TRADE & INDUSTRIAL POLICY STRATEGIES

Terms of Reference for Development of Medical Devices Master Plan

MARCH 2022

1. PURPOSE

Trade and Industrial Policy Strategies (TIPS) on behalf of the Department of Trade, Industry and Competition (the dtic) in partnership with the Medical Device Manufacturers (MDMSA), the South African Medical Device Industry Association (SAMED) and the South African Laboratory and Diagnostics Association (SALDA) seeks the services of independent consultants with extensive and proven experience and knowledge of the South African medical device industry, its participants, and the South African industrial policy environment, to facilitate the development of the medical devices industry master plan.

2. BACKGROUND

2.1 Government approved the Re-invigorated Industrial Strategy (RIS) for South Africa (SA) in June 2019. A cornerstone of the Industrial Strategy is the development of sector-focused Master Plans in 15 priority sectors. The Master Plan approach has been implemented in the Autos sector over the last decade and has proven to be a highly effective means of creating stakeholder support for a coordinated approach to developing industrial sectors.

2.2 A Master Plan is a comprehensive plan of action developed by Government and Business which seeks to achieve a common policy objective e.g. protect jobs, create jobs, deepen capabilities in the sector, expand exports, and/or prepare for the impact of possible policy changes. The Master Plan is typically time-bound and incorporates various actions across the 3 main stakeholders, sequenced to achieve maximum socio-economic impact.

2.3 Who Owns Whom 2017 report estimated the size of the South African Medical devices market at approximately R21 billion in 2021, projected grow to R29,6 billion by 2025 making it one of the largest in the Middle East and Africa (MEA) region. The growth trends are primarily attributed to an increasing elderly population, universal health coverage, the development and upgrade of hospitals through public-private partnerships.

2.4 The global market is projected to grow substantially and growth drivers include a rising elderly population, epidemiology trends focused on chronic diseases and technology innovation. Living standards have given rise to the rapid growth in the demand for various medical products.

2.5 The South African industry has pockets of excellence with a capacity to manufacture innovative products that are globally competitive. Most local manufacturers of Medical Devices export to several mature markets such as the USA and the EU. Asia and Africa are among the growing markets that have a rapidly growing potential to absorb locally manufactured medical devices.

2.6 South Africa's medical device sector is a highly diversified export-oriented industry that manufactures various medical equipment and supplies. It is able to draw on world-class innovative research being conducted in South Africa by universities, research institutes and hospitals, some of which have been spun-off into Medical device companies. The local SMEs dominate the local industry by number, and foreign-owned global companies by market share.

2.7 The base of most Medical devices companies is Gauteng, Western Cape and Kwa-Zulu Natal. More than 150 Medical device companies operate along the entire value chain - from R&D, to proprietary products, contract design and manufacturing, packaging and sterilisation. South Africa has an excellent skills base, good education system, a thriving R&D sector, and a capacity of bringing innovative products and services to market.

3. PROBLEM STATEMENT

3.1 The South African medical devices industry is characterised by imports. Although the South African market is estimated at around R21 billion, more than 90% is supplied by imports. This deprives South Africa of the jobs that could be created locally. Medical devices and Pharmaceutical jointly make the top 5 major contributor to trade deficit. This situation is expected to worsen as the demand for medical products continues to increase.

3.2 Political unrest and uncertainty; Government service supply such as inconsistent electricity and water supply; infrastructure deficiencies such as poorly maintained roads; and labour unrest and disputes such as strikes, contribute to a challenging manufacturing output and success.

3.3 The infancy of legislation for regulatory control and requirements of good manufacturing practices following defined quality management system requirements to International Organisation of Standards (ISO) and published South African National Standards (SANS) for medical devices, and local innovations requiring design principles to these safety and quality requirements hinders commercialisation.

3.4 The RIS and the ERRP has identified the need for a masterplan and social compact for health products with a specific focus on the medical devices manufacture potential and related R&D and clinical trial opportunities.

4. OBJECTIVES OF THE MASTERPLAN

4.1 The primary objective of the Master Plan process is to develop an agreed-upon set of actions, with timeframes, that all stakeholders in a sector or value-chain commit to implementing for the benefit of the sector or value-chain.

4.2 The objectives of masterplan include encouraging sector growth, investment, job creation and competitiveness; reduce the trade deficit with increased exports especially with South Africa as a gateway to Africa; provide a legislative framework for production of competitive medical devices that meet internationally approved safety and performance requirements.

5. SCOPE OF THE MASTER PLAN PROJECT

5.1 The Master Plan must give a clear guidance on priority areas for government and industry in order to achieve the following sector focus areas:

I. to provide **skills development** to increase capability and capacity of labour to grow local content in products.
II. to create an enabling ecosystem for local firms and multinationals to start and grow their **local manufacturing** and create skilled local jobs through provision of support of infrastructure, regulatory compliance and good manufacturing practice (GMP).
III. to develop **local market access** using cluster and market network practices and following achievable procurement methodologies (tender / formularies/ essential products list).
IV. to be **globally competitive** (CE / FDA / MHRA – partnership for recognition of regulator as a stringent Competent Authority).
V. to form part of the **Global Value Chains** (GVCs) (Localise all or some components/part of the value chain to enable local manufacturing).
VI. to create **export enablers** e.g. manufacture and export of components for overseas production / markets.

5.2 The Master Plan must also include a review of R&D, clinical trial and commercial manufacturing opportunities for SA where substantial investment can be made.

5.3 The scope of this assignment includes the consideration of the following:

I. Coverage of burden of disease in South Africa
    - in respect of medical devices for private / public markets e.g. more loan set and items for trauma events (accidents and violence incidents), cannulas, disinfection (Surgical site infection and hospital acquired infection controls).
II. Skills development
    - Review products in the sector to establish skill requirements for innovation, regulatory requirements and good manufacture practice realization.

III. Innovation support and assistance
    - R&D pathways, resources and support;
    - pre-commercialization verification testing, clinical evaluation and validation resources (clinical investigations, usability studies, process or product validations);
    - pathways, support, resources, to realize commercialization and sustainable operations.

IV. Infrastructure and GMP
    - Establish bionetwork through a 4IR platform to identify and enable a network for Infrastructure and GMP / regulatory requirements namely;

- buildings, workspace and associated utilities (HVAC, treated compressed air and water);
- process equipment (both hardware and software);
- supporting services (such as transport, communication, or information systems);
- components, packaging, services (sterilization), cleanroom;
- local regional conformity assessment development for management system certification, testing, validation.

V. Private / public markets purchasing processes

- how to accommodate new technologies or follow current practice for historical consumable and old therapy (triangular bandages instead of new technology limb support products that offer support, healing and improved back to work outcomes)

VI. Current private / public markets product mix (volumes)

- Understand and focus capacity and capability private / public procurement departments in line with product mix and volumes, address shortages and gaps that may assist, provide policy certainty for local investment in manufacture and facilitate development of tools and interventions to assist with achieving global competitiveness.

VII. Overseas export product mix (volumes)

- The product mix that can add export opportunities (that could be launched into local private / public markets) and provide capacity building for production e.g. diabetic cellular data ports for glucometric data acquisition and insulin dispensing (Diabetes burden of disease), hypertension BP, heart rate cellular data collection and data transfer to HCPs (Cardio burden of disease).

VIII. Public market ecosystem review

- DOH HCP current picture vs new innovation opportunities e.g. current x-ray machines that use plates vs new digital technology – explore funding and skills needs for use of new equipment, maintenance and installation.

IX. Export facilitation

- That is sustainable to support the industry develop world class products - that is also able to provide assistance for costly tests and validations; funding expensive plant and equipment; assistance with international approvals.

X. Incentives to buy locally produced medical devices
   - restricted import product policies, practice and governance.

6. QUALIFICATIONS AND EXPERIENCE REQUIREMENTS

6.1 The consultant must have an extensive and proven experience and knowledge of the following:

a) The South African healthcare industry and its participants;
b) the Medical devices industry including research, development, clinical trials, manufacturing and regulatory requirements worldwide;
c) The export potential of South Africa-made medical devices; and
d) The South African industrial policy environment.
e) Demonstrable development of masterplans or similar and social compacting, negotiating commitments, etc.

7. DELIVERABLES

7.1 **The following specific outputs are expected on the completion of the project:**

- Inception report
- Stakeholder interview schedule and questionnaire
- Stakeholder consultative meeting records
- Situation Analysis, including the analytical review report of the existing sub sector strategies
- Industry value chain analysis and identify competitiveness bottlenecks
- Report on the structure of the industry, clearly identifying key players, especially those exporting to other markets
- Report identifying sector gaps/bottlenecks and a strategy to address these gaps
- Stakeholder feedback workshop report
- Medical Devices Masterplan for South Africa
- Implementation and monitoring & evaluation plans

7.1.1 Phase 1: Project Inception

- Upon appointment the service provider is required to commence by drafting an inception report that will detail the overall approach, methodology and expected timeframe in which each phase of the project activities will be completed and the related estimated costs and resources required.
- The inception report will serve as a discussion document and will be the basis on which the detailed approach to the project is agreed.
- The inception report is an interim deliverable that is expected to be completed in two weeks from the time that the service provider is appointed.

7.1.2 **Phase 2: Situation Analysis**

- Undertake literature review on existing sub-sector strategies, Regional and National Medical Devices Industry Strategy and related strategies, policies and plans. Synthesise information, screen for adequacy and identify gaps.
- Review current productivity and competitiveness levels in the medical devices industry.
- Conduct an overview of the broad South African priorities in respect of job creation and reduction of poverty.
- Identify opportunities and challenges on the major sub-sectors and at each value node and propose key interventions for each.
- Review international standards to be used as benchmarks.
- Review trade agreements and/restrictions affecting the sector, especially in the region;
- Review reprioritisation of key growth sub-sectors in respect of industry growth, export promotion and unemployment reduction.
- Identify appropriate private and public sector roles, and outline key strategies and actions necessary to give effect to the above.
- Identify competitiveness gaps/bottlenecks across the medical devices manufacturing value chain.
- Identify best practice models in the development, implementation and monitoring of similar interventions in a similar environment.
- Develop detailed scenarios.

7.1.3 **Phase 3: Consultation Meetings and Scoping Workshop with the Stakeholders for the Policy Framework and Strategy Development**

- Conduct wider consultation with all key stakeholders in the country, including private sector, government departments, municipalities, organised labour and tertiary/training institutions.
- Assess key successes, impact and failures in the implementation of different initiatives in the industry.
- Assess the growth challenges encountered by the industry. Further discussions on limitations of current tools such as funding (government incentives and FDIs), Local Procurement, and Market Access.
- Organise dialogue between government and the private sector to develop a shared vision of a competitive medical devises industry. Dialogues should also be organised at decision-makers' level, where company executives can have discussion with political heads such as the Minister or Deputy Minister of the Department of Trade, Industry and Competition.
- Identify key challenges and gaps, and recommend mechanisms of addressing them.
- Identify best practice models in the development, implementation and monitoring of similar interventions in a similar environment of the Medical Devices for South Africa.

7.1.4 **Phase 4: Compiling Medical Devices Masterplan for South Africa**

- Compile the Medical Devices Industry Masterplan for South Africa based on the above analysis.
- Develop an implementation, monitoring and evaluation frameworks for the Medical Devices Master Plan for South Africa.
- Conduct stakeholder workshops/dialogue sessions (at least two) on the development of the plan, and for communicating the findings once the plan is developed.

7.1.5 **Phase 5: Project Close Out**

The following are expected outputs in order to meet the objectives of this initiative:

- Project Inception Report
- Situation Analysis Report
- Stakeholder Engagement Report
- Medical Devices Master Plan
- Implementation Action Plan
- Monitoring and Evaluation Framework

The reports have to be presented in appropriate electronic as well as printed format, and must be easily accessible and user-friendly. Minutes and other documents emanating from all meetings are general deliverables throughout the duration of the project.

8. TIMEFRAME

Proposals shall include a comprehensive project plan with clearly identified milestones and a firm delivery date for the completion of the total project. The duration of this project is expected to last **seven months**.

9. REQUIREMENTS

The proposal must provide a detailed profile of skills and competencies of the key experts. A Company and or Consortium profile must be provided detailing previous work history and experience.

9.1. **Skills and competencies**

For the purpose of this work, TIPS requires appointment of a service provider with the following competencies: For each expert proposed, curriculum vitae of no more than four pages, should be submitted. This section specifies the expertise (qualifications, experience) required for each person assigned to the study.

- Experience in and knowledge of the South African pharmaceutical/medical devices industry; global and local Healthcare and life science value chains; industry support programmes, incentives and institutions;

- Experience and knowledge of policy analysis and evaluation;
- Strategy development and project experience;
- A thorough understanding of regional, national and global economies and relevance in industrial policy development;
- A thorough understanding of broad raw material inputs into the medical devices industry, backward and forward linkages;
- Experience in programme strategy or policy impact assessments;
- Research methodologies and analysis;
- Experience in policy development and Strategic Planning;
- Experience in project implementation, monitoring and reporting;
- Writing and Communication Skills
    - Good report writing and editing skills
    - A good command of the English language

- All experts who have a crucial role in implementing the contract are referred to as key experts

The bidder must provide three (3) references of any work done for and/ or within medical devices sector in the past five years, e.g. techno-economic research, development of strategic action plans etc.

9.2 **Team Composition**

The appointment of the Service Provider will be based on the strength of key experts' curriculum vitae that will contribute to the successful execution of the project. The profiles of the key experts for this contract are as follows:

9.2.1 **Team Leader**

The incumbent must be a Development Strategist with the following key qualification and experience:

- Post graduate qualification in Economics/ International Trade or related disciplines;
- Strong leadership qualities and the ability to communicate effectively;
- Minimum 7 years practical and technical experience in macroeconomic policy development;
- Knowledge of Spatial Development Initiatives; Growth Development Strategies, Local Economic Development, Industrial Sectors and clusters and Enterprise development issues;
- High attention to detail and ability to prioritise workload, multi-task and work to tight deadlines;

- Strong understanding of provincial macroeconomic policies;
- Knowledge of public sector procurement policies;

9.2.2 **Industrial Development/ Resources Beneficiation Specialist**

- Relevant Development Economics qualification;
- 5 years' experience in local economic development and macroeconomic policy analysis;
- Policy development, implementation, monitoring and reporting;
- Good analytical, writing and communication skills;
- Knowledge of South Africa macroeconomic policies;
- High attention to detail and ability to work to tight deadlines;
- Good analytical, writing and communication skills;
- Knowledge of medical devices industries and macroeconomic development policies;
- Knowledge of public sector procurement policies;
- Strong administration skills.

9.2.3 **Sector Specialists**

- Relevant tertiary qualification;
- A minimum of 5 years' experience in industrial sector analysis specifically medical devices manufacturing industry.
- Good analytical, writing and communication skills;
- Knowledge of medical devices sector and its value chain;
- A thorough understanding of broad raw material inputs into the medical devices manufacturing industry, backward and forward linkages;
- Strong administration skills.

The service provider based on the methodology and approach suggested may recommend additional key experts. In this regard the service provider should justify and motivate the inclusion of any additional experts.

10. REPORTING

TIPS, the DTIC and MDMSA will jointly form a Steering Committee to oversee the project with a specified Project Manager and Project team as the contact for the service provider to report on progress of the project within the stipulated timeframes. The reports will be required to be documented in a specific format as provided by the project manager.

The service provider must provide the **Project Manager and Project team** with a project plan indicating time frames, processes of implementation and provide reports, evaluation and statistical data.

The **Steering Committee** will evaluate each phase before any payment is approved. The final report should be presented to the Steering Committee**.** All meetings are to be arranged by the Service Provider who is expected to keep the record of such meetings and to deliver the record of a meeting within 10 working days of it having taken place.

On conclusion of the project, a meeting will be held between the service provider and the key stakeholders who will be identified by the Steering Committee.

11. PROPOSAL REQUIREMENTS

The proposal will comprise the following elements:

- Understanding of the Programme Context and the Assignment
- Organisation and methodology
- Proposed Team Composition and Key Experts Profile
- Financial proposal with a budget breakdown and a cash flow forecast
- Attachment of the BEE certificate

The **budget breakdown** will include:

- The estimated number of days per expert and other personnel and fee rate per expert/personnel and output.
- The incidental and disbursement costs (including travel, stationery etc.) (including outsourced or in sourced costs not covered by key expert fee days) per output.
- Any additional costs.

12. BID EVALUATION CRITERIA

The Service Providers will be evaluated on the following five criteria as elaborated in **Annexure 1 – The Evaluation Grid**:

- Team qualifications
- Technical proposal
- B-BBEE status
- Price
- Presentation of the bid to the Steering Committee

13. PROPOSALS

Closing Date: 03 June 2022

Proposals should be sent to Trade and Industrial Policy Research Strategies (TIPS) for the attention of **Ms. Daphney Mabuza (daphney@tips.org.za)**

Annexure 1

Evaluation Criteria for Terms of Reference for Development of Medical Devices Master Plan for South Africa

MARCH 2022

ANNEXURE 1: EVALUATION GRID

1. Technical Requirements

The following weightings will be applicable:

ELEMENT	WEIGHT
Bidder's Relevant Experience	15
Experience, Skills and Qualifications of the key personnel	25
Bidder's Proposed Methodology	25
Project Plan	5
Presentations	30
TOTAL	100%

Note:

•The bidder must score a total of at least 49.00 points on experience of the bidder and the team, proposed methodology and project plan in order to qualify for the presentations.

The minimum qualifying score for technical bid is 70%. All bids that fail to achieve the minimum qualifying score on the technical bid shall not be considered for further evaluation on Price and B-BBEE, in Phase 2.

CRITERIA	POINTS
Price	80
B-BBEE	20
TOTAL	**100 points**

1.1 Technical Evaluation Criteria

1.1.1 Non-Mandatory Technical Requirements

The bidder must indicate its compliance / non-compliance to the requirements and should substantiate its response in the space provided below. If more space is required to justify

compliance, please ensure that the substantiation is clearly cross-referenced to the relevant requirement.

1.1.1.1 BIDDER'S EXPERIENCE	**Comply**	**Partially Comply**	**Not Comply**
The bidder must demonstrate relevant experience working in South African pharmaceutical/medical devices or related industry. The bidder must provide three (3) relevant contactable references of similar work done in the past five (5) years. **Note**: The following scoring will be used to evaluate these criteria. • 1 relevant references in pharmaceuticals/medical devices or related Sector = 2 points • 3 relevant references in the pharmaceuticals/medical devices or related sector including one technical area = 3 points • 4 to 5 relevant references in the pharmaceuticals/medical devices or related sector including 2 technical area = 4 points • 6 and more relevant references in the pharmaceuticals/medical devices or related sector including four technical areas = 5 points			
Substantiate / Comments			

1.1.1.2 QUALIFICATIONS AND SKILLS OF KEY PERSONNEL	Comply	Partially Comply	Not Comply
The bidder's key personnel of the proposed team must have relevant qualifications, skills and experience. Technical competency: ➢ Knowledge of government policies relating to the medical devices or related industry; ➢ Knowledge of the medical devices industry, backward and forward linkages; ➢ Demonstrated experience in and knowledge of the South African pharmaceutical/medical devices industry; global and local Healthcare and life science value chains; industry support programmes, incentives and institutions; ➢ Demonstrated experience in programme strategy or policy impact assessments; ➢ experience with developing masterplans or similar and social compacting, negotiating commitments, etc.; ➢ Research methodologies and analysis; ➢ Experience in project implementation, monitoring and reporting; ➢ Data analysis. In addition to the above skills and qualifications, the project team is required to collectively have a minimum of 15 years' experience in the medical devices. The project leader is expected to have a minimum of 7 years' experience in the medical devices or related industry and the minimum of a 4-year tertiary degree qualification. Each team member is expected to have a minimum of a 3-year tertiary qualification (degree or diploma) and minimum of 3 years' medical devices or related industry experience. The bidder must submit, as part of its proposal, the following: ➢ The structure and composition of the proposed team, clearly outlining the main disciplines/ specialties of this project and the key personnel responsible for each specialty, reference letters from previous projects/clients. ➢ CVs of the key personnel; and the CVs must clearly highlight qualifications, areas of experience/ competence relevant to the tasks and objectives of this project as outlined above.			
Substantiate / Comments			

1.1.1.3 BIDDER'S PROPOSED METHODOLOGY	Comply	Partially Comply	Not Comply
The bidder must provide a detailed proposal of the methodology/ approach to be used to carry out the scope of work outlined above and clearly demonstrate how the objectives of the study will be achieved. The proposal must outline, amongst other things, the following: • Qualitative and quantitative techniques to be used • Desktop and first-hand research approaches • Stakeholder facilitation and engagement model			

1.1.1.4 PROJECT PLAN	Comply	Partially Comply	Not Comply
The bidder must provide a detailed project plan to undertake the study; the plan must indicate key activities, timelines, milestones/ deliverables.			
Substantiate / Comments			

1.2 Practical Evaluation: Presentations

All shortlisted bidders will be invited for presentations to the evaluating Panel.

Bidders will be required to present on amongst other things but not limited to the following:

- Interpretation of the ToRs
- Proposed project methodology
- Bidder's relevant experience
- Experience, skills and qualifications of the key personnel