South African Medical Technology Industry Association (*SAMED*)

SAMED SUBMISSION ON NHI BILL 11B OF 2019

For attention

Select Committee on Health and Social Services
National Council of Provinces

c/o: Chairperson: Hon Edward Zoyisile Njadu: enjandu@parliament.gov.za
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A. Introduction to SAMED

SAMED was founded in 1985 and is a not-for-gain voluntary trade association that represents the medical technology industry in South Africa. Its 152 members include manufacturers, distributors, and wholesalers, ranging from micro enterprises to large multinational companies, of medical devices, medical equipment and invitro diagnostics (collectively termed medical technologies or medtech). SAMED is committed to ensuring a sustainable, transformed and ethical medical technology industry in South Africa. SAMED's members are governed by and required to adhere to the Medical Device Code of ethical marketing and business practice.

B. Summary of SAMED's views on the NHI Bill

1. The principles and objectives of Universal healthcare coverage and a National Health Insurance (NHI) system to achieve this are supported.
2. A well-formulated NHI system is crucial to assist South Africa in advancing universality and social solidarity as the pillars of a patient-centred health system that does not discriminate along economic lines.
3. A staged approach to the implementation of health system reform of the nature proposed in the NHI Bill is supported.
4. A milestone-based implementation plan of 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.
5. It is desirable that the health system reform of the nature that is proposed in the Bill be supported by a clear understanding of the financing model. Care should be taken to prevent possible unintended consequences as a result of, for example, the potential increase in taxes as the main financing mechanism of the system.
6. An independent, transparent and fit for purpose Health Technology Assessment (HTA) process is supported to ensure the suitable deployment of medical technology in South Africa.
7. A fair, transparent, corrupt free, value-based procurement process that takes into account the specific nuances of medical technology must be implemented within an NHI framework.
8. It is essential that reimbursement of medtech suppliers is timeous as this will impact on the availability of suitable and quality medical technology to support patient care of good quality.
9. 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).
10. The NHI Bill in its current form is not fit for purpose and should not be passed as such, as many, including SAMED's previous submissions have not been taken into account.

SAMED recognizes that the current fragmented healthcare system is untenable and leads to inequalities and that both private and public healthcare face challenges. 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 Bill in its current format will achieve this. Failed implementation of NHI will have negative consequences for patients and the broader economy. SAMED recommends that thorough research of other international NHI models and an economic impact analysis be done to diagnose and evaluate the best models to be applied. 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 health care services (Bill of rights S27)*.

We set out below six key areas pertaining primarily to the Bill's impact for medical technology. These are not the only areas that SAMED believes need to be considered. Others appear in our numerous submissions and presentation to the Portfolio Committee of Health. See the latest submission, Annexure A and the Presentation, Annexure B. It is unfortunate that much of the contents of these previous submissions does not seem to have been taken into account in the final draft of the Bill.

1. Health Technology Assessment and Agency

SAMED supports and endorses the proposal in the NHI Bill that an HTA process is required to ensure the suitable deployment of medical technology in South Africa.

The proposed Ministerial Advisory Committee on HTA proposed in section 57 of the Bill to serve as a precursor to the HTA agency is noted. However, no information is provided in the Bill on the composition and decision-making processes of such a Committee. SAMED urges that this be a multi-stakeholder forum with the requisite skills and insights, that operates transparently with regular monitoring and evaluation. The NHI Bill should include this important detail.

It is also requested that the NHI Bill should state that the Terms of Reference of this Committee be published in the Government Gazette and that a transparent process, which includes nomination of persons with appropriate expertise by stakeholders, must be followed in the establishment of this committee. This recommendation equally applies to all interim Committees proposed to be established in section 57 of the Bill.

SAMED also urges that the Bill provide greater clarity on the final HTA process / agency, which in our view should be an independent body. The Bill submits that the NHI fund will be the sole procurer of services and products. Having the HTA agency within the fund is tantamount to acting as both judge and juror. SAMED therefore submits the following principles to underpin the establishing of an HTA Agency for South Africa and that these should be included in the Bill:

- Independence, effectiveness and sustainability;
- Transparent and open processes;
- Involve multi-sector stakeholders;
- Take into account evidenced-based assessment of the cost-effectiveness and efficiency of health technology.
- Evaluated periodically

WHO estimates that there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups. South Africa has over 300 000 medical technologies with 1000's entering the market every month. Some of these are very 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 medical technology and as such these vast volumes and array of medical technology needs to be factored into when arriving at when considering HTA processes for medical technology.

2. Procurement

Although the Bill provides some insight into how health services will be purchased at different levels, it contains no details on how medical technology (devices and IVDs) will be procured or reimbursed. It should be noted that different conditions (and as such different medical disciplines) require different technologies for the effective treatment and care of patients. It is essential that the required technology is available at the relevant point of care, when it is needed, which includes primary, secondary, tertiary and quaternary levels.

More clarity is required as to who would be authorised to procure from the formulary i.e. who are the contracted health care service providers and health establishments. On a primary care level,

clarity is sought on 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 health care sector is currently managed and controlled by National Treasury and the provinces. It is not clear how the proposed procurement system in the NHI Bill will be aligned with the existing processes and systems in view of the establishment of the Office of Health Products Procurement within the office of the NHI Fund. 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.

SAMED submits that the concept of value-based procurement be included in the Bill. Value-based procurement places at its core the simple value-based health-care equation of patient outcomes divided by the costs of achieving these outcomes. Value-based procurement then is making purchasing decisions that consider how a product or solution can best deliver the outcomes being measured and reduce the total cost of care — rather than focusing exclusively on purchasing a specific product at the lowest possible price.

SAMED would like to encourage a review of international markets to establish best practice in the procurement of medical technology. A number of productive and functional models exist within these international markets, and the recommendation is to consider these well-established practices and processes to allow for a fully functional procurement system. SAMED is willing to engage with the NdoH and the NHI Fund to share these insights.

The establishment of a formulary to include lists of essential medical devices and other medical technologies is supported with the following conditions (which is not evident in the Bill):

- A transparent, objective and reasonable process, including an appropriate HTA process (if necessary), is followed in the determination of these lists.
- Provision is made for procurement from small- and medium-sized medical technology suppliers, including from previously disadvantaged suppliers, whilst acknowledging that some of these suppliers might not have a national capability.
- The process of procurement must be clear and efficient. It must, for example, be clear how frequently a service provider or health establishment could procure from the formulary coupled with appropriate reimbursement arrangements.
- Suppliers must be timeously reimbursed.

It is submitted that the following special features of medical technology must be recognised in the establishment of the procurement process:

- Medical technology is not a commodity. It undergoes rapid cycles of improvement (e.g. every 6 to 24 months) and variation, to meet patient and service provider needs. A procurement process should acknowledge and take into account this product improvement cycle as well as clinical variation in patients' conditions and different patient needs. Moreover, a procurement system that considers price as the predominant factor, will fail to account for cost and value over the entire episode of care and will tend to favour older and simpler technology, and may as such eliminate new and innovative models with benefits for meeting different clinical and patient needs and better health outcomes.

- Medical technology often relates to more than selling of individual items, but rather to integrated / interwoven solutions e.g. software with data management, medical equipment with consumables, after sales service, maintenance and training, equipment such as MRI or X ray machines that require special infrastructure to prevent radiation contamination.
- Medical technology is complex. Hence an approach tailored to accommodate sub-specialities of devices, rather than trying to group products into broad categories, is advisable. For example, external fixators, divided into upper and lower limbs, sterile versus non-sterile and single-use versus reusable medical technologies.
- Competitive procurement should support and recognise the value of innovation in medical technology to patients, clinicians and the health care system, and should reward features that bring new capabilities and improved efficiencies and options to the clinical pathway.
- Medical devices often remain implanted in a patient or in use at a hospital for many years. Much of the cost and economic value of medical devices is not only the purchase price but also the quality, service, technical support, training and education provided by the supplier and the 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 willing to provide such products and support services for the duration of the contract.
- 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.
- Many conditions require the availability of a variety of medical devices. For example, patients differ in size, age, co-morbidities and may require specific devices. There should be alternatives available for such patients.
- Expenditure on innovative and appropriate medical technology can free resources to provide greater health care 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. Innovative and appropriate medical technology can free resources to provide better healthcare coverage to growing populations. 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 up 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. (See below box on laparoscopic surgery).

Laparoscopes: One small device – a host of benefits

Laparoscopic surgery, performed with a laparoscope that enables the surgeon to visualise organs in the abdomen, avoids large incisions. This, and the use of fine instruments, reduces blood loss, tissue

trauma, pain and discomfort. Patients need less analgesia and suffer fewer side-effects of analgesia. The rate of postoperative complications is generally lower.

Performing the operation within the body cavity avoids the cooling, drying, excessive handling and retraction of internal organs associated with "open" techniques. This may reduce postoperative peritoneal adhesions with the subsequent risk of bowel obstruction.

Laparoscopic surgery means less direct contact between surgeon and patient and therefore reduces the risk of infection passing between them.[1]

The recovery period is also shorter, lowering the risks of bone loss, muscle atrophy and urinary retention associated with lengthy bed rest. Other benefits of early mobilisation are lower rates of chest infection and deep vein thrombosis. Finally, patients prefer small scars and laparoscopic surgery reduce post-operative anxiety related to self-image.

- It is critical that benefits of innovation are well understood and included in annual procurement planning frameworks to facilitate value-based procurement.
- 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 i.e. available to allow for immediate patient care.

Centralised procurement

The Bill appears to favour centralised procurement. There is a perception that central procurement of medical technology items is a panacea to drive down the costs of technology in health care. SAMED believes that centralised procurement may also have shortcomings that need to be considered:

- An efficient and cost-effective central procurement process requires one national data base of all medical items, which is continuously updated regarding stock levels at every health care facility. Procurement without such a system is known to cause extreme shortages (stock-outs) or over-supply. Stock-outs make it impossible for health care facilities to deliver contracted services and over-supply leads to excessive carrying 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.
- The maintenance of equipment is critical for quality health care 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

[1] Journal of the Royal Society of Medicine: Does laparoscopic surgery spell the end of the open surgeon?

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC539626/#:~:text=In%20patient%20terms%2C%20laparoscopic%20surgery,tissue%20trauma%20and%20blood%20loss.

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.
- Even with a good information system, it may be difficult to strike a balance between avoiding device stock-outs that undermine healthcare delivery and maintaining an over-supply of devices, which leads to excessive carrying costs.
- The system must be capable of passing the "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 of districts for training in product use, maintenance and technical support.
- Finally, a centralised procurement system needs to remain sensitive to the value of competitive tendering in fostering innovation in medical technology and should reward features that bring new capabilities and improved options to the clinical pathway.

Procurement of medical devices require significantly different considerations to medicines. For this reason transversal term contracts, and centralized procurement, as is envisaged under the NHI Bill is not always appropriate for medical devices. For example, procurement of implants (such as hips or knees or screws and plates) are patient specific and require 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, for example operations involving implants because of a car accident. It is only when the patient is opened up and on the operating bed that the surgeon knows what size screw or plate, knee, cardiac stent etc is required and as such centrally procuring such products might result in the incorrect exact size or type of device required being available.

Consignment stock and loan sets are an example of this where medtech companies provide these items to the health facility and the surgeon can then choose from a range of products when they need them. The sets are then refilled by the supplier. Centralised procurement for these types of medical technology 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 also necessary considerations. In addition, staff must be trained ("proctored") on using the specific medical devices. Not all surgeons have experience or are trained on the same devices. Hence centrally procuring could mean that the surgeon is not adequately trained to use the centrally procured device and this 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.

Contradictions with the Procurement Bill

The NHI Bill contains provisions relating to procurement that contradicts the Procurement Bill. It proposes a centralized system where all procurement, is prescribed and implemented by the NHI Fund, where provinces and individual health establishments in both the public and private sectors

lose the right to be procuring institutions. It should also be noted that various capital equipment and other medical devices would already be in such establishments, and even in health care professional practices. What will be done with these devices and the current contracts in place should the NHI bill be passed? The Bill does not talk to any transition arrangements in this regard. Other provisions in the NHI Bill that are contradictory to the Procurement Bill include the exclusion of the Competition Act and the envisaged system of price-setting by the NHI Fund. Having a parallel procurement system in the NHI, is not in the interest of patient-centred, responsive healthcare. The proposed parallel system runs counter to the many principles as espoused in the Procurement Bill. It also limits the property rights of private health establishments and practices. The right to procure rests, for the private sector, in being able to "work" their property, i.e. to decide which equipment to have and to use, which medtech systems would create efficiency and align with their specific patients' needs. SAMED does not support the NHI Bill's exceptional procurement approach. There is also concern that should the NHI fund become the sole procurer and funder, many in supply chain management and payment departments will lose their jobs, become redundant. South Africa has one of the highest unemployment rates in the world and this will only add to these statistics.

3. Reimbursement, section 11 of the Bill

SAMED does not support the requirement in the NHI Bill (Section 11) that the NHI Fund must "negotiate the lowest possible prices for goods and health care 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 Bill how medical technologies that have been procured by health care service providers and health establishments would be reimbursed.

It is essential that reimbursement of suppliers is appropriate and timeous as this will impact on the availability of suitable and quality medical technology to support patient care of good quality. SAMED supports the following reimbursement principles in respect of medical technology:

- **The medical technology industry is unique.** Hence, processes, methodologies and expertise used in pharmaceutical evidence appraisals, are not always applicable to medical devices and no single approach should be applied to the diversity of medical technology in multiple service delivery settings.
- **Transparency.** Reimbursement policies should be vetted and implemented in an open process, in which the decision-making criteria and process for implementation are fully disclosed in advance to stakeholders.
- **Timing, notice and comment.** The NHI Fund and any entity authorised to implement procurement policies should provide ample time and opportunity for stakeholders - including members of the public - for notice and comment on the proposed policies.
- **Stakeholder role and input.** The NHI Fund and any entity authorised to implement procurement processes should be required to disclose and discuss the input provided and consider this input in finalising benefit and reimbursement decisions.
- **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 from well-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.
- **Reward innovation.** There should be an acknowledgement that systems and resources are needed to encourage innovation, which provides continuous progress in patient outcomes.

4. Protect the right to choose – role of medical aid schemes

SAMED supports a dispensation in which persons can choose how and where they spend their private money i.e. constitutional right to choice. Furthermore, national health systems across the world exist alongside private health systems. Hence restrictions on the cover that medical schemes or other private health insurance schemes may offer is not supported. In a free market economy such restrictions are not appropriate. As the Health Market Inquiry report has 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 medical technology) 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.

5. Legal framework, transparency – NHI regulatory framework – vagueness threatens implementation

SAMED submits that the complete/overall regulatory framework required for the system introduced by the NHI Bill remains vague.

It is very difficult for stakeholders to understand the complete regulatory framework that will govern the envisaged NHI system and to make meaningful comment. The reason for this is first and foremost the fact that a significant number of details of the proposed system are still outstanding, most notably the financing model, the contents of the benefits package and the details of the procurement and HTA process. Furthermore, the Schedule in the NHI Bill contains proposed amendments to 11 laws, which will have a significant impact on the roll-out of NHI.

SAMED hereby requests that the overarching legal framework of the proposed NHI system be clarified and made available prior to passing of the Bill. It is proposed that the various laws be amended through Bills that follow the prescribed legal process for comment instead of proposing amendments to key laws in the Schedule to the Bill.

The Constitution, section 42(3) places the people at the centre of lawmaking in a parliament that should "ensure government by the people" whether "passing legislation" or "scrutinising and overseeing executive action". Sections 59(1)(a)(b) and 72(1)(a)(b) and(2) prescribes reasonable and

justifiable open legislative processes of parliament's National Assembly and National Council of Provinces and its committees.

Furthermore, although it is understood that the Bill contains only enabling provisions, and that many of the details will be included in Regulations, SAMED had requested that the Portfolio Committee of Health facilitate the publication of the draft Regulations under the Bill for stakeholders to obtain a comprehensive understanding of the entire legal framework that will govern NHI, before the Bill be passed. It was also requested that stakeholders are provided with sufficient time to comment on these Regulations. SAMED also opposes the exclusion of the Competition Act from the NHI Bill.

6. Financing the NHI Bill through taxes, guided by Section 77

The financing proposal in the NHI Bill through additional taxes raises concern. South Africa has a small tax base which is already under significant strain due to the current challenging economic environment. Raising additional taxes, either 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, including alternative models than that of a sole funder and procurer. Many countries that have a NHI system in place have multi funder and procurer models in place that are successful. As such more research is needed and collaboration with the private sector on what is the best, most affordable NHI model for South Africa that won't bring more hardship to already difficult economic circumstances 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.

C. Conclusion

SAMED appreciates the opportunity to comment and hopes and trusts that the Select committee will heed our submission. We humbly also request an opportunity to make a verbal submission to the committee and are more than willing to engage and present further on the above to the Select Committee.

SAMED can be contacted at the following and is available to clarify any aspect of this submission or provide further information.

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