MEDDIC is also trying to set up a raw materials platform in the same portal so that companies can see who is ordering which material and perhaps collaborate to negotiate discounts. However, this is where input was needed most from manufacturers. Emails have been sent to companies to curate data and get permission, but ultimately the project relies on stakeholder's cooperation.
- On markets, one of the working group members from Idea2Business noted the foundation was working on a portal that brings manufacturing and buyers together and aims to ensure that buyers can see if a device is locally made. However, both parties have a challenge. Manufacturers need to engage with hospital groups as to what are local and new products. When the portal is up and running anyone can search and anything new can be highlighted. However, that at times buyers do not know what is local, which was imperative for manufacturers. Continuous funding is essential to complete and launch the portal as well as to incorporate the use of Global Medical Device Nomenclature (GMDN), the international codes for medical devices. Or the European system coding can be used, which may be easier, though research on this is still being done. There has been conversation with SAHPRA, as it has these codes. Many relationships still need to be built with both parties. A stakeholder meeting is needed for this to work. It was recommended to check if this portal is similar to the African Medical Supply Platform and to explore synergies.
- Overall, a call was made for collaboration for all portals being launched to avoid duplication; already MEDDIC and Idea2Business are collaborating.
- Access to markets can also be fostered within regional trading groups. A stakeholder meeting on the African Continental Free Trade Agreement was proposed. Each African country's regulations and product assessments should be streamlined. Some countries do not have these and so collaboration is needed. This is so that when exporting a firm does not need to spend money and effort to meet a specific country's regulations. For now, it was noted that this has been limited to vaccines and the pharmaceuticals industry. The African Medicines Agency initiative, for example, only concerns pharmaceuticals.
- Access to local markets also requires knowledge of local goods and the capacity to look for these goods in large procurers, such as hospitals. Hospitals may have, for example, 30 000 line items. The challenge for those in charge of procurement at hospitals is to know who is manufacturing what products. Products may be abundant, but time to meet local manufacturers limited. Platforms encompassing stakeholders from hospitals and manufacturers and procurement tenders would help. In addition, the DTIC and Department of Health should collaborate on procurement systems to ensure that all efforts have been made to procure from local manufacturers.
- Accreditation and testing systems are also fundamental to support manufacturers, exports, and local procurement. Increasing local testing abilities and helping firms get international accreditation were seen as urgent.

- The DTIC should help end users especially in other departments such as Health, buy local. Products can be certified but uptake is essential.

5.2.2 Current initiatives and champions

1. SAMED has a page on its website that has consolidated different avenues of funding from government departments such as SEDA, SEFA, IDC, DTIC, GGDA, and WESGRO.
2. SAMRC through MEDDIC launched a platform, embedded in the Innovation Bridge Portal, where manufacturers and developers can list their product(s). MEDDIC is also trying to set up a raw materials platform in the same portal so that companies can see who is ordering which material and perhaps collaborate to negotiate discounts. However, it was noted that this is where input was needed from most manufacturers.
3. A portal is being developed by Idea2Business to bring manufacturers and buyers together and would aim to ensure that buyers could see if a device is locally made. More information is listed in the summary.

5.2.3 Outcomes – to be implemented in the short-term

1. Communicate with ITAC on pro-active application processes and requirements for tariff protection of medical devices as well as applications for tariff rebates on imported raw materials and intermediate products.
2. Create industry portal of locally manufactured products for prospective buyers – would require funding.
3. Stakeholder meetings between buyers and sellers.
4. Ramp up localised testing, including accreditation of laboratories, which is needed for exports.
5. Promote harmonisation of regulations across African markets taking into consideration the opportunities under the AfCFTA as well as regulatory costs. Advocacy is needed here.

5.3 Quick Win 3 - Skills and capacity development

5.3.1 Discussions

- The lack of appropriate qualifications, especially in vocational education, must be tackled. Qualifications and industry needs are misaligned. International partnerships for capacity building should be forged to learn how to fix this misalignment.
- And imbalance exists of graduates with academic knowledge and artisans for manufacturing as well as maintenance of equipment in various hospitals. This calls for the creation of a clear category in clinical engineering and increasing graduate skills in manufacturing. For maintaining equipment, working with technical schools in KZN, GP and WC is crucial.
- Another challenge with a long-term solution was modernising infrastructure, including integrating artificial intelligence. Also technology training is necessary for graduates, especially for public hospitals that do not necessarily have the most updated or the most high-tech equipment.
- On new technology commercialisation, partnering with UCT on the fellowship it can offer could be a short-term solution. Moreover, cross-pollinating skills programmes between various industries, leaning on the previous masterplans was seen to be critical.
- An additional long-term solution would be to upskill universities to conduct trials at international standards.

- Other issues included tenders and private commercialisation processes and incentives, though no solutions were proposed.
- A unified approach to skills development for the sector rather than only one educational institution providing a short course, as Stellenbosch does, would be optimal.
- Generally, formally accredited clinical training courses are already offered. The challenge is lack of professional registration for clinical engineering. Clinical engineering is part of the Engineering Council of South Africa (ECSA) but is traditionally categorised under general engineering. An ongoing initiative has been to engage with ECSA to define a clear category of clinical engineering. The aim is to professionalise clinical engineering services within ECSA. A document has been developed, pending further discussion. Other categories need to be looked into as well in consultation with other stakeholders. DoH is championing the initiative and a sub-committee has been set up.
- Trade qualified artisans are needed. These are vocational training schools graduates who can fix and maintain machines. Learnerships for trade qualifications must be started at Grade 10 level.
- A study of the critical skills that are lacking must be undertaken to come up with a skills development plan.
- The Chemical Industries Education and Training Authority (CHIETA) is developing a health product regulatory assistant qualification. This person will be an assistant to the authorised pharmacist/representative. A working group established by CHIETA includes industry representatives and training providers to the industry. The curriculum is under development.
- The document, still at an early stage, that has been shared so far is titled the Occupational Profile Scientific Affairs Officer and is about SAQA putting a qualification together. It also deals with regulation.
- Medical devices are diverse and so are the appropriate skills, and cut across different SETAs e.g., textiles, chemicals, metals.
- Also, skills are needed in regulatory affairs, but this is difficult to navigate when South Africa has no clear regulations. The industry knows what it needs. Training can be offered either locally or internationally, though international training is costly. Furthermore, training is available at workplaces.
- What skills are needed is a subject of debate. There are already two paths. One is through traditional education and the other is employer-driven, with artisans trained according to what the industry wants rather than taking years in TVET. It is important to understand how qualifications and training are structured. It would be good to understand from local manufacturers, especially for artisans, what is their level of openness to providing training. Learnerships have been around for some time. However, learnerships do not guarantee employment or employability. The appropriateness of what is taught in the learnership needs to be linked to market appropriateness and employability.
- A skills audit, with involvement of industry players, is a necessity.
- One of the quick wins would be to talk to hospital groups about which machines break the most so that artisans can be trained on those. Working with the Technology Innovation Agency, as they collaborate with different universities of technology to develop short learning programmes to increase employability of artisans, would be critical.
- Setting up a Medical Devices SETA will be a longer-term initiative not a quick win.

5.3.2 Current initiatives and champions

- Professional registration of clinical engineering and other categories, championed by NDoH.
- Developing a health product regulatory assistant qualification, championed by CHIETA.

5.3.3 Outcomes – to be implemented in the short-term

1. Create visibility of all current courses and training offered in the sector to deal with academic qualifications not being market appropriate and the lack of regulatory skills.
2. Do a skills audit in collaboration with companies, including local manufacturers, buyers, the Technology Innovation Agency, and educational institutions such as the Tshwane University of Technology, to identify crucial skills, such as equipment maintenance, testing and laboratory skills.
3. Implement vocational skills training.
4. Finalise professionalising qualifications, e.g. the clinical engineering qualification, with the NDoH & CHIETA

5.4 Quick Win 4 - Improving market access and export enablers

5.4.1 Discussions

- Overlap with other initiatives.
- R & D tax exemptions are already being used.
- Which banks can give credit if demand is in place and can be shown, but how do we mitigate risk? Predictability of demand will satisfy the risk appetite of funders. Having a stakeholder meeting to bring together buyers and sellers would help. An example is a buyers and sellers' forum.
- Keep in mind competition law. Take care to avoid collusion.
- An MOU between the buyer and the seller indicating how much the buyer will procure from the seller, will enable the seller to obtain credit from the bank to ramp up its production.
- To avoid falling foul of competition law demand must include public sector demand and not merely focus on the big three private hospitals, and independents.

5.4.2 Current initiatives and champions

There were no specific initiatives for this pillar.

5.4.3 Outcomes – to be implemented in the short-term

1. Leverage tax incentive for the benefit of the sector. Some initiatives already exist.
2. Stakeholder meetings must include issues of predictable demand, buyer commitments, banks for funding commitments for growth stage of companies, and satisfying risk appetite.

5.5 Quick Win 5 – Achievement of global competitiveness

5.5.1 Discussions

There was no discussion on this Quick Win. However, the importance of having a technical task group focused on regulation was stressed. Having device registration regulations and hopefully a single African regulatory framework are important.

5.5.2 Current initiatives and champions

There were no specific initiatives under this pillar.

5.5.3 Outcomes – to be implemented in the short-term

The quick win interventions for achieving global competitiveness were not discussed as the group members could not find a linkage between what was presented and what was discussed in the group. An Interim Report was shared with the TIPS team for information on the Quick Wins from the group and they are listed below.

1. Having an effective regulator
 - a. Increase capabilities, capacity of regulatory bodies, create notified bodies.
 - b. Support local manufacturers to increase levels of compliance with global standards.
 - c. Train local inspectors for compliance-readiness assessments.
 - d. Use higher institution infrastructure for product testing
2. Ensuring access to private sector for local products
 - a. Align procurement requirements (price, local content) between NDOH and Treasury.
 - b. Make legislation, regulations and incentives to support procurement from private hospital groups.
3. Reducing Cost and Admin of Exports
 - a. Give rebates on exports logistics for exports below R1 - 10 million.
4. Conversion of Distributors to Manufacturing
 - a. Create an incentive package for transitioning (example: capital investment rebates, tax-free incentives).
 - b. Partner with multi-national corporations to promote transition from component production to final product.
5. Localising Raw Materials - Polymers
 - a. Use international relations to improve access to raw materials.
 - b. Work closely with raw material suppliers through an innovation hub cluster model.
6. Use SEZ infrastructure to create medtech clusters.
 - a. Promote and facilitate the use of SEZs by Medtech firms and consider designation of SEZs as medtech clusters.

5.6 Quick Win 6 – Integration into global value chain

5.6.1 Discussions

- Growing local capacity is a must, and other working groups will make this pillar grow.
- SA must build capacity that makes it a global player in medical devices.
- Drive transformation initiatives in the sector.

- Reduce shipping costs.

5.6.2 Current initiatives and champions

No current initiatives were mentioned.

5.6.3 Outcomes – to be implemented in the short-term

This pillar is dependent on building of local capacity.

Conclusion and way forward

In conclusion, it was agreed that the identified quick wins need to be prioritised according to the definition and viability in implementation. Each identified initiative will need a champion. Furthermore, the working groups are encouraged to comment or provide more input as the masterplan process continues. A workshop will be held with broad stakeholders in the medical devices industry to validate and garner commitment on the quick wins and their immediate implementation.

Annexure A: Workshop Agenda

The agenda and programme for the workshop is provided below:

CHAIR: DEPARTMENT OF TRADE, INDUSTRY AND COMPETITION		
Time	Agenda Item	Action by
09h00 – 09h15	Opening and background <ul style="list-style-type: none"> • Purpose of project and workshop 	The dtic
09h15 – 09h45	Project approach and methodology	TIPS
09h45 - 10h00	Consensus on criteria for “quick wins”	TIPS and Health Value Consultants
10h00 – 10h30	Quick win 1 – Regulation	
10h30 – 11h00	Quick win 2 – Creating an enabling ecosystem	
11h00 – 11h15	BREAK	
11h15 - 11h45	Quick win 3 - Skills and capacity development	
11h45 – 12h15	Quick win 4 - Improving market access and export enablers	
12h15 – 12h30	Quick win 5 - Achievement of Global Competitiveness	
12h30 – 12h45	Quick win 6 - Integration into global value chains	TIPS
12h45 – 13h00	Conclusion and way forward	

Annexure B: Project Methodology

VALUE CHAIN ANALYSIS	INDUSTRY, GOVERNMENT AND LABOUR CONSULTATIVE PROCESS	LIMITATIONS
<ul style="list-style-type: none"> Supply side Demand side <p>Overall</p> <ul style="list-style-type: none"> Current productivity competitiveness Constraints Opportunities and interventions <p>Case studies</p> <ul style="list-style-type: none"> International best practices Lessons 	<ul style="list-style-type: none"> Workshop 1 Workshop 2 Other dialogues and engagements 	<ul style="list-style-type: none"> Extremely complex value chain Cuts across different industries such as <ul style="list-style-type: none"> Steel Plastic Glass Textiles. Elements of medical devices are also captured in existing masterplans Fragmented data

Value Chain Analysis	Industry, Government, Labor Consultative Process	Limitations
<ul style="list-style-type: none"> Supply Side Demand Side <p>Overall</p> <ul style="list-style-type: none"> Current Productivity, Competitiveness Challenges, Constraints, Chokepoints Opportunities And Interventions <p>Case Studies</p> <ul style="list-style-type: none"> International Best Practice Lessons 	<ul style="list-style-type: none"> Workshop 1 Workshop 2 Other dialogues and engagements 	<ol style="list-style-type: none"> Extremely Complex Value Chain Cuts Across Different Industries <ul style="list-style-type: none"> Steel Plastics Glass Textiles Elements Of MD Are Also Captured In Existing Masterplans Fragmented data

MASTERPLAN PHASE	ACTIVITY	TIMEFRAME
Phase 1	Quick Wins	February 2023
	i. Workshop 1 - Working Groups	
	ii. Workshop 2 Validation of the quick wins with industry stakeholders	March - April 2023
Phase 2	Ongoing Research	March 2023
	i. Industry Situational Analysis entails the value chain analysis, looking at the demand and supply	

	side issues; productivity; competitiveness; constraints; opportunities; interventions and case studies (on international best practices).	
	ii. Multiple industry, government, and labour consultative engagements	March 2023
Phase 3	Policy interventions	March 2023
Phase 4	Facilitation of industry commitments	April – May 2023
Phase 5	Draft Masterplan and handover to the DTIC	June 2023

Annexure C: Quick wins presented

Quick Win 1: Regulatory and Policy Advocacy

Implement post-market surveillance system for medical devices on the SA market.

Mock audit SAHPRA and local manufacturers for implementation of good regulatory practices.

Clear differentiation between medical devices and pharmaceuticals in regulatory frameworks.

Ensure support for local medical device manufacturers for international accreditation through institutions such as CE, FDA, and WHO.

Establish a regulatory fee structure for medical device registration which is widely accepted and will facilitate growth of the sector.

Test feasibility of MD product registrations both in the MD sector and regulatory authorities.

Establish dedicated medical devices engagement platforms for adequate representation to government and regulators, ensuring that there is no conflict of interest.

Ensure that all applicable policy frameworks/regulations highlight needs of medical devices sector e.g. R&D Tax incentive, procurement regulations, and the NHI Bill.

Advocate more reasonable access to international accreditation mechanisms for locally manufactured medical devices.

Quick Win 2: Creation of an Enabling Ecosystem

Imported raw and intermediate materials exemptions, rebates

Centralised Industrial Finance Initiatives (public and private)

Centralised Accreditation Support Centre

- Subsidise international accreditation costs
- Readily available international regulations
- Mock audits

Uptake and Market Expansion

- Retail, hospital, medical aids
- Government procurement

Quick Win 3: Skills and capacity development

International partnership for capacity building e.g. autos and agricultural vocational training.

Revive industry proposal on social compact model for skills training across the industry and government with independent funding and governance model.

Creation of a clear category of clinical engineering – some processes are underway, but further coordination, funding and momentum is required.

Select 3 technical schools [Gauteng/WC/KZN]. Pilot ad hoc curriculum.

Partner with new industrialisation fellowship at UCT.

Quick Win 4: Improving market access and export enablers

Incentives for manufacturing (e.g: tax breaks, export rebates).

Designation of class A and class B products.

Regulation and standards certification and accreditation.

Implement initiatives to improve cohesiveness and connectivity in the innovation space.

Set up and implement a coherent capital-raising mechanism/strategy.

Leverage changes in the R&D tax incentives for local manufacturers through active advocacy.

Establish alliances and cooperation agreements in the local market to create efficiencies in marketing and sales functions to optimise reach and revenue for smaller manufacturers.

Quick win 5: Achievement of global competitiveness

Centralised Database Global Procurement Opportunities

- WHO
- Global Health Initiatives

Central export market support (DTIC has Export Marketing and Investment Assistance).

- Trade facilitation and offtake agreements.
- Rebates, export fairs
- Centralised knowledge base (local and international) for partnerships in R&D, product design.
- Building MOUs with Global Health Initiatives in SADC.

Firm collaboration to market internationally

Quick win 6: Integration into global value chains

Build manufacturing experience, leveraging SA's sophisticated manufacturing base and excellent universities, not commonly found in emerging markets.

Set up processes to build advanced internal manufacturing capabilities to overcome institutional voids while forging multiple knowledge collaborations to complement in-house capabilities.

Set up processes to be in control of all stages of the manufacturing process.

Trade & Industrial Policies Strategies (TIPS) supports policy development through research and dialogue. Its two areas of focus are trade and inclusive industrial policy, and sustainable development.

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