South African Medical Technology Industry Association (SAMED)
Position Paper on the National Health Insurance (NHI) System
March 2025

Introduction

SAMED recognises that the current fragmented healthcare system in South Africa (SA) is untenable and supports universal healthcare and a workable NHI as a means to transform the health system and manage current fragmentation and inequities across both private and public healthcare services and outcomes. A well-formulated NHI system is crucial to assist SA in advancing universality, social solidarity and an equitable patient-centred health system that does not discriminate along economic lines.

Failed implementation of NHI will have negative consequences for patients and the economy, as well as erode public trust in the concept of NHI as a tool for universal healthcare access.

Government must address issues that are paramount for both the medtech industry and for uninterrupted provision of quality health services. Healthcare services cannot operate without thousands of different medtech products. SAMED calls on government as the custodian of NHI to ensure that the policy and its implementing structures ensure the uninterrupted, sustainable and effective provision of medtech as needed by SA patients and healthcare providers.

SAMED urges a fiscally responsible, objectively measurable milestone approach to NHI that combines public and private expertise and resources. The state should take *reasonable legislative and other measures*, *within its available resources*, *to achieve the progressive realisation of access to healthcare services (Bill of Rights S27)*.

1. SAMED **supports universal healthcare** and a **functional NHI** system as the vehicle to achieve universality
2. An appropriate and efficient **purchasing and procurement framework for medtech** is a must-have
3. Policy should provide for **independent HTA** (health technology assessment process/agency)
4. **Value-based procurement,** rather than lowest-possible price negotiable, yields better outcomes
5. Timeous and accurate **payment for medtech** and related services requires adequate administration
6. SAMED supports the **right of choice** and a multi-payor reimbursement method
7. New/increased taxes should **not be used to finance NHI** to avoid further socio-economic disparity
8. NHI **implementation should be milestone**- and not time-based
9. **Consultative and inclusive policy** formation will strengthen and progress NHI
10. **Strong governance framework** for the NHI should align with King IV and other best practice

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POSITION 1: SAMED supports universal healthcare and a functional NHI system

A well-formulated NHI system should advance universality and social solidarity and ensure a patient-centric, equitable and value-based health system. SAMED however does not believe that the NHI Act in its current format will achieve this inclusive goal. The current NHI Act lacks adequate principles and policies that can facilitate the fundamental administrative functions.

Specifically, unless certain aspects of the Act are rectified and changed, it may prove detrimental for the uninterrupted, effective and resource-efficient supply and application of essential medical technology (medtech including medical devices and in vitro diagnostics (IVDs)).

POSITION 2: Medtech-appropriate and efficient purchasing and procurement framework is necessary

Appropriate and efficient purchasing and procurement are critical to the success and sustainability of an NHI system. An effective system is one which has the correct medical equipment, consumables and implants at the point of service delivery to allow for immediate patient care.

Although the Act provides some insight into how health services will be purchased at different levels, it contains no details on how medtech will be procured or reimbursed.

Furthermore, the Act appears to favour centralised procurement. There is a perception that centralised procurement of medical technology is a panacea to drive down the costs of technology, but its shortcomings should be considered.

- An efficient and cost-effective central procurement process requires a single national database of thousands of medical technology items, which is continuously updated with stock levels at every healthcare facility. Procurement without such a system is known to cause shortages (stock-outs) or over-supply. Stock-outs make it impossible for healthcare facilities to deliver contracted services and over-supply increases costs. In the former scenario, performance-based remuneration or incentives for health care providers will not be feasible, and the latter scenario will be wasteful.
- Even with a good information system, it may be difficult to strike a balance and avoid device stock-outs/over-supply that undermine healthcare delivery and increase costs. It is essential that the relevant technology is available at primary, secondary, tertiary and quaternary levels and at multiple points of care. The system must be capable of passing such a “point of care test” – having the correct medical equipment, consumables and implants at the correct health establishment at the patient’s time of need. The system must be able to accommodate variations in demand from different districts, based on demographics, burden of disease and the capacity of healthcare providers. Similarly, it would need to accommodate the varying needs for training in product use, maintenance and technical support.

Different conditions and different medical disciplines require different technologies for patient services.

- Medical technology often relates to more than selling of individual items, but also to integrated/interwoven solutions and sub-specialities of devices. Dependent on their size, age and co-morbidities, patients may require specific devices e.g. software with data management, medical equipment with consumables, after-sales service, maintenance and training.
- Medical technology is also complex, and it is not a commodity. It undergoes rapid cycles of improvement and variation, to meet patient and service provider needs. Unlike pharmaceuticals, medical technologies have a short product life cycle and investment recovery period (typically 18 months on market). As opposed to a centralised system, a decentralised procurement process should acknowledge and consider this cycle along with clinical variation in patients’ conditions and different patient needs.
- To meet different service provider and patient needs, medical technology procurement contracts should not be exclusive, but should allow for participation of multiple models and types where feasible.

A procurement system needs to consider more than the unit price as the predominant factor to account for the total cost and value over the entire episode of care. Price-based procurement favours older and simpler technology, and may as such eliminate innovative models whose benefits entail meeting different clinical and patient needs and better health outcomes.

POSITION 3: The health technology assessment/agency needs to be independent

SAMED supports and endorses the proposal in the NHI Act that an HTA process is required to ensure suitable, safe, effective and resource-efficient deployment of medtech in SA. SAMED urges that greater clarity be provided on the final HTA process / agency, which in our view must be an independent body.

The Act currently stipulates that the NHI Fund will be the sole procurer of services and products – a topic that has proven to be highly contentious – and that the HTA Agency be part of the NHI Fund structure. This carries an inherent governance risk, as it can lead to a lack of impartiality if the same person/department is responsible for evaluating evidence as well as making a decision on selection and procurement of medtech.

Without the checks and balances provided by a separate HTA agency that is capable of objectively assessing the facts, this can potentially allow personal biases to influence outcomes. SAMED therefore submits the following principles to underpin the establishing of an "HTA Agency for South Africa":

- Independence, effectiveness and sustainability.
- Transparent and open processes.
- Involve multi-sector stakeholders.
- Produce evidenced-based assessments of the cost-effectiveness and efficiency of health technology.
- Evaluated periodically.

WHO estimates that there are about 2 million types of medical devices on the world market, categorised into more than 7 000 generic devices groups. South Africa has over 300 000 medical technologies with thousands of new/upgraded products entering the market every month. Some of these are innovative technologies entering the market for the first time and others are comparators / competitor products of those already in the market. It would be impractical and nigh impossible for the HTA agency to do an HTA on every single medtech and as such these vast and diverse volumes of products need to be factored when considering HTA processes for medtech.

The Ministerial Advisory Committee on HTA proposed in section 57 of the Act to serve as a precursor to the HTA agency is noted. However, no information is provided in the Act on the composition and decision-making processes of such a Committee. SAMED recommends that this should be a multi-stakeholder forum with the requisite skills and insights, that operates transparently with regular monitoring and evaluation. The Terms of Reference of this Committee must be published in the Government Gazette and a transparent process, which includes nomination of persons with appropriate expertise by stakeholders, must be followed in the establishment of this committee. This recommendation applies to all interim Committees proposed in section 57 of the Act.

- More clarity is required on which contracted service providers and establishments would be authorised to procure from the formulary. It needs to be ascertained which component of the contracting unit for primary care services (CUPS) would be authorised to procure from the formulary and how procurement would be tracked to ensure reimbursement by the NHI Fund.
- Procurement in the public sector is currently managed and controlled by National Treasury and the provinces. It remains unclear how the proposed procurement system envisaged in the NHI Act and for the proposed Office of Health Products Procurement will be aligned with existing processes and systems. The Central Supplier Database (CSD), which is managed by National Treasury, works well. It is recommended that the CSD be maintained in the future system but that it be linked to SAHPRA's register of licenced medical device establishments.

POSITION 4: Value-based procurement and innovation instead of lowest-possible price negotiable

SAMED submits that the concept of value-based procurement be included in the medtech-related regulations under the Act. However, because it can undermine value-based procurement objectives and outcomes, SAMED does not support the requirement in the NHI Act (Section 11) that the NHI Fund must "negotiate the lowest possible prices for goods and healthcare services".

Price alone is not an indicator of quality, need or appropriateness of any technology and does not recognise the services required to support the technology. Furthermore, it is not clear in the NHI Act how medtech procured by healthcare service providers and health establishments would be reimbursed.

Value-based procurement encompasses the value-based healthcare equation of patient outcomes divided by the costs of achieving these outcomes. Value-based procurement ensures that purchasing decisions consider how a product/solution can best deliver measured outcomes and reduce the total cost of care rather than focusing exclusively on purchasing a specific product at the lowest possible price with little regard for the product/solution suitability for SA patients and health outcomes in the immediate and longer-term.

Competitive procurement should support and recognise the value of innovation in medical technology to patients, clinicians and the healthcare system, and should reward features that bring new capabilities and improved efficiencies and options to the clinical pathway.

- Medtech often remains implanted in a patient or in use at a hospital for many years. Much of the cost and economic value of medtech is not only in the purchase price but also the quality, service, technical support, training and education provided by the supplier and the holistic value it adds to the patient's life, quality of life and life expectancy over the years. In the case of implantable devices, much of the service and support comes subsequent to implantation. Extra hospital procedures to replace or adjust low-quality devices add greatly to overall costs. To be cost efficient, a procurement process must take overall value into account over the duration of the patient's clinical condition.
- Medical equipment maintenance is critical. A supplier may offer a good price but not provide any maintenance services or spare parts as part of the contract. In certain instances, particular consumables/disposables associated with the medical equipment are needed on an ongoing basis and a supplier should be able to provide such products and support services for the duration of the contract.
- Expenditure on innovative and appropriate medical technology can free resources to provide greater healthcare coverage to growing populations. Provision should be made for the introduction of new and innovative technology.
    - Innovation often creates value by improving the quality and efficiency of health services. Unfortunately, this concept is often not acknowledged and instead a short-term mindset, focused on immediate cost control, governs purchasing decisions.
    - Minimally invasive surgery – including robotic surgery, endoscopic surgery and laparoscopic surgery – has been one of the great success stories of innovation in medical technology. The use of advanced instruments allows surgeons to work through small incisions instead of opening large areas of the body. Cameras, computers and instruments capable of very precise movements make these procedures possible. The benefits include less scarring, increased accuracy, lower risk of complications, shorter hospital stays, less pain and shorter recovery periods.
    - It is critical that benefits of innovation are well understood and included in annual procurement planning frameworks to facilitate value-based procurement.

The maintenance of equipment is critical for quality healthcare and value on investment. Districts may have different burdens of disease and different demographics. This would require variance in the procurement and maintenance needs.

- Many devices require direct training of staff and commitments to ensure product maintenance and similar technical support (e.g. availability of spare parts and technicians), which are best arranged and provided locally, and not centrally.
- Excessive use of centralised procurement risks creating monopsony (single-buyer) market conditions that can impede supplier competition and reduce the participation of small and medium-sized enterprises (SMEs) without a national footprint.
- Centralised tendering can severely limit therapeutic and diagnostic options across an entire healthcare system and may discourage innovation in standards of care.

Procurement of medical devices requires significantly different considerations to medicines.

- For this reason, transversal term contracts and centralised procurement, as envisaged under the NHI Act are not always appropriate for medtech. For example, procurement of implants (such as hips, knees, screws and plates) is patient-specific and requires a variety of instrument sets to be supplied and available at the time of the operation/procedure. Much of this is on an emergency basis. Only when the patient is on the operating bed can the surgeon determine what size screw or plate, knee, cardiac stent etc is required and as such centrally procuring such products might result in the incorrect size or type of device being available.
- Consignment stock and loan sets are examples of where medtech companies provide these items to the

health facility for the surgeon to choose from a range of products as they are needed. The sets are then refilled by the supplier. Centralised procurement for these types of medtech would not be possible due to the unknown quantity of goods required but would also be prohibitive due to the cost of all goods required.
    - Consignment stock, consumables and disposables that fit with the specific capital equipment, or other pieces of a medical device, are necessary considerations. In addition, staff must be trained ("proctored") on using the specific medtech. Not all surgeons have experience or are trained on the same medtech. Hence centrally procuring could mean that the surgeon is not adequately trained to use the technology, which could lead to incorrect administration and use of the product and harm to the patient. There are also important after-sale obligations, such as maintenance and technical assistance.

SAMED supports the establishment of a formulary to include lists of essential medtech as proposed in the NHI Act. The following reimbursement principles in respect of medtech are strongly recommended:

- **The medical technology industry is unique.** Hence, processes, methodologies and expertise used in pharmaceutical evidence appraisals are not always applicable to medtech and no single approach should be applied considering the diversity of medtech and its use in diverse point-of-care settings.
- **Transparency.** A transparent, objective and reasonable process, including an appropriate HTA process (if necessary), should be followed in the determination of formularies.
    - Reimbursement policies should be vetted and implemented in an open manner, in which the criteria for decision-making and implementation are fully disclosed in advance to stakeholders. The process of procurement must be clear and efficient.
    - The frequency of service provider/health establishment procurement from the formulary needs to be aligned to appropriate reimbursement arrangements.
- **Consistency.** The NHI Fund and any entity authorised to implement procurement should attempt to adhere to a predictable schedule for proposed updates and/or system reforms.
- **Best value.** A payment system should recognise the resources needed to deliver a group of services, or entire episode of care. The resources should be based on established clinical guidelines, reflect the long-term value of medical technology and not focus on short-term costs.
- **Use market competition to evaluate the domestic price of the product.** There should be an acknowledgement that market forces are allowed to operate to maximise efficiency and improve patient care. Provision should be made for procurement from SMEs, including from previously disadvantaged suppliers, while acknowledging that some of these suppliers might not have a national capability. Over 80% SME companies make up the medtech industry, which along with promoting localisation is aligned to the MEDTECH Master Plan.
- **Reward innovation.** There should be an acknowledgement that systems and resources are needed to encourage innovation, which provides continuous progress in patient outcomes.

POSITION 5: Timeous and accurate payment to suppliers requires adequate administration

It is essential that reimbursement of suppliers is appropriate and timeous as this will impact on the availability of suitable, quality medical technology to support adequate patient care.

The NHI Act needs appropriate policies to facilitate the establishment of frameworks for fundamental administrative functions. These include human resources and information and communication infrastructure necessary for processing millions of claims, invoices and payments. These administrative elements are absolutely necessary for the efficient procurement, reimbursement and independent health technology assessment.

Currently, a sizable number of suppliers – regrettably mostly SME enterprises – are under severe financial pressure with their invoices not being paid timeously due to the public sector's administrative incapacity. This has contributed to a ballooning outstanding government debt that runs into billions of Rand and that has forced suppliers to discontinue certain lines or, alarmingly, terminate their businesses. This systemic challenge has persisted for over 15 years and the implementation of NHI is an opportunity to resolve it.

POSITION 6: The right of choice and a multi-payor reimbursement method

SAMED supports a dispensation in which persons can choose how and where they spend their private money ie constitutional right to choice. Furthermore, national health systems across the world exist alongside private health systems. SAMED encourages a review of international markets and existing productive and functional models to establish relevant best practice for the procurement of health products and services including medtech in SA.

Restrictions on the cover that medical schemes or other health insurance schemes may offer is not supported. Such restrictions are inappropriate in a free-market economy. As the Health Market Inquiry report indicated, competition promotes better health outcomes. The rationale for imposing a restriction on the ability of medical schemes to offer parallel cover to the NHI Fund is not clear. It should be noted that SAMED's opposition to the proposed role for medical schemes should not be construed as opposition to the principles of universal health coverage.

SAMED does support the opportunity for complementary cover to be purchased as delineated in sections 6(o). Patients should be able to purchase the medical care (including the type of medtech) that they require with their own money without restriction. Greater clarity of the definition of complementary cover, and the consequences thereof, as mentioned in section 33 is required so as not to create a restriction on private medical schemes, contingent on the scope of benefits offered under NHI.

POSITION 7: Financing models and alternatives to new/increased taxes

The financing proposal in the NHI Act through additional taxes is concerning. SA has a small tax base which is already strained due to the challenging economic environment. Raising additional taxes via VAT, income tax or an employer tax may further stress the impoverished and negatively impact foreign direct investment. SAMED proposes that other financing models be researched and considered together with the private sector. Many countries with NHI systems in place have successful multi funder and procurer models. We need more research and collaboration with the private sector on what is the best, most affordable NHI funding model for South Africa that will not exacerbate economic difficulties for South Africans. In addition, without a money bill / funding legislation it is unclear as to whether the NHI Fund will be sufficiently and sustainably funded.

POSITION 8: A milestone-based NHI implementation

A milestone-based implementation plan for NHI aligned with the National Department of Health strategic plan, which is fiscally responsible and approved by National Treasury, as opposed to a time-based plan, is recommended to ensure the successful roll-out of NHI in the best interests of patients.

POSITION 9: Consultative and inclusive policy formation will strengthen and progress NHI

Stakeholder role and input are paramount for functional NHI policy and implementation and will provide understanding between government, experts and other key role-players. The NHI Fund and any entity authorised to conduct procurement should:

- Be required to disclose and discuss the input provided and consider this input in finalising benefit and reimbursement decisions.
- Provide ample time and opportunity for stakeholders – including members of the public – for notice and comment on the proposed policies.

POSITION 10: Robust, corruption-resistant governance framework

A fair, transparent, corruption-free, value-based procurement process that takes into account the specific nuances of medical technology must be implemented within an NHI framework. The governance framework of the NHI Fund should be in accordance with best practice standards most notably the King IV Report on Corporate Governance for South Africa 2016 (King IV).

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