SAMED
advancing patient care through MedTech

SAMED SUBMISSION ON PROCUREMENT BILL 18 OF 2023

Finance Standing Committee
National Assembly
Parliament of the RSA
c/o: Mr Allen Wicomb and Ms Teboho Sepanya
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1. 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.

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 the current 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 have been published for comment);

- The users of medtech, in many cases being healthcare professionals, being subject to the Health Professionals Council of South Africa, including a prohibition of such professionals from being involved in the medical device supply chain (and hence from being involved in an entity supplying medical devices as a manufacturer / importer / wholesaler in terms of Bills such as these, relating to procurement);

- 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 – 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 in its version 11B of 2019) 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. 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 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**. For this reason transversal term contracts, and centralized procurement, as is currently being done for medicines, 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.

Centralised procurement for these type of medical goods would not be possible due to the 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. There are also important after-sale obligations, such as maintenance and technical assistance. The life cycles of medical devices must also be considered. These other services are often called "value-added services" and SAMED's members reported on it in its 2020-survey, including 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 of Supply Chain Management decreases the likelihood that there would be would appropriate consideration as a matter of law, of these elements.

2.4 The concept of **Value-based Procurement**, which has also been removed from the Draft Bill, and which no longer exists in the Bill before the Standing Committee, sets out important parameters to ensure that medical device procurement is appropriate, and responsive. 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 with value-based healthcare. Public procurement can however be a major barrier as currently most public health institutions purchase goods based on 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 definitions clause. This is key when evaluating the cost-effectiveness of procurement, and should be reinstated, considering

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

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 (version number 11B of 2019). Both Bill's state that it would override contradicting legislation.

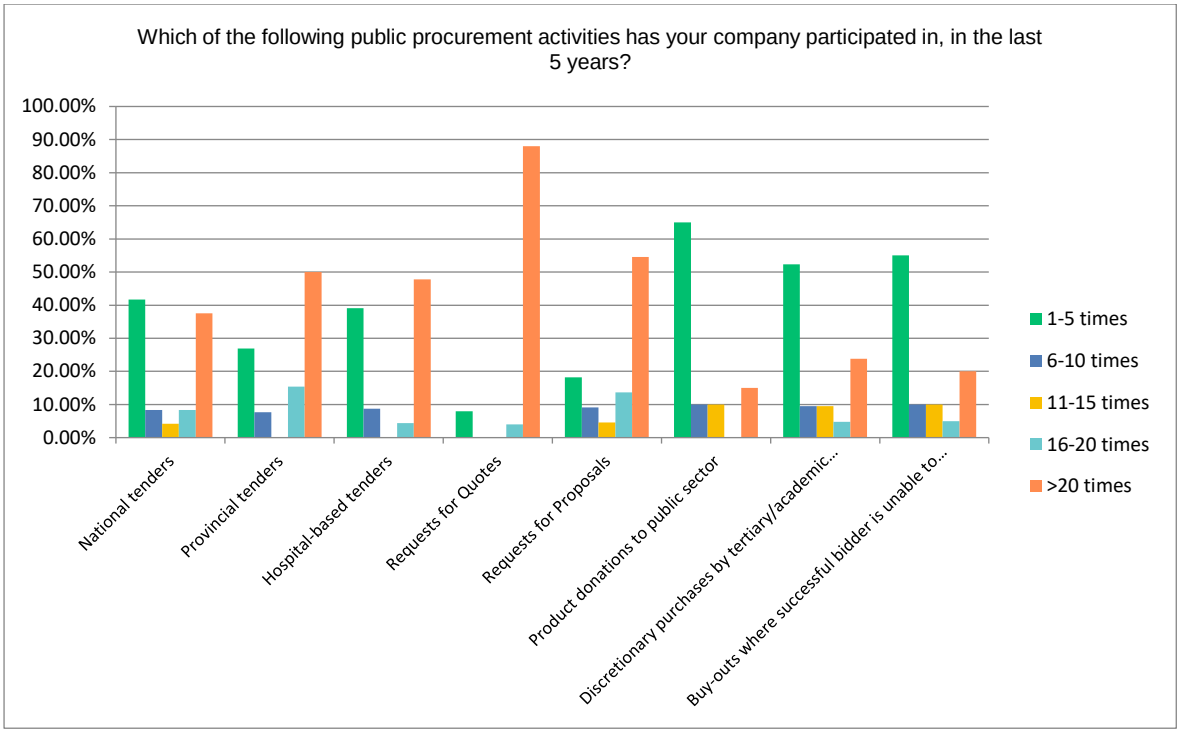
This leaves a fundamental conflict in the procurement of goods for the future NHI. The NHI Bill envisages a centralised procurement system, that not only procures on behalf of all health facilities (this is in spite of its purported purchaser – provider split), but also on behalf of the private sector. Given what is set out above in 2.2 and 2.3, this would not only be impractical, but unconstitutional and not in line with the provisions of the Procurement Bill. 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, etc.

The NHI Bill's creation of a *sui generis* procurement system not only negates the application of the Procurement Bill in the health sector, it also strips provinces and public facilities from their powers as procuring institutions. In addition, 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

SAMED supports the legislated establishment of the Public Procurement Office, 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 medtech procurement and the differences from medicines procurement.

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 centralisation 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, 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.

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 publicised, and other instances included as examples in this submission. 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 – as we have most recently seen with the issue of vaccine procurement, which has also now led to vaccine unavailablilty in the private sector, and severe constraints in the public sector. 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 55(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 on procurement in the health sector, of the lack of care and diligence 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. However, 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 seem to lead to a failure to protect, and without amendment, will continue to fail to lead to the protection and enforcement of the good procurement practice.

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.

3.4. Chapter 4: Preferential Procurement

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 that principle set in section 217(1) of the Constitution.

The transformational factors set out in clause 17 are important, but not all may align with section 217(2). The system of setting aside an award, as authorized by clause 17(2)(c)(i), and the emphasis on specific economic activities, irrespective of whether those indeed contribute to the overarching objective of economic transformation, require re-consideration. Localisation and beneficiation, for example are all laudable objectives, but suppliers could contribute to the economy and the transformation thereof, in different ways, such as contributions to science and research & development, as well as support to the academic sector and education & training. SAMED supports the inclusion of the recognition of "innovation" in clause 17(2)(c)(iv).

SAMED proposes that various forms of contributions to the economy and to transformation be considered as measures under section 217, i.e. beyond those listed as a closed list in clause 17(c).

The requirement of sub-contracting (in terms of clause 17(2)(c)(iii) to preferred entities may also have unintended consequences. Under the Medicines Act and Medical Device Regulations, there are criteria on who 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 proposed that the clause 17(2)(c)(iii) be amended to include the underlined phrase:

"(iii) for subcontracting by suppliers awarded bids that promote any of the preferences referred to in paragraph (b), <u>where feasible and practicable</u>"

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 medtech procurement. It is also understandable, 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 supply chain management process: 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.

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 relation to the composition and powers of the Bid Committees (current clause 23 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 increase rates of sepsis due to the use of inappropriate products, not suited to clinical needs. 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.

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 existing medical capital equipment) 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 equipment and medtech "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, etc.

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 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 19 authorises 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 medtech 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.

Clause 20 provides for the out-sourcing of procurement. Apart from requiring such procurement to be undertaken in line with the Procurement Bill, SAMED proposes that specific considerations be included relating to the appointment of such entities, which, in itself, must be subject to the procurement legal regime. Where such entities, who in effect act as intermediaries, are 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

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

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 21, 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
- 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 31, 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 have been not 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.

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 55. 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 55(1)(e).

4. Conclusion

SAMED is more than willing to engage further with the Standing Committee on these matters. SAMED can be contacted at:

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