SAMED
advancing patient care through MedTech

SAMED SUBMISSION ON PROCUREMENT BILL 18B OF 2023

Finance Select Committee
National Council of Provinces
Parliament of the RSA
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1. Introduction to SAMED (The South African Medical Technology Industry Association)

SAMED was founded in 1985 and is a not-for-gain voluntary trade association that represents the medical technology industry in South Africa. Its 174 members include manufacturers, distributors, and wholesalers, ranging from micro enterprises to large multinational companies, who import, export, distribute, wholesale and locally manufacture medical devices, medical equipment and in vitro diagnostics (collectively termed medical devices). 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.

In this submission SAMED refers to the "Draft Bill", i.e. the version released by National Treasury prior to its introduction into Parliament, the "Bill" being the version B18-2023, and the "current version", or "current Bill", being B18B-2023, serving before the NCOP at present.

2. Important principles

SAMED supports the principles contained in section 217 of the Constitution of the Republic of South Africa ("the Constitution") in procurement, namely fairness, equity, transparency, competitiveness and cost-effectiveness. These principles are, however not finding practical manifestation in all aspects of the current version of the Bill, as we set out in this submission.

SAMED hereby attaches its submission made to the National Treasury in relation to the Draft Bill, as it was published for comment in 2020 ("Annexure A"). In it, SAMED raised, and hereby raises again, important concepts, which should be considered in order to ensure that the current challenges in

procurement within the health sector, can be addressed. The submission is attached again for ease of reference. The issues previously raised by SAMED can be summarized as follows:

2.1 Procurement should consider the **unique regulatory frameworks**, as pertaining to:

- Medical devices and In vitro diagnostics through the Medicines and Related Substances Act, 1965 ("Medicines Act"), and the Medical Device Regulations (recently amended regulations are in the process of being finalised). By way of example, subcontracting as is proposed in Chapter 4 of the current version of the Bill, is limited by considerations of licensing (section 22C of the Medicines Act (i.e. subcontractors must be licenced and able to fulfil all associated requirements), supply chain constraints (who can sell to whom and who can buy from whom – section 22H of the Medicines Act).

- The users of medical devices, in many cases being healthcare professionals, are subject to the Health Professionals Council of South Africa, including the prohibition of such professionals from participating in the manufacture for commercial purposes or in the sale, advertising or promotion of any medicine or medical device (which excludes them as potential suppliers). In addition, certain devices can only be used by persons who are appropriately trained in the use of such devices, which is a relevant consideration in procurement, and suppliers should be able to ensure that such training can take place.

- Professional rules on scopes of various professions, as set out by such legislation and the National Health Act, requiring such professionals to be available in order to ensure the appropriate use of such devices means that procurement should consider the limits imposed by professional competences, and ensure that the appropriate professionals are available to operate / implement medical devices and related interventions as procured.

2.2 **The NHI Bill (now adopted by Parliament as law) 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 healthcare establishments in both the public and private sectors lose the right to be procuring institutions, and where there is no competitive bidding, but rather price-setting by the NHI Fund. It should also be noted that various capital equipment and other medical devices would already be in use in such establishments, and in healthcare professional practices. Another provision in the NHI Bill that is contradictory to the Procurement Bill includes the exclusion of the Competition Act. Having a procurement system in the NHI that runs parallel to the Public Procurement Bill is not in the interest of value-based, patient-centred, responsive healthcare. The proposed parallel system runs counter to the many principles as espoused in the Constitution and the Public Procurement Bill. It also limits the property rights of private healthcare establishments and healthcare 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 medical devices would create efficiency and align with their specific patients' needs. SAMED supports the application of a Procurement Bill that aligns with the Constitution, subject

to its comments in this submission. SAMED does not support the NHI Bill's exceptional procurement approach.

2.3 **Procurement of medical devices require significantly different considerations to medicines**.

Procurement of medical devices require significantly different considerations to medicines. For this reason transversal term contracts, and centralized procurement, as is currently being done for medicines and 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 or violent trauma. 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 medical device 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.

The life cycles of medical devices must also be considered. 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.

Procurement of certain Medical devices 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 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.

There are also other services provided by medical device companies, often called "value-added services" and SAMED's members reported on it in its 2020-survey, included in the SAMED submission on the 2020 Bill.

These considerations are not present in medicines procurement, and illustrates the importance of inclusion of provisions in the Procurement Bill that ensures it being taken into account. The removal of the principles around Bid Specification Committees and the Chapter on Supply Chain Management from the Draft Bill, in both the previous version of the Bill (B18-2023) and in the current Bill, decreases the likelihood that there would be appropriate consideration as a matter of law, of these elements.

2.4 Removal of the concept of **Value-based Procurement**

The concept of **Value-based Procurement**, which has also been removed from the Draft Bill, and which no longer exists in the current Bill before the Select Committee, sets out important parameters to ensure that medical device procurement is appropriate, and responsive. "Strategic sourcing" is also now removed as a definition in the current version of the Bill. SAMED notes that the phrase "a strategic approach to procurement" is included in Chapter 5 for which the Minister may prescribe a framework, and although not defined, submits that it should be defined as value-based procurement, which we outline in more detail here:

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.

This concept is presented in an article published in 2015 by Boston Consulting Group[1] as a solution to two problems experienced in the EU, that is variation in patient outcomes and spiralling costs. For example: *"In the Netherlands, whose health care consistently ranks among the best in Europe, there is a ninefold variation in the rate of post-surgical complications from radical prostate surgery.… In Sweden, the complication rate for some patients who under- go cataract surgery can be 36 times that of other patients."* The second problem stated in the article is spiralling costs. This was experienced in the Netherlands where healthcare spending rose seven times faster than GDP from 2004 through to 2014. Value-based procurement can cure both problems, as it focusses on both patient outcomes and costs and industry can assist to achieve value-based healthcare. Public procurement can however be a major barrier to value-based healthcare as currently many purchasing decisions are based on the lowest bidder and up-front purchase costs.

3. Comment on clauses in the Bill

3.1. Chapter 1: Definitions, Application

SAMED notes the removal of the definition of "value for money" from the Draft Bill-version in the definitions clause. This is key when evaluating the cost-effectiveness of procurement, and should be reinstated, considering SAMED's previous comments in relation to "value-based procurement", and the best practice examples previously provided.

Clause 3(4) of the Procurement Bill is contradicted by clause 3(5) of the NHI Bill as approved. Both laws would therefore state that *it* would override the other contradicting legislation.

This leaves a fundamental conflict in the procurement of goods for the future NHI. The NHI Bill envisages a centralised procurement system, that not only procures on behalf of all health facilities (this is in spite of its purported purchaser – provider split), including public (provinces) and the private sector. This is in contradiction to the the Public Procurement Bill which recognises provinces (in line with the Constitution) as procuring entities. Given what is set out above in 2.2 and 2.3, this would not only be impractical, but unconstitutional, stripping specifically provinces from powers to procure, through the amendments brought about by the NHI Bill to the National Health Act, 2003. It will also create an unwieldy bureaucracy, and the near-impossible task to procure thousands of lines of consumables and disposables for all the various pieces of medical devices and equipment, in response to specific facility and their patients' needs.

The NHI Bill's creation of a *sui generis* procurement system not only negates the application of the Public Procurement Bill, it interferes with the procurement rights of private facilities, whether hospitals, step-downs, or private practices.

3.2. Chapter 2: Public Procurement Office, Provincial Treasuries and Procuring Institutions

[1] https://www.bcg.com/publications/2015/medical-devices-technology-procurement-unexpected-driver-value-based-health-care.aspx.

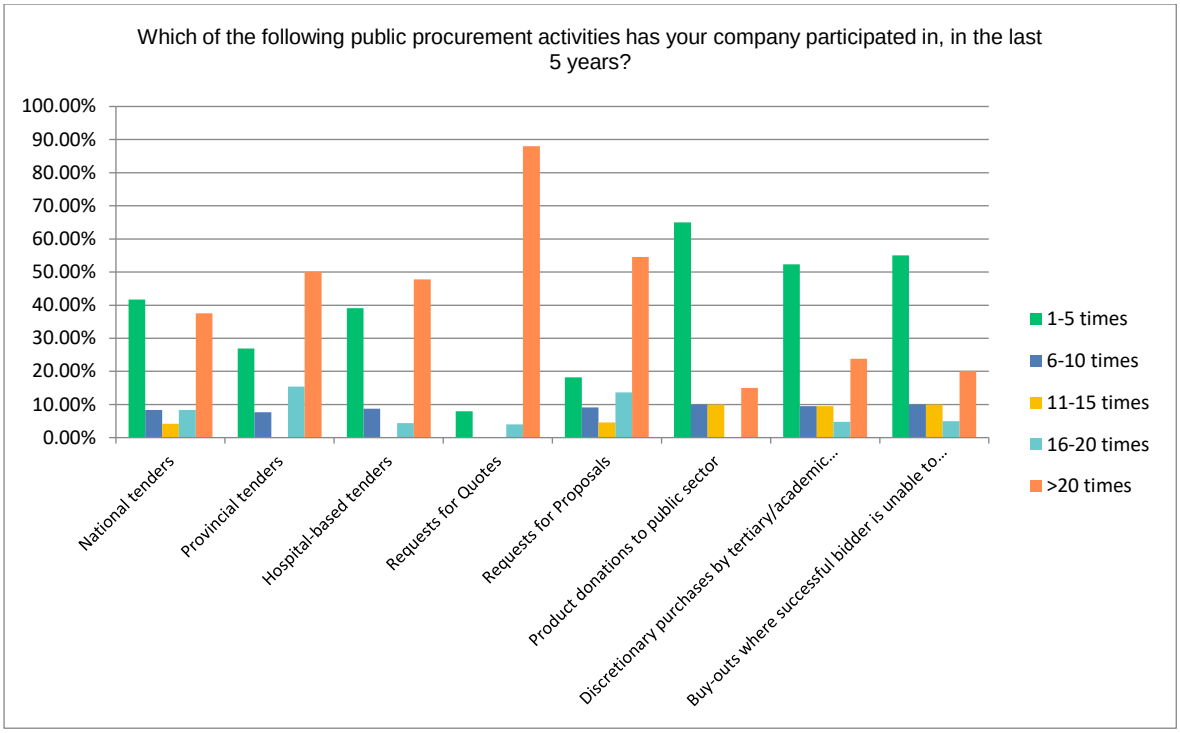
SAMED supports the proposed consultative approach in clause 5(2)(c) to develop model procurement policies for different types of procurement, such as medical devices, in vitro diagnostics and medical equipment procurement.

SAMED supports the legislated establishment of the Public Procurement Office ("PPO"), and the functions, specifically the power to issue different instructions for different categories of procurement (clause 5(3)(b)). This is a much-needed function, given the unique nuances pertaining to medical device procurement and the differences from medicines procurement.

However, the Bill in its current version, B18B of 2023, removes certain functions from the PPO, such as the review of procurement policies by procuring entities (previously in clause 5(2)), the power to declare a certain procurement practice prohibited (previously in that clause 15), the powers under "Debarment" (now clause 15) for the PPO to maintain a debarment register, and to make it publicly available. The power of the PPO to be provided with information was also removed in what is now clause 8(1) (it was clause 8(1)(g). These removals seriously limit the requisite transparency in procurement, and the prevention of repeat-offenders from being able to continue to bid.

Where a provincial treasury has the power to issue instructions, the removal of the remedy through the office of the PPO with whom it can consult (previous sub-clause (4) under clause 6 – Functions of provincial treasuries, is a concern: what is the recourse then in such circumstances?

SAMED's research (as included in its submission on the Draft Bill – "Annexure A") has shown, provincial and hospital-based tenders are the most prevalent (see graph below). Provincial procuring institutions and provincial treasuries will not have the powers in relation to health set out in the Procurement Bill, once the NHI Bill becomes law. If this is indeed the intention of government, there is no transition plan for existing procurement systems, and the Procurement Bill's procurement systems, into those envisaged by the NHI. Such centralization of procurement will, however, in SAMED's considered opinion, not be in the interest of patients, nor will it give effect to section 217 of the Constitution.



Clause 8 states that procuring entities must procure "in accordance with the provisions of the Act", once in effect. However, with the removing of the principles to be considered when undertaking this, the challenges in health sector procurement will not be overcome. Subordinate legislation (i.e. regulations), will not cure such gaps in the main empowering Act, as there would be no legislated framework relating to the principles that should frame such regulations. Furthermore, it would amount to a delegation of legislative power in a manner that could render such regulations subject to challenge, for not being properly authorised by the empowering Act.

The removal of sub-clauses (f) and (g) in clause 8(1) opens scope for problematic procurement practices and corruption. SAMED proposes that the two provisions be re-inserted, namely that the methodology and criteria for evaluation of bids be clear, and that procuring institutions must provide information to the PPO or the relevant treasury. Such oversight is, in SAMED's experience, absolutely necessary. Transparency is absolutely critical for fairness in procurement.

SAMED remains concerned that the Bill, as it stands, does not respond to the challenges in procurement in the health sector, much of which have been publicized. In centralised settings, a procurement malfunction will have disastrous effects on access to healthcare, as well as on suppliers. In simple terms, a failure at a nature system will be a failure throughout the system. Just the extension of a tender in cases of procurement delays could lead to product unavailability – had a tender been de-centralised, the de-centralised entities could continue with procurement processes, and not face the impact of a national extension, and the possible inability of such a supplier to continue to supply at such a large scale.

3.3. Chapter 3: Procurement Integrity and Practice

The principles listed in this chapter, both for procuring institutions, as well as for suppliers and providers, are supported. However, contravention of the principles of acting with care and diligence (clause 10(a)) and the avoidance of conflict of interests (clause 10(d)) are not penalised in clause 61(1)(e). Many procurement irregularities and abuses pertaining to lack of care and diligence and a failure to sanction these would secure its sustained prevalence in procurement systems. It must be penalized at par with improper gain (clause 10(b)) and undue influence (clause 10(c)), under the offences clause.

The impact of corruption and the lack of diligence regarding procurement in the public health sector currently, is one of the key sources of procurement debacles that affects the rights of access to healthcare of patients. The details provided in clause 11 relating to care and due diligence lose its force and effect in the absence of contraventions being made offences under the Act.

SAMED supports clauses 12 to 15 in this Chapter as aiming to eradicate procurement malpractices. SAMED supports that contravention of clause 12 is an offence in terms of clause 61.

SAMED notes however, with alarming concern, the removal of the previous clause 13(3), namely: "(3) A person related to a person referred to in paragraph (a), (c), (d), (e) or (f) of subsection (1) may not submit a bid in the institution in which the person is a member or employed." Whilst the rights of related persons to be commercially active is recognized, experience has shown that non-disclosures and other inter-linked commercial relationships have become a convenient loophole for employees and officials to actually be involved in procurement spoils. At the very least, related persons must publically disclose their relationships with persons in procuring entities.

SAMED proposes that timelines be attached to the process under clause 14(2), where an affected person informs the PPO of the untoward directions s/he/they have received. SAMED also urges consideration of measures that will prevent the victimization, and possible constructive dismissal of affected persons / whistleblowers.

Enforcement, and the inability to successfully, and expeditiously prosecute under the usual criminal law system (theft, fraud, corruption, etc.), necessitates a consideration relating to the creating of specific procurement offences. The labour law system, under the Public Service Act, and specifically for the senior management service ("SMS") also seems to lead to a failure to protect, and without amendment, will continue to fail to lead to the protection and enforcement of a fair, transparent and integrous procurement system.

It is also vital that the Bill adds protections for procurement whistleblowers, and creates a safe place where such whistleblowing could be made, and investigated, without risking the lives or safety of any person. The recent case involving Babita Deokaran is a case in point.

The removal of the subclauses in clause 15(3), namely the issuance of a claim for payment where there is no order (previous sub-clause (e)) also causes deep concern, as that activity is one of the known ways in which procurement irregularities occur. Sub-clause (f), which was also removed, in

relation to refusal to sign a contract, must be reinserted to prevent the corruptor and corruptee colluding in such circumstances.

3.4. Chapter 4: Preferential Procurement

This chapter has been substantially redrafted in the current version B18B of the Bill. SAMED recognises that this chapter gives effect to section 217(3) of the Constitution, which enables such legislation, in terms of section 217(2), and as restated in clause 17(1) to implement -

"a procurement policy providing for—
(a) categories of preference in the allocation of contracts; and
(b) the protection or advancement of persons, or categories of persons, disadvantaged by unfair discrimination" (emphases provided).

SAMED urges that the exercise of the powers in section 217 and clause 17 be weighed against the right of access to healthcare, which is the overriding constitutional mandate where health sector procurement is concerned. It is also in this context that imported goods may be the more cost-effective, and therefore in line with the principle set out in section 217(1) of the Constitution.

Clauses 17, 19 and 20 however does not give preference, but mandates the achievement of certain prescribed ownership targets or mandatory subcontracting, and makes such compliance a pre-condition for participation in a bid, or for bids to be "set aside". The system of setting aside an award and the requirement of specific targets in terms of ownership, irrespective of whether those indeed contribute to the overarching objective of economic transformation, require re-consideration. It is no longer a system of preference and advance, i.e. a flexible system that considers various types of advancement. This inflexibility renders these clauses unconstitutional.

The unintended consequence of the latest amendments to this chapter is that the broad-based nature of the B-BBEE system is now replaced with an ownership-only system, with targets that may, or may not, align with those set in the B-BBEE Codes. Many multinationals may never be able to participate in tenders (even in instances where their products are needed), and even entities that are at B-BBEE level 1 may find themselves unable to comply with whatever ownership targets are being set. The effect is that the points-system that was created by the Preferential Procurement Regulations, 2017, is now replaced by an "all or nothing" system, which will, in effect, disincentivize compliance with the B-BBEE codes.

Subcontracting also increases the prices of products – an aspect that is extremely sensitive in the health sector, where budget constraints are creating dire situations in terms of being able to provide the population with access to healthcare. Procurement decisions must consider the rights of access to healthcare, the right to a safe environment, the rights to property, the right to trade, as well as transformation. The system has to be flexible and multifaceted to cater for the complexity of the South African health sector and Constitution.

SAMED supports the inclusion of the recognition of "innovation" in clause 21.

The requirement of sub-contracting in clause 19 to entities listed therein may also have unintended consequences. Under the Medicines Act and Medical Device Regulations, there are criteria on who which entities are able to be medical device establishments, and only such licenced entities are permitted to supply medical devices. Mandatory subcontracting assumes the availability of licensed sub-contractors. The absence of supply chain management details, as was the case in the previous draft version of the Bill, again exacerbates this risk, as there may not be consideration of the possibility of such suppliers. Section 22H of the Medicines Act also places a prohibition on the supply of products by one wholesaler, to another, and where a provincial health sector depot is licenced as a wholesaler, successful bidders, who may be wholesalers themselves are and will be, unable to supply to such depots.

SAMED proposes that all the transformational clauses in Chapter 4 be prefaced by "where feasible and practicable" and that a flexible, points-based system be adopted, instead of a set ownership percentage system.

Local production and contents (clause 20), must also consider the pricing impact, in particular where the economic benefits are lost due to the limited economies of scale. If a tender is only opened up to local manufacturers the most cost effective solutions may not be able to be sourced. SAMED is in support of building the capacity of local manufacturing in South Africa, however as it stands a significant portion of medical devices is imported, and only approximately 10% of medical devices are locally manufactured. There is no database on the extent of local manufacturing: this was evident when the COVID pandemic occurred, there was no central source of information with clear indication of what medical devices are manufactured, by whom, and to what capacity. Quality standards are also a challenge. Implementation of this blanket requirement without full sectoral consultations and a review of the readiness of the sector could potentially be detrimental to the South African medical technology sector. Verification of manufacturing sites will need to take place to, for example, differentiate manufacturing from repackaging. Without collaborative efforts, simply requiring local manufacturing will not effect change: skills transfer is key in a developmental state: the reality of capacity and infrastructure development locally is limited and the reality we sit with is that most medical devices is imported.

3.5. Chapter 5: General Procurement Requirements (and the absence of details in Supply Chain provisions)

SAMED's research (as included in its previous submission), indicates that Requests for Proposals (RFPs) and Requests for Quotations (RFQs) are fairly common ways of medical device procurement. This is due to the variations in medical devices, and the complexities of equipment systems, that are not scalable to, for example, even a provincial tender. These forms of public sector supply are important, but must equally be subject to principles set in the Bill, in order to prevent its abuse, as was widely reported in the case of Thembisa hospital. That case also illustrates the importance of a fair, transparent and integrous supply chain management process aligned with the Constitutional clauses pertaining to health: why were certain buckets, for example, needed, and not others? What health need was fulfilled by specific types of chairs. Not only will the inclusion of these principles in

the Act lead to better framed regulations, it will guide procuring institutions as to all processes that lead to better procurement, and better implementation of procurement decisions.

Although clause 27 states that the accounting officer must take "necessary steps" to prevent non-compliance, or to respond to interference or tampering with the procurement system, not setting out what these steps are makes this clause difficult to enforce. SAMED proposes that accounting officers be guided by the steps that can, and should, be taken.

The removal of the previous Chapter 6 in the Draft Bill is problematic. Chapter 5 now only lists the aspects of which principles were previously set. The provisions in relation to the composition and powers of the Bid Committees (currently clause 29 only lists the committees), and the removal of the Supply Chain chapter creates room for procurement practices that are not appropriate for the specific procuring institution, and, ultimately, for the patients they serve.

Inadequate (and in some cases incorrect) specifications, due to the absence of expert and technical input, as a matter of law, have led to instances of costly (cost-ineffective) and inappropriate procurement. For example, wound dressing systems whose specifications are not adequately described for the specific clinical need could lead to the procurement of goods that rather than address the specific clinical need are misaligned and cause increased rates of sepsis due to the use of inappropriate products, not suited to clinical needs. For example in Stoma or wound care. The procurement of consumables, e.g. diabetes test strips, without considering the availability of the equipment that uses those strips, is another example of this. The prevalence of this is significant so as to warrant the re-institution of the provisions that were in the Draft Bill pertaining to procurement committees and supporting structures.

The change to the current clause 32 in terms of the Minister prescribing measures to allow for scrutiny and monitoring, should be enhanced by the previous version of the clause, specifically in the explicit requirement to "monitor high-value or complex procurement that entail significant risks of mismanagement and corruption".

It is vital for the fairness, cost-effectiveness and competitiveness of procurement (as is prescribed in section 217 of the Constitution), that principles, such as a proper assessment of needs, existing resources (human and other, such as demographics, disease burden, existing infrastructure, skills, medical capital equipment or lack thereof) are safeguarded in the Procurement Bill. SAMED's members have seen too many instances where procurement does not consider the specifics required to make medical devices "work" as it should, and as outlined above in 2.3 and 2.4. Further examples include the procurement of implants without theatre sets and support from the supplier, procuring capital equipment without specifications (and budgeting) for maintenance, or transversal procurement that leads to products not being appropriate for a specific facility or patient needs.

If these important factors are not considered, due to the absence of a *legislated* (and not just a policy-) framework relating to supply chain management and the way in which the Bid Specifications Committees work, one will continue to see instances where inappropriate products

are procured, inappropriate implementation of contracts, healthcare professionals with products not working as they should, and ultimately, sub-optimal health outcomes. The Office of Health Standards at present reports[2] that quality of care in most health facilities, in the region of 70%, cannot be certified as compliant with the basic standards required. Various aspects of health products, including specifically medical device and equipment management, are included in the standards.

This leaves the Bill in its current format, unresponsive to the actual challenges being experienced in specifically the health sector, and more specifically in relation to medical device procurement.

Clause 64(1)(a)(xi) authorises regulations to be made on transversal contracts. It does not authorise, as the intention under the NHI Bill is, procurement on behalf of the private sector. The unique requirements relating to medical device procurement makes such centralisation and standardization impossible and impractical, and not responsive to the needs of patients, or specific types of patients, and of particular facilities and/or in specific geographical areas.

The previous clause 20 provided for the out-sourcing of procurement – this has now been removed, and the purpose of such removal is not clear. Where such entities, now only covered in the current version's clause 3(3)(c), as intermediaries or agents for procuring entities, are still to be appointed, that must be done in line with procurement legislation, and specific contractual provisions must be mandatory, by law, such as penalties and fines, as well as summary termination provisions, should such procurement functions not be exercised in line with the constitutional principles and/or the procurement legislation. There must be measures to prevent procurement malpractice continuing whilst criminal investigations are ongoing.

Clause 27, aimed at preventing abuses, is supported. However, the clause should not only be applicable to the accounting officer in the manner it currently does. It should also add any procurement malpractice committed *by any person involved* in procurement processes, including the payment of suppliers and implementation of procurement activities. As stated above, the general criminal law offences- and the labour law protections under the Public Service Act are not adequate to protect the fiscus, or the principles of fairness, equity, cost-effectiveness, competition and transparency. Specific procurement malpractices should be listed and compliance with it should be mandatory for all involved in the supply chain and procurement processes. This list could include:

- Procurement without a needs assessment
- Procurement without technical and specialist input into specifications, irrespective of the type of procurement (e.g. RFQs, RFPs, tenders, etc.)
- Procurement without an assessment of cost-effectiveness
- Procurement manipulation to avoid bids being called for
- Procurement and payment for procured goods and services at inflated prices
- Procurement without consideration of existing infrastructure, equipment, skills and training
- Procurement from entities not licensed to provide such goods and/or services

[2] https://ohsc.org.za/wp-content/uploads/Annual-Inspection-Report-2020-21.pdf.

- Procurement from entities with no proven experience to provide such goods and/or services
- Procurement of products that do not meet specified compliance standards or have required regulatory certification

Access to information is critical when placing a procurement decision in dispute, including the process included in Chapter 6 (Dispute Resolution). In practice, procuring institutions always ask the permission of other bidders before disclosing the necessary information, and this is nearly always refused, leading to the aggrieved entity being unable to challenge the procurement process or award. The interpretation of the right to refuse access to key elements of a bid (e.g. the testing that was done on samples), means that the procurement process is not transparent, as is required by section 217(1) of the Constitution. SAMED proposes that reference is made to the Promotion of Access to Information Act, 2000 ("PAIA"). We recommend that the Procurement Bill should not list its own grounds for refusal (as it does at present), which would or could contradict the PAIA framework.

A further issue in public health procurement relates to the extension of contracts, sometimes for repeated periods. This means that the successful bidder has to continue to supply, often at the same price, and in spite of the impact this has on its business planning. For others, the process then becomes uncompetitive, as the extensions mean they are excluded from bidding for such extended periods. The absences of the principles relating to supply chain and bid planning processes in the Bill is problematic, and will make it more difficult to address this practical scenario.

3.6. Chapter 6: Dispute resolution

SAMED supports this chapter. In addition, it proposes that, in clause 37(1), it is not only the results of a procurement process that could be in dispute, but also processes preceding an award. For example, there may be an error on a bid specification document, or on an invitation for proposal or quotation, or a key specification might not have been included for consideration, or the invitation may be incomplete (e.g. not requiring the necessary training and support, additional equipment (such as theatre sets of testing apparatus) or exclude the necessary maintenance, or installation criteria (e.g. building design, electricity and water supply, etc.). It must be possible to trigger the dispute system at such a stage, and to halt the process until this is sorted.

SAMED notes that the Procurement Tribunal will only be able to consider review applications, and not appeals. Reviews only relate to procedural matters. This means that disputes of a substance nature, such as product test results, cannot be adjudicated by the Tribunal. Given the time that ordinary court processes take, combined with the applications under PAIA and PAJA (to obtain reasons), challenges to tenders are often of no effect, in that it is not completed by the time a disputed tender runs out.

SAMED proposes that the Tribunal be able to hear procedural (reviews), and substantive (appeals) matters, and that it be able to do so in a timeline and with a process that is efficient and expeditious.

The Stand still process in clause 55 could lead to shortages of supply, as Transversal contracts are not always available, and departments are not always happy to use what is available as the specifications may not meet their needs.

3.7. Chapter 7: General provisions

SAMED supports the powers of the Procurement Office to investigate matters. These powers are however limited by the non-inclusion of some of the clause 10 prohibited conduct in the offences clause 61. It must be possible for the Office to investigate a failure to exercise care and due diligence, and to refer it to relevant bodies under clause 61(1)(e).

The removal of some of the provisions (sub-clause 3) relating to emergency procurement from what is in the current version clause 55, is also concerning, given previous abuses under the guise of such emergencies. SAMED urges the consideration of inclusion of provisions that will increase transparency and scrutiny in instances of emergency procurement.

SAMED fears that clause 60, on the limitation of liability, could result in an excuse for non-compliance by simply saying it was done in "good faith". "Good faith" would have to be defined to prevent this.

The setting of ceiling pricing in procurement by regulation, as envisaged by clause 64(1)(a)(vi), should be measured against competition law requirements, and could undermine value-based procurement.

4. Conclusion

In addition to this written submission SAMED respectfully requests an opportunity to make an oral presentation to the Standing Committee on this vitally important piece of legislation. SAMED can be contacted at:

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