SAMED

advancing patient care through MedTech

National Health Insurance Bill Submission to

Portfolio Committee of Health

20 JULY 2021

SAMED and the MedTech sector

The South African Medical Technology Industry Association - SAMED

SAMED is a not-for-gain voluntary industry association founded in 1985

Grown significantly > 250 members

- Diverse membership reflective of highly complex industry: multinationals, distributors, wholesalers, local manufacturers
- Association (MDMSA, SALDA) and Associate members

Our vision: SAMED is committed to enabling a sustainable, ethical and transformed medical technology industry that ensures patient access to quality technologies and innovative solutions

Our mission: Our mission is to provide the industry with a collective, objective and credible platform for engaging with all stakeholders

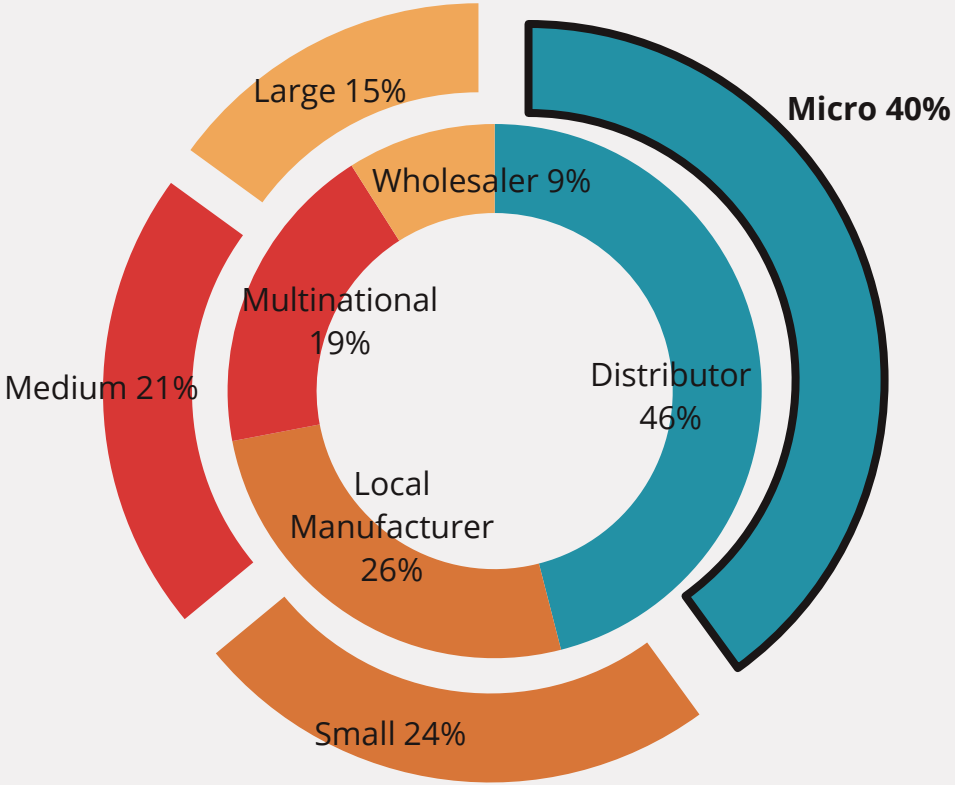
Transformation: SAMED is committed to sustainable and on-going transformation within the MedTech sector.

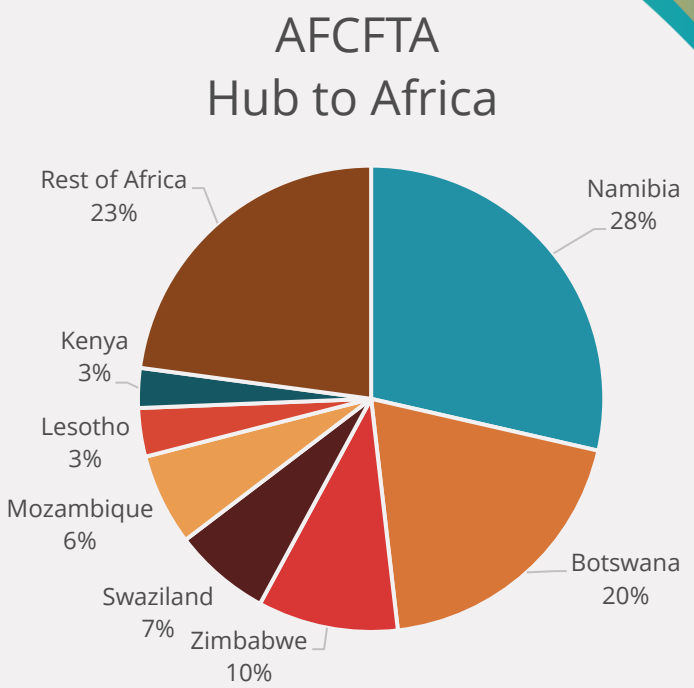
President's Health Sector Anti-Corruption Forum members

Steer-com member supporting localisation agenda

- Voice of SA MedTech
- Increase the visibility of MedTech industry
- Advocacy to inform healthcare policy and improve healthcare delivery
- Share latest market trends and promote industry best practices
- Networking platform
- Work with international best practice for global harmonisation

Our membership and industry





Snapshot of The Code

Part 1: Interactions with healthcare professionals

- Company & third-party arranged educational events
- Promotional items, competitions & charitable donations
- Demo products, samples, loaned & placed devices
- Consultant fees & royalties
- Patient registries
- False claims to medical schemes
- Conduct of healthcare representatives
- Advertising of medical devices

Part 2: Dealing with infringements

- Complaint procedure
- Whistle-blowing hotline
- Formal complaint
- Independent chairperson
- Ethics committee
- Hearings
- Sanctions

Part 3: Questions and answers

Part 4: Complaint form

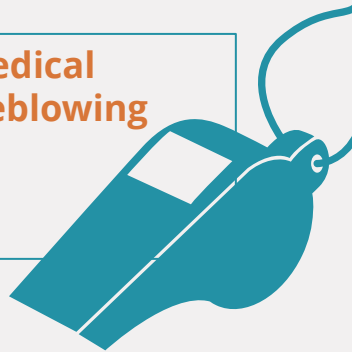
Part 5: Addendums

DON'T SUPPORT IT.

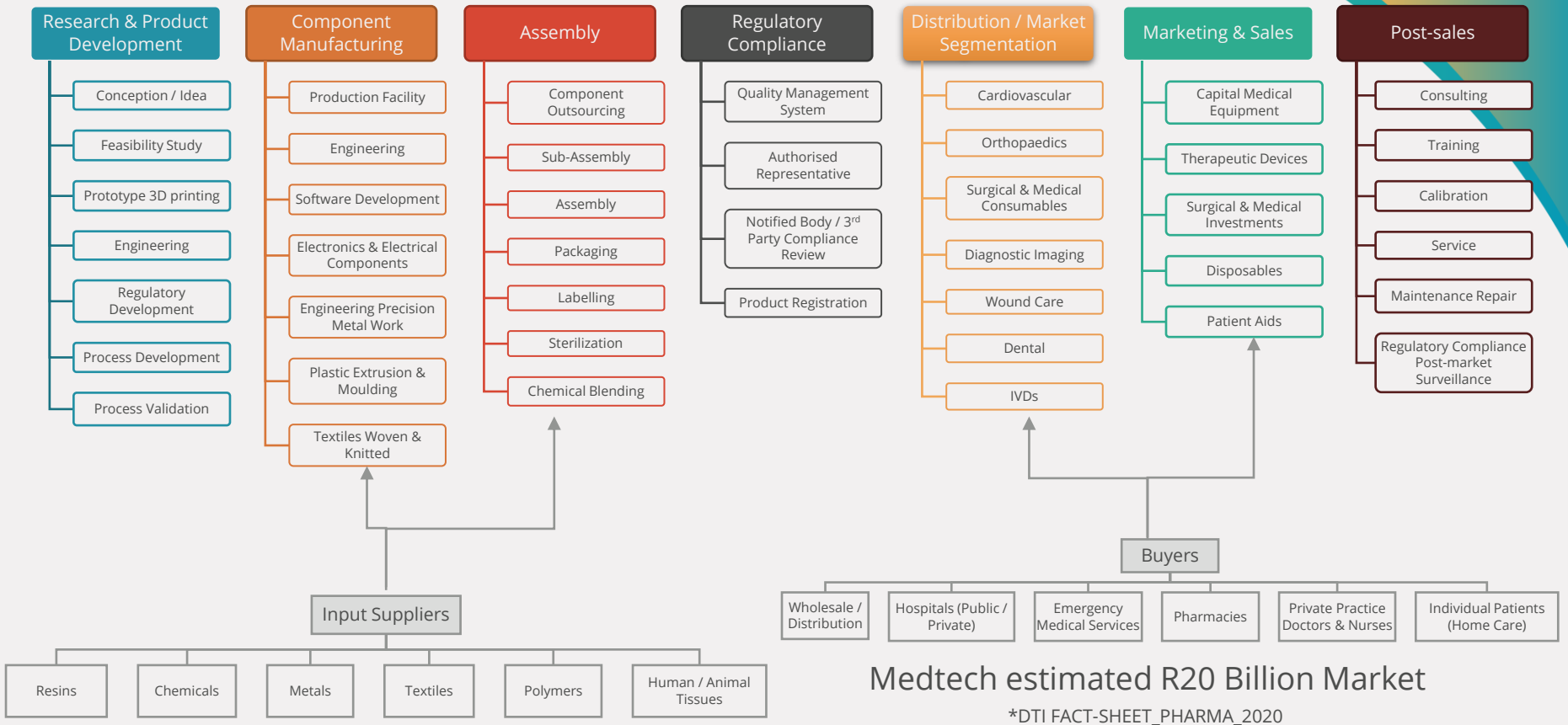
REPORT IT.

24/7 Anonymous Medical Device Code Whistleblowing Hotline

Free call: 0800 00 04 68



Medtech value chain



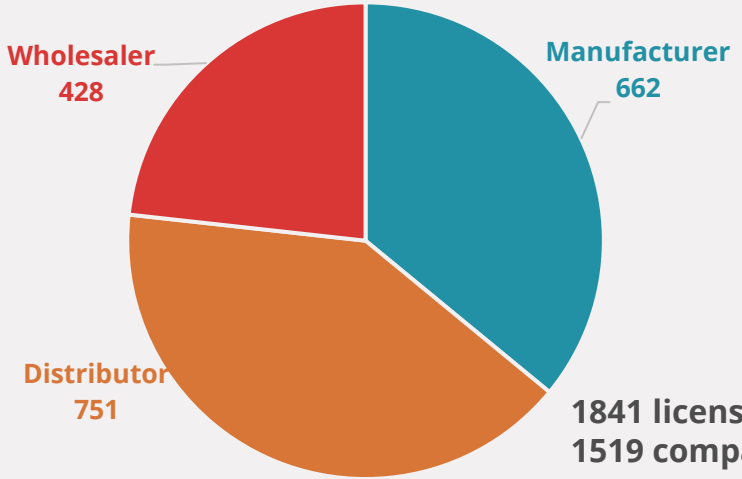
Medtech estimated R20 Billion Market

*DTI FACT-SHEET_PHARMA_2020

The SA MedTech industry

Effective regulation required

No of licenses



1841 licenses / 1519 companies

*SAHPRA's listing of Medical Device Establishment Licenses May 2021

ACCESS

5 YEARS

COVID related procedural backlog in private and public healthcare

The Medical Device Code of Ethical Marketing and Business Practice

SAMED commitment journey to NHI

SAMED journey with NHI

Submission on the Green Paper 2011

Submission on the White Paper 2016

Submitted nominations for the various NHI committees

Submission on the Draft NHI Bill 2018

President Health Compact SAMED on Presidential Health Task Team 2018

Dr Anban Pillay presents at the SAMED Annual Conference July 2019

SAMED participated in BUSA and the launch of the NHI Bill on 8 August 2019

Member forum with Dr Nicholas Crisp Oct 2019

Submission on the Draft NHI Bill Nov 2019

Sept 2020 Dr Nicholas Crisp presents at the SAMED Annual Conference

Verbal presentation to the Portfolio Committee

Fund established as public entity and operational by 2021/2022

Begin purchasing services by 2022/2023

Progressive process: 90% of South Africans covered by 2030

Universal health coverage

SAMED supports the principles and objectives of NHI, recognising:

- Inequities of current healthcare system
- Well-formulated NHI is crucial to greater equity
- Both private and public healthcare face challenges
- Milestone approach is required
- Adequate implementation will affect patient care and outcomes

SAMED is a vital stakeholder and committed to public-private collaboration

SAMED recommendations on the Bill

Key focus areas of submission

- Constitution and Legal framework
- Definitions of medical technology
- Accreditation of MedTech suppliers
- Procurement
- HTA
- Governance of NHI fund

Key observations

Policy integration is essential to the successful implementation of NHI

Risk of legislating uncertainty which will delay implementation and limit investment in the sector

Phased implementation through measurable milestones

Resolution of corporate governance concerns and overlaps on procurement

Constitution: spheres—services—accountability

The Constitution	NHI Bill
• **Section 41**: Cooperative governance….	District Health Management Offices
• **Section 114**: Provincial legislature oversight of "any provincial organ of state"……	Office of Health Products Procurement

- SAMED is concerned about potential legal challenges delaying implementation and prolonging uncertainty in the sector
- SAMED recommends clarification on residual functions of provincial health departments, public accountability structures for healthcare, and preservation of Constitutional principles

Legal framework

Mis-alignment challenge

- Absence of alignment of the NHI Bill with other legislation e.g *Procurement Bill*
- Outstanding details:
  - Finance model
  - Benefits package
  - Procurement process

SAMED recommendations

Portfolio Committee to undertake:

- A review of entire legal framework of proposed NHI system
- Amendment of 11 laws in the Bill Schedule
- Present draft regulation for comment
- Facilitate inter-ministerial collaboration, policy integration and alignment of legislation to provide certainty and for NHI to succeed

What is a medical device and IVD?

As per Medicines and Related Substances Act as amended:

"**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;";

" **'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;"

Medical device and IVD in the NHI bill?

As per Medicines and Related Substances Act as amended:

For ease of reference and consistency across regulations SAMED recommends the NHI Bill adopts the same definitions as per the Medicines and Related Substances Act as amended

Accreditation
section 33 & 39

- No indication of accreditation requirements, process and period of accreditation
- The definition of “accredited” is only applicable to service providers and not suppliers.

Recommendations

- Process should be **relevant** and provide for a diverse range of products and service providers in diverse geographical locations
- Avoid **administratively burdensome or prohibitive**
- **Alignment with SAHPRA and the CSD** on information already collected and reviewed
- **All suppliers must be accredited and/or vetted** before entering procurement process

Procurement

Constitution—NHI Bill & Procurement Bill

Constitution: Procurement and Funding Considerations	Financial allocation from fiscus, must ensure that provinces and municipalities can provide basic services and perform their functions

Section 10 & 38 – NHI Bill	Procurement Bill
Clause 38(2) centralised facilitation and coordination of functions related to public procurement	Part 2 & 3: Provincial treasuries and procuring institutions can procure (de-centralised).
Chapter 3 NHI Fund	Section 69: Institutions have procurement budgets and procurement plans
Clause 10(1)(b): *actively purchase and procure health care services, medicines, health goods and health related products from health care service providers, health establishments and suppliers that are certified and accredited in accordance with the provisions of this Act, the National Health Act and the Public Finance Management Act;*	

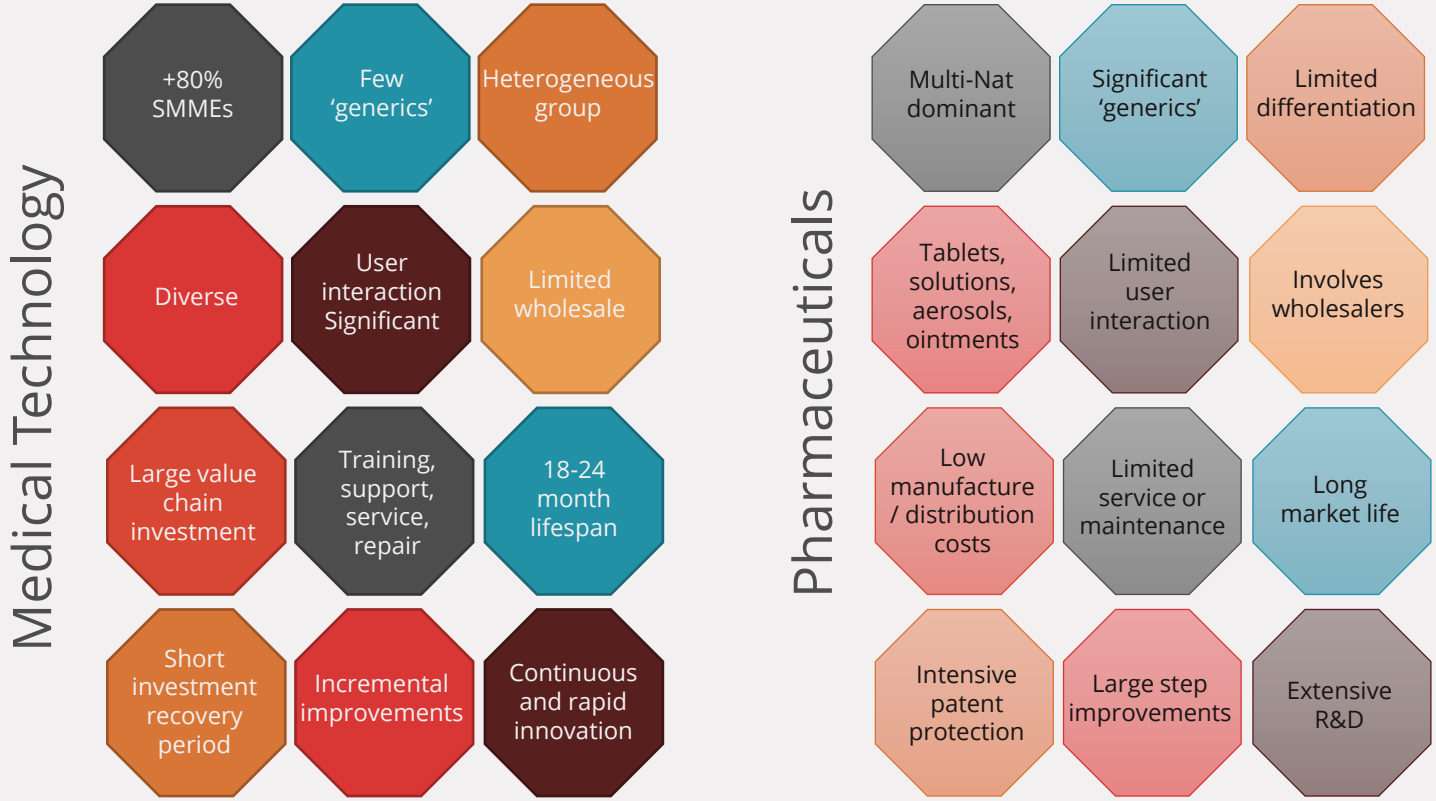
Absence of clarification sets the basis for protracted litigation

Procurement pilot

Constitution—NHI Bill & Procurement Bill

SAMED recommends that the National Dept. of Health runs a pilot alongside National Treasury & other stakeholders to test the feasibility (legal& operational) of a central procurement office as propose in the NHI Bill

Medtech differentiation from medicines
impact on procurement processes and practices



Medtech procurement considerations

Disadvantages of central procurement of Medtech

- Medtech items are not simple “commodities”
- Purchase involves, maintenance, servicing, spares
- Training and ongoing support to healthcare providers
- Cater for customised delivery –patients and specialist doctors
- Majority SMME medical technology suppliers, some lack national footprint
- Diversified supply : Multiple and non-exclusive contracts

Medtech procurement considerations cont.

Best practice in MedTech procurement centres on holistic definition of "value".

This takes account of:

- Life-time benefit to patient (not merely short-term)
- Benefit to healthcare professional
- Broader efficiencies in health system (better diagnosis, shorter admissions, fewer complications etc)

Medtech procurement needs to accommodate rapid innovation cycles

- Innovation in MedTech is more rapid than in pharmaceuticals (e.g. ventilator options in COVID period) and often contributes to better health outcomes and efficiency
- Flexibility in procurement is necessary for health systems to benefit from innovation

Key considerations Office of Health Products Procurement

- **Transparency and accountability for procurement are vital to checking corruption**
- **Specific knowledge of Medtech is required to procure effectively and employ best practice**

Thus, SAMED recommends

- Clause 25(2) The membership of the Benefits Advisory Committee, appointed by the Minister, **must consist of persons with specialist knowledge of medical devices and IVDs in addition to the stipulated technical expertise**

Transparent & Robust Procurement

- Adopt Open contracting data standard [https://www.open-contracting.org/data-standard/]
- CSD be maintained with input from SAHPRA on licensed companies in the future system
- Provincial health departments and contracted service providers explicitly be permitted
- through measures for exemptions must be stated and expressed in law
- Expect all suppliers to be signatories of the adapted medical device and pharmaceutical codes of conduct

Health Technology Assessment
section 10 & 38

SAMED acknowledges relevance of HTAs for MedTech

- HTA is a tool supporting decision making at different levels in the healthcare system
- SAMED acknowledges that HTAs are an essential component to evaluation and procurement under NHI

Recommendations

An HTA process for MedTech should:

- **Enable access/not restrict access**
- **Be appropriate based on the complexity of the product**
- **Be transparent**
- **Be an Independent agency**
- **Not be costly or lengthy**
- **Be a multi-stakeholder forum**
- **Aligned with other related legislation**
- **Have Gazetted Terms of Reference**
- **Be resourced sufficiently to prevent market delays**

Consider the proposals on HTA as found in the HMI Report

Governance of the NHI Fund

Chapter 4

- Establishment of the board
- Constitution and composition of the board
- Functions and powers of the board

Recommendations

- The 11 non-executive members must be appointed by the President on the advise of the National Assembly *(ch.5 broadcasting act of 1999*
- Portfolio committee to conduct public interviews of nominees
- Staggered rotation of board members to ensure continuity and mitigate against governance failure
- Provision for stakeholder inputs to Advisory Committees

A public parliamentary process of appointing the board will inspire public confidence and engender trust in the governance of the Fund

Key observations

Policy integration is essential to the successful implementation of NHI

Risk of legislating uncertainty which will delay implementation and limit investment in the sector

Phased implementation through measurable milestones

Resolution of corporate governance concerns and overlaps on procurement

Conclusion

- SAMED recognises the inequities of the current fragmented health care system and is an eager partner in the mission to improve the nation's health care and achieve universal health coverage

- SAMED is committed to building required capacity and skills and finding ways to effectively address the health care needs of all South Africans

Thank you

Questions?